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Pharmaceutical Policies:  
Rationale and Design  

by  
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Abstract

The creation, production and sale of pharmaceuticals have become the subject of increasingly complex laws, regulations and administrative procedures in every industrialized country and in much of the developing world. These concern themselves primarily with the quality, safety and efficacy of pharmaceutical products, manufacturing practices, information supplied about drugs and drug expenditures. This paper explores the "Western model" of national drug regulation and policy, recent challenges to this model and approaches in developing countries.
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Introduction

1. In industrialized and developing countries alike, pharmaceuticals have come to occupy a dominant place in health care and the treatment of illness. They also constitute a significant share of health spending, particularly in developing countries (see Box 1). Pharmaceutical sales also fund the greater part of the research needed to develop new forms of treatment. Since pharmaceuticals are produced by a competitive industry and typically serve a thriving market, it would at first sight be natural to conclude that their development and sale can be best left to the play of market forces. One might imagine that regulation and national policy should remain confined to areas common to other forms of industry and commerce such as the countering of deliberate fraud, the promotion of worker and consumer safety, and the avoidance of environmental pollution.

2. But in actuality, in every industrialized country and in much of the developing world, the creation, production and sale of pharmaceuticals have become the subject of increasingly complex sets of laws, regulations and administrative procedures. These concern themselves primarily with the quality, safety, and efficacy of pharmaceutical products, manufacturing practices, information supplied about drugs, and drug expenditures. Some of these rules and regulations have been in place for decades or even centuries (Box 2). Others have been developed in the past thirty years. These rules and regulations have often been developed in a piecemeal fashion, and however well-justified they may be individually, they sometimes prove to conflict with one another. Spokesmen both for the public health sector and for the pharmaceutical industry have pointed out that all such rules and standards need to be coherent elements in an overall "national pharmaceutical policy," but to date this has rarely been achieved.

3. Rationale for regulation. The pharmaceutical market does not regulate itself in the absence of State interference, because it differs from other markets in several important characteristics which do not apply to other consumer goods:

   (a) the user (patient) generally does not select the drug--it is prescribed by a physician or other health worker;

   (b) even when the user selects the drug (as in the case of over-the-counter medicine which are often pictured as part of a more market-based system), he or she lacks the specialized knowledge to make a critical comparison of various products in terms of suitability, quality, and value for money;

Box 1. World Market for Pharmaceuticals

Global drug expenditures were estimated at US$100 billion in 1985, having doubled over the previous decade. Growth in expenditures has continued at a rapid pace: by 1992, the world market for pharmaceuticals was estimated at US$226 billion. In OECD countries, pharmaceuticals accounted in 1990 for 13.8 percent of total health expenditures (ranging from about 8.2 percent in Sweden to 24.4 percent in Greece). The proportion of health spending for drugs can be much higher in developing countries. In the Cote d'Ivoire and Pakistan, up to 90 percent of household health expenditures are for pharmaceuticals.
(c) even health care workers are insufficiently trained to make a full assessment of drugs, and depend largely on the claims of the seller. Furthermore, positive results of pre-marketing studies of safety and efficacy are sometimes contradicted by results when the drugs are used widely;

(d) the user is often insulated from the price consequences of consumption decisions, as the public sector or private insurers often pay for the drugs;

(e) even after the drug has been taken, neither the user nor the health care provider are fully able to assess its effects, since these are highly variable and the course of the ailment may be influenced by other factors;

(f) in cases where the user might in theory be capable of objective assessment, this can be impaired by hope and expectations: some 35 percent of the physically ill and 40 percent or more of the mentally ill respond to an ineffective product (placebo); and

(g) fear of illness can create illogical and costly demands: health professionals and patients have often generated a vast demand for worthless drugs.

4. In any particular country, the design of national pharmaceutical policies must be appropriate to the country context — factors such as the country's institutional capacity to regulate and undertake quality assurance, the level of spending on pharmaceuticals, and the characteristics of the actors involved in procuring, distributing and prescribing drugs. This paper explores the "Western model" of national drug regulation and policy, recent challenges

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1 In depth knowledge of a drug's effect on man requires carefully controlled studies in hundreds or thousands of patients. Even these, however, may leave open the possibility that further effects will emerge when the drug is used on a large scale and for a long period: Reye's syndrome in children was identified as a possibly fatal side-effect of aspirin only after the drug had been on sale worldwide for more than eighty years. Conversely, clioquinol was used for forty years to prevent and cure travellers' diarrhea before it became clear that it had little if any useful effect and might actually cause diarrheal problems.

