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Making National Drug Policies a Development Priority

A Strategy Paper and Six Country Stories

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Editorial Note

It might reasonably be assumed that the provision of safe, effective and affordable medicinal drugs of good quality and in the right quantity to the whole population would be a priority in the health policy of any country and a relatively uncomplicated goal to achieve. Reality seems to show otherwise.

Apparently, it is not enough that the most effective essential drugs have been identified and that they can be produced efficiently, at low cost and at an acceptable level of quality, in most parts of the world. Nor does it matter, it seems, that many lives can be saved and that the financial savings that derive from a rational use of drugs can be considerable. What at first glance looks like a simple matter becomes utterly complicated when confronted with the realities of today's world, where vested interest, economic gain and professional prestige predominate and where different actors tend to further their own interests rather than those of the majority of the population. Consequently, in most countries, the parties concerned have not been able to reach a consensus and form a drug policy which can benefit all strata in society.

The importance of National Drug Policies as an integral part of—and a strong building block in—an overall national health system came to the fore in the 1970s, although important advances in the field of pharmaceutical policies had been made in some countries much earlier, as is evident from the country stories related here. One important initiative was taken by the Non-Aligned Movement at its Meeting of Heads of State in Colombo in 1976, when the political aspects of the pharmaceuticals problematique were highlighted and the role of transnational corporations (TNCs) as an instrument of northern domination was particularly criticised. UNCTAD followed up on the recommendations from Colombo with its important work on transfer pricing mechanisms and the patent system, both of which are used to obstruct the development of indigenous pharmaceutical industries in Third World countries. The UN Centre on Transnational Corporations also played an important role during this period by drawing up a Consolidated List of banned, withdrawn or severely restricted products.

It was. however, only natural that the World Health Organization (WHO) should take the lead in the complicated work of formulating drug policies and supporting their implementation in the increasingly complex political, economic, social and technological environment of the modern world. The introduction of the concepts of Essential Drugs and the Rational Use of Drugs, the Nairobi Conference on this subject in 1985, and the Ethical Criteria for Medicinal Drug Promotion should be mentioned as milestones in this work.

A wealth of literature on the political, economic and social aspects of medicinal drugs and their use. particularly in Third World countries, was published in the 1970s and stimulated interest in this particular field. However, relatively few countries managed to take up the challenge raised in the international debate and to carry through a comprehensive policy; many of those who tried to do so ran into considerable problems with implementation. In the latter part of the 1980s, as neo-liberalism, privatisation and a belief in unrestrained market forces gained the ascendancy, the interest in public initiatives in the area of drug policies decreased and attention was directed elsewhere.

Some people may argue that the question of National Drug Policies is purely technical and logistical, and of limited interest to those who work in the broad field of development. A few statistics may correct this false image. About 2.5 billion people—or half the world's population—continue to be denied their right to health. They lack reliable access to essential drugs, while at the same time overuse and abuse of medicines is frequently reported. The global pharmaceutical industry is estimated to turn over about USD 220

billion annually, out of which Third World countries, with three-quarters of the world's population, account for only USD 44 billion. About 90 per cent of the world's production of pharmaceuticals originates in industrialised countries, which also account for 80 per cent of consumption. TNCs are steadily increasing in size while their number is decreasing as a result of continuous mergers of companies in a context of intense competition for markets and products. This trend illustrates their powerful domination of the market. Where is the consumer in these developments and who is taking care of his or her interests?

It has been noted repeatedly that innovation and the search for new products are not directed towards satisfying the basic health needs of countries in the South, which would prefer to see bold initiatives to combat the most serious illnesses that afflict their populations, such as malaria, tuberculosis and sexually transmitted diseases. Instead, the R&D initiatives of the industry in the North are primarily directed towards the development of high-technology, specialised and often expensive medicines for use in industrialised countries where customers can more easily pay for increasingly expensive pharmaceuticals.

The vast majority of people in Third World countries have little or no access to effective and safe medicines. Although many Third World governments spend 30-50 per cent of their health budgets, and sometimes more, on medicinal drugs, compared to about 10 per cent in many industrialised countries, the overall health budget and health service coverage in the countries of the South remain severely limited. Moreover, in some Third World countries, up to 75 per cent of the drugs moving in the market may be outside the control of health ministries. This highly unsatisfactory situation may have become even more serious during the last few years of extensive deregulation. The attitude underlying it contrasts sharply with the previously predominant view that there must be some kind of official control to ensure that drugs are efficacious, safe and of adequate quality, and that the information provided about them is reliable.

This state of affairs highlights the regrettable fact that WHO has had little influence over the big private market. Waves of privatisations during the past decade have aggravated the situation and have in some countries reached absurd proportions. Vietnam and Laos are examples of countries where private pharmacies have been mushrooming in recent years and people go and buy whatever they want. In Brazil, according to recent reports, thalidomide is on sale again without proper safeguards against its misuse.

What makes the situation so serious is that the intensive marketing of pharmaceutical products has diluted the comprehensive concept of health to such an extent that for many people health now equals 'Doctor+Medicine' or just 'Medicine', irrespective of safety, price or quality. In the context of the new philosophy that is spreading all too rapidly, concern for basic factors such as nutrition, clean water and sanitation as the pillars of good health seems to be lost in the remote distance.

Another problem is the difficulty of involving the users—the consumers—in a discussion which has been presented to the public as a scientific and technical issue and the preserve of the medical profession. Despite the work of a few enlightened governments, such as those of Australia and Norway, and the indefatigable efforts of Non-Governmental Organisations (NGOs) such as Health Action International (HAI) and the Consumers International (formerly the International Organisation of Consumers Unions, IOCU), attempts to 'democratise' the debate on drug policies are proceeding much too slowly.

It was with the aim of contributing to a much wider discussion on this theme that the Dag Hammarskjöld Foundation organised a seminar on 'Another Development in Pharmaceuticals' at the Dag Hammarskjöld Centre in Uppsala in June 1985 and a follow-up 'Third World Journalists Seminar' on the same

subject during the World Health Assembly in Geneva in May 1986. The material produced for the seminars and the ideas and proposals generated in the Uppsala discussions were published in *Development Dialogue* 1985:2. The point of departure for these discussions was that pharmaceutical issues have to be examined from a health perspective and not from a limited medicinal drugs perspective and that the crisis in pharmaceuticals is an international problem which demands international action—even if National Drug Policies are the most important part of the solution. The central proposal was an international code on pharmaceuticals to regulate not just the industry but 'all the concerned parties', i.e. governments, industry, consumers and the medical profession. Among other suggestions, to only mention one, was the appointing of 'pill ombudsmen' as part of a global non-governmental body concerned with the production and consumption of pharmaceuticals.

The explicit aim of encouraging greater participation by 'the third system', i.e. citizens and their associations, in the discussions and decisions on pharmaceutical issues was also an important driving force behind the Manila seminar/workshop on 'The Role of National Drug Policies in Social Transformation: A Challenge for the Media' held in February 1992. This was organised by the Dag Hammarskjöld Foundation in cooperation with the Philippine Department of Health and the Philippine Center for Investigative Journalism (PCIJ) with the assistance of the Unit of International Health Care Research (IHCAR) of the Department of International Health and Social Medicine at Karolinska Institutet in Stockholm and the Philippine NGO, Health Action Information Network (HAIN). It focused on the situation in Southeast Asia and South Asia, where breakthroughs in the field of National Drug Policies might be made in the coming few years, and was particularly designed for media people in the region. Among several important outcomes of the meeting was the Seminar Report, *Prescription for Change: National Drug Policies, Social Transformation and the Media.* This was produced and published by the Philippine Center for Investigative Journalism under the directorship of Ms Sheila Coronel and edited by a group of journalists at the Center under the leadership of Ms Malou Mangahas. Other follow-up activities organised by the Center for Investigative Journalism and Malou Mangahas were a national seminar on the Philippine drug policy and the commissioning and publication of a series of in-depth articles on the pharmaceutical situation in the country.

in addition to these activities it was also decided by a small group of concerned participants who assembled informally at the end of the Manila meeting that a more policy-oriented and thoroughly researched document should be prepared on the basis of revised and enlarged country presentations. This was to take the form of a strategy paper analysing past and present experience gained by countries in the South and in the North in developing and implementing National Drug Policies. It was also to make policy suggestions for the future. A small working group was established, composed of Ms Mary Murray (Australia). Dr Nadine Gasman (Mexico), Dr Göran Tomson (Sweden) and the editors of this journal. The group and the other contributors of the country studies have met twice *in corpore* during the time of drafting the document, and individual meetings and contacts by phone and fax have been innumerable. What finally came out of the process was a strategy paper, 'Health and Drug Policies: Making Them the Top of the Agenda' and six country stories on different roads to a National Drug Policy.

The selected countries are Australia, Bangladesh, India, Mexico, Norway and Sri Lanka. Experience from the Philippines was initially planned to be part of this publication but due to constraints of space and time it was not possible to include this contribution. A detailed analysis of the Philippine experience is, however, given in *Prescription for Change* in the chapter entitled 'Making Policy: Focus on the Philippines'.

The aim of the six country stories presented in this issue of *Development Dialogue* is to discuss the circumstances, specific to each country, and the factors that shaped their NDPs with varying degrees of success. Furthermore, the country stories should provide a substantial and comprehensive resource base for those who are grappling with important questions: Is there a pattern to the varied experiences that different countries have had in formulating and implementing NDPs? What determines the common elements in this pattern? Can some general conclusions be drawn that reflect the commonalities? To what extent might these help in the formulation of individual country strategies and in the promotion of concerted global action through multilateral efforts within the UN system and by other international organisations, or initiatives on the part of NGOs and consumers? The 'Strategy Paper', which begins this issue of *Development Dialogue,* should be seen 'neither as a substitute for, nor a summary of, the country studies, but a macro-level discussion that could provide pointers not so much to an *action plan* as to a *strategy',* to quote from the paper itself. It is obvious that each country has to build a strategy and an NDP of its own in accordance with its own needs and resources. However, it is commonly admitted that general and sometimes quite detailed lessons can be drawn from the past experiences of other countries.

To date, very little in the way of analysis of NDPs has occurred. Recognition of this has led WHO to propose a set of indicators to monitor and evaluate National Drug Policies and to initiate, with IHCAR and Harvard School of Public Health, a multicountry research project to examine the situation. The ideas and suggestions put forward in the strategy paper and case studies in this issue of *Development Dialogue* are a contribution to that work.

While the general perspective of the 1985 issue of *Development Dialogue,* emphasising the importance of adopting a health perspective on pharmaceutical problems and an international approach even when policies are country-specific, remains as relevant as ever, the international code on pharmaceuticals may no longer be a first priority in the work on health and drug policies. Other issues have come to the fore: the necessity of dealing with both the public and the private sector under the same policy; the impact of harmonisation and other initiatives by GATT/WTO, NAFTA and the EU on the trade in pharmaceuticals and the development of NDPs; and, beyond these, the whole question of the social insurance system, the financing of national health systems and the organisation and decentralisation of the health sector.

Finally, it could be said that while the work on this issue of *Development Dialogue* has been going on, the parallels between the sectorial developments in the health and pharmaceutical field and the problems of global development generally have become increasingly evident. Just as an unregulated, privatised market system cannot solve the medicinal drug problems of the majority of people in the world, it is equally unable to solve global development problems as a whole. What is needed is not only 'Another Development in Pharmaceuticals' but Another Development. This renewed effort might well take the pharmaceutical issue as an important point of departure.

Health and Drug Policies: Making Them the Top of the Agenda

A Strategy Paper on the Development of National Drug Policies

I. Introduction

Today, 20 years after the Essential Drugs Concept (EDC) was formulated at the international level, 17 years after the 'Health for All' declaration was made at Alma Ata, and 10 years after the Nairobi Conference on the Rational Use of Drugs was held, some 2.5 billion people, or one-half of the world's population, continue to be denied their right to health and to lack secure access to essential medicines.

Concerns about health care and drugs have recently fuelled public debate everywhere. After the 'lost decade' of the 1980s, the Third World has witnessed horrifying levels of deprivation, misery, starvation and threats to survival. The majority of the population of the Third World lacks access to basic facilities and essential drugs. In what has been called the Second World, comprising former socialist countries of central and eastern Europe, poverty and destitution have reached alarming levels, leading to unprecedented decreases in longevity and increases in morbidity and mortality.

Even in the First World, there has been worrying regression after a high level of achievement of access to drugs and improved health care. In some First World countries, a significant proportion of the population now suffers from poor health due to lack of secure access to drugs and medical facilities. In many parts of the world, gains made in the past in the health field are under threat.

Health issues have reached the top of the policy agenda in many countries. The World Bank acknowledged their salience by dedicating its *World Development Report 1993* to health. There is, on the one hand, growing recognition in the world that health care is central to the concept of development and that a health policy of conscious intervention through public agencies is required in order to reach certain basic health objectives: essential components of a health policy include measures to promote the rational use of drugs and ensure the availability of medicines of adequate quality at a reasonable price. On the other hand, health sector reforms in recent years have often involved redefinition of the roles of the state and the market and placed increasing emphasis on the private sector as a channel for drug supply. Sometimes the emphasis tends to be excessive, and safeguards that ensure the supply of drugs relevant to health-care needs are often absent from health sector reforms.

To achieve health objectives, provision for the basic requirements of food, clean water and sanitation is top priority. The major diseases for which preventive or curative strategies are needed are diarrhoeal diseases, acute respiratory infections, malaria, tuberculosis and sexually transmitted dis-

eases. The Essential Drugs Concept evolved as a means of planning, identifying, quantifying and establishing structures for providing essential drugs needed to treat the majority of these illnesses.

Public concern about the availability, cost, safety and quality of medicines has grown as the world drug situation as a whole has remained unsatisfactory despite significant improvements in some countries. Therapeutically unnecessary or irrational, dangerous, counterfeit and poor-quality products are still freely available in spite of attempts by countries to ban or regulate them. Many countries that have the means to evolve rational and rigorous criteria for registration and quality-testing of medicines have not put in place mechanisms to do so. In countries that lack resources and political will, the situation remains by and large dismal.

With a few exceptions, the cost of medicines remains high, and has grown at a faster rate than the general level of inflation in most countries. The pharmaceuticals market continues to be dominated by a relatively small number of transnational corporations, some of them known for questionable high-pressure marketing and promotional practices. There have been relatively few genuine 'breakthrough' inventions in pharmaceuticals over the past decade or more, while drugs that are minor molecular modifications of an original drug, and have no discernible therapeutic advantage ('me-too' drugs), have proliferated.

WHO has urged member countries to develop and implement National Drug Policies (NDPs) and many countries have attempted to do so. Countries have addressed the issues in different ways, reflecting the different contexts in each, and several have made substantial progress. However, there are also growing threats to progress, lost opportunities, and challenges. In many ways, the environment for progress has deteriorated due to intentional or unintentional changes in international and regional trade regimes, policies promoted by multilateral and international institutions, economic recession since the late 1980s, and altered global pharmaceutical trends. The problems that are appearing as a result of these trends are shared by virtually all countries but are especially acute in the Third World.

At the same time, there is a serious lack of training available to health professionals, at undergraduate and continuing education levels, in rational drug use management and related skills. Irrational use incurs a high risk of harm or treatment failure and jeopardises the potential efficacy of medicines. Objective information about drugs is scarce in many parts of the world, particularly in remote areas. The medical community in Third World

countries and many industrialised countries lacks access to independent information about indications, contra-indications and side-effects of drugs. Consumer education is urgently needed. Legislation, infrastructure and means of implementing policies are still poorly developed in many countries.

Public-sector drug budgets are often too small to procure sufficient quantities of low-cost, essential drugs for the population in need. Yet these budgets can consume 30-50 per cent of the total health expenditure of many Third World countries. The basic infrastructure to ensure that drugs reach the people is undeveloped. The private sector continues to supply and promote expensive and unnecessary products, such as vitamins and tonics to people whose incomes are pitifully small, and there are many signs of its increasing role as a major drug supplier. This necessitates even closer regulation by the state.

Public-sector finance is affected by severe economic constraints related to such factors as declining per capita domestic product, heavy international debt and insufficient amounts of foreign currency reserves. In health sectors that have been weakened by economic conditions and Structural Adjustment policies, drugs are often scarce. This factor forces communities to look for new financing mechanisms and to the private sector to help meet their health-care needs. Many countries are grappling with the difficulty of harnessing private enterprise and directing it towards the goals of public health. Innovative ways should be sought of attaining these goals, which include equitable access to essential drugs for even the most impoverished rural areas and the maintenance of affordable prices. Collaboration with the private sector in support of these objectives might well yield significant results provided that the public interest considerations are kept in mind.

To articulate a basic need and formulate objectives to meet that need is easy, but successfully to implement a workable plan of action and allocate resources is more difficult. Many countries which suffer profoundly from the diseases caused by poverty have scarce resources to allocate to competing basic priorities. However, in many countries, the development of basic policy and increased political commitment to its implementation have improved.

It is two decades since WHO introduced the Essential Drugs Concept and a decade since it first advocated rational drug use; during this time, several countries have implemented, or attempted to implement, National Drug Policies. The time has come to take stock of these experiences, to evaluate

the successes and failures, and to analyse their causes. On the strength of such an assessment, and learning from the lessons of the past, we can then work out strategies for the future. Because of the priority such health and drug policies have acquired in public debates in many countries, this provides a particularly opportune moment to undertake such an exercise.

II. Lessons from the recent past

Is there a pattern to the varied recent experiences that different countries have had with their National Drug Policies? What determines the common elements in the patterns? Can some general conclusions be drawn that reflect the commonalities? To what extent might these help in the formulation of individual country strategies as well as concerted global action through multilateral efforts in the UN system and other international organisations, or initiatives by NGOs and consumers?

The six country stories presented here will discuss the country-specific circumstances and factors that shaped their NDPs with varying degrees of success. What follows is not a substitute for, nor a summary of, the country studies, but a macro-level discussion that could provide pointers not so much to an *action plan* as to a *strategy*. Each country must shape its own strategy and specific NDP in accordance with its needs and resources. There is simply no substitute for that. However, some general, if not universal, lessons can still be drawn from the past experience of other countries.

International policy context

Perhaps one of the most important of such lessons pertains to the international setting and policy context, in which the attempt to put together an NDP is situated, and the environment which sets the limits for sustainability. We return to this subject at greater length in Section III for the implications it has for action by WHO, the UN system and multilateral agencies, as well as governments, NGOs, professionals and consumers. However, it bears stating here that certain trends and developments have acquired extraordinary importance; amongst these are the trend towards globalisation and homogenisation of the world market, the emergence and strengthening of international economic actors, and the formulation of a new world trade agreement under the auspices of GATT/WTO*. Not only do these influence

* The 'GATT Agreement' in question is the treaty signed in December 1993 under the auspices of the Uruguay Round of trade negotiations, which was endorsed and ratified by ministers of signatory governments at Marrakesh, Morocco, in April 1994. The Marrakesh meeting resolved to set up the World Trade Organization (WTO) to supervise the implementation of the Agreement and to provide for dispute resolution mechanisms, penalties, etc. under it. WTO came into being on January 1, 1995.

national policy-making in many direct and indirect ways; they severely limit the scope of state-level action in ways virtually unknown before.

Thus, the new GATT/WTO agreement leads to an erosion of the sovereign decision-making power of national governments in respect of intellectual property rights, control over drug prices, tariffs and duties, subsidies for the health-care system, and the scope of public intervention in the pharmaceuticals market. Similarly, the likely effect of the North American Free Trade Agreement (NAFTA) and new economic ground rules within the European Union (EU) will be to homogenise policies, while eroding autonomy.

This is the most important conclusion that emerges from an analysis of the NDPs of Australia, Bangladesh, India, Mexico, Norway and Sri Lanka as presented here. The greatest threats to the advances registered by these countries through their NDPs—whether by way of promoting essential drugs or encouraging a strong domestic pharmaceuticals industry—are today represented by GATT/WTO, regional trade and economic compacts, and the global trend towards 'harmonisation'. 'Harmonisation' has some positive features in areas of drug regulation and resource sharing, but it can have extremely deleterious effects on national health programmes, social welfare schemes and NDPs. The new global trends may have the effect of removing the constraints placed upon pharmaceutical transnational corporations (TNCs) by countries in response to their price excesses and unethical practices. There are no guarantees or sanctions in place to prevent a removal of these constraints, especially in many Third World countries.

This represents a loss of public control over access to drugs, their prices, and marketing practices and, not least, a loss of consumer protection within the relationship between the patient, industry and the medical profession. This is a particularly regressive development—and a threat to NDPs— that the international community as well as national governments must do their utmost to counter effectively.

NDPs have many components: the concept of essential drugs; use of generic names; promotion of Rational Use of Drugs (RUD); measures to improve or ensure access; control over prices; public procurement and distribution programmes; measures to improve or ensure supply by promoting domestic manufacture; quality assurance; a regulatory system for the registration, safe delivery and use of drugs; establishment of national formularies and independent, objective sources of information about drugs; and control over drug marketing and promotional practices.

The most successful NDPs in the industrialised world, such as those of Norway and Australia, have evolved as part of a national commitment to social welfare and health as a basic right. They have also involved an emphasis at the earliest stages (predating WHO's activities) on a list of drugs that embodied the spirit of the Essential Drugs Concept and have evolved to promote rational drug use. The importance of these health and pharmacological criteria cannot be exaggerated. They outweigh primarily economic criteria (such as cost and the self-sufficiency of domestic industry); indeed, they provide the context in which these other criteria can be given play,

Here it is crucial to emphasise that the Essential Drugs List (EDL) is not just a list of the most important medications needed for the most prevalent illnesses affecting the largest segments of the population. It is also based on the therapeutically rational view that drugs are essential only when they adequately fulfil medical requirements of efficacy and safety; otherwise they are not essential. Essential drugs are useful and must be promoted; drugs not in the EDL are much less important. Many of them can, in fact, be eliminated without any harm to human health and at considerable economic benefit to the consumer.

NDPs that emphasise or prioritise other criteria over those of essential drugs and their rational use usually tend to be lopsided and unsustainable. This is highlighted most starkly by the Indian case, where the concern for price control and the aim of promoting industry took precedence over the Essential Drugs List and Rational Use of Drugs and led to an unhealthy growth of the industry, proliferation of an unmanageable number of useless, irrational and harmful drugs, and ultimately, the severe dilution of price control itself. Indeed, promoting the pharmaceuticals industry in the absence of EDL and RUD carries a high risk: it will increase the power of the industry so disproportionately that it emerges as an interest group or lobby that can defeat the larger RUD objective and thus undermine the core of the drug policy itself.

The importance of essential drugs in the NDP should not detract from their practical value as an economic concept, which gives a purpose and direction to the role of government in securing access to essential drugs through procurement for public distribution and through the imposition of price controls. Usually, a combination of the two has served the objectives of the NDP well. This is as true of Mexico as it was of Norway; or of Bangladesh as it is of Australia.

The development of NDPs is dependent on a political commitment on the part of government, an existing basic infrastructure and the support of key stakeholders such as doctors and pharmacists. In many situations, the formulation of a drug policy or some of its elements has been preceded by a crisis of some kind: war-time shortages in Norway, exploding debt and a balance-of-payments crisis in Mexico, the 'people power' revolution in the Philippines, sharp drug-price hikes in some countries in the 1960s, or disclosure of unethical transfer pricing and profiteering by drug companies in others. That is why different countries have different starting points related to their specific circumstances and usually take wholly different routes to NDPs. However, one general lesson is that no matter where one starts, it is crucial to develop comprehensive strategies for all objectives, especially those focused on securing access to essential drugs, as resources become available. Countries which get stuck in a groove and fail to move towards comprehensive policies usually slip badly and end up without effective NDPs.

Such failures are not uncommon. They are related to the fact that the pharmaceuticals field is typically characterised by the presence of strong vested interests, including trade, industry, health professionals and sometimes government agencies. Any change usually draws a hostile response from these interests. That is why the transition towards a stable, long-term NDP can be difficult and uncertain, punctuated with setbacks. The cases of Sri Lanka in the 1970s, and Bangladesh in the 1980s, exemplify this. In these countries, the move towards evolving an Essential Drugs Concept based on need, and the first, tentative attempts to procure medicines for the public health system, attracted so much hostility from the drug industry, in particular the TNC-dominated segment of it, that the whole transition was seriously threatened.

In Sri Lanka, there were major reverses: the TNCs lobbied hard to undermine the components of the policies; and in conjunction with an overall economic policy shift to the right, with the installation of the Jayawardene government in 1977, they were partially successful. Sri Lanka began to dismantle much of the social security and welfare system that it had pioneered in the Third World to become a model of healthy, equitable social development.

In Bangladesh, the opposition to the NDP from TNCs and private doctors was so fierce that it was in danger of being abandoned altogether by the early-1990s. It was only rescued through political intervention at the highest level.

There are other cases of inadequate resistance to such opposition, the most notable being that of Pakistan. In 1967, Pakistan introduced new norms for the generic prescribing of drugs. The TNCs' response was alarmist. They launched a strident, indeed hysterical, media campaign directed at the medical profession and the public, which conjured up awesome scenarios of mass poisoning due to substandard, low-quality drugs. The government failed to counter the propaganda and soon developed cold feet. The whole endeavour was abandoned.

In the Philippines, too, drug companies have done their utmost to undermine, if not destroy, the generics clause by bringing private members' bills into the national parliament. Years after the NDP was announced, their campaign against its provisions remained unremitting.

Government role in reliable procurement of drugs

Another major lesson to emerge from the experience with NDPs is that access to essential drugs can be secured only if government plays a strategic role in procuring drugs through a centralised agency such as the Norwegian Medicinal Depot, or Sri Lanka's State Pharmaceuticals Corporation, or, as in Australia, through subsidising universal access. Simultaneously, it must institute a system of price control which allows manufacturers and traders modest or reasonable profits. The ability of the procurement agencies to obtain reasonable prices depends upon the size of purchases and their capacity to secure a bargain in a highly imperfect, oligopolistic market. This market is notorious for cartelisation, price-rigging and arm-twisting, or outright blackmail in situations of acute shortages of drugs, especially when, say, an epidemic breaks out. Although there is much to be said for decentralisation of decision-making in the health field—as in many others—effective procurement of drugs is best done by centralised public sector-agencies which are familiar with the market and have adequate skills to anticipate demand and supply, and which seal the right bargains in good time.

In this regard, the creation and augmentation of local manufacturing capacity can play a useful role. Indeed, some relatively large countries, such as Bangladesh or Mexico, probably had no choice but to adopt such industrial policies (in the case of Bangladesh, to set up a fully-fledged pharmaceuticals corporation in the public sector to ensure regular and reliable supply of medicines). This was also true of India in the 1950s and 1960s, when the private sector was reluctant or unable to produce the new drugs needed for public health programmes.

This may be at odds with the kind of economic thinking that argues against

national-level protection, but it could be a good option for countries under certain circumstances, such as acute pressure on foreign exchange reserves, or when there is a need to translate technological capacities into production, or to ensure regular and reliable supplies. However, over-emphasis on industrial policy can mean a retreat from more important health goals, as the Indian example so clearly demonstrates.

Regrettably, new trade agreements such as NAFTA and GATT/WTO, as well as the Structural Adjustment policies advocated by multilateral institutions such as the World Bank and the IMF, tend to undermine public-sector intervention in trade and industry on grounds that are primarily ideological, and often inappropriate, misguided or unrelated to specific country needs. Thus, Mexico now faces a serious threat to its state procurement programme on account of NAFTA.

Regulation of pharmaceuticals

The state's role in the regulation of pharmaceuticals is critical and irreplaceable. There is simply no substitute for food and drug administrations (FDAs) or similar organisations that follow strict criteria for registration of drugs based on an objective evaluation of their efficacy and safety, as well as the need for them. The importance of regulation is even more obvious in cases of health sector reform, when the private sector is expected to take over much of the drug supply through private pharmacies. The 'need clause', for which Norway holds a unique distinction, represents a great step forward in the evolution of the concept of an NDP. It has, more than anything else, enabled Norway to keep the number of drugs in use down to about 2,200 while maintaining high health standards and without creating a situation of scarcity.

Equally important is the task of setting and enforcing standards for quality, including norms for good manufacturing practice (GMP), bio-availability (where applicable), dosage forms, the quantity of active ingredients, packaging, storage, shelf-life, and so on. Without such standards rational drug use has little meaning. And yet, in the absence of an ability to enforce such standards, if necessary with the help of stiff punitive measures, their formulation has very little relevance, as the case of the Philippines shows. It is not enough that the regulatory agency merely tests thousands of samples randomly collected from the market, thus adding to the burden on its limited facilities. It is equally important that it evolves good manufacturing practices and other safeguards to eliminate low-quality or unreliable practices, and educates producers in these through workshops and training programmes.

Here a word of caution is necessary. Quality is not an abstract concept connoting meaningless refinement of a product, but must be linked to therapeutic value, as well as cost. If, for example, there is no difference in terms of the therapeutic efficacy and safety of a particular drug between 99.5 per cent and 99.9 per cent purity, it would be irrational to make a large investment in upgrading its purity. Therapeutically irrelevant, abstract, 'more-is-better' notions of quality can be used to restrict competition and block the entry of cheaper products—and hence to keep costs high.

Here WHO'S Action Programme on Essential Drugs or Drug Action Programme (DAP), and its model list of essential drugs can be of great help to a number of Third World countries, as can programmes to train professionals in GMPs and quality testing. These training schemes should be reviewed for effectiveness. They might be better targeted by providing support to ministries of health in planning training of staff and future career structures more strategically, and specifying more clearly their training needs and the context in which ongoing work will take place.

Thus a more planned approach to capacity building, including regional and South-South cooperation, could be designed. Training for Technical Cooperation of Developing Countries (TCDC) needs expert support. Training should also include acquiring the ability to analyse drug evaluation and regulation requirements and procedures, with a view to constant evolution of a cost-effective system which takes the most helpful features of harmonisation but also ensures that the national requirements necessary to deal with country-specific problems, such as counterfeit drugs and black market formulations, remain in place.

Another important lesson can be learned from strategies using generic formulations to provide affordable drugs, to achieve substantial cost savings in the public sector and, in a more general way, to inform the consumer. The logic of generic prescribing is so powerful that it does not need restating. It has special significance for lowering drug prices. Interestingly, the generics issue as a means of controlling price was never significant in Australia. where the system of price control was extremely effective and the price differential between branded and generic formulations was not very large until recently. In the Philippines, the Generics Act was seen as the only realistic strategy for providing consumers with choice and thus, by working on the demand side, make drugs more affordable. However, without significant price control of the private market, this strategy may not produce the level of price competition originally intended.

Generics also play an important role in rational drug use strategies but do not alone ensure Rational Use of Drugs. Enforcing generic prescribing norms without first educating the medical profession and creating an independent, objective source of information on drugs is unlikely to yield results. Of crucial importance here is a national formulary disseminated widely among prescribers, and the creation of drugs and therapeutics committees in hospitals, especially teaching hospitals.

It is necessary to evolve a comprehensive, holistic approach to an NDP. This demands time, political commitment, the involvement of key health ministry officials, an activist group of pharmacologists with a commitment to RUD (such as have played a key role in Sri Lanka, Australia and Norway). support from and cooperation with the medical profession, and the involvement of health activists and NGOs.

Given the nature and power of the entrenched interests in the pharmaceuticals sector, conflict, attempts to short-circuit or sabotage policies, legal confrontation, and political manouvering are endemic and must be expected. It would be naive for governments and advocates of an NDP to plead helplessness in the face of opposition. They must anticipate such opposition and take appropriate steps to neutralise it. Enforceable key legislation must be put in place.

In the ultimate analysis, ordinary people—for whose benefit the NDP was evolved—must acquire a stake in it. Atop-down approach on its own cannot possibly help here. The involvement of people in a participatory drug programme is of the utmost importance. This can be brought about only if policy-makers are sensitive to popular perceptions of health and traditional healing practices.

Here, Australia may have a significant lesson to offer. An important development in the Australian rational drug-use policy and practice has been the adoption of a partnership approach and the evolution of appropriate processes to establish closer working relationships between all the interested parties. Interestingly, this partnership involves the pharmaceuticals industry to the extent that shared objectives for rational use of drugs have been articulated and joint action formulated.

III. ***Strategies for the future: Recommendations***

A global lesson from the experiences of different countries is that National Drug Policies have the highest chances of success in conditions which are marked by responsible and purposive conduct on the part of the different parties involved in their conception, formulation and implementation. Ultimately, NDPs will succeed only if all the interest groups and stakeholders involved recognise the unassailable importance of the role of government and administration in policy development, regulation of quality, safety and efficacy of products, and in taking a need-based approach to guaranteeing a reliable and affordable supply of pharmaceuticals accessible to the whole population. Government's role in facilitating the rational use of drugs is crucial. A dialogue among the various interested parties is all-important, even where there is no social consensus and group interests clash.

Here we can do no more than make some suggestions and recommendations of a general nature about how the different parties might contribute in a positive way to the success of NDPs as part of a health policy that is relevant to citizens' needs. What follows is a schematic discussion which is largely in keeping with empirical experience. It should be acknowledged that the issues and problems are different in Third World and industrialised countries and that the solutions are not always universally applicable. The basic perspective applied should, however, be the same around the world.

International and multilateral organisations

Although the principal focus of NDPs is *national,* the importance of the *international* setting, both in terms of the overall economic policy environment and the structure of the pharmaceuticals industry and market, cannot be exaggerated. A hostile international environment can nullify the effort to make an NDP work. Conversely, a supportive global environment can contribute greatly to an NDP's success. The crucial role of WHO'S Drug Action Programme (DAP) in developing this support over the last 15 years must be emphasised.

International and multilateral institutions and bilateral donor agencies bear a special responsibility, particularly in the 1990s, in assisting governments, as well as NGOs and consumers, with National Drug Policies. They alone can bring adequate countervailing pressure and restraint to bear upon the global drug industry to contain its hostility towards NDPs in many countries. The industry has a uniquely international presence, well-knit transnational operations, and close coordination both between and within companies throughout the world.

Multilateral institutions in the UN and Bretton Woods systems must

explicitly commit themselves to supporting NDPs and health policies as part of their development mandate, *inter alia,* through increased funding to these areas. Agencies could facilitate governments' management of their national budgets to ensure they move to a commitment to spend five per cent of their GDP on health. They could also work with individual countries to help them develop a strategic plan for ensuring that this budget is used effectively, and to build over time a sustainable basis for equitable access to health care, including drugs, for its citizens.

Health is central to any viable notion of development. Survival and physical well-being are perhaps the most important measures of development and the success of development programmes. This is precisely why commercial and other economic considerations must be subordinated to health promotion and well-being, which in turn provide crucial support for further economic development. This is also why free-trade agreements and industrial growth must be held accountable to human concerns and the public-interest content of health and drug policies.

The logic of making exceptions for the most essential public health-related products in patent protection is powerful. The benefit of restricting trade and allowing efficient public sector 'monopolies' in procurement, in order to achieve basic public health needs, is clearly demonstrated by the experience of several countries. The onus should be on the pharmaceuticals industry, and the international agencies sponsoring GATT/WTO and other trade agreements, to guarantee that proposed changes will not adversely affect public health needs. The strengthening of state structures in some contexts is highly desirable.

As shown in the India, Mexico and Norway stories, the new arrangements under GATT/WTO, NAFTA and EU/EEA are likely to have significant impact on health goals, raise drug prices, and strengthen private TNC monopolies. The combined effect of these moves may be even greater. Therefore, WHO should consider sponsoring a study on the impact of these arrangements, assessing the options for exceptions and exemptions in the GATT/WTO agreement for key health-related needs, especially for drugs.

The Drug Action Programme has an extremely important role to play in leading international facilitation of NDP development. Its value derives from its unique experience in developing policy and technical guidelines, its direct experience within countries and operational research. It should be used in coordinating global NDP activities in collaboration with other agencies, including UNICEF and the World Bank. Moreover, WHO'S normative

role constitutes a basis for providing advice to individual countries, and the Documentation Centre of DAP is a well-utilised resource for South-South cooperation. The Revised Drug Strategy, adopted in 1986 by the World Health Assembly, should be implemented efficiently and urgently. To this end, WHO should give priority attention to providing effective and supportive management to DAP and should clarify the operational procedures. National governments should increase their funding to DAP subject to the establishment of satisfactory management procedures and guarantees that DAP will be given a high priority and clear support by WHO leadership. For the implementation of the Revised Drug Strategy, DAP must strengthen the relevant mechanisms at the global, national and local levels. More detailed analysis is required of experience so far in capacity building. A more effective means might be developed in cooperation with member countries for a more strategic approach to their own planning, training and improvements based on learning from past experience.

National governments

National governments are the principal agency and driving force in the formulation and implementation of drug policies. Intervention in the national terrain falls within their sovereign domain. Although many governments since the 1970s have made some effort to improve drug supply, and, in cases, to ban harmful drugs and promote essential medicines, most are still a long way from integrating drugs into their health policies—where such policies exist—and from placing rational drug use and the Essential Drugs Concept at the centre of their approach to drug policies.

A unique responsibility devolves on national governments to formulate health and drug policies, to raise spending on health to the levels recommended by the UNDP, to evolve EDLs, to promote rational drug use, to deregister and ban harmful and irrational drugs, to take price control measures, to institute public-sector procurement ensuring a regular, reliable supply of low-cost drugs, and to fund the establishment of a national formulary.

Governments in Third World countries should find ways and means to increase South-South cooperation in areas such as drug supply arrangements. common training programmes, exchange of testing facilities, and transfer of manufacturing technology. Cooperation programmes should also be established between industrialised countries with good NDPs and Third World countries moving towards them, and between the industrialised countries themselves.

National fora for the discussion of NDPs and quality issues concerning traditional medicine should be created, consisting of representatives of all stakeholders.

Where domestic pharmaceutical production is considered essential to meet NDP objectives, it should be supported by a strong quality-assurance programme. The possibilities of installing an independent system of intellectual property rights and patent laws should be looked into. Such arrangements would encourage innovation and lead to lower prices. In this context, governments should also work for exceptions and exemptions from the GATT/WTO agreement.

Health professionals

Health professionals, including physicians, pharmacists and paramedical personnel, are indispensable to and inseparable from the prevention and management of illness. They need to be knowledgeable and skilful in the wise use and delivery of drugs. Their cooperation—or lack of it—can make or break NDPs. Physicians have a unique position here: in contrast to the users of most other goods and services, they prescribe goods (drugs) although they are not their main users; they choose goods on the consumer's behalf but do not pay for them.

Similarly, pharmacists play a major role in the actual dispensing of medicines and in the substitution of one brand for another, including generics. They also give advice on the choice of medicines by consumers themselves, although this advice is not always conducive to rational use. In many Third World countries, they often act as surrogate prescribers. Nurses, too, play an important role, far exceeding the mere administration of medicines, as do pharmacy assistants and the owners of village stores, particularly as informal suppliers of drugs. As more and more governments promote the private sector as the main drug supplier, and there is less and less control over the dispensing of 'prescription-only medicines', the importance of the training of personnel increases dramatically. Most Third World private sector pharmacists depend on the turn over rather than a dispensing fee for their income; this naturally encourages them to try and sell the more expensive brands. Thus, regulatory measures and incentives or restructured payment systems ensuring 'good pharmacy practices' (GPP) are urgently needed in the development of National Drug Policies.

Given their importance, health professionals have to understand health and pharmaceutical policies. Raising their awareness of rational drug use and essential drugs, and improving their familiarity with products on the market,

are therefore urgent tasks. They call for a reform of medical and paramedical education to include courses on pharmacology, sociology, ethics and economics, as well as rational drug use and generic prescribing.

At the same time, the criteria consumers use to make decisions need to be understood and the quality of health outcomes assessed by incorporating drug utilisation studies and self-audit systems into everyday practice.

Independent and objective drug information should be evolved and made available to everyone working in the field. National formularies should be created, suitable for everyday use by practitioners both in the public and private sector, and be supplied free of charge or at nominal cost. Generic prescribing should be encouraged from the earliest stage onwards. Economic incentives should be used to foster pharmacists' selling of essential drugs. In order to develop the kinds of programme outlined, operational research needs to be undertaken by DAP as well as other concerned parties, with the objective of developing country models.

The involvement of the industry in professional and consumer education should be critically examined and the Ethical Criteria for Medicinal Drug Promotion developed by WHO in 1988 must be adopted and adherence to them monitored.

NGOs

The perspective of NGOs is crucial in the development of a rational drug policy safeguarding the needs of the consumer, even if the organisations may have different strengths in different countries. NGOs have a special role to play in assessing, communicating and articulating people's needs, their attitude to health and drugs, and their perceptions of the health profession, industry, trade and government. They are situated at a vantage point at the consumer/prescriber/industry interface and can often detect harmful drug-use patterns and adverse drug reactions more adequately than state agencies. They are uniquely able to design and implement consumer education with input from professional experts.

In recognition of this position, NGOs must have a major role in the formulation, evaluation and implementation of NDPs. They should be formally associated with, or represented on advisory committees and be recognised as an important instrument for monitoring adverse reactions. Furthermore, NGOs could play a special role in complaint cells in food and drug administrations and in consumer tribunals, and the testimonies of NGOs should be accepted on a par with expert testimony in courts and consumer tribunals.

NGOs should be fully assisted, utilised and respected in their work on awareness-raising on RUD, safety, side-effects, monitoring of such effects, and on information and research. They should themselves take initiatives to involve health professionals and government in understanding and developing an integrated approach to the use of Western medical practices and traditional healing. An equal partnership in knowledge and skill of both systems of medicine should be developed and delivered through effective practices at the local level. Joint meetings might be held to facilitate this.

The work of NGOs and their networks should be supported by national and international organisations. Coalitions of groups with the same or similar interests could naturally feed information into consumer groups.

Pharmaceuticals industry

As the producer of drugs, the pharmaceuticals industry is a crucial actor in the drug field and in determining the fate of NDPs. Segments of the industry have tended to inherit a problematic and unfavourable public image as opponents of NDPs, rational drug use and restrictions on the 'free market' in medical products. Although some companies have adopted a cooperative and responsible approach, the overall image of the industry still hobbles it, limiting its contribution to the success of NDPs.

There is an urgent need for the industry to reform its image and practices, and to recognise the inevitability and rationality of a transition towards a rational drug policy as an integral part of a humane health policy. This could best be done by complying with WHO's Ethical Criteria for Medicinal Drug Promotion laid down in 1988. Drug regulation should include monitoring systems to ensure the enforcement of these criteria. Where transparent, open and effective self-regulation of the industry is not in place, these criteria should be backed up by government sanctions. Controlling misleading drug information is even more important in a decade which has seen growing privatisation of drug supply.

At both national and international levels, companies should be encouraged to make a formal commitment to NDP objectives. An increasing number of mission statements by pharmaceutical companies express in one way or another their commitment to improving the world's health. Dialogue with companies should increase mutual understanding of how this goal can be achieved, with health concerns being an overriding objective driving economic priorities. The industry must acknowledge the need for price control, strategies to make drugs affordable to the majority of the world's population, and responsibility for compensation to victims of drug-related health

damage. Governments must, in turn, accept that pharmaceutical companies get a fair return on their investments.

Other important issues of particular concern to Third World countries are industry commitment to the transfer of new production technology for key public health needs; agreement to regulate intellectual property rights nationally and to implement patents genuinely rather than monopolise them; and the development of quality-assurance programmes by parent companies to improve and monitor the ethical marketing practices of their subsidiaries and agents with a view to ending the disparity of drug promotion between industrialised and Third World countries. Strategies to achieve these goals should be discussed in joint fora with other interest groups.

Consideration could be given to developing a multidisciplinary dialogue, perhaps beginning in an informal way with some key actors along the lines of a recently successful initiative on plant genetic resources, under the auspices of an independent foundation. This would have the aim of creating the beginnings of a better environment for mutual understanding which might lead to joint action in areas of shared objectives.

Consumers

The consumer is the final, irreducible and complete measure of the success of a drug policy. The consumer's—or the public's—satisfaction with, and involvement and stake in, **NDPs** will determine their success. The consumer is the principal target of the entire NDP effort. Unfortunately, the targeting is usually done in a top-down and paternalistic way. The time has come to support a bottom-up approach which is compatible and consistent with an expert-based overall policy of rational use. This is best done by involving consumers' representatives in the formulation of **NDPs** from the earliest stage onwards, setting up special fora for redressing consumer grievances, and monitoring drug consumption and adverse reactions.

Consumer education is a right and a necessary condition for the ultimate success of NDPs. It is important to explore consumers' attitudes and practices in relation to drugs and, where appropriate, to help them give up harmful dependence on drugs, either prescribed by medical professionals or self-prescribed, especially when this leads to considerable debt and the sale of basic survival assets in order to obtain them. Consumers need to be able knowledgeably and rationally to make decisions about treating diseases themselves or seeking professional help.

Mothers and grandmothers in the vast majority of societies are the gatekeepers to family decision-making in health. They are strong advocates and important educators of each other at the local level. Women who have been trained as health workers can go on to develop more and more effective popular education techniques tailored to the needs and resources of particular communities. More support is needed for consumer-initiated programmes in which the issue of medicines is firmly integrated, with an emphasis on the prevention and management of illness.

The next steps

An atmosphere of cooperation rather than confrontation will create the conditions for effective and affordable investment in health. A participatory approach will build a dynamic system in which education and regulation both empower and protect consumers. This will combine the expertise, power and resources of government, the expert learning and skill of health professionals, the technological power of the drug industry and the practical considerations of health and well-being of consumers. It is necessary to develop a better understanding of what works to ensure a balance between health and economic objectives at policy and practice levels. This should be based on the primacy of the concept that health and well-being are the final indicators of the success of human-centred development. The development of processes to start dialogue about the issues raised in this paper is urgently needed. Informal and formal exploration of the issues through national and international conferences and other means should be facilitated by all the parties concerned.

The next phase in the implementation of NDPs demands concerted, cooperative efforts on the part of all actors at the international, regional and national level. As the preceding analysis has shown, effective health policies cannot be developed if not supported by National Drug Policies. The 'Drug Action Programme' plays a crucial role in this context. Nothing in the Revised Drug Strategy has declined in importance in the last decade. The experiences of different countries, on which this paper is based, show, on the contrary, that it is more important and that the emphasis on the rational use of drugs must be strengthened. The recent changes in global trade policies will make it increasingly difficult to achieve this objective. Ensuring that basic health and essential drug needs are equitably met is more important than market considerations and the global harmonisation of trade. New roles for the actors, as outlined here, must be defined through an ongoing and intensified dialogue.

Three areas should be given priority:

1. Analyses of the impact of the trade and harmonisation initiatives of GATT/WTO, NAFTA and the EU on the trade in pharmaceuticals and on the development of NDPs, with a view to preserving and safeguarding well-functioning NDPs and improving less well-functioning ones. In the new climate of world trade reforms, there is an urgent need to monitor and control unethical marketing practices, biased education programmes and unfair prices.
2. Support of the Drug Action Programme, the Revised Drug Strategy and its management, with a view to enabling the DAP to act as a resource base and as a coordinator of the studies and activities required to counteract the negative effects of GATT/WTO and other trade agreements.
3. An educational campaign aimed at all concerned parties, especially health professionals and consumers, highlighting the new NDP debate and what needs to be done to preserve the gains made in this area and to improve on unsatisfactory existing policies.

As is evident from this paper, everyone concerned can benefit from better sharing of national NDP experiences. The value of this material is such that it should provide guidance and inspiration not only to national and international policy-makers but also to voluntary organisations working for a new and equitable system of health care and drugs provision.

Norway's National Drug Policy

Its Evolution and Lessons for the Future

By Marit Andrew, Bjørn Jøldal and Göran Tomson

Norway provides an interesting and significant example of a successful National Drug Policy. Characteristics such as a 'need clause' (which implies that a drug is assessed not only from a scientific and technical viewpoint but also in relation to medical need, and thus the social perspective of health priorities), a restrictive attitude to fixed combination drugs and the limiting of approval and registration of a drug to a five-year period have kept the number of pharmaceuticals at a reasonable level—just over 2,000—and protected consumers from useless or unnecessary drugs. This development towards an equitable National Drug Policy has occurred without any major conflicts between the health authorities, the professional organisations and the drug industry. The reason for this may be that the Norwegian drug policy has developed in stages through most of this century and has been part of a health policy and an overall social policy—which may be characterised as typically Scandinavian—where the emphasis on equity has been one of the main pillars. This emphasis goes right through the system as it now works and has been particularly evident in the field of drug distribution, where the less profitable pharmacies in marginal areas are sustained by more profitable ones located in more populated areas, a modern 'Robin Hood approach'. The importance attached to the last link in the drug chain—patients and prescribers—is another example of this emphasis.

The story of Norway's highly relevant experience in this field is told here by two Norwegians and a Swede who all have been closely involved in the development of drug policies, nationally and internationally. Marit Andrew is Assistant Director of the Department of Pharmaceutical Services at the Norwegian Board of Health in Oslo. Before taking up this position she spent ten years working with the government pharmaceutical wholesaler, the Norwegian Medical Depot, and another ten years at the Department of Pharmacotherapeutics at the University of Oslo. She has also been involved in the development of WHO's Ethical Criteria for the Promotion of Medicinal Products. Bjørn Jøldal served as Director of the Department of Pharmaceutical Services on the Norwegian Board of Health from 1964 to 7997 *in close cooperation with the Directors-General Karl Evang and Torbjørn Mork, who together were instrumental in forming the Norwegian drug policy. He was also very active in Nordic and European cooperation efforts in the field of medicinal drugs,*

and, above all, within WHO where together with Mork and Professor Per Knut M Lunde, now at the Department of Pharmacotherapeutics, he played an important role in the development of the Essential Drugs Concept and the Drug Action Programme. Since 1991, he has been the proprietor of Sandvika Apotek (Pharmacy). Göran Tomson, an Associate Professor at the Unit of International Health Care Research (IHCAR) at Karolinska Institutet *in Stockholm, is a paediatrician who has worked in the broad fields of public health and health policy, international health systems research and global pharmaceutical issues. His doctoral dissertation was entitled* Drug Utilization Studies in Sri Lanka. Towards an Understanding of Medicines in Society *(1990). Göran Tomson coordinated the work on the study presented here.*

Background

A country's National Drug Policy (NDP), although it may have many similarities with the drug policies of other countries, is specific to the context in which it is formed. It emerges gradually and is shaped by a range of factors relating to geography and natural resources, history and culture, and the social, economic and political climate. What are these factors in the case of Norway?

Norway stretches further north than any other country in Europe, with a substantial part of its territory, including Svalbard, to the north of the arctic circle. With only 4 million people living in an area covering 326,000 square kilometres, it is the second most sparsely populated country in Europe after Iceland. Less than a quarter of the area is suitable for cultivation: 3 per cent for agriculture and 20 per cent for productive forest.

Although Norway is on the same latitude as southern Greenland, its climate is relatively mild because of the proximity of the Gulf Stream. Most of the country has an average temperature of 15°C or below in mid-summer and -5°C or below in mid-winter. In the past, the high mountains and heavy snowfalls made contact between different parts of the country difficult during winter. Today, the situation is different, with road, rail and air networks generally usable all year round. However, every now and then nature takes over, leaving trains stuck in the snow and roads temporarily closed.

The 20th century has seen a transition in Norway from a society based on the primary industries of farming, forestry, hunting and fishing, to one based mainly on secondary industries, including mining, construction and hydro-

electric power, and tertiary activities such as transport, trade, business and private and public services. Most of this development has taken place since the Second World War, when Norway was occupied, and has been the basis of strong economic growth and the development of the welfare state. During the last 20 years, oil and gas production in the North Sea has emerged as a principal industry, and Norway is today the major oil- and gas-exporting country in Europe.

The post-war period united the Norwegian people in an atmosphere of reconstruction and solidarity. In the first election after the war, the Social Democratic Party gained an overall majority. It remained in power for 20 consecutive years until 1965, when the Conservatives came to power for a period of six years. This was followed by another 10 years of Social Democratic government. Since 1981 there have been several changes of government. Although the Social Democrats have not always been able to form a majority government the party has maintained its leading position.

Being a small and remote country, Norway has by tradition been strongly internationally oriented, and has had a high international profile considering its size. For example, it could be mentioned that the first Secretary General of the United Nations, Trygve Lie, was a Norwegian.

Since the late 1980s, Norway, as other European countries, has been faced with reduced economic growth and dramatically increasing unemployment, from 2.3 per cent in 1988 to around 8 per cent in 1994. The economy is still. however, among the healthiest in Europe.

Development of the welfare state

The notion of the welfare state implies among many things that the government strives to give every citizen an equal opportunity for self-realisation, through access to education, health care, housing, and adequately remunerated employment. The essential elements of the system are public insurance, covering costs incurred in the case of illness, accident or social problems; and social security, including, for example, public pension schemes, and well-developed medical and social services. One result of the equity policy is that the difference in wages between high- and low-income groups is among the smallest in Europe, while both direct and indirect taxes are fairly high. Norway is generally acknowledged to have one of the highest standards of living in the world.

The government's health care policy for 1994-1997 is based on the principle of solidarity and equal access to high-quality services. It emphasises the im-

portance of every citizen having confidence in the health care system.[1] All the major political parties support the fundamental concepts behind the welfare state but there is a continuing debate about what is or is not realistic and how best to organise the system. This reflects the fact that the work-force has to pay for a growing number of retired and, more recently, unemployed people, increasing the per capita cost of welfare provision. Another factor is a delay in young people entering the active work-force, because they stay longer within the education system. This tendency is reinforced by reduced employment opportunities.

In common with many other industrialised countries, Norway has a 'greying' population, with a 2.5 percent annual increase in the number of people over 75 years of age. As approximately 50 per cent of all drugs are used by those who are over 65 years of age, this factor will have clear implications for drug use in the years to come.

The national health and social insurance scheme is financed through the tax system, shared by employers and the public.

Health and health care

The health care system is the largest 'company' in Norway, employing 10 per cent of the labour force.[2] The municipalities are responsible for organising primary health care for all inhabitants, including the provision of nursing homes. Hospitals are run by the counties and all hospital treatment is free. Until the early 1980s, curative medicine and hospital development overshadowed preventive medicine and care.[3] However, the Municipal Health Act of 1982 reflected a change of priorities. This gave the municipalities both the responsibility and the power to provide health services for those living in their area.

Health concerns are also in a general way integrated in the legislation to a larger extent than in most other European countries.[4]

The development of a Norwegian drug policy

The development of a drug policy, as in any other country, is influenced by factors such as the health situation, the health care system, education and training of health personnel, social security and health insurance, research, national drug production, drug distribution, drug control and international drug policies.

For centuries, mountains, fjords, and vast, uninhabited forests divided the Norwegian people into small, separate communities which had to be largely

self-sufficient, as they were completely cut off from neighbouring communities for long periods of the year. In such close-knit small communities with a high degree of stability and homogeneity, the philosophy of mutual assistance—and what might be called social conscience—comes naturally. This community model of mutual help lays the basis for replication on a national scale.

More than 350 years ago, the first physicians to establish themselves in Norway were paid by the government, as it was assumed that most people were not in a position to pay for medical services out of their private resources. This first step towards a nationwide system of medical care was 'socialised' medicine in its purest form, but it was operating a couple of centuries before the term socialism was invented. Although problems and outlooks have changed considerably since that time, we believe that this tradition of solidarity and mutual assistance influenced the solutions that were arrived at later in the country's history.

The basic aim of the Norwegian drug policy is to ensure that effective and safe drugs of good quality are accessible and that measures are taken to ensure their rational use in keeping with the health needs of the country.

Traditionally, Norwegian society has tried to control the quality and use of medicines in order to safeguard the public and to ensure proper medical treatment. Before the industrial era of ethical drug production, the major efforts towards control were in the education of medical personnel, the establishment of drug standards in official formularies, the control of the production and distribution chain, mainly pharmacies, and the introduction of prescription rules. The first Norwegian pharmacy was founded in 1595 in Bergen—400 years ago!—and the second, 'The Swan Pharmacy', in Oslo in 1628. The latter is today the oldest functioning enterprise in Oslo.

With the industrialisation and commercialisation of drug production and marketing, new control measures became necessary. The first of these came with the first Drugs and Poisons Act as early as 1914. In 1928, these regulations were extended by an act of parliament, according to which the marketing of each drug product had to be approved by a government authority. Drug advertising was regulated and restricted by the same act.

The importance of the individual

As important as the social, political and economic framework are the actions of people with vision and commitment. Especially in the post-war period, with the huge growth in the numbers of drugs and growing pressure

from the transnational pharmaceutical companies, Norway had strong directors of health services and far-sighted leaders of pharmaceutical services.

Karl Evang, who was Director of Health Services from 1938 until 1972, was the main architect of the Norwegian welfare state as we see it today, and also one of the pioneers whose ideas led to the establishment of the World Health Organization. He was a convinced Social Democrat, and had strong views about the need for government responsibility for the development of the health care system. He also had a very special interest in and insight into drug issues, and wrote a book about the use and misuse of medicines, with a public health perspective, as early as 1965.[5] The need for a healthy pharmaceutical industry was also addressed.

Torbjørn Mork, his successor, continued along the same lines, both nationally and internationally, emphasising the need for a drug policy as an integral part of overall health policies. He was one of the key people behind the launching of WHO'S Action Programme on Essential Drugs (DAP), instituted in 1981.

The Director of Pharmaceutical Services in Norway for 26 years until 1991, *Bjørn Jøldal,* played the role of pharmaceutical policy architect and implementor and was, together with colleagues, responsible for gaining international acceptance for the WHO Drug Action Programme.

Per Knut Lunde, at the University of Oslo, Professor and Head of the Department of Pharmacotherapeutics, paved the way for the international acceptance of the Essential Drugs Concept (EDC) and was one of the individuals who drafted the first Essential Drugs List,[6] published in 1977.

Norwegian drug policy today

Like many other industrialised countries, Norway had until recently no single document setting out its drug policy. Elements relating to quality, safety, efficacy, need, control of prices, and promotion, are included in the drug act, while those relating to distribution are embodied in the pharmacy act. Pharmaceutical benefits are covered by the national insurance act.

However, in 1987, a government white paper entitled *Health services towards the year 2000* (No. 41, 1986-87) was brought before Parliament. A small but crucial part of the document deals with the pharmaceutical area. The main aim is to provide the best possible pharmaceutical service to society. The need for coordinating the development of pharmacy services and other health services is emphasised.

In accordance with the main aim, expressed in the document, the pharmacy services should contribute to:

- easy access to safe and effective medicines of high quality in all parts of the country, at reasonable prices which should be the same in all parts of the country;
- proper and medically sound use of medicines. Health personnel should have the necessary information on drugs, and pharmacies, together with other parts of the health care system, should join forces to promote the rational prescribing and use of drugs.

Essential elements in the Norwegian drug policy are: a drug regulatory control body; a strictly regulated distribution system; a reimbursement system; and a strategy for the rational prescribing and use of drugs.

National drug regulatory control

A well-functioning drug regulatory agency is vital for the implementation of a rational national drug policy. In 1930, a government agency with a quality control laboratory was established, and in 1948 a laboratory for drug standardisation was set up. In 1974, these services were merged and reorganised with the establishment of the Norwegian Medicines Control Authority, the main functions of which are described below.

Financing of drug regulation activities

Drug control activities have traditionally been financed directly or indirectly through registration fees, partly an application fee and partly an annual fee. In 1994, the application fee was NOK 35,000 (US$ 5,000) and the annual fee was 0.7 per cent of the wholesale turnover of the drug.

Selection of drugs

At the time of the thalidomide disaster in the early 1960s, only very few countries, among them Norway and Sweden—where the relevant legislation dates from 1928 and 1935 respectively—had gained experience with systems to assess the efficacy of new drugs.

Since the Drugs Act of 1928, quality, safety, efficacy and cost have been the main criteria for drug evaluation and registration in Norway. Some 10 years later the concept of *need* was introduced as a further criterion. Emphasis on particular criteria has varied over the years. In the 1950s the focus was on quality, in the 1960s on safety and in the 1970s on efficacy. During the 1980s the economic aspects of drug provision have received increased attention, as has rational drug use.

Since the 1940s the criteria for the selection of drugs have been as listed below. However, in 1994, as a result of Norway joining the European Economic Area (EEA)—previously a trade agreement between EEC and EFTA countries, today in practice EU, Norway and Iceland—the need clause had to be sacrificed. This will lead to an estimated increase in the number of products on the Norwegian market by 50-100 per cent. (See pages 46-48 for further comments on the EEA-agreement.)

- Selection should be based on scientific documentation;
- the efficacy/toxicity ratio must be weighed against the severity of the disease;
- new drugs should represent better therapeutic alternatives than those already on the market;
- fixed drug combinations should be avoided unless the combination shows a clear advantage over that of each active ingredient used separately;
- there should be a clear-cut medical need for any new product (the need clause);
- the number of drugs should be limited;
- approval should be given for a limited period (five years);
- a drug may be restricted to use in hospitals or by specialists.

There arc three criteria in the Norwegian drug selection process which may deserve special comment:

— the need clause;
— the restrictive attitude to fixed combination drugs;
— the limited period of approval/registration.

These have all been important in keeping the number of drugs at a reasonable level, and have been specific to Norway and have not been adopted by most other industrialised countries. Reasons advanced for the limitation of the number of drugs are simplicity, safety, and economics.

It has been estimated that a general practitioner can have pharmacological knowledge of about 50 drugs and be familiar with another 150.[7] In the distribution chain both the wholesalers and the pharmacies can keep a limited number of drugs in stock. With approximately 2,000 products on the market, medical needs are met, while confusion, waste and logistic problems are minimised. This, in turn, contributes to keeping costs down.

As a safety valve, it is possible to apply for a licence to import non-registered drugs.

The need clause

Until 1994, the Norwegian regulations required that a pharmaceutical product, in addition to being medically justified, should also be *needed.*

Through the inclusion of the need clause in the Norwegian legislation some 50 years ago, a social dimension was introduced into drug policy at a very early stage. Drugs were assessed not only from a scientific or technical point of view but also in the light of health priorities and with the aim of protecting the individual from exposure to unnecessary drugs.

The draft parliamentary documents do little to explain the rationale for the inclusion of a need clause. In retrospect, it is also interesting to note that this important principle of medicine with a social dimension was so readily accepted by the medical profession, in contrast to other country cases, where attempts to rationalise drug markets have met with major resistance.[8-9-10]

In the registration process the control authorities have routinely consulted leading medical experts in order to select the most valuable drugs within each therapeutic group. By actively involving opinion leaders in different fields in the drug selection procedure, the regulators gained the support of these crucial actors and stakeholders for the policy.

The number of drugs on the market has in fact been surprisingly constant during the last 20 years. In 1974, there were 1,903 products, in 1977, 1,889, in 1985, 2,080, and in 1992, 2,244 products. The acceptance of a modest number of drugs has also mainly persisted until today. The number of registered drugs thus seems to have met the real needs of the population.

As the term 'need' has not been defined precisely, the Registration Board has had to establish its own practice. The need clause has been used to limit the number of similar products and of combination drugs. However, a small number of similar or synonym products has been allowed to ensure price competition as well as the continuing supply of drugs.

A study of decisions taken by the Registration Board during the years 1981 - 1983 shows that approximately 40 per cent of applications were rejected." Need considerations were involved in more than 60 per cent of these. During the course of 1992, 32 per cent of the applications were rejected and 42 per cent of these were on the grounds of absence of need.[12]

Fixed combinations

Combination drugs, when formulated for commercial purposes without regard to therapeutic gains, as is commonly the case, are at best fraudulent and at worst dangerous.[13]

The Norwegian policy has been based on some essential requirements:

- each component should make a documented contribution to the claimed effect;
- a component may be added to enhance the effectiveness or safety of the active ingredient, or to minimise potential abuse of the active ingredient;
- the components should have approximately the same duration of action.

In addition, a patient population of reasonable size should benefit from the combination. During the last decade, combination drugs have constituted approximately 10 per cent of the Norwegian market. This contrasts sharply with, for example, Spain where they make up approximately 40 per cent of the market.[14]

In Norway, different stakeholders have taken different views on the issue of fixed combination drugs. The medical profession has been supportive of the policy, the industry has been negative but has strategically kept a low profile whereas the general public has been little involved.

Limited period of registration

Drug safety and efficacy cannot be established definitively. Many problems, such as dependence-producing liabilities, appear only after widespread and/or prolonged use. Regular re-evaluation, periodic or continual, is therefore essential. This needs to be based on experience with the drug in common use, and on information derived from monitoring both efficacy and adverse reactions.

In Norway, it has been common practice that the registration period for a drug expires after five years. The drug company must then make a re-application, which may require submission of up-dated safety and efficacy data. The Registration Board has an opportunity to determine whether the drug is still appropriate for marketing or whether indications should be changed. At times, the mere request for efficacy data has resulted in voluntary withdrawal by the manufacturer. In addition, unscheduled revision may be carried out at any time, usually when there is evidence of undue side effects. The principle of having a limited period of registration has now also been adopted by the European Union (EU).

Over the last 20 years, several withdrawals have been initiated by the regulatory agency, most often because of poorly documented clinical effects or harmful effects. Examples of drugs that have been withdrawn are throat lozenges, barbiturates, phenylbutazone, hydroxyquinoline and triazolam.

Hospitals and doctors are routinely granted import licences for non-registered drugs. These are most often required for special purposes such as the treatment of patients with unusual illnesses ('orphan drugs'), and trials of new medication prior to registration. Annually, approximately 20,000 applications for non-registered drugs are granted. This 'loophole' may have contributed to the general acceptance among medical personnel of the strict registration policy.

According to the Norwegian legislation, the price of a pharmaceutical product shall not be 'in disproportion to its therapeutic value'. The cost of a drug should be commensurate with its direct or indirect benefits, as compared to those of alternative products. Data on these matters is, however, difficult to obtain in an objective form and most countries appear to adopt an arbitrary approach.

In Norway, price consideration has, up to 1994, been an integral part of the registration procedure, both for prescription and non-prescription drugs. Negotiations have been conducted with the manufacturer until an acceptable price has been agreed upon. The prices of new products are compared with those of similar products on the market and with prices in other European countries, particularly in the country of manufacturing origin. The system has been more comprehensive than that operating in most other European countries. Prices in Norway, as in Sweden, are substantially lower than those in Switzerland and Germany, for example.[15] Although since 1994, as a result of the EEA agreement- price negotiations can no longer be directly linked to the registration procedure, government approval of price is still required before marketing of prescription-only drugs can be marketed.

It is less difficult to judge if a price increase during the registration period is reasonable. In many countries the authorities have concentrated on this kind of control. In the early 1980s, the Norwegian public health authorities and the pharmaceutical industry developed and agreed on models for price adjustments which take into account factors such as inflation and changes in exchange rates. As would be expected, the pharmaceutical industry has at times opposed the registration and pricing policy. During the early 1980s,

after unsuccessful price negotiations with the National Board of Health, drug manufacturers turned directly to the Ministry and achieved a 15 per cent hike in prices—a substantial increase. Since this 'accident' there has been close cooperation between the Ministry and the National Board of Health in these matters. Since 1994 price issues have become the responsibility of the Norwegian Medicines Control Authority. This institution will be strengthened in 1995 through the establishment of a pharmacoeconomic section.

Advertising and promotion

In general, Norwegian regulations regarding promotion activities correspond closely with WHO'S Ethical Criteria for the Promotion of Medicinal Products.[16] On certain points they have been more strict, for example in not allowing advertising on radio or television or in cinemas, public premises, streets or roads. There are also strict rules on the distribution of samples, and advertising of non-registered drugs is prohibited. During the last few years comprehensive guidelines have been developed on ethical conduct in terms of contact between the industry, physicians and pharmacists.

Advertising must be moderate and objective, not give a misleading or exaggerated impression of the product's medical value, and not be so formulated as to encourage unnecessary or non-medical use of the product. Advertising to the public is limited to selected non-prescription drugs. All advertising which is not strictly based on approved data sheets has been approved by the Norwegian Medicines Control Authority *prior* to use. Preapproval of advertising to the public has been given high priority. In an international study of advertisements in medical journals, those in Norwegian publications emerged as being of a relatively high quality.[17] The greatest challenge, however, is represented not by written ads but by hidden promotional activities, such as 'marketing' clinical trials and meetings, even though these too are covered by the regulations.

Marketing regulations are formally enforced by the Norwegian Medicines Control Authority. Breaking the rules may result in a demand for the distribution of a written corrective statement—5-10 cases a year—or a one-year ban on advertising—1-2 cases a year.

Violations of marketing regulations are also dealt with within the industry itself. A secretariat, staffed by one individual employed by the industry, screens ads in the most common professional journals, identifying 50-70 cases of misconduct a year. Of these, the more complicated cases (approximately 10 per year) are brought before an independent council. Most cases

are, in fact, raised by the secretariat itself or by the competing companies, and only a very small number by doctors and pharmacists. Violations resulting in such reactions may, for example, be promotional claims, indicating a medical effect that is not documented, or hidden advertisements for prescription drugs directed at the general public. The council may impose a fine.

The pharmaceutical industry operating in Norway, while mainly adhering to the rules, also tries out the limits. Marketing activities follow both written and unwritten laws; the pharmaceutical industry, as other actors, adapts its behaviour according to the prevailing ethical codes of conduct and its knowledge of acceptable limits. In Norway, the industry may risk more by stretching the rules than from complying, as the probability of negative publicity is high.

As part of the EEA agreement, the regulations governing advertising and promotion have been slightly amended and now allow, for example, advertising on radio and in public places (but not on TV). Also, more responsibility for monitoring promotional practices has been transferred to the industry itself. Reactions to violations will, however, still be prompt.

It is a declared policy in Norway that all citizens shall have reasonable and reliable access to medicines, medical and health equipment or appliances and related goods for medical use. This requires a sufficient number of pharmacies, an even geographical distribution, opening hours that are in accordance with the needs of the public, an adequate stock of medicines and qualified personnel. No drugs may be sold outside the pharmacy system.

With 4 million inhabitants, Norway has 322 privately owned pharmacies, 68 of which are branch pharmacies. Linked to the pharmacies there are also 1,200 pharmacy sales outlets with a restricted assortment of over-the-counter (OTC) drugs. In addition, there are 26 hospital pharmacies owned by the counties or the state. The population per pharmacy varies from 20,000 in certain rural areas to 10,000 in the Oslo area.

In Norway, distances represent the real challenge. That is why location as much as the number of pharmacies is an important issue. The Norwegian Board of Health decides where pharmacies shall be located, in accordance with a national plan which is regularly revised. Pharmacies are established primarily on the basis of the needs of the public, and not on the basis of business opportunities. The decision to open or close a pharmacy is guided by

such considerations as population per pharmacy, distance between pharmacies, and transport facilities. The local health authorities are responsible for identifying in which locations new pharmacies may be needed.

Because of this policy, a significant number of pharmacies in Norway has insufficient business to be profitable. In these cases, private enterprise would fail without some form of state intervention. To keep these pharmacies, going, the government has set up a system of tax benefits and subsidies to ensure equity, which aims at levelling out inequalities of income stemming from more or less economically favourable locations: the Robin Hood principle. The system is of fundamental importance for the operation of Norwegian pharmacies. Parliament imposes the pharmacies tax each year while the Norwegian Board of Health monitors the economic performance of the individual pharmacy.[18] The tax is progressive and is calculated on the basis of the annual turnover of the pharmacy. The greater part of the revenue is used to subsidise pharmacies whose profit patterns are not satisfactory. Subsidies are not granted automatically, but only after scrutiny of the accounts, especially with respect to wholesale expenses, the cost of wages, and depreciation. If costs are within acceptable limits, pharmacy proprietors in less densely populated areas may rely upon making a reasonable living.

Wholesale distribution: the Norwegian Medicinal Depot

The wholesale distribution of pharmaceutical products in Norway has up to mid-1995 been carried out by a government wholesaler, the Norwegian Medicinal Depot (NMD). Its main premises are in Oslo, and branch depots have been established in three other regions of the country. Although pharmacies vary widely in size and many are situated at a great distance from the nearest branch depot, the prices charged to them have been the same, irrespective of quantities ordered and of delivery distance. All orders are processed with the aid of computers, and the computing unit provides statistics for administrative, scientific, and other purposes.

The NMD was established by law in 1953 as a consequence of the difficult supply situation that prevailed during the Second World War and the tense international political situation in the late 1940s, and was operative from 1957. In addition to being a central organisation for import and wholesale of drugs, the NMD has played an important role in implementing the Norwegian drug policy.

Part of the net income of the NMD has been used for funding the Department of Pharmacotherapeutics at the University of Oslo, which provides the medical profession and also the pharmacies with independent informa-

tion on drugs. It has also been used to support clinical pharmacological and pharmaceutical research.

Until 1994 the NMD had a formal monopoly status. With the implementation of the EEA agreement, the monopoly was abolished, but the NMD will continue as a government-owned wholesaler. New wholesalers will be operative during 1995. However, legal obligations as to delivery to all parts of the country and ability to provide all registered drugs have been introduced.

General medical care is provided either by local public health officers or by private general practitioners. People are free to go to the doctor of their choice, but in the more isolated regions, especially in the north and west, there may be only one doctor who can easily be reached for treatment. Hospital treatment including drug treatment is free of charge, while in outpatient care a cost-sharing system operates. The patient pays a nominal fee per consultation, and the physician claims the remainder of the fee from the government, through the national insurance scheme. The consultation fee does not include drug costs.

The basis of the Norwegian drug cost reimbursement programme is that it applies to patients with prolonged or chronic diseases and sexually transmitted diseases. The diseases for which treatment costs may be reimbursed are specified in the regulations. They should be in a chronic stage and the physician must be convinced that long-term medication is necessary. The formulary now includes 40 chronic diagnoses. The prescribing of certain categories of drugs within the reimbursement system is limited to specialists only and the amount which can be dispensed from a pharmacy is limited to a 3-month supply. For non-chronic ailments, such as acute infections and acute pain, patients pay the full costs. The same applies to non-prescription drugs and contraceptives. Also most hypnotics and sedatives are not reimbursed.

From 1960 up until the end of 1980, medications for all persons suffering from the listed prolonged or chronic ailments, irrespective of age, were completely covered by the health insurance. Then in 1981, concerns about increasing costs led to a change in the regulations and the introduction of cost-sharing. Up until 1988, the patient share was a fixed amount per prescription. In 1989, it was changed to a percentage of the total prescription cost (30 per cent in 1994), up to a maximum amount per year (approximately 150 USD in 1994). The remaining costs are covered by the insurance. Retired people pay a smaller amount per prescription, but the maximum payment

per year is the same as for other patients. There is no charge for children under 7 years of age. An important point is that the annual maximum payment also includes certain other patient shares, e.g. those for consultations.

Due to escalating reimbursement costs, prescribing of low-cost synonyms has been encouraged for many years. In 1991, it became compulsory within the reimbursement scheme to prescribe the cheapest synonym products unless there are compelling medical reasons for doing otherwise. The effect of this cost-saving initiative was limited, mostly due to reluctance among physicians, and by 1992 low-price synonyms accounted for only 50 per cent of the market segment in question (calculated in defined daily doses). In 1993, a maximum reimbursement amount per product where synonyms are available (price of cheapest synonym product + 5 per cent—reference price) was introduced. The additional amount must be paid by the patient, and doctors are required to inform patients about consequences if they prescribe a drug which imposes extra costs. This immediately led to manufacturers dropping prices voluntarily. Presently, only a handful of drugs are priced higher than the maximum amount that will be reimbursed. The price drop was on average approximately 15 per cent, corresponding to an annual saving of 65 million Norwegian crowns (USD 9 million).

The savings should be judged in relation to a total reimbursement budget for drugs of approximately USD 450 million. Most of the reimbursement budget is, in fact, generated by drugs where patents have not expired, and thus synonyms are not available. Therefore, in Norway the potential for cost-saving through prescribing of cheap synonyms is limited.

The increase in reimbursement costs is dependent on several factors: price increases, the growth in the number of elderly people and the introduction of new and more costly drugs. The latter accounts for most of the increase in reimbursement costs.

In Norway, two-thirds of the total national drug bill (including OTC-drugs) are paid by the government, either through hospitals where drugs are free, or through prescription reimbursement. Thus, the government, as the main customer, is in a strong position to negotiate terms on the basis of cost-effectiveness. In order to strengthen this position, it was proposed that a more systematic 'health economics' evaluation as basis for granting reimbursement should be introduced. A government-funded pharmaco-economic unit to support such evaluations will be established at the Norwegian Medicines Control Authority during 1995.

With the increasing tendency in most countries to focus attention on health budgets, the pharmaceutical industry has found it advantageous to present cost-effectiveness data for marketing purposes. Such data are obviously important for health authorities, who correspondingly need competence to evaluate them and also make *independent* assessments of health economic aspects of drug use.

Even a high-quality drug, effectively distributed and affordable by both the government and the individual patient, will not have a positive health impact unless it is appropriately selected (prescribed or self-medicated) and consumed in a rational way.[19] Alongside concern about the proliferation of drugs, the irrational use of drugs became an important issue in the mid-1960s.

More than in many other countries, producer-independent drug information has been used consciously in Norway as an instrument for achieving more rational drug use.

To understand the determinants of use it is necessary to draw on insights from pharmacology, epidemiology and the social sciences,[20] and from political science.[21],[22] Drug use, as part of the process of medical care, requires the people who give and take drugs to make various types of decisions. At all points, they are affected by their varied cultural values, social networks and existing legislations and regulations. The importance of the last link in the drug chain—that of utilisation—was recognised early on in Norway.

An important prerequisite to appropriate selection and use of drugs is the availability of comprehensive and reliable information. To balance the promotional activities of the pharmaceutical industry, various local and central initiatives have therefore been taken. Prescriber-oriented information are provided through independent sources such as:

- drug information bulletins and medical and pharmaceutical journals;
- data sheets for new drugs;
- booklets on therapies and treatments for the major illnesses and ailments;
- therapy-oriented drug formularies giving comparative criteria for selection by the prescriber;
- national and local institutions, such as university departments of clinical pharmacology and hospital pharmacy units, providing information on drugs and poisons.

The need for producer-independent information was promoted by a strong joint team of pharmacologists and pharmacists, and resulted in the establishment of a very unusual institution, a *Department of Pharmacotherapeutics,* at the University of Oslo in 1964.[23] Funds were provided by the Norwegian Medicinal Depot out of its income from drug sales. The first professor of the department (Knut Naess) was a pharmacologist with a strong personality, who was held in high esteem by colleagues, including influential clinicians. A network of clinicians/therapy groups was established, involving the medical community and opinion leaders. A special column in the Norwegian medical journal, entitled 'Drug therapy in practice', gave the department a unique channel through which to convey clear messages and recommendations, based on thorough scientific considerations, to the medical community. The column may at times have been controversial, but it was seldom dull. As producer-independent drug and therapy information has become more readily available, the department has not needed to supply as much traditional information on the most common drugs and has been able to concentrate on communicating problem-oriented therapy issues, and also to carry out its own research into the use of drugs. It is difficult to assess the impact that the Department of Pharmacotherapeutics has had on drug use in Norway, but many of its activities, involving opinion-leading clinicians in discussions, as well as its provision of printed information materials have certainly contributed to a generally increased awareness among clinicians and probably also to the relatively low drug use in Norway.

Since the 1960s, drug and therapeutic committees, with clinicians and clinical pharmacologists, pharmacists and nurses working together, became common. More than 60 of these, based at hospitals around the country, have been involved in discussing principles and recommendations for drug use, along the same lines as the WHO'S essential drugs concept. In fact, in many ways drug and therapeutics committees in countries such as Norway and Sweden could be said to have paved the way for the WHO initiative.[24] They have led to the publication of a number of limited drug lists and guidelines and, more occasionally, of handbooks. However, government demands for increased effectiveness in hospitals, and a preoccupation with budgetary concerns, have left committees with less time for in-depth work and have resulted in waning enthusiasm. The terms of reference for the committees and their authority vis-à-vis prescribers have also often been unclear. Since 1985, the Department of Pharmacotherapeutics has arranged biannual meetings for the committees. Experiments have been going on since the mid-1980s with drug and therapeutic committees in general practice.

In 1994, a pilot project with regional drug information centres were

launched. The centres will collaborate closely with drug and therapeutics committees, clinical pharmacologists and clinicians and provide services to the primary health care system as well as to hospitals and other health institutions.

As new and sometimes extremely expensive drug therapies are introduced (e.g. new serotonin antagonist antiemetics, antidepressants and migraine drugs, hematopoietic growth therapies, erythropoietin, plasminogen activators (TPA), cancer drugs (such as taxol), and also because more drugs will become available as a result of the EEA agreement, drug and therapeutic committees are now arousing new interest and will be important actors on the future drug scene. Developing therapy guidelines, weighing benefits and costs of alternative options and also monitoring adherence to recommendations are clearly becoming more important than just providing limited lists of drugs.

The Norwegian Drug and Therapeutics Formulary, published regularly since 1984 (later than in many other countries) is a joint venture between the Norwegian Medicinal Depot, the Norwegian Medical Association, the Norwegian Pharmacy Proprietors Association and the Norwegian Medicines Control Authority. The Department of Pharmacotherapeutics is strongly involved in the editorial work. It provides independent comparative information on drug therapy and is provided free to all prescribers and pharmacies. Treatment recommendations are given for all common conditions, and all necessary prescribing information about registered drugs is included. Although the formulary is increasingly being used by prescribers, the manufacturers' catalogue, with products arranged alphabetically, still remains a major source of prescribing information for physicians. *This remains a challenge!*

Producer-independent drug information leaflets covering the most widely used prescription drugs are distributed through pharmacies as part of the dispensing. They are far more user-friendly than traditional package inserts. Since 1984, a Drug and Therapeutic Formulary for the general public has been published.[25] Since package inserts will be compulsory as a result of the EEA agreement, these will in most cases replace the information leaflets.

With the establishment of the Norwegian Medicinal Depot a unique opportunity for obtaining data on sales of drugs and raw materials was created. Then, in the early 1970s, two important methodological tools for the study of drug utilisation were developed in Norway. A common drug classification

system, known as the Anatomical Therapeutic Chemical (ATC) classification system, was developed and has since been adopted by WHO for international use; and a new and more precise unit of measurement for drug consumption—the defined daily dose (DDD)—was established and is now used internationally in comparative drug utilisation studies.[26], [27] The NMD played a crucial role in this work. In 1982, a WHO Collaborating Centre for Drug Statistics Methodology was established at the NMD. The centre is responsible for maintenance and further development of the ATC and DDD systems and serves all interested countries.

Norway was one of the first countries in the world to publish regular drug sales data, showing general trends as well as regional differences. This service, which began in 1977, has brought a transparency into the system which enables monitoring of various interventions in the sale, prescribing and use of drugs. For the first few years the industry was represented on the editorial committee. The general approach and level of detail of published figures have reflected medical rather than commercial interests, and protests from the industry have been negligible. The publication is now regarded as a matter of routine, and there is no longer need for an editorial board.[28]

Drug use in Norway is lower per inhabitant than in other Nordic countries and in most European countries. Norwegian health care indicators are rated among the best in the world, with a low infant mortality rate and high life expectancy,[29] indicating that moderation in drug use is not jeopardising health.

Overall sales data showing intra- and international differences may generate hypotheses, open up new areas for research and provide important information on trends and developments. 'The Norwegian Prescription Survey' has been running since 1990, and provides broad prescribing information, linked to patient age, sex and diagnosis and also prescriber characteristics for a rotating sample of prescribers and a registration period of one week for each prescriber. Feedback on prescribing habits is provided to participating doctors, giving them a basis from which to assess and improve the quality of their prescribing. The data are available for research purposes, and have to a limited extent been edited for general publication. The further development of the system to provide long-term drug profiles on an individual level (prescriber and patient), for example based on computerised pharmacy records, represents a challenge, but it also raises professional and ethical concerns about confidentiality. Pharmacy-based projects involving feedback to prescribers have shown that discussions can have an effect on prescribing habits.

After some years of sales data being published, a book entitled *Drug Utilisation in Norway in the 1970s—increases, inequalities, innovations* was published.[30] The use of 15 selected drug categories was analysed in depth. Among the conclusions were that some groups were overused (laxatives, iron, vitamin B 12), some were partly underused (heparin) and others were misused (minor tranquilisers, hypnotics, analgesics). Medically sound explanations could not be found for the majority of the regional differences observed.

It is our belief that general transparency around data on drug use, and regular comments on usage trends in professional as well as general-interest publications, have contributed to increased awareness and accountability among prescribers, the public and health authorities. That the public is sensitised to the issues is of value to all actors on the drug scene.[31],[32] Contrary to experiences in other countries, such as Germany, the industry has not opposed the relative openness around sales data,[33] possibly because it has assessed the attitudes of the other major medical actors to be strongly supportive. It may also have reached the conclusion that such openness does not pose a threat to its interests. Today, there is full agreement on the usefulness of publicly available drug utilisation data.

Transparency alone, however, does not bring about change. It is more important that there is regular debate among health personnel, especially doctors and pharmacists, as well as a high level of accountability. Doctors need to scrutinise their prescribing patterns—individually and together with close colleagues—and modify their practice according to the lessons learnt. Generally, there is a need for better understanding of decision-making in the context of general practice where the majority of prescribing takes place.

Drug use is determined by many factors. The increased use of drugs, partly brought about by aggressive promotion—especially in the Third World—has had an obvious cultural impact.[34] On a global scale, it has increased dependency on allopathy and therefore on doctors and pharmacists as social groups.

Governments are responsible for carrying out regulatory functions to ensure that all drugs on the market are of acceptable quality, safety and efficacy. A most basic question is whether drug regulation achieves its declared aim, that is protection of the public from ineffective, unsafe, or inadequately tested drugs. One way to assess the degree to which a regulatory agency is serving the purposes set for it is to count the drugs on the market.

Norway, through application of the need concept, has kept the number of drugs marketed at a low level for the past 25 years, with around 2,200 products (brands, dosage forms and strengths included). This compares with non-Nordic European countries where numbers range between 7,000 and 25,000.[35]

However, medical views on the *range* of drugs required to meet health needs can differ from country to country. Looking at the acceptance and rejection of drug applications should throw some light on the registration process. Applications for irrational drug combinations have commonly been rejected in Norway. The need clause has kept the number of drugs per therapeutic group very low; in 1980 there were for example just seven non-steroidal anti-inflammatory drugs, compared to 50 in Italy,[36] and only five benzodiazepines: probably the lowest number on the market in any industrial country.

International harmonisation

In small countries, only limited resources are available, and extensive programmes for the continuous evaluation of all kinds of drug therapy problems are not possible. This situation calls for international cooperation. Within the Nordic area the control authorities of different countries have cooperated closely for many years on the evaluation, standardisation, and post-marketing control of drugs, including providing statistics on medicines, and more recently on the harmonising of requirements for clinical trials, application forms and labelling. In this way it has been possible to make better use of limited resources. As long as the main objectives of a National Drug Policy can be maintained, international harmonisation must be looked upon as positive.

Also on a broader international scale, regulatory agencies have been working to harmonise procedures and to increase acceptance of data and standards generated in other countries.[37,38] This cooperation has had some important consequences:

- the criteria for quality, safety and efficacy of drugs have been progressively harmonised, as have many aspects of registration procedures;
- duplication of analytical and toxicological tests and clinical trials can be avoided;
- tests on manufacturing batches carried out in the producing country are accepted by other countries; and
- general requirements concerning labelling and package inserts have been harmonised.

As part of the development of a free market for medicinal products within the EU, a complete new registration procedure will be implemented from 1995. The European Medicines Evaluation Agency is operative from 1995. These developments within the Community will obviously have consequences for Third World countries too and regular contacts have been established with USA, Japan and European countries outside the EU.

In November 1994, the Norwegian people voted against Norway joining the EU. Most of the changes relevant to the pharmaceutical area are, however, part of the EEA agreement. This otherwise important decision will, therefore, not have a significant impact on the development of the pharmaceutical sector.

The ongoing and forthcoming changes in the Norwegian NDP, partly as a result of Norway joining the European Economic Area and harmonisation with the EU, give some cause for concern. Obviously, some of the changes are results of negotiations on a give-and-take basis, including other areas than health, and are in reality a setback. The Norwegian Medicinal Depot's monopoly on import, export and wholesale of drugs formally came to an end in January 1994.[39],[40] At the same time the need clause was abolished, which is likely to result in an increase in the number of products from 2,200 to around 3,000–4,000 within a few years.[41] A larger number of synonyms will make the daily life of doctors, pharmacists and patients more difficult. A larger number of names on the market will cause confusion. The duration of patents may indirectly be prolonged, if the protection period of 15 years from first date of actual marketing in an EU country is introduced. This will delay the introduction of cheaper synonyms and contribute to increased drug costs. Intensified marketing of drugs by the industry is expected as a result of increased competition. A more liberal promotion of OTC drugs to the public, through radio, journals and the mass media, will be allowed. Television commercials are, however, not allowed.

Many of these changes represent a challenge to the government's goal of a rational use of drugs. It must be emphasised, though, that as a result of international developments on the drug scene, with new and expensive drugs, often markedly increasing drug costs, increasing expectations among the public and limited government resources for health care, many of the changes have been necessary independently of the EEA/EU harmonisation.

Measures to meet these new challenges include:

- strengthening of the drug regulatory agency, especially as regards producer-independent drug information (in total 15 new posts have been created during the last three years);
- the creation of Regional Drug Information Centres;
- an increase in producer-independent drug information available to physicians and the public through the above measures;
- strengthened price control in relation to reimbursement and the establishment of a government pharmacoeconomics unit.

The Department of Pharmacotherapeutics, a main resource centre for drug information, is now funded directly by the Ministry of Health and Social Affairs, and the gathering of statistics on drug regulation previously paid for by the Norwegian Medicinal Depot has been transferred to the Norwegian Board of Health. There is in fact a general unease about the effect of the EU not only on the future of drug regulation in Europe but on health issues in a wider perspective.[42] The cornerstone of EU regulations is the original philosophy of a free market, rather than concern for public health. The Norwegian drug regulatory system evolved as a means of serving and protecting consumers. Norway has a very different starting position from that of many other European countries, and mechanisms are needed to ensure that basic aims are maintained. This includes preserving the good elements of the Nordic registration model and drug policy.[43]

The challenge involves preserving as far as possible the principles of the Essential Drugs Concept in the face of strong pressure for free trade at the expense of the well-being of consumers. Some maintain that the risks are overstated but emphasise that governments, professionals, the industry and other actors involved, need to be aware of the dangers.[44]

Whereas for several decades the Norwegian market was governed by a National Drug Policy which operated on a basis of cooperation rather than confrontation, the process of discussing accommodation to EU requirements has meant that conflicting opinions are now being expressed.[45,46,47]

Thus, in the debate previous to the referendum on Norwegian membership of the EU, representatives of the industry were claiming retrospectively that the Norwegian NDP has been contrary to its interests,[48] while regulators warned about the risks of deregulation,[49] and researchers questioned whether a drug supply controlled by the free market could be in line with major public health goals.[50]

Previously, the general policy situation paved the way for a relatively harmonious development of an equitable National Drug Policy. Consultation rather than confrontation has characterised the process. Tools such as the need clause, the five-year rule and a critical attitude to fixed drug combinations have kept the number of registered drugs at a strictly low level, corresponding to about 2,000 drug products. This restricted list, one of the shortest in the world, makes it possible for doctors, pharmacists and patients to get to know the drugs they are exposed to in their various capacities.

For a quarter of a century there have been few, if any, major conflicts between the health authorities, the professional organisations and the drug industry in relation to pharmaceutical issues. Naturally, the industry has been critical of the registration and pricing policy, but, by and large, it has kept a fairly low profile, adapting to the political environment.

One central question to ask is in which way and to what extent tight drug regulation has served public interests. As with social regulation in general, there are conflicting interests. Some have argued that excessive regulation delays the marketing of useful new drugs, thus hindering the research process and impeding the future introduction of new products. The responsible actors have, however, no reason to believe that the restrictive drug policy has deprived Norwegians of necessary drugs.

Equity has been important in the drug distribution system, with the Robin Hood principle safeguarding the sustainability of less profitable pharmacies in supplying drugs and pharmaceutical services in remote rural areas; likewise, social security and reimbursement schemes have enabled access to necessary drugs independent of income.

For three decades Norway has emphasised the importance of the last link in the drug chain—patients and prescribers. Using part of the profit from drug sales to inform patients, doctors and pharmacists about drugs has helped sensitise society to the issue of the rational use of drugs, including when *not* to take drugs as solutions to everyday problems.

Consultation with opinion-leading clinicians in the drug regulatory process proved effective in overcoming potential opposition to a policy restricting the number of registered drugs and thereby the sacrosanct right of doctors to prescribe as they wish. A majority became convinced of the benefits of a rational drug policy, in fact supporting the right of all people to be informed about appropriate drugs. The crucial role of visionary leadership in policy-making and implemention has also been demonstrated.

The present process of working towards harmonisation with the EU, together with the general development in the pharmaceutical field, represents an intervention into a situation where balance between the actors involved had previously been established. New positions will be taken up. The industry is most in favour of the ongoing and expected changes in the pharmaceutical area, whereas health care workers as well as the public are expressing concerns.[51] A democratic society has the responsibility to share information so that the public can make informed choices. This becomes all the more important when a national policy is at risk of being subsumed in a pan-European one, and the media's role in providing the public with information has therefore to be strengthened.[52] The challenge is to maintain a well-functioning National Drug Policy with a public health perspective that has served as a model internationally. The vision of a society in which medicines are seen as something more than a commodity must be allowed to survive.

Norway
Key Facts

I. General
Size: 324,000 km^2 (mainland)
Population: 4,300,000 inhabitants; 20 per cent under 15 years, 14 per cent over 67 years.
Population density: 13 per km^2
Proportion of population living in urban areas: 72 per cent
Capital: Oslo
Languages: Norwegian, Lapp
Religion: Christian protestant
GNP per capita (1991): 23,000 USD
Literacy: close to 100 per cent in relevant age groups

II. Health
Health care expenditure (1991): NOK 55 billion
Health care expenditure, as percentage of GNP: 8 per cent
Life expectancy: women 80 years, men 73 years
Infant mortality rate (1990): 7.0 deaths under 1 year of age per 1000 live births, 2.0 under 24 hrs after birth
Doctors (in active employment): 9,443
Population per doctor: 455
Pharmacists: 2,033 (1136 cand.pharm., university level)
Pharmacies (not including hospital pharmacies): 322

Population per pharmacist: 2,116
Population per pharmacy: 14,000

III. Drugs

Total costs: NOK 5.5 billion (consumer price) (USD 0.8 billion)
Patient share of total drug costs: 34 per cent
Total drug costs (incl. patient share) as percentage of health care expenditure (1991): 9.6 per cent
Number of drugs on the market (brands, strengths, dosage forms): 2,200
Chemical entities: 750
Combination drugs (examples):

antibiotics: 5 out of 80 registered brands: trimethoprim+sulfonamide (3), combination of sulfonamides (1), imipenem+cilastin (1)
cardiovascular: 9 out of 96 registered brands: diuretic+potassium (3), tiazide+amiloride (6)
minor analgesics: 9 out of 22 registered brands: acetylsalisylic acid+codeine (2), paracetamol+codeine (4), fenazon+coffein or codeine (3)
hypnotics and sedatives: 0 out of 15 registered brands

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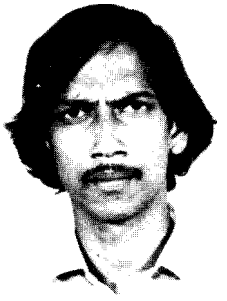
A Search for Balance: Pharmaceuticals in Sri Lanka

Pioneering Steps in a Receptive Environment and Subsequent Accommodations

By Krisantha Weerasuriya



Sri Lanka's pharmaceutical policy represents a classical case of a far-sighted National Drug Policy, even if it is not set out in a single comprehensive government document. Instead it is based on a number of laws, reports and recommendations which have evolved over time and been adjusted and balanced by the political, scientific and administrative process that has been going on since the 1950s and continues today. As the author of this study points out, even if 'much of it is unwritten, a lot of it is in place'. The basis of this pharmaceutical policy is to be found in the democratic traditions of Sri Lanka characterising the early decades of this century, long before the country became independent in 1948, and in its advanced social policies. These provided education and health services free or at low cost to the broad mass of the population earlier than in most countries in the South and, for that matter, than some countries in the North.

A democratic and socially responsible policy does not, however, come about by itself. It requires a person who has both a strong vision and the capacity to make this vision come true. Such a person was the brilliant and charismatic physician and pharmacologist, the late Professor Senaka Bibile who was able to implement step by step Sri Lanka's comprehensive pharmaceutical policy. Important parts of this development were the creation of the National Formulary Committee in 1962, which reduced the number of drugs in the country to about 2,100, and, above all, Bibile's report on 'Management of Pharmaceuticals in Ceylon' (1971), which, inter alia, *proposed the creation of a centralised purchasing authority (called the State Pharmaceuticals Corporation, SPC), the development of an indigenous pharmaceutical industry, the increased use of generic names instead of brand names, and a functioning quality control system. Although his early death in 1977 prevented Professor Bibile from carrying through all his ideas, his work has been continued—despite a more market-oriented government coming to power—by his many colleagues and students, and important reforms have been introduced in the 1980s and 1990s. Examples of such reforms are a strict and formal system for the registration of drugs, which was based on drugs relevant to the health care needs of the country, strong requirements for evidence from clinical trials before the approval of new pharmaceuticals, and an increased emphasis on unbiased drug information.*

The article published here shows how the legacy of Professor

Bibile has been preserved, developed and adjusted to prevailing political, social and economic circumstances during the past two decades. In summing up his study, the author writes: 'Perhaps the future of pharmaceuticals will reflect the fabric of the nation itself. Democracy has survived despite severe economic, social and political threats; the concept of pharmaceuticals as a part of health and not as an item to be exploited will also survive, despite similar tensions. Like democracy, this concept of pharmaceuticals is not perfect or acceptable to all, but will triumph simply by prevailing.'

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Introduction

The Non-Aligned Movement born in the 1950s was the major forum for nations seeking to chart an independent course from the two world power blocs. Third World leaders such as Nasser, Castro and Tito actively participated in the movement's activities and it was an influential force in international affairs. The Non-Aligned Summit Conference held in August 1976 in Colombo, Sri Lanka, was attended by representatives from over 70 nations, including several heads of state, and was probably the most significant international conference of the year. At this conference, the Sri Lankan experience in regulating pharmaceuticals was held up as a model for Third World countries. Sri Lanka had succeeded in rationalising the procurement of pharmaceuticals, purchasing inexpensively for the state health sector and providing drugs at affordable prices to the private sector, while maintaining a sound scientific basis for these activities. It viewed pharmaceuticals in terms of health care needs rather than profitability. The driving force behind these activities was Professor Senaka Bibile, a brilliant and charismatic academic and a physician educated in Sri Lanka and subsequently trained in pharmacology in the United Kingdom. Bibile became the first Professor of Pharmacology in Sri Lanka. His motivation came as much from his roots as from his education: his name signified the backward area of rural Sri Lanka where he was born. Medical education at the time was the preserve of those who could afford it and Bibile financed his education through donations from relations and by winning scholarships. The pharmaceuticals programme he proposed and implemented from 1970 to 1976 had been to the benefit of his country and its people, and now had the potential to assist a much larger population.

However, the programme faltered in late 1976 because the government hesitated over implementing its final stages. Disheartened by the events in his country, Bibile died prematurely the following year while on a mission to assist the Caribbean countries in their pharmaceutical affairs. Although a university colleague continued his work, this was in pharmaceuticals for the Third World generally and not for Sri Lanka itself. Professor Bibile was the co-author of a classic account of Sri Lanka's experience in regulating pharmaceuticals, and interest in the article was such that it was published by three separate journals, from the fields of international development, health sciences and economics.[1]

The ruling party in Sri Lanka was defeated in the general elections in 1977 and the new government reversed some of the earlier measures relating to pharmaceuticals. A study by Bibile's successor at the State Pharmaceuticals Corporation (SPC), Dr Gladys Jayawardena, cast doubts on the achievements of the corporation.[2] Some thought this meant the failure and reversal of all that Bibile had worked for.[3] In the 1980s, Sri Lanka's pharmaceutical activities went largely unobserved by other countries. Recent publications have concentrated on factors that influence prescribing practices, drug utilisation, promotion and registration, and have rarely mentioned the overall situation in pharmaceuticals.[4]

What does this silence mean? Have all the progressive measures been dismantled? Are pharmaceuticals now uncontrolled in Sri Lanka, with commercial interests coming first and the health care needs of the population coming a distant second, or even lower? Or have the basic elements remained intact, with some adaptation to new forces? This article attempts to place the Sri Lankan pharmaceutical situation within the historical context of health-related activities in general. It then describes and analyses the main actors and events, particularly events after 1977, the post-Bibile era.

Although this is an article on pharmaceutical policy in an issue of a journal devoted to the topic, the term 'pharmaceutical policy' has yet to be used. This is for the simple reason that Sri Lanka has no written pharmaceutical policy. There are laws, reports and recommendations which point towards an aim, but there is no government document that lays down aims and objectives in pharmaceutical policy. That is, there is no National Drug Policy. 'Pharmaceutical policy' in Sri Lanka is similar to the British Constitution: much of it is unwritten but a lot of it is in place.

Except for a few key publications, information on pharmaceuticals in Sri Lanka is not in the public domain. Some of the events described in this ar-

ticle are based on unpublished documents and on the personal recollections of those involved. Where possible these sources have been verified. For clarity the country is referred to as Sri Lanka, even though the name was officially adopted only in 1972; the previous name was Ceylon, a name given by the Western countries which conquered the island.

Sri Lanka is an island nation. It has a written history of over 1,500 years and is predominantly a Sinhalese Buddhist country. Invasions from South India throughout the ages have resulted in a Tamil Hindu minority concentrated in the north. The Portuguese, the Dutch and the British colonised Sri Lanka in turn, each ruling for approximately 150 years, starting from the early 1500s. When independence was granted in 1948, the population was mainly rural, with its Sinhalese Buddhist values still intact. The ruling elite, however, had mastered the English tongue and assumed a large portion of the attitudes and culture that went with it.

Universal suffrage was granted in 1931, while Sri Lanka was still under British rule. Ministers were mainly appointed from among the elected members of the House of Representatives—the exceptions being a few key posts appointed by the British Governor General. The Health and Education ministers were from the House of Representatives and were therefore responsible to the population, even though the country was under British rule. People learned very quickly to use their votes to persuade the politicians to provide facilities and services. One of the politicians who persuaded the British to grant universal franchise, thereby demonstrating his faith in popular judgement, later became a Minister of Health. After independence, Sri Lanka was a fully functioning democracy, with regular elections until the mid-1970s. At each of these elections the Opposition was returned to power. Since the mid-1970s the civil war in the north and east (and for a time in the south) has curtailed some of the democratic processes but the government has remained sensitive to popular opinion. The parliamentary elections held in August 1994 returned the Opposition to power after 17 years, re-establishing the pattern of earlier years.

During the period of British rule the most valuable crop was tea. The indigenous Sinhalese population was unwilling to work in the tea estates, and so labourers were brought in from the Tamil community in South India. Since it was economically vital to have a healthy labour force, the government provided a free medical service for the estate labourers. Hence government involvement in health care stretches back at least to the early

part of this century. It is important to note that this involvement was for economic reasons. The pattern was to be repeated in the future; the primary motivation for many of the government's other pharmaceuticals-related activities was also economic rather than health-related. In 1934-35, there was a devastating malaria epidemic which further focused the attention of the government on health care. This time the focus was on the indigenous Sinhalese population as there was little malaria in the tea estates where the Tamil labourers lived. It is worth noting that the infrastructure to record this epidemic and to measure its effect through such indices as crude death rate, maternal mortality and infant mortality was available. The health services were free and accessible to the whole population and were well patronised. A Member of the Parliament would raise questions if the service was unsatisfactory since re-election could be affected by a poor health service in a constituency. This involvement has continued to this day.

The state invested not only in curative medicine but in preventive measures, too. Malaria was almost eradicated in the early 1960s, with only 17 reported cases in one year (though sadly it was to reappear in force later, with over 200,000 cases per year). Malaria was almost eradicated not only because chloroquine and insecticides were available but also because the necessary infrastructure and personnel existed to see that they were used correctly. A literate population (see below) also cooperated. Government activities in the area of pharmaceuticals (to be described below) should be seen within the context of this long-standing provision of health care and not as an isolated phenomenon.

Health and physicians have a special place in any culture but their significance in Sri Lanka is particularly well articulated in the Sinhalese proverb, 'If not a king, then a physician'. In 1956, eight years after independence, when a radical nationalist change swept the country, one of the five key elements in the coalition responsible for the change were the ayurvedic physicians, those who practised the indigenous system of medicine. Drugs of the allopathic and ayurvedic systems are poles apart but the role of the latter does illustrate the important part health played in society at that time.

Another of the five key elements was the village teacher. Education was highly regarded in society; it was a safe route to a secure job and material advancement. It plays a major role, both directly and indirectly, in health; maternal education, for example, is a major determinant of such indices as nutritional status and infant mortality. In 1945, the government abolished tuition fees for pre-university education and in the early 1950s it extended the abolition to the universities. There was no gender discrimination. Health education thus fell on receptive, educated ears.

A medical school was established in Colombo as long ago as 1870 and continues to be the premier faculty to this day. By the 1940s, Sri Lanka's medical services were entirely staffed by doctors trained in this medical school. Unlike in Africa, Sri Lanka never had a significant system of church-based mission hospitals; nor did expatriate doctors play a prominent part in local medicine. Though British medical tradition and postgraduate training held sway, there were doctors who boldly attempted to fashion solutions relevant to Sri Lanka. Professor Bibile, a graduate of the Colombo medical college, was a particularly good example.

Health and education services were part of a generous welfare package provided by the government, which also included food subsidies. The very favourable influence of this on the well-being of the population has been clearly outlined.[5] Infant mortality is 17.2 deaths per 1,000 live births; life expectancy is 67.8 years for men and 71.7 years for women.[6] Nevertheless the services did have gaps and failures. A few decades could not wipe out age-old societal inequalities and the available resources were insufficient to provide a comprehensive service. In addition, some segments of the population, such as the Church, preferred to provide their own services. For these various reasons there was a vigorous but small non-government sector which mainly served the more affluent segments of society in the areas of education and health. As a consequence, a considerable private sector market for drugs has existed for decades. In the 1960s the private sector imported more pharmaceuticals (by value) than the government sector.[7]

Measured steps

There was an explosion of new drug discoveries in the world in the 1950s. These drugs were imported for use in Sri Lanka soon after they were available in the industrialised countries. Postgraduate education for doctors trained in Sri Lanka was invariably in the United Kingdom and those returning home continued the prescribing habits they had acquired abroad. For example, penicillins and sulphonamides, which came to be widely used in the industrialised world in the late 1940s, were available in Sri Lankan hospitals as early as 1951. These drugs were not limited to those who could afford them but were available in hospitals as part of government health care.

Government regulation of pharmaceuticals soon followed. Regulations were enacted in 1955 under the Food and Drugs Act to govern the sale and distribution of drugs. These regulations specified that only drugs listed in specified foreign pharmacopoeias could be imported. Superficially this may appear to have been an abandonment of the right of the country to choose the drugs that could be imported, but in practice it was a wise step. At the

time, Sri Lanka did not have the expertise to make informed choices, and depending on specified pharmacopoeias ensured reliable drugs. The Food and Drugs Act also required that drugs be sold only by those with an approved licence. It specified the details that should appear on the labels, which included the active ingredients. These actions demonstrate that, from the beginning, drugs were viewed as items that had to be regulated. Although such a view is now very common, it would have been radical in the 1950s.

In 1957, concerned by the cost and the multitude of the drugs that were being ordered by state health services, the government formed a Formulary Committee to give advice on the use of pharmaceuticals in government hospitals. The committee consisted of three physicians from the largest government hospital, a paediatrician from the government sector, Professor Bibile and a non-medical secretary. It compiled the Ceylon Hospitals Formulary (CHF), edited by Professor Bibile, which was published in 1959.[8] The comprehensive list of drugs in the CHF provides an indirect indication of what was available at the time. Generic names were used throughout and the dosages were given in the more rational metric system. The prestigious *British Medical Journal commented* that the CHF was 'compact, compendious and helpful'.[9] The formulary was one of the earliest state hospital formularies in the world and was an important contribution towards encouraging the rational use of drugs. The formulary became the *de facto* list from which the government ordered drugs. From the beginning, the Formulary Committee insisted on scientific evidence before a drug could be approved, a tradition continued by the committees that succeeded it. Establishing this criterion was vital as it prevented the approval of drugs of dubious clinical value on the recommendation of influential clinicians. However, it must be noted that the Formulary Committee's authority was limited to the government hospitals; the private sector could and did import and market any drug that it chose.

Faced with diminishing foreign currency reserves in the 1960s, the government needed to restrict imports. In 1962, encouraged by the success of the Formulary Committee in the public hospital sector, the government renamed it the National Formulary Committee (NFC) and expanded its authority to all drugs imported into the country. The NFC was made a statutory body in the Ministry of Health. The Professor of Pharmacology was made the *ex officio* secretary of the committee, and representatives from the professional medical associations were included, too. In effect, the NFC became the regulatory body for drugs in the country. The Drugs Sub-committee of the NFC reviewed the 4,000 available drugs (6,000 dosage forms) and

recommended that the number be reduced to 2,100 drugs (3,000 dosage forms). The recommendation was accepted by the government and imports were restricted to the approved drugs. Any new drug had to be approved by the NFC before it was imported. This type of regulation was not common at that time; the United Kingdom only formed its own Committee on the Safety of Drugs two years later, in 1964.[10] It is interesting to note that economic factors gave rise to the regulation of drugs in Sri Lanka, whereas the safety concerns generated by thalidomide were responsible for the regulation in the United Kingdom. However, regulation in both countries was based on sound scientific principles. The principle of approving drugs before allowing their use remains to the present day in Sri Lanka.

During this period, regulation ensured not only the usefulness of drugs but also their affordability. Due to the high cost of drugs, a state take-over of pharmaceutical imports was considered in the late 1950s and a cabinet paper was prepared. However, no further action was taken. The Control of Prices Act, enacted in 1950, was designed to regulate and control prices as well as ensure the supply of commodities. The Minister of Health brought drugs under this act in 1968, and the wholesale and retail prices were fixed by notification in the *Ceylon Government Gazette*.[11] Other measures used to regulate pharmaceuticals were the Import and Export Control Act and the Customs Ordinance. The rationale behind these measures appears to have been that drugs were commodities to be controlled by health considerations and not by the market. It is also important to note that, while Acts of Parliament provided the framework, the measures were enforced by regulations which were mainly administrative procedures. These regulations also limited the availability of prescription drugs to pharmacies, an influence which persists to this day. Other Third World countries may have had similar legislation and intentions but Sri Lanka was able to enforce them.

A new government was elected in 1970 with a large majority. This government asked Professor Bibile and Dr S.A. Wickremasinghe (a Member of Parliament in the government party and a medical doctor) to inquire into the import, manufacture, distribution and sale of pharmaceuticals and to recommend measures to ensure an adequate supply at reasonable prices. The report, written mainly by Bibile, was clear, concise, practical and very perceptive.[12] After giving background information on total pharmaceutical imports into the country, it recommended further rationalisation of the drugs being imported, the setting-up of a centralised state purchasing authority and the take-over of imports by the government. The report also proposed the development of the Sri Lankan pharmaceutical industry to enable it to

manufacture dosage forms from raw materials, the use of the generic (scientific) name in prescribing, the provision of unbiased drug information and the phasing-out of drug advertising. It favoured modification of the patent laws to enable purchases to be made from cheaper, non-traditional sources. The report strongly recommended the setting-up of a quality control system for pharmaceuticals. All the academic staff of the departments of Pharmacology in the two faculties of medicine (a new faculty having been created in the 1960s in Peradeniya near Kandy) contributed to the report and are acknowledged in it.

The *Ceylon Medical Journal* agreed with all the recommendations except the ban on drug advertising, but urged caution in their implementation.[13] The *British Medical Journal* published a shortened version of the report and commented editorially on it.[14] While it agreed with some of the conclusions it had reservations on others, including the replacement of phenacetin by paracetamol. Most countries have since banned phenacetin, bearing out the conclusions of the report.

The Ministry of Health also had some reservations about the report and formed a committee to study the recommendations further. Despite this, the government went ahead and formed the State Pharmaceuticals Corporation (SPC) under the aegis of the Ministry of Industries. With characteristic efficiency, Bibile organised the SPC and took control of imports in a phased manner, with minimum disruption to the supply of pharmaceuticals.

A report by Bibile for the United Nations Conference on Trade and Development (UNCTAD) describes the strategies used to ensure quality and the savings achieved by the SPC.[15] The successes were significant—the same or an even larger quantity of drugs was imported for the private sector at a fraction of previous prices. Purchasing from non-traditional sources produced enormous savings on commonly used drugs such as diazepam and propranolol. Importing inexpensive generic drugs instead of expensive brand-name ones produced benefits for all except the importers of the latter. The story of the SPC is described in detail by Bibile and it is sufficient to mention here that drugs of good quality were provided at reasonable prices.[16]

There was, however, an inevitable reaction from the brand-name manufacturers. Rumours about the poor quality of generics were rife, though none was ever substantiated. The Pharmaceutical Manufacturers Association of the United States even recruited its government as an ally in its opposition to the policy. The withholding of food aid from the USA was used as a threat. The reaction was quite disproportionate to the financial loss since Sri

Lanka was only a minuscule portion of the world pharmaceutical market. Probably a far greater threat was the example of a Third World country succeeding with generic drugs and a rational procurement policy. Professor Bibile also had to counter the local opponents of reform, who used innuendo, rumour and whatever pseudo-scientific arguments they could muster to support the import and use of more expensive brand-name pharmaceuticals.[17] No documentary evidence of poor-quality drugs reaching patients was ever produced. Unfortunately, there was no organised support from within the medical profession and Professor Bibile often fought the battle alone. In late 1976, the serious economic crisis forced the government to halt the final stage of its pharmaceuticals programme. Disheartened by the lack of government support, Bibile resigned from the SPC.

The elections in July 1977 returned a government that was more receptive to 'free market' economic policies. The new government represented a radical shift in state policy, similar to that in the United Kingdom under Margaret Thatcher. In some years, 40 per cent of total government spending had been on social services and food subsidies.[18] This was basically unsustainable so the government decreased the role of the state in the economy and encouraged the private sector.

Professor Bibile sensed some of the political changes that were to occur in 1977 and wondered what might happen to the reforms that had been achieved in the pharmaceutical sector.[19] His premonitions were well founded but fortunately the reversals were only partial. A group of 'concerned citizens' urged the newly elected government to allow the private sector to import pharmaceuticals.[20] This group never made any other statements of public concern and the full constitution of the group was never known. The academics who supported Bibile's policies demolished every argument put forward by the group but the government still decided to allow the private sector to import pharmaceuticals. The other advances of 1970-76 remained intact and the SPC continued to be the monopoly importer for state drug requirements and also to import and distribute to the private sector.

In 1977, the new government removed the SPC from the Ministry of Industries and placed it under the aegis of the Ministry of Health. This was fortuitous. The Minister of Industries had seen the SPC in a national context, whereas the Ministers of Health during the term of the new government saw it as an instrument to serve the needs of the Ministry of Health. Adminis-

trators from this ministry were made *ex officio* directors of the SPC, which enabled closer coordination.

Dr Gladys Jayawardena, a medical microbiologist retired from the government service who was also the sister-in-law of the President of Sri Lanka, was appointed to the Chair of the SPC. In March 1978, she chaired the WHO South-East Asia Regional Seminar on Drug Policies and Management, which was attended by participants from eight countries in the region. The recommendations of the report that came out of the seminar were broadly similar to those advocated by Professor Bibile.[21] The report also mentioned the problems of transfer pricing, over-invoicing and fluctuation in prices of raw materials, which Bibile had written about. Dr Jayawardena was most probably influenced by these conclusions, although her initial actions suggested otherwise. She published a document that questioned the achievements of the SPC in the 1970s.[22] She gradually took full charge of the SPC, assuming the post of Managing Director in addition to her post as Chairperson. Colleagues on the SPC remember her as a very efficient, at times abrasive, proponent of the Committee. The fact that she was the sister-in-law of the President allowed her to function without political interference. The establishment of the Oral Rehydration Salts manufacturing facility and the State Pharmaceuticals Manufacturing Corporation were mainly due to her efforts. The SPC loomed large on the pharmaceutical scene in the mid 1980s and Dr Jayawardena's policies at that time were indistinguishable from those of Professor Bibile.