2 Particularly during the period 1970-80, the product Laetrile developed a wide public following as a treatment of hopeless cases of cancer. Regulatory action was necessary to prevent its use since it was shown to have no useful effect and indeed to be poisonous because it contained prussic acid.
to this model, and approaches in developing countries. It also considers how two areas, namely, one, trade in sub-standard drugs and two, pharmaceutical research and development oriented to the health problems of developing countries, might be best addressed through international collaboration.

The Emergence of Drug Regulation and Policy: "the Western Model"

5. By far the most widespread model for drug regulation and policy is the one that emerged in consistent forms (though at differing times) in Western industrialized countries. This model involves extensive public interference in the functioning of the private sector without the state itself engaging directly in pharmaceutical manufacturing and trade. The principal aspects of the model are detailed below.

6. Adequate quality assurance. Countries enforce quality standards through regulations that provide for regular inspection and impose severe penalties on those selling medicines that do not correspond to the description on the label. Quality requirements, which led to the imposition of high manufacturing standards, have been strongly enforced in Western countries, and have received full support from the bona fide drug industry. The "Elixir of Sulfanilamide" disaster (see Box 3) was neither the first nor the last of public health problems that have arisen as a result of the marketing of unsafe drugs. Many other drug-related disasters were to follow, resulting in much more stringent safety legislation, both in the United States and in other countries. In particular, the tragedy involving thalidomide (Softenon), an apparently safe sleeping remedy from Germany that was used in pregnancy, caused thousands of fetuses to develop with grossly malformed limbs. The thalidomide episode stimulated the introduction of more stringent safety standards and closer inspection on the safety studies carried out by manufacturers.

Box 3. Safety

In 1937, a U.S. company marketed an "Elixir of Sulfanilamide." The drug was dissolved in diethylene glycol, a known substance but one which had not previously been used in medicines and which the producer had not tested for safety. Several died before the danger was made known and the drug withdrawn. The events led directly to the passage of the 1938 Food, Drugs and Cosmetics Act in the United States, imposing detailed obligations on manufacturers to test drug products for safety.

7. Manufacturing standards. By the mid-19th century, most Western countries provided for inspection of pharmacies and the definition of standards by which drugs would be made, for example, in a pharmacopeia. The need for high standards, to ensure that drugs are effective, pure and of consistent quality, has grown further with the increasing sophistication of drugs in

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3 In that "pre-pharmaceutical industry" age, most drugs were prepared in pharmacies, which had both functions of manufacture and distribution. In many Eastern European countries and the former Soviet Union, the manufacturing functions of retail and hospital pharmacies has remained important to date, especially for topicals, unguents and infusion fluids.
the present century, as many contemporary products can only be adequately produced under highly specialized industrial conditions. Detailed standards of "Good Manufacturing Practice" for pharmaceuticals have been laid down in recent years and have been widely recognized and implemented.\(^4\) WHO defined global standards in 1987 but some national authorities (such as the U.S. Food and Drug Administration) require substantially higher standards.\(^{12}\)

8. **Efficacy.** With the rise of "clinical pharmacology" as a science from about 1960 onward, it became clear that many drugs believed to be effective were in fact ineffective when tested with new methods.\(^{13,14}\) Scientific papers\(^{15}\) provided evidence of the wastage resulting from the widespread use of useless drugs. National laws were therefore extended and new regulations enacted to require formal efficacy testing.

9. **Correction.** The situation has taken much time, especially since new regulations tend to address new products rather than to apply to pharmaceuticals introduced long ago. A 1993 WHO study showed that even in industrialized markets a high proportion of the market was still made up of drugs that had never been shown to be effective and in many cases clearly were not.\(^{17}\) In developing countries with weaker regulatory systems, studies have pointed to the prominence of ineffective drugs in the market.\(^{18}\) The problem in developing countries is further complicated by the widespread use of traditional medicines, for which Western standards do not directly apply.

10. **Information.** The greater part of the information provided by the pharmaceutical industry is directed towards physicians. Because of continuing innovation in the drug market, the physician is constantly faced with new (and in some cases extremely novel) products, and is often incapable of determining whether the information provided by the manufacturer is reliable or not. Current national policies with respect to drug information are directed to ensuring that the data provided (for example in package inserts and reference volumes) are correct and complete. Increasingly, however, policies are moving beyond this and seeking to improve the education of medical students and physicians on the nature and use of drugs\(^{19}\) so that they can better make judgement for themselves about drugs.

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\(^{4}\) Even well-repected firms have sometimes produced drugs which failed to meet sufficient standards. A classic example relates to a supposedly improved formulation of digoxin, which was put into production in 1972 and caused serious poisoning because the active substance was released too readily into the body.
11. The extreme complexity of pharmaceutical knowledge has led Western Governments to try to implement stringent regulations for what they consider protection of the public and promotion of rational and informed use of drugs. The unreliability of drug advertising is a particular concern in the developing world, where regulations are lacking or hardly enforced. However, there are numerous instances from the industrialized world which illustrate the fact that manufacturers may fail to maintain proper standards in their advertising and promotion (see Box 4).

12. Requirements of competence. In most countries, only pharmacists are allowed to manufacture and sell drugs, and only physicians are authorized to prescribe them. However, variations exist as regards delegation of responsibility by physicians and pharmacists to nurses and pharmaceutical assistants. The authorization to prescribe a range of products for midwives and other para-medical professionals is also heavily regulated, as is the right to prescribe potentially addictive or highly toxic substances. Western countries also closely regulate which drugs are subject to medical prescription and which can be sold over the counter.

13. Drug costs. Among developed countries (Canada and the U.S. excepted, where more than 50 percent of drug expenditure is in the private sector), most drug expenditures are publicly financed, and fiscal concerns are important. Many industrialized countries have developed cost containment policies aiming at reducing pharmaceutical expenditures while avoiding risk to the patient (see Box 5). Techniques range from direct price controls, to limits on advertising expenses and profits, the use of non-branded alternative drugs, and restrictions on the range of products that a physician is free to prescribe. Opportunities to reduce waste are large in developing countries, where money is often squandered due to poor procurement, inefficient distribution, failure of patients to use the drugs properly, poor prescribing by health staff and theft.

Box 5. The Impact of Price Reform on Drug Prescribing in Germany

Germany introduced in 1992 a ceiling for the amount of drugs that physicians could prescribe, with financial sanctions on physicians if that amount was surpassed. This reform was undertaken in order to reduce the growth of pharmaceutical expenditures. Drug prescriptions for products with no or little efficacy dropped sharply (by 25% to 35%), revealing that prescribers were aware of which drugs were "medically justified" versus those with low efficacy.


14. Pharmaceutical expenditures are also a concern in most industrialized countries in terms of public health and equity. Governments are concerned that costs not pose a barrier for certain

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5 In most Western countries, drug manufacturing still has to be undertaken under the responsibility of a pharmacist, although his role today is more that of a member of an interdisciplinary industrial production team.
drug treatments (such as vaccines, tuberculosis treatment, and treatment for sexually-transmitted diseases) because of their public health importance. In developing countries, concerns about access to essential drugs take on even more importance in pharmaceutical policies. Finally, many governments consider that access to essential drugs should be equitable and not be restricted by ability to pay. These various objectives often conflict with one another.  

15. **Internationalization of drug policies.** While western pharmaceutical policies have generally been developed at the national level, there is increasing international harmonization. The twelve countries of the European Union have adopted almost identical laws and regulations, and since 1984, the European Union, Japan and the United States have cooperated closely to bring their systems more in line with one another. Up to the present, such harmonization trends have related primarily to the regulation of quality, safety, efficacy and information. The control of pharmaceutical expenditures has remained almost exclusively a national matter, with differing approaches in different countries.

**Other Models of Pharmaceutical Policy**

16. **Centrally planned economies.** The former Soviet Union and East European countries adopted systems in which the state engaged directly in the manufacturing, distribution and sale of drugs, generally having a monopoly in these areas. In Central and Eastern Europe, this approach has since 1988 been progressively abandoned in favor of the Western model. In much of the former Soviet Union the system is under review. It should be noted that even when centralized production systems were in place, control organs independent of the manufacturing plants were maintained by Ministries of Health in order to ensure the quality, safety and efficacy of drugs; these organs operated in a manner similar to those of Western countries, though in general they did not achieve the highest standards of quality.

17. **Developing countries.** In developing countries, pharmaceutical production is often limited and concerns relate primarily to the adequacy of imported drug supplies. The private sector of drug distribution generally limits itself to the supply of expensive drugs for relatively affluent urban populations, and public sector drug procurement is often inefficient and wasteful (see para 33). At the same time, there is much concern as to the unreliability of drug information and the poor quality of medicines circulating in both the public and private sectors. Even middle income developing countries exhibit similar problems: alongside manufacturers of the highest repute are makers of counterfeit drugs for both the home and export markets.