The 1980s were a very successful period for the SPC, a fact that has gone largely unnoticed. While advocating the use of generic products, it also provided branded products when the market demanded them. It consistently made a profit as well as making the obligatory contribution to the government treasury. In the 1990s, the SPC is the monopoly supplier of pharmaceuticals to the government, a situation which has remained unchanged since the 1970s. It is also the major supplier to the private sector. In 1989, Dr Jayawardena was assassinated during the height of the civil disturbances that gripped the country; the assassins have not been caught and there has never been a satisfactory explanation of their motives. In the 1990s, the SPC has continued along the path mapped out by its two forceful leaders, though with a less visible profile.

Legislation in pharmaceuticals

In 1980, the government passed the Cosmetics, Devices and Drugs Act, a comprehensive piece of legislation.[23] This was based in part on Canadian legislation, which placed a strong emphasis on generics. What was import-

ant was that the legislation was suitable for Sri Lanka; all too often Third World countries adopt rather than adapt legislation from industrialised countries and then find it difficult to implement. However, as is often the case in the Third World, it took six years for enabling regulations for the act to be prepared and approved. At present, all sections have been implemented except for a few that require trained human resources.

The act also indirectly defines the role of the private sector and the SPC by specifying the composition of the Technical Advisory Committee (TAC). which advises the Ministry of Health. The 15-member committee consists mainly of medical personnel. The Chairperson of the SPC is an *ex officio* member and a private sector industry representative is nominated by the Pharmaceutical Manufacturers Association. The act does not require the members of the TAC to declare their interests and links to the pharmaceutical industry, even though most countries require all members of regulatory committees to declare such interests. In the United Kingdom, for example, some members of the Medicines Commission are wholly remunerated by pharmaceutical companies and a majority have financial links with the industry which have to be declared.[24] The lack of similar requirements in Sri Lanka creates the potential for undue influence.

One aspect of the act that has been fully implemented is the registration of drugs. The registration is valid for five years. All pharmaceutical products have been registered since 1987; since 1992, obsolete drugs have been refused re-registration. Advertisements for over-the-counter drugs have to be approved by a committee appointed by the Ministry of Health.[25] New regulations that specify the format in which brand and generic names appear on labels have been enacted but are yet to be enforced.[26]

Essential drugs

In 1985, the Ministry of Health held a meeting at which Sri Lanka's Essential Drug List (EDL) was developed.[27] The meeting also issued a report on the management of pharmaceuticals. This formalised what had been in practice for decades. State health care institutions had ordered from an approved list of drugs since the early 1960s. These drugs were then purchased through international generic tender. Most of the participants at this meeting on essential drugs were officials from the Ministry of Health, with a few from academia and the medical associations. The meeting was not without drama. An official of the Sri Lanka Medical Association, who was also a vigorous proponent of the pharmaceutical industry, firmly stated that the association was opposed to the Essential Drug List. However, when challenged to produce an official statement from the association to support his

contention, he had none and was forced to retract. A second meeting was held in 1988 and the EDL was revised. At this meeting, a National Drug Policy was discussed and a report was subsequently issued by the Ministry.[28] The crucial question of the price of pharmaceuticals was not considered at either of these meetings.

Both these meetings were supported by the WHO Action Programme on Essential Drugs and produced valuable documents for the Ministry of Health. However, these were not formally adopted by the state as policy documents. On the other hand, officials of the Ministry of Health who were involved with the regulation of pharmaceuticals had a chance to discuss essential drugs and the priorities of the Ministry.

Prices of pharmaceuticals

Price control was imposed on pharmaceuticals in 1968 and was abolished by the new government in 1977. The price of pharmaceuticals rose sharply, one reason being the devaluation of the rupee, another being the cost of brand-name drugs. There were examples of gross profiteering: a brand of cimetidine from India was sold to patients at 1,600 per cent of the cost, insurance and freight (CIF) value. Nevertheless, the private sector could not charge exorbitant prices because the SPC continued to import the equivalent generic drugs. In 1986, discussions began with the pharmaceutical trade on a pricing formula. At the end of 1988, a formula of 178 per cent of the CIF value was agreed on for the retail price. In late 1988, a new president was elected and the imposition of this formula provided him with a politically popular decision at the beginning of his term. At present, the retail price is 165 per cent of the CIF value. Superficially this appears to control the prices; in reality it does not, since the CIF price is not controlled.

The private sector

The private health care sector grew markedly after 1977, with the encouragement of the government. The private pharmaceuticals sector grew, too, the growth coming from imports rather than local manufacture. The change in the sources of pharmaceuticals also affected the private sector. In the 1960s, most pharmaceuticals were imported from Western European countries. In the early 1970s, with the establishment of the SPC and its monopoly on imports, pharmaceuticals were obtained from Eastern European sources, though a significant proportion was still obtained from Western Europe. In 1977, when the private sector was allowed to import again, the SPC was importing mainly from countries like India and China, and the private sector also started importing from India. Throughout these years, the subsidiaries and agents of transnational corporations had imported from

their principals, mainly from Western Europe though also from the Indian subcontinent.

When the import of pharmaceuticals was liberalised in 1977, generics grew to be a significant portion of the imports of the private sector. In the mid-1980s, an importer of generics became the largest pharmaceutical company in the private sector. This is a good indirect indication of the penetration of generics into the pharmaceutical market in Sri Lanka. This occurred in spite of the presence of every major transnational pharmaceutical company in the country.[29] (In most countries these brand-name manufacturers dominate the market, and generic manufacturers and importers are minor players.) Casting aspersions on the quality of generic drugs became a common tactic of the medical representatives of the transnational companies. However, importers of the products of transnational companies realised that they were losing out to the cheaper generic products and soon found inexpensive sources of generic drugs for themselves. Currently, some importers have one set of medical representatives promoting products from transnational companies and denigrating the quality of Indian products, while another set promotes generic products on the strength of their affordability. Recently, the transnational companies themselves have adopted this duality in their home countries; in the face of fierce price competition, many transnational companies have acquired existing generic companies to provide an inexpensive line of pharmaceuticals.[30]

A Presidential Task Force for the formulation of a National Health Policy was appointed in March 1992. In his introductory address, the President asked the task force to address the question of what Sri Lanka's policy on drugs should be.[31] After wide consultation, the task force submitted its report in late 1992. Drugs did not have a separate section in the report, but they did form almost the entire chapter on logistics. The focus was not entirely on supply: rational use was also emphasised. Many of the recommendations were Utopian but some aspects of pharmaceuticals were considered for the first time in an official state document. Among these were a 'need' clause for registering drugs, a reduction in the number of brands of a particular drug, a ban of over-the-counter drug advertising in the media, and control of promotion by the pharmaceutical firms. The report also recommended stricter control of prices, acknowledging that present regulation was not satisfactory, and the strengthening of independent drug information.

In summary, after 1977 there were a few abrupt and major changes, but most

changes were gradual accommodations to evolving conditions. This is in contrast to the early 1970s, when radical changes were propelled by a clear vision. Though lessening its direct intervention, the government still intervened and used regulation to influence the pharmaceutical sector. The pharmaceutical situation was in a slow state of flux, with some drift towards the private sector. At present, the SPC is the major presence in the pharmaceutical sector but the private sector is growing. This growth of the private sector is due partly to greater volume, indicating an increased market share, and partly to increased prices, especially for brand-name products.

The balance at present

This section describes and analyses factors and actors from the late 1970s to the present which have contributed to the current situation in pharmaceuticals. Geography, the registration of pharmaceuticals, the patent system, politicians, the administrators, the medical profession, the SPC, and the private sector have all influenced pharmaceuticals to varying degrees. Some played an active role whereas others, who had the potential to be active, were content to be passive observers. The following section looks at the losers in this period.

The country

Sri Lanka is an island, a geographical fact which has certainly helped in the control of pharmaceuticals since strict regulation within a country can be thwarted by the smuggling of drugs across land borders.[32] Drugs are brought into Sri Lanka through the port of Colombo and the airport in the suburbs. Recently the Ministry of Finance has been actively seeking to maximise revenue. The registration certificate for drugs supplied by the Ministry of Health provides revenue through application and registration fees, and customs officers have been ordered not to allow any imports without this certificate. Hence the strict imposition of regulations is due less to health policy than the need to maximise revenue.

Geography has helped in other ways. India, Sri Lanka's closest neighbour, has a vigorous pharmaceutical industry and is a good source of low-cost pharmaceuticals, though on a few occasions there have been problems in quality. Having a ready supplier of affordable pharmaceuticals in close proximity has helped Sri Lankan importers to supply low-cost items.

The relatively small size of the country has advantages. The Ministry of Health is responsible for almost all health-related activities (which in itself enhances its authority) and, although centralisation has its own problems, in pharmaceuticals this has meant coordinated and uniform activities. A

doctor working in the government sector can find the same familiar drugs from one institution to another. Hospitals order by generic name and are supplied accordingly, avoiding the confusion associated with brand names.

The prolonged and savage armed conflict in the north and east of the country between the government and the various Tamil groups has dominated national life for the past 15 years. Surprisingly, it has had little effect on pharmaceuticals. The dependence of both sides on the pharmaceuticals supplied by the government may be the main reason for this minimal impact. Unlike the situation in some other countries, where the armed forces have their own medical colleges, those in Sri Lanka coopt medical personnel from the civilian services. These doctors naturally request the drugs they were familiar with in civilian practice. The various Tamil groups have depended on the drugs supplied by the government to the civilian population in the north and east. These drugs are no different from those supplied to the other parts of the country. Control of any kind is necessarily lax during a conflict, and smuggling is a possibility. There have been no reports of such smuggling, but it is not possible to be certain in these situations.

Registration of pharmaceuticals

From 1962, the National Formulary Committee (NFC) advised the Ministry of Health on the drugs that should be used in the government and private sectors. Since the vast majority of drugs were imported, this effectively meant approving drug imports. Government regulations required the importing company (which had to be based in Sri Lanka) to obtain approval, thereby making one company totally responsible for a particular product. This made it administratively easier to tackle any problem in supply, quality or promotion. In some countries, by contrast, approval is obtained by a local agent of the manufacturer, and any wholesaler can purchase and import direct from the manufacturer. If there is a problem with a product, such as poor quality, the importer responsible for that particular batch of the product has to be identified, which is not always easy.

The NFC notified the pharmaceutical products it had approved in the *Ceylon Government Gazette*. With the implementation of new regulations in 1987, this system of approval was superseded by registration of pharmaceutical products. It should also be noted that some non-prescription drugs were being formulated in Sri Lanka and, therefore, that locally manufactured products were also being approved. This system of approval has been a crucial and effective method of regulating pharmaceuticals in the country since the 1960s. Most countries now have some form of registration, but only a few have a system that has functioned continuously for 30 years.

Even at present, some countries in Europe, such as Malta, have no registration systems and allow any pharmaceutical product to be imported on the basis of a free sales certificate (that is, it is sold in the country of origin). Both the process and the personnel involved in this critical task of drug approval in Sri Lanka are described in some detail below.

From its beginning, the committee that approved pharmaceutical products was based in the Department of Pharmacology in the Faculty of Medicine in Colombo. The committee has functioned under many names throughout its long existence, the latest being the Drug Evaluation Sub-committee. The Ministry of Health has depended on the committee since its inception and has virtually rubber-stamped all of its decisions. Professor Bibile was the guiding force in the first committee. After him, the dominant figure was Professor N.D.W. Lionel, a clinical pharmacologist from the Faculty of Medicine in Colombo who had trained in London in the 1950s, along with the pioneers of the newly emerging discipline of Clinical Pharmacology. On his return to Sri Lanka, he became a Senior Lecturer and later Professor of Pharmacology at the University of Colombo. He moulded the thinking of generations of both undergraduate and postgraduate medical students. In 1970, Professor Lionel provided a large amount of technical input into the Wickremasinghe-Bibile report and is fondly acknowledged in it. He was respected by the medical profession and was President of both the Sri Lanka Medical Association and the Ceylon College of Physicians. He was an independent authority with no ties to industry, and thus his decisions and comments on drugs were accepted by the medical profession without question. Professor Lionel was also accepted by industry, because his decisions were based only on scientific grounds. He was secretary to the expert committee that drew up the first WHO-model Essential Drug List in 1977.[33] In 1977, along with Margaretha Helling-Borda, the present Director of the Action Programme on Essential Drugs, Lionel co-authored a survey of drug policies and management in Sri Lanka.[34] In 1981, he wrote another article on drug policies which undoubtedly drew on the Sri Lankan experience, though no specific examples were mentioned.[35] His premature death in 1982 was a loss from which clinical pharmacology in Sri Lanka has never fully recovered.

The only formal legislative criteria for the approval of drugs related to safety and efficacy, not need. However, the pattern of approvals showed the strong influence of the British medical tradition, with its therapeutic conservatism and a reluctance to approve drugs that had not been approved by a good regulatory authority in an industrialised country. Professor Lionel further strengthened the requirements for evidence from clinical trials before ap-

proval of a drug, and neither anecdotal nor testimonial evidence was accepted. This is routine practice in many regulatory authorities now, but it represented a bold and unusual practice in the late 1960s and the 1970s. Insistence on clinical trials placed the decisions on a scientific basis, which prevented pharmaceutical firms from applying for registration with only vague evidence of efficacy and safety.

Although a 'need' clause did not officially exist, not every substance that was safe and effective and approved in an industrialised country was registered. This was especially noticeable in the 1980s, when Professor W.M.T. Weerasinghe, Lionel's successor, was head of the Drug Evaluation Sub-committee.[36] Only a limited number of the beta-blockers, non-steroidal anti-inflammatory drugs (pain killers), and benzodiazepines (sedatives) that were submitted for approval were registered. 'Me-too' drugs (molecular manipulations of the original drug with no additional therapeutic benefit) were rarely registered in Sri Lanka. There are no records of the discussions of the Drug Evaluation Sub-committee, so the exact basis of these decisions is unknown. However, most of the clinicians in the sub-committee were from the state sector and practised with a limited list of drugs which they found to be satisfactory; thus, they probably saw no reason to approve 'me-too' drugs.

However, the sub-committee could not prevent the registration of the many brands of an approved substance, except for reasons of quality. This has led to many registrations of the same substance, the most extreme example being the 70 registrations for different ampicillin products. This may have had the minor advantage of demonstrating the fairness of the sub-committee: once a substance was approved there were no arbitrary barriers to registrations from multiple suppliers. The recommendations of the Presidential Task Force on National Health Policy have now provided a basis for limiting the number of brands of a particular product, though they have yet to be implemented.

The Drug Evaluation Sub-committee is not a very high-profile body but it has maintained its credibility among the medical profession. None of the sub-committee members has links with the pharmaceutical trade. This may be due, in part, to the small size of the pharmaceutical trade; nevertheless, it remains the case that the sub-committee is perceived by the medical profession to act in a manner where justice is not only done but also seen to be done.

The patent system

In the 1960s, the law in Sri Lanka provided for the patenting of both a product and the process of manufacturing it. Despite this, in an effort to provide drugs to the people, the government imported drugs for the state health services at a very low price from manufacturers who did not hold the patent. The private sector, which imported from the patent-holders, obtained the drug at an astronomical 2,000 per cent more.[37] The Bibile report recommended changes to the patent system, but no action was taken. In the 1970s, the SPC imported other items which were under patent (for example, propranolol and diazepam) from alternative sources at substantial savings, and provided them to the private sector, too. The patent-holders sent warning letters but did not proceed any further—perhaps because they did not relish the prospect of fighting a state corporation.[38]

In the 1990s, Sri Lanka continues to provide strong patent protection. This system provides very little or no benefit to the consumer in the Third World but results in high prices for the patented product.[39] Omissions in patent registrations in Sri Lanka have been exploited by importers of low-cost products. Some products under patent protection in industrialised countries are not protected in Sri Lanka as their patents have not been applied for. These include the newer cephalosporin and quinolone antibiotics, and the new ACE inhibitors for blood pressure. The original manufacturers of these drugs have obtained registration from the Drug Evaluation Sub-committee and introduced them into Sri Lanka, only to find inexpensive competing brands being introduced a few months later.[40] This is a good example of market forces providing less expensive drugs, but such examples are rare, partly due to the unusual nature of the pharmaceutical trade.

The future of the patent system remains very uncertain. The General Agreement on Trades and Tariffs (GATT) signed in May 1994 limits the flexibility of governments to modify patent laws to serve the needs of their people. Pharmaceutical patents have been included among Trade-Related Intellectual Property Rights (TRIPS) in the GATT agreement and the exact consequences of this are still unclear. The patents on virtually all the drugs in Sri Lanka's Essential Drug List have run out (a common pattern for national EDLs) and will not be affected by the GATT agreement. However, in the future, a product of vital importance to Third World countries, such as a vaccine for malaria, if protected by patent, could be unaffordable for the majority of the people who need it.

The 'rules of the game' in the pharmaceutical industry (in which patents play a large part) have been influenced by research-based companies, sometimes with the tacit consent of the governments of industrialised countries. This is

not necessarily immoral or illegal; governments may, in consultation with the businesses and industries they regulate, have decided that ultimately this was the best move for their health, social and economic interests. However, the interests of those outside the national boundaries are not considered. Therefore, governments and industry in industrialised countries must acknowledge, in turn, that Third World countries have the right to define the rules within their national borders, regardless of external interests. If the policies of Third World countries, aimed at getting the most out of their all-too-often meagre resources, were to disadvantage the research-based companies, there would be claims that research into diseases of the human race was being affected. However, these claims should not be considered seriously. Research has not been into all diseases of the human race but into those that benefited the financial interests of the pharmaceutical companies. It has not included the major diseases that affect the people of Third World countries. At present, the rules of the game require these countries to pay the full cost of an expensive meal while getting only the scraps that fall from the table.

The conflict between patent protection and affordable pharmaceuticals is an issue that will have to be addressed by National Drug Policies in the 1990s. Like many other countries in the Third World, Sri Lanka has so far been a passive observer of this issue and may ultimately have to bear the costs of inaction.

The political masters

Ministers of Health, with one notable exception, have had political control over pharmaceutical issues in Sri Lanka. Some of these have had a professional background which has been helpful in understanding the complex issues involved. The fact that the first Sri Lankan Minister of Health (in the 1930s) was a veterinarian may have initiated the tendency to have a technical person in the post. The Minister of Health during the 1980s (a crucial time for the SPC) was a student of Professor Bibile who had a clear idea of national pharmaceutical requirements. He had worked in government hospitals at the beginning of his professional career and found the range of drugs provided to be adequate. Subsequently, as a family practitioner in a rural area, he needed to supply affordable drugs to his patients—an experience which convinced him of the benefits of low-cost generics. As Minister of Health, he concentrated on improving the supply of available drugs rather than increasing their range. One of his major achievements was the construction of the modern Central Medical Stores for the island, which made a valuable contribution to the efficient distribution of pharmaceuticals to government hospitals. As a medical man and a cabinet minister, he

provided sensible opinions to counteract the views of his lay colleagues, who were at times influenced by the pharmaceutical trade. He supported the SPC within the cabinet and was partly responsible for its continued progress during the 1980s.

The exception to the involvement of Ministers of Health occurred in the first half of the 1970s. The then Minister of Health hesitated over implementing the Wickremasinghe-Bibile report and the Minister of Industries was given the task. Although he was from a non-medical background, he had a clear idea of the issues involved and supported Bibile unreservedly. It is doubtful whether the SPC would have established itself and carried out its vital role in the early stages without this crucial support at the beginning.

Without access to official documents, it is difficult to explain why Sri Lanka had Ministers of Health generally sympathetic to rational activities in pharmaceuticals. Those who were from non-technical backgrounds probably saw pharmaceuticals, and thus health, as part of the political agenda. If they had misgivings about state involvement in pharmaceuticals, they might have been convinced of its value when the administrators in the Ministry of Health demonstrated the enormous benefits of centralised generic purchasing to the drug budget. As politicians, they would also, no doubt, have appreciated the fact that state health services (of which pharmaceuticals were an important component) would be an issue during elections.

The administrators

Administrators in the Ministry of Health are another group that has played a major role in pharmaceuticals in Sri Lanka. These are doctors who have initially served in state hospitals and then risen through the ranks. Many of them have benefited from the free education system and thus appreciate the idea of health being, like education, a basic right. The interests of the pharmaceutical industry are a very distant second. As doctors themselves, they are familiar with pharmaceuticals and so, unlike non-medical administrators, are not influenced by superficial arguments. In the 1950s, the Ministry of Health delegated responsibility for evaluating pharmaceuticals to academics, whose decisions were helpful to the administrators in supplying appropriate drugs at reasonable cost. In its efforts to regulate pharmaceuticals Sri Lanka has only rarely witnessed the conflicts between different interest groups which other Third World countries have experienced.

The administrators have made an enormous practical contribution in fashioning (at times even originating) and implementing regulations. While the political masters may have given general directions (at times on the ad-

vice of the administrators), it has been the administrators who have given body and life to the actions. The opening paragraph of a Ministry of Health document states, 'Sri Lanka is committed to a policy of free health service to all its people. A major concern of the administration is to ensure the ready availability of safe and effective pharmaceuticals of acceptable quality at a reasonable cost and the rational use of such products.'[41] The wording is significant; 'the administration' rather than 'government' or 'state' signifies the group that regulates pharmaceuticals. It is also worth noting that the Director General of Health Services is also the head of the Cosmetics, Devices and Drugs Authority and has considerable powers with regard to drugs. Recent regulations have de-registered drugs of dubious therapeutic value and controlled advertising of non-prescription drugs to the public. One notable administrator was Dr George Fernando, who, as a middle-level administrator and ultimately Director General of Health Services, promulgated regulations on advertising and labelling and also de-registered ineffective anti-diarrhoeal products.[42]

At time, administrators have played an important role simply by ensuring continuity. From the early 1950s to the 1980s, the Superintendent of the Central Medical Stores (CMS) was one of the few qualified pharmacists in the country; this continuity contributed to the efficiency of the CMS.

The role played by the administrators in pharmaceuticals has gone largely unnoticed but has been vital in maintaining the view of pharmaceuticals as a commodity to be regulated according to health needs. This view has been a crucial underpinning of the regulation of the private sector.

Outside observers have been surprised by the Sri Lankan medical profession's tacit acceptance of these rational pharmaceutical activities. It is the medical profession which often proves one of the major obstacles to a country's implementation of rational pharmaceutical policies. The medical profession in Sri Lanka is not dissimilar to the profession elsewhere—conservative, generally authoritative, a social and economic elite quick to defend its interests. However, one fact stands out—the profession consists overwhelmingly of Sri Lankans trained in their country's medical colleges and only a handful of expatriate doctors. As medical students they were taught about drugs by their generic names, by such teachers as Bibile and Lionel. These teachers were also part of the regulatory authority that decided which drugs would be available in Sri Lanka and taught about the drugs that were used in the country. In countries where non-medical teachers (pure pharmacologists or pharmacists) teach about drugs, clinicians, who after all are

the prescribers, have a greater influence on medical students than those who teach them. Such was not the case in Sri Lanka.

Sri Lankan doctors begin their professional life as trainees in government hospitals, where they prescribe from the limited list of proven and effective drugs that they have been taught about during their undergraduate years. The harmony between what was taught and what they practise after graduation reinforces acceptance of the use of a limited list of drugs.

Another important influence in the acceptance of generic drugs is that it is advantageous for family practitioners in the private sector, who provide drugs as a part of their consultation, to have low-cost generic drugs. If an expensive drug is required, the patient is often asked to purchase it from the pharmacy, which avoids the doctor having to charge a high fee and makes the patient aware of the cost of the drug. It is unlikely to promote a favourable disposition towards the pharmaceutical trade. Private sector specialists, who run a consultation practice but do not dispense, also have a role for generic drugs. They issue a prescription for drugs to be bought from a pharmacy by the patient. The prescription will vary according to the patient—if the patient appears able to afford it, an expensive brand-name drug may be prescribed; otherwise an inexpensive generic product may be prescribed.

The medical profession considers those in the pharmaceutical industry to be mere traders involved in an activity devoid of any intellectual or scientific content. While doctors may enjoy their hospitality and accept the free gifts, they rarely extend the association further. Nevertheless, the information in drug advertisements does have an effect on them and is a major contributor to irrational prescribing.

Long familiarity with a limited, but effective, number of available drugs means that the medical profession in Sri Lanka appears not to see the need for a vast range of drugs. It is unlikely that this attitude could be altered substantially; nor, due to the controlled registration of pharmaceuticals, is a vast range of drugs likely to materialise.

The State Pharmaceuticals Corporation (SPC)

It is the SPC that has enabled the practical realisation of most of the rational pharmaceutical activities and the supply of low-cost pharmaceuticals in Sri Lanka. Professor Bibile provided a vision and enthused the employees; Dr Jayawardena saw it more as a supply organisation providing low-cost drugs in the face of an industry bent on promoting expensive brand-name and 'me-too' drugs. It is difficult to find a parallel in other countries for the role

the SPC has played; the closest would probably be Apotex, the largest Canadian generic manufacturer, which has played a major role in ensuring that Canada has some of the most affordable pharmaceuticals in the industrialised world. However, the SPC was a fully functioning institution when Apotex was established in 1974.

Two events involving the SPC that occurred in the late 1970s need to be described here since they are frequently misinterpreted.

With the change of government in 1977, the SPC monopoly on the import of pharmaceuticals was ended. Problems in supply and quality (and therefore, by implication, the failure of the SPC) have been quoted without evidence as being a contributory factor.[43] Reports of poor quality were found to be baseless on investigation.[44] There were many statements about patients being affected by the inferior pharmaceuticals provided by the SPC but none was substantiated. The private sector, which was aiming to regain its importation rights, was not a disinterested observer and was frequently the source of these claims. In the newspaper correspondence that took place at the time, the arguments in support of private sector imports and the criticisms of the SPC were effectively demolished by academics and clinicians. In short, there was no scientific or objective evidence for the failure of the SPC. Thus, the decision to allow the private sector to import pharmaceuticals cannot be seen as anything other than political. This is borne out by the manner in which the decision was implemented: the monopoly of the SPC was terminated by a directive from the Ministry of Finance without consultation with either the Ministry of Health (which would have commented on quality and supply) or the Ministry of Industries (under which the SPC functioned at the time).

The decision to allow pharmaceuticals to be imported by the private sector was in keeping with the political direction of the new government of 1977, which had pledged to dismantle state monopolies and allow greater freedom for the private sector. However, this policy was selective: the huge and profitable state monopoly on petroleum and its products through the Ceylon Petroleum Corporation remains to this day. The SPC, too, was a profitable corporation supplying vital commodities, but its monopoly was terminated. Rewarding political supporters eager to reclaim a share of the pharmaceutical trade, which had been lucrative in the past and could be so in the future, may have been part of the hidden agenda. The government also appointed a commission of inquiry to probe the alleged misdeeds of the SPC during the Bibile era, but its report has never been published, presumably because there were no misdeeds to report.[45]

The second event that is often misinterpreted was the publication in 1981 by Dr Jayawardena of a document critical of the savings mentioned in the UNCTAD report by Professor Bibile. The title begins with the words 'A Critical Study', setting the tone of the publication, which carries Jayawardena's designation as Chairperson of the SPC.[46] This publication has often been uncritically quoted as evidence of failure of the SPC.[47] Its analysis is superficial and disputes the extent of the savings made by importing from generic suppliers and not the fact that savings were made. It also assumes that 'delivery problems' meant that stocks were lost completely, when they could, in fact, simply have been delayed. The study illustrates that problems did occur in the early stages of the SPC, but even with these problems it is clear from the study itself that the SPC did achieve savings from the very beginning. The study was published privately, unlike Bibile's official UNCTAD report and his other publications on pharmaceuticals. It is not known whether the study was submitted to any scientific journal, where the topic would certainly have been of interest. There was no rebuttal since Professor Bibile had died four years earlier.

Even during the time of these two incidents, the SPC continued to provide low-cost pharmaceuticals. From the beginning, it had provided a limited range of widely prescribed brand-name drugs; together with SPC products, these constituted a wide range of drugs which made the retail outlets of the SPC popular. After 1977, when even the government was promoting the private sector, the SPC was one of the few government institutions that flourished. The SPC monitored the pharmaceuticals market and imported low-cost alternatives when it saw a demand for an expensive product. This influenced the prices that the private sector set for its products. Thus, the influence of the SPC has not only been in providing low-cost pharmaceuticals but also in forcing the private sector to provide products at competitive prices. There has been constant hostility from the private sector towards the SPC. When the SPC has purchased brand-name pharmaceuticals from the local agents of transnational pharmaceutical companies, it has been denied the volume discounts given to other wholesalers.

After the assassination of Dr Jayawardena in 1989, a lawyer connected with the newly elected President was made Chairperson of the SPC but there was no change in its policies. In 1992, this chairperson was removed and a former administrator of the Ministry of Health was appointed to the post. He was succeeded for a few months in 1994 by another administrator. Therefore, for the last five years, the SPC has functioned with a non-technical person in the Chair.

For a time in the early 1990s, there was a danger that the SPC would be privatised. Privatisation of state institutions involved in commerce had become the current orthodoxy, irrespective of the efficiency or profitability of the institution. If that had happened, it would have been a supreme example of blind observance of a theoretical principle irrespective of the reality. With the election in August 1994 of a new government that is more sympathetic to state institutions, the prospect of privatisation is definitely less. Moreover, the new government is the spiritual heir to the government of 1970-77, which provided Professor Bibile with the opportunity to initiate momentous changes in pharmaceuticals in Sri Lanka.

It is difficult to identify the exact reason(s) for the continued success of the SPC. In 1991, in addition to totally supplying the needs of the government sector, it supplied one-third of the requirements of the private sector. All of the approximately 60 importers who supplied the other two-thirds are small concerns when compared to the SPC. Under the previous government, which followed that of Dr Jayawardena, the SPC had competent but not particularly outstanding management. There appears to be a trend towards generic prescribing, which must have helped the SPC. The profitable nature of the pharmaceutical trade may be a factor; once the SPC was established, a reasonably constant supply of pharmaceuticals of adequate quality and affordability may have been sufficient for it to maintain itself. A less efficient private sector hobbled by the high prices it charges for brand-name products may also have been a contributory factor.

The SPC was the flagship for the successful measures that decreased the cost of pharmaceuticals. It was born out of economic necessity during a period of shortage of foreign exchange, and when foreign exchange became freely available in the late 1980s and a market economy was created, the SPC adapted and prospered. Just as importantly, it has been a useful instrument in controlling the prices of pharmaceuticals, which are notoriously insensitive to price fluctuations.

The pharmaceutical trade

Since Sri Lanka imports its pharmaceuticals (especially prescription drugs), the trade consists mainly of importers. There is no interest in manufacturing anything other than minor non-prescription medicines in Sri Lanka. As a part of its liberalised economic policy, the last government offered the incentive of a Free Trade Zone for the manufacture of pharmaceuticals, but the offer was never taken up by the private sector. Whether a sufficiently large market exists in the private sector for the local manufacture of prescription medicines is also unclear.

A manufacturer who exports to Sri Lanka is required by regulations to have an official importer, the latter being totally responsible for the manufacturer's products in Sri Lanka. Transnational companies are represented either by their subsidiaries or agents; some importers are agents for a number of manufacturers. Presently, generics from India take a major share of the market, and their affordability limits the prices that can be charged for branded products manufactured in industrialised countries. Whatever the manufacturer or country of origin, the product has to be registered in Sri Lanka before it is imported. The trade does seem to adhere to this regulation: informal surveys of products on pharmacy shelves have only rarely revealed unregistered products.

This adherence to the regulations may be due to a preference for a regular, predictable profit in a regulated market over an unpredictable and irregular one in an unregulated market. Pharmaceutical companies themselves have complained to the regulatory authority about the irregular practices of their competitors. This demonstrates a confidence in the authority as well as a legitimate attempt by companies to see that they reap the benefits of following the correct and approved practices.

Since the trade is basically an import and marketing operation, it has few roots in local society or in the academic world; nor has it developed connections with the media, as is often the case in other countries. Neither can it claim to have contributed to the country's development through manufacturing technology. The pharmaceutical companies do not have a broad-based ownership nor the overt backing of political interests. Thus, the trade has few allies to draw upon during a crisis. The public's perception is coloured by the price of the medicines, which is always thought to be exorbitant. Doctors, too, consider the price of brand-name drugs to be too high.[48] A newspaper report on a meeting of the Sri Lanka Pharmaceutical Traders Association in 1993 was entirely devoted to the association's denial of high prices for drugs.[49] In other countries, one might expect such meetings to focus on extolling the virtues of the latest drugs imported by the trade.

Despite all of this, the trade has promoted products in the same aggressive and close-to-illegal (and sometimes illegal) way as in other countries. New products are standardly launched with gifts to clinicians, foreign trips and seminars in luxury hotels. The practice of examining prescriptions in local pharmacies and using that information to influence prescribing is widespread. Recently, a transnational company was able to persuade clinicians to increase the order for a particular expensive product for one disease by 30,000 per cent and the Ministry of Health acquiesced. Whether this disease

was grossly under-treated in the past or now has a gross over-supply of treatment remains to be seen.

The only large-scale import of a drug outside the legal channel has been that of sulphadoxine/pyrimethamine (S/P), and even this illustrates the influence of the legitimate market. S/P is used in the treatment of chloroquine-resistant malaria, a relatively new phenomenon in Sri Lanka. The Anti-Malaria Campaign, in conjunction with the Ministry of Health, has decided to limit the drug to the state hospitals, a decision which has both advantages and disadvantages. Due to the widespread occurrence of chloroquine resistance there is a demand for the drug in the private sector. As a result, an official importer has smuggled the drug into the country and distributed it along with legally imported products. A company totally outside the system could not do this since it would not have had access to the legal distribution channel. Neither would it be possible to do it with a drug that was not used in the country at all.

The consumers

Sri Lankan consumers have not played a major role in the history of pharmaceuticals though they have benefited considerably. Whatever little interest they had was in the price of pharmaceuticals, which has invariably been considered too high. The minimal interest may be the result of the lack of organised consumer groups; the only ones that exist are support organisations for specific issues, such as diabetes, and even these are dominated by doctors rather than consumers. Some student groups have in the 1990s examined and exposed improper marketing activities by pharmaceutical companies and have called for more control over promotional practices.[50] In one incident, medical students objected to, and forcibly removed, inaccurate promotional material from a medical meeting. It remains to be seen whether the desirable features of this radicalism can be maintained.

There has also been a reawakened interest in Professor Bibile's work and life. A journalist serialised a biography of Bibile in a Sinhalese weekly science paper aimed at high school students and the articles were later published in a book. As a result of this, the younger generation of the 1990s is much more aware of Bibile and his work in pharmaceuticals than the one of the 1980s.

The losers and failures

The main losers in pharmaceuticals have been the pharmacists, and the main failures have occurred in the areas of price regulation, independent drug information and prescribing practices.

Pharmacists

Pharmacists have gained little from the activities in pharmaceuticals in Sri Lanka, which were designed and implemented mainly by doctors whose outlook was entirely medical. The interests of the pharmacists were rarely considered. The Ministry of Health began a training course for pharmacists in 1958 which has remained virtually the same to this day. Though trainees are considered to be pharmacists on graduation, their level of training is only that of a pharmacy technician. A postgraduate Diploma in Pharmacy was set up by the University of Colombo in 1991 but the Ministry of Health has yet to recognise it as an approved qualification or to give any official encouragement. The Ministry appears to regard pharmacists as mere supply and dispensing officers for its health care institutions and does not visualise a more professional role.

The inability of pharmacy to establish itself as a profession is a pervasive feature of the Third World. In countries where pharmacy has been established as a profession (which have generally been industrialised countries), there is a strong pharmaceutical industry providing support, employment and a role that is independent of the supply and dispensing of drugs in hospitals or the community. In the Third World, where hospital and community pharmacy provide the major source of employment, pharmacists have little chance of developing an independent role and remain subordinate to the prescribers and administrators. The remuneration of community pharmacists often depends on turnover and not on professional fees, which encourages pharmacists to dispense according to financial rather than professional aims. Any programme to improve the professional status of pharmacists will require a fundamental rethinking of their role.

In Sri Lanka, pharmacists are currently among the most under-utilised human resources in the health sector and their professional esteem is low. They have the potential to be a considerable influence in pharmaceuticals but until now there has been very little attempt to harness this potential.

Price regulation

In the private sector, patients have to pay the full cost of the drugs since reimbursement schemes are limited to the tiny minority who are covered by health insurance. The price of drugs is the most tangible aspect of the pharmaceutical companies that the patient encounters. Normally, the price a consumer pays for a commodity is decided by market forces; however, drugs and the market for them do not conform to this principle. In drug transactions, unlike other consumer transactions, the person who decides on the purchase (the prescriber) is not the one who pays (the patient). Hence the decider does not need to give careful consideration to the cost—and often does not.

The retail price of pharmaceutical products in Sri Lanka is regulated on a 'cost-plus' basis, as a percentage mark-up of the CIF (cost, insurance and freight) value. This encourages the import and sale of expensive products, since the profit is greater. A report by a consultant to the World Bank who examined the pharmaceutical sector said, 'this particular type of (price) control mechanism has proven failings.... Merchants are motivated to maximise profits, and they will promote products that have the highest CIF, and therefore, the highest retail price.'[51]

One of the main reasons for the private sector's opposition to Professor Bibile and the SPC was their inability to import drugs with a high CIF value. While the SPC had a monopoly on imports, the wholesale mark-up (which came to the private sector distributors) did not alter, but the lower CIF prices produced lower profits. The retail trade was relatively silent about imports by the SPC; it is possible that increased turnover for pharmacies as a result of the lower prices meant a relatively unchanged income.

Deciding the retail price on a 'cost-plus' basis has produced gross differences between brand and generic products. Diazepam, a commonly used sedative, is available as a generic for 2 cents and as a branded product for Rs 2. Diclofenac sodium, a commonly used pain-killer, is available as a generic for Rs 1, whereas the brand-name product costs Rs 8.

In the health care systems of industrialised countries, such differentials are rarely seen. Governments decide a level of reimbursement which is generally close to the price of the generic products; anything higher has to be borne by the patient. Hence brand-name manufacturers price their product very close to this reference price so that there will be minimal resistance by patients to the extra payment.

Sri Lanka has not considered the retail price as the starting point for regulating the price of pharmaceuticals, even though this is the logical starting point if the object is to provide affordable pharmaceuticals. A reasonable price (or price band) for a drug should be decided after consultation with the relevant parties, and products within this price range could then be registered. This would still allow a regulated 'market economy' to operate in drugs. Until the cost to the consumer becomes the central consideration, the regulation of pricing will continue to be unsatisfactory; letting the CIF value determine the retail price is analogous to the tail wagging the dog.

Independent drug information

Sri Lanka now has drugs which are safe and effective and which are registered according to sound scientific criteria. Irrational combinations or ineffective drugs are few and far between. However, this rationality in approving drugs is matched by the irrationality of their use: antibiotics are prescribed for any fever, it is not uncommon to find five or six drugs per prescription, and brand-name prescribing is ubiquitous. The fault is not with the prescribers alone. Those concerned with regulating pharmaceuticals have not looked further than the provision of rational drugs. They have failed to provide the independent information which is necessary for their rational use.

The importance of independent drug information was recognised very early, and emphasised in the Wickremasinghe-Bibile report. But informational activities have been irregular. The SPC published a journal which carried independent drug information called *The Prescriber* on the model of a similar publication in the United Kingdom. It was coordinated by the Department of Pharmacology in the Faculty of Medicine, Colombo, and was quite popular with prescribers, especially family practitioners. In the late 1970s and early 1980s there were technical production problems and issues were repeatedly delayed, until finally the SPC withdrew its support in the late 1980s. In 1993, the SPC renewed its support and a new version of the *The Prescriber* is now being published regularly. The good sale of the issues published so far demonstrates the unmet demand for independent drug information.

Appropriate information attractively presented is undoubtedly useful in encouraging rational prescribing. However, the Sri Lankan government, like most other governments, considers provision of drug information to be a peripheral and inessential activity. Recently, there has been a change of attitude and a national formulary was prepared, which was published in 1994.[52] This is the first publication of this type since the Ceylon Hospitals Formulary, which was edited by Professor Bibile and published in the late 1950s. A greater effort is needed if Sri Lanka is to counteract the vigorous promotional efforts of the private sector.

Prescribing practices

The public and private sectors have similarities as well as dissimilarities in their prescribing patterns. The top ten drugs in the public sector are from the Sri Lankan EDL and a majority of the drugs registered are from the EDL or its alternatives.[53] The registrations provide an indirect indication of the prescribing practices in the private sector.[54]

Regulations stipulate that all prescriptions should be written by generic name, but even a cursory examination of prescribing practices in government hospitals would show brand names being used extensively, and the situation is much worse in the private sector. The use of brand names has no practical consequences as, for the past 20 years, the government hospitals have been supplied only with generic drugs, which were dispensed despite the brand names on the prescription. However, the regular use of brand names demonstrates the indiscipline of prescribing practices.

The administrators in the state health sector have criticised the prescribing practices of the doctors as wasteful and exorbitant, and have spoken of being up against 'the doctor mafia' and of not being able to dictate doctors' prescribing habits in a democracy.[55] While this is true, the administrators can, in turn, be accused of having a short-term objective of reducing costs. which is anathema to doctors, who see it as providing second-class drugs. If the emphasis is placed on correct treatment then both the doctors' concern for the quality of treatment and the administrators' concern for keeping drug costs low can be addressed. For example, methyldopa, an expensive drug that was the first-line treatment for hypertension in the 1970s, is still used widely in the state health sector and constitutes approximately 5 per cent of the total drug budget. Much more effective and cheaper drugs are available for the treatment of hypertension. The administrators have yet to focus on the idea of a better treatment, although the cost has already been repeatedly emphasised. Such attitudes are unfortunately not limited to the medical administrators in Sri Lanka alone.

Drug advertisements undoubtedly influence prescribing. There have been gross abuses in the advertisements of prescription drugs, though an improvement is evident in recent medical journals.[56] Prior approval from the Ministry of Health is necessary for advertisements for over-the-counter drugs but advertisements with unacceptable claims have still appeared in the newspapers. Affordable drugs are widely available in the private sector; a day's treatment with almost any of the drugs in the EDL would not cost more than Rs 5. However, the consumers are not aware of this and can easily pay Rs 50—and often do. It is also possible for a labourer to pay a day's wages for a bottle of vitamin tonic, even though these vitamins are available in tablet form free of charge at the nearest government health facility. A patient will invariably be given a prescription after a consultation but injections are not a ubiquitous practice in Sri Lanka, unlike in some Third World countries. In summary, the efforts at providing drugs suitable for the country have been thwarted by the frequent unsuitable use of these drugs.

Conclusions

In the post-Bibile era, there have been changes in the balance of power and the roles of those involved in pharmaceuticals issues. The state (through the Ministry of Health, the regulatory authority and the SPC) is still the dominant force, though less so than in the 1970s. The private sector has increased its role and influence but has been held in check by the state. Others, including the doctors, have remained on the sidelines, either indifferent or else content with the available supply of drugs. Some of the losers, such as the pharmacists, have remained losers, whereas independent drug information appears to be increasing in importance.

How will all the actors, influences and forces discussed above influence the future? **It** is obviously impossible to make a definite prediction but some observations are possible.

The balance in the future

In August 1994, the ruling party which had been in power since 1977 was defeated in the general elections. The party currently in power (which mainly consists of elements of the 1970-77 government) has a very small majority and is unlikely to make major changes immediately. The economy will continue to be open but with stricter regulation; in pharmaceuticals, there are already plans to appoint a commission to recommend methods of decreasing the price of drugs in the private sector. The new government is likely to be more sympathetic to the policies of Professor Bibile. The new Chairperson of the SPC is Professor Colvin Goonaratne, a student and later a colleague of Bibile. There is no doubt that Bibile's vision will now be pursued more enthusiastically and vigorously.

It is unlikely that any government could dismantle in one stroke the framework of legislation, regulations, committees and traditions associated with pharmaceuticals. However, these structures are susceptible to slow and sustained attack. The function and status of the SPC could be influenced much more readily than regulations and sub-committees, and a reduction in its role would be a serious blow. In this context, it would be useful to note the following comments from a report by a consultant to the World Bank: 'SPC plays a powerful and valuable role in providing pharmaceuticals to Sri Lanka's public sector. Establishing a tendering process with a virtual monopoly in the public sector has proven to be an effective mechanism for dealing with transnational pharmaceutical companies in Sri Lanka and elsewhere.'[57]

In the current economic climate, there is a tendency for the commercial aspect of pharmaceuticals to be emphasised over the health aspect. Formalis-

ing the view of drugs as a commodity which should be regulated according to health needs would be useful in counteracting this tendency. The Cosmetics, Devices and Drugs Act has provisions for regulating pharmaceuticals much more effectively to enable low-cost drugs to be provided within a regulated market. Whether the administrators will see the current political climate as conducive to such regulation remains to be seen.

The adoption of a National Drug Policy (NDP) embodying what has been achieved up to now could be useful in maintaining the status quo. Nevertheless, in the light of previous events in pharmaceuticals in Sri Lanka, there could be disadvantages in defining a policy. Professor Bibile's highly visible, admirable, pioneering and radical work between 1970 and 1976 attracted constant criticism because it threatened the core of the private sector. Before 1970 and after 1977, action was taken much less visibly—and generally effectively—through regulation, which did not threaten the private sector so strongly. Defining an NDP might again provide a highly visible target and endanger the unwritten compromises that have been achieved. Such unwritten but acknowledged compromises have been seen in pharmaceuticals in other countries; the Norwegian 'need' clause, for example, has never been precisely defined in a published document.[58]

However, even the private sector, which was Bibile's main critic between 1970 and 1977, might not have a uniform view now. Generics imported from both industrialised and Third World countries form a very significant portion of the market and the importers of these drugs could favour a policy of affordability. Brand-name manufacturers are unlikely to adopt a 'take it or leave it' attitude, since, if they 'leave', generic importers will gladly 'take' their market share.

In the absence of an NDP it has been the administrators who have directed the implementation of pharmaceuticals regulations, with a view of drugs as being necessarily controlled by health considerations. There is no sign of a change in this view but it cannot be guaranteed to continue unchanged. An NDP based on this view would help to ensure continuity.

The economic climate has been a major cause of pharmaceuticals-related activities. In the 1960s and 1970s, a chronic shortage of foreign currency was the impetus for the rationalisation of selection and procurement. The economy has been growing in the 1990s, although this growth has not been distributed throughout all sections of society.[59] The World Bank has identified liberalisation of the economy and trade reform (which it advocated strongly) as the main reasons for this growth. The government's aim is to

achieve the status of a Newly Industrialised Country (NIC) by the year 2000. What implications this would have for pharmaceuticals is unclear; none of the NICs in Asia is known for pharmaceutical policies that have health needs as the basis. Activities in Thailand are, in fact, mainly driven by a vigorous pharmaceuticals industry. Thus, in its journey towards becoming an NIC, Sri Lanka might be able to retain the health perspective on pharmaceuticals provided it does not develop a strong pharmaceuticals industry.

There is another consideration. The World Bank itself has admitted that the market is an inefficient provider of health services and has advocated greater use of financial, informational and regulatory instruments to improve performance in this sector.[60] This is precisely what has been done in Sri Lanka, though not by political will but by administrative regulation. The previous government followed the advice of the World Bank on the economy, producing both growth and increased disparities in income, but let the health administrators manage pharmaceuticals. Whether the new government will take a greater interest in pharmaceuticals, and in what direction this interest will be, remains to be seen.

One politically sensitive area that has yet to be tackled is the financing of drug supplies in the government health sector. At present, drugs are provided free of charge, which leads to waste. There is a good example of this: in 1972 the government imposed a nominal flat fee (equivalent to the minimum bus fare) for a visit to outpatient departments; all other facilities continued to be free. There was a 26 per cent decrease in attendance at outpatient departments, with no change in inpatient admissions, or in health status indicators for 1973. It is quite likely that a good portion of this 26 per cent reduction was in services and drugs that were actually being provided unnecessarily. The outpatient fee was removed in 1977, and drugs have been available free of charge since.

A small payment for the drugs dispensed in government hospitals could help make patients aware of the cost of drugs, and control government expenditure. At present, drugs are supplied out of the available funds and intermittent shortages do occur. The system could become unsustainable in the future, at which time it could degenerate into chronic shortages. On the other hand, it could be resuscitated with some kind of cost-sharing.

The only definite conclusion for the future appears to be that radical changes will not take place. Legislation and other elements of a framework for nudging (or even pushing) in the right direction do exist, but the will to use them is lacking. Perhaps the future of pharmaceuticals will reflect the

fabric of the nation itself. Democracy has survived despite severe economic, social and political threats; similarly, the concept of pharmaceuticals as a part of health and not as an item to be exploited in illness will survive too, despite tensions. Like democracy, this concept in drugs is not perfect or acceptable to all, but will triumph simply by prevailing.

The lessons

Every country handles its own challenges, problems and dilemmas differently. However, it is possible for one country to learn from the actions (and mistakes) of another. How could the experiences of Sri Lanka help other Third World countries?

A longstanding emphasis on education, health and other social welfare benefits was the result of a functioning democracy which made the state receptive to the needs of the population. The high level of education and health fostered a climate favourable to the developments in the area of pharmaceuticals. Unfortunately these cannot be easily transferred; nor are they short-term solutions. They do, however, demonstrate that activities in pharmaceuticals cannot be isolated from the general development of a country.

The availability of skilled and trained medical personnel and clinical pharmacologists within the country meant that a strategy that was self-sustaining could be developed. A key element within this has been the appreciation of pharmaceuticals within the context of society as a whole by those who shaped events. All too often, policy-makers in the pharmaceuticals field (and doctors are especially guilty of this) focus on narrow therapeutic aspects to the exclusion of the needs of society. Though he was a physician and clinical pharmacologist who spent his whole life in pharmaceuticals, Senaka Bibile was able to see this broader aspect of pharmaceuticals. A country developing a pharmaceuticals policy should be careful to include among its policy-makers people who are aware of the many and different influences that pharmaceuticals have on society.

As soon as it achieved independence, Sri Lanka controlled pharmaceuticals through the Food and Drugs Act. This established the principle that drugs are items that should be controlled by the government. In a newly independent country, it might be worth imposing legislation on pharmaceuticals as early as possible, not only to control them but also to establish symbolically that drugs are a controlled commodity. Eritrea has set such an example. It achieved independence in May 1991 and by 1993 it had taken the WHO Essential Drug List as the Draft National Standard Drug List and established mechanisms to control the import and distribution of drugs.[61]

Drugs have been controlled in Sri Lanka by the Ministry of Health rather than by the Ministries of Commerce or Industry. This relationship has reinforced the conception of pharmaceuticals as relating most immediately to health, rather than trade. It also provides administrators who understand that drugs are a specialised commodity. In some countries, the Ministry of Health is both the regulator and the promoter of the pharmaceuticals industry. In the United Kingdom, for example, the Department of Health is a sponsor as well as the main customer of the industry, and the positive balance of trade in pharmaceuticals makes a significant contribution to the country's economy. However, this dual role creates problems in regulating the industry. Third World countries need inexpensive drugs relevant to national health care needs and would have to be very careful in assuming the role of sponsor of their pharmaceutical industries. The disadvantages would outweigh the advantages.

The impetus for change in pharmaceuticals in Sri Lanka was neither scientific nor health-related but economic. However, it was used to place pharmaceuticals activities on a sound scientific basis. It is rare for the impetus to come from the medical profession, industry or any other actors closely involved in pharmaceuticals; hence reformers must be prepared to seize any opportunity that presents itself.

The role of the administrators has been crucial in Sri Lanka. It is difficult to judge whether similar situations occur in other countries; but, if they do, it is important to realise the potential of the administrators and to recruit them as allies wherever possible.

Every country must make its own journey in providing basic rights to its people. If Sri Lanka's experience in pharmaceuticals were to help other countries on this journey, no one would be more pleased than those who have toiled to provide the same basic rights in Sri Lanka.

Postscript: September 1995

The postscript to Professor Bibile's article in 1976 was full of foreboding about the changes that might occur after a change of government in 1977. The present article, concluded in late 1994 (when the spiritual heirs to the government of the early 1970s were voted into power), should have a much happier postscript but does not.

The new government has been preoccupied with making a genuine and bold effort to end the civil conflict in the north of the country. Decisions on phar-

maceuticals have been left mainly to the administrators. A non-medical administrator has been appointed as the Secretary to the Ministry of Health, the highest administrative post in the Ministry. **He** has been influenced by the pharmaceutical industry and advised by some medical and non-medical personnel with no experience in pharmaceuticals. The main focus has been on the delays in the registration of pharmaceutical products, although these are much less than in other developing countries and approach the levels seen in industrialised countries. However, these delays have been used as an excuse and there have been attempts to get 'blanket' registrations without evaluation for certain categories of products to widen the criteria for registration, all without discussion with the technical committee on registrations, the Drug Evaluation Sub-committee. All these suggestions have been rejected by the Sub-committee and the technical aspect of registration remains intact. However, for the first time in the long history of drug registration in Sri Lanka, a drug rejected on grounds of quality has been forcibly registered by the Ministry on an administrative order of a non-medical administrator. Attitudes too have changed; previously, administrators did not attend pharmaceutical functions as they could not accept the hospitality offered as well as doing their job as regulators. Some of the present administrators have no such qualms and have been the 'Chief Guests' at such functions. There have been allegations in the newspapers of corruption and maladministration on the part of some of the administrators, new items and cartoons making very direct accusations appearing almost weekly.

A heartening aspect of these battles has been the emergence of Non-Government Organisations (NGOs) as a force in the national pharmaceuticals scene. Students involved in Rational Health Activities (SIRHA), a medical student organisation, has expertly made the case in the popular media for continuing the system of drug registration and exposed the hidden considerations behind the manoeuvers to subvert the system of drug registration. The creation of organisations such as Health Action International (HAI) signalled the emergence of NGOs campaigning on pharmaceuticals in the international arena. The emergence of SIRHA can be seen as this phenomenon coming down to the national level.

At present, there is turmoil in pharmaceuticals, much of it being due to administrators being able to override technical considerations, a 'structural' defect of the laws and regulations. The extent of the damage has yet to be assessed: only time will tell whether the harm has been grievous or whether it can be shrugged off as in the past.

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Notes

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45. In 1977, a foreign official of a transnational pharmaceutical company joined in the newspaper correspondence as a 'responsible corporate citizen', only to have his arguments thoroughly demolished. No more was heard from him—presumably he was withdrawn from Sri Lanka. Although his company did not cooperate with the SPC, it did conduct business successfully during the period of the SPC's monopoly on pharmaceutical imports. After 1977, the company, along with others, was allowed to import pharmaceuticals. In 1993, it sold its assets and withdrew from Sri Lanka. It appears that this company found that it could operate better under the SPC monopoly than in the present free market. This

was also the company that refused to cooperate with the government in producing tetracycline capsules during the cholera epidemic in the mid-1970s, thus putting the lives of patients in danger. However, the emotive accusation of putting patients' lives at risk was more frequently levelled at the SPC without any evidence.

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Bangladesh: A Tough Battle for a National Drug Policy

By Zafrullah Chowdhury

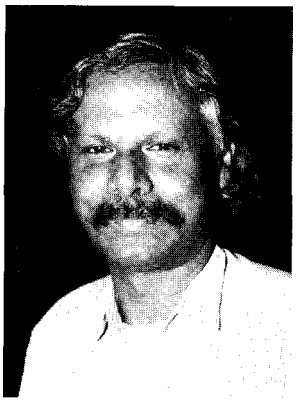

Photo: Hans Knodt

When on May 29, 1982, the Bangladesh Council of Ministers approved the proposals for a National Drug Policy, the news was a bombshell to those concerned nationally and internationally with pharmaceuticals. Unlike in other countries, where medicinal drug policies have developed gradually over a period of time and may not be found in one single comprehensive document but several, the Bangladesh example reflects the intensive activity of the Expert Committee which worked out the policy, based on 16 criteria, in 15 days. Its Report, almost unchanged, was made law on 12 June. Thirteen years later it can be observed that despite opposition from many actors, such as the national and international pharmaceutical industry with support from some governments in the North, the Bangladesh Medical Association, parts of the Press, and at a later stage, the Bangladesh Government itself, the output of essential drugs has increased from about 30 to about 80 per cent, prices have in almost all cases gone down considerably, the domestic industry has grown rapidly, the quality of its production has increased dramatically, and people's awareness about medicinal drugs has been steadily growing.

The Bangladesh story has been told before and is well known not only to those active in the field of pharmaceuticals but also to the wider circle of concerned citizens in the South and the North who are searching for broad-based, democratic, people-oriented solutions to societal problems. What makes this article unique is that it is told by the central actor in this dramatic process, Dr Zafrullah Chowdhury, from the inside. In 1972, this indefatigable activist set up Gonoshasthaya Kendra (the People's Health Centre), which initially concentrated on primary health care and the training of paramedics but later expanded beyond the health sector to include in its work education, nutrition, agriculture, employment generation and women's emancipation. These activities now serve more than 500,000 people. In 1981, Dr Zafrullah Chowdhury set up Gonoshasthaya Pharmaceuticals in order to manufacture essential drugs of high quality and at low cost.

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Introduction

Bangladesh became an independent country on 16 December 1971. The problems facing the country were summarised in the First Five Year Plan of 1973:

> Bangladesh inherited a poor, undiversified economy, characterised by an underdeveloped infrastructure, stagnant agriculture, and rapidly growing population. She had suffered from years of colonial exploitation and missed opportunities, with debilitating effects on initiative and enterprise.[1]

Those debilitating effects included an infant mortality rate estimated in 1972 at 140 per 1,000 live births; a maternal mortality rate of 30 per 1,000 pregnancies; and a death rate of 260 per 1,000 children under five years of age, which was mostly due to preventable disease and malnutrition.

This dismal state of affairs was largely attributable to inadequate and badly distributed health facilities. Essential drugs were highly priced and not easily available. According to the First Five Year Plan: 'Many so-called manufacturers are engaged in bottling drugs imported in bulk, acting indirectly as the sales agents of foreign firms. Quality control of drugs is insufficient and spurious drugs are quite common.'

To remedy this, a series of steps was taken in Bangladesh throughout the 1970s, leading up to the enactment of a radical and far-reaching National Drug Policy (NDP) in 1982.

Initial efforts included the centralised procurement of cheaper generic drugs, often through barter arrangements with European socialist countries. Predictably, transnational corporations (TNCs) were hostile to this approach. As had happened in Sri Lanka,[2] they embarked on a campaign of misinformation among the medical profession and elite consumers. The TNCs spread rumours about the dubious quality of drugs from Eastern Europe.