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6 An actual example relates to an attempt to save public money by awarding an "over-the counter" (OTC) status to certain expensive remedies for which the patient will pay himself rather than as prescription medicines which will ordinarily be financed in part by a health insurance scheme. If this entails releasing for free sale drugs which in fact can only safely be used under medical supervision, the attempt to economize will be successful at the expense of the patient’s safety, and may lead to further unexpected expenses.

7 Some developing countries have an important sector of pharmaceutical manufacturing (India, China, Brazil) but sometimes fail to encourage manufacture at international standards.
Regulatory systems, while loosely based on the "Western model," often show numerous loopholes, and there is rarely any successful development of policies to encourage objective advertising and promotion of drugs.

**Challenges to the "Western model" of Pharmaceutical Policies**

18. The development of massive public involvement in the control of the pharmaceutical sector, even in countries with the most "liberal" of economies, has not gone unchallenged. The research-based pharmaceutical industry in particular, while fully accepting the need for the maintenance of the highest standards, argues that the bulk of the industry should be fully capable of disciplining itself without extensive state interference. More specifically, it has pointed to the risks of shackling what is essentially a healthy and productive industry (see Box 6).

19. During the period 1975-1985, the challenge was directed primarily to the burgeoning regulation of quality, safety, efficacy and information by bodies such as the U.S. Food and Drug Administration and the organs of the European Community and its member states. Since 1985, industry's concern has been roused more by the efforts of governments to contain pharmaceutical expenditures. On both counts, the argument has centered on the risk that heavier regulation would choke the ability of the pharmaceutical industry to attract investment and perform innovative research for the public benefit.

**Box 6. Private Sector Viewpoints on Pharmaceutical Policies**

"... there is considerable evidence that regulation of drugs since the early Sixties has been a major factor underlying the negative trends in drug innovation. As regulatory standards become more stringent and demanding, the safety benefits must necessarily diminish while Research and Development costs and development times correspondingly increase. Although patent protection should provide a means by which to recoup these expenses and ensure adequate returns on investment, the effective patent life has continually been eroded over the past two decades. In many important non-US markets, pricing at introduction is dictated by or negotiated with Government regulators and price increases in subsequent years often fail to keep pace with inflation. In addition, such policies as government-encouraged use of generics after patent expiration counteract brand exclusivity and loyalty, thus reducing the expected returns to innovative firms in the post-patent period. Erosion of the innovative firms vis-a-vis generics increases the effects of some of the regulatory costs. In particular, regulatory time delays will have a greater impact on the total time period over which investment costs can be recovered... Although many regulatory efforts may be characterized as well intentioned and addressed to valid social grounds, taken in combination they have a significant adverse effect on economic incentives and capabilities of many firms investing in pharmaceutical Research and Development."

20. The importance of pharmaceutical research to medical progress is indeed well documented. In 1988, member companies of the U.S. Pharmaceutical Manufacturers’ Association re-invested about 14 percent of their turnover in research and development. Comparable figures for France are estimated to be 12 percent and 15 percent for the then West Germany. The world’s ten largest producers introduced a total of 462 new chemical entities into medical practice between 1961 and 1985. There is no challenge to the statement that the great majority of significant new drug advances achieved in the last fifty years are a direct result of research conducted and coordinated by the innovative pharmaceutical industry. However, this is a process that can easily be undermined; the increasing need for "developmental research," partly in order to meet officially imposed standards of proof, competes heavily with innovative research for resources. In the United Kingdom in 1985, 69 percent of research was classified as "developmental" and only 31 percent as "discovery research."

21. Many of these controversies have persisted because the presentation of evidence has often been selective and incomplete. On the pharmaceutical industry’s side, investment in research may be relatively overstated by industry (see Box 7), which is reluctant to admit that sums spent on research are still much less than those spent on various forms of advertising. On the government’s side, drug regulatory experts only rarely document the extent to which their activities serve the public interest. Statements made as to the ability of the pharmaceutical industry to regulate itself adequately actually apply only to a minority of major innovative firms. The International Federation of Pharmaceutical Manufacturers Associations has been prominent in drawing attention to the extent to which activities of undesirable firms result in the widespread sale of sub-standard and ineffective drugs in countries without effective controls.

22. Emerging of a technical consensus. On the basic elements of quality, safety, efficacy, information and manufacturing standards in drug policy, consensus is very wide. The major organizations representing the pharmaceutical industry have increasingly played a constructive role in the development of harmonized standards by leading industrialized countries. In so far as differences of opinion persist, they usually are secondary: they may relate, for instance, to the duration of particular safety studies or the exact limits of variation allowed in product content during manufacturing. Since confrontation has largely been superseded by collaboration, such issues are progressively being settled. It seems highly likely that any new problem that may arise, for example, from newly recognized safety risks, will be tackled in the same spirit.

Box 7. How Vulnerable is Research?

Figures advanced for the proportion of industrial earnings devoted to innovation are no doubt largely correct, but the extent to which this process is endangered by cost control measures can only be properly addressed if one also knows the proportion of earnings currently used for other purposes. Expenditure on advertising, in particular, may considerably exceed that on research, and might be eligible for reduction before any economies are made on innovation.

Recent reforms in drug pricing procedures in Germany and France have shown that research-based companies tend to reduce budgets for communication and advertisement and slow down new investment before reducing innovative research budgets.
It thus would seem logical to conclude that on these technical aspects of drug policy, agreement has become so broad that the practices of Western industrialized societies form a non-controversial model on which the rest of the world can draw. The widespread use of the European Union’s or the U.S. Food and Drug Authority’s drug regulations by countries of the former Soviet Union are characteristic of this trend. However, although theoretical agreement with such policies is wide, enforcement procedures vary from one country to another, and what is presented like a policy consensus actually glosses over serious discrepancies that sometimes undermine the very basis of such policy.

Pricing and cost control. Widespread government interference in pharmaceutical expenditures is a relatively recent phenomenon and generally corresponds to a fast rise in drug expenditures. It came into prominence in Europe in the 1980s (even though countries such as France already had cost and price control mechanisms long before). It has become a major issue in the United States only after the Clinton Administration took office in 1993 and adopted health reform and cost control as major policy objectives. The objectives of cost control measures, in general, are to avoid further acceleration in expenditures on medicines and to reduce those forms of expenditures that appear wasteful.

Examining the European scene in 1991, a WHO study noted the multiplicity of solutions proposed or implemented, the difficulty of assessing their results, and of distilling from them any applicable guidelines for policy. The same is clearly applicable, as of 1994, to the proposals advanced in the United States to contain pharmaceutical expenditures. Like many of the systems implemented in Europe, those proposals have already been criticized as constituting a danger to health care and innovative research.

As of 1994, the lessons from cost control in Western industrialized societies are not conclusive. It is not possible to develop policy models for developing countries or for countries moving from a centralized planned to a market economy, despite the clear need for these countries to develop their health services with close attention to cost containment. Western experience provides a catalogue of the techniques that can be considered, a view of the risks and pitfalls to be avoided, and some means of monitoring results. Persuasive measures, for example to counter the wasteful use of medicines or excessive promotional expenditures, certainly appear to merit priority over measures that may obstruct investment or innovation.

National Pharmaceutical Policies in Developing Countries

In the majority of developing countries, access to affordable drugs is the most pressing policy concern in pharmaceuticals. Pharmaceutical production tends to be limited in most developing countries and pharmaceutical policy concerns relate primarily to the adequacy of the
quality of imported drugs and the supply of drugs in the public sector, since resources are limited and the private sector has generally limited itself to marketing relatively expensive drugs for more affluent urban populations. As a consequence, the public sector has engaged heavily, often with international assistance, in the central procurement and distribution of medicines, for example through institutions such as "central medical stores." Such systems are commonly inefficient, as discussed below. At the same time, the unreliability of drug information provided in the private sector and the widespread availability of counterfeit and potentially hazardous products are key problems.

28. In low-income countries, one typically finds that the private sector does little to provide essential drugs to the majority of the population. Generally, drugs sold in private urban pharmacies are prohibitively expensive by local standards, and are sold to a relatively affluent minority. Others in the population receive medicines through charitable institutions, notably mission hospitals and health centers. Governments have sought to complement private sector activity by developing public channels of supply, typically with a publicly-run "Central Medical Stores" that imports and distributes drugs for use in the public sector. Such structures have commonly failed to supply the entire population with even basic needs. Donors have supported these organizations and promoted policy changes within them in recent years. These policy changes include more independence from the state and greater financial autonomy through cost recovery.

29. The severity of the problem of poor access to essential drugs in developing countries has led to much research to identify policies to improve access to drugs in the short run and to create a sustainable pharmaceutical supply system, independent of donor aid, in the long run. Several starting points have emerged from studies in a number of countries by the World Health Organization and other bodies, including the recent World Bank report Better Health in Africa.