A new government which took charge in 1975 began to amend drug legislation. The Drugs Act of 1940 was grossly inadequate for the control of prices of pharmaceutical raw materials and processed drugs. It also largely failed to prevent the appearance of substandard and spurious drugs on the market, unethical promotion, and the proliferation of harmful and useless drugs.

In 1979, the *Bangladesh Aushadh Shilpa Shamity* (BASS, the Bangladesh Association of Pharmaceutical Industries), comprised mainly of transna-

tional and few large national pharmaceutical companies and trading houses, discovered that the then Minister of Health, Dr M. M. Huq, a retired colonel and a trustee of Gonoshasthaya Kendra (GK), had finalised the drafting of rational and tougher drug legislation. BASS not only blocked the introduction of the bill, but also successfully encouraged the removal of Dr Huq from his ministerial post.

The next major move came after a bloodless military coup, led by General Hussain Muhammad Ershad in March 1982.

The formation of the Expert Committee

Only a month later, on 27 April 1982, the military government appointed an eight-member Expert Committee to review the drug situation in the country and make recommendations for a National Drug Policy consistent with the health needs of the country.

The committee consisted of three categories of people: academics, regulatory personnel and health activists. The members of the Expert Committee were:

- Professor Nurul Islam (Chairman), Professor of Medicine, Director of the Institute of Postgraduate Medicine and Research (IPGMR) and Dean of Postgraduate Medicine at Dhaka University;
- Dr Humayun K. M. A. Hye, Director of Medical Education and Hospitals, a pharmacologist and former Director of the Drug Administration;
- Professor M. A. Mannan, a pharmacologist who later became the Vice-Chancellor of Dhaka University;
- Professor Mobarak Ali, Director of the Institute of Ophthalmology, Dhaka;
- Professor M. Q. K. Talukdar, Associate Professor of Paediatrics, IPGMR;
- Dr Azizur Rahman, surgeon and President of the Bangladesh Private Medical Practitioners Association, Dhaka;
- Dr Zafrullah Chowdhury, surgeon, health activist and Projects Co-ordinator of Gonoshasthaya Kendra, Savar, Dhaka;
- Dr Nurul Anwar (Member Secretary), pharmacologist, pharmaceutical chemist and Director of the Drug Administration.

The committee had three significant characteristics. First, no representative of the transnational drug industry was included, for obvious reasons. This principle led to the exclusion of the chief executives of the Bangladesh Medical Association (BMA) because of their formal associations with trans-

nationals. However, all eight members of the Expert Committee were general members of the BMA. Moreover, Dr Humayun Hye was one of the two members of the BMA's Drug Evaluation Sub-committee.

Second, it was a well-informed committee. Many of its members had been profoundly influenced by a number of books published in the 1970s which exposed the misdeeds of drug companies and promoted new policies on drugs.[3] Some members were also well acquainted with the problems experienced by India, Pakistan and Sri Lanka in their attempts to regulate drugs and were aware of the efforts under way in Europe and the USA to bring about changes in the pharmaceutical industry through the democratic process.

Third, this was probably the first and last drug committee in Bangladesh which did not include a civil servant. Third World countries, whether under democratic or military rule, are usually governed by the civil bureaucrats alone, or by a combination of the civil service and the military bureaucracy. Ministers, appointed politically or otherwise, are usually figureheads.

The work of the Expert Committee

At its first meeting, the Expert Committee made a rough calculation that most practitioners usually prescribe from a total of around 50 drugs and that the figure rarely exceeds 100. Thus, it was decided that a drugs list should be drawn up in line with the advice given in the WHO publication. *The Selection of Essential Drugs.*[4]

Three other important decisions were taken on the first day. First, it was decided that current, authentic and unbiased scientific literature would be used extensively, and various specialists would be consulted and asked for their opinion on the basis of 'scientific reasoning'. Deletion of a drug would be recommended only if there was a unanimous decision by the committee.

Second, it was decided that the report, including the rationale and plan of action, should be short enough for decision makers to read in one sitting. It was to be written in simple language, avoiding all jargon and difficult scientific words, for easy understanding by all concerned persons.

Third, to prevent information leaks, the committee did not use any secretarial staff from the Drug Administration. All members vowed strict secrecy until the document could be made public by the government. Meetings were held behind closed doors and no information filtered out, a state of affairs which angered the pharmaceutical industry.

The Expert Committee worked intensively, taking over 1,000 man-hours to complete and submit the report to the Minister of Health on 11 May 1982. Members of the committee reached a unanimous decision that 16 criteria should guide the evaluation of all registered/licensed pharmaceutical products already manufactured in, or imported into, Bangladesh, as well as the evaluation of all new drugs (see Box).

The first 11 criteria were based exclusively on scientific reasoning while number 14 was based on political and economic considerations as well: the hope was that TNCs, no longer allowed to manufacture or market antacids and oral vitamins, would concentrate on producing more useful drugs such as antibiotics and other life-saving drugs, and that the ban would also help in preventing monopoly cartels. The remaining four criteria (12,13, 15 and 16) were for the benefit of the local national industry.

The banned drugs

At the time the NDP was formulated, 166 licensed pharmaceutical manufacturers were actually producing drugs in the country. There were also 122 foreign companies exporting drugs to Bangladesh from 23 countries (see Table 1).The total number of registered products, both locally produced and imported, was 4,340.

Table 1 Number of foreign companies exporting drugs to Bangladesh in 1981-82 by country of origin

Country of origin	Number of companies	Country of origin	Number of companies
UK	29	Denmark	3
USA	12	Greece	3
India	11	Holland	3
Switzerland	10	Hong Kong	3
Germany	9	China	2
Japan	7	France	2
Hungary	6	Bulgaria	1
Italy	6	Ireland	1
Belgium	4	Philippines	1
Yugoslavia	4	Poland	1
Australia	3	Singapore	1
		Total	122

The 16 criteria

1. The combination of an antibiotic with another antibiotic, or antibiotics with corticosteroid, or other active substances will be prohibited.

The manufacture in liquid form of antibiotics harmful to children (e.g. tetracycline) will not be allowed.

2. The combination of analgesics in any form is not allowed as there is no therapeutic advantage and it only increases toxicity, especially in the case of kidney damage. The combination of analgesics with iron, vitamins or alcohol is not allowed.

3. The use of codeine in any combination form is not allowed as it causes addiction.

4. In general, no combination drugs will be used unless there is absolutely no alternative single drug available for treatment or if no alternative single drug is cost-effective for the purpose.

Certain exceptions will be made in the cases of eye, skin, respiratory and haemorrhoidal preparations, co-trimaxazole, oral rehydration salts, antimalarial, iron-folic, etc., as well as certain vitamin preparations, allowing combinations of more than one active ingredient in one product.

5. Vitamins should be prepared as single ingredient products with the exception of B complex. Members of vitamin B complex, with the exception of B12, may be combined into one product. B12 should always be produced as a single-ingredient injectable product. Other members of B complex may also be produced as a single-ingredient product (e.g. B1, B2, B6, etc). The combining of Vitamins with any other ingredient such as minerals, glycerophosphate, etc., will not be allowed. Vitamins may be produced in tablet, capsule and injectable form only.

No liquid forms will be permitted because of wastage of financial resources and the tremendous misuse involved. However, the manufacture of paediatric liquid multivitamins (with no B12, E, K and/or minerals) will be allowed in bottles of 15 ml size with droppers. The manufacture of paediatric liquid preparations of single ingredient vitamins will also be allowed in bottles of up to 15 ml with droppers.

6. No cough mixtures, throat lozenges, gripe water, alkalis, etc. should be manufactured or imported as these are of little or no therapeutic value and amount to great wastage of our meagre resources.

7. The sale of tonics, enzyme mixtures/preparations and so-called restorative products flourish on consumer ignorance. Most are habit-forming and, with the exception of pancreatin and lactase, these are of no therapeutic value. Henceforth, local manufacture or importation of such products will be discontinued. However, pancreatin and lactase may be manufactured and/or imported as single-ingredient products.

8. Some drugs are being manufactured with only a slight difference in composition from another product but having similar action. This confuses both patients and doctors. This will not be allowed.

9. Products of doubtful, little or no therapeutic value, and rather sometimes harmful and subject to misuse, will be banned.

10. All prescription chemicals and galenical preparations not included in the latest edition of the *British Pharmacopeia* or the *British Pharmaceutical Codex* will be prohibited.

11. Certain drugs, in spite of known serious side-effects and the possibility of misuse, may be produced in limited quantity for restricted use if the risk:benefit ratio is favourable. These will be prescribed by specialists only.

12. The importing of a drug which is the same or one produced in the country, or a close substitute for it, may not be imported, as a measure of protection for the local industry. However, if local production is far short of need, this condition may be relaxed in some cases.

13. A basic pharmaceutical raw material which is locally manufactured will be given protection by disallowing it or its substitute to be imported if sufficient quantity is available in the country.

14. The role of multinationals in providing medicine for this country is acknowledged with appreciation. In view of the calibre of machinery and technical know-how which lies in their hands for producing important and innovative drugs for the country, the task of producing antacids and vitamins will lie solely with the national companies, leaving the multinationals free to concentrate their efforts and resources on those items not so easily produced by smaller national companies. Multinationals will, however, be allowed to produce injectable vitamins as single-ingredient products.

15. No foreign brands may be manufactured under license in any factory in Bangladesh if the same or similar products are available/manufactured in Bangladesh, as this leads to unnecessarily high prices and payment of royalties. In the light of this policy, all existing licensing agreements should be reviewed.

16. No multinational company without their own factory in Bangladesh will be allowed to market their products after manufacturing them in another factory in Bangladesh on a toll basis.

Using the 16 evaluation criteria, the Expert Committee identified 1,742 non-essential or ineffective drugs to be banned (see Table 2). The banned drugs concerned were placed in one of three categories:

Schedule I: Production of these drugs was to be stopped immediately and stocks were to be collected from pharmacies and destroyed within three months of the acceptance of the report.
Schedule II: These drugs were to be reformulated within six months on the basis of the guidelines suggested by the committee.
Schedule III: A maximum of nine months was allowed for using up stocks of these drugs.

Importation of raw materials for Schedule I and II drugs was prohibited.

Each of the 166 manufacturing companies in the country except Reckitt & Colman was affected by the recommendations of the Expert Committee. Local companies, including Gonoshasthaya Pharmaceuticals Limited (GPL), were the worst affected. G-sulphathalazole, one of the products of GPL, was included in Schedule III.

Table 2 Numbers of drugs banned in the Drugs (Control) Ordinance, 1982, of Bangladesh according to criterion and by country of origin

Criterion	Locally produced drugs		Imported drugs							
	National company	TNC	USA	UK	Germany	Switzerland	Hungary	India*	Japan	Others
1	19	45	14	14	4	2	1	1	2	28
2	54	10	1	11	2	6	2	-	1	2
3	2	-	-	-	1	2	2	-	-	-
4	5	1	-	2	4	2	2	2	-	-
5	149	37	11	10	20	10	4	-	2	25
6	262	13	2	8	-	-	-	-	-	4
7	181	8	2	8	2	1	-	-	1	-
8	18	11	-	-	-	-	-	-	-	-
9	192	25	15	30	20	16	6	6	8	14
10	39	1	2	6	1	2	-	-	-	1
11	3**	3**	1	3	1	3	3	1	1	5
12	-	-	16	45	24	29	15	10	-	109
13	1	3	-	-	-	-	-	-	-	-
14	-	10	-	-	-	-	-	-	-	-
15	24	9	-	-	-	-	-	-	-	-
16	7	***	-	-	-	-	-	-	-	-
Total number of drugs	949	176	64	137	79	82	35	20	15	185
Number of companies	156	10	12	29	9	10	6	11	7	38

Among 11 exporting companies, 6 were India-based TNC subsidiaries and 5 were Indian companies.
Later on placed on the Restricted List.
Reckett and Coleman, the only producer of soluble aspirin, was exempted.

Major recommendations

The objective of the NDP was to ensure that procurement, local production, quality control, distribution and use of all drugs came under unified legislative and administrative control. The NDP was to be the uniform policy for both the private and public sector, and for both the traditional and modern medical systems. It was intended to be an integral part of a national health policy. The major recommendations were:

- establish a basic list of 150 essential drugs and a supplementary list of 100 specialised drugs. The basic list was subdivided into three levels of use: 12 drugs for village workers; 45 drugs for primary health care; and all 150 drugs for tertiary care;
- use generic names for the manufacture and sale of the 45 primary care drugs;

- prepare and publish a National Formulary by 1983;
- eliminate product patents and limit the use of process patents;
- revise the 1940 Drugs Act to include:
  - a registration system for Ayurvedic, Unani and homeopathic medicines;
  - enforcement of good manufacturing practices (GMP), including adequate quality control;
  - control of labelling and advertising;
  - price control;
  - prescription control of toxic/poisonous and habit-forming drugs;
  - establishment of special drug courts and heavy penalties;
  - regulation of technology transfer and licensing agreements with foreign collaborators;
  - restriction of ownership of retail pharmacies to professional pharmacists only;
- set up a National Drug Control Laboratory by 1985;
- prevent TNCs from manufacturing simple products like common analgesics, vitamins, antacids;
- establish registered retail pharmacies, under the supervision of qualified pharmacists, at every government hospital;
- strengthen the Drug Administration by training all Thana[5] health administrators to act as drug inspectors.

A storm unleashed

The report of the Expert Committee was approved by the Council of Ministers on 29 May 1982. When news of the NDP emerged, TNCs, some of the larger national pharmaceutical companies, the Bangladesh Medical Association (BMA) and representatives of many Western governments all began efforts to undermine the NDP or delay its implementation.

Within hours of the news breaking, Jane Coon, the US ambassador to Bangladesh, called without prior appointment on the Chief Martial Law Administrator, General Ershad. Her purpose was to convince him that the policy should not be implemented because it was unacceptable to the USA. She insisted that, at the very least, implementation of the policy should be postponed.

General Ershad was new to the political arena and was perhaps unaware of the politics of aid and its close connections with the business interests of donor governments. He had been reluctant to believe that, in 1975, the US ambassador in Sri Lanka had issued an implied threat of withdrawal of food aid because of the country's drug policy, seeing no reason why the USA

should interfere in Sri Lanka's domestic policy. Now he found himself equally astonished that the new NDP formulated by Bangladesh should be a matter of concern to the USA.

Over the next few days, Mrs Coon had meetings with the editor of the most widely-circulated Bengali daily, *Ittefaq,* the managing directors of US transnational companies, and a number of other people to work out a strategy for preventing implementation of the NDP. She also informed offices of the US Agency for International Development (USAID) in neighbouring countries about the dangers of a policy like the one in Bangladesh.[6]

British, Dutch and West German ambassadors also called on General Ershad to express their dismay at the proposed drug policy. The West German ambassador was particularly angry and said that the policy would deter German investment in the country. He said that the German TNC, Hoechst, had intended to expand in Bangladesh but was now reluctant to do so.

The West German government was clearly prepared to defend the interests of German companies. When two members of the medical faculty of Dar es Salaam University in Tanzania circulated a paper criticising the German company Asta Werke for marketing in Africa a drug which was banned in the UK and USA for safety reasons, the West German embassy sent a warning letter to the university, reminding it of its dependence on German aid for the construction of a new engineering school.[7]

The British threat was more subtle. The foreign secretary, Douglas Hurd, said in the UK House of Commons:

> We are keen that the Bangladesh Government should use its scarce resources wisely. We are also keen that they should succeed in their policy of encouraging foreign investment to help them with the development of an industrial economy. We, in common with other Western governments, have explained this to the Bangladesh Government through our High Commission in Dhaka. It is important that in trying to achieve the aims of the pharmaceutical policy they do not discriminate against foreign-owned manufacturing companies in Bangladesh and do not frighten off prospective foreign investors.[8]

A public hearing and a private meeting

Transnational companies started mobilising the BMA and elite public opinion. Many TNCs had retired army officers as their directors and administrators who were able to lobby the Martial Law Administration. Drug manufacturers met with senior officials of the army and the civil administration and with members of the Council of Ministers and persuaded almost every-

body that the NDP was a ludicrous policy with no scientific basis. These pressures led General Ershad to call a public hearing for 6 June 1982.

The meeting lasted for over three hours. Rather than debate the scientific rationale of the NDP, the TNC representatives argued that generic drugs policies had failed all over the world and that Bangladesh was attempting to ban drugs widely available elsewhere. Echoing the US ambassador, they called for the implementation of the proposed NDP to be delayed, pending a review by an independent body. Arguing that the policy would deter foreign investors, they made a veiled threat to withdraw from Bangladesh.

The small companies took a more reasonable approach. Recognising that 90 per cent of their products had no scientific validity, they argued that the fault lay with the Drug Administration which should not have permitted their production in the first place. They said that the negligence of the Drug Administration should not result in their financial ruin. They asked for a two-year extension on the banned drugs, and access to easy credit to compensate for their loss.

During the public hearing, government officials realised that the TNCs' campaign was based on total falsehood and that the TNCs were simply wielding their power in defence of their commercial interests. On 7 June 1982, the health minister made the NDP document public, as the first step in giving it a legal framework.

That evening, Rosslyn Bower, John Quinn, commercial officer at the British High Commission, and Gordon Powers, Acting Deputy Chief of the US Mission in Bangladesh, held a meeting at Bower's home.

Powers expressed the opinion that the Bangladesh government 'might be more receptive to an approach pointing to the conflict between the pharmaceutical policy and the industrial policy and to a suggestion that [it] would be unilaterally breaking both written and implied contracts with international firms, than to any form of attack on the new policy.'[9]

The next day, General Ershad had an unexpected invitation from the White House to visit the USA. For rulers of Third World countries, such an invitation is viewed as recognition of their governments.

Draft policy made law

The Council of Ministers participated with unusual vigour in a second discussion on the NDP on the evening of 11 June, chaired by General Ershad.

Both the finance minister and the industry minister voiced the sentiments of the TNCs, while the health minister, Dr Hug, pleaded the case for the NDP well and insisted that General Ershad sign the legal document for the NDP, the Drug (Control) Ordinance 1982, before leaving for the USA the next day.

Dr Huq ensured that the news was flashed on Bangladesh radio and television the same night. An *Extraordinary Gazette* of the Bangladesh government was published on 12 June by the Ministry of Law and Land Reforms.[10] At the end of the document were two significant statements: 'These lists [Schedules I, II, and III] are not absolute. According to the criteria laid down there may be some addition or deletion of products from any category.' Thus, it was clear from the outset that regular amendments were envisaged.

On 16 June, Lewis A. Engman, President of the US Pharmaceutical Manufacturers Association (PMA) wrote a three-page letter to General Ershad in which he warned of the 'negative impact' that the new policy could have on health care in Bangladesh. He said that several provisions of the new policy, including the 'excessively rigid interpretation of the concept of an essential drugs list', had already been 'tried and rejected' in countries such as Sri Lanka and Pakistan. Engman lamented: 'It would be particularly unfortunate if Bangladesh, which has made such impressive progress in recent years, were to follow the mistaken pharmaceutical policies of such countries.' Finally, Engman proposed to General Ershad that the implementation of the policy be delayed, and that as the 'issues at hand' were 'vital both to the well-being of the people of Bangladesh and to the investment climate in your country', a review panel should be formed to 'study the matter in depth'. He suggested that such a review panel should include delegates selected by and from the BMA, the Bangladesh Pharmaceutical Society and from BASS.

General Ershad's visit to the USA was extremely important for him. He met President Reagan on 18 June. Later he met Vice-President George Bush, with whom he agreed to a review of the Bangladesh NDP. General Ershad also said, in response, to George Bush's suggestion, that he would welcome a visit to Bangladesh by independent US scientists to advise him on the policy. What he did not realise was that George Bush was a director of the seventh-largest US TNC, Eli Lilly, and had substantial shares in other drug companies. Nor was he aware that only a few days earlier. Bush had told senior pharmaceutical industry executives from 22 countries that the Reagan administration planned to limit regulation of the pharmaceutical in-

dustry and end the 'adverse relationship' between government and industry.[11] During General Ershad's visit to the USA, a meeting with the PMA was also arranged.

Increasing pressure

While General Ershad was away, theTNCs continued to lobby the élite, the politicians and the newspapers. The media played a crucial role in the campaign against the NDP. The TNCs and the US ambassador were successful in persuading the pro-US *Ittefaq-New Nation* group of newspapers to make bleak forecasts concerning the NDP. Most of the major national dailies and weeklies started publishing reports against the NDP which were prepared and circulated by BASS. A BASS advertisement which maintained that the national drug industry would be ruined as a result of the NDP, appeared in all the national dailies on 23 June 1982, coinciding with General Ershad's return from the USA.

BASS also took out large advertisements in all the newspapers claiming that there was an international conspiracy by 'Christian' donor agencies such as Oxfam and War on Want and their local partners to destroy Muslim Bangladesh. The advertisements also questioned the role of Gonoshasthaya Kendra, cleverly playing with words to insinuate that GPL was owned by NOVIB, the Dutch aid organisation providing grants to Third World voluntary organisations. BASS tried to portray NOVIB as a Dutch business competing with British and US TNCs.

Drug company sales representatives campaigned vigorously against the NDP. They encouraged doctors to see the policy as a curb on their right to prescribe and an infringement of their clinical freedom. TNC manoeuvrings resulted in 23 professors and 40 senior doctors presenting a petition to the BMA President, demanding disciplinary action against Professor Nurul Islam and Dr Zafrullah Chowdhury for their active role in the propagation of the NDP and for 'maligning' the medical profession through their writings in support of the policy. They threatened to resign from the BMA if serious action were not taken against these two individuals.

Other sections of the public had misgivings about the policy. Intellectuals were confused by the suddenness of the decision to implement a new policy, unexpected from a military government. The urban élite were annoyed as their favourite digestive enzymes, tonics, elixirs and cough mixtures were banned. Mothers were angered by the banning of gripe water. Unfortunately, the government did nothing to ally their fears and correct misinformation.

As a response to the confusion created by TNCs and to the government s sudden silence and failure to promote the NDP, a new consumer organisation, Sabar Janya Shasthaya (Health for All, HFA) was established by a group of politically conscious physicians, lawyers, journalists, women activists, freedom fighters and university teachers to promote health education and to publicise the other side of the story. Advertisements and booklets produced by HFA in support of the NDP had a tremendous reception. People who had been alerted to the controversy as a result of the publicity generated by the BMA and the TNCs were interested in hearing the other side of the story. Apart from a few Dhaka daily newspapers and weeklies, other newspapers around the country eagerly published features written by HFA on the role ofTNCs in various countries and the preponderance of useless drugs even in the West.

On 24 June the US State Department had a meeting with the PMA. The meeting reviewed the basic points that the NDP would 'damage health standards' and 'increase smuggling, due to the continuing need for drugs' and stated that the proposed measures 'would make infeasible the continued presence of virtually all MNC companies [multinational companies]'. The State Department informed the meeting that Ambassador Jane Coon had already mentioned these concerns to General Ershad and that the embassy officer Gordon Powers had been pursuing the matter.

The PMA informed the State Department about a meeting in New York with the Bangladesh foreign minister, A. R. S. Doha, who was non-committal but suggested that a US team came to Bangladesh 'to talk'. Finally, it was decided that the embassy in Bangladesh should be formally instructed 'to send aide-memoires outlining earlier points and passing along a PMA letter'. The meeting noted: 'PMA will draft both'. ^The PMA followed up this meeting with one with Ambassador Coon when she visited Washington on 12 July.

Ambassador Coon broke the news to health minister Dr Shamsul Huq that a four-member 'independent scientific committee' would be arriving in Dhaka on 20 July 1982 to examine the drug policy and advise the Bangladesh government. When the health minister asked for the curriculum vitae of each of these experts, the US ambassador was furious, implying that it was impertinent for a minister of a Third World country to ask for the CVs of experts from the USA. She discourteously left the minister without having tea, which had already been laid on the table. Before leaving

she informed him that the 'independent scientific committee' had been agreed by General Ershad during his visit to the US. The health minister was unaware of this development, but he persisted with his request for the CVs which were finally made available.

Not one of the members of the so-called 'scientific committee' was an independent scientist. Two were senior executives from Wyeth Laboratories, one was a vice president from Squibb, and the last was a director with the PMA. General Ershad later told the health minister that when he had agreed to an independent advisory committee he had expected it to consist of officials from the US Food and Drug Administration and members of the National Academy of Sciences and other academics, but definitely not representatives from the pharmaceutical industry.

The US 'independent scientific committee' met executives from drug companies and from BASS and also had a few meetings with the Bangladesh Medical Association and the Review Committee. They did not wish to meet the members of the Expert Committee. The report of their findings was never made public.

US citizens challenge their government

Although Bangladesh's drug policy was opposed by the US government, it received unexpected support from US citizens. Ralph Nader, the famous public rights crusader, as well as concerned US citizens, consumer bodies, various church groups and human rights activists were among those who expressed their support for the Bangladesh NDP and started raising questions about US opposition to the policy with their senators, congressional representatives and the State Department. Many of them reminded the State Department of the US Government's expression of support for WHO's Action Programme on Essential Drugs at the 35th World Health Assembly (WHA) held in May 1982. At the WHA, Professor Arthur Hull Hayes, Commissioner of the US Food and Drug Administration, said that:

> All delegates appreciated the need for the people of all countries to have access to pharmaceutical products that were relevant to their health needs and priced within their means: that need was particularly acute in developing countries. The Action Programme on Essential Drugs had the potential for helping countries meet their needs, and the United States strongly supported it.[13]

Dr Sidney Wolfe and Benjamin Gordon of the Public Citizen Health Research Group in Washington wrote to the Bangladesh health minister on 9 August praising the introduction of the NDP. Referring to the removal of

harmful and ineffective drugs from the Bangladesh market, they wrote: 'Many of these drugs were removed from the US market during the past 12 years on the recommendation of eminent medical scientists; many of the drug mixtures you are removing were deemed to be "irrational combinations" by the former Committee on Drugs of the American Medical Association and their use was "not recommended".'

The Public Citizen Health Research Group also wrote to George Schultz, the US Secretary of State on 18 August 1982: 'To pressure the Bangladesh Government to delay the withdrawal from the market of dangerous, ineffective, useless or unnecessarily expensive drugs is unconscionable.'

Referring to the Bangladesh government's decision not to allow TNCs to manufacture and market oral vitamins and antacids, two out of over 250 products, the group asked Mr Schultz: 'Is it not hypocritical for us to protect many of our domestic industries from foreign competition by tariffs, quotas and subsidies while at the same time protesting against Bangladesh's program to develop a domestic drug industry?'

On 19 August 1982, the *Washington Post,* published a front-page news story entitled 'US is aiding drug companies in Bangladesh' which reported that the US government was putting pressure on the Bangladesh government to delay implementation of the new drug policy. It quoted a government spokesman as saying: 'The State Department has a statutory responsibility for assisting American interests abroad. In this particular case, the US government is also concerned that these regulations may inhibit future foreign investment in Bangladesh.' General Ershad subsequently asked the external Publicity Department of the Bangladesh Ministry of Foreign Affairs to circulate this article which had exposed the US government's interference and pressure.

Also on 19 August, the State Department issued a statement which brought to the surface the collusion of the BMA and certain government officials with the **TNCs** and the American Embassy in Bangladesh. The State Department declared:

> The US government has not brought 'pressure' on the government of Bangladesh to reconsider its new drug policy. Members of the health care profession in Bangladesh and a number of Bangladesh government officials have expressed concern over what they view as the precipitous way in which the ordinance was promulgated and over the limited participation of the health care community in Bangladesh in formulating

the ordinance. In the light of the concern in Bangladesh, the government of Bangladesh *on its own initiative* [author's emphasis] has undertaken to review the ordinance before final implementation.[14]

In an internal document written a few days later, the State Department said:

After consultation with the pharmaceutical companies and on instruction, Ambassador Coon made representations to several ministers with the purpose of facilitating contacts between the GOB [Government of Bangladesh] and US firms. ... She noted the policy would discourage investment by, *inter alia,* not affording national treatment, and suggested that implementation of the policy be delayed and reviewed by a panel of interested experts. *A joint demarche with other concerned countries (UK, FRG, Netherlands and Switzerland) was also made* [author's emphasis], and PMA representatives journeyed to Dacca to make similar points.[15]

In response to Dr Wolfe of the Public Citizen Health Research Group, the State Department said that 'consistent with State Department policy' the Embassy in Dhaka had simply 'facilitated a dialogue' between the industry and the Bangladesh government. It also expressed the 'hope' that implementation of the NDP might be delayed while this dialogue took place.[16]

Dr Wolfe replied:

Imagine the outrage of the US public if a foreign government asked us to delay implementing a health-protecting decision of our Food and Drug Administration or the Environmental Protection Agency! Moreover, it is rather naive to ignore that Bangladesh is a US aid recipient and that a 'hope' expressed by our State Department is perceived as a threat, veiled or unexpressed though it may be.[17]

National and international support for the NDP

Congratulatory letters and telegrams to the Bangladesh government from politicians, churches, non-governmental organisations, scientists, social scientists, doctors and academics from countries in the North and the South started pouring in.

The oldest and most prestigious medical journal, *The Lancet,* made a pertinent observation on Bangladesh's drug policy on 19 June 1982:

The power of the transnational is great and the stakes are high. In the past, governments and their ministers have sometimes yielded to pressure. If the government [of Bangladesh] brings its new policy to fruition the message will not be lost on other parts of the third world.

The London *Guardian* commented:

> The military government of Bangladesh has at a stroke done something that no other developing country or developed one for that matter has dared to do—it has enacted, almost in its entirety, the World Health Assembly's resolution on essential drugs. This draconian act has been interpreted as a massive assault on the multinational companies that dominate the country's drug market. In fact, it should mean that many more Bangladeshis will get the drugs they really need at a price the country can afford.[18]

Unexpected national support for the NDP came from progressive intellectuals in Bangladesh when, on 4 August 1982, important members of the Dhaka University Teachers Association (DUTA) and a number of physicians and journalists made a statement in the press that the NDP was a pro-people policy and would bring practical benefit to the people of Bangladesh if implemented fully. This group of 229 highly respected people called upon the government to inform all concerned professions about the scientific reasons for banning various kinds of medicines.

WHO: a peculiar silence

One source of expected support for the NDP was slow to materialise. The WHO representative in Dhaka, Dr Z. Sestak, neither congratulated the Bangladesh government on enacting the NDP nor offered any services to make the policy effective. When asked about his silence, he said that comment could only be made by the regional office in Delhi and the head office in Geneva. It was also most astonishing that Dr Halfdan Mahler, WHO'S Director-General, did not send a letter of congratulations or support for the successful implementation of the policy. It had, after all, been Dr Mahler who had declared at the 28th World Health Assembly in 1975 that it was important to assist countries in formulating and implementing national drug policies.

Dr Mahler came to Bangladesh to attend the 35th session of WHO's South-East Asian regional meeting in September 1982. In his speech, Dr Mahler praised the Bangladesh government for its commitment to Health for All and for being the first country in the region to have a health charter, but he did not comment on the drug policy. Asked about this by a journalist, he said: 'Your government is to make the policy and WHO'S main concern is that the people get the medicine.'[19] Pressed by another journalist on the same subject, Dr Mahler once again avoided a direct reply, saying only that it was for the government to decide policies for the people.[20] It was only

when the media left that Dr Mahler expressed to the delegates at the meeting his congratulations for the government of Bangladesh 'on its courage in starting to put its drug house in order'.[21]

The first review of the NDP

However, the support came too late to deflect the early pressure on General Ershad. He set up a Review Committee consisting of six army doctors on 6 July 1982. Family members of two of the committee members had high level jobs with national pharmaceutical companies which had licensing agreements with TNCs.

The Review Committee interviewed representatives of the national drug industry, TNCs, BASS, the Chemists and Druggists Association, the Chamber of Commerce and the BMA. It also met separately with the former president of the BMA, Professor Firoza Begum, who was a director of Pfizer and owned shares in three other drug companies. The BMA's statement was submitted to the Review Committee by the former general secretary of the BMA, Dr SarwarAli, who was also the Assistant Medical Director of Pfizer (Bangladesh). The BMA said that many of the drugs that had been banned were safe, effective and necessary, and that adverse reactions and side effects were rare and only came about as the result of inappropriate self-medication. The BMA concluded that the problem lay not in the drugs themselves, but in the unrestricted availability of these drugs without prescription. Therefore, the only policy measure the government should undertake was to ensure that these drugs were available on prescription only.

The Expert Committee, on its own initiative, met the Review Committee and enquired whether its members wanted explanations on any point in the **NDP.** The Review Committee politely declined the offer and said it had a copy of the **NDP,** which was self-explanatory.

A flawed report

The Review Committee submitted its repon. alongside submissions from various other groups, direct to General Ershad on 12 August. The Review-Committee's report was diametrically opposed to that of the Expert Committee. Following a suggestion from a member of the Expert Committee. General Ershad decided to bring the two committees face to face on 7 September in an attempt to establish the scientific validity of their report;,

The meeting was like a courtroom battle, with General Ershad in the chiiir. The Expert Committee appeared, with current editions ot *Vhurmui. oir^v,* the British and US pharmacopoeia, relevant journals and the latest ediiion

of WHO'S *The Selection of Essential Drugs*. The debate lasted five hours. The presentation convinced General Ershad of the scientific validity of the NDP.

However, the time allowed for reformulation of Schedule II drugs was extended to one year and that for the use of Schedule III drugs to 18 months. No extension was given for Schedule I drugs, but six products were taken off the proscribed list. Thirty-three drugs produced under third-party licence were permitted until the expiry of the contracts. Fifty-five other drugs manufactured by 52 small national companies were placed in a new schedule with a two-year allowance. After these adjustments, the final list of banned drugs stood at 1,666.

Two further adjustments to the NDP occurred: one to deal with traditional medicines and the other to cover prices.

Traditional medicines reviewed

Manufacturers of Ayurvedic and Unani medicines, taking advantage of the loopholes in the old drug legislation, and in response to market demand, started producing banned allopathic drugs. To prevent them producing allopathic medicines and to apply the NDP criteria to Ayurvedic, Unani and homeopathic medicines, a 13-member expert committee was formed in February 1983 with Dr Nurul Anwar, Director of the Drug Administration, as its convenor. Three experts on each type of traditional medicine were included in the committee.

The committee was able to verify the existence of 270 manufacturers, mostly functioning with primitive and crude facilities. The committee also discovered 16 registered and a few dozen unregistered distilleries producing alcohol, attached to Ayurvedic manufacturing plants. These manufacturers were producing over 25,000 brands of traditional medicine. The committee recommended only 431 medicines.

The committee also found that homeopathic medicines have an alcohol content of between 10 and 20 per cent while many Ayurvedic medicines contain over 40 per cent ethyl alcohol. The committee recommended that no medicine, whether homoeopathic, Unani or Ayurvedic, should have an alcohol content of more than 5 per cent. The committee submitted its report to the Drug Control Committee on 20 October 1983. It was accepted immediately. High-alcohol drugs were to be destroyed within three months. Traditional manufacturers were also instructed not to use Western allopathic names and not to produce allopathic medicines under the guise of traditional medicine.

The useless medicines of Schedule III and those of the traditional medicinal systems were given another, but final, extension of life, to 30 June 1984. Most newspapers, including those which opposed the NDP, supported the government's action on traditional medicines. For example, an *Ittefaq* editorial on 23 October 1983 commented that one traditional product, *Mritosanjibani,* which contained over 40 per cent alcohol, was creating social problems and that immediate action must be taken to prevent its production.

Pricing policy reviewed

A four-person committee headed by Professor M. A. Mannan, Vice-Chancellor of Dhaka University and Professor of Pharmacy, was set up in 1987 to formulate a pricing policy, as recommended by the NDP. The other committee members were Salman Rahman, the managing director of Beximco Pharmaceutical and President of both BASS and the Chamber of Commerce; Dr Humayun K. M. A. Hye, and Dr Zafrullah Chowdhury.

The committee based its recommendations on a simple formula of adding 100 per cent to the unit price, inclusive of import duties, taxes, import licence feeds and transportation costs of individual raw materials and packaging materials. An extra mark-up of between 50 and 225 per cent was allowed for the cost of processing, quality control, commission for distribution and retailing. The scale of the mark-up was as follows:

A. 0 per cent for simple repacking which does not require any processing.
B. 100 per cent for oral products other than antibiotics, creams and ointments.
C. 125 per cent for oral antibiotics, coated tablets, sustained-release dosage forms, soluble tablets, suppositories and vaginal tablets.
D. 175 per cent for products requiring terminal sterilisations and hormonal preparations.
E. 225 per cent for products requiring total aseptic facilities.

Sales tax, value added tax (VAT), other duties and surcharges, were also added to arrive at the maximum retail price (MRP).

A Pricing Sub-committee was set up to review the prices of imported raw material and packaging material charged by two large and medium companies and five small companies. On this basis, prices are reviewed every six months and take into account dollar fluctuations and changes in government taxation.

In 1989, a further increase in mark-up resulted in an increase from 100 to 125 per cent in group B; from 125 to 130 per cent in group C; from 175 to 180 per cent in group D; and from 225 to 240 per cent in group E. Despite this price regime, many companies, both national and transnational, sell below the MRP.

It was not the specific mark-up restrictions but the principle of price controls introduced by the Bangladesh government that upset the TNCs. The drug industry's voice was later strengthened by the head of the Industry and Energy Unit of the World Bank, who wrote to the Bangladesh government on 8 June 1992: '[The] prices of most drugs are determined by competitive market forces rather than their MRP. Flat-rate price controls hurt those firms which spend money on quality assurance and maintain good manufacturing practices'. The same World Bank letter further states: 'It is the generally held view, which we share, that a decontrol of prices would not lead to an abnormal rise in prices because of the competitive structure of the market.'[22]

In a similar way, the main objection to the policy as a whole was not because TNCs had a particularly large market in Bangladesh. Rather, they were concerned that unless the NDP was nipped in the bud, the Bangladesh example could affect the policies of other countries. Their fears began to come true: on 23 July 1983, the Indian government banned, with immediate effect, the manufacture and sale of 25 irrational or potentially harmful drugs.[23]

Even in the UK, the Bangladesh National Drug Policy was cited as an example of effective action on drugs in a House of Commons debate on ways to limit the high costs of drugs to the National Health Service (NHS). Ultimately, the UK government decided to withdraw 1,800 drugs from the list of medicines that could be prescribed under the NHS.[24]

Achievements and limitations

Substantial benefits have derived from Bangladesh's National Drug Policy. The gains are evident when prices, production figures and quality indicators at the time the policy was introduced are compared with those of a decade later. Between 1982 and 1992:

- essential drugs increased from 30 to 80 per cent of local production;
- drug prices stabilised, increasing by only 20 per cent, compared to an increase of 179 per cent in the consumer price index. The drop in price in real terms made drugs more affordable for consumers;

Table 3 Increase in local production of drugs in Bangladesh during 1981 -91 in million Taka and nominal prices; decrease in imports of finished drugs in million US$

Year	Total local production (in million Taka)	Production by local national companies (in million Taka)	Imports of finished drugs (in million US$)	Imports of finished drugs (in million Taka)	Official conversion rate of US$ 1 to Taka
1981	1,730	613	17.5	284	16.26
1982	2,160	842	13.5	270	20.07
1983	2,260	1,160	9.7	232	23.80
1984	2,830	1,470	12.1	301	24.94
1985	3,283	1,864	13.0	337	25.96
1986	3,500	2,080	16,1	482	29.89
1987	4,048	2,315	10.1	310	30.63
1988	4,383	2,944	8.4	263	31.25
1989	5,000	3,008	7.6	244	32.25
1990	5,300	3,429	8.9	294	32.89
1991	5,500	3,375	8.9	315	35.25

Source: Bangladesh Drug Administration, 1992.

- Bangladesh companies increased their share of local production from 35 to more than 60 per cent—overall, local production increased by 217 per cent;
- less dependency on imports and prioritisation of useful products saved the country approximately US$ 600 million;
- the quality of products improved—the proportion of drugs tested which were found to be substandard fell from 36 per cent to 9 per cent.[25]

Increased local drug production and lower prices

The availability of essential drugs has increased remarkably with the increase in local production, the value of which grew from Taka 1,730 million in 1981 to Taka 5,500 million in 1991 (Table 3). The director of the Drug Administration estimated that total drug production in 1994 would reach Taka 10,000 million.[26]

Increased local production led to a decrease in imported drugs, which are now mainly items on the supplementary list. Eighty per cent of locally produced drugs are for primary and secondary health care. Pursuance of NDP objectives to procure raw materials at the most competitive prices led to a sharp decrease in the prices of raw materials (Table 4) and in turn to a fall in maximum retail price (MRP) of finished drugs.

Table 4 Reduction in prices of raw materials 1981-91

Raw material	Prices in US$/kg 1981	1991	Reduction in percentage
Amoxycillin trihydrate (local)	130	3,225*	29.6
Ampicillin trihydrate (local)	120	2,870*	32.1
Cloxacillin	95	70	26.3
Doxycycline	1,500	78	94.8
Fursemide	703	70	90.0
Glibenclamide	2,350	180	92.3
Hyoscine Butylbromide	1,358	390	71.3
Ibuprofen	32	16	50.0
Levamisole	128	31	75.8
Mebendazole	287	19	93.4
Metaclopramide	200	105	47.5
Metronidazole	56	17	69.6
Oxytetracycline	54	16	70.4
Propranolol	490	25	94.9
Rifampicin	473	178	62.4
Sulphamethoxazole	37	14	62.2
Tetracycline HCl	64	24	62.5
Trimethprim	60	33	45.0

* Raw materials produced locally and sold in Taka currency. The conversion rate in 1991 was 35.25 Taka to 1 US$. The price in US$ would then be 91 and 81 respectively.

Source: Bangladesh Drug Administration, 1992.

The pricing system for finished drugs recommended by the 1987 Mannan Committee discouraged the use of superfluous or luxury packaging materials. Accordingly, the Drug Administration does not include costs of unnecessary packaging materials when calculating the cost of finished drugs. The effect is clearly reflected in the decrease in imported packaging material and the increase in imported raw materials. Imported packaging material decreased from 42 per cent of the value of imported raw material in 1981 to just over 13 per cent in 1991.

The retail prices of most of the drugs produced locally showed a downward trend between 1981 and 1991/2, or at worst were static. Table 5 shows retail prices in Taka and, for easy reference, in US dollars. The downward trend of prices is more dramatic in US dollars: the minimum price decrease was 23 per cent while the maximum decrease was 97 per cent. The highest price increase occurred in the case of aspirin, which went up from Taka 0.10 to Taka 0.44.

Table 5 Changes in nominal retail prices of 30 important drugs in Taka and, for comparison, US$ in the period 1981-1991/92

Product	Retail price in Taka			Retail price in US$		
	1981	1991/92	change (percentage)	1981	1991/92	change (percentage)
Amitriptyline tablet 25 mg	0.80	0.45	-43.7	0.05	0.01	-74.1
Amoxycillin capsule 250 mg	2.50	2.90	16.0	0.15	0.08	-46.6
Ampicillin capsule 250 mg	1.70	2.50	47.1	0.10	0.07	-30.0
Ampicillin syrup 60 ml	21.00	33.00*	57.1	1.29	0.94	-27.1
Antacid tablet	0.30	0.50	66.7	0.02	0.01	-23.1
Aspirin tablet 300 mg	0.10	0.44	340.0	0.01	0.01	103.0
Atenolol tablet 100 mg	6.00	3.30	-45.0	0.37	0.09	-74.6
Chlorrhexidine sol. 112 ml	10.53	16.68	58.4	0.65	0.47	-26.9
Chloroquine tablet 250 mg	0.39	1.00	156.4	0.02	0.03	18.3
Cimetidine tablet 200 mg coated	2.00 a	1.45	-27.5	0.08	0.04	-51.0
Cloxacillin capsule 500 mg	3.60 b	5.65	56.9	0.14	0.16	11.0
Cotrimoxazole tablet	2.00	0.65	-67.5	0.12	0.02	-85.0
Buprofen tablet 10 mg	1.36	0.83	-39.0	0.08	0.02	-71.8
Dapsone tablet 100 mg	0.20	0.16	-20.0	0.01	0.00	-63.1
Diazepam tablet 5 mg	0.30	0.20	-33.3	0.02	0.01	-69.2
Fluocinolone cream 5 mg	12.00	26.00	116.7	0.74	0.74	-0.1
Fursemide tablet 40 mg	0.60	0.50	-16.7	0.04	0.01	-61.6
Indomethacin capsule 25 mg	1.91	0.52	-72.8	0.12	0.01	-87.4
Levamisole syrup 30 ml	13.00	9.35	-28.1	0.80	0.27	-66.8
Levamisole tablet 40 mg	1.30	0.41	-68.5	0.08	0.01	-85.5
Mebendazole tablet 100 mg	2.11	0.70	-66.8	0.13	0.02	-84.7
Metronidazole tablet 200 mg	0.70	0.63	-10.0	0.04	0.02	-58.5
Metronidazole I.V. 500 mg/100 ml	248.75	55.00	-77.9	15.30	1.56	-89.8
Nifedipine capsule 10 mg	4.60	0.32	-428.0	0.28	0.01	-96.8
Oxytetracycline capsule 250 mg	1.05	1.00	-4.8	0.06	0.03	-56.1
Paracetamol tablet 500 mg	0.25	0.52	-108.0	0.02	0.02	14.4
Propranolol tablet 40 mg	1.00	0.32	-68.0	0.06	0.01	-85.2
Ranitidine tablet 150 mg	3.00 c	2.05	-31.7	0.12	0.06	-49.7
Rifampicin capsule 150 mg	5.18	3.50	-32.4	0.32	0.10	-68.8
Vitamin B complex tablet	0.74	0.42	-43.2	0.05	0.01	-73.8

a) 1983 price, b) 1984 price, c) 1985 price
for 100 ml bottle
Source: Bangladesh Drug Administration, 1992.

The abolition of transfer pricing

Drug manufacturers' total profits have gone up, because of the increased volume of production, while the unit profit has gone down, to the benefit of consumers. The NDP effectively brought to an end transfer pricing and over-invoicing for imports of capital machinery, raw materials and packaging materials, which were common practices before 1982.

As is evident in the case of Bangladesh, TNCs investments in the Third World through finance capital are negligible; actual cash capital investment is even less. Through their high volume of sales in relation to their paltry investments, TNCs in Bangladesh make enough profit to recover their whole investment within two to three years of beginning operations. The investments of TNCs are not for the manufacture of drugs from raw materials but for establishing repackaging warehouses in the Third World.[27]

Many countries have attempted to introduce generic prescribing. Since brand names ensure that a company continues to benefit from a patent even after its expiry, it is not surprising that drug companies everywhere have fought hard with the help of the medical establishment to prevent the introduction of a 'generics-only' policy and have often won.

Initially, the Bangladesh Expert Committee proposed that the 45 drugs for use in primary health care be manufactured and sold only under generic names. But the committee was well aware of the records of failure in other countries and decided not to go for a head-on collision on the generics issue. Instead, it devised a strategy to achieve the main benefits of generic drugs without making the marketing of drugs under generic names compulsory. It therefore made it clear that manufacturers were free to market their drugs under brand names, providing the generic name was printed underneath the brand name in the same size of type. Furthermore, it recommended that drugs with the same active ingredients be sold at the same price, irrespective of whether they were brand name drugs, branded generics or commodity generics. With this alternative strategy, Bangladesh avoided the generics tussle, but achieved the goal of making quality drugs plentifully available at a cheaper price.

The quality of locally manufactured drugs has improved significantly since the introduction of the NDP because of greater vigilance and because testing procedures are easier now as most products contain only one active ingredient. In 1981, only 327 products were tested, of which 36 per cent were found to be substandard, while in 1992, more than 2,600 samples were taken, with less than seven per cent found to be of substandard quality (see Table 6).

The top 15 companies, including GPL, control 88.7 per cent of the drugs market. Thirty medium-sized pharmaceutical units share about 6 per cent of

Table 6 Results of drug samples tested by drug-testing laboratories in1981–92

Year	Total samples tested	Number of substandard drugs	Percentage of substandard drugs
1981	327	118	36.0
1985	1,187	169	14.6
1989	2,367	238	10.0
1990	3,555	298	8.4
1991	2,331	219	9.4
1992	2,617	174	6.6

Source: Bangladesh Drug Administration, 1993.

the market, while the remaining 5 per cent is shared by 154 small units. Substandard drugs are produced mainly by small units and some by medium-sized enterprises. One of the worst examples of a substandard drug concerned several brands of paracetamol syrup in 1992 (see Box).

An independent study, conducted in 1992 by Professor Jiben Roy and colleagues at the Pharmacy Department of Jahangirnagar University,[28] found that 37 out of 137 drugs tested were substandard. The drugs tested—paracetamol, antacid, ampicillin and vitamin B—were among the most commonly used in Bangladesh and were from 13 of the top 15 companies and 57 medium-sized and small companies (see Table 7).

The 37 substandard drugs were produced by 24 small companies. Fortunately, all the companies producing substandard drugs, if taken together, occupy only about 1 per cent of the market.

There have been a small number of cases of substandard drug production by large companies. A glaring example concerned the manufacture and mar-

Table 7 Number of producers of various dosage forms of four common drugs

	Number of producers				
Product	Tablet	Capsule	Syrup	Suspension	Injection
Paracetamol	103	-	126	5	
Antacid	79	-	-	132	
Ampicillin	-	63	45 (dry syrup)	-	8
Vitamin B complex	33	49	14	-	6

Source: Bangladesh Drug Administration, 1993.

The case of Flamodel paracetamol syrup

A lethal paracetamol syrup manufactured with an adulterated solvent made headlines in November 1992. The events leading up to the media coverage began two years earlier when 30 children admitted to Dhaka Shishu (Children's) Hospital died of acute kidney failure, although they had no previous history of kidney infections. A young paediatrician, Dr Mohammed Hanif, suspected the intake of adulterated paracetamol syrup as the cause of death, after reading a *Newsweek* article on a similar incident in Nigeria.

His suspicion was that instead of propylene glycol, which is normally used to dilute paracetamol and make it more soluble, the excipient used in the manufacture might turn out to be diethylene glycol, a substance used in lacquer, cosmetics and as an antifreeze, lubricant or softening agent. Diethylene glycol is about 30 per cent cheaper than propylene glycol and is handled by a range of commercial importers in Bangladesh, while propylene glycol is imported exclusively by drug manufacturers with the authorisation of the Drug Administration. It is difficult to import propylene glycol in small quantities, so small companies buy it from wholesalers.

Various tests were carried out. Finally, in November 1992, the Drug Administration imposed a temporary ban on all brands of paracetamol syrup. Samples of 113 brands of paracetamol syrup were collected from various parts of the country and tested under the supervision of a WHO consultant. Five brands were found to contain diethylene glycol. By December 1992, the manufacturing licences of all five companies had been revoked and the companies were asked to withdraw all their paracetamol syrups.

One of the five companies, City Pharmaceuticals and Chemical Works, contested the ban and their case was dismissed in March 1993. However, an appeal has been filed, which is still pending, alleging irregularities on the part of the Drug Administration for its handling of the case.

keting by Pfizer (Bangladesh) of the short-acting penicillin G procaine injection as long-acting penicillin G benzathine. Six consecutive batches, totalling 1.2 million units, were marketed under the wrong product name.

The raw material for the benzathine came from Rhone Poulenc in 1987. Shortly after the consignment was sent, Rhone Poulenc informed Pfizer by telex and letter that the containers had been mislabelled and contained procaine.

Despite the notification, production continued for some time. Pfizer's quality assurance department failed to note the difference between the contents and the declared labels. When it was discovered by the authorities, the product was deregistered for two years and Pfizer was forced to place more than

the usual number of withdrawal notices in the national newspapers. The quality control manager lost his job and had his registration as a pharmacist suspended for two years.

The Drug Administration has never seriously tried to apply the law and punish offenders, although Article 17 of the Drug (Control) Ordinance 1982 clearly specifies that whoever manufactures or sells any substandard drug shall be punishable with imprisonment of up to five years or with a fine of up to Taka 100,000 or with both. It seems quite likely that some officials in the Drug Administration supplement their low salaries by accepting bribes from manufacturers of substandard drugs.

Spurious drugs: a logical consequence of unregulated profits

The NDP, with its organised price structure which keeps drug prices low, has ensured that the incidence of counterfeiting is low in Bangladesh. It is usually high-priced drugs, whether imported or locally produced, that are subject to counterfeiting. For example, no case of counterfeiting of locally produced injectable antibiotics had been reported by 1994, because most hospitals and private clinics buy locally produced injectables directly from the manufacturer at a reasonably low price.

Some counterfeiting of other injectable products has been reported, usually of drugs that are imported and therefore sold at a higher price than the government MRP. For example, locally produced diclofenac injections sold at just under Taka 15 in 1992, while the imported brand made by Ciba, Volteran, cost Taka 50. The higher profit that can be made on the imported drug, encourages greed and deceit in others. So long as expensive brands are permitted, there is a danger of spurious drugs penetrating the market.

Misbranded and spurious drugs are occasionally reported in the newspapers. A number of spurious drugs banned under the NDP continue to be prescribed by unqualified village practitioners. These practitioners are not registered, and government documents refer to them as quacks, but often they are the only health providers in rural areas. Their lack of access to recent information on drugs encourages them to continue with brands that have been banned. The products are mostly smuggled into the country from India, although some are produced locally through illegal means.

Improved prescribing patterns

Most medical practitioners obtain their information on drugs from the drug companies themselves. Most medical journals in Bangladesh are published irregularly and are largely financed through drug company advertisements.

Prescriptions issued by senior physicians are immediately copied by juniors, and more gradually by general practitioners. Inappropriate prescribing of antibiotics—in respect of indications for disease or duration of application—is the most common symptom of bad prescribing habits. In 1986, an audit of a medical unit in a teaching hospital showed that 10 out of 13 antibiotic combinations used were ineffective or harmful.[29]

Professor Nurul Anwar of the Department of Pharmacology at Dhaka Medical College reported in 1992 that 79 per cent of prescriptions contained at least one error, resulting in overdose, undertreatment or adverse interaction.[30] He identifies aggressive promotion by drug companies as the main cause of bad prescription.

The extent of bad prescription is directly related to the health ministry's lack of concern for patients and failure to make efforts on their behalf. A national formulary is one tool in the prevention of bad prescription and is a good aide in deciding the proper use of a particular drug. The NDP recommended that a national formulary be published by 1983. It has not been published. The government made no attempt to communicate to consumers about the scientific and other reasons for the drug policy, the use of generic names, the control of treatments costs and, above all, non-drug therapy.

Unfortunately, the problem of bad prescription is not even acknowledged by the president of the BMA, Dr M. A. Majed, a former principal of Dhaka Medical College. He claims that drug misuse is not caused by any deficiency in knowledge, and when a doctor appears to be prescribing irrationally, his intention is usually to cover all the possible diagnoses at the time and he is probably right to do so.[31]

However, even in the absence of continuing education on clinical pharmacology, the number of drugs per prescription issued by doctors in general practice and specialist practice alike has decreased considerably. Between 1982 and 1990, there was a drop from five or six drugs per prescription to between two and four. The average number of medicines prescribed per patient in 1990 was 2.77 for general practitioners, 3.52 for paediatricians and 3.91 for other specialist consultants.[32] This change can be attributed to the impact of the NDP in removing many useless products and replacing most combination drugs with single-ingredient products.

In November 1992, the International Network for the Rational Use of Drugs, in collaboration with the community medicine and pharmacology departments of four medical colleges in Bangladesh, conducted a survey to

informed the government about the international prices of raw materials and packaging materials and which supplied information whenever the government sought it. GPL considered this to be part of its public responsibility.

On 18 August 1984, over 2,000 hooligans attempted to set fire to the GPL factory. While trying to fend off the attackers, 63 female and 21 male GK workers were wounded. The attempted arson was soon followed by malicious newspaper propaganda about GPL and GK, which continued over the next four months. Various political parties were misled into taking sides against GPL without a full understanding of the problem. However, despite a call by *The Pulse* to review the drug policy in January 1986, all became quiet on the pharmaceutical front until the end of 1986.

An interesting development occurred on 9 November 1986 when BASS, which had fought tooth and nail against the NDP since 1982, suddenly printed full-page newspaper advertisements in several dailies, declaring that:

> ... the ordinance [the Drugs (Control) Ordinance (1982)] represents a philosophy whose scope extends beyond the need of today into [the] realms of [the] future. ... It has been applied, tested and has to its credit today many examples of beneficial aspects.

In the advertisements, BASS showed by means of graphs, the substantial drop in imports but dramatic growth in local production. It urged MPs to ratify the ordinance into an Act in the forthcoming winter session of the Bangladesh Parliament, 'thereby ensuring the local pharmaceutical industry and the Bangladesh people continue to benefit from revolutionary policy'.

National health policy

The next major skirmish over the NDP came when an attempt was made to introduce a new national health policy. Although the NDP Expert Committee pointed out in 1982 the importance of seeing the national drug policy as a part of a national health policy, it was another five years before a four-member presidential committee was appointed—on 18 March 1987—to formulate a national health policy (NHP). The committee members were: Major General M. R. Chowdhury, director of the Army Institute of Pathology and Blood Transfusion Services (Chairman); Professor S. I. M. G. Mannan, a former professor of anatomy, a former president of the Pakistan Medical Association and then a member of the Executive Committee of the Bangladesh Medical Association (Member Secretary); Professor M. Yunus,

an economist and Managing Director of the world-famous Grameen Bank; and Dr Zafrullah Chowdhury. The committee submitted its report on 25 August 1988. The salient features of the proposed NHP were:

- decentralisation of health and family planning activities and administration with the establishment of Health Authorities at regional, district and Upazila levels;
- integration of health and family planning departments;
- an increase in the government's health budget from 2.5 per cent to 10 per cent within five years;
- people's participation in the management of Health Authorities;
- introduction of a Medical Audit, and the registration of all health workers;
- introduction of community-based medical education;
- abolition of private practice for all teachers in government medical colleges and postgraduate institutes and for trained doctors up to the level of junior consultant (equivalent to senior registrar in the British National Health Service or chief resident in the US system);
- introduction of laws to ensure quality health care and compensation to persons who have suffered as a result of negligence by the medical profession;
- introduction of various other legislative and administrative measures.

However, the NHP never came into effect. At the opening of the winter session of Parliament in January 1990, President Ershad outlined the NHP and announced the renamed Ministry of Health and Family Welfare. The opposition parties privately admitted that this was a good policy but doubted whether the government would ever introduce it in Parliament.