30. Rules, regulation and their enforcement. In order to influence the drug market, national pharmaceutical policies must first include a definition of the actors in the system and their responsibilities: who can produce or import pharmaceuticals, who can prescribe which types of products, who can store and sell drugs, and which institution has responsibility for monitoring and enforcing regulations. Policies aiming at training a core group of staff to handle pharmaceutical regulations and further develop drug policies have become more and more necessary. One of the early priorities is the development of basic forms of drug registration so that the sale of sub-standard and ineffective drugs can be countered on the one hand, and that conditions for real competition in the market for essential drugs be developed. Good drug registration policies must allow for generic drugs to penetrate the pharmaceutical market as easily (or more than) brand name products. Drug registration must be performed by an expert

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9 Restructured central drug procurement agencies are typically semi-autonomous public institutions with an independent board and the ability to manage personnel and operations as private ventures.

10 In April 1994, a meeting of African drug regulators agreed on clear guidelines for the development of regulations in their countries.
committee, using standard and reasonable criteria. In many developing countries, in spite of elaborate sets of rules, regulations are often inadequately enforced and may contradict other goals set by pharmaceutical policies. Often there is no real system of sanctions for those who break the rules, nor real enforcement of penalties and sanctions. A review of the main rules applying to the sector may lead to proposals to amend them towards more simplicity and better adaptation to local realities (such as the abolition of the exclusive right to sell drugs granted to pharmacists in countries with very few pharmacists, which can lead to drug shortages and higher prices).

31. **Adequate quality assurance.** Pharmaceuticals of low quality, either imported or locally produced, should not reach the population. This calls for a system of quality control (including a national or regional control laboratory) and strict criteria for enforcement of the quality of distribution (storage, transport, packaging). The approach recommended by WHO is to restrict drug purchasing to drug suppliers who follow Good Manufacturing Practices (GMP) in production facilities, both for imported and locally produced goods. Local producers should proceed as fast as possible towards GMP standards and not be awarded a "right" to produce substandard drugs because of their nationality. However, upgrading of manufacturing standards often has to be staged over time. Regulations regarding quality must be enforced by a well-organized and trained inspection administration, independent from commercial pressure.

32. **Essential drugs.** There is general consensus about the principle of building policies in the first instance around national lists of "essential drugs" — drugs considered most vital for saving lives and alleviating serious and common diseases in the majority of the population. An essential drug list includes a limited number of drugs, contraceptives and vaccines of proven safety and efficacy, for which the activity and side effects are well known and documented. Essential drugs are almost always no longer protected by a patent, and are often available on the international market in generic form, which should allow countries to procure these elements of the "basic package" of health care in the most cost-efficient way. An essential drug list should represent the minimum list of drugs to which the population should have guaranteed access. Pioneered by developing countries such as Sri Lanka and by WHO from 1977 onwards, this concept was first criticized by private sector operators who feared it would impose a ceiling on the range of drugs allowed on the market. Gradually however, the notion that basic needs must be met before expenditures on other matters be considered gained ground, and the debate has shifted from the concept of essential drugs to more specific issues of implementation. Few countries actually enforce their essential drug policy to the point of barring all other drugs entry to the market. Many do, however, ensure that essential drugs are made available and that their use is encouraged. They disseminate information on their properties and proper use, and the national list of essential drugs is properly updated.

33. **Reforming "central medical stores.** State monopoly of drug procurement and distribution should be avoided, as this has in general proved inefficient and wasteful. The —

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11 That policy was attempted by Nigeria at the end of the 1980s.
improvement of procurement policies often has to deal with the reconstruction of "central medical stores" systems, which are often plagued with wasteful procurement, inefficient operation and wastage. Recent developments have led to the support of autonomous entities, structured in such a manner that they can be privatized at a later phase when competition has emerged and a more normal market situation exists. Still, there are grounds for improvement in procurement policies, especially in procurement planning, inventory management and international market intelligence. Some Governments also tend now to recommend sound procurement policies to the private sector.

34. **Adequate and stable financing for drugs.** The shortage of public funds for drugs has led to various systems of cost recovery, particularly in Sub-Saharan African, including community financing and cost sharing. Experience shows that the population is generally able and willing to pay for essential drugs, and that an improvement in drug availability (a general consequence of better availability of funds to buy drugs) can lead to improved attendance at primary care facilities. However, cost recovery policies for drugs have to avoid some serious pitfalls. The general health financing system has to be revisited when such policies are implemented. Using drug revenues to finance the operation of primary care facilities may lead to high prices and inequities, including reduced access by the poor.

35. **Training, education and information.** Promoting the rational use of drugs requires appropriate training of prescribers (physicians, nurses, health workers) and sellers (pharmacists and others). The involvement of medical schools and nursing programs in the promotion of essential drugs is important, and Ministries of Health also have a role to play in improving knowledge and practices in drug management and rational use. Ministries can produce formularies, drug bulletins, and better information, education and communication towards the general population. Information aimed at the public should focus on preventing the misuse of self-administered products, increasing patients' compliance with drug treatments prescribed, and improving the public understanding of generic substitution possibilities, and, if relevant, price controls. Governments can also introduce strict regulation of advertisement for pharmaceuticals.

36. **Improving private sector performance.** Policies providing appropriate incentives for the development of the private sector are increasingly being considered in developing countries. In some countries, protectionist policies have sheltered national private pharmaceutical producers, leading to high costs and poor productivity in the absence of international competition. Policies can encourage the private sector to extend its services to a larger proportion of the population, basing its growth on high volumes rather than (as hitherto) on high prices. Such policies, which aim at promoting the distribution of cheap generic products through the private sector, still raise controversies among drug producers and distributors. Public policies can also encourage

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12 In the aftermath of the devaluation of the CFA Franc in January 1994, the Government of Cote d'Ivoire required that the price of 65 pharmaceutical products remain at the pre-devaluation level and asked private pharmacists to procure them through international tender and to make a profit through improved procurement rather than increased prices.
professionals and patients to accept generic products for most purposes, thus pressing the private sector of drug distribution to meet demands of low-priced products.

37. From the evidence reviewed above, it is clear that some form of public involvement is desirable in the pharmaceutical field, especially in view of the risk of major tragedies in the absence of appropriate regulations. However, it also appears that there is no one single model to follow. In developed and developing countries alike, policies must continuously be reviewed and adapted to time, place and circumstances.

38. Implications for monitoring and evaluation. Policies have to be adapted to the specific context of each country and their effects carefully monitored. Whenever a national drug policy is implemented, provision must be made, however simply, for monitoring its effects as the situation develops. Policies may have important unintended negative consequences. If the removal of a simple stomach remedy from an insurance list or essential drugs list leads physicians to prescribe more exotic and expensive products, the result may be self-defeating in economic terms and also potentially harmful to patients. Monitoring often shows that persuasion, information and education rather than rigid restriction can better achieve a given policy objective.

39. In adapting pharmaceutical policies to national needs, policies can be better structured and more likely to succeed if they are built on dialogue with all parties concerned, both in and outside of government. Within government, several actors are involved in pharmaceutical policies: departments of health, education, finance, industry and trade. These groups should all contribute to planning and designing pharmaceutical policies, so that they can understand each other’s interests and concerns, and subsequently work harmoniously together.

Global Issues

40. Most pharmaceutical problems are best addressed at the national level through national pharmaceutical policies. But some policies are best addressed at a global or regional level because they are problems that go beyond the boundaries of national borders. Two such areas will be highlighted here: trade in sub-standard, ineffective, and/or counterfeit products, and pharmaceutical research and product development oriented to health problems unique to developing countries.

41. Trade in sub-standard products. In the world as a whole, there is a large trade in substandard and ineffective drug products. Some are based on recognized components but are so badly made as to be useless or even dangerous, others are formulated around substances or mixtures of no known value, and many are forgeries, or illegal copies of bona fide drugs. Trade in counterfeit drugs is suspected to account for almost 6 percent of pharmaceutical sales worldwide, and up to 70 percent in some in sub-Saharan African countries. Some sub-standard drugs can be hazardous to patients, they represent a net waste of pharmaceutical expenditures, and threaten the proper organization of pharmaceutical markets. A great many countries without fully developed regulatory controls are unable to recognize and counter such products. Some
exporting countries which do have the necessary controls for their own market fail to prohibit the export of sub-standard products to other nations. WHO's certification scheme does not effectively address this problem. There may be international mechanisms that could be developed to provide developing countries with services to better determine the quality of drugs they are importing. These services could include laboratory testing as well as maintaining a data base on the products and quality of different suppliers. Such a system would have the benefit, among others, of promoting the products of reputable developing country suppliers and weeding out disreputable ones. It would offer services unavailable to many low-income countries today. The need for such services would be lessened over time as countries improve their own regulatory controls.