Seven months later, DrAzizur Rahman, the Minister for Health and Family Welfare and a former member of the NDP Expert Committee, did introduce the policy in a bill in Parliament and said the policy would be formally enacted on 17 October if the bill was passed.

Protests and attacks

The same evening, the BMA called for a 72-hour strike by all doctors in protest at what it termed an anti-people health policy. The executive body cancelled without notice the general membership of Drs Azizur Rahman, S.I. M. G. Mannan and Zafrullah Chowdhury, for their role in formulating the policy. The three expelled doctors were given no opportunity to defend their roles as formulators of the NHP. The strike continued with the support of the opposition political parties.

On 27 October 1990, a group of hooligans attacked and burned the office, stores and vehicles of GPL. Tension mounted and a month later, on 27 November, Dr Shamsul Alam Khan Milon, Joint Secretary of the BMA, was killed by an assassin's bullet while passing through Dhaka University campus in a rickshaw.

Politicians immediately seized the opportunity offered by the doctors' strike and Dr Milon's death to mobilise protests which continued to escalate and ultimately led to the fall of the Ershad government on 6 December 1990.

An interim government was set up. The BMA president, Dr Majed, was appointed Health Advisor (Minister) in the interim government. On the very first day of the interim government, Parliament was dissolved and the NHP bill was cancelled by the acting President.

The loss of the health policy was highly regrettable. However, in the political turmoil that ensued, it began to look as if the NDP would also be lost. The BMA called for the cancellation of the NDP (which it also termed an anti-people policy), an investigation into GK and a government takeover of both GK and GPL. It also demanded the arrest of Dr Zafrullah Chowdhury of GK and DrAzizur Rahman. BASS supported the BMA's demand for an investigation into GK and GPL.

The NDP was not withdrawn, but a six-member committee under the chairmanship of Major General Anis Waiz was announced by the Health Advisor on 9 February 1991 to carry out an investigation into GK, GPL, and the Bangladesh Association of Voluntary Sterilisation, an NGO of which Dr Azizur Rahman was President. Major General Anis Waiz was known for his virulent opposition to the NDP. Dr Majed ordered the cancellation of Dr Zafrullah Chowdhury's membership of the Drug Control Committee and the Drug Pricing Committee.

Political stability began to return to the country following elections in February 1991. Begum Khaleda Zia was sworn in as Prime Minister in March 1991 and Parliament was convened a month later. However, on the last day of April 1991, another emergency struck as a cyclone devastated the southern part of Bangladesh. In the midst of this disaster, the NDP survived one of its most rigorous tests since its introduction.

A consultative meeting with NGOs and foreign diplomats was held to address the need for the provision of effective relief to the victims of the cyclone. At this meeting, which was presided over by the new prime minister,

assess drug use patterns for six common diseases. The study found that the average number of drugs per prescription was 1.4. Eighty-one per cent of patients received drugs according to prescription and were given adequate information about them; 85 per cent of the drugs were selected from the essential drugs list and 78 per cent were prescribed by generic name; and only 24.5 per cent of patients were treated with antibiotics.[33]

Like doctors in industrialised countries, doctors in Bangladesh are keen to preserve their rights to clinical freedom and *laissez-faire* prescription, but adverse to a medical audit of their prescription habits. On 12 June 1990, the eighth anniversary of the NDP, the Bangladesh government introduced compulsory prescription for the four most frequently misused groups of drugs—antibiotics, narcotics, hormones (except contraceptives) and benzodiazepines—in Dhaka.

The system included the use of a triplicate prescription pad which would allow for follow-up audits to monitor prescribing habits. The BMA refused to endorse the system.

Simmering opposition

Despite the obvious benefits of the NDP, opposition to it simmered throughout the 1980s and early 1990s, flaring up every now and then.

From mid-1984, the drug companies launched a major assault on the NDP. An article in *The Pulse* on 16 April 1984 claimed: '23 million dollars withdrawn from planned investments by transnationals: Drug Policy now a total failure'. This is a common tactic: whenever a new government tries to change existing policy in favour of consumers, corporations all over the world issue threats about the withdrawal of investments. In 1993, the US PMA tried to frighten Clinton Administration from reforming health care by claiming that investors were losing confidence in pharmaceutical industry stock and that pharmaceutical companies had lost US$150 billion off their market value in just one year of uncertainty about the direction of the reforms.[34]

In Bangladesh, the drug industry tried hard to discredit *Sabar Janya Shasthaya* (Health For All, HFA) and its publication which was effectively propagating the ideas of the NDP. HFA was reasonably successful in exposing, through newspaper features and advertisements, the wrong use of medicines and the reasons for the banning of certain medicines.

The drug industry was also angry with GK and GPL, as it was GPL which

diplomats from Switzerland and the USA said that their planes were already loaded with medicine and baby food, ready to fly into Bangladesh, but that the country's drug policy created an obstacle.

All the ambassadors and other participants were stunned by Khaleda Zia's prompt reply. She said that she greatly appreciated the offer to provide assistance but that any medicine brought into Bangladesh must conform with the essential drugs list.

The threatening cloud had passed over the NDP; if not permanently, at least for the time being.

The National Drug Policy under attack again

It was a short-lived respite. In the midst of sensitive negotiations with the World Bank over loans for industrial development, the new government faced continued pressure from the BMA for the withdrawal of the 'anti-people drug policy'. The Foreign Investors Chamber of Commerce and Industry (FICCI) also demanded a review of the NDP. The leader of the FICCI at the time was S. H. Kabir, Managing Director of Pfizer (Bangladesh) Ltd.

On 6 March 1992, the government announced a 15-member Review Committee, chaired by the secretary of the Ministry of Health and Family Welfare, to review the National Drug Policy of 1982 (NDP 82) and formulate a revised drug policy by 30 April 1992. Among the 14 other members, four were medical teachers, three from the pharmaceutical industry, two from the army and one from the Chemists and Druggists Association. The deputy secretary of the ministry, the director of the Drug Administration, the president of the BMA and two MPs were also members of the committee.

At the time the Review Committee was being formed one influential weekly made an astute observation: 'Interestingly, no strong demand has been made by the opposition to change the drug policy of the former regime. Yet the government seems to be attaching much importance to the issue.'[35]

One section of the World Bank, however, did consider the review important. In April 1992, Abid Hasan, Head of the Industry and Energy Unit of the World Bank's office in Bangladesh, met relevant government officials to discuss negotiations for an industrial sector loan. He followed up the meeting with a letter to Ayub Quadri, Joint Secretary of the government's Economic Relations Division, in which he made five specific recommendations pertaining to pharmaceuticals. World Bank recommendations, es-

pecially when loans are being negotiated, are in reality directives to Third World governments. The recommendations were:

- to allow the introduction of new products by using free sales certificates;
- to lift all controls on prices;
- to remove the control over advertising from the drug licensing authority;
- to remove existing restrictions on foreign firms in the area of choice of products they can produce;
- to abolish controls on the import of pharmaceutical raw materials.

At about the same time, the FICCI presented the Health Minister. Chowdhury Kamal Ibne Yusuf, with a set of proposed amendments to the NDP. These simply echoed the recommendations of the World Bank, with one small exception. The FICCI was not concerned about the removal of controls over advertising as drug companies were already printing and distributing product showcards giving misleading or untrue information.

Concern over these developments led WHO and UNICEF to defend the NDP. The country representatives of both organisations wrote to the head of the World Bank in Bangladesh, Christopher Willoughby. The WHO representative wrote:

> Bangladesh initiated the National Drug Policy in 1982, which was very much appreciated, due to its ability to provide low-cost and price-controlled basic essential drugs, affordable by the majority of the population, ensuring cost-effective process in primary health care.

Both WHO and UNICEF recognised the need to update and strengthen the policy, but were calling on the World Bank to ensure that gains that had been secured by the NDP were not undermined.

The strategy worked, up to a point. Abid Hasan was ordered to send another letter to Ayub Quadri clarifying the World Bank's position on the NDP. His letter of 8 June 1992 was cleverly written. It began with the statement, 'First and most important, we fully support the drug policy objective of increasing the supply of essential drugs (EDs) and making these available at affordable prices'. It went on to argue that the present controls could be replaced by more liberal policies/procedures 'without sacrificing the objective of increasing availability of good quality and affordable EDs'. The five recommendations were repeated, albeit in a modified form.

The final paragraph was a veiled threat: 'We would appreciate if these views are brought to the attention of the drug policy review committee urgently, specially since one aspect (import controls) of the above is germane to ISAC-II [Industrial Sector Adjustment Credit-11] negotiations.'

Even with the changes, this letter still promoted foreign commercial interests rather than the health interests of the people. At the time, another division of the World Bank's office in Bangladesh—the Population and Health Unit—was finalising agreement with the government and with major donor agencies on a five-year programme that included a significant component on the rational use of drugs. This stressed the need to support the National Drug Policy through education and information activities. This effort was subsequently referred to in the World Bank's 1993 report. *Investing in Health,* as a prime example of donor cooperation in planning better health programmes.

The confusion caused by these two World Bank positions was unhelpful. A spokesperson for a major donor agency in Bangladesh said that 'there should have been a public denunciation of the position' ofAbid Hasan.[36]

The role of WHO

A similar lack of consistency has also been a problem with WHO. In supporting efforts to develop national drug policies based on the sensible and safe use of a restricted number of drugs, and in facing up to the might of the pharmaceutical industry, WHO clearly has a crucial leadership role to play. In some respects, its leadership has been strong, but this has not been consistent.

WHO local offices are not very active in distributing their own publications. The resident WHO representative in Bangladesh even stated in 1992 that the NDP encouraged the smuggling of drugs.[37]

Why is WHO not more consistent in its efforts to support national drug policies and rational drug use? Is it because of the reluctance of the US government to endorse its policies? If such disagreement led to the withdrawal of the US from WHO, the financial consequences would be severe for WHO, as the USA contributes almost 25 per cent of the organisation's regular budget.

There are other possible explanations. WHO'S staff consists primarily of doctors. These doctors are skilled in the scientific diagnosis and treatment of diseases, but rarely show concern for social and environmental factors.

Most of them fail to appreciate that a disease such as tuberculosis is an indicator of social inequality or that malnutrition and unsanitary conditions contribute significantly to the incidence of the most common diseases of the Third World. They are unwilling to analyse these problems from a political or economic point of view.

WHO always takes an apolitical, neutral stand and, in adherence to its principle of non-interference, refrains from mentioning colonialism, neocolonialism and imperialism, all of which have played a significant role in the cause and spread of diseases among the exploited and oppressed people of the world.[38] As the *British Medical Journal* has pointed out, 'WHO should be doing more to tackle the root cause of most diseases—poverty—and doing more to improve infrastructure of health care in the developing world'.[39]

Such action as WHO has taken on drugs is typical of the technological approach to health problems with which medical officers working for WHO feel familiar and comfortable. Doctors understand drugs in so far as they know about prescription and usage, efficacy and quality, but they do not apply their minds to the problems of how drugs reach the people who need them most. They do not realise that the class character and political will of the government determine the affordability and provision of essential drugs.

WHO has been slow to clearly state in its documents that its essential drugs list is for both the private and the public sector. By the end of the 1980s, the drug industry had come to accept, albeit reluctantly, the essential drugs strategy for the public or welfare sector, but insisted that the private sector should be left to market forces and to the clinical wisdom of doctors. This provoked a sharp response from Professor Olikoye Ransome-Kuti, former health minister of Nigeria: 'Drugs are meant for diseases, not sectors. If you can demonstrate to me that the diseases affecting people in the private sector are different to those affecting people in the public sector, we shall adjust the list accordingly.'[40]

In the absence of a clear declaration by WHO, plenty of room exists for easy penetration of ineffective and harmful drugs, first into the private sector and then into the public hospitals and the primary health care (PHC) sector. In reality, non-essential drugs eat up a large proportion of the PHC sector drug budget.

WHO is known for its 'fixation on medical technology—vaccines, drugs and

doctors—[and] its unwillingness to grapple with the practicalities of delivering health care'.[41] It does not state clearly that disease is not merely the consequence of poor health services and that the provision of primary health care alone does not bring better health. To break the chain responsible for diseases among the poor requires a political decision to act. To publish materials and then not to distribute them widely; to produce documents on drug policy but not to defend them actively, as in the case of Bangladesh's National Drug Policy: these contradictions reflect a political decision *not* to act.

The Review Committee's deliberations drag on

At its first meeting the Review Committee was unable, even after long hours of debate, to reach a consensus about the terms of reference for the review ofNDP 82. Taking advantage of the situation, the chairman formed a sub-committee with five members, three of whom were connected with the drug industry, to prepare a draft National Drug Policy (1992) rather than review the NDP 82. Dr Majed, the BMA president, was made convenor, while Brigadier Mukhlesur Rahman Khan, the director of the Drug Administration, was appointed member secretary.

The term of the Review Committee was extended by another six months to 31 October 1992. Two days before that date, the drug review sub-committee agreed on draft National Drug Policy 1992 (NDP 92). It was little more than a camouflaged and elaborate version of the recommendations in Abid Hasan's letter and in the memorandum sent by the FICCI.

The sub-committee recommended the creation of a Drug Registration Advisory Committee (DRAC) in place of the Drug Control Committee (DCC), comprising experts from the disciplines of medicine, pharmacology and pharmacy, and representatives from the manufacturers and other trades and professional groups. The expression 'professional groups' would effectively exclude consumer groups but open the gate to a number of groups, directly or indirectly related to the industry, with professional and vested interests. The DRAC would be authorised to approve the safety, efficacy and quality. It would determine patterns of disease prevalence and therapeutic need. The sub-committee was particularly concerned to prepare a list of over-the-counter (OTC) drugs which are to be sold without prescription for the short-term relief of symptoms when medical advice and accurate diagnosis are not required. Obviously, self-prescription and self-purchase fit well with the World Bank's structural adjustment programme. The sub-committee's other main recommendations were:

- promotion of under-licence manufacturing and special incentives to foreign companies to set up manufacturing plants to encourage production of their 'research-based' new products;
- protection of intellectual property rights;
- removal of the requirement of prior approval for the importation of raw and packaging materials;
- the setting of their own MRP by manufacturers;
- separate administration of traditional medicines 'which should not be amalgamated with allopathic drugs at any level be it manufacturers or dispensaries'.

NDP 92 was not able to make its maiden voyage. In November 1992, the association of the traditional medical systems sued the Ministry of Health and Family Welfare and the director of the Drug Administration, claiming that the Review Committee was invalid as it included no traditional practitioners. The court issued a stay order, preventing the government from giving any further consideration to the report.

A lull in the storm?

For almost a year, it appeared that the main elements of the NDP would survive, even if attempts were still being made to erode some of its provisions. One of the major proponents of change, the BMA, went quiet about the NDP. It did not make any comment on either NDP 82 or the proposed NDP 92 in its own draft of a national health policy, released to BMA members in 1993. In late 1993, the BMA submitted a charter of 21 demands to the Prime Minister which did not include their usual clarion call for cancellation of the 'anti-people drug policy'.

In mid-October 1993, the BMA president, Dr Majed, and general secretary, Dr Gazi Abdul Haque, even issued a press release which denounced attempts to deregulate drug pricing. They agreed with the need for a review of the NDP, but not with the withdrawal of price controls.

A bigger threat to the NDP in 1993 came from Bangladesh's finance minister, M. Saifur Rahman. He believed that the NDP was a major impediment to foreign investment in Bangladesh. He told a seminar on the 'Present status and future prospects of the Bangladesh Pharmaceutical Industry', run by BASS on 12 October 1993, that NDP 82 should be 'immediately scrapped' and that the policy was 'ruining the blue-chip pharmaceutical industry'. He added that the industry should be free of all controls.

About a week later, the health minister said in a meeting that the govern-

ment might review the drug policy. That was sufficient warning for representatives from WHO and UNICEF to approach Christopher R. Willoughby, Head of the World Bank Resident Mission in the country. The three heads of mission wrote a joint letter to Shameen Ahsan, Secretary of Health and Family Welfare, which they copied to the finance minister and the health minister. In this, they said that the World Bank and other relevant UN agencies considered Bangladesh's National Drug Policy of 1982 to be a good policy which had had a major positive impact on the health situation of the country as well as favourable consequences for the economics of the pharmaceutical industry.

They also had a meeting with the finance minister and the health minister the following week. Saifur Rahman was visibly angry and asked why the three men had come together. To threaten him? To frighten him? And which directive should he comply with: Abid Hasan's or theirs? Willoughby replied that Abid Hasan's letter of 8 June 1992 had been sent without proper clearance and proceeded to reiterate the World Bank's and other UN agencies' support for the NDP.

After this meeting, Saifur Rahman realised that it was not possible to kill NDP 82 in one go and that a change of strategy was necessary. Instead of attempting formally to abandon the basic principle of a limited list of essential drugs, it was decided to unban a number of drugs at every meeting of the Drug Control Committee (DCC).

Eroding the NDP

Since the DCC had been reconstituted in early 1992, a pattern of new approvals for drugs was set in motion. An abundance of new members representing the drug industry helped ensure decisions favourable to the industry. At the first meeting, in March 1992, a non-essential combination cough rub, Vaporub, was approved, along with 12 single-ingredient products of no proven superiority over existing ones. Three of the drugs were not even recorded in the British Pharmacopoeia, the US Pharmacopoeia or *Martindale: The Extra Pharmacopoeia*.

In late 1992, a DCC meeting that was barely quorate, and attended mainly by members from the pharmaceutical industry, took two important decisions that violated the principles of the drug policy. During discussions under the agenda item 'Miscellaneous', it was decided to allow products such as antacids and simethicone, multivitamins with minerals, and vitamin B-complex syrup. The argument put forward was that since Ayurvedic and Unani manufacturers were cheating rural people with their primitive tonics

Table 8 Number of manufacturing units 1992 and increase in registered medicinal products in the period of 1991-August 1992

Type of system	Number of manufacturing units	Registered medicinal products	
		1991	August 1992
Allopathic	199	4,471	4,625*
Unani	237	670	1,320
Ayurvedie	171	3,150	3,506
Homeopathie	61	650	750

* With 871 importable registered products, total number of registered products is 5,496 inclusive of all formulations and dosage forms.

Source: Bangladesh Drug Administration, 1992.

concocted from herbs and minerals, it was better to allow allopathic drug producers to manufacture these products. Over the next three months, a number of vitamin B-complex syrups appeared on the market and the number of new products registered for manufacture grew at a faster rate than before: more than 150 products in a six-month period (see Table 8).

Limited price control

The price of drugs is a sensitive issue and the question of deregulation of prices could not easily be raised without an adverse reaction from both consumers and professionals. To get round this problem, it was proposed that a small list of essential drugs should remain regulated and that other drugs should not be subject to any kind of price control. A committee chaired by Professor Nurun Nabi, Director General of Health Services, was formed to finalise this smaller list of essential drugs. The six-member committee was composed of three doctors, two pharmacists and the president of BASS, the majority of whom were well known for their opposition to NDP 82.

The Nurun Nabi Committee met on 11 January 1994 and submitted its recommendations on the same day. The recommendations were presented to the DCC on 12 January 1994 without prior inclusion in the agenda. The DCC agreed to four of the six recommendations. These were:

- A list of 117 drugs (referred to as 'listed drugs') should be subject to price control. (The term 'listed drugs' was introduced to describe this new list in order to avoid the definitional problems associated with the concept of essential drugs as well as to bypass the High Court's restrictions imposed on amendments to the essential drugs list. The list was an arbitrary one and the criteria for inclusion on it were not defined by the committee.

High-selling common drugs as well as expensive newer drugs, were not included.)
- No imports of drugs produced locally should be allowed.
- Price control of imported raw and packaging materials should be discontinued. Manufacturers of drugs not included in the list should be free to fix their own price (referred to as the 'indicative price') and inform the Drug Administration of this.
- Every manufacturer should ensure that 60 per cent of the drugs it produces are listed drugs. (How this was to be ensured was not explained by the committee.)

An extensive press campaign by the local organisation. Health For All (HFA), succeeded in delaying the execution of the recommendations until June 1994. As expected, the prices of drugs which are not 'listed' have started shooting up. HFA, the Consumer Association of Bangladesh and various newspapers have raised questions as to why there are two prices for the same drug.

'A noble experiment'

The Bangladesh National Drug Policy has been both praised and attacked over the years. It has survived a series of onslaughts from vested interests that should have destroyed it completely. Yet there are still parts of the policy in place.

Consumer organisations, health activists and a few journalists are struggling together to retain the benefits which the country achieved through the drug policy. On behalf of HFA, lawyers prepared a public interest case against the Bangladesh government for violation of various provisions of NDP 82. The case was filed at the High Court in early 1995.

In 1992, Milton Silverman and his colleagues described the efforts of the people of Bangladesh to craft a successful National Drug Policy as a 'noble experiment', one which had been 'widely acclaimed', 'applauded', and 'enthusiastically depicted as the forerunner of similar programs destined to sweep throughout the Third World'.[42] They also noted that the experiment had yet to be adopted in full by another country and concluded enigmatically: 'The end of the chapter is yet to be written'.

So too with the National Drug Policy itself. Much has been achieved; much still remains to be done. Clearly, there is a need for a tighter policy.

Virtually every year since the NDP was adopted, there has been prominent

coverage—front-page reports and inside-page editorials in both daily newspapers and periodicals—of substandard, counterfeit and spurious drugs, the sale of expired drugs, the smuggling of banned drugs, the preponderance of unauthorised retail pharmacies, the increased price of drugs above the maximum retail price and the inadequacy of level provision to control all these violations. The need for a review of NDP 82, and the conspiracy against the policy, have been extensively discussed.

Not one popular newspaper has called for the withdrawal or suspension of NDP 82. Significantly, there has also been no call for the NDP 82 to be fully implemented. Much of the debate around the policy has focused on banned drugs and the essential drugs list. However, NDP 82 contained a series of recommendations that, had they been put into effect, might have led to a different drug situation in Bangladesh today, and to a different debate.

Quality assurance

A perennial problem has been the assurance of quality of drugs. In 1982 there were some 14,000 retail pharmacies in Bangladesh. By 1993, there were more than 60,000. During the same time period the number of supervisory officers at the Drug Administration went up from 32 to only 38. Their job is to monitor drug promotion, visit drug firms, collect samples from retail shops and conduct bi-annual inspections of manufacturing premises to decide whether to renew manufacturing licences. It was impossible for them to do the job in 1982, let alone now.

Graduate pharmacists are in short supply. Because of budgetary constraints, it was recommended in NDP 82 that all existing Upazila (Thana) Health Administrators be empowered to inspect and monitor all retail pharmacies, wholesalers and drug pedlars in their operational areas and take action if necessary. Unfortunately, this recommendation was not put into practice.

NDP 82 also recommended the establishment of another central national drug control laboratory for the quality testing of traditional medicines and for the development of specifications on these. This has yet to be implemented.

At present, decisions made by the government drug-testing laboratory cannot be challenged, a situation which is, of course, unfair. There should be an appeal system in place so that the Drug Licensing Authority could appoint an independent scientific observer to oversee a repeat analysis if a manufacturer disagrees with the findings of the laboratory. The costs of this could be

borne by the manufacturer initially; if the new analysis results in a favourable finding for the manufacturer, these costs should be reimbursed.

Quality assurance begins at the production stage, however. Within Bangladesh, there have been no initiatives to help small manufacturers establish a properly equipped and staffed quality control laboratory on a collective basis in each area. Laboratories are attached to individual small companies, although often they exist in name only as the majority are non-operative.

NDP 82 recommended heavier penalties, including confiscation of equipment, for companies persistently manufacturing substandard drugs. The definition of substandard in Bangladesh is not rational. This term should specifically be applied to a product which fails to match up to the declared content, with a maximum variation of 5 per cent. In the case of substandard drugs, there is an elaborate process of public notification, and the offending drugs are collected and taken to the Drug Administration for destruction. The product must be de-registered for at least three years if it contains less than 80 per cent of the declared content.

In the public interest, any company which consistently produces substandard drugs—for example, producing within one year two or more products with less than 80 per cent of the declared amount of ingredients—should have its manufacturing licence revoked for at least three years.

Quality assurance procedures for imported drugs and raw materials are also deficient at present. In an ideal world, WHO would be able to organise a thorough independent inspection of factories producing raw materials and finished drugs and be able to assure the quality of such factories. WHO'S concern for quality control of drugs, irrespective of whether they are produced by local or transnational manufacturers, is well known. The organisation does occasionally provide consultants on quality control to Third World countries. WHO'S first Certification Scheme on Good Practices in the Manufacture and Quality Control of Drugs was adopted in 1969, and in 1988 it introduced a Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce.[43]

A recent evaluation of WHO's Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce found that it is not being applied to most products.[44] Without careful validation, no matter how grand or authentic it sounds, WHO's certification scheme is nothing more than a free sales certificate in WHO format. Free sales certificates were in-

troduced as a means of serving the vested interests of transnational drug companies. The system is approved by WHO and provides a camouflage for manufacturers and suppliers which expedites registration of drugs in Third World countries. This is definitely not in the interests of Third World countries or individual consumers.

If adequate measures had been put into place over the years since the adoption of NDP 82, many of the concerns about drug quality in Bangladesh might now be history. However, this has not happened, and uncertainty continues about the quality of drugs.

Tighter registration controls

That uncertainty also extends to the selection of drugs on the market. An increasing flood of products are coming onto the market, many of which were banned in 1982. The most crucial omission of the Drug (Control) Ordinance 1982 was that although the schedule of banned drugs was annexed with the ordinance, the NDP policy document itself was not formally incorporated. Lists of essential drugs and supplementary drugs were not made an integral part of the ordinance. These are observed or adhered to under administrative orders, not by legislative requirements.

Similarly, the composition of the Drug Control Committee (DCC) and criteria for the registration of a drug were not detailed in the Drug (Control) Ordinance 1982. Thus, the decisions being made today about which drugs to allow on the market, and the people who should be allowed to make those decisions are more difficult to challenge.

Certainly, these are not decisions that should be made by people who have a vested interest in the pharmaceutical industry. In most countries with a strong regulatory authority, a committee such as the DCC would be made up of independent medical professionals, clinical pharmacologists, and pharmacists. Representatives from consumer and women's organisations may also be included as observers.

All countries exercise judgement over which drugs to allow on their markets. Medical need and cost-effectiveness are important criteria for evaluating a drug for registration, but were not mentioned in the Drug (Control) Ordinance 1982. For there to be clear, transparent procedures for the registration of drugs in Bangladesh, the DCC should use two basic guidelines for allowing a new drug:

- if its claims to increased safety, efficacy and cost-effectiveness are sup-

ported by clinical trials acceptable to the DCC. An improved dosing schedule and reduced potential for abuse or inappropriate use should be considered additional benefits;

- if there is no drug on the market with similar therapeutic action or if the new drug has a better risk/benefit ratio and is cheaper than an existing equivalent.

Misleading drug promotion: a continuing problem

The quality of promotional materials frequently fails to conform to WHO'S *Ethical Criteria for Medicinal Drug* **Promotion.** The majority of misleading and fraudulent advertisements which appear in the daily newspapers and periodicals are placed by the manufacturers of homeopathic, Ayurvedic and Unani medicines. Taking advantage of people's ignorance about physiology and sexual functions, they emphasise enhancement of sexual powers. Advertisements also offer treatments for cancer, mental illness, heart diseases, diabetes, jaundice, and a range of other conditions. Most of these problems do not have simple treatments and in many cases allopathic cures do not exist. As the advertisements do not mention any names of drugs, the advertiser cannot be prosecuted under the Drug (Control) Ordinance 1982. Because of such loopholes, advertisers were found guilty of misrepresentation in only seven out of 165 cases. Because the penalty is nominal, offenders continue undeterred.[45] In 1993, there were 76 cases pending in the drug court against 17 traditional medicine manufacturers for illegal advertisements.[46]

TNCs are not blameless, however. In 1988, SmithKline and French claimed success rates of between 86 and 100 per cent for the treatment of a range of infections with its brand of the antibiotic, ampicillin. All the references cited in the promotional material were published in 1963 or 1964.

When Ciba-Geigy opened its factory in Bangladesh in the late 1980s, one of the drugs it was hoping to market was an antidepressant, maprotiline (brand name: Ludiomil). A marketing strategy for Ludiomil was planned at the firm's headquarters in Switzerland. A key element of the strategy was not simply to promote the drug, but to promote depression. Accordingly, in May 1991, Ciba held a large public health meeting at a five-star hotel, attended by senior doctors, influential members of society, and the media. The Bangladeshi marketing manager explained that symptoms such as insomnia and lack of energy and initiative were 'cardinal symptoms of depression'. The event was followed up with a campaign of advertising on peak-time television, on the radio and in the press. This was supported by the widespread distribution of a full-colour poster depicting a beautiful

young girl, with large sorrowful eyes, obviously in a depressed mood. In the television spots, the same girl was seen sitting in her study, mindlessly turning the pages of a book and then moving on to a rocking chair. The voice-over message was that 'depression is a disease', and viewers were advised to seek advice from a doctor.

Doctors had already been briefed. Drug stores, seduced by the usual discount, had stocks of Ludiomil. Two months later, after legal action was threatened by the consumer organisation HFA, the Drug Administration stopped the 'public awareness campaign' in the media. A researcher who had access to some of Ciba's internal documents noted, however, that the company had managed to nearly double its sales of Ludiomil as a result of the campaign.[47] The company continued to distribute a glossy brochure to doctors with the same picture as on the poster.

Ciba-Geigy had clearly violated WHO'S *Ethical Criteria* which state that 'promotional material should not be designed so as to disguise its real nature', and that 'psychotropic drugs should not be advertised to the general public'.[48]

Another Swiss TNC, Roche, has been encouraging irrational prescribing through the promotion of its third-generation cephalosporin antibiotic ceftriaxone, marketed under the brand name, Rocephin.

Ceftriaxone is an antibiotic used for the treatment of serious bacterial infections. It is more convenient than antibiotics which require more frequent doses to maintain potency. However, it is a very costly drug. The cost of treatment of meningitis with ceftriaxone in Bangladesh is 20–30 times higher per day than the cost of conventional therapy, which has a similar outcome. Ceftriaxone may also cause some blood abnormalities in patients suffering from liver disease or malnutrition. In Bangladesh, more than 50 per cent of the population have less than a 2,000 calorie intake of food each day; malnutrition and chronic liver disease are common. Thus, for Bangladesh, ceftriaxone may be a useful medicine in the treatment of some very serious bacterial infections that cannot be dealt with by other antibiotics.

When Rocephin was registered in 1989, Roche assured the Drug Control Committee that the product would be promoted only to specialists. Within two years, Rocephin became a top seller and one of the most misused drugs. Many senior surgeons and paediatricians use it routinely. Some paediatricians prescribe it for every case of acute respiratory infection and

many surgeons prescribe it as a prophylactic in all sorts of surgical cases, both major and minor.

Roche made an arrangement with a top Dhaka surgeon to write 10 prescriptions for Rocephin daily in return for a cash payment of Taka 100,000 (US$2,500) at the end of the month. Similar payments, described as 'research grants', in the USA resulted in an investigation by the Office of the Inspector-General for Civil Fraud and Administrative Adjudication which found that 'some doctors had not completed the research but had received the full payment and that in many cases the research had not been of any scientific value'.[49] Roche agreed to pay US$450,000 to the US Department of Health and Human Services as a penalty for improper inducements to physicians.

Dr Sidney Wolfe, director of the US Public Health Research Group, referred to the so-called research inducements as 'a bribery campaign designed to induce prescribing'.[50] How much Roche paid selected surgeons at the Institute of Cardiovascular Disease Research in Dhaka and the Bangladesh Institute of Research on Disorders of Endocrinology and Metabolism—besides presenting them with gold-cap Parker Pens with which to write their Rocephin prescriptions—has not yet been made public, but it is known that payments were made.

Unfinished business

Measures to deal with these three areas of quality assurance, transparency of registration decisions, and control of drug promotion would do much to clear up the controversy that still lingers over NDP 82. The mere existence of that controversy demonstrates how much more there is to do to ensure that people in Bangladesh have access to the essential drugs they need to treat their illnesses. Meanwhile, the groups which have opposed the drug policy since its introduction continue their efforts to undermine it. TNCs and local producers alike, backed by sections of the World Bank, are pressing for deregulation and liberalisation.

Milton Silverman and his colleagues said 'the end of the chapter is yet to be written'. That end often looked like a summary execution. Now, however, the end appears more likely to be a gradual erosion of the basic principles upon which NDP 82 was based.

But there is another ending that is possible, an ending which puts people's health first, which delivers essential drugs, which encourages a strong pharmaceutical sector that operates within reasonable regulations to ensure pub-

lie health concerns are foremost. That is the ending envisaged in 1982 when the National Drug Policy was drafted. The struggle to achieve that goal continues.

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Australian National Drug Policies

Facilitating or Fragmenting Health?

By Mary Murray

One of the most dynamic developments towards the elaboration of a comprehensive National Drug Policy to he found in the world today is in Australia. It started some 50 years ago when the Australian governments irrespective of what party was in power, began to allocate resources for the provision of medicinal drugs to the population as a conscious social policy. The decision in the 1950s to make the supply of a limited number of life-saving drugs available free of charge to all citizens was another cornerstone in the formulation of a comprehensive policy. Another important building block was the price control mechanism established by the government. This has resulted in very low drug prices during the past few decades, at the level of 60 per cent of the EU prices. An important achievement on the part of the government has also been its success in reaching and maintaining high standard in pharmaceuticals by subsidising access to a broad range of high-quality products and pushing less serious manufacturers to the outskirts of the market. The ongoing and productive dialogue between the pharmaceutical industry and the government is a feature worth noting on the Australian scene. All the actors in the field of the Australian drug policy participate in this dialogue which is kept very open and frank. But one important problem area has not yet been properly dealt with, namely the rational use of drugs. It is quite clear that more conventional approaches through 'objective information' and 'therapeutic guidelines' used alone will not be sufficient. They have to be re-examined and supplemented by creative educational programmes designed to meet in a flexible way the needs of different groups in society with diverse attitudes to medicines and health in general.

This comprehensive study of Australia's National Drug Policy, which depicts today's situation against the broad background of Australia's social history, is written by Mary Murray, who has held a central position in the work for the development of this policy. Thus, in the period 1991-94 she chaired a National Expert Advisory Committee for the Minister of Health, the PHARM Committee, which has developed policy and implemented strategies to optimise health outcomes through the Quality Use of Medicines. With her background in pharmacy and hospital clinical pharmacy and through her experience in drug information services, Mary Murray is playing an important role in developing educational programmes in her field whether targeted at particular professionals, consumer groups or the community at large.

Introduction

Australia has built a comprehensive national drug policy slowly but solidly over the last 40 years. It provides equitable access to a wide range of pharmaceuticals, whose quality, safety and efficacy is well regulated. A scheme for increasing the viability and capacity of the pharmaceutical industry in research and development and manufacturing in Australia is producing promising results. Innovative educational strategies for improving rational drug use are also being developed.

Fortunately a strong, enduring foundation was built first through the decision to provide essential lifesaving drugs free to the entire population in the 1950s. In hindsight, this was important for the progressive later development of other parts of the policy although it was never consciously intended that way. The mechanism of providing access evolved into one which enabled the government to control the market for prescription pharmaceuticals. This gave it the means to exercise tough price control through the 1960s and 70s, the period of rapid price escalation. As a result, the prices for drugs are today among the lowest in the Western world—60 per cent of EU average.

The legislation underpinning the quality assurance and registration of pharmaceuticals was weak but the government succeeded in assuring quality through its control of the market: non-subsidisation meant the companies had no significant market share and therefore a strong incentive to comply with increasingly high quality standards. Price control was so effective that it threatened the viability of manufacturing capability. An incentive mechanism was introduced in 1989.

Although problems of equity, access, quality and industry viability have been addressed, the complex and important problem of rational use has remained. There are indications of overuse, wastage, underuse and misuse. Australia has developed a participatory approach to developing improvements in rational drug use, recognising the involvement of many players. There are great challenges in developing educational programmes for rational drug use that meet the needs of diverse groups with diverse attitudes to drugs and health care. A real attempt has been made to address the complex forces and constraints that affect the choice and use of drugs by consumers and practitioners.

In developing a policy on the rational use of drugs it has been realised that Australia has, *de facto,* developed a comprehensive drug policy that should now be clearly articulated. However, the process of managing the tensions between health and economic objectives in integrating the separate components of drug policy is slow and complex.

The emergence of solutions to suit the Australian context was a strong feature of the development of the NDP. Some of these solutions have taken a long time to develop which reflects the conservative nature of the country but also an increasing desire to develop policies, structures and processes which are likely to be sustainable in the long term.

Historically, Australia witnessed a long period in which the development of social welfare policies was stifled by arguments about how they should be financed. Access to pharmaceuticals was one of the first national welfare schemes to be successfully introduced, after early attempts caused the doctors to precipitate a constitutional crisis. Hence Australians have a long experience and a high expectation of affordable access to medicines which will be harder to meet with rapidly rising costs.

While Australia's early economy was highly protected, due in part to concern about the potential impact of cheap *migrant* labour, Australia has over the last 15 years been restructuring its economy and has begun to reduce its dependence on primary industries. Its high foreign debt is harder to reduce. Although the pharmaceutical industry is targeted as an important future export earner, the government is not prepared to protect inefficient industries or allow an excessive flow of dollars to parent companies overseas.

Large-scale immigration from Europe and Asia has forced a re-examination of Australia's place in the region and its cohesiveness as an Anglo-Saxon, English speaking society. Partnership is also happening in other areas of Australian society as the pressure grows to evolve a national identity, cohesive and effective systems of industrial relations, productive business enterprises, better professional services and management practices and a sense of local community.

Overall, Australia's policies have resulted in a successful system for managing drug costs, access, product quality and an emerging system for optimising drug use. This is complemented by a system of universal health insurance which provides access to good standards of hospital and medical care, professional and community services. In 1993/94 health expenditure accounts for 8.1 per cent of GDP and the pharmaceutical subsidy budget is 9 per cent of the health expenditure of the Federal government. Health status as defined by indices such as life expectancy and perinatal mortality for white and immigrant Australians compare favourably to the best in the world. However, current health and drug policies have failed those most in need. Aboriginal Australians have a death rate two and a half times higher than the average and up to 11 times higher in some age groups. Their life expectancy is 22 years lower and infant mortality is four times higher.

Why have equitable health outcomes not been achieved? Pharmaceutical health is not enough. There is a lack of an overall health policy for a drug policy to serve. It is unclear what concept of health would provide the framework for a health policy. In the past, Aboriginal people conceptualised health as the outcome of a life lived in harmony with the nature, in which physical, social, economic and spiritual elements were all important and managed appropriately. White invasion nearly destroyed the people and the fabric of their society, produced extreme social and economic deprivation and dependence and introduced catastrophic elements of ill health.

Modern society is being forced to recognise the interrelationship of mind and body and that of socio-economic conditions and ill-health. Belatedly it is evolving a concept of health which increasingly must respect the original Aboriginal concept of health. To understand the challenges in securing real health especially for those most in need, we need to look at some of the important historical influences that have shaped our character, our society, and our health and drug policies. Some of these will explain our strengths, some will remind us of important elements that we have neglected.

Aboriginal Australia: 50,000 BC–AD 1788

Australia is a 'new world' country in Western terms (200 years) but very 'old world' in Aboriginal terms (50,000 years). The continuity of the life force through the millennia is fundamental to the Aboriginal belief system, as is the intimate connection of human beings with the land. Health for Aboriginals is a continuum between the land, their own life spirit, and a wider, older spirituality linking past and future. It is a matter of integrating all aspects of life, of a way of life which gives dignity, nurtures community self-esteem and respects justice.

In Aboriginal society there is no term for 'health' as understood in Western society, which conceptualises health as the absence of disease and incapacity (and health care as the provision of doctors, hospitals and medicines). The Aboriginal concept could be expressed as 'life is health is life'.[1]

Before colonisation, Aboriginal health appears to have been good. According to contemporary descriptions, Aboriginals were physically, socially and emotionally healthier than most Europeans and were well nourished. Common diseases were yaws and infectious diseases of the eye, bowel, respiratory tract and skin. Epidemic viral and bacterial infections and cardiovascular disease were uncommon.

Aboriginals recognised that ill health was caused by a variety of factors—

physical, social and spiritual—and hence treatment encompassed all these aspects.[2] If a complaint was believed to be naturally caused then it could be treated by an extensive pharmacopoeia of herbal medicines, the observance of a particular diet, or the application of external remedies such as heat, smoke, steam or ochre. Each tribal group seems to have had a *materia medica* drawn from plant, animal and mineral sources.

Treatment of minor ailments would initially be self-administered, or managed within the immediate family. Women seem to have best understood the potential of native flora to relieve such ailments as the pains of childbirth, and lung, skin, eye and gastric complaints. Men were skilled in the use of fire and cold water to stop the spread of venom from bites and stings and had mechanical treatments for injuries. In Arnhem land (in the tropical North) and probably in many other areas, the eucalyptus tree formed a significant part of the pharmacopoeia, with poultices of bruised and heated leaves for the treatment of rheumatism, inhalation of steam from heated leaves for headaches, infusions for the relief of colds and fevers, the oil applied locally for ophthalmia and the bark as a poultice for snake bites.

A healer would be consulted only if an illness was prolonged or serious, of a particular type, or deemed to be due to spirit invasion or the breaking of tribal law.

When the white man came into contact with Aboriginals, he was dismissive of the 'medicine man', seeing his function in terms of sorcery, and ascribing his power to sleight of hand and the trust of his patients. However, a few white botanists took the Aboriginal *materia medica* seriously, and now, in the search for new active ingredients, there is a renewed interest in examining Aboriginal knowledge.

After the white invasion, Aboriginals gradually became the poorest, sickest group in Australia. The introduction of Western diseases, especially measles and smallpox, the constant relocation to accommodate the white search for land, and the outright massacre of some groups led to significant depopulation, grief and the break-up of Aboriginal society. Communities became passive recipients of a violent and foreign culture rather than active participants with control over all aspects of their lives. They gradually lost their understanding of health and its determinants and the way in which traditional drugs and practices were skilfully balanced. Their clear understanding now is that health is not likely to be attained until the core fabric of their culture is restored through self-determination.[3]

Early white Australia was a British prison colony, a desperate place with a population of outcasts, remote from home. The physical welfare of the colony's inhabitants was the responsibility of the naval surgeons. Personnel and supplies were inadequate.

As other small colonies grew around the coastline of Australia, the government of each was, for a long time, the only provider of medical services. Dysentery, consumption, eye infections and dropsy were common, and their treatment was based on British practice of the time. Thus, medicines were also imported. Doctors made handsome profits and also enjoyed the services of convicts as dispensers.[4]

Australia also received waves of free settlers, especially after 1840. Most were from Britain and brought with them its ideas and values. The fight for equality and land between independent settlers and emancipated convicts became symbolic of other social and economic issues as the colonies developed. Much Australian liberalism and radicalism sprang from the bush mateship which developed at this time and extended to those living in colonial cities. Australia grew wealthy by exploiting its rich grazing land and also became, from early on, one of the most urbanised countries in the world. In various ways, these characteristics were to influence the development of pharmacy and medical practice and were reflected in early attempts to introduce elements of a National Drug Policy.

Meanwhile, the Aboriginal population began to fall, especially in Tasmania and Victoria. Aboriginal people were increasingly deprived of their land, their culture and even their children, and seen as cheap labour for landowners.[5]

After the Apothecaries Act of 1815, in Britain there were three accepted medical groups, the physicians, the surgeons and the apothecaries. Most of this last group practised medicine, surgery and obstetrics, while clinging to their role of supplying and dispensing drugs. They became 'general practitioners'.[6] 'Chemists and druggists had begun to buy and sell wholesale and retail medicines but-the Act excluded them from owning or controlling apothecaries.' Their response was to attempt to raise their status by regulating their members and improving their education. This led to the formation of the Pharmaceutical Society in 1841.

Most colonial pharmacists coming to Australia at this time valued highly the notion of a professional association and the establishment of recognised

qualifications. Most shared a belief in private enterprise and individual ownership of shops. **By** the 1880s, the economic climate including a stable currency and banking system was right for pharmacy to develop as an independent, business-based occupation.[7]

Early medical practitioners in the colony ranged from those with recognised qualifications to outright 'quacks'. However, 'medical registration was not too long delayed, and not too lax, to permit reasonable control over the situation, so that, with the stimulus of strong competition, satisfactory standards were soon established and maintained'.[8]

By the 1890s, the medical and pharmaceutical professions had resolved the main aspects of their demarcation dispute. Doctors were beginning to abandon shop trading and most chemists were restricting their prescribing to minor complaints as they presented themselves in the shop. The independence of the states of the colony made it difficult to establish uniform or interchangeable standards of practice, laws and qualifications, though most states had followed the example of Victoria and set up Pharmacy Boards and passed a Sale and Use of Poisons Act which made it illegal to sell medicines outside a registered pharmacy. The strength of retail pharmacy set the scene for the future means for the distribution of medicines.

Manufactured medicines were beginning to be ordered on prescription and to take over dispensary shelves. This prompted the search for a new role for pharmacy, a search that is continuing today. The search has been made more difficult by the tension between the very commercial success of pharmacy dependent on the sale of products and the professional desire to counsel clients about drugs without charge.

Social welfare: values and mechanisms

Voluntary agencies

Voluntary agencies, including hospitals, which were run as charities assisting the poor, were the major providers of social welfare services before state intervention in the late 1800s. Friendly Societies, or 'lodges', had grown considerably in both membership and activity since their origins in the 1830s. By 1910 they provided sickness insurance schemes for about one third of the population, usually workers.[9]

The focus of Friendly Societies was on sickness and on medical, pharmaceutical and dental benefits. Medicines and other goods were sold to members, and sometimes to non-members, at prices below those generally charged by independent chemists. This self-help system of assistance and so-

cial security was seen by most members of the healing professions as a threat to private practice, helping to bring chemists and doctors closer together.[10]

This voluntary, non-profit system worked reasonably well in the period of rapid economic growth from 1860 to 1890, but was totally incapable of dealing with the magnitude of the social problems caused by the severe depression in the 1890s. It could not cope with the increase in the poor, especially the aged.

The depression of the 1890s

The 1890s were one of the most difficult periods in Australia's history and saw the nation's dramatic fall from being probably the richest country per capita in the world. Yet the period immediately following this was one of great social innovation as a depressed economy attempted to maintain past standards of living.[11]

For Aboriginals, however, it was a period of segregation which lasted until 1950. During this 'era of protection' the government set up reserves for Aboriginals, curtailed their political and civil rights, and excluded Aboriginal children from state schools. Housing, health and employment of Aboriginals were all poor.[12]

In 1901 the independent states decided to federate into a new nation. The Australian Labour Party, formed in the late 1880s, slowly achieved hegemony over working-class politics. It articulated a national vision of social welfare which was translated into a political and social programme in the early years of federation. However, this programme contained a strong commitment to protection which imposed high tariffs on goods imported into Australia, compulsory state arbitration for fair and reasonable wages. and direct state-funded welfare schemes to provide minimal standard-of-living requirements. It also involved a White Australia Policy, restricting immigration in order to protect Australia's standard of living from migrants prepared to work for much lower wages and in worse conditions—a policy which had a major effect on the indigenous people of Australia.[13]

Other important influences in forming Australian attitudes to social policy and welfare were demographic change and the toll of disease. The birth rate fell from 38 per thousand in 1870 to 27 per thousand in 1900. The average issue for each family in 1891 was seven; in 1911 it was four.[14] This alarmed a government trying to build up Australia's population in a 'vast and empty land'.

The explanation given for the fall in the birth rate was the increasing use of contraception, a tendency described by some as 'race suicide'. After an inquiry in 1903, the advertising of contraceptives was made illegal. As it was impossible to force women to have babies, the next best thing was to make sure that as many babies as possible were born and kept alive. Because cow's milk was often impure, doctors encouraged breast-feeding. As few babies were born in hospital, it was necessary to take medical information into the home. Between 1904 and 1914 child care officers visited 29,000 mothers. In Sydney, books on child care were sent to every address where a birth was recorded.[15]

Fear of disease was also a major factor. Bubonic plague struck Sydney in 1900 and panicked the eastern mainland states into a further strengthening of the Health Acts. However, unless local government inspectors were appointed and prosecutions carried through, laws were meaningless. Even where the need for public health measures was accepted, according to Queensland's Director-General of Health, they were limited to 'abolishing stinks, clearing choked drains, removing dead animals and cleaning up backyards'.[16] Fatal infectious diseases were common, especially among children. Positive steps such as inoculation campaigns and special care of children were mostly left to individuals, which meant that they were only available to those who could afford to pay for them. Quack cures were popular.

The Great Depression

The 1930s saw the Depression wreak havoc. Unemployment rose to 40 per cent. Public health standards fell, largely because local governments were unwilling to enforce laws which many ordinary citizens could no longer afford. The Depression widened the gap between those patients who could afford to pay for their own doctors and those who could not. A few doctors set themselves up in the poorer districts running virtually free health clinics. Most doctors increased the number of people they did not bill. In 1932, an editorial appeared in the *Medical Journal of Australia* reminding doctors that scientific professionalism had to come before the acquisition of wealth.

The new experience of poverty and a refusal to accept charity meant that many middle-class Australians failed to seek medical advice and treatment for serious diseases until it was too late. Concern about the ability of Australians to afford health care mounted. New wonder drugs seemed very effective but were very costly. The major health or health-related issues after the Depression and the Second World War were the scourge of tuberculosis, the need for improved general practice, hospitals, chemists and research, and for statutory sick pay.[17]

The scene was now set for the development of components of a formal National Drug Policy. The two crucial factors associated with the provision of drugs and services were free supply and the cooperation of doctors and pharmacists.

Aboriginal health

The destruction of Aboriginal health was far advanced by this stage. However, this fact was invisible to the rest of society because Aboriginals were effectively segregated until the 1960s. No statistics were collected on Aboriginal health until the 1970s. Not until research was published revealing that one in five infants died before the age of four was it realised that this was one of the highest infant mortality rates in the world. Other indicators were also markedly worse than the Australian average.[18]

The role of national government 1938-50

The first attempt at formulating drug policy focused on the equitable supply of drugs as part of a comprehensive health and welfare plan. The period between the wars was one where both Conservative and Labour political parties agreed that a social services scheme was needed, but differed over their approach to financing it. The actual introduction of social welfare legislation was delayed, probably due to fears about its cost, based on the experience of the non-contributory old-age pension established after federation, which threatened to outstrip government revenue. The difficult task of balancing social welfare principles and values with economic reality had emerged starkly and bureaucrats started to become much more involved in policy-making.[19]

The first attempt to introduce a plan for comprehensive benefits was made in 1938 by the Conservative government. The National Health and Pension Insurance Plan was to be financed on a contributory basis. This approach was opposed by the Labour Party, which wanted a unified social service fund financed in a way that would redistribute income in real terms. Widespread opposition led to the plan being dropped: farmers were hostile because they were left out of the scheme, doctors because their independence appeared to be threatened by government interference. The Friendly Societies, too, were opposed to the plan.

The Second World War rapidly changed the economic and political context of government policy-making. On election in 1941, the Labour government finally had to resolve the tensions between economic reality, political philosophy and social vision by linking welfare benefits to a universal taxation scheme. They were able to impose taxation immediately, using the

money to finance the war and introduce a few relatively low-cost benefits with the promise of more to come.

Constitutional crisis

Pharmaceutical benefits, introduced in 1944, were to be provided free. The support of the pharmacists was initially gained but later withdrawn. Doctors once again opposed the changes. Their strong private practice ethos not only protected their independence in economic matters but also reflected the ethical basis of their professional training. In particular, they disagreed with restricting items available for prescribing to a set formulary, the compulsory use of government forms and certain penalty clauses applicable to doctors.[20]

The Medical Society of Victoria successfully challenged the constitutional power of the Commonwealth to legislate in any area of social welfare not explicitly laid down in the original Constitution. Interestingly, even though some welfare legislation not specified in the Constitution had in fact been introduced by both political parties since federation, it took the issue of health and the sensitivities of those involved in its provision to produce the challenge.[21]

The Labour government went to the polls in 1946 with a referendum asking for power to legislate in 10 areas of social welfare but not in any way that would constitute civil conscription, a very sensitive issue in Australia. Unusually, it won overwhelmingly. This issue reflected peoples concerns about health and the consequences of fatal infection.

The Commonwealth government now had the right to legislate on the provision of maternity allowances, widows' pensions, child benefits and family allowance, sickness and unemployment benefits, medical and dental services, pharmaceutical and hospital benefits, and benefits to students.[22]

After an unsuccessful attempt to introduce health insurance in 1948, the Labour government lost office in 1949. The Conservative government that came to power was to stay there for 23 years. From previous experience they knew that any health plans could not be enacted without the full cooperation of the medical profession.

The National Drug Policy 1950-79

From 1950, the National Drug Policy developed as a series of *ad hoc* measures. Its overall aim was free access to life-saving drugs, the introduction of a national health insurance scheme, and regulation to ensure the safety, efficacy and quality of products.

In 1950, the new Conservative government acted to remedy the confusion created by previous failure to implement a comprehensive health and pharmaceuticals scheme. It provided a list of 139 life-saving drugs free to the whole community. To pensioners, it also provided free any drug listed in the British Pharmacopoeia as well as other specified medicinal preparations.[23]

In 1953, the government introduced a comprehensive National Health Act which combined medical, hospital and pharmaceutical benefits. This legislation, with subsequent amendments, is still the basis of today's Pharmaceutical Benefits Scheme (PBS). The rationale behind the scheme was to combat sickness by reducing treatment costs borne by the patient. Life-saving and disease-preventing drugs were provided free to all persons.

The 1953 PBS had the flexibility and freedom desired by all those involved. The government reimbursed, to an agreed level, people who had taken out voluntary insurance with a private health insurance fund. Doctors supported the scheme because they were assured that there was no direct government interference in their relationship with the patient. Patients still had the freedom to choose their doctors, and doctors were free to set their own fees. There was some conflict over the requirement to use government-supplied prescription forms, and doctors again won a legal battle against what was deemed to be another attempt at civil conscription.[24] However, most pharmacists signed up, and those who received prescriptions were pleased with the increase in business.[25]

The major issues throughout the successful operation of the scheme have been the range of drugs recommended for listing by the Pharmaceutical Benefits Advisory Committee (PBAC), price negotiation with manufacturers, and the remuneration of pharmacists.

The range of drugs

In 1953, doctors' objections to a formulary listing a limited number of drugs were overcome by entrusting the choice of drugs to an independent expert committee composed of doctors, pharmacists and a pharmacologist.[26] The major issues surrounding this committee over the years have been public knowledge of its composition, the rationale for its decisions, whether cost should be taken into account in its decisions, and how to ensure that doctors prescribe according to the conditions of subsidy.

Price negotiation

The prices of drugs included in the formulary were the result of direct negotiations between the Department of Health and the manufacturers.

The price was based on the 'price to the chemist', which is the sum of the manufacturer's price to the wholesaler and the agreed wholesaler's mark-up. The government had a strong incentive to provide these benefits at the lowest possible price. The issue of price and the consequences of tough price control was to become a major lever for all parties in the development of other arms of Australia's drug policies.

Remuneration of pharmacists

The government was always concerned about the universality of the PBS and the need to provide broad access to pharmaceuticals. Therefore, the cooperation of pharmacists was important. Pharmacists were reimbursed for supplying a medicine according to a formula which included a mark-up of 33.3 per cent and a dispensing fee.

Until 1966, the number of pharmacies grew faster than the population. It continued to increase, reaching a peak in 1971. It has since fallen, but in 1992 it was still well above the 'economic standard' of one pharmacy for every 5,000 people suggested by the Pharmacy Guild.[27] The policy was economically beneficial to the pharmacy profession. However, it was now structurally locked into a supply function linked financially to numbers of dispensed prescriptions and the sale of over-the-counter (OTC) medicines. This is a significant barrier to the development of unpaid professional counselling services which may not result in the sale of a medicine.

Negotiation between government and pharmacists has been a recurring theme over the years. In 1953, the government, faced with the cost of supporting Australia's involvement in the Korean War, looked for savings in a number of areas, including the cost structure of pharmaceutical benefits. The Pharmacy Guild gained the support of pharmacists to withdraw from the pensioner part of the PBS unless the government backed down, which it did. The remuneration of pharmacists was subsequently determined by the Department of Health after negotiation with the Guild, which consolidated its power as the negotiating body as a consequence. An independent tribunal now determines the level of remuneration.[28]

Disagreements about the administrative conditions and requirements for payment and about payment for extra professional services to customers will be part of the uneasy, and sometimes bitter, negotiation process for the foreseeable future.

The cost of the PBS

In 1960, a significant decision was taken to widen the scope of the scheme for the general public. About 150 new drugs were listed and the pensioner and general scheme combined into one, although pensioners continued to have more liberal, fully subsidised access to drugs. The other significant associated change was the introduction of a charge for the general public. Thus there was a trade-off between making the scheme a contributory one, to cover rising costs, and widening access to most pharmaceuticals considered to be useful for mild or serious conditions. These measures gave the government enormous leverage over prices since manufacturers needed their drugs on the scheme in order to gain a share of the market.

During the early 1960s the costs of the PBS more than doubled, due to the expanded list of benefits (some of which were very expensive), more frequent prescribing and, to a lesser degree, a rise in the population. In 1963 drugs formed the largest single item of expenditure by the government on national health benefits. In Parliament, ministers were trying to grapple with a dilemma. On the one hand, drugs were threatening the whole structure of the national health programme—causing fears that a situation similar to the post-federation old-age pension would arise. On the other hand, it was acknowledged that the number, uses and purposes of drugs had, through fresh discoveries, so expanded during recent years as to produce a 'therapeutic revolution in the treatment of disease'.[29]

At this time there were strong criticisms of the huge yield from drugs by foreign companies and some members of Parliament called for a Royal Commission to investigate.

Price negotiations with manufacturers

Negotiations with manufacturers to reduce the price of drugs resulted in price decreases in the early 1960s, and the cost of the PBS (excluding the pensioners' component) actually fell in 1963-64.

The negotiated price of a drug also influenced pharmacists' income. In the early 1960s, the percentage mark-up allowed to wholesale and retail chemists together accounted for 51 per cent of the cost of the scheme and was the second highest item in the cost of the PBS.

In this climate, the government held drug prices down by tough negotiation. The skills and dedication of an effective Department of Health negotiator held the system in check during ten years. By 1979, Australia had lower drug prices than all other Western countries and some Asian countries as well.[3"] This led to a series of enquiries into the viability of the drug industry.