Box 8. Various Types of Counterfeit Drugs

In general, the term "counterfeit drugs" applies only to fake drugs using the packaging specificities and trade name of another manufacturer. Some counterfeit drugs do not even include any active ingredients. In 1993, the manufacturer of an anti-inflammatory cream discovered that counterfeit tubes of that product were on the market in two African countries. Analysis showed that the counterfeit was made of slightly thickened shaving cream. Other counterfeit products include some active ingredient, (often at a lower concentration than the original products), combined with inappropriate excipient (inert substances that form the vehicle for the active ingredient), and are manufactured in unacceptable conditions.

The term "counterfeit" is also sometimes applied to drugs under a brand name (with no attempt to deceive consumers), that are similar to a drug protected by a patent. This use of the term "counterfeit" for drugs manufactured in countries where pharmaceutical patents were not recognized has raised some controversy. However, the 1994 GATT removed some of the grounds for such controversies as patent legislation is being generalized over the next 10 years to countries that hitherto opposed such legislation (such as India, Brazil and even China, which is not a GATT signatory yet).

42. **Pharmaceutical research and product development.** The 1993 World Development Report estimated that developing countries account for almost 90 percent of the global burden of disease. A significant share of that burden is from conditions such as malaria and tuberculosis that primarily occur in those countries. But according to estimates made by the Commission on Health Research for Development, only about 5 percent of the $30 billion spent on health research in 1986 went to health problems unique to developing countries.

43. Over a long period, the pharmaceutical industry was able to ensure funding and attract investment by its ability to charge relatively higher prices for its products in those markets best capable of bearing them, while providing products at lower prices to less affluent countries.\(^{13}\)

\(^{13}\) In the case of vaccines, that two-tiered price system is even more evident, and vaccines are sold in developing countries by UNICEF at prices sometimes 50 times lower than those of OECD countries.
It might be thought that, on balance, this resulted in an "equitable" distribution of the burden of costs, though in the latter countries there was a growing feeling that their population was being charged for research performed elsewhere and largely benefiting the population of wealthy Western countries. Increasingly, the ability of pharmaceutical companies to control markets has become eroded. Western countries have introduced a range of measures to reduce prices and costs; some cover a part of their needs by "parallel importation" from low-cost areas. Both more and less wealthy countries have increasingly promoted competition by encouraging (and in some cases mandating) the prescription of generic rather than higher prices brand-name drugs. This has encouraged the growth of manufacturers that rely for success on low production costs and do not engage in innovative research.

44. Examples of health research and development that would largely benefit populations in developing countries include the development of a malaria vaccine; improved drugs for treating malaria; a palatable, stable, and slow dissolving iron pill; and a contraceptive virucide to protect women against HIV-transmission. The private pharmaceutical industry may not find these types of research and product development activities attractive because of the weak markets that these problems represent. It is the poor in developing countries who suffer the most from disease, and have the least capacity to pay for pharmaceutical products. When private investment in pharmaceutical research and development falls well short of that which is socially optimal, there is a strong justification for public support to catalyze research and product development. This research is best funded and coordinated at an international level, because the benefits accrue to many countries. Groups such as the Special Program for Research and Training in Tropical Diseases at WHO have developed fruitful partnerships with commercial entities, national governments, scientists and NGOs to support research and drug development oriented to health problems of developing countries.

45. The 1993 World Development Report concluded that total investment in health technology research relevant to needs of developing countries is woefully inadequate in relation to its potential benefits and that the level of international coordination and cooperation falls short of what is required. An international mechanism could be considered to set priorities for public funding for health research and product development oriented at health problems of developing countries, to mobilize funds, and to finance research activities. Funding would go, in part, to the private pharmaceutical sector in both developed and developing countries. Drugs and vaccines often represent one of the most cost-effective ways to fight disease, and the need for

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14 Because of price discrepancies between countries of the European Union, the market share of parallel imports from countries where prices are low (France, Greece, Portugal) to countries such as Denmark or Germany was more than 5 percent in 1992.

15 In 1991, the market share of generics in Europe was 7 percent of the total drug market, with figures as high as 15 percent in Germany (source: IMS). However, the distinction between research based in generic companies is getting blurred as: (i) successful generic producers are being taken over by research-based companies (especially in the United States); and (ii) the latter often run generic versions of their own brand name drugs when their patents expire.
innovative pharmaceutical products and drugs remains high. More debate is needed on how these two global issues — trade in sub-standard products and the financing of health research and product development oriented to developing countries — might be better addressed at the international level. Possible World Bank involvement could be discussed in the near future regarding these issues.
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