Costs again rose significantly in the 1970s and 1980s due to increased per capita consumption of PBS drugs, the effects of inflation on drug prices, population growth, increase in pharmacists' dispensing fees and the addition of oral contraceptives to the list of drugs. The patient contribution was gradually increased as another strategy to contain cost. As the patient contribution rose and the lower-cost drugs were purchased without PBS subsidy, the share of the scheme accounted for by pensioners and concessional users increased from over 40 per cent in 1975-76 to nearly 75 per cent in 1984–85.[31]

The current PBS scheme

The current purpose of the Scheme as stated is 'to provide the Australian Community access to effective and necessary prescribed medications at a reasonable cost to the Government and consumers, consistent with a reliable supply'. The formulary has evolved from the initial 139 life-saving drugs in 1950 to contain 1,714 items representing 537 drug substances in 1995.

The structure of the scheme and the mechanisms of decision-making have been modified over the years but they remain essentially the same as in 1953. The listed products are provided as pharmaceutical benefits if they are prescribed by a registered medical practitioner or, for certain drugs, by a dentist, and if they are dispensed by an approved pharmacist or, in limited cases, an approved medical practitioner.

There are programmes for special cases such as growth hormone for eligible children; highly specialised medicines supplied from public hospitals (e.g. cyclosporin, erythropoetin, and certain anti-AIDS drugs); methadone; hormones used in *in vitro* fertilisation; refunding of copayment costs to shelters providing essential medicines to displaced people; provision of PBS medicines to isolated Aboriginal communities; grants to the Bush Nursing Service in remote areas, and 'Doctor Bag' emergency medicines.

The criteria for listing of drugs have recently been amended. Earlier, only medical needs were taken into account, but now the expert advisory committee must consider the cost-effectiveness of drugs considered for listing. New drugs may be considered for listing if they are needed for the prevention or treatment of conditions not already covered or adequately covered by drugs in the existing list; if they are more effective, less toxic (or both) than a drug already listed for the same indications; or if they are at least as effective and safe as a drug already listed for the same indications and of similar cost. Cost-effectiveness guidelines emphasise comparative analysis

of the marginal cost of gaining additional health benefits with the new drug compared to existing therapies.

Drugs may be removed from the list if a more effective or equally effective but less toxic drug becomes available or if, in the light of further knowledge, the therapeutic efficacy of a drug is found to be unsatisfactory. Removal also occurs if toxicity, suspected toxicity or abuse potential proves to outweigh the therapeutic value; if a drug has fallen into disuse or is no longer available; or if treatment with the drug is no longer deemed cost-effective relative to other therapies. Fixed combinations of drugs are rarely acceptable.

Cost-effectiveness criteria

Health decisions are increasingly financially driven.The drug budget has ranged from 8 to 12 per cent of the health care budget, and is frequently the subject of the Department of Finance's attention when its rate of increase is higher than other areas. In 1994/95, government expenditure on subsidised access to drugs was $1.9 billion. As a percentage of GDP, the figure has moved from 0.45 per cent in 1962, to 0.23 per cent in 1980, to 0.42 per cent in 1993/94. A series of complex administrative and economic measures have been applied to the PBS to contain costs and introduce greater awareness of price among doctors and consumers. Thus, where the more expensive of two equivalent brands on the PBS is prescribed, reimbursement is on the basis of the lower price, with any difference being met by the patient. Copayment is now an established feature of the scheme. General patients contribute up to $16.80 towards the cost of an item; concessional and pensioner patients contribute $2.60. There are inflation-linked safety nets for people with longer-term or chronic needs. At the moment, once the expenses of a person and his or her dependents exceed $600 within one calendar year, the maximum contribution per item decreases from $16.80 to $2.60 for the next 20 items, and to zero thereafter. For concessional and pensioner patients, the $2.60 contribution is removed after their year's expenditure exceeds $135.20.

Doctors are caught between government insistence on cost-effectiveness and the review of their decision-making, on the one hand, and their role in defending standards-of patient care, on the other. Consumers need to be more involved in debate about standards, in hard decisions about how the health dollar is spent, and in developing indicators for measuring the effectiveness of health policy.[32] This involvement might be managed through the local divisions of GPs now being set up as part of new primary health care structures.

Thus challenges still remain. The increasing attention on setting standards of health care risks institutionalising normative standards that will be factored into a cost-effectiveness formula without acknowledging the variety of contexts in which people live and physicians practise. Administrative tinkering to meet budget targets begs the question of whether isolated decisions to reduce expenditure on drugs actually have greater cost implications in other costly areas of the health budget. For example, if decisions in the drug programme lead to procedural overservicing, is health increased or decreased? Without any means to study the response of the system as a whole, it is impossible to develop equitable means of deciding where cost-capping should bite. Meantime, the cost pressures rise rapidly.

The PBS gradually grew to encompass more drugs in parallel with rapid research and development. Many of these innovations were perceived to be miracle cures potentially able to change the outcome of common life-threatening illnesses as dramatically as antibiotics had done. Doctors and the community began to rely on the free supply of drugs and access to drugs was generally considered to be revolutionising medical care.

The scheme continues to be supported and influenced by the medical profession. The PBAC nominees are carefully chosen as respected experts in their field, and the committee consults with specialist bodies, as the need

Universal health insurance

The National Health Act improved access to doctors. In the early years of its operation, government payments towards doctors' fees and hospital charges were high enough to meet the needs of most patients, including those who chose the minimum rate of contribution to their insurance organisation. By the second half of the 1960s there had been very substantial rises in both public and private hospital charges (following rises in wages and living costs). These new charges, together with some steep rises in doctors' fees, over which the government had no control, led to higher contributions being required by the hospital benefits organisations, ranging from 120 per cent to 500 per cent in most states. The margin between the fees that the patient had to pay and the combined amount received from the organisation and from government subsidy also substantially increased.[33] This was to become a major political issue in the 1970s.

In 1972, the Conservative government, in power for 23 years, was voted out of office. The Labour Party that came to power had a strong platform of social reform, much of which it rapidly implemented. It was to last only three

years, being criticised for poor management of the economy and lack of attention to detail.

One of its social reform measures was to investigate discrimination against women. As a result, oral contraceptives were listed on the PBS. The ban on the advertising of other forms of contraception and the sales tax on contraceptives were lifted. The attitudes of 1903 were gone.[34]

The Labour Party of the 1970s had changed its long-standing view that social reform was best met by nationalisation of key areas.[35] Its focus on nationalising the medical profession turned to a commitment to the right of the community to health and a concern about the availability and affordability of private and hospital care.

Thus, a politically controversial universal health insurance scheme was brought in, eventually financed by a levy of 1.35 per cent on all incomes. The opposition at the time from doctors and voluntary health schemes was very strong, following the patterns already set. It is generally accepted that the early 1990s have seen the community declare its clear support for universal insurance. However, the cost pressures inevitable in such a scheme ensure that the search for a balance between the equitable provision of social welfare and economic affordability continues.

Safety, efficacy and quality control

Before the Second World War, government involvement in pharmaceuticals was limited primarily to state government intervention in the sale of drugs and poisons, requirements for prescriptions, and regulations governing the ownership and operation of retail pharmacies.

By 1938 significant breakthroughs in biological products and antibiotics had been made. Parliament passed a bill to ensure the quality of vaccines through standardisation of biologically derived products, but the war prevented its implementation. Later, pressure for standardisation continued, notably from veterinarians using a wide range of vaccines with cattle and sheep.

After the establishment of the Pharmaceutical Benefits Scheme, it was necessary to ensure quality and value for increasing government expenditure on pharmaceuticals. In 1954, the 1938 Therapeutic Substances Act was amended, although the amendments were not implemented until 1958. The new law provided the framework for the standardisation of therapeutic goods but had limitations imposed by the constitutional jurisdiction of the Commonwealth.

The National Biological Standards Laboratory (NBSL) was established, its policy and function influenced by an investigation of the control of therapeutic goods in other countries (notably the UK, the USA and Canada) and contemporary WHO documents. It was to set standards against which goods could be tested before being imported into Australia, supplied to the Commonwealth or traded between states. If goods failed, the manufacturer would be fined.

Standards were adopted from other countries, especially the USA. Where these were absent, standards were obtained from the best of the manufacturers. Quite soon a significant number of deficient products were being turned up. The law could not adequately enforce standards, and it did not appear that the federal government was prepared to test issues such as interstate trade. However, the law clearly did apply to imported drugs (under the Customs Act) and to those listed on the Pharmaceutical Benefits Scheme. Since antibiotics represented between 20 and 30 per cent of expenditure under the PBS, these were made a priority. A powerful solution was to use the Minister of Health's prerogative to delete defective goods from the PBS list.

As chemical synthesis and chemical manipulation became the norm in drug development, the facilities of the NBSL were expanded to include virology, bacteriology and endocrinology, pharmaceutical chemistry and antibiotics.

The Code of Good Manufacturing Practice

Australia reflected the worldwide regulatory practice of the time that quality control was sufficient to ensure safety and efficacy, but several problems emerged in quality control regulation. Many of the standards were unchanged from the days of small-scale manufacture, and thus inapplicable to the developing drug industry.

The Kefauver Enquiry in the USA at the end of the 1960s raised many issues in relation to the pharmaceutical industry including excess in prices and unsatisfactory quality of some manufacturers. The pharmaceutical industry advanced the view that quality ought to be built into each step of the manufacturing process and not rely solely on testing the finished product. The USA, which already had the most comprehensive legislation and the best developed drug control system in the world, evolved the notion of a Code of Good Manufacturing Practice whereby the government guaranteed the quality of non-brand-name manufacturers' products who met the standard.

Australia immediately seized upon this idea and developed a Code of Good

Manufacturing Practice to permit the NBSL to inspect goods to be listed on the Pharmaceutical Benefits Scheme. The NBSL negotiated a draft guidelines document with the industry, and recruited inspectors who had at least 15 years' experience of production management. Feedback from the industry was that the Code and the system of inspection were among the most effective things the Department of Health had ever done to affect the quality of goods.

Safety and efficacy regulation

In the early 1960s, the thalidomide disaster resulted in the worldwide reassessment of the need to investigate the safety of new drugs before they were marketed. In Australia, the Therapeutic Goods Act of 1966 and customs regulations were introduced to provide a formal mechanism for the evaluation of drug safety and efficacy. The Act included standard requirements for labelling and packaging, and for expiry dates and batch numbers to be printed on labels. It related primarily to prescription drugs and applied to over-the-counter medicines only if these were supplied under the PBS.

The government set up the Australian Drug Evaluation Committee to advise the Minister of Health on the safety of new drugs and monitor the safety of drugs already on the market. Requirements for safety and efficacy gradually developed in parallel with those in other countries covering bioavailability, that is the ability of a tablet or capsule to release its active ingredient at a rate comparable with formulations already marketed, animal toxicology and clinical data. The Therapeutic Goods Administration was established to approve the product information used in the marketing of a drug. Advertising was also regulated solely by the government, until 1987, when a system of co-regulation evolved. Industry self-regulated many aspects of its advertising practices and government plays a watchdog role able to enforce its legislation if necessary.

Tighter legislation

Therapeutic drugs and devices in Australia have been subject to a largely uncoordinated and unsatisfactory potpourri of Commonwealth, state and territory legislation evolved over several decades. By the late 1980s, there was substantial agreement that new legislation should be enacted to provide for the enforcement of a national manufacturing standard, the licensing of manufacturers and the registration of all products on the Australian market.

The Therapeutic Goods Act of 1989 changed the focus of control from the point of import to the point of supply. It adopted Commonwealth powers over imports, exports, inter-state trade and corporations, to provide a sub-

stantially uniform national system of control covering all locally produced products as well as non-prescription and alternative medicines. A Traditional Medicines Evaluation Committee has been set up, consisting of experts in the use, toxicology and manufacture of traditional products. Guidelines for the evaluation of traditional and non-prescription drugs have been developed. Alternative or traditional medicines have a lower level of pre-market scrutiny than conventional medicines because of 'their long history of safe use'.[36]

The new legislation now comprehensively covers the requirements and procedures for:

- evaluation of registrable drugs and devices;
- clinical trial and individual patient use of experimental drugs;
- certification of drugs for export;
- reporting of adverse drug reactions and other problems;
- recall of drugs and devices;
- testing of products on the market;
- licensing of Australian manufacturers;
- control over advertising and labelling; and
- appeals.

Delays in the introduction of new drugs

Various reviews of the drug evaluation system have been carried out. In 1986, an enquiry investigated the industry's concern that Australia had developed one of the strictest regulatory systems in the world, which operated too slowly and required unique data. The response was that Australia had a right to set its own standards, and that Australian standards had resulted in significant decisions not to market drugs that had subsequently been taken off the market in other countries. It was also argued that data should be collected to ensure that drug effects did not differ in Australian climatic conditions.[37]

A major reform of administrative procedures to increase the efficiency of the process of evaluation and regulation has subsequently been completed.[38] The objective was to ensure timely entry of drugs onto the Australian market, while still evaluating their quality, safety and efficacy for the consumer. Since 1990, the industry has paid fees for the evaluation of new products and it is expected that faster approval times will result.

Australia's tough price-setting policy risks the delayed introduction of new drugs if transnational manufacturers resist allowing early price precedents

before other countries have set their own regulated prices. However, there is no evidence that this is the case. In fact, since successful price negotiation is not a precondition of marketing approval, the government can be tougher on prices, knowing that non-subsidisation does not actually deny the community the drugs it needs—although their prices will be higher.

A recent study of Australia's pricing policy questioned the morality of 'free-riding' on the innovation of larger countries where higher prices provide governments with a greater incentive to invest in R&D. It concluded that the subsidy scheme substantially reduces the overall cost of prescription drugs to the Australian community and also reduces 'efficiency loss' of the monopoly power of drug manufacturers by transferring some potential profit that a company would have in a more non-competitive market back to the consumer. The net cost to the nation is negative.[39]

The NBSL, now called the Therapeutic Goods Administration, has developed into an organisation of international status. It participates in the development and implementation of national policy in the regulation of therapeutic goods and collaborates with the WHO, the British Pharmacopoeial Commission, the International Organisation for Standardisation, and the Standards Association of Australia in developing standards and reference materials.

It now has the resources to analyse most therapeutic products available on the Australian market and to evaluate and incorporate new technology quickly. Sampling is selective and directed towards products likely to be substandard. In 1990, it analysed 1,164 samples of products for human use and 59 for veterinary use (13 per cent of the former failed and 22 per cent of the latter). Its role in regulating an industry with an annual turnover in excess of $1 billion involving over 50,000 items is just as necessary as it was in the 1950s. Australia is a member of the Pharmaceutical Inspection Convention, which allows exchange of manufacturers' audit reports and quality assurance information with other member countries.

In 1979, the Department of Industry, Commerce and Technology set up the Ralph Enquiry into the role and structure of the pharmaceutical industry, the relationship between industry viability and government policies, and the need for an independent price determination mechanism.

The industry argued that its profits had reduced substantially since the 1960s

because of the large number of new drugs introduced. The sales of patented drugs had been decreasing as a proportion of total pharmaceutical sales. The drug approval system was criticised as complex, slow and confrontationalist, thus contributing to reduced patent lives because drugs are marketed in Australia much later than in other countries. A longer patent would recoup R&D costs and ensure a profit margin.

The government argued that it had to exercise control over its outlays on the PBS. It also had a responsibility, as part of its social programme, to ensure an adequate supply of drugs at a reasonable cost. Control was exercised by a variety of measures, including a limit on the number of items eligible for a subsidy, intervention in the determination of prices of listed items, restrictions on prescribing, and adjustments to the patient contribution.

The enquiry found 'a substantial decline in the profitability of the PBS pharmaceutical sector over the period 1972-78 from a level well above manufacturing industry average in 1972 to below the average in 1975, remaining significantly lower since then. In contrast the non-PBS drugs showed a relatively steady level of profitability.'[40]

It observed that PBS listing and pricing decisions were made without regard to their effects on profitability, and that PBS prices for major branded products were on average lower than in the industrialised and Third World countries for which it had obtained data. On the other hand, non-patented drugs were priced lower overseas than in Australia, although they formed only a small part of the PBS. Other influences on the profitability of individual firms were the patent status of products, volume of output, exchange rates, costs of imported materials and changes in locally incurred costs.

The recommendations of the enquiry were aimed at reducing the need for direct administrative intervention in price-setting under the PBS by encouraging doctors and patients to consider price and value, and by the promotion of more vigorous competition between manufacturers while at the same time preventing excessive profits.

This enquiry was sophisticated. The complexity of the pharmaceutical industry and its international character were well understood. Its recommendations were relevant to the developing Australian business philosophy but probably ahead of their time. They represented a significant departure from current arrangements. There was uncertainty about the likely impact on consumers, manufacturers, doctors and pharmacists. Indeed, one analysis calculated that prices would significantly increase.

Therefore, the government deferred any decision to allow further assessment. As an interim measure to assist drug suppliers, an across-the-board increase in drug prices was granted, and such increases continued to be granted until 1984. This was the beginning of a difficult period for the government in resolving the conflict between controlling the cost of the PBS and having regard to the profitability of the local industry.

The government tried to implement the recommendation to allow competition between pharmacists by discounting patient contributions and the dispensing fee but reversed its decision after two days of strong lobbying by pharmacists.[41]

Further enquiries

In 1986, the government commissioned another enquiry, by the Industry Assistance Commission, into the cost and benefit of drug regulation. This concluded that for Australian consumers and taxpayers, the benefits from lower drug prices attributable to the PBS substantially exceeded the costs of increased delays in access to new drugs, reduced local R&D into pharmaceutical products and any adverse effects on pharmaceutical exports attributable to the scheme. It suggested that the reduction in drug prices, which required expenditure of the order of $600 million per annum, might be better targeted in the way it protected consumers from financial hardship in their need for drug treatment.

This enquiry led to the introduction of a safety net scheme, minimum pricing and generic substitution, changes to increase competition between pharmacies, plans to increase the awareness of prescribers and consumers about the appropriate use and cost of drugs, and changes in drug evaluation procedures.[42]

'Factor f'

In 1987, as a result of the many enquiries into the viability of the pharmaceutical industry in Australia, the government introduced an incentive scheme called the independent Pharmaceutical Development Program, or 'factor f'. Drug prices are set by the independent Pharmaceutical Benefits Pricing Authority. The price paid to manufacturers rewards increased local activity by companies and is one of eight factors taken into account in setting prices:

(a) the prices of alternative brands of a drug;
(b) comparative prices of drugs in the same therapeutic group;
(c) cost information, when supplied by the manufacturer;

(d) prescription volumes, economies of scale and other manufacturing considerations;
(e) prices of the drug in reasonably comparable overseas countries;
(f) the level of activity being undertaken by the company in Australia including new investment, production and research and development;
(g) other relevant factors which the applicant company wishes to be considered; and
(h) other directions as advised by the Minister of Health.

Tables 1–3 give data on the size of the pharmaceutical market, predictions for export and export value-added sales under the 'Factor f' scheme, and the predicted turnover in the balance of pharmaceuticals imports/exports.

Table 1 Viability of the pharmaceutical industry in terms of annual sales

	Industry sales ($ million)		
	1987	1990	1991
Prescription:			
domestic	914.6	1,185.9	1,301.1
export	-	114.2	167.3
OTC:			
domestic	350.2	389.8	420.3
export	-	39.3	45.3
TOTAL	1,264.8	1,729.2	1,934.0

The goal is to encourage internationally competitive pharmaceutical activity in Australia by increasing the value added on exports (excluding the impact of changes in price), increasing the value added on domestic sales (excluding the impact of changes in price or volume), and increasing the expenditure on R&D. Companies apply for price increases under 'Factor f'

Table 2 'Factor f company predictions for export and export value-added sales

	Predictions ($ million)		
	1993-94	1996-97	1998-99
Export	410.0	809.5	1,004.0
Export value-added	229.1	471.8	586.6

Table 3 Balance of pharmaceutical imports to exports

1991	3:1	1995	1:1*
1993	2.3:1	2000	1:2*

*predicted figure

separately from other factors. In 1994,12 companies are participating in the 'Factor f' scheme, of which two are Australian-owned.

The 'Factor f' scheme was evaluated by the Bureau of Industry Economics (BIE) in 1990–91.[43] The prices of drugs in Australia in 1991 were found to be 30 per cent below the EEC average and about 50 per cent of the world average. The BIE stated the clear principle that prices in Australia should operate to a ceiling such as would exist in a deregulated market. As the world average is highly weighted by prices in the USA, Canada and Japan, this was not considered an appropriate ceiling. The industry itself thought that in a deregulated environment Australian prices would rise by only about 5 to 20 per cent, and therefore the BIE recommended that the ceiling be the EEC average.

The BIE also stated that the subsidy paid to companies to invest in local activity must contribute to the economic welfare of Australia. Australia has increasingly been searching for ways to establish a solid economic base through the efficient manufacture and export of innovative products and services. The opportunity to increase the country's involvement in local R&D is strongly supported by the medical research community, which has worldwide cutting-edge expertise in several areas. Australia is also seen as a country where clinical trials can be carried out more easily than elsewhere, with well-trained clinical researchers having easier access to patients. Australia has been almost entirely dependent on imported pharmaceuticals manufactured by transnational companies: the opportunity to increase its pharmaceutical export activity, particularly to the local Asia-Pacific region, but also through specialised production for world supply, is very attractive.

In recommending changes to the regulatory environment and evaluating the impact of the incentive scheme to develop the local pharmaceutical industry, a more cooperative and open partnership between the TGA and industry was called for.[44] This should still allow for the fact that some government changes, especially those with an impact on government expenditure,

will be announced without previous consultation with industry. In order to achieve transparency, a high-level consultative forum has been set up, with representation from industry, the Departments of Industry and Technology, and Health and Human Services, and statutory agencies whose actions can affect the pharmaceutical industry. Its function is to improve understanding of the overall environment for the pharmaceutical industry and allow the health and economic objectives to be better debated. The forum reports to the industry and health ministers jointly.[45]

Education

Many of the enquiries through the 1970s and 80s, while looking primarily at cost, quality or management issues, increasingly raised the issue of educating all those involved in prescribing, dispensing and using medicines.

Changes were occurring in consumer attitudes and expectations. Continuing education of health professionals to increase professional standards of practice was developing. The discipline of clinical pharmacology was evolving. Questions were being asked about whether the medical education curriculum adequately prepared students for general practice.

Generalpractice

The Royal Australian College of General Practitioners was founded in the early 1960s with the ideal of giving the people of Australia the best possible medical service. Its aim was to foster and maintain high standards of general practice by promoting a scientific approach to problems of disease at the level of the individual and the family. Its priorities were undergraduate education to enable students to see general practice in perspective, vocational training for those seeking to enter general practice, and continuing education to keep the GP up to date.

The College understood very well the contextual differences of the specialist and the GP role and the challenge of providing a collegiate service to GPs who were very individualistic and used to practising in isolation, geographically as well as professionally. While drug salesmen alleviated some of this sense of isolation, they were not to be tolerated as the principal postgraduate educators of general practitioners. In 1966, the College developed a Postgraduate Fellowship Plan whereby experienced GPs with an ability to influence colleagues and an interest in promoting medical education were to visit their colleagues and seek answers to the various problems they were encountering. This form of personalised medical education was funded by donation and ran very successfully for three years. Today, a form of personalised visiting is once again being researched as a means of educat-

ing doctors about peer-produced prescribing guidelines, to balance the promotional messages of the drug representatives.

The College was later financed by the federal government to set up the Family Medicine Program, which vocationally trains medical graduates for general practice. Major restructuring of general practice is occurring in Australia at present. Vocationally trained GPs are reimbursed at a higher rate and on a different payment basis. Approved continuing education is linked to a quality assurance point system which ensures ongoing eligibility for higher payment. This scheme is presently being re-evaluated. In addition, the profession is actively setting up mechanisms for local groups of GPs to form networks and jointly explore innovative ways of serving patients and interacting with consumer and other professional groups. National standards for GPs have been trialled. A national system of voluntary practice accreditation is being developed which may attract government financial incentives.

Consumers

Consumer groups had become concerned about the toxicity of drugs and were beginning to expect better information about products and services. A survey of pharmacies using people posing as patients showed that consumers were very rarely given advice. Campaigns were run by consumer groups to raise awareness about the overuse of benzodiazepines. The activities of drug companies in Third World countries engendered suspicion. Under the aegis of the Consumers Health Forum, a core group of consumers wrote a document called 'Towards a National Medicinal Drug Policy'. It circulated drafts of the document widely to all interested parties and obtained replies supportive of many of the issues raised. Consumer groups' submissions to many enquiries had also kept the issue of education alive. They articulated clearly that the consumer is the ultimate recipient of drug therapy and that policy objectives should reflect this.

Clinical pharmacology

Concern about the level of therapeutics education in medical schools led the small but growing number of clinical pharmacologists to recommend the establishment of Departments of Clinical Pharmacology in all medical schools. A Parliamentary Senate enquiry supported this and the government financed their establishment in the 1970s.

Pharmacy

Pharmacy education underwent profound change in the 1970s, away from an emphasis on physical skills for compounding and manufacturing, and to-

wards increased education about the drugs themselves. Communication skills were taught. In hospital practice, drug information centres were started and clinical pharmacists monitored the effects of therapy on the wards. They also became active in hospital drug committees, developing formularies and other procedures to monitor drug usage. The application of the new education at the community level has spread more slowly, complicated by the retail basis of practice and state differences in setting competence standards. The formation of a national professional body for pharmacy began to bring these influences together. The Australian College of Pharmacy Practice is now taking a lead in setting standards and designing educational programmes to raise the professional standard of pharmacy practice.

Government

The Drug Evaluation Section of the Therapeutic Goods Administration recognised that doctors and the community needed both the protection afforded by high standards of drug evaluation and objective education about the drugs themselves. A journal called the *Australian Prescriber* was established to publish independent articles about aspects of drug therapy and new drugs. Educational messages were sent to doctors by the PBAC and inserted in the formulary of Pharmaceutical Benefits, and a bulletin about adverse drug reactions was published.

Another major initiative was the establishment of a National Drug Information Service, with the agreement of all states. At the national level it built and maintained a comprehensive database of objective, evaluated drug profiles and also allowed access to other databases or specialist services operated by the national government. State Drug Information Centres had online access to this database and used it in answering queries from doctors. In addition, hard copy or microfiche copies of the profiles were sent directly to many doctors and pharmacists.

Most users of the drug information service were hospital specialists. It did not realise its objective of reaching the community level. It was disbanded in 1989 before initiatives in rational use were formalised and before it was clearly understood what contribution it was making to rational drug use.

Industry

Changes in the regulation of advertising and promotion meant that much responsibility moved from government to industry self-regulatory schemes. While government regulation still places restrictions on advertising, the two main industry associations have Codes of Conduct for monitoring and im-

plementing sanctions. These codes are regularly reviewed by the Trade Practices Commission, which consults widely with the community in the process.

Data on drug use

In 1988, the Drug Utilisation Subcommittee of the Pharmaceutical Benefits Advisory Committee was formed to develop and refine databases on drug use, and to advise the PBAC on changes in drug use patterns as a consequence of changes in drug availability or restrictions on use. It was to facilitate the dissemination of information on drug utilisation and to contribute to educational initiatives to encourage the rational use and prescribing of drugs. It has slowly built a drug database which monitors pharmacy dispensing trends of PBS drugs (70 per cent of Australian prescribing) and an estimate of non-PBS prescribing by surveying pharmacies. It now produces a yearly report on prescription counts, total community costs for PBS items, and defined daily doses (the usual adult dose for the major indication of the drug, which allows international consistency).[46] It systematically reviews statistics on all major drug groups for the PBAC each year to assist its decisions on listing drugs for subsidy. This provides data on which hypotheses can be made about problems in appropriate or safe use of classes of drugs. It has published data on the use of lipid-lowering drugs, systemic antibiotics and benzodiazepines which indicated the need for clearer guidelines on use, educational strategies for prescribers or studies in the community to identify further the factors contributing to apparent trends in drug use.

Reappraisal of the objectives of drug education

Towards the end of the 1980s, critical questions were asked about whether objective information, on its own, could educate prescribers and counter the promotional efforts of drug companies. In a paper on drug education commissioned by the Department of Health, the need to clarify the objective underlying the development of educational activities was stated.[47] It argued that the objective should be to ensure that drug use was rational by developing the skills, awareness, knowledge and motivation of those making prescribing and drug-taking decisions. Provision of good-quality information alone, hoping that professionals would do the right thing, or cost-cutting measures that did not judge whether the changes made in prescribing were appropriate would not be likely to influence doctors and consumers in a sustainable way.

The question of who should set standards for prescribing was raised. A Victorian group had begun to produce peer-consensus prescribing guidelines and had considerable success within hospitals in reducing the inappropriate

prescribing of antibiotics by marketing them to the doctors in imaginative ways, and auditing prescribing.

Medical specialist, general practitioner, pharmacy, or consumer groups had tried, in responding to various needs, to fill the gaps in objective education. Much of this activity had been tacked on to the end of full-time jobs and done on shoestring budgets. The range of programmes was impressive, although some were insufficiently tried out on their intended audience. Because of time and budget constraints, strategies had not been developed for getting them taken up broadly by community or professional groups. There was little cooperation, and some hostility, between groups, and piecemeal programmes were unlikely to have maximum impact.

Among consumers, research showed that many people, especially the elderly, perceived the doctors' time as too precious for seemingly trivial questions. Others feared that their questions demonstrated ignorance, or else forgot them in the consultation itself. Doctors were criticised as bad communicators by those who felt that the patient should not have to ask all the questions.

Consumer-developed programmes were designed to empower. For example, they trained a group of elderly women to act as a resource to others who had problems with their medicines, not by providing non-expert advice about medicines or health, but by formulating questions for their next visit to the doctor or pharmacist.

The structural issues contributing to drug use were also being questioned. Had the system of providing access to drugs been too effective? How did the means by which doctors and pharmacists were paid influence the environment in which drugs were prescribed and dispensed and the quality of the advice and knowledge given to consumers?

The community and professional groups' investigations were innovative and committed. Pharmacists hosted a joint meeting trying to stimulate the development of a national body to coordinate activity. The government began to fund the development of more programmes which helped different groups to come together to discuss the issues and make recommendations for action. These included a task force on polypharmacy (the use of multiple drugs concurrently) in the elderly and a conference exploring the influences on prescribing. Consumers and clinical pharmacologists jointly sponsored a meeting to discuss the challenges for medical education in teaching rational drug use.

Has improved physical and financial access created an uncritical attitude to drugs? There is no hard data to answer this question, but drugs are certainly widely used. Prescribed or OTC medicines were used by 76 per cent of women and 65 per cent of men at some time in the two weeks preceding the 1989-90 Australian National Health Survey, and a survey of people over 65 indicated that 90 per cent were currently using medication.

In fact, although considerable control is exercised over the distribution and use of drugs, information about most aspects of medicinal drug use is poor. Good data do not exist for the aggregated use of drugs (such as total expenditure by hospitals or individuals on prescription drugs) or for patterns of use by individuals. Data available suggest that the total number of prescriptions used annually increased from 7.7 to 9 per person during the 1980s. For subsidised drugs, the number increased from 6.9 in 1980-81 to 8.4 in 1984-85 and declined steadily to 6 in 1990-91, reflecting changes in the subsidy provisions. The subsidised prescription rate for pensioners increased from 23 in 1980-81 to 28.6 in 1989–90.[48]

The quality use of medicines

In 1991, the Department of Health formed the Pharmaceutical Health and Rational Use of Medicines Working Party (PHARM) to develop an educational strategy, identify and encourage groups to develop effective education initiatives, and recommend funding of projects from a budget of around $2 million per year. Within 12 months, it was to provide a report on the most appropriate structure by which to organise a coherent, ongoing educational strategy related to real issues and needs in pharmaceutical education. From the outset the Working Party conceived its task as addressing the issue of the rational use of medicines, anchoring drug policy objectives to health outcomes for Australian people.

PHARM was a cross-sectoral group representing consumers, industry, government and health professionals, with skills in areas including health education and promotion, research, behavioural science, specialist and general practice, community ownership and participation, nursing and pharmacy. Its approach was based on the current understanding of medicines and good clinical practice, and on relevant ethical principles and consumer rights. Different experiences, approaches, concepts and processes could be applied to the issues under consideration in a consultative manner geared towards action.

The Minister of Health Services, keen to move quickly before the end of his term of government, asked PHARM to bring forward its schedule and de-

velop a policy and a national education campaign. He not only wanted to increase the efficiency of spending on the PBS but also had a strong interest and concern for people in the community, particularly the elderly, who generally take multiple drugs, without much information, and who are at considerable risk of toxicity.

In Western Australia, between 1981 and 1982, the rate of hospitalisation due to therapeutic poisoning had doubled; the rate for those over 65 had more than doubled. Each year, an estimated 30,000 people were admitted to hospital due to medicine-related problems. There was evidence of overuse of antibiotics, including inappropriate choice of broad spectrum antibiotics. In 1992, it was estimated that 330,000 Australians were using benzodiazepines daily for six months or more. Of all patients admitted to hospital, 50 per cent of those taking benzodiazepines had done so for six months or more. This was also found in a study of residents in care accommodation for the elderly. Underuse of blood pressure medicines and of the most appropriate asthma medications was common. About 20 per cent of medicines disposed of in disposal campaigns was totally unused.[49]

The QUM policy

In 1992, Australia adopted a Quality Use of Medicines (QUM) Policy which endorses the WHO definition of rational drug use. Its goal is to optimise the use of medicines to improve health outcomes for all Australians. Three terms are used to describe the basis of good drug use. *Judicious use* refers to the need to define the role of drugs in treating illness and maintaining health and to facilitate the selection of effective management options, including non-drug therapy. When a drug is indicated, *appropriate use* ensures that such factors as the choice of drugs, dosage regimen and length of treatment are appropriate to the person and the condition being treated. *Safe use* of medicines means enabling people to take appropriate actions to solve actual or potential medicine-related problems, thereby minimising misuse, underuse and overuse, and encouraging safe storage.

The approach, which acknowledges the many influences and stages in changing the actions of people and organisations, is:

- to use consumer and professional education as a primary tool, addressing at the same time structural issues such as the organisation of the health system and payment systems, which affect the ability of people to take successful action;
- to stimulate a partnership relationship between those who take, prescribe, dispense or make medicines, those who facilitate their use, and

monitor their safety and efficacy, and those who provide equity of access to them;
- to stimulate initiatives from various groups in a number of strategic areas;
- to develop indicators and data sources;
- to identify and support the further development of already effective programmes through various mechanisms, including proactive consultation, targeted grants and the building of support structures;
- to identify means of empowering consumers to use drugs well and health professionals to help them do this;
- to identify what constitutes effective education and the combination of information, skills and motivation that will be effective for different groups;
- to identify what will work in practice, what standards should apply and who should set them.

Meetings with industry have articulated shared objectives in developing industry-sponsored education and promotion that contribute to the quality use of medicines. PHARM and members of both the prescription and OTC industry are in the process of designing a joint study. It will examine a range of industry education and promotional programmes in order to develop criteria for best practice in meeting educational and legitimate commercial objectives. The experiences of GPs and drug representatives will be used to develop educational programmes to improve the quality of their interaction to improve QUM.[50]

Consultation with pharmacists resulted in a workshop of professional, academic and practising pharmacists to develop strategies to maximise their professional contribution to the quality use of medicines. Consultation has commenced with GPs to integrate the quality use of medicines into the current restructuring of general practice as a major component of primary health care. A workshop in late 1994 made recommendations to meet the needs and expand the central role of nurses in promoting QUM. Targeted grants were advertised to stimulate projects for discussion at the workshop. Moreover, consultation with a broad range of consumer groups has commenced with the aim of discussing the policy and stimulating more community-sponsored medicines projects.

Two very successful major workshops brought workers from all major groups together to discuss academic detailing[51] and consumer education and information.[52]

A task force began working with industry and professional and consumer groups to make written product information as consumer-friendly as possible. Since there were no implementation strategies in place to facilitate the introduction of legislation, the task force was charged with developing practical solutions that meet legal and ethical requirements, take account of the practical constraints of professional practice, and reflect the need to allow some flexibility in professional judgement while ensuring that all the relevant information is actually given to patients. At a 1994 meeting of executives and advisers of all the stakeholders, practical recommendations for addressing the next phase of implementation were developed.[53]

Strategic areas where initiatives have been developed

The preparation of national prescribing guidelines, a national formulary and consumer information have been supported. For the development of treatment guidelines for complex or controversial issues, consensus conferences have been sponsored on lipid treatment and hypertension. Another on hormone replacement therapy is planned. A mechanism for encouraging independent monitoring of drug advertising has also been supported. Emphasis was placed on ways to involve groups in the development of information and its use to improve practice.

Training

A curriculum in clinical pharmacology has been developed for medical schools, and initiatives at the undergraduate and postgraduate levels to teach rational use of drugs in the context of the GP consultation. Clinical pharmacy training courses have also been supported. A schools kit for children and a popular comic for adolescents on QUM have been funded.

Consumer services

Education programmes have been developed to encourage consumers to ask health professionals more questions about medicines and to support them in running local campaigns on drug use. Tools for better medication management such as medication record cards have also been targeted.

Provider services

Several types of academic detailing programmes have been developed, as well as a programme to increase the effectiveness of **GPs'** non-drug management of patients' cardio-vascular risk. Programmes to improve drug use in nursing homes and to improve communication about drug management between hospital and community practitioners for discharged patients have been supported. New models of practice, especially those that attempt multidisciplinary practice, have been funded.

National data sets

An evaluation framework and a set of indicators for measuring progress have been developed in consultation with all the stakeholders. A pharmacoepidemiology database is under discussion for use in a quality assurance, self-audit process.

Education campaigns

Two national education campaigns were run in 1992. One aimed to educate health professionals and the community about the safety aspects of using non-steroidal anti-inflammatory drugs and publicised changes in the availability of these drugs on the PBS.

The second, called the 'Be Wise with Medicines' campaign, was a major national community awareness campaign initiated early in the development of the policy. Small grants were made to 350 local community groups representing a broad range of age, cultural origin, rural and urban interests to design educational activities. Activities included health fairs, discussion groups, talks by local doctors or pharmacists, and shopping centre displays. Two community groups trained members of other groups from all around Australia in the skills necessary to plan and conduct education workshops for consumers. Many groups developed their own material, in consultation with the campaign. An Aboriginal group developed materials in several of their own languages and a video to be used in remote communities by the Aboriginal health worker.

The campaign uncovered an enormous thirst for information and reflected the changed cultural mix of Australia since the Second World War. For example, a tape produced for multicultural radio was translated into 22 community languages. There were many requests for translation of medication record cards and fact sheets. The campaign worked with professional groups to design materials and encourage them to initiate discussion and review of medicines. A medication review consultation form was developed for general practitioners with parallel guidelines for review and referral mechanisms for pharmacists and community nurses. Consumers' questions about medicines were answered by a team of health professionals on a national phone-in. Consumers were encouraged to ask their local doctor and pharmacist about their medicine-related problems on a regular basis. A national strategy to dispose of unneeded medicines was also tested.[54]

Institutionalisation: building a sustainable two-way system

QUM is predicated on the close involvement of professional and community groups, supported by the policy, research, evaluation and practice of government and industry. New programmes and ideas need to be stimulated

while existing effective initiatives within local communities or professional and consumer groups are supported wherever possible. Sustainable infrastructure is needed to facilitate, coordinate and support initiatives at state, regional and local levels. There is some evidence of the nature and extent of morbidity due to sub-optimal use of medicines in health care institutions, but very little evidence in the community. The challenge is to develop systems that provide better data at the primary health care level and to develop effective programmes to address problems already documented. Work towards the development of a national network is under way but will require extensive consultation to ensure that it meets the core needs of all players. Although the slowness of the process is frustrating for some, the resulting model is more likely to be sustainable in the long term and meet the needs of local and regional communities of consumers and health professionals.

Australian Pharmaceutical Advisory Council

The Australian Pharmaceutical Advisory Council (APAC) was formed in 1991 at the same time as PHARM. The Minister of Health's original intention was to provide himself with a visible mechanism for raising issues and procuring advice about pharmaceuticals following a period of conflict, especially with the pharmacy profession. APAC conceptualised itself as a consultative forum for the peak professional, industry, union and consumer organisations, who, together with the Commonwealth Government, have demonstrated a commitment to the formulation of a National Medicinal Drug Policy. In its four-year life, it has dealt with some important structural issues relating to medicines.[55] It has drawn up guidelines for the supply of pharmaceutical services in nursing homes and for the advertising of certain OTC products. It has examined the impact of new casemix funding on the use of pharmaceuticals in hospitals, quality of care and discharge planning. It has also studied and reported on the role of nurses, begun work on the development of a national disposal strategy, and given in-principle support to generic substitution.

Articulating a comprehensive drug policy

Following the successful establishment of PHARM and APAC, the government has begun to consider the articulation of a National Medical Drug Policy. In 1993, the Department of Human Services and Health took the first step by producing the 'Draft Australian Medicines Strategy'.

Integration of the major arms of the National Drug Policy will be a major challenge. Communication between the Equity of Access and the Quality, Safety and Efficacy arms has always been reasonable. The latter is currently developing consumer product information in cooperation with the Quality

Use of Medicines arm.The regulatory arm is responsible for ensuring that information is accurate and consistent with official product information. The QUM arm has developed benchmark standards for information which influences rational use, such as readability, presentation, delivery and absence of promotional claims.

PHARM and PBAC have recently collaborated in a campaign to educate professionals and consumers about the toxicity of anti-inflammatory drugs and changes to listing arrangements designed to reduce the chance of toxicity. Among its priorities for the short term, PHARM has included targeted consultation with key groups and opinion leaders in important areas to encourage them to put QUM on their agenda and become more proactive in policy, education and practice support.

The coordination of a comprehensive policy from a history of separate objectives and programmes requires time and dialogue to ensure that all players are comfortable with closer relationships, and that health outcomes are balanced with economic objectives. The growing, fragile consensus needs to be fostered so that groups approach new problems or areas of development at early stages in concert. This is essentially a preventive approach. Experience in working together shows signs of significantly improving the understanding of other groups' responsibilities and constraints. However, partnership should not lead to a subtle form of cooption. Rather it should clarify which issues can be resolved through cooperative action, and which require tensions to be argued out in a political or regulatory process.

Collaboration will also be fundamental to resolving the tensions between health professionals and government in maintaining the privacy of the doctor-patient relationship while also allowing for the government's legitimate concern about accountability for public expenditure. Primary health care is currently under scrutiny in an effort to balance the provisions of the tertiary, specialist and primary tiers. In the future, the most important mechanism for delivering primary health care will be efficient, profitable small business run by GPs and pharmacists, and subsidised by government. The challenge is to build a system that allows the government an appropriate level of compliance monitoring but avoids interference with a doctor's actions in treating individual patients. Health professionals need to establish their own effective quality-assurance systems to ensure that peer review is in place to the satisfaction of the whole community.

The changing business environment

The timeliness of the partnership approach to drug policy can be better understood in the context of a 10-year period of social, economic and structural change. Increased international competitiveness is viewed as the means to fund Australia's commitment to the values of social welfare and justice.[56] Economic and industrial reforms to promote better management and the engagement of employees in company objectives have resulted in a more skilled workforce, a more competitive regulatory environment, decreased industrial disputes, one of the lowest inflation rates in the world, and increased exports. At the same time, long-term unemployment has risen and social conflict has increased. However, in many areas the reform process has institutionalised processes of dialogue and cooperative approaches to problem-solving. It is claimed that consensus has accelerated change and that confrontation is a slower process.

Overseas aid

Internationally, NDP initiatives are also being reflected in the work of the Australian International Development Assistance Bureau, which has funded a number of projects dealing with National Drug Policy and rational use of drugs in the Asia-Pacific region. It is currently identifying objectives for assisting developing countries in the region with development-related pharmaceutical issues. Projects are being implemented in Bangladesh and the Philippines, and Australian workers are participating in workshops organised by the NGO networks operating in the Asia-Pacific region. A multicountry study on Ethical Criteria for Drug Promotion has been funded.

Achievements and challenges

Australia is one of the healthiest countries in the world and is continuing to improve. Death rates declined slowly from the 1920s to the 1960s, since when the rate of decline has been even faster. Cardio-vascular disease, the primary cause of death, has also declined. Life expectancy has increased to 73.9 years for men and 80 years for women. Infant mortality has declined steadily. In 1990, it was 8.2 deaths per 1,000 births, which is comparable to the UK and Norway, though higher than Japan, Sweden, the Netherlands and Canada. Perinatal mortality has also decreased, to 10.3 deaths for every 1,000 births.[57]

By these indicators, Australia has achieved much in the way of a conventional definition of health. The safety and quality of medicinal goods are high, access and distribution is effective, industry viability is well supported, good sanitation and other public health structures are in place. The problem remains, though, that we cannot say what contribution to our health medicines alone have made. According to one US writer, 'The best

estimates are that the medical system (doctors, drugs, hospitals) affects only about 10 per cent of the usual indices for measuring health.'[58]

Our definition of health is broadening towards a concept of well-being beyond the management of illness and chronic diseases with technological solutions. We are beginning to understand and demonstrate how socio-economic differentials affect health.[59] The 1994 edition of *Australia's Health,* which reports national data on health status and health services, opens with a discussion of the determinants of health which includes social, economic, environmental and spiritual well-being. [60]

Hugh MacKay, one of Australia's foremost social researchers, has surveyed the rapid changes in Australian society over the last 20 years. His view is that Australian society is uncertain and afraid. Many familiar institutions and landmarks have disappeared, leaving people with no clear understanding of what it is to be 'Australian.'[61] Most people identify stress as a feature of their lives. The redefinition of gender roles and family, rising divorce rates and declining marriage rates have left 50 per cent of homes containing only one or two people. Loneliness is a major feature of contemporary life. Attitudes to money and class have changed. The top 30 per cent of homes controls 55 per cent of the nation's wealth, and the egalitarian dream is over. Party politics are less clear cut, and the floating vote has increased from 5 to 30 per cent. Australian society has also become very multicultural.

MacKay finds that esteem for traditional authority figures, including doctors and pharmacists, is in decline, as people move to take control of their own lives. As the medical profession has become more transparent, in fighting, politicking and a concern with money have been revealed. This demystification means that, although people still go to the doctor to cure illness, they increasingly wonder how much the doctor can really do. Some people feel that it is a long time since the last real medical miracle, antibiotics, were introduced, and that they are being overprescribed.

MacKay's research suggests that people see self-medication through natural and alternative remedies as a way to relieve symptoms without recourse to the medical system.[62] Rapid external change has resulted in a move towards an internal locus of control, the power of the mind. Health promotion and its adoption and definition as part of the Ottawa Charter arising from the first International Conference on Health Promotion in 1986 have encouraged people to take a more holistic approach to health.

Evidence of a quest for self-determination in the area of health is slowly emerging and—more generally—of a trend towards a society that is more participatory and self-reliant, and values social cohesion as well as expert skills and experience. Perhaps we can say that Australia is gradually moving towards the type of society, and towards a concept of health, valued by Aboriginals? If so, then there may be some chance that we can create an appropriate environment to support genuine Aboriginal self-determination in addressing the issue of Aboriginal health, which is well below the Australian average.[63]

Aboriginal health status

No national data are available for Aboriginal health status. The regional data that are available show death rates at least two-and-a-half times those of the total Australian population, with a particularly high mortality rate among young and middle-aged Aboriginals: 11 times higher than the average among men aged 35-44 and nine times higher for women aged 35-54. Life-expectancy is correspondingly lower: 55.2 years for men and 63.6 years for women. The leading cause of death is disease of the circulatory system, followed by injury. Infant mortality is 24.6 deaths per 1,000 live births, three times the Australian average. It has declined since 1979, but more slowly than the national average. At 30.3 deaths per 1,000 births, perinatal mortality is also about three times the national average. These figures show a continued marginal improvement, but the rate is considerably slower than the national average.

Increased expenditure on health provision for Aboriginal Australians and immediate attention to a number of facility, service and clinical issues are clearly called for. However, the implications of these health status statistics are more complex. It is not enough to document the health service needs of Aboriginal people and then mainstream them into the existing system. It is necessary to recognise the Aboriginal concept of health encompassing all aspects of life, discussed at the beginning of this article. The effect of the continual denial of this has been despair, violence, alcoholism, and many other spirit-broken responses. With this evidence, white society has judged Aboriginal society incapable of self-determination and of controlling money given to it.

Aboriginal people themselves state over and over again that no real change will occur until they become active partners rather than passive recipients, until trying to ﬁt them into the existing system stops.[64] An initiative in Cape York, in which the Aboriginal community came together to determine its needs, resources and priorities, is encouraging. National and regional

health policy-makers were present, but the Aboriginal community will take full responsibility for guiding and implementing the programme.[65]

Building a balanced health policy

Health policy must be based on an appropriate and relevant concept of health for today's world. Self-determination, local control and responsibility should be built into the structures and working relationships between policy-makers, health professionals and the community so that national policy-making, funding and accountability decisions reflect the needs of groups in many settings, from different backgrounds and with different ways of managing their lives. In this approach, regulation should protect the community and, through structural reforms, give real control and freedom to groups to explore and evolve mechanisms that satisfy these different needs and ideals. Aboriginal people are the top priority in this.

White settlers invaded black people's land and culture, killed, starved and pushed them out of the way, and took their children to save them from 'savagery'. For Aboriginals, the cohesion in physical, social, economic and spiritual life was broken. Yet Aboriginal society in some places has preserved, or is rediscovering, its traditional culture.[66] It is combining its traditional approach to health and medicines with the benefits of the Western approach, within its own context.[67]

Aboriginal culture had much wisdom to impart on what constitutes a healthy well-balanced society—wisdom that has so far been kept secret from its oppressors. Perhaps it is time to learn from real, everyday human experience in order to balance, complement, make relevant and enhance the systems of law, data, accountability and order that we have developed so well.

Healthy drug policies are only partly about the drugs themselves and the technical issues surrounding them. They are really about the people and their relationships with each other. We need to find a balance between the various forces: self-knowledge and knowledge outside self, economic reality and social service, solid routine and creative change, legislation and empowerment, partnership and self-reliance, self-regulation and independent monitoring, costs and benefits, health and iatrogenic illness, tangible outcomes and 'feel-good' outcomes, specialist skills and expertise and common sense and everyday experience ... and so on.

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One Step Forward, Many Steps Back

Dismemberment of India's National Drug Policy

By Praful Bidwai

India was among the first countries of the Third World which attempted to formulate a National Drug Policy, promote indigenous manufacturing and technological capability in pharmaceuticals, and control the prices of selected essential medicines. The effort was somewhat half-hearted, never properly focused on the concept of essential drugs or a need clause, and not adequately backed by public funding or regulations.

The attempt reached a high point in the 1970s and resulted in the robust growth of an indigenous pharmaceuticals industry which benefited from a favourable regime of intellectual property rights (IPR) that allowed innovation. In practice, the policy was substantially diluted during the 1980s under pressure from the powerful drug industry. By the early 1990s, it was very nearly abandoned as the Indian government, under the tutelage of the World Bank and the International Monetary Fund (IMF), embraced a new economic policy. This policy favoured indiscriminate deregulation, extensive liberalisation, privatisation of the public sector and cutbacks in public investment in health care, along with a dismantling of the effort to achieve self-reliance and protect indigenous producers against oligopolistic foreign cartels.

With the signing in December 1993 of a new international trade agreement under the Uruguay Round of the General Agreement on Tariffs and Trade (GATT), involving a severe change in the IPR regime, there are signs that India's gains—improved (but by no means adequate) availability of relatively low-priced medicines, and a vigorous technological capability in the drug industry—will be wiped out. There is a growing danger of a considerable deterioration in the drug supply situation in India and adverse effects on the country's poor. This danger results from the failure to impose rational controls on the registration of drugs or prescribing practices—itself related to the ideology underlying the new economic policy—the absence of an independent source of information on drugs, and the soaring prices of medicines.

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Table 1 Health profile: India's health expenditure compared to other countries

	Public expenditure on health (% of GNP)	
	1960	1987
High human development (HHD)	1.7	1.6
Medium human development (MHD)	1.0	1.5
Low human development (LHD)	0.6	0.9
All developing countries (ADC)	1.0	1.4
India	0.5	0.9

Source: United Nations Development Programme, *Human Development Report 1992,* Oxford University Press Inc., New York.

Note: Human development index (HDI) combines indicators of national incomes, life expectancy and educational attainment to give a composite measure of human progress.

The early context

When independent India embarked on its project of industrialisation and development, it made a conscious decision to reject a purely market-driven, exogenous, dependent pattern of growth. Instead it attempted, under the Nehruvian paradigm, to build a diversified, relatively balanced, self-reliant economy in which growth would be accompanied by a modicum of distributive justice—officially called 'socialism' or a 'socialistic pattern of society'.[1]

In the first quarter-century of independence, there was a fairly close fit between economic policy and the other principles underlying the project to build a strong and viable India: democracy, secularism and non-alignment. The state played a critical role in building core industries, boosting agricultural growth to achieve self-reliance in food production, creating a diversified research and development infrastructure, training skilled and scientific personnel, and building a basic, if limited, public distribution system.

India put in place a comprehensive system of industrial licensing and controls, which did not always work efficiently, but which did bring areas of private economic activity under public scrutiny. However, the state's intervention in the social sector was less vigorous: education, health and social security received inadequate attention and were increasingly starved of funding. The ratio of health spending to GDP in India is on average 55 per cent lower than that for Third World countries as a whole.

Tables 1 and 2 establish India's position as the lowest among all the Third World countries in terms of investment in education and health.

Thus by the early 1980s, India had more illiterate people in absolute numbers than the entire population of the country at independence in 1947. The official estimate of the absolute poor—measured by subsistence levels of calorie intake—is about 390 million today. The state of elementary education in the country remains appalling, especially in the underdeveloped, underprivileged—and highly populous—eastern and central regions of the country. Indian society and the economy present a picture of growing polar-

Table 2 Wealth, poverty and social investment: India compared to other countries

	Total GNP per capita 1989 (US$)	Population below poverty line 1980–89		Public expenditure on education 1989 (% of GNP)
		Total (%)	Rural (%)	
HHD	3,057			3.5
MHD	924			3.8
LHD	364			3.2
ADC	770	32	36	3.6
India	340	48	51	3.2

Source: United Nations Development Programme, *Human Development Report 1992*, Oxford University Press Inc., New York.

isation between the poor and the rich, the plebeian majority and the privileged elite.

Within this overall picture, there has nevertheless been some progress, and many signs of hope. Life expectancy at birth has risen from 32 in 1951 to 60.4 years in 1992. Rickety as it is, the public health system does deliver immunisation, and a minimal supply of modern medicines and services. India has eradicated smallpox, once a major killer, and registered some improvement in the control of TB and a few other diseases. The spread and quality of medical education has improved, as has the availability of doctors (although not of trained nurses). Over the years, there has emerged a rudimentary network of rural and urban primary health centres, and specialised secondary and tertiary centres. The Indian drug industry has made substantial advances in output. It has not only achieved a high degree of technological self-reliance, but also emerged as a significant exporter.

However, most of these gains are highly skewed in their rural/urban and regional distribution, and discriminate heavily against the poor and the underprivileged through denial of access, unaffordable pricing of drugs and services, and deeply ingrained social prejudices. Over the past decade or so, some of the advances, such as the public hospital system, and programmes to control malaria and blindness, have tended to be undermined as the state has withdrawn more and more funds from health-related activities. Although the output of medicines has increased greatly, several essential drugs, indispensable for the treatment of diseases specific to the Indian population, remain in short supply. The price of medicines has tended to increase rapidly. The market is flooded with therapeutically questionable, 'me-too', irrational and actually harmful drugs. Worse, the very concept of a National Drug Policy is in danger of being jettisoned altogether.

How has this situation come about? In what ways is it related to changes in public policy? And what prospect does the immediate future hold as India embraces an altogether different model of development in its bid to achieve

Table 3 Time gap between establishment and beginning of bulk drug production

Name of company*	Year of establishment in India	Year of commencement of production	
		Formulation	Bulk
Parke Davis	1907	1954	1961
Burroughs Wellcome	1912	1950	1960
Anglo French	1923	1955	–
Glaxo	1924	1947	1956
Ciba Geigy	1926	1951	1957
May & Baker	1928	1943	1948
Boots	1929	1949	1965
Alkali & Chem. Corp. of India (ICI, subsidiary)	1938	1977	1965
Geoffrey Manners	1943	–	1957
Abbott	1946	1960	–
Cyanamid	1947	1953	1961
Sandoz	1947	1958	1959
German Remedies	1950	1961	1962

* Pertains to firms established before 1950

Source: Chaudhuri, S., 'Licensing policies and growth of drug TNCs in India' in Amit Sengupta (ed.), *Drug Industry and the Indian People*, Delhi Science Forum, New Delhi 1986.

rapid industrialisation along the neo-liberal route—market-driven, globalising, biased against the 'informal' sector, and involving extensive de-regulation, liberalisation and privatisation of the public sector and state initiatives?

More specifically, what is the likely impact of the World Bank-IMF-sponsored policy orientation followed since 1991, combined with the signing of the Final Act of a new international trade treaty under the Uruguay Round of GATTin December 1993 and the emergence of a new global trade regime under the World Trade Organisation?

Evolution of India's drug policy

At the time of independence, the drug supply situation in India was marked by a preponderance of mainly transnational corporations (TNCs) running a small number of plants which mainly imported and formulated a limited range of medicines. There was a poorly developed health-care infrastructure, a rudimentary medical education system, and modern health-care coverage was confined to less than a tenth of the population, mainly in the bigger cities and towns. There was little or no control over the quality of drugs, prices tended to be high and ungoverned, and profiteering was rampant. Misprescription was widespread; so too the arbitrary choice of drugs for patients by dispensing chemists who were usually untrained, but often equated by the poor and illiterate witch doctors ('the poor man's doctor'). There was a total absence of monitoring of adverse reactions and side-effects.

A government committee noted enormous levels of profiteering by TNCs."

Independent investigations revealed that in one instance, a TNC charged a mark-up exceeding 11,000 per cent. There was very little production of bulk drugs, and hardly any were manufactured from raw materials. This was a situation that particularly favoured TNCs, which could import bulk drugs (or, less frequently, intermediates) from their principals and formulate them into tablets or syrups.

Table 3 shows the delay between the establishment of TNCs in India and their beginning to produce bulk drugs in the country. The substantial time gap in each case is a strong indication of the dependence of these companies on imported bulk drugs.

The rules relating to intellectual property rights were inherited from the colonial period; they actively discriminated against innovation by Indian-owned firms, and promoted foreign-dominated monopolies through granting patents for products as well as processes, which could be used to block competitors' entry into a large number of product markets.[3]

The TNCs transferred their high-pressure marketing and promotional methods from the USA and Western Europe at an early stage. By the 1950s, a close nexus had developed between them and the medical profession. They were particularly active as political lobbyists, and were among the largest declared donors to political parties in the period when such donations were **legal.**[4] This allowed them to gain disproportionate weight among industry groups influencing government policy, which they vigorously used to promote their commercial interests.

Thus, even when strict licensing rules were introduced for industry, many drug TNCs managed to evade their demands for extremely detailed information on such matters as technology, processes and forms of packaging, as well as corporate management structures and patterns of equity holding. Thus, some TNCs had licences to produce not a certain quantity of a particular drug in a specific formulation, but a certain number of 'vials' or 'tablets', or so many litres of syrups for 'pediatric use'. There were no standard dosages, no effective labelling regulations, and no controls on the kind or quality of information to be provided with medicinal formulations—on indications, contra-indications, adverse reactions or side-effects.[5]

In this free-for-all, several companies which were direct beneficiaries of the global pharmaceuticals boom of the 1950s and 1960s (when many new discoveries and inventions were made) exploited the absence of regulation to the hilt. An example is Parke Davis, a US-based TNC, which promoted

the extremely toxic antibiotic chloramphenicol—the drug commonly prescribed for typhoid fever, and otherwise only recommended for life-threatening conditions such as meningitis—as a common cure for a spectacular range of infections, including coughs and common colds.[6] The effects of such outrageously unethical promotion were horrifying. The overuse of chloramphenicol led to resistance to the drug among typhoid bacteria, and eventually rendered the drug ineffective. Thus, when typhoid assumed almost epidemic proportions in South India in the 1960s, the bacteria were found to be strongly resistant to chloramphenicol. The company also promoted a wholly irrational chloramphenicol-streptomycin combination as a cure for bacterial dysentery. This has since been banned.

It is against this backdrop that the Indian government took measures, many of them mutually unconnected and partial, to create alternative sources of drug supply and evolve an elementary system of industry regulation. The Drug (Display of Prices) Order was passed in 1962, and in 1963 the Drug (Prices Control) Order, which covered a small number of products, was issued under the Defence of India Act. The government did three other things. First, it set up production units in the public sector to manufacture new drugs needed for the treatment of infectious diseases, in particular penicillin and streptomycin. These were drugs which private-sector, in particular foreign-owned, companies were reluctant or unable to produce.[7]

Second, it changed the IPR system radically through the Indian Patents Act of 1970, which itself followed a detailed inquiry into the working of the patents system and prolonged public debate over what would serve the national interest.[8] The intention was to create a major incentive for domestic pharmaceuticals producers to innovate and develop new processes and products. The new law disallowed product patents altogether in food- and health-related areas, and in the case of pharmaceuticals, it limited the duration of the process patent to between five and seven years. This effectively meant a weak form of patent protection and the discouragement of monopolies. The law also provided for compulsory licensing in health-related items in the public interest: if a patent-holder did not work a patent for a certain period of time, he could be compelled to license others to make the product using the patented process, after charging them a nominal fee.

The third reform created a basic, indeed primitive, system for testing drug quality, operated by state-level Food and Drug Administrations (FDAs). (Health comes under the concurrent jurisdiction of both the central and provincial governments under the Indian Constitution.) It also provided for the registration of drugs through the Drug Controller's office at the central

level. Here, for reasons that are still obscure, the central government, normally reluctant to share its powers with the states, vested all control in respect of quality assurance in the state governments, many of which lacked the means to set up and run reliable FDAs.

It is noteworthy that these initiatives were inspired more by a concern with the industrial, commercial side of pharmaceuticals than by health-related or medical considerations. The government was keener to develop an indigenous industry and a broad technological base than to make the right kind of good-quality medicines available to the people at reasonable prices, in response to their specific health needs.

The government's efforts to procure drugs for public distribution, even for special disease-targeted programmes, were half-hearted; they usually lagged behind its more energetic industrial initiatives. Until 1970, the government made hardly any efforts to control the prices of important medicines, although it had issued the Drug (Price Control) Order in 1963.

The Drug (Price Control) Order of 1970 was significant in two respects. First it limited the scope of price control to 16, and eventually to 33 essential medicines, on which a mark-up of 75 per cent over cost was permitted. This was a limited gain. A more significant gain was in the imposition of a maximum mark-up of 150 per cent over cost on the price of all other medicines. However, as we shall see, this concept of a ceiling on drug prices (as distinct from direct price control) was soon abandoned.

The government did not set up, as in Sri Lanka, a large public sector firm specialising in pharmaceuticals purchases and strategic market intervention. Apart from a few special programmes, it left the task of drug delivery to market forces, even though these would necessarily be biased against and exclude the majority of the population, people who were not part of the market, or who were too poor to be able to afford allopathic drugs.

This emphasis on the 'supply side' of pharmaceuticals, at the expense of the 'demand side', was a basic flaw in the official Indian attitude towards the concept of a National Drug Policy from the start. As we shall see, it continued through the 1970s and 1980s. Despite official rhetoric about the immorality of making profits at the expense of the weak, the poor, and the ill, both policy and actual practice followed a largely elitist orientation.[9]

Between the late 1960s and the early 1970s, a series of major developments

produced a historic opportunity for the formulation of a radical new drug policy: Indira Gandhi's rise to power in the face of opposition from entrenched right-wing interests in the ruling Congress Party, her expedient 'left turn' in nationalising big commercial banks and strengthening anti-monopoly and protectionist measures, and a new ideological shift in society towards the Left. A vigorous public sector, and the growing wholly Indian-owned component of the private sector, had emerged as interest groups demanding a larger role for themselves.

In 1974, this new balance of forces found expression in the setting-up of a Committee on Drugs and Pharmaceuticals, headed by Jaisukhlal Hathi, a respected senior political leader. In 1975, the committee produced a long, detailed report on the workings of the drug industry, calling for major policy changes. Among the principal recommendations of the Hathi Committee's report were the following:

- A clear distinction should be made between the public, wholly Indian sectors of the industry on the one hand, and foreign sectors on the other.
- Some product lines should be reserved for the public sector.
- The indigenous Indian drug industry should be encouraged through the phased imposition of bans on the import of bulk drugs.
- The state should take complete responsibility for supporting research to develop new drugs, especially for tropical diseases.
- Foreign companies should reduce their equity in pharmaceuticals companies to 40 per cent forthwith and gradually to 26 per cent. Moreover, to ensure that this actually dilutes foreign control, the government should purchase their shares either directly or through public sector undertakings.
- Foreign companies using imported bulk drugs should start manufacturing from the basic stage within a period of three years.
- An effective system of monitoring should be evolved to check compliance.
- Foreign companies should not be allowed to operate in the small-scale sector.
- Within one year foreign firms should switch over 50 per cent of their production to manufacturing bulk drugs and formulations.
- There should be a gradual changeover from brand names to generic names.
- Future steps towards a national drug formulary, better prescription practices, and monitoring of drug abuse should be planned.

When adopted with modifications in 1978 under a non-Congress (Janata)

government, the Hathi Report was widely acclaimed, even though the committee had been set up under a Congress government. In this sense, the document represented a fairly broad consensus within a by-now divided and factious political system. The Hathi Committee's report was without doubt one of the better, more coherent and thorough policy documents ever produced in India, despite the higher priority accorded in it to an *industrial* pharmaceutical policy than to a *health* policy.

In drawing up its new drug policy in 1978, the government did not fully accept the report's recommendations; it diluted some, and only partially effected others.

One of the primary concerns of the Hathi Committee was the dependence of the drug industry on imports. A decade after the report, this dependence on bulk drugs was no lower. The dilution of foreign equity did not lead to a dilution of foreign control because the divested equity stock was widely distributed among a large number of Indian shareholders. Thirty-four majority-owned foreign companies had a 40.17 per cent share in production of formulations at the time of the report, whereas about 14 companies controlled 39 per cent of the market in 1983–84. In 1975, the Indian sector of the industry was capable of producing at least 76.8 per cent of bulk drugs and 97.5 per cent of formulations. Since 1978, it has been virtually unable to increase its capability in this area. While the committee had recommended the reservation of 34 essential drugs for production by the public sector, the government reserved only 25. The committee placed a major emphasis on R&D activities to upgrade technology, but the government's new drug policy did not pay enough attention to related recommendations such as checks on payments for technology imports. The committee recommended a pricing policy where the mark-ups on essential drugs would be reduced and those on non-essential drugs raised. Ten years on, some basic drugs have risen by more than 30 per cent in price. The changeover to generic names was not seen as an issue.[10]

Equally important, the government gave up the most interesting element of the Drug (Price Control) Order 1970, the imposition of a ceiling of 150 per cent on the mark-up over costs of all drugs, irrespective of whether or not they were essential or part of the national health programme. This retreat, as we see below, was to have major implications for the availability of essential medicines to the Indian public.

The principal mechanisms adopted to implement the government's watered-down version of the Hathi Report were the Drug (Price Control)

Order (DPCO) 1979, specific schemes such as the Drug Price Equalisation Fund, and a system of monitoring the production of bulk drugs and the ratio of bulk drugs: formulations in the output of different firms. The agencies which operated them were the Ministry of Chemicals and Fertilisers, and the Bureau of Industrial Costs and Prices, under the Ministry of Industry, not the Ministry of Health.

All these schemes and instruments, however, quickly became contentious, the arena of a battle of wits between industry and government, and between individual firms and ministry officials. By the early 1980s, drug companies had breached numerous regulations, and had often misinterpreted rules to their own advantage. The government had become complicit in much of this: it threw a veil of secrecy around its handling of the drug policy, and hundreds of parliamentary questions had to be asked to elicit even elementary information from the Ministry. Whenever the replies did provide authentic numbers—which they frequently did not, as the government often stonewalled by saying that information was being collected—they told a sordid story. They revealed manipulation of prices on false or unsubstantiated claims of cost increases, suppression of relevant facts about the stage of manufacture (basic or intermediate), failure to comply with the stipulated ratio of bulk drugs: formulations, failure to transfer excess profits to the Drug Price Equalisation Fund, and claims of a higher mark-up for wholly incredible or frivolous reasons, such as a change in the type-face on the label of a bottle of pills![11]

It was soon clear that large segments of the pharmaceuticals industry, in particular the foreign-owned companies, were out to sabotage DPCO 1979. By the early 1980s, the TNCs' subsidiaries had evolved an ingenious strategy to bypass some regulations altogether. In the late 1970s, under the 1973 Foreign Exchange Regulation Act, they began to reduce their foreign equity holding to 40 per cent or less so that they would be treated on a par with companies that were wholly owned and controlled by Indian interests. The reduction was achieved without lessening effective management control by the parent firm; often, it was used to coopt sections of the medical establishment by offering them equity on a preferential basis or by actively canvassing support among doctors. Despite equity reduction, which counteracted the obligation to produce bulk drugs, the drug TNCs remained models of centralised, tight, metropolitan control.

Another device used to bypass the DPCO 1979 was 'loan-licensing'. DPCO 1979 exempted small-scale plants from price control, as part of a general official policy of encouraging small industries. Large firms, especially TNCs,

Table 4 Value of production of bulk drugs and formulations

	Bulk drugs (Rs millions)	Formulations (Rs millions)
1982-83	345	1,660
1983-84	355	1,760
1984-85	377	1,827
1985-86	416	1,945
1986-87	458	2,140
1987-88	480	2,350
1988-89	530	2,690
1989-90	607	–
1991-92	1,300*	–

*provisional figure

took full advantage of these exemptions by licensing small units to 'manufacture' (in reality, only make into tablets or package) their product under the original brand name. These unethical arrangements were prolific by the late 1980s. To this day, these malpractices continue unabated.

Strategies aimed at manipulating and short-circuiting DPCO 1979 tended to alter the terms of competition between the TNC-controlled and wholly Indian sectors. But by then the Indian firms had started innovating or entering into technical collaboration with public sector research laboratories, which allowed new, more efficient processes to be developed to produce new drug molecules just patented abroad.

These are some of the most successful examples of cooperation between industry and public R&D laboratories to be found in India. Of particular importance here are the National Chemical Laboratory, Pune, the Central Drug Research Institute, Lucknow, and the Regional Research Laboratory (later the Indian Institute of Chemical Technology), Hyderabad. Between the mid-1970s and the late 1980s, they developed no fewer than a hundred energy-efficient, cost-effective processes, and some new products which could compete internationally with the dominant manufacturers' or original inventors' products. Table 4 shows the annual value of the production of bulk drugs and formulations between 1982–3 and 1991–2.

The dissemination of this technology was relatively rapid and widespread. For instance, by 1990, at least a dozen Indian companies, including six small-scale ones, could make relatively new drugs such as ciprofloxacin (an antibiotic of the 4-quinolone group) or ranitidine (an anti-ulcer drug), from the basic or quasi-basic stage upwards. In 1993, the price of ranitidine in India was 16.58 times lower than the price at which Glaxo sold it in the UK. Table 5 provides a detailed comparative price-list of some essential drugs.

Contrary to what TNCs claim about such development in manufacturing processes, it does not involve theft, illegitimate acquisition of secret infor-

Table 5 Comparative price-list of some essential drugs

Drug	Year of patent expiry	Dosage & pack	Prices Prices in in India (Rs)	Pakistan (in Indian Rs)	Times costlier*	Prices in USA (in Indian Rs)	Times costlier*	Prices in UK (in Indian Rs)	Times costlier*
ANTI-BACTERIALS									
Ofloxacin	–	200 mg × 4s	66.00	117.23	1.78	196.27	2.97	155.35	2.35
Cefadroxil	1987	500 mg × 4s	30.00	82.68	2.76	325.88	10.86	104.79	3.49
Ciprofloxacin	–	500 mg × 4s	51.00	234.63	4.60	305.21	5.98	315.96	6.20
Norfloxacin	1996	400 mg × 10s	39.36	125.50	3.19	626.15	15.91	252.77	6.42
Tobramycin	1989	0.3% × 5 ml	22.17	116.31	5.25	395.32	17.83	75.30	3.40
ANTI-INFLAMMATORY									
Diclofenac	1988	50 tabs × 10s	5.67	55.80	9.84	239.47	42.23	95.84	16.90
Piroxicam	1988	20 caps × 10s	13.87	78.12	5.63	603.93	43.54	166.93	12.04
ANTI-ULCERANTS									
Ranitidine	1995	300 tabs × 10s	29.03	260.40	8.97	744.65	25.65	481.31	16.58
Panotidine	1998	40 tabs × 10s	26.24	260.40	9.92	726.14	27.67	500.27	19.07
Oneperazole	–	20 mg × 10s	71.25	N.A.	–	992.46	13.93	684.05	9.50
CARDIOVASCULARS									
Atenolol	1989	50 tabs × 10s	7.50	86.63	11.55	228.36	30.45	103.21	13.76
Diltiazen	1988	60 mg × 10s	20.24	74.40	3.68	165.10	8.16	78.99	3.90
Enalaprin Maleate	2000	5 mg × 10s	9.00	37.20	4.13	230.83	25.65	147.97	16.44
Prazosin	1987	2 mg × 10s	16.50	13.64	0.83	159.24	9.65	39.50	2.39
Aniodarone	1983	200 mg × 10s	45.00	N.A.	–	673.67	14.97	157.98	3.51
ANTI-VIRAL/FUNGAL									
Acyclovir	1997	5% cream × 5 gm	33.75	363.32	10.77	356.74	10.57	577.68	17.12
Ketaconazole	1999	200 tabs × 10s	43.00	221.96	5.16	673.67	15.67	250.14	5.82
Minoxidil lotion	1985	60 ml	131.25	N.A.	–	1,311.55	9.99	1,053.20	8.02
ANTI-HISTAMINE									
Aztemizole	–	10 mg × 10's	6.00	120.90	20.15	436.36	72.73	100.05	16.68
Terfenadine	1994	60 mg × 10's	13.50	60.93	4.51	293.17	21.72	78.99	5.85
ANTI-AUXIOLYTICS									
Alprozolan	1990	0.5 mg × 10s	5.40	N.A.	–	171.27	31.72	22.64	4.19
Trazodone	1985	50 mg × 10s	15.25	17.77	1.17	291.01	19.08	108.48	7.11
Buspirone	–	5 mg × 10s	4.05	89.69	22.15	150.60	37.19	168.51	41.61
ANTI-CANCER									
Mitoxantrone	–	2 mg/ml × 10 ml	446.25	N.A.	–15,176.64	34.01	7,921.64	17.75	
Carboplatin	–	150 mg	746.25	N.A.	–	N.A.	–	3,608.26	4.84
Vincristine	1982	1 mg Vial	28.80	323.16	11.22	1,068.37	37.10	542.92	18.85
Vinblastine	1982	10 mg Vial	108.00	333.85	3.09	1,102.01	10.20	541.87	5.02
Estranustine	1984	140 mg	16.95	N.A.	–	N.A.	–	550.30	32.47
Etoposide	1987	100 mg injection	158.60	N.A.	–	3,612.47	22.78	750.93	4.73
ANTI-DEPRESSANT									
Fluoxetine		2 mg × 10s	29.00	618.76	21.34	517.83	17.86	562.41	19.39
MISCELLANEOUS									
Genfibrozil	1989	300 × 100s	341.00	178.56	0.52	1,294.89	3.80	1,263.84	3.71

"Times costlier than Indian price

Source: Patent Regime in TRIPS: Critical Analysis, National Working Group on Patent Laws, New Delhi, 1993.

Sources for prices: US Prices-Annual Pharmacists reference 1991; UK Prices-UK MIMS Nov 1991; Pakistan Prices—OIMP Annual 1991-92.

Notes: Wholesale prices have been considered; Exchange rates considered for conversion: 1 US $ = Rs 30.86,1 Pound Sterling - Rs 52.66 and 1 Pakistan Rupee - Rs 1.24.

Table 6 Introduction of new drugs in country of origin and in India

Drug	Year of launch	
	World	India
Ranitidine (anti-ulcer)	1983	1985
Cimetidine (anti-ulcer)	1976	1981
Norfloxacin (anti-bacterial)	1984	1988
Astemizole (non-sedating anti-histamine)	1986	1988
Acyclovir (anti-viral)	1985	1988
Salbutamol (bronchodilator)	1973	1976
Mebendazole (anti-helmintic)	1974	1978
Ibuprofen (anti-inflammatory)	1967	1973
Lorazepam (anxiolytic)	1977	1978

mation, or misuse of intellectual property developed by others. Most of the basic information obtained by wholly Indian-owned drug firms about new products comes from published material or patent offices. It is well known that this information is never quite complete and usually contains a critical gap. Indian companies and laboratories have now sufficiently mastered organic chemistry to be able to produce the same molecules by using different, often more efficient and cost-effective, methods of synthesis. The Patents Act 1970 encourages such innovation and prevents monopolies. Furthermore, there are many examples of wholly Indian firms developing new products and processes *ab initio*. Table 6 shows the new drugs that Indian companies are producing and the lag before they have been introduced to the Indian market. In all the cases, the span is reasonably short. Table 7 shows the relative contributions of the national and foreign sectors in 1975 and 1987.[12]

The TNC-controlled firms, by contrast, have typically been loath to transfer technology and have refused to introduce new products into the Indian market, even when their principals have developed them.[13] A particularly obnoxious TNC malpractice has been to create shortages of essential drugs by restricting their output. This has happened periodically in the case of vitamin A (Roche), anti-leprosic dapsone (Burroughs Wellcome), the anti-glaucoma drug pilocarpin, and the vasodilator salbutamol.

The TNCs' failure to manufacture their principal new products without long delays means that Indian patients remain deprived of access to effective medicines until Indian firms begin to make them. This is particularly true of the new-generation 4-quinolone and cephalosporin classes of antibiotics, but it also holds true for salbutamol, mebendazole and several other medicines of particular relevance to Indian needs. Indeed, almost all recent examples of innovation in drugs in the country are attributable to wholly indigenous initiatives. (See Table 6.)

The TNCs have, however, always been strident in their criticism of the drug policy. They have lobbied fiercely against DPCO 1979, both directly at the level of individual firms, and through the Organisation of Pharmaceutical Producers of India (OPPI), which is affiliated at the international level to

Table 7 Relative contribution of national and foreign sectors

	1975		1987	
	Bulk drugs (%)	Formulations (%)	Bulk drugs (%)	Formulations (%)
Foreign sector	38	50	18	40
National sector	62	50	82	60

The following are the major bulk drugs manufactured in India:

albendazole	dextropropoxyphene	mebendazole	pyrazinamide
amoxicillin	diazepam	methacarbamol	quinine
ampicillin	diphenylhydantoin	methyldopa	rifampicin
aspirin	doxycycline	metoprolol	salbutamol
atenolol	emetine	metronidazole	sodium valproate
betamethasone	erythromycin	nalidixic Acid	sulfamethoxazole
cephalexin	ethambutol	nifedipine	terbutaline
chloroquin	frusemide	nitrofurantoin	theophylline
chlorpropamide	furazolidone	norfloxacin	tinidazole
cisplatin	gentamycin	paracetamol	trimethoprim
clonidlne	glybenclamlde	piroxicam	vinblastine
cloxacillin	hydrochlorothiazide	prednisolone	vincristine
codeine	ibuprofen	propranolol	
danazol	insulin	pyrantel pamoate	

the powerful Pharmaceutical Manufacturers' Association. This lobbying has produced dividends in the form of a severe modification of the original scheme of controls. In 1986, the government announced not a new policy but what it called 'measures'—in effect a new diluted or liberalised policy. In 1987, it announced an altogether new DPCO. In this effort to replace DPCO 1979, the OPPI was not alone. Despite its differences with them, it received support from the Indian Drug Manufacturers' Association (IDMA), representing the indigenous sector, and the Pharmaceuticals and Allied Dealers' Association, representing the wholesale and retail trade. The dilution of DPCO 1979 in relation to DPCO 1987 can be made evident with a point-by-point comparison of the two Orders on some of the major issues as is evident from Table 8.

Sabotage of DPCO 1979 and DPCO 1987

The transition from DPCO 1979 to DPCO 1987 meant a further retreat from some of the policy goals set in the Hathi Committee's report. But even that did not satisfy industry, which did to DPCO 1987 precisely what it had done to its predecessor. It bypassed, violated, misused, or sabotaged its provisions in every conceivable way. Thus, the profit before tax of the major drug firms increased from Rs 527 million in 1987-88 to Rs 1,195 million in 1991-92. As Tables 9-11 demonstrate, all figures belie the industry's claim—based on a highly unrealistic and unrepresentative price index—that,

Table 8 The dilution of the Drug (Price Control) Order (DPCO) 1979 in the DPCO 1987

	DPCO 1979	DPCO 1987
	i. The government was required to take into consideration the average cost of production of a bulk drug and allow a reasonable return on net worth.	The government fixes different prices for different manufacturers or a weighted average price. What could happen to the difference between the prices of the producer of a bulk drug and the weighted average has not been considered.
	ii. There were provisions for fixing the retention price of a bulk drug for individual manufacturers and a common price for the sale of a bulk drug.	No corresponding provision.
	iii. Manufacturers of a new bulk drug were required to give details in a prescribed form within 14 days of commencing of production.	No corresponding provision.
	iv. The government had the power to fix the import price of a bulk drug.	No corresponding provision.
	v. The government had the power to fix retention prices for bulk drugs indigenously manufactured as well as imported.	No corresponding provision.
	vi. The normal course for a manufacturer of formulations was to seek a price revision when there was a change in the price of the bulk drug.	No corresponding provision.
	vii. No corresponding provision.	Manufacturers can revise the price of non-scheduled bulk drugs after providing details to the Government.
viii.	All bulk drugs produced exclusively in India for the first time through indigenous research were exempt from price control for a period of five years.	No corresponding provision.
ix.	The limit on mark-ups was 40 per cent for category 1,55 per cent for category II, and up to 100 per cent for category III formulations.	The new mark-up limits are: 75 per cent for new category I and 100 per cent for category II formulations.
x.	There were provisions for Drugs Price Equalisation Accounts.	No corresponding provision.

thanks to tight price controls, the prices of medicines have risen more slowly than the general price level, and hence that profits have been eroded.[14] **By** the late 1980s, the industry's profits were booming, share values showed a steady upward curve, and there was a profusion of new projects even as exports rose. These were all indications of a real pharmaceuticals boom.

Table 9 Growth of profits before tax (PBT) and sales of top drug companies (figures in Rs million)

	1987-88			1990-91			1991-92		
Company	Sales	PBT	Ratio (%)	Sales	PBT	Ratio (%)	Sales	PBT	Ratio (%)
Ranbaxy	111.80	3.25	2.91	260.41	16.41	6.30	334.10	23.40	7.00
Alembic	74.65	0.92	1.23	139.19	4.31	3.10	168.00	5.10	3.04
Ambalal Sarabhai	162.60	2.52	1.55	136.28	–	–	228.40	-16.90	–
Unichem	39.00	0.80	2.05	66.77	2.84	4.25	83.20	4.80	5.77
Glaxo	230.10	16.50	7.17	410.93	26.25	6.39	428.60	21.60	5.04
Pfizer	73.40	1.34	1.83	118.83	8.17	6.88	138.20	4.60	3.33
Hoechst	158.80	1.76	1.11	264.00	13.20	5.00	261.10	12.10	4.63
Boots	55.30	6.32	11.43	85.95	11.58	13.47	104.60	12.90	12.33
Parke Davis	69.60	2.96	4.25	92.39	7.23	7.82	104.40	7.80	7.47
German Remedies	39.00	1.12	2.87	70.95	4.04	5.70	67.40	2.60	3.86
Eskayef	62.80	9.55	15.21	140.00	14.12	10.09	100.80	21.10	20.93
Roche	33.90	1.40	4.13	49.40	1.52	3.08	58.10	1.60	2.75
Sandoz	98.00	1.76	1.80	203.15	14.19	6.99	206.20	13.40	6.50
Abbott	20.80	-0.20	–	32.60	1.02	3.13	38.40	0.90	2.34
Infar	23.00	2.71	11.78	44.67	4.14	9.26	42.70	4.50	10.54
Total	1252.75	52.71	4.21	2,115.52	129.02	6.10	2,364.20	119.50	5.05

Source: Calculated from data in *Business Standard,* June 30, 1990, and *The Economic Times.*

Table 10 Ratio of profits after tax (PAT) to net worth of top companies (figures in Rs million)

	1987–88			1988–89		
Company	Net worth	PAT	Ratio (%)	Net worth	PAT	Ratio (%)
Ranbaxy	18.04	2.73	15.13	34.11	4.46	13.08
Alembic	18.22	0.78	4.28	19.33	1.60	8.28
Ambalal Sarabhai	34.89	2.52	7.22	33.09	3.56	10.76
Unichem	8.48	0.59	6.95	8.40	0.16	1.90
Glaxo	56.43	9.97	17.66	78.92	10.13	12.84
Pfizer	27.37	0.32	1.17	27.19	1.78	6.55
Hoechst	58.47	1.76	3.01	59.56	3.61	6.06
Boots	14.86	3.21	21.60	16.86	4.42	26.22
Parke Davis	14.11	1.77	12.54	14.67	2.30	15.68
German Remedies	8.20	0.93	11.34	8.59	0.57	6.64
Eskayef	21.76	5.79	26.60	35.22	6.17	17.52
Roche	10.20	1.12	10.98	11.04	1.57	14.22
Sandoz	24.98	1.56	6.24	25.73	2.07	8.05
Abbott	3.87	-0.20	–	4.60	0.70	15.22
Infar	7.23	1,25	17.28	8.25	1.32	16.00
Total	327.11	34.10	10.42	385.56	44.42	11.52

Source: Business Standard, June 30,1990.

Table 11 Dividends paid by top companies in 1991-92

Company	Dividend (%)	Company	Dividend (%)
Ranbaxy	25.00	Parke Davis	10.00
Alembic	16.00	German Remedies	9.00
Ambalal Sarabhai	-	Eskayef	10.00
Unichem	30.00	Roche	5.00
Glaxo	18.00	Sandoz	16.00
Pfizer	10.00	Abbott	–
Hoechst	20.00	Infar	30.00
Boots	34.00		

Source: The Economic Times

As can be seen from Table 9, both the profits and turnover of drug companies show a steady increase. Drug companies have tried to cloud the issue by claiming that a four to six per cent ratio of profits to sales is not adequate, and is lower than in other industries. However, inter-industry comparisons of this kind are meaningless. The pharmaceutical industry is not capital intensive. The Committee on Category II Drugs, Government of India, 1987 says 'compared to other industries, this is much less capital intensive.... Capital invested for drugs & pharmaceutical industry ... works out at only Rs 94,000 per worker; for petrochemicals and synthetic fibres, capital invested in labour employed works out at Rs 6.1 million, Rs 3.9 million and Rs 2.4 million'.

Table 10 shows a rate of return of almost 12 per cent in the period 1986-88, that is before the actual implementation of DPCO 1987. Since then the rate of return has risen.

Meanwhile, hopes that the government would move towards a drug policy based on the concept of essential drugs, and take steps to promote rational, unbiased drug information receded further. Indeed, in 1983 the government moved further towards liberalisation by constituting a wholly new National Drugs and Pharmaceuticals Development Council (NDPDC). This was part of the newfangled concept of industry promotion committees, which were without statutory sanction, and dominated for the most part by manufacturers' and traders' nominees. There was virtually no independent component representing either consumers or unaffiliated and independent pharmacologists and other medical practitioners. Rather, there were highly politicised, pro-industry or industry-coopted officials from so-called 'Medical Associations'.

The NDPDC's report is a poorly drafted, incoherent document full of *non sequiturs* and self-serving recommendations. Its acceptance by one of the most right-wing ministers in the Rajiv Gandhi government, which was itself keen to liberalise the economy and build strong links with industry, led to the reversal of some significant steps in earlier drug policy. It negated ad-

vances pertaining to licensing, the scope of price control, and trade commissions, and effected a modification of the list of products in Categories I, II and III.[15] The Council's report is a product of haggling and bargaining to effect major changes in policy parameters under the guise of 'simplification of procedures'.[16]

The report was followed in 1987 by the appointment of another committee, headed by Vijay Kelkar, chairman of the Bureau of Industrial Costs and Prices. Its brief was to evolve a series of formulas for exempting several drugs from price control. While some of these formulas seemed fairly innocuous—for example, exempting drugs manufactured by a multiplicity of firms—they were not applied consistently; nor did the formula take into consideration such factors as market imperfections, cartelisation, the high premium on early entry into a product line leading to monopolies, and high-pressure selling tactics that distort competition. Some changes were downright irrational. One such irrational change was the exempting of drugs—such as the new-generation cephalosporins—that currently have a low annual turnover (under Rs 5 million) but which are either significant for (all-important) health reasons, or likely to increase their market share as their use spreads.[17]

In some cases, the changes were inspired by unethical considerations and lobbying of corrupt officials. One glaring instance was the case of the psychotropic drug, diazepam, widely used as a tranquilliser and pre-operative sedative and manufactured by an Indian firm with high political connections. The firm disingenuously pleaded that although diazepam was a component of the national mental health programme, it was not really a 'serious' drug, since it was taken by a large number of affluent people for frivolous reasons. Hence, they argued, it should be exempted from price control. The result was startling. Diazepam (leading brand name, 'Calmpose') prices have risen by 243 per cent over the period 1988-94. (See Table 12.)

The abolition of price control on some drugs was accompanied by non-implementation of the Drug Price Equalisation Fund. This meant, quite simply, virtually giving up the attempt to collect dues from importers and traders and to get them to surrender their windfall profits (due to the use of cheaper intermediates, rather than manufacturing from the basic stage for which the DPCO fixes the price). As of 1992, various TNC subsidiaries owed a total of between Rs 4 billion and Rs 5 billion to the Drug Price Equalisation Fund, not counting interest.[18]

Table 12 The rising price of Calmpose in different formulations 1986-94

Formulation	Price					
	1986	1988	1990	1992	1993	1994
Injection 10mg per 2ml (pack of 10 amps)	21.32	21.44	26.04	29.97	60,00	60.00
Syrup 2mg per 5 ml (60ml bottle)	8.22	8.27	8.27	11.70	16.80	16.90
Tablets 5mg per tablet (strip of 10)	2.99	3.28	3.89	7.30	8.00	8.00
Capsule 10mg per capsule (pack of 10)	4.43	4.46	4.46	10.42	11.88	11.88

Source: Monthly Index Of Medical Specialities, India, various issues.

Emergence of public/NGO protest

This dilution, corruption and distortion of the original Drug Policy of 1978 and the DPCO did not go uncontested. The 1980s saw the emergence of articulate voluntary groups, NGOs and consumers' forums, and the launch of some successful campaigns, through the Drug Action Network and other coalitions, to demand controls on drug prices and a ban on harmful and irrational drugs. The NGOs have tried to enlist the help of public-spirited doctors and trade-union activists in the pharmaceuticals industry, including groups of medical sales representatives employed by the drug companies to make extravagant claims about their products and promote them in ways that have long attracted criticism.

Thanks to some insider information, NGOs are now able to document precisely how the industry unethically distorts information about drugs. For example, the industry has moved from distributing printed literature which the doctor might keep, to displaying posters which contain such blatant lies that they are quickly taken away after the medical representative's hard-sell performance is over.[19]

The new NGO networks are also able to provide objective and unbiased information on drugs. This has helped them achieve some success in having a few toxic drugs banned, including a high-dose estrogen-progesterone combination, EP Forte. They have also created a remarkable, albeit small, space in which critical public opinion can survive and thrive. And in some cases, as in Maharashtra in Western India, one of the main centres of drug production, they have run independent checks on the quality of products on the market and helped the FDA to weed out spurious or obsolete products.

Recent NGO initiatives and FDA actions have certainly succeeded in dispelling to some extent the erroneous impression that TNC products are better or more reliable in quality than those of Indian companies. In late 1993 and 1994, for instance, the Maharashtra FDA took penal action against Glaxo, asking it to shut down a major old plant in central Bombay for ten days. Glaxo protested against the order and declared that it would close the facility altogether.[20] Table 13 provides a list of selected TNCs whose drugs have been found to be substandard. Table 14 lists some drugs available in

Table 13 Selected TNCs which produced substandard drugs

Name of company	Country of origin	Substandard samples found
Bayer	FRG	13
Boots	UK	9
Burroughs Wellcome	UK	8
CibaGeigy	Switzerland	4
E Merck	FRG	2
Glaxo	UK	10
Hoechst	FRG	7
Merind (MSD)	USA	11
Pfizer	USA	9
Roche	Switzerland	5

Source: UNI Economic Services, Vol III, No. 3, p. 5, January, 1981.

India in 1986 even though they were banned in the manufacturing company's home country.

However, the NGO initiatives are still too weak to be able to effect policy changes and persuade the government to change course. The nature and power of the entrenched interests in the industry, and its influence with the government within the new right-wing neo-liberal policy environment, are such that it will be extremely difficult for small initiatives to be effective in the absence of some sympathetic change at the level of policy-making.

India's New **Economic Policy**

The year 1991 saw the inauguration of a new economic policy paradigm in India. Under Narasimha Rao and Manmohan Singh, the government adopted the agenda of long-term Structural Adjustment, coupled with a short-term strategy of macroeconomic stabilisation dictated by the World Bank and the IMF. Thanks to long years of state profligacy, runaway growth in unproductive spending, and reliance on an elitist, consumption-led,

Table 14 Selected drugs available in India in 1986 but banned in country of origin

Name of drug	Company	Country of origin
Avil expectorant	Hoechst	FRG
Soventol expectorant	Boehringer Knoll	FRG
Piriton Expectorant	Glaxo	UK
Periactin	Merind (MSD)	USA
Ostocalcium B 12	Glaxo	UK
Amoebiotic	Pfizer	USA
Novalgin	Hoechst	FRG
Baralgan	Hoechst	FRG
Suganril	Ciba Geigy	Switzerland

Source: A Rational Drug Policy, The Voluntary Health Association of India, New Delhi, 1986.

import-intensive, energy-consuming growth model, India found itself in the midst of a severe balance of payments crisis in mid-1991. The central government's fiscal deficit shot beyond 8.4 per cent of gross domestic product, the external debt mounted to US $70 billion, and debt servicing claimed about a third of all export earnings. By July 1991, the country's foreign exchange reserves, depleted by the withdrawal of 'hot money' deposits by expatriate Indians, had shrunk alarmingly—leaving not enough even to pay for a month's imports.

Manmohan Singh used the short-term crisis to push through a long-term agenda, not so much of stabilisation (through the usual mix of state spending cutbacks, monetary contraction and 'austerity') as of Structural Adjustment. This involves extensive deregulation, and indiscriminate dismantling of controls on entry into industry groups and of anti-monopoly laws. It results in marketisation, reducing protection for domestic industry across the board, freer entry for foreign capital, the separation of technology inputs and technical collaboration from foreign investment, and privatisation of the public sector.

While a good deal of this was linked to 'conditionality' for a stand-by loan from the IMF contracted in 1991, some of it was not. Singh has also promoted his own neo-liberal agenda. In the last two years, for instance, he has unified the exchange rate of the rupee and made it convertible on the current account—something that even the newly industrialising countries (NICs) of East and Southeast Asia had not done a full decade after stabilisation and after registering major gains in output and productivity. Similarly, in his first two years as Finance Minister, he made savage cuts in social sector spending, which so embarrassed even the World Bank that it offered funds to him to restore the cuts.

The new policy generated a great deal of euphoria in élite circles in India and abroad, although it is unpopular and viewed with suspicion by large numbers of ordinary Indians. The latter see it as a charter of servitude and an example of a development model that has nothing to do with their needs, the country's resources, or considerations of social equity.[21] In the new policy environment, the predominant business view—and increasingly the official view, too—worship *laissez faire* and is against any kind of state intervention. It is also fervently ideological in rejecting the notion of governing or directing market forces, even where questions of life and death, or high social priorities, might be involved. The market, it is argued, must be allowed to determine the 'appropriate' price level and influence the 'right' investment choices under all conditions.

Where specific or minor exceptions are made, they too get subordinated in practice to this dominant, currently fashionable, view. Thus, the Industrial Policy Statement of 1991 did retain licensing for 18 industry groups, including pharmaceuticals and hazardous chemicals. In practice, however, the list has shrunk and so have the requirements for licensing. Clearances are granted quickly, without a detailed examination of project proposals, their technological content, relevance and need, or their health and environmental impact.

The office of the Drug Controller has been downgraded and its occupant is so concerned not to prove an obstacle to the great liberalisation programme, which is supposed to open new vistas of prosperity and growth, that he has scarcely applied his mind to any of the horrifying problems that mark the pharmaceuticals sector: between 30,000 and 60,000 drugs; a profusion of irrational and therapeutically questionable products; the lack of availability of medicines for national health programmes (e.g., TB, leprosy and blindness control); unethical promotional and prescribing practices, and the granting of 'provisional' clearance to products without adequate trial, which is often extended year after year.

The picture at the end of 1993, then, was of an unbalanced, rapacious drug industry that typically charges mark-ups of 200, 400, even 700 per cent on most drugs. It is less and less relevant to and focused on popular needs, less and less regulated in socially desirable ways, and more and more able to put pressure on the government to postpone the formulation and announcement of a new drug policy. Between 1991 and 1993, the government delayed such an announcement no fewer than ten times. It did present a 'Background Note on Review of Drug Policy 1986' before Parliament in mid-1993, which was followed by a robust debate in November of that year. The government promised to modify the statement and announce a new policy within two months, after giving due consideration to the views expressed by MPs. It has yet to do so, partly because of indecision, but largely because of industry pressure.

It is widely believed that it proposes to prune the number of drugs under price control to 50 or 60 common compounds, many of them used mainly in public health programmes. It also intends to do away with parameters specifying the bulk drugs:formulations ratio to which different sectors of the drug industry must conform in order to ensure that they do not only make fast-selling formulations with no input into technology.

By thus limiting the scope of price control, and restricting it to drugs for

Table 15 Rise in prices of drugs July 1990–May 1992 (selected drugs showing more than 100 per cent rise)

Product	Description	Pack	Price in July 1990 (Rs)	Price in May 1992 (Rs)	Percentage rise
Aquaviron	Hormonal prep.	1 ml	7.19	19.39	169.68
Duphastol	Hormonal prep.	10 tab.	40.00	85.68	114.20
Ovral	Oral contraceptive	21 tab.	8.00	16.56	107.00
Premarin	Hormonal prep.	20 tab.	22.60	50.51	123.50
Pitocin	Obstetric prep.	1 amp	1.08	2.42	124.07
Alprax	Tranquiliser	10 tab.	3.20	6.41	100.31
Alzolam	Tranquiliser	10 tab.	5.50	11.60	110.91
Anatensol	Tranquiliser	10 tab.	2.45	6.00	144.90
Zenax	Tranquiliser	10 tab.	2.20	6.00	172.73
Diligan	Anti-vertigo	4 tab.	0.90	2.80	211.11
Marzine	Anti-emetic	4 tab.	1.10	2.22	101.82
Siquil	Anti-emetic	10 tab.	3.00	6.00	100.00
Inderal	Cardiovascular	10 tab.	1.73	3.70	113.87
Angised	Cardiovascular	100 tab.	9.98	30.50	205.61
Nicinal	Cardiovascular	10 tab.	2.14	7.04	228.97
Natrilix	Cardiovascular	10 tab.	19.00	39.62	108.53
Longifene	Anti-histamine	100 ml	4.63	13.66	195.03
Alupent	Anti-asthma	1 ml	1.45	4.12	184.14
Hythaltone	Diuretic	10 tab.	9.33	26.04	179.10
Xipamid	Diuretic	10 tab.	7.42	17.24	132.35
Ralcidin	Cough and Cold	10 tab.	2.49	6.04	142.57
Selvigon	Cough and Cold	10 tab.	6.99	16.29	133.05
Triominic	Cough and Cold	100 ml	9.80	27.32	178.78
Aerosporin	Antibiotic	1 vial	60.54	269.60	345.33
Chloromycetin	Antibiotic	6 caps.	9.06	21.23	134.33
Enteromycetin	Antibiotic	12 caps.	8.31	20.40	145.49
Eradaci	Antibiotic	1 vial	91.64	188.91	106.14

Source: *Economic & Political Weekly,* August 1–8, 1992.

which there is a multiplicity of manufacturers, the government will have made a mockery of the original rationale of preventing profiteering on illness. The price control list will exclude precisely those drugs for which the markets are monopolistic, and where there is price-rigging by cartels, or other restrictive practices.

One-and-a-half decades after its incomplete, half-hearted and uncertain experiment with a National Drug Policy, India is now back to a situation dominated by the avarice and rapaciousness of unimpeded entrenched interests. The prices of most important drugs doubled or trebled between 1990 and 1992, as shown in Table 15.[22] Going by stock-market indications as well as private assessments, prices and profits must be even higher in 1994.

The principal limitation on the industry's growth is of course the size of the home market, which is in turn itself limited by mass poverty, illiteracy, lack of access to elementary health care, and a network of primary health centres

(PHCs) that is about to collapse for want of funds and medicines. (Recent surveys show that not even one-tenth of the drugs meant to be stocked in the PHCs are available there.)

However, here too, the industry may have found a short-term way of bypassing the long-term limitation: viz., through the expanding export market. India's annual exports of pharmaceuticals and related products, which were under US $50 million until the mid-1980s, are now moving towards the US $500 million mark. Their composition has changed from plants, raw materials and low-technology drugs, to sophisticated, state-of-the-art, high value-added products. Indian manufacturers are believed to have captured a sizeable chunk of the generics market in the USA, itself a fifth of the total in national sales. The prices of new drugs in India tend to be between 30 and 200 per cent cheaper than retail prices in the USA and some Western European countries. Given this competitiveness, these exports are likely to grow, making India a major player in the world pharmaceuticals market.[23]

The potential for export growth has a negative side: it could afford the drug industry the luxury of élitist practices in the domestic market. That is, it could cater to the relatively affluent who can afford the high price of drugs—perhaps between a fifth and a quarter of the population—while neglecting the mass of the people.

This dualism is of course identical to what is now happening in other sectors of Indian industry, the economy, and society as a whole: greater income inequality; increased polarisation between classes; widening chasms between a minority of 'developed', relatively affluent, fast-growth enclaves, on the one hand, and highly populous, depressed, stagnant or low-growth regions, on the other. The consequences of this dualism for health are bound to be more damaging than for the economy as a whole. They could neutralise some of the major gains India has made over the past four-and-a-half decades in reducing mortality and morbidity rates and in extending life-expectancy. The magnitude of such a loss is too horrifying to contemplate. India, which seemed two decades ago to be moving towards an alternative, people-friendly approach to pharmaceuticals, now seems to offer no more than a grim and sordid prospect for the majority of its people. Dualism is indeed fraught with fatal consequences for the poor.

GATT: the final nail in the drug policy's coffin?

As if this were not bad enough, the Indian government decided, in the face of stiff resistance from the entire political opposition, as well as dissidence in its own ranks, to sign the new Uruguay Round international trade agree-

ment under GATT (since replaced by WTO—World Trade Organisation). This is probably the most divisive and invasive global economic treaty ever signed. It seriously erodes the sovereign decision-making power of national governments in many fields, including intellectual property rights, agriculture, food subsidies, control over plant genetic resources, and decisions about granting plant-breeders' rights.

By signing the agreement, without even trying to fight and amend it in Southern and North-South forums, New Delhi has committed itself to effecting far-reaching changes in India's IPR regime. This will directly affect the pharmaceuticals industry in a variety of ways: product patents will return and their duration will be extended to 20 years (in place of seven, as at present), thus strengthening monopolies; importation will be treated as equivalent to working the patent; compulsory licensing will be all but abolished, and the burden of proof in charges of theft of a new invention will be reversed.

The final agreement (Final Act, as it is called) leaves little room for manoeuvre or negotiation on the issue of patents: 'There is a general obligation to comply with the substantive provisions of the Paris Convention'—a treaty that India has resisted signing for decades despite enormous pressures and inducements to do so. It adds anew and dangerous clause. Anew substance (product) can first be patented for 20 years. After that, a process patent could be taken out for another 20 years'. According to one interpretation, it might even be possible to extend this protection for a further 40-50 years in the case of more than one process of making the same substance!

The Final Act makes it mandatory for India to shift from process-only patents in pharmaceuticals and chemicals to full-fledged product patents over a period of ten years. However, India must immediately institute a system of exclusive marketing rights (EMRs), which are also monopoly rights, much earlier—as soon as WTO comes into effect, which it did on January 1, 1995. Under this 'transitional' system, a company gets the monopoly privilege to market a new product provided it has obtained a product patent or applied for one, and also secured marketing approval from the relevant drug and food authority from any WTO member-state. The government is obliged to grant such EMRs so long as these two conditions are fulfilled. However, several WTO member-states have no FDAs worth the name, nor even proper procedures for evaluating the eligibility and safety of a new drug for full-scale marketing. Some lack a proper patent law. Hence, this provision is liable to be misused to create monopoly rights, especially in respect of new TNC-patented largely 'me-too' drugs.

In keeping with these WTO obligations. New Delhi put an EMR system in place in January 1995 and moved a Bill to amend the Patents Act through the Lower House of Parliament. But, certain that it would be defeated in the Upper House—where the ruling party is in a minority—the government hastily withdrew it in early 1995. The legislative logjam has created an anomalous situation. It is far from clear how this might be broken.

The IPR regime that is being put in place entails the destruction of the level playing-field that allowed Indian firms to compete and grow. The new tilt will strongly favour the TNCs and their subsidiaries and make innovation difficult, if not altogether impossible. Most important, it will raise pharmaceutical prices to extremely high levels. More than half of the output of the Indian industry consists of drugs to which strict patent protection will be extended under the new dispensation. Industry sources expect their prices to rise substantially as TNCs start charging globally comparable rates to those that prevail in countries, such as Pakistan, where an unfavourable, product-patent based IPR regime exists. (See Table 5.) It is noteworthy that the DPCO does not extend to imports at all. Hence, TNC subsidiaries can import any drug from their parent companies with impunity and legally charge any price they like.

The Uruguay Round agreement represents nothing short of a disaster from the point of view of most Indian consumers. In conjunction with Structural Adjustment, it will promote a new social, economic and public policy environment that subjects the notion of a need-based, National Drug Policy to a four-pronged attack. First, as privatisation of health care grows, the public health care system will suffer further erosion. This will weaken or undermine public health programmes and delegitimise the idea of according priorities in the health field that are not market-dictated, but need-based.

Second, the government seems all set to relinquish such control as it has over the licensing of pharmaceutical products and registration of drugs. Indeed, after the dismantling of the office of the Director General of Technical Development, there are few mechanisms left even to evaluate licensing criteria. This will mean the rampant growth of irrelevant, 'me-too', useless and dangerous drugs: the operation of the law of the jungle in a vital field.

Third, the government is preparing to free all but 50 to 60 drugs from price control. At present, price control extends to 265 drugs, reduced from 360. This, along with a new IPR system under GATT, will mean considerably higher prices and hence reduced availability of medicines for the mass of the population.[24]

And fourth, under the ideological impact of the new economic policy, as it is understood and interpreted by the Indian élite, the very concept of an essential drug list is in danger of being jettisoned altogether. So, too, is the rationale of limiting the number of pharmaceutical products to a reasonable figure based on need, and of evaluating the need for medicines in terms of the prevalent pattern of morbidity and mortality in the country.

The new paradigm assumes that non-social, non-political, 'neutral' agencies and criteria, such as market forces, should determine product choices and define what is essential and what is not. Such choices are necessarily exogenous to the concept of public or social control of, and intervention in, areas of economic activity which are vitally related to human survival and well-being. A wholesale ideological shift to the new market paradigm is not compatible with a National Drug Policy or a list of essential drugs, or even with price controls. These all pertain to *governing* the market, acting in spite of it, as distinct from promoting it or facilitating its working.

The prospect, then, is dismal. Whatever India's post-1991 new economic policy does for the growth of the country's economy and industry—and it has done precious little so far—it is certainly likely to claim the very concept of a drug and health policy among its first victims. Two decades after India launched its tentative effort at a National Drug Policy, its decision-making élite is all set to hammer the last nail into its coffin.

1. *Industrial Policy Resolutions,* The Government of India, 1948 and 1956.
2. In 1953, the Government of India set up the Pharmaceutical Enquiry Committee. The Committee made certain recommendations and observed that the existing pharmaceutical industry in India could be considered almost non-existent when compared with the industry in the UK and the USA. After the War ended, the pharmaceutical industry developed along with a robust export market. But this happy position did not continue for long. Foreign firms soon replaced Indian products in the export market. The indigenous drug industry faced problems even within the country. For details, see the *Report of The Committee on Drugs and Pharmaceuticals* (commonly known as the Hathi Committee Report), Government of India, 1975.
3. Dhawan, R. *et al.,* 'Whose interest? Independent India's patent law and policy', in *Conquest by Patent: On Patent Law and Policy,* occasional paper presented at the National Seminar on Patent Laws, National Working Group on Patent Laws, New Delhi, 1990.
4. Kochanek, S., *Business and Politics in India,* University of California Press, Berkeley, 1974; and Kidron, M., *Foreign Investments in India,* Oxford University Press, Oxford, 1965.

5. In-depth studies of the old patent system by two committees, one headed by Justice Bakshi Tek Chand and the other by Justice Rajagopal Ayyangar, indicated that there was evidence of misuse of patent protection by foreign companies to corner markets. The committees also revealed that more than 90 per cent of the patents in registered India by foreigners were not being worked in the country. Most drugs were imported from abroad at extremely high prices. For a detailed discussion, see Keayla, B.K., *Patent Regime: Indian Experience and Options Available,* National Working Group on Patent Laws, New Delhi, 1990.
6. Shah, P., 'Hazardous drugs and their promotion—history and present status', in Amit Sen Gupta (ed.), *Drug Industry and the Indian People,* Delhi Science Forum, New Delhi, 1986.
7. Majumdar, J.S., 'Background paper', in Amit Sen Gupta (ed.), *Drug Industry and the Indian People,* Delhi Science Forum, New Delhi, 1986.
8. See Dhawan, R., 'A monopoly by any other name: an introduction', in *Conquest by Patent: On Patent Law and Policy,* occasional paper presented at the National Seminar on Patent Laws, National Working Group on Patent Laws, New Delhi, 1990.
9. See Majumdar, J.S., 'Background paper', in Amit Sen Gupta (ed.), *Drug Industry and the Indian People,* Delhi Science Forum, New Delhi, 1986. Majumdar points out that Indira Gandhi called for the abolition of patents for medical discoveries while addressing the 156-nation World Health Assembly at Geneva on May 8, 1981. However, during her lifetime, the Government of India started to backtrack on patent rights.
10. For a more detailed discussion, see Ekbal, B. (ed.), *A Decade After the Hathi Committee,* Kerala Sastra Sahitya Parishad, Sivakashi, 1988.
11. Bidwai, P., 'For a rational drug policy: control over industry not enough', *The Times of India,* October 25, 1985, and 'Control of medicines: key to a rational drug policy', *The Times of India,* November 9, 1985. The problem with the Indian drug industry is too much—not too little—freedom to decide on the parameters of drug production, such as what drugs to make and sell, to what purity and in what combination, what kind of promotional strategy to employ, and what claims to make about efficacy and such factors as safety. The result is that the Indian drug industry is burdened with somewhere between 30,000 and 60,000 superfluous, useless or positively harmful drugs.
12. See also Hamied, Y.K., 'The Indian Patents Act, 1970 and the pharmaceutical industry', paper presented at the National Seminar on Patent Laws, New Delhi, November 22, 1988.
13. Some of the successful drugs developed by TNC principals during this period were cimitidine (anti-ulcer), rifampicin (anti-TB), tetramisole and thiabendazole (anti-worms), indomethacin (anti-inflammatory), methyldopa (cardiovascular), ethambutol (anti-leprosy). None of these has been introduced into India. For a more complete account, see Bidwai, P., 'Blow to indigenisation', *The Times of India,* June 22, 1985.
14. Bidwai, P., 'Myth of low prices, profits', *The Times of India,* June 25, 1985.
15. Under DPCO 1979, drugs were divided into four categories for the purpose of

price control. Category I and II comprised 'essential drugs'. Category IV was exempted from price control altogether. The mark-ups on the first two categories were 40 and 55 per cent respectively. And the mark-up on the intermediate Category III was up to 100 per cent. Together, the three categories comprised between 260 and 360 drugs at different points of time.

16. Bidwai, P., 'An irrational priority list', *The Times of India,* June 23, 1985. The NDPDC recommended that only 95 drugs be included in the priority list under price control instead of 360, as before. Its priority list also excluded several essential drugs that ought to have had a high priority in any scheme of providing an adequate number of medicines to a large number of consumers at reasonable prices. The NDPDC left out of price control at least ten major products whose annual retail sales are in excess of Rs 10 million, another 15 whose sales are between Rs 5 million and Rs 10 million, and more than 20 with sales between Rs 2 million and Rs 5 million.
17. In view of the fact that the availability of the anti-leprosy drug dapsone had declined very substantially since it was not available in the international market, the Kelkar Committee wanted to keep it outside of price control. Since it was likely that the drug would have been in Category I, the Committee decided to keep it in Category II, which enjoys a higher mark-up. *Report of the Committee on Category I I Drugs,* Government of India, New Delhi, 1987.
18. For a more complete account, see Bidwai, P., 'For a rational drug policy—When decontrol is no more than dogma', *The Times of India,* March 13, 1992. Thanks to the non-implementation of the Drug Price Equalisation Fund, consumers have been cheated of between Rs 400 and Rs 500 million. The government itself has admitted that it was owed Rs 211 million (a gross understatement), but took no steps to recover the money. This is no recent phenomenon. An earlier article in *The Economic Times,* August 5, 1986, ('Unintended profits on formulations') reported that at least 120 drug companies, mostly Indian-owned, were to be served payment notices by the government for making profits on formulations based on rifampicin, analgin, betamethasone and gentamycin. The company that carries the largest single liability—at Rs 21.1 million—is Glaxo Laboratories for betamethasone formulations.
19. A glaring example is provided by a 1982 case. The Kerala High Court directed the central and state drug control authorities 'to publish the list of trade/brand names and the names of the manufacturers of [banned] drugs'. This directive has not been complied with; the excuse being that the drugs have been licensed and registered with state health authorities and the central authority has no clue about the various formulations and brands involved. Other examples include manufacturing, importing and selling drugs in Third World countries which have been banned elsewhere, and pharmaceutical companies indirectly bribing medical practitioners. For more detail, see *A Rational Drug Policy,* Voluntary Health Association of India, New Delhi, 1986.
20. In January 1994, the Maharashtra Food & Drug Administration held Glaxo India guilty of a number of breaches of safety and quality standards. It cited 17 instances of 'previous penalties ... for production of sub-standard drugs' and listed another ten current instances of unsafe or bad practices. These included

manufacture of drugs without the presence and supervision of a technical person, and selling drugs whose shelf-life had expired. Glaxo had been served with another closure notice earlier for violating drug manufacturing rules pertaining to disposal of its rejects. After months of litigation, the company finally closed down the factory at its head office in centra] Bombay for two days from March 18, 1994. It had also closed down its bulk drugs factory and warehouse at Thane, Bombay for two days in February 1994. For details on hazardous, spurious and substandard drugs marketed in India even as late as 1989, see Chinai, R., 'Drug firms' reckless policies hazardous', *Indian Express,* October 29, 1989.

21. An opinion poll on economic reforms conducted in Delhi in February 1994 by the Confederation of Indian Industry (CII) showed that over two-thirds of the respondents were not even aware of the reforms' existence. Only four per cent believed that the country's economic condition had improved as a result of reforms. Further, the survey found an extremely low awareness of reforms among the women and the poor. The only positive feature, if it can be called that, is that 90 per cent of those polled agreed that they had a wider choice of luxury goods than two years ago. This means that the already yawning gulf between élite priorities and popular concerns has further widened over the past two-and-a-half years.
22. Rane, W., 'Rising drug prices', *Economic and Political Weekly,* April 7, 1993, pp.743–46.
23. Keayla, B.K., and Dhar, B., 'Indian pharmaceutical industry and patent regime for drug security', *Journal of Scientific and Industrial Research,* April 1993, vol. 52, pp. 271–77. Since the Indian Patents Act 1970, the production of pharmaceutical products has grown more than eight-fold: from Rs 5 billion in 1974 to over Rs 40 billion in 1991. This has been accompanied by a sharp rise in exports: between 1985–86 and 1991-92, exports rose from Rs 1.4 billion to Rs 13 billion and are currently running at Rs 14–15 billion. Exports to the USA alone have increased about three-fold: from Rs 290 million in 1990-91 to Rs 760 million in 1991-92. The Indian drug industry has emerged as a world leader in the production of bulk drugs like ciprofloxacin, dextrapropoxyphene, ethambutol, ibuprofen, norfloxacin, sulphamethoxazole, and trimethoprim. Significantly, of the top five companies operating in the country, only one is an affiliate of a TNC. Further, 80 per cent of the bulk drugs manufactured in the country are produced by Indian companies.
24. Bidwai, P., 'An irrational priority list', *The Times of India,* June 23, 1985.

Drifting Through Time

Pharmaceutical Policies in Mexico

By Nadine Gasman

The Mexican National Drug Policy was triggered by the 1982 economic crisis which resulted in an acute shortage of many essential goods, including medicinal drugs. However, government action in this area was not new in 1982 but had been developing over the decades. As far back as 1958, the Mexican Institute for Social Security had selected a list of important drugs to be used in its facilities; and in the 1960s and 1970s, the Ministry of Health had developed a formulary, encouraged the work of the national pharmaceutical industry and created a unified procurement system. But the economic crisis in the early 1980s forced the government to enact a more comprehensive policy. The aims of this policy were threefold: to secure access to good-quality essential drugs for the population, both in the public and private sector; to support the development of the national pharmaceutical industry in order to decrease dependence on the transnationals; and to promote the rational use of drugs.

Although most of the ingredients in a healthy medicinal drug policy were in place, except possibly the necessary involvement of all actors in the 'pharmaceutical chain' and particularly the consumers, the time allowed for its implementation was too short; its effects, therefore, were limited. The reason for this was that towards the end of the 1980s the Mexican government decided on a drastic change in economic policy, abandoning a closed and protectionist model in favour of maximum integration in the global economy. This involved, inter alia, the rapid privatisation of state-owned industries and services, reductions in government administration, and the promotion of foreign investment. For the government, the main instrument for this policy was the North American Free Trade Agreement (NAFTA). The Treaty became operational on January 1, 1994.

It is evident that NAFTA created a completely new situation in Mexican society and that since the agreement came into force, many contradictions have developed, political, social and economic. Since health was not explicitly dealt with in the NAFTA negotiations, it is still too early to say how much the National Drug Policy will be affected and what can be saved of its original intentions. What is necessary, however, is that the new administration under President Ernesto Zedillo Ponce de Leon takes a firm initiative in the field of health and pharmaceutical policies to remove the widespread uncertainty that prevails.

This highly interesting development is thoroughly discussed in

the contribution by Nadine Gasman. She is a Mexican with a doctorate in Public Health, specialising in health policy and management. She has worked at the National Institute of Public Health in Mexico as a researcher and professor, and as a consultant/or WHO, PAHO and several national development agencies. She has coordinated the pharmaceuticals programme in Nicaragua and is at present the Director General of the Latin American Health Group (GLAS).

Introduction

At the end of the century it is still a challenge for societies and governments to ensure access to basic health and essential drugs for the whole population. Although technology continues to advance and there are better ways to prevent and cure an increasing number of diseases, almost half of the world's population does not have regular access to these basic services. Moreover, although drugs are there and physical access has probably improved, real access is increasingly difficult given the rise in drug prices and the decreased purchasing capacity of people due to the trend towards lower incomes in most parts of the world.

At the macroeconomic and political level, the end of the 1980s has seen the consolidation of the neo-liberal philosophy, a tendency towards globalisation and regionalisation, and the implementation of the 'prescription' of the World Bank and the International Monetary Fund all over the world. This has had the effect of decreasing the coverage and quality of health services, especially for the low income population, as is acknowledged in a recent publication of the Inter-American Development Bank (IDB):

> As the region has undertaken extensive macroeconomic reform, shifting from state-controlled to market economies, health care has suffered. The reduction of governments' capacity to provide social services has caused the quality of health care delivery to decline steadily, especially for low income populations. Budget cuts have meant salary reductions for health personnel, insufficient medical supplies and medicines, as well as physical deterioration of health facilities.'

In this context, it seems unlikely, even for the more extreme neo-liberals, that without governments' commitment and intervention the population will have access to basic health services and the essential drugs they require to alleviate pain, and to cure and prevent diseases. The 7993 World Development Report: Investing in Health proposes a triple strategy to improve the global health situation that acknowledges this need. It proposes to promote a family environment that fosters health, to improve public health spending, and to promote diversity and competition.[2]

Mexico has not escaped this economic trend. In the last 20 years it has gone through a dramatic transformation in its economy and policies. During the 1960s and 1970s there was important economic growth. The state was protectionist, promoted a mixed economy, owned a large number of industries and public services, was an active player in the economy, and used trade barriers as tools for protecting the national industry. However, the acute crisis of the 1980s, triggered by the rise in interest rates on the national debt and the decline of oil prices, coupled with the poor administration of the economy, brought about an aggressive adjustment programme and changes in the overall economic philosophy.

These changes are characterised by the privatisation of most state-owned industries, the drastic reduction of the number of government employees and its budget, efforts to curve the fiscal deficit, and measures to open the economy to foreign investment by removing trade barriers. In the last few years the economic policy has been dominated by the need to adjust legislation and actions to the requirements of the North American Free Trade Agreement (NAFTA) with the United States and Canada.

In the area of health these changes in the overall economic philosophy and framework have had a dramatic and direct impact. In the 1960s and 1970s the state was concerned with universal coverage, which resulted in the inclusion of health as an universal right in the Constitution in 1984. However, by the time it had to be implemented, the emphasis had shifted towards increasing competition and the creation of options to foster private-sector participation in the health sector, which coincided with an important decrease in public spending on health and a lack of aggressive activity in the public social security institutions to increase coverage.[3]

In the pharmaceutical sector the highly structured policy of the 1980s has been replaced by a de facto, laisser-faire policy where the government has changed its role to that of sector regulator. Currently, access to drugs is not treated as a public health issue, nor local production as a strategic issue. This is a dramatic change from the previous policy, which viewed this area as strategic and actively promoted self-reliance as the way to ensure access to drugs.

The Mexican National Drug Policy (NDP) was conceived as comprehensive but started by addressing issues directly related to the supply of drugs. To ensure its success, quality of drugs was viewed as essential, and measures were developed to improve it and make the industry comply. The policy used the purchasing power of the public sector as an incentive for the national phar-

maceutical industry and developed mechanisms to encourage its development. However, it did not involve all the interest groups and placed little emphasis on promoting the rational use of drugs (RUD).

Although the NDP aimed to address some of the most pressing issues, its effects were limited, mainly as the result of its short implementation period. The changes in overall philosophy at the end of the 1980s limited the impact of the policy and created important conflicts in its implementation. However, the Salinas government did not explicitly acknowledge these changes and conflicts, nor did it take a new policy position. The new government will have to address these issues in the context of health sector reform.

In the NAFTA negotiations the effects of the treaty on health were not dealt with. The issues raised were economic and related to private sector development and foreign investment in health care, the possibilities and requirement for professional practice in the three countries, the development of private insurance, and pharmaceutical production and purchases.

This paper will analyse the changes in the NDP in Mexico in the last decade. It starts with a description of Mexico's demographic, economic and health characteristics and an historical account of the development in the field of pharmaceuticals, the accomplishments and failures of the NDP. The second part describes the issues related to the pharmaceutical sector that were relevant during NAFTA negotiations, while the last part discusses the possible effects of this agreement on the pharmaceutical sector, specifically in relation to health and the implementation of the NDP.

Mexico: demographic and social indicators

From its geographical position Mexico is part of three economic and political blocks: the North American, increasingly important as we will see later; the Latin American, where traditionally it has had an important economic and political influence; and more recently the Pacific Basin.

In general, Mexico is considered to be one of the most highly industrialised countries in Latin America. According to a UNDP report it belongs to the group of countries with high human development and is ranked 46th in the world.[4] However, this definition does not reflect the important internal differences in the distribution of wealth and standard of living.

Mexico's population was 83 million in 1991, predominantly urban (73 per cent) with a highly dispersed rural population. Of the total population, 25 per cent live in Mexico City.

The fertility rate has decreased from 6.6 children per woman aged 14-49 years old in 1970, to 3.3 in 1990. Life expectancy at birth was 70 years in 1991, up from 57 in 1960. General mortality in 1991 was 5 per 1,000 inhabitants, with an infant mortality rate of 36 per 1,000 live births and an under-5-year-old rate of 51. Malnutrition in children under five is still 14 per cent. Literacy in adults in 1990 was 87.3 per cent with an average of five years' schooling.

By 1990, 71 per cent of the population had access to drinking water and 76 per cent to sewage and waste disposal with wide variations between urban and rural areas, which had 49 per cent and 12 per cent coverage of drinking water and 100 per cent and 79 per cent sewage and waste disposal, respectively.

Except for life expectancy, women's indicators in 1990 were lower than men's; schooling is 3.6 years on average, maternal mortality 44 per 100,000 live births, and only 21 per cent participated in the salaried work force.

Economic outlook

The production patterns of Mexico have changed in recent decades. In 1965 the labour force was mainly employed in the agricultural sector (50 per cent), while by 1989 this activity accounted only for 23 per cent. The industrial sector employed 22 per cent of the labour force in 1965 and 20 per cent in 1986-90. The main increase has been in the service sector which went from 29 per cent of the labour force in 1965 to 57 per cent in 1986-90. A subsector that has grown dramatically in the last decade is the assembly industry *(maquiladoras)*, which is located mainly near the Northern border and employs mainly women.[5]

After a period of rapid development and industrialisation in the 1960s and the discovery of oil reserves in the 1970s, Mexico had an economic growth rate of about 5 per cent a year and easy access to credit from foreign banks. This credit was used for the development of the oil industry, infrastructural development, and the implementation of some social programmes.

During the 1980s Mexico's economy stagnated as a result of the sharp decrease in oil prices and the need to repay a foreign debt of about US $110,000 million at high interest rates. The debt represented 51 per cent of the GNP and its service rose from 24 per cent to 40 per cent of exports.

During this crisis, inflation rates were high—an average of 73 per cent for the period 1980-89—the currency lost its stability as the peso dropped from

12.50 pesos per US dollar in 1982 to 3,100 in 1993, and there was a sharp decrease in the purchasing power of most of the population. Only 37 per cent of the population participated in the labour force during the period 1988-90.

In 1982, this critical situation triggered the implementation of a severe adjustment programme. The programme decreased the number of government employees and its budget, started the privatisation of state-owned companies, lifted trade barriers, implemented a stringent fiscal policy, and reached an agreement between the different social actors for economic stability and growth.

The efforts of the Mexican government to stabilise and restructure the economy, and to increase efficiency and competitiveness continued throughout the 1980s and have had mixed results. On one hand, there was until recently an increase in economic activity, favoured by the foreign debt negotiation, the success of the internal Economic Pact, increases in oil prices, the rapid privatisation of companies (the number of state-owned companies dropped from 1,155 in 1982 to 255 in 1990) and the negotiation of NAFTA. This has resulted in a growth in private investment, primarily used for private consumption and financed with stock market resources, repatriation of large amounts of Mexican capital in 1991 and 1992, and the availability of credit at lower rates. The external debt negotiation concluded in March 1990 with a scheme of bonus for debt exchange, and NAFTA negotiations were perceived as an opportunity to join one of the largest economies in the world and improve the country's international competitive position.

On the other hand, the adjustment programme resulted in a 9.6 per cent foreign debt increase (to reach US $125,000 million in 1993), a 60 per cent decrease in the purchasing power of the minimum wage compared to 1980, increases in urban poverty from 23 per cent of households in 1984 to 30 per cent in 1990, and increases in extreme poverty from 6 per cent to 8 per cent over the same period.

Wealth has been concentrated among fewer people. While in 1987 the richest 10 per cent owned 29 per cent of the country's income, the proportion increased to 36 per cent in 1990. Conversely, the income share of the poorest 40 per cent of the population decreased from 15 per cent to 12 per cent over the same period. The number of households earning incomes below the poverty line increased from the already high 72 per cent in 1987 to 76 per cent in 1990.

GNP per capita in 199] was US $3,030 dollars with a cumulative change between 1981 and 1993 of –6.4 per cent, explained by the sharp decreases suffered during the period of economic crisis.

By 1993, the economic growth of previous years had slowed down and the deficit had grown. National output decreased as a result of foreign competition, and increased imports, and the stalled economies of Mexico's trading partners, which resulted in a net decrease in exports. The sixth phase of the Pact for Stability and Economic Growth was signed in 1993 but required slowing down the devaluation rate, decreasing value added tax from 15 per cent to 10 per cent, and increasing wages by 7 per cent.

Nevertheless, the macroeconomic structural reform continues with important changes in public sector dominated areas such as the approval of a Private Retirement Saving system, changes in the land-tenure articles of the Constitution, the privatisation of the banking system, and restructuring of the government-owned oil industry (PEMEX) to allow joint ventures with foreign companies in secondary petrochemical activities for the first time since nationalisation in 1938.

At the microeconomic level, in the context of deregulation, new laws were approved by Congress: the new Federal Law on Economic Competition to prevent unfair practices; the Federal Law on Water, which gives concessions for the use of federal water and permits to exchange water rights, and the Weights, Measures and Standardisation Law, which permits the participation of the private sector in developing standards, and in inspection and certification bodies. The latter had a direct relevance to pharmaceuticals.

Mexico has a mixed and polarised morbidity and mortality pattern. While diarrhoeal diseases and upper respiratory tract infections are still the main causes of death among children under five, an increasing number of deaths in adults are due to cardiovascular and chronic and degenerative diseases. Accidents, especially motor vehicle accidents, are among the principal causes of death in the 15-49 age group.

To provide health services to the population Mexico has three kinds of institutions: the public sector services geared to the general population, those for people affiliated to the different types of social security institutions, and the private sector.

The services of the Ministry of Health *(Secretaría de Salud,* referred to here

as MOH) are financed by the federal government and currently, in decentralised states, by local governments. They are responsible for the provision of health services to the general population and covered about 29 per cent of the population in 1990.[6]

In 1982, at the same time as the development of the NDP, a policy of decentralisation was developed to provide services to the uninsured. The decentralisation strategy should increase efficiency in the use of resources, and equity in their distribution, promote decision-making at the regional and local levels, and increase the financial participation in health of local government.

Although implementation was aggressive in the mid-1980s, and by 1985 almost 50 per cent of the states—or 14—had decentralised their services and tried some kind of integration with social security at the local level, this policy stopped under the Salinas administration. None of the states has decentralised its services during the period 1988–94, despite Mexico's commitment to the development of the local health system strategy promoted by the members of the Pan American Health Organization (PAHO/WHO).

The Mexican Institute for Social Security (*Instituto Mexicano de Seguridad Social,* or IMSS) was founded in 1943 and is financed by three sources: federal government, employers and employees. IMSS covers about 47 per cent of the population and has the largest number of health facilities and employees, mainly specialist. Since the 1970s it has organised a system to reach the poorest communities in the rural areas, co-financed by the MOH. This system was called IMSS-COPLAMAR and was renamed IMSS-Solidaridad by the Salinas government. It covers about 11 per cent of the population with exclusively primary health care services. The Social Security Institute for Government Workers (*Instituto de Seguridad Social para los Trabajadores del Estado* or ISSSTE) is financed by the government (as employer) and by government employees. It covers about 10 per cent of the population. Other, smaller social security systems, such as PEMEX for oil-industry workers, exist and have their own health plans. In general, the social security institutions have their own health facilities and salaried personnel. The private sector is represented by physicians and group practices, and by several hospitals, both large and small. This is a fast-growing sector but its coverage is still unknown.[7]

There is evidence that about 20 million Mexicans have no real access to health services.

Pharmaceutical policies in the 1980s

Drugs and other medical supplies are among the main items required by well-functioning health services; their availability also improves the services, legitimacy and credibility. It is common to hear comments such as, When I see drugs arriving at the health centre I go, if they are not there why bother?'

The organisation and legislation of the different areas of the pharmaceutical sector were included in the Mexican Sanitary Code of 1973, and specific norms were developed to enforce the law in 1982. They were included in the 1983 General Health Law and specific rules of 1986. Although the 1991 amendments to the General Law state intervention in many areas in the health sector, the rules have not changed for drugs.

The IMSS selected and implemented a list of drugs to be used in its facilities in 1958, and since then physicians have had to prescribe from this list. The MOH established an institutional formulary where they selected the drugs to be used in their facilities, and also organised the Inter-Sectorial Commission for the Pharmaceutical Industry in 1977. The Unified Procurement System for purchasing drugs for the public sector was created in 1980 but did not function until 1985–6.

However, policy and regulation were isolated and developed to solve specific problems, such as the shortage of drugs in specific institutions, or to regulate the entrance of products into the country. Although criteria were defined, implementation was loose and there were no attempts to integrate these actions into a comprehensive policy to guide and develop this sector.

The national pharmaceutical industry (NPI) developed in the 1960s in the context of the import substitution policy. It produced mainly final products and always depended on the transnational corporations (TNCs) for the supply of its raw materials. Most large TNCs have had subsidiaries in the country since the late 1950s.

The current developments of the NDP in Mexico have to be analysed in two different eras. The first, which produced the main changes in drug policy, was triggered by the 1982 economic crisis, which resulted in a critical shortage of drugs. This situation prompted a strong reaction from the government, which decided to act to ensure the availability of drugs and to develop a medium-term strategy to decrease the country's dependence on foreign producers.

The second era is the present period, when, after implementing the meas-

ures developed during the first era, pharmaceutical issues are being dealt with in the context of major changes in economic policy as they relate to NAFTA and the opening of the Mexican economy. Here some of the previous efforts and accomplishments made in the rationalisation of the market are seriously threatened or have suffered set-backs in the process of integrating this industry in to the rest of the economy.

The 1982 crisis: The National Drug Policy (NDP)

It was not until the country experienced an acute shortage of drugs at the end of 1982 and beginning of 1983, that the weaknesses of the NPI and the lack of a comprehensive policy became evident. Although by 1982 the NPI produced about 98 per cent of the finished products required for internal consumption, it was highly dependent on the TNCs for the procurement of raw materials. It only produced a few intermediates and less than a third of its raw materials; it had limited access to modern technology and made only marginal investments in R&D. Likewise, the TNCs' subsidiaries were strictly controlled by their parent companies.

During the 1982 crisis the TNCs requested price increases for their products to compensate for the peso devaluation. This increase was denied by the government, which saw it as an important measure to ensure access to strategic commodities and to prevent or limit inflation. As a result, the TNCs took a confrontational stance, threatening to stop producing and selling drugs to Mexico.

At the same time, the public sector did not have a functional system capable of procuring the drugs required in an environment of increasing economic uncertainty and budget limitations, which made them vulnerable to industry pressures. This situation and the vision of some of the health officials in charge (especially Dr Guillermo Soberon, Minister of Health, Bernardo Sepulveda, a prominent physician and researcher working at the IMSS and advising the MOH, and Dr Mario Lieberman, also a ministry adviser) triggered the development of the National Drug Policy in 1982. They chose to support the development of the NPI as the strategy for the implementation of the NDP, which was in line with the overall economic development model of the late-1970s.

The rationale for this strategy was that by favouring the development of the national industry, access to safe and good-quality drugs would be guaranteed. The purchasing capacity of the public sector would be used to create the opportunities for the NPI and it, in turn, would have to become competitive, decrease prices, and improve performance and quality. This strategy

assumed that the NPI would see this as an opportunity to grow and, given the required support, would have the capacity to increase and improve production in the short term.

In general, the Mexican pharmaceutical policy had three objectives:

- To secure access to good-quality essential drugs for the population, both in the public and private sector, thus rationalising the pharmaceutical market;
- To support the development of the NPI in order to decrease dependence on foreign companies;
- To promote the rational use of drugs.

The pharmaceutical policy was embodied in the 'Comprehensive Programme for the Development of the Pharmaceutical Industry 1984–1988', presidential decrees, enactment and enforcement of legislation to strengthen the regulatory capacity of the MOH in registration, inspection and quality control. It also made compulsory the use of the National Essential Drug List (EDL), strengthened and made operational the Unified Procurement System, gave a mandate to the Ministry of Finance to control drug prices, and made provisions for the control of the private sector.

However, the 1984 legislation, which was comprehensive, had to be revised in 1985 after strong opposition and pressure from TNCs and their governments. Almost all TNCs filed suit against the MOH and signature of the US-Mexico Trade Agreement was delayed for five months, mainly as a result of the pressure of pharmaceutical industry lobbyists on their government.[8]

To make each of the objectives of the NDP operational, different instruments and policies were developed. These are described in the following sections.

Accessibility

To increase accessibility a rational scheme for the production and marketing of drugs was created,.aimed at satisfying the health needs of the population. Four instruments were developed and implemented.[9]

- The National Essential Drug List for public sector institutions (*Cuadro Básico de Medicamentos*);
- The Unified Procurement System for Medical Supplies for the public sector (*Compras Consolidadas*);

- A price control system for the private sector;
- The use of generic names in the private sector.

Essential drugs and medical supplies lists (Cuadros Basicos de Insumos Medicos)

The Essential Drugs Lists (EDLs) of all the public sector institutions were reviewed and a single list was developed and made mandatory for all public sector health facilities. Lists of disposable materials, instruments and equipment were also developed. These lists have been implemented and reviewed over the years. The current EDL, developed in 1989 and revised in 1992, includes 370 active substances and 450 dosage forms. These lists were considered as a prerequisite for the efficient functioning of the health system,[10] and as a tool to unify therapeutic criteria in the sector and to limit the number of items that would be purchased through the Unified Procurement System. The EDL was published in 1984 as a bulky book, but has never been widely distributed or promoted. This has limited its dissemination and its utilisation by physicians and other prescribers.

The institutions complied with the requirements and used the EDL to buy most of their drugs. However, they also continued to use direct purchasing mechanisms to obtain drugs not included in the EDL but requested by physicians. The amount spent on these items has never been disclosed but there are some estimates that have calculated that it could account for up to 40 per cent of the drug budget.

In practice, the use of the EDL is not uniform and varies among health institutions. It depends on the availability of drugs in the health facilities and the knowledge and acceptance of the concept by prescribers. While in the social security institutions physicians adhere to the EDL, because they know about the list and drugs are available, in the MOH facilities physicians prescribe any drug on the market, whether or not it is included in the EDL, since drugs are generally not available and patients have to buy them in the private pharmacies. Here, there are periodic shortages of drugs, despite the fact that 67 per cent of current Ministry of Health budget is spent on pharmacy, chemical and laboratory products." (Other reports state that public expenditure on drugs was 38 per cent of the total health budget in 1990.)'[2]

Information about access to drugs in the public and private sectors is not readily available in Mexico since the mechanisms and systems to gather it were never developed and coverage and the availability of supplies is not monitored.

The concept of essential drugs and the EDL was rarely incorporated in university curricula. Students, the future prescribers, have little or no exposure to this concept in comparison to their early and continued exposure to the pharmaceutical companies' information.

One of the few exceptions is in the health programmes of the Universidad Autonoma Metropolitana (UAM) in Mexico City, where medical and pharmacy students are taught using the EDL as the guideline in their pharmacology and therapeutics courses. However, no evaluation has been made of the impact of these programmes in the actual prescribing habits of these professionals.

Unified procurement system for the public sector (Compras Consolidadas)

Using the purchasing power of the state and a limited number of effective drugs included in the EDL, a public bidding system was developed where not only price, but also performance and quality were taken into account. This system was made compulsory for all public health institutions. Factors such as the origin of the capital, the production of raw materials, integration of the production process, and investment in research and development (R&D) were valued in the allocation decision.[13]

The Unified Procurement System decreased the prices of drugs and created incentives for the NPI to participate in the supply of the public sector. It was calculated that the system saved between 30 and 50 per cent of the institutions' budget, and hypothetically increased the population's access to drugs.[14] However, this has not been confirmed due to the lack of data.

By 1986, the NPI supplied 70 per cent of public sector needs, increasing its overall participation in the market. This proportion has remained between 65 and 70 per cent since then. Out of all public sector purchases, IMSS has traditionally purchased 70 per cent of drugs for the public sector. The policy resulted in a *de facto* division of the market between the national companies, supplying 70 per cent of the public sector, and the TNCs' subsidiaries supplying 80 per cent of the private market, which in turn represents about 80 per cent of the whole pharmaceuticals market. This division of the market became 'convenient' for the two types of industry. TNCs still control most of the market and over time have come to realise that they did not loose income with the policy implementation.

Currently, the decentralized states decide how much to spend and on what drugs, but they place their orders at the central level in order to benefit from

the low prices of the system. In the centralized states the selection is still done at the central level with very little input from the local level. The MOH managed the bidding system during the first few years after the NDP was implemented. However, since the IMSS buys the majority of drugs, it pressed the MOH to be allowed to take charge of the process. This created some tensions between the institutions and delayed some of the purchases, but still the system is in place.

In addition to the direct purchases there are some distortions in the drugs and quantities purchased. The drug Naproxen (an anti-rheumatoid drug) accounts for more than 25 per cent of the total purchases of the public sector, even though arthritis is not among the primary causes of morbidity in Mexico. This drug is used as an analgesic when more appropriate and cheaper drugs are available.[15]

A price control system for the private sector

The first proposal, developed in 1984, established a policy of equal price for equal products and provisions to develop a programme where EDL drugs sold in the private sector had to have the same dosage, presentation and their generic name printed under the brand name. This measure encountered major opposition from the TNCs and had to be changed in the 1985 decree.

The Ministry of Commerce developed mandatory price control for drugs to be sold in the private sector based on the production and commercialisation costs, which had to be negotiated with the Ministry, plus a fixed profit margin. This system prevented drug prices from matching inflation.[16] The system proved effective in that it has kept drug prices in Mexico lower than in the rest of the region over the years.

The system is still in place despite increasing pressure from the industry (national and transnational) for liberalisation. However, it is unlikely that the system will remain intact once NAFTA and GATT/WTO are functioning; and once these controls are lifted drug prices are expected to increase dramatically.

Generic names in the private sector

In the first decree generic names had to be printed in the same size as their brand names both on the box and on the product. This measure was vigorously opposed by TNCs. Due to these pressures, changes were made to the original decree in April 1985, and the printing of the generic names was not

made mandatory. As part of a larger international trend over time most companies have included the generic names in the presentation, but still non-brand generic drugs are not sold in the country.

Rational use of drugs

Although the emphasis of the policy was on the area of production, promotion of the rational use of drugs (RUD) was also an issue. Taking a regulatory approach, it was expected that RUD would be achieved by ensuring that drugs were available in sufficient quantities, would be of good quality, both in the public and private sectors, and would be promoted under their generic names, and by creating sources of unbiased information. This was the weakest part of the policy since efforts were not made to involve other social groups, such as the universities, professional associations and consumers, actively in the development and implementation of the policy. Most of the efforts were made with an institutional approach, focused on improving the regulatory framework and developing some means for its enforcement.

To promote the use of generic names and foster confidence in the NPI-produced drugs required reassuring the public that the quality of the drugs, in terms of their safety and efficacy, was optimal. To this end, the regulatory capacity of the MOH was strengthened: registration criteria were revised and the products that did not match these criteria were withdrawn or reformulated. The number of drugs registered decreased from 20,000 in 1984 to 7,500 by 1988.[17] The process of 'cleaning' the registry started and gained momentum but was never completed due to shortage of time and personnel at the beginning of the process and lack of interest and commitment later.

Another instrument to ensure quality was the Mexican Pharmacopeia. This was revised, and a fifth edition was published in 1988. A Permanent Expert Committee was appointed and is still working. A programme for the inspection and control of production plants was organised to ensure the implementation of good manufacturing practices (GMPs), quality assurance systems and the validation of the production processes. A certification programme for producers was created, aimed at developing a control system whereby the regulatory authorities would certify companies, which would make a gentlemen's agreement to maintain standards.

Although printed materials for drug promotion had to be approved by the MOH, the criteria were not fully enforced and this remained a weak area. Drugs still have no information inserts and it is difficult for health workers and the public to have access to unbiased information about drugs.

An Adverse Drug Reaction Centre was proposed by the MOH, where IMSS and the National University would join the Ministry's effort to promote the use of information in clinical decision-making. However, this Centre was never created. Instead the National University opened an information centre in an IMSS clinic which is only used by the physicians and students of that clinic.

Development of the national pharmaceutical industry

The development of the NPI became the backbone of the NDP. The main objective of this strategy was to substitute imports and increase exports while establishing a modern technological infrastructure and consolidating the management capacity of the industry. By using the purchasing power of government, the national industry would have incentives to produce efficiently the drugs that were needed to address the health needs of the population. Essential to the programme was the production of raw materials to integrate the production process in order to increase the independence of the country and shift the trade balance of the industry. A group of Mexican companies took up the challenge, invested in the development of plants, and produced some raw and intermediate products.

As part of the NDP, investment in R&D was promoted. Industry had to invest 4 per cent of its sales revenue in R&D and modernise its technology. Although agreements were signed these regulations were never implemented, since no enforcement mechanisms were available. Some clinical research was promoted by making it compulsory to do Phase III clinical trials among the Mexican population for product registration.

Intellectual property became a global issue in the mid-1980s when the USA stressed the need to protect R&D investment by improving the patent system. Third World countries in general, and countries like Brazil, Argentina and Mexico in particular, argued against this change because of their lack of capacity and means to develop R&D. It was clear that such patent law would become a non-tariff barrier to national industries.

The Mexican government had to review its patent law by the end of the 1980s and made some provisions for the inclusion of product and process protection by the year 2000. However, dramatic changes occurred with the patent law in the context of NAFTA negotiations, as will be described in the next section.

As a result of the NDP, the NPI increased its participation in the production of raw materials and finished products. It now produces about 50 per cent

of finished products[18] and although there is disagreement on how much integration has been achieved, ranging from 30 per cent to 60 per cent in the opinion of different authors, there is agreement that production of raw materials and investment in this area has increased.[19]

In general, there were advances in the development of the NDP and, although there was conflict and much to do to achieve the NDP's goals, the policy was evolving and could have achieved its objectives. However, the context changed by the end of the 1980s and with it the importance of, and commitment to, the NDP.

The main lessons learned from this period start with the recognition of the country's dependence in sensitive areas such as drug supply and the government's vulnerability to such shortages. The main achievements relate to the areas of regulation, supply and production. In general, NDP helped to empower and organise the public sector and became an example of inter-institutional coordination. Regulation was greatly strengthened and became the main tool for policy implementation. Achievements in drug registration, inspection and quality control became evident in the short term. Efforts to make rational use of resources started with the unified EDL and the purchasing system that demonstrated the savings that could be achieved by its use. Price control maintained the price of drugs at a lower level, increasing access in the private sector. However, the conflicts and confrontations that resulted from the enactment and enforcement of these measures took up the time and energy of health officials and probably decreased the policy impact. The lack of broad social support and the slow build-up of a dialogue between the different social actors prevented the implementation of some key measures.

The policy was designed and implemented with a top-down view, using a regulatory approach that stressed measures at the central level with little concern for what was required at the health service level to implement it, to change the attitudes and practices of physicians and other health personnel. and to strengthen the actual management of drugs in the health facilities.

The fact that the policy was so institutional prevented the involvement of other participants in the dialogue and made the NDP vulnerable to changes in institutional policy, which did not encounter an organised opposition to its dismantlement, except from the NPI and the Pharmacists Association.

Pharmaceutical policies in the 1990s

The context

The Mexican political and economic scene has been dominated in recent years by the actions required to transform the economy from closed and protectionist to modern and integrated into the global economy. The trend has been towards the rapid privatisation of state-owned industries and services, decreasing the size of government, actively promoting foreign investment through reforms in the fiscal and tariff systems, opening the market to imports, and fostering non-oil exports. These policies are expected to promote economic growth through the reactivation of the economy by attracting foreign investment, creating jobs, increasing salaries, and paying the external debt.

For the government of President Carlos Salinas de Gortari, the main instrument for this policy of modernisation and integration was the negotiation of NAFTA. NAFTA represents the main strategy to face the globalisation of the world economy, promoted by the large TNCs and the international banks, and the regionalisation promoted by the governments of the North.[20] NAFTA gives Mexico the opportunity to become a partner in a powerful economic block with access to a regional market of 360 million consumers (potentially 800 million when including all Latin American countries), and with an expected combined GNP of US $6,000 billion by 1993. NAFTA is considered the way to incorporate Mexico into the industrialised world.

After years of negotiations, the Canadian, US and Mexican Congresses approved the implementation of the treaty, which became operational on January 1, 1994. Paradoxically, on the same day Mexico was to enter the 'developed world', government and society were reminded by the natives of Chiapas (the Southeastern and poorest part of the country) that the basic needs of the majority has not yet been met. The Ejército Zapatista de Liberación Nacional (Zapatist Army of National Liberation, EZLN), an unknown group that organised several thousand peasants, launched a large and unexpected military offensive demanding changes in Mexico's social, economic and political order. 'It is better to die fighting than from diarrhoea' was one of the arguments for joining the EZLN.[21]

Although the fighting has stopped and negotiations are being held at the moment, the long-term consequences of this movement will have to be assessed in the future. For the time being these actions have questioned the *status quo* and the illusions of Mexican society about its well-being, ideas that were fostered during the Salinas administration by government and the media.

Health, education and social development, issues which had been neglected during the Salinas administration, have to become part of the political and government agenda again if a peaceful solution is to be reached.

NAFTA is the response of Mexico, the USA and Canada to the current global changes. The treaty is expected to foster the complementarities of the three economies in terms of resources and production in order to improve the region's competitiveness. From the Mexican standpoint the trade agreement will have to improve and secure the access of Mexican products to the three countries' markets, reduce the vulnerability of Mexican exports to unilateral measures, promote the required economic structural changes by strengthening national industry, develop a solid and competitive export sector, and create better paid jobs to improve the living conditions of the population.[22] This will be achieved mainly through negotiations that will eliminate trade barriers, by establishing transparent, non-discriminatory investment rules, and by setting up arbitration mechanisms for trade disputes. The challenge to NAFTA is to improve the competitiveness of the region through two fundamental elements; namely, an internal element, related to the definition of the relationship between the state and society, and an external element, related to the link with the external economies.

In the opinion of Mexico's officials there are five sources of competitiveness in NAFTA that would benefit Mexico.[23]

- *Transparency and permanence of economic policies*: With NAFTA clear and transparent rules will be set for international trade. This will create a confident environment that will stimulate internal investment in the long term.
- *Access to a series of technological options*: Through NAFTA companies should have access to a wide variety of technologies. To develop and be competitive Mexico needs to look at the technological options and chose carefully those in which to invest.
- *Rational use of the comparative advantages; i.e. demographic, technologic, scientific and production factors*: The treaty will make use of the natural comparative advantages of the economies. For Mexico these are its cheap (though unqualified) labour, and its natural resources.
- *Optimal scales of operation in the framework of market enlargement*: Diversification will improve the niches where Mexican products can enter the market.

- *Effective operation of the markets*: Long-term access to the three countries' markets will be assured through NAFTA. The treaty is compatible with GATT and does not limit the relationship with other countries.

For each of this sources of competitivity Mexico will have to face some problems, namely:[24]

- Transparency and permanence of the economic policies will be useful to Mexico as long as the rules are clear, arbitration mechanisms are established, and Mexico gets, as a Third World country, the status of preferred nation. Although these issues have been negotiated it is still unclear how they will be implemented.
- The risks for Mexico in relation to having access to a series of technological options are between continuing to buy outdated technology not necessarily appropriate for the industry needs, and getting US state-of-the-art technology that will involve having to pay enormous amounts for licences and patents which might become the modern mortgage of the country.
- To specialise as providers of unskilled work will condemn the country to underdevelopment and dependence. Mexico should avoid becoming a cheap labour provider and the erosion of its natural resources.
- Mexican producers have no experience in the US and Canadian markets, no expertise in market research, and there is even the tendency to prefer foreign products in Mexico. Thus, to insert themselves in a larger market will require large adjustments, learning and investment.

NAFTA and the health and pharmaceutical sector

The pharmaceutical sector has been actively involved in consultations and negotiations about NAFTA. The following sections analyse the Canadian, US and Mexican pharmaceutical markets and their differences, the objectives of NAFTA in this area, the changes that have already taken place in preparing for the agreement, and the agreements reached. They will also examine the expected effects of the treaty on the pharmaceutical sector in Mexico in relation to the accessibility and rational use of drugs, and the development of the NPI.

The North American pharmaceutical market

The analysis of the market data shows great asymmetry between these three markets and industries. While the USA is the largest consumer and producer of drugs in the world with a US $55 billion market, Canada is the eight, with a market of almost US $4 billion, and Mexico the tenth, with a

market of US $2 billion.[25] Per capita consumption of drugs in the USA and in Canada is 8 and 6 times larger, respectively, than in Mexico, and the average price of drugs follows the same pattern.

In 1990, the pharmaceutical market in the three countries is summarised in the following table:

Table 1 The pharmaceutical market in Canada, United States and Mexico

	Canada	United States	Mexico	Total
Population (million)	26	251	81	358
Pharmaceutical market (billion US $)	3.9	54.9	2.1	60.9
Consumption per capita (US $)	150	201	26	158*
Average price of drugs (US $)	10.15	11.70	1.25	7.60*

*Weighted average

Source: Canifarma, 'Suplemento Canifarma: La Industria Farmacéutica en numeros'. Mexico, November-December, 1991.

Likewise, the US-based pharmaceutical industry is the largest in the world: it exports goods worth a total of US $4.4 billion, imports US $3.5 billion and employs 178,000 people.[26] While the US-based companies spent an estimated US $7.2 billion on R&D in 1991, the Canadian and Mexican firms are not research-intensive and have traditionally targeted production to the internal, and in the case of Mexico public sector market.

To compete in this market the main problems faced by the Mexican pharmaceutical industry are the obsolescence of its technology, the lack of investment in R&D, an infrastructure that does not meet international standards, lack of experience in the international markets, and a paucity of new products. However, the Mexican industry has a number of healthy companies, satisfactory productivity levels, competitive production in some raw materials, general awareness of quality, and a large enough market to foster exports.[27]

Objectives of NAFTA in the pharmaceutical sector

The closed Mexican economy of the mid-1980s strongly protected the NPI, preventing its exposure to international markets. The new policies, especially of GATT/WTO and NAFTA, are expected to eliminate the main trade barriers in order to establish a transparent, non-discriminatory invest-

ment environment.[28] The goals of NAFTA in this area are to improve the overall situation of the industry by promoting exports within and outside the region, creating investment and job opportunities. Unfortunately the health objectives inherent in this area have not been mentioned or taken into account during the negotiation. Neither has the existence of a functioning NDP in the country been acknowledged. Only issues related to regulation and trade were discussed and to some extent agreed upon.

Conditions for negotiation: patent law

Patents were seen as a prerequisite for any negotiation since they would ensure the protection of future products and prevent massive losses due to the duplication of drugs and piracy. In 1990, a spokesperson for the US Pharmaceutical Manufacturers Association commented that: 'this industry does not want to see pharmaceuticals fall under a comprehensive free trade agreement (NAFTA). Rather the US government should watch for the fulfillment of a new patent law as a "sign of good faith".'[29]

Although from the US perspective the patent protection was the main problem, they also worried about some other aspects of Mexico's pharmaceutical sector, such as: the public sector Unified Procurement System, which, in their opinion, discriminated against TNCs, the price control system, inadequate infrastructure, lengthy and unpredictable procedures, lack of market knowledge and limited availability of finance.[30]

The R&D-based industry proposals for the reform of the patent law were:

- That patents should be honoured for 20 years, for all classes of invention (product and process), should include biotechnology, and should have limitations on compulsory licensing and strict limitations on public health exceptions to licensing;
- That trade secrets should be protected and governments should ensure that the data they require for registration has a period of exclusive use;
- That there should be strong and effective enforcement measures, and adequate transition provisions to ensure that pharmaceutical products enjoy the same benefits from improved patent protection as do other inventions.

From the Mexican standpoint, entering NAFTA had problems in the areas of patent law, which they opposed due to industry's limited capacity to invest in innovative R&D, the changes required in the general health legislation, the definition of the new role of the NPI, government regulatory functions,

and the options for professional practice. The Canadian industry had similar problems as the Mexican and was attacked for having a weak patent law.

Despite Mexican industry opposition, by June 1991 the Intellectual Property Promotion and Protection Law was changed to grant protection to products and processes for 20 years, with the option of extending it by three years for products where the patent holder grants a license to any party with a majority of Mexican capital. Also, the patent would have to be exploited within three years and there is a clause for compulsory licensing. The law protects products for which patent applications have been filed in another country and which have not been marketed or imported.[31]

According to a Pharmaceutical Manufacturers Association representative, the Mexican law is the best in the world and they would like the Canadians to adopt it. However, the Mexican industry believes that US pressure led Mexico to give too much away without gaining any real concessions for the Mexican industry.

Main areas of negotiation

There were negotiations in five areas in the pharmaceutical sector:

- *Tariff removal*: the negotiation dealt with the timing and type of products that will have their tariffs removed. Here the asymmetry between the three industries required time to adjust and create the competitive capacity for Mexico and Canada.
- *Rules of origin*: provisions were drawn up to ensure that the preferential trade tariffs mainly benefit the North American region. To qualify, products or parts must be produced in one of the three countries, and raw materials must undergo a minimum level of transformation in the region. Mexican NPI representatives believed it was important to prevent the massive imports of low-price generics from the USA and Canada.[32]
- *Norms and standards*: since pharmaceuticals are products used for health it is important that health safety issues, as well as commercial issues, are taken into account. The main issues here were whose standards to use for regulation and how to prevent these becoming non-commercial barriers for Mexican products. Mexico's government resisted the option that, based on their prestige, the US FDA or the Canadian Health Protection Bureau take over from Mexico authority to regulate in this area.
- *Government purchases*: Mexico has a special system that has achieved its objective of providing low-cost, good-quality drugs to its population. This system has been criticized by TNCs, which consider it discriminatory. It

was important to preserve this system and time was required to adjust it to allow for potential new competitors.
- *Intellectual property*: as discussed earlier, patents were seen as the main issue to be addressed before negotiating, since not having protection would further expose the US industry to piracy.

Table 2 describes the positions held and the changes over time. The first column describes the original position of Mexico, the second, the position held during negotiations and the third the agreement signed in August 1992.

In summary, the main agreements reached were that Mexico would remove tariffs for 37 per cent of raw materials and 90 per cent of drugs in ten years, and immediately for products that are currently not produced. The USA agreed to remove tariffs for 70 per cent of its drugs and raw materials immediately, and Canada to remove tariffs for 42 per cent immediately and 51 per cent in five years. The rules of origin applied to raw materials are that 50 per cent should be produced in the region, measured by the net-cost method. For government purchases, Mexico accepted an eight-year delay in opening this market to the US and Canadian firms. In relation to norms and standards, further negotiation and agreement is required, but efforts are being made to standardise the requirements and procedures without creating a single enforcement agency. Finally, the stringency of the Promotion and Protection of Intellectual Property Law of Mexico permitted the progress of the overall negotiations.

The expected consequences of NAFTA in the health and pharmaceutical sector

NAFTA was negotiated without explicit concern for health issues. The underlying theoretical assumption is that the free market has the mechanisms for distribution and a natural tendency towards equilibrium and equity. Also, the important differences between the health system of the three countries and the lack of interest in the issues prevented the inclusion of health in the NAFTA agenda.

Pharmaceuticals, on the other hand, were included only in terms of their economic value. It is clear that this is an excellent example of an imperfect market and that policy actions are required both in the economic and health arenas to ensure access and quality to and prevent distortions of the market. Nevertheless, these issues were neglected and the already functioning Mexican NDP had to slow down and was under serious threat during the negotiations. By the time of NAFTA's implementation (1994) some health-related issues had emerged as a result of changes in the countries' policies and pressures from different groups to include or prevent actions in the areas of ac-

Table 2 Mexico's position in NAFTA negotiations 1990-92

Original position 1990	Position during negotiation 1991	Signature August 1992
	Tariffs	
- A 15-year period to remove tariffs. - A 5-year transition period where tariffs are maintained. - For imports use the GATT-negotiated rates. - Consider the overall production process to apply sensible measures.	- Mexico should be considered a Third World country and have advantages like in GATT. - A 5-year period for tariffs and then 10% per year reduction until 0 at the 15th year. - Products that are not currently produced will have no tariffs at the implementation of NAFTA. - Removal has to be done according to the negotiated schedule with the Ministry of Commerce: 5% to raw materials, 15% chemicals and 20% drugs. - Products that start production during the transition period will be taxed at the current level.	* The required 15 and 5 years were not granted but all the products got into the slow (10-year) schedule. * Chemicals: **Mexico:** 37% of its products will have tariffs removed in 10 years; 60% of those not produced have to be removed as soon as NAFTA is approved. **Canada:** will remove tariffs for 42% of its products immediately and for 51 % in 5 years. **USA:** will remove tariffs immediately for 70% of their products. * Drugs: **Mexico:** will remove tariffs in 10 years for 90% of its products. **Canada:** already has removed tariffs for 21 % of the products and 76% will be removed in 10 years. **USA:** will immediately remove tariffs for 70% of its products and already has 22% without. * Auxilliary products: **Mexico:** will remove tariffs immediately for 46% of its products, 22% in 5 years and 32% in 10 years. **Canada:** 45% already do not have, 14% will remove them immediately and 21 % in 10 years. **USA:** 80% immediately and 9% in 10 years.
	Rules of origin	
- Mexico has to be recognised as a Third World country and given a special, preferential status as in GATT. - Products coming from the USA or Canada have to have a minimum of 50% regional aggregate value. - Mexican products will have to comply with 35% of regional aggregate value.	- There are discussions on how to measure aggregate value and differences are made between raw materials and finished goods.	- For drugs Mexico accepted 60% of the transaction value or 50% based on the net cost.

Original position 1990	Position during negotiation 1991	Signature August 1992
	Norms and standards	
- It was agreed that in terms of health regulation there were similarities and differences that required extra time to be studied and mechanisms had to be proposed to homogenise the standards in order to safeguard the health of the Mexican population, sovereignty and autonomy. - The position of the MOH should be presented and discussed in terms of accepting or not the US and Canadian standards.	- Mexico needs to keep its autonomy in health and environmental regulation and cannot adopt the US or Canadian regulation. - The MOH and the Ministry of Agriculture and Water Resources need to participate in the negotiations. - The Mexican requirements for imports should prevail for all products, and exporters should comply with US and Canadian regulation. - Imports of pharmaceutical products should be done through recognised companies based in Mexico. - Enough time should be allowed for the negotiations. 'The NPI presented its position: - Efforts should be made to make requirements compatible. - Recognise economic, technological and other differences. - Allow time for the adjustments. - Recognise each other's rules and regulations.	- All countries have obligatory rules. They have to aim at protecting life, the environment, and fostering consumer protection. - To promote commerce it is important to promote compatibility to ensure that these do not become non-tariff barriers. - They developed proposals to homogenise and make transparent the design and application process. - It was agreed that each country would use its national authorities and international standards to promote future convergence, adjust the validation processes to comply with the norms, promote technical cooperation and information exchange and to create a Technical Committee.
	Government purchases	
- Mexico has a centralised system which is different from the USA and Canada. - It is essential to maintain the preferential treatment of the NPI since this market should be used to promote the development of the sector. - Concessions should not be made to the USA and Canada if there is no reciprocity.	- Given its strategic character this area should not be included in the treaty.	- During the first 8 years Mexico has no obligation to open bidding to US and Canadian companies for the public sector.
	Intellectual property	
- This should not be negotiated until the new legislation is approved.	- In June 1991 the new Promotion and Protection of Intellectual Property was approved.	- The law is comprehensive and protects products and processes.

Source: Valencia, M.A., *Tratado de Libre Comerico Mexico, Estados Unidos y Canada. Posición del Sector Farmaceutico. Suplemento Canifarma,* Mexico, 1993.

cess to the professional labour market in the three countries, environmental protection and occupational health.

This change in attitudes has a number of roots. Although most of the negotiations were done by the Bush Administration, the treaty was signed by President Clinton, which has had effects in the priorities and issues. The Clinton Administration has a greater interest in domestic health care reform which aims at improving coverage and efficiency of the health services. There was a general trend in Third World countries towards health sector reform promoted by the World Bank. New pressures were raised by the Chiapas uprising in Mexico. Canada was concerned to preserve its well-functioning health system intact.

These changes could be the opportunity to give health special treatment in the treaty, to incorporate the health dimension of the pharmaceutical sector into the negotiations, and to promote a wider consensus on pharmaceutical policies. This would imply actively promoting a strong position in the negotiations for health sector officials, who are committed to ensuring that the whole population is covered by good-quality health services. It would also require holding the unpopular position of strengthening the role of the state as a regulator and redistributor to ensure access to effective, efficient and equitable health services.

Particularly in Mexico, the proposed health sector reform of the present government should be driven by these objectives and by efforts to increase decentralisation of resources and decision-making. Active social participation should be fostered by policy-makers, as should the actual allocation of resources to provide these services at the local level.

In this new stage, health should be treated in its constitutional dimension as a human right and an investment, and the NDP as a mechanism for its achievement. This would provide the required framework for a balanced relation with industry, the local health services and different groups involved in improving access to, and promoting the rational use of. drugs, while supporting in a competitive environment the development of the NPI.

This new era with its changes in overall economic philosophy and approach necessitates adjusting the strategies for NDP implementation. While the overall objectives have to remain the same, the emphasis on the development and protection of the NPI will have to shift towards ensuring that the public sector has effective and efficient procurement and quality assurance systems. It will also have to ensure that different interest groups are in-

volved in decision-making and that active consumer participation is promoted and enabled by increasing knowledge about different options, opportunities and the mechanisms for their involvement in decision-making.

To find ways to achieve this, the results of the NDP should be evaluated and proposals developed to adjust it to the new circumstances, preserving the systems and instruments that proved to be effective, such as the EDL, the Unified Procurement System in the public sector and price control in the private sector. New instruments will also need to be developed. The revised policy should ensure that actions are taken to strengthen three areas: accessibility, rational use of drugs, and production of essential drugs.

Accessibility

The speed of NDP implementation, and commitment to it, have decreased dramatically in the last few years as a result of the overall economic and political agenda of the government. However, some of its instruments are still in place and efforts should be made to adjust and improve them. To do so, it is important to acknowledge that the traditional model of health service organisation is being challenged and has changed over the past few years as a result of the economic policies and NAFTA. The trend towards privatisation and especially the decreased commitment of the public institutions, such as those responsible for social security, towards extending coverage will require adjustments and policy definitions by the new government in relation to the model and organisation of health services, the role of the state and each of its institutions in the health sector, the provision of good-quality services for the poor, and the sources of finance.

Once this new model is defined, and depending on its characteristics and the definition of the roles of the subsectors and their relationship, the mechanisms to ensure access to essential drugs can be worked out. What is important is to ensure that the definition addresses effectively the health needs of the poor and vulnerable and to acknowledge the importance of ensuring access to good-quality drugs.

National Drug Policies has proven to be, both in Mexico and internationally, an important instrument for organising and negotiating with all those affected solutions to the problems of accessibility and the rational use of drugs. Some of the instruments of the policy which are still in place have proven their effectiveness. These include the EDL, the regulatory framework, the Unified Procurement System for the public sector, and price control in the private sector. They should be adjusted and reinforced. Other

instruments, such as a generics programme for the private sector, will have to be developed. An important requirement for policy implementation will be improvement of the quality assurance system, to guarantee to the public that low-cost generic drugs bought in the international market are safe and effective.

The contradiction between the overall economic model and the decision to maintain the public health purchasing system intact, favouring the NPI for the time being, will have to be solved.This has been the only apparent concession made to the industry. In a competitive environment with decreasing resources for the public sector, officials have to analyse what is their best option. They can either open this segment of the market, trying to lower drug prices further, or continue to support the national industry. However, there might not be any contradiction as some analysts believe that national generics are 20 per cent cheaper than the US and Canadian forms.[33]

For the private sector, NAFTA creates the opportunity to increase access by launching an aggressive generic programme. Here timely efforts have to be made to ensure quality, inform and educate consumers about the different options, and persuade physicians to become active in their promotion. (Given the lack of enforcement of the prescription law in Mexico, mandatory substitution is not necessarily essential but would be important in the future.)

Rational use of drugs

In general, the Mexican NDP addressed the issues of RUD from a normative perspective, thinking that by creating stringent regulation the safety and efficacy of drugs would be assured. The policy did not acknowledge or address the importance of behavioural aspects of drug use at the level of both prescriber and consumer. Thus, registration, inspection and quality control were developed, but research or information is still not available either about or to prescribers, or to consumers.

NAFTA's tendency towards deregulation threatens the basis of this approach at the same time as stringent laws both in the USA and Canada foster it. Here the problems of autonomy and sovereignty are essential. It has been unacceptable to the Mexican authorities to let either the US FDA or the Canadian Health Protection Bureau take over their legitimate regulatory role. However, they will have to strengthen the transparency of the procedures and the capacity for enforcement to maintain this role in the future.

If an explicit policy and commitment to promoting RUD is available, NAFTA could become an opportunity to improve the exchange of information between regulatory agencies, providers and consumers, through programmes and joint campaigns against drug misuse in the three countries. This would allow the integration of government, academic and consumer organisations in to the treaty. Mexico's organisations could take advantage of US and Canadian experience in the development of information, communication and health-promotion campaigns, as long as the specific cultural characteristics of each country were taken into account.

The national pharmaceutical industry

Most of the changes foreseen in the future relate to the role of the NPI and the protection it has received over the past decade. It seems unlikely that, given the actual environment, the government would be willing or able to preserve a special stance towards the NPI.

Also, the industry is facing a different business environment. It needs to demonstrate its competitiveness and aggressiveness to increase its share of the private market in Mexico and foster exports to the North and Latin American markets.

What can be expected is that NAFTA will improve the position of the US industry because of better intellectual property protection. This should increase investment in R&D in Mexico and Canada, although this would be marginal given the strong US technological and scientific position, the elimination of Mexican tariffs on US exports, opening the Mexican public sector tender system, and the increase in US imports from Mexico.[34]

The situation is not as promising for the Mexican industry. Analysts believe that what Mexican companies have to do to compete is quite difficult and costly. They would have to reach a critical mass through strategic alliances, marketing agreements and cross-capital ventures, and obtain new products through licensing agreements. Companies would also have to modernise plants, raise GMP standards, set training programmes for personnel, and invest in R&D. Other strategies may involve specialising in specific pharmaceutical forms and a small number of successful products, reducing product ranges, maintaining supply levels to the public sector, manufacturing generics for the private sector, and developing over the counter (OTC) lines.[35] However, others believe that if the Mexican producers adapt to the new circumstances this will increase export opportunities, especially to other Latin American countries still facing the challenge of positioning themselves in the North American market.[36]

Here the problem is that the current regulations and mechanisms of the USA and Canada can become a non-tariff barrier to the Mexican industry if it does not improve and harmonise its quality procedures and standards. The most likely scenario is that Mexico's market will be increasingly dominated by TNCs, that small- and medium-sized companies will go bankrupt, and larger companies will merge or be sold to TNCs, following the path of the international market.[37]

Conclusions

Mexican history in this area shows how the rapid transformations of the political and economic system have had a direct effect on every area of Mexican life, including the health and pharmaceutical sectors. In the pharmaceutical sector a policy that was developing with some degree of success has had to adjust to the radical changes in economic policy in order to respond to the new logic. The challenge is to ensure that what has been successful is preserved and that opportunities are taken to fulfil the health objectives of the pharmaceutical sector. New and better ways to involve different participants have to be looked at, and efforts should be made to ensure that health issues are placed on the agenda since, for the time being, economic considerations have taken the lead and the health aspects of these commodities have been neglected.

Regulation, promotion of good quality standards and their enforcement, and the development of an aggressive generics programme seem the most important short-term actions needed to maintain access to drugs in the private sector. Preserving the integrity and mechanisms developed by the Unified Procurement System of the public sector is important while the government takes the opportunity to improve its knowledge of the international market and develops mechanisms to increase access to low-cost, good-quality drugs to promote complete drug coverage in its services. Different sectors of society have to work together to promote the development and diffusion of unbiased information about drugs for prescribers and consumers.

The overall health policy of the present government will have to define its health care model and ensure that it increases coverage and quality, especially for the **poor** and vulnerable. This definition will serve as the framework for the development of the new NDP mechanisms which will have to improve access to good-quality essential drugs, promote their rational use, and support as much as possible the development of the NPI using a broad participative approach. It will have to transform its almost exclusive regulatory approach into a more participative and consensus-building position where the different social actors are represented. It will

also have to foster actions that modify users, attitudes and help to achieve the objectives of the NDP.

Postscript: September 1995

Ernesto Zedillo Ponce de Leon took office in November 1994. By the end of December of the same year it became clear that many of the assumptions and expectations of the Mexican economy were not realistic. A significative amount of speculative capital left the country, the peso was devalued from 3.10 per dollar to 7.50 (then it stabilised around 6.00 pesos), and inflation reached 40 per cent in the first quarter of 1995. An emergency adjustment programme had to be put in place, involving an investment by the US and the IMF of around USD 50 billion to save the Mexican economy.

This situation has created a high degree of uncertainty and instability in the country. Small businesses and industries have gone bankrupt and it is unclear what is the way out of the crisis in the short and long term. On the political front the uncertainty of the economic situation, the ongoing negotiations with the EZLN and the assassinations of a number of political figures have resulted in pressure on the government to allow wide-ranging dialogue which is expected to start a real democratisation process.

The pharmaceutical sector has suffered the effects of the crisis and it is unclear now what the future of the NPI will be. The dismantling of the raw materials industry that started as a result of NAFTA negotiations has accelerated with the new economic crisis. On the consumer's side price control has been lifted and prices of drugs have risen dramatically in the past few months, increasing the pressure on the already depressed salaries of the majority of the population.

The Ministry of Health is preparing its decentralisation strategy which will include a basic package of interventions likely to include essential drugs, but the financing and implementation of which are still unclear.

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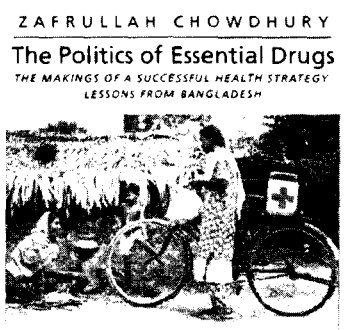

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