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PUBLIC-PRIVATE ROLES IN THE PHARMACEUTICAL SECTOR:

Implications for equitable access and rational drug use

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Contents

Authors
Acknowledgements

Contents

Abbreviations and Acronyms

Executive summary i

1. Public and private roles in the pharmaceutical sector 1
1.1 Some definitions of public-private roles 2
1.2 Questions on public-private roles 3
1.3 The context of change 4
1.4 Principles for assessing public-private roles 7

2. Pharmaceutical markets: structure and performance 12
2.1 Drug financing and distribution systems 12
2.2 The pharmaceutical market: structures and actors 16
2.3 Pharmaceutical market failure 22

3. Essential state responsibilities 28
3.1 Policy-making 28
3.2 Drug regulation 28
3.3 Professional standards 32
3.4 Access to essential drugs 32
3.5 Rational drug use 33

4. The public-private mix in drug markets: a global picture 35
4.1 Production 35
4.2 National expenditure 37
4.3 Drug distribution systems 39
4.4 Household expenditures and sources of drugs 40
4.5 Summary points 41

5. Market mechanisms in public drug supply 44
5.1 Organization of the supply system 45
5.2 Desirability of using market mechanisms 50
5.3 Summary points 51

6. Promoting public health needs through the private sector 54
6.1 Public health concerns 54
6.2 Availability (geographical access) 56
6.3 Making drug prices affordable 61
6.4 Affordable financing for drugs 72

6.5 Rational drug use....74
6.6 Drug quality, safety and efficacy....76
6.7 Summary points....77

7. Pharmaceutical production and public-private roles....79
7.1 Arguments for and against public sector pharmaceutical production..79
7.2 The government's role in strengthening local production capacity....83
7.3 Summary points....86

8. Capacity-building and the process of change....89
8.1 The nature of capacity and capacity constraints....89
8.2 Approaches to enhancing capacity....94
8.3 The process of change....94
8.4 Summary points....99

9. Managing public-private roles....102
9.1 Developing a strategy....102
9.2 Monitoring and evaluation....104
9.3 Unanswered questions....105
9.4 Conclusions....108

References....91

Glossary....125

List of boxes

Box 1 Trade liberalization and deregulation: effects on the pharmaceutical sector in Latin America....6
Box 2 MEDS: an NGO essential drugs service in East Africa....17
Box 3 China: when government lets go of the reins....25
Box 4 The public-private mix in drug production, expenditure and distribution in the Newly Independent States....30
Box 5 Norway: increasing supply competition in a highly regulated environment....41
Box 6 Geographical equity of private drug distributors: evidence from francophone Africa....48
Box 7 Practices of dispensing doctors - drug use and health economics....49
Box 8 Promoting generic drugs....55
Box 9 Experience with price control systems....58
Box 10 Problems with rational drug use in the private sector....64
Box 11 Public sector production of pharmaceuticals - some difficult challenges....68
Box 12 NGO roles in contributing to regulatory capacity....75
Box 13 Self-financed drug registration....76
Box 14 Rapid reform: Central and Eastern Europe and the Newly Independent States....78

Box 15 A participatory approach to rational drug use in Australia 79
Box 16 An appropriate public-private mix for the pharmaceutical sector in Tunisia 84
Box 17 Evaluating evolving public-private roles in Guinea 87

List of tables

Table 1 Systems for financing and distributing drugs 12
Table 2 Public and private actors in the pharmaceutical market 14
Table 3 Essential state functions in pharmaceutical markets 24
Table 4 Health expenditures by region (1990) 31
Table 5 Pharmaceutical expenditures by region (1990) 32
Table 6 Comparison of supply systems for government and institutional health services 39
Table 7 Measures to promote access, rational drug use and drug quality in the private sector 46
Table 8 Generic drug use: some enabling factors 54
Table 9 Wholesale margins, retail margins, and tax as % of consumer price 59
Table 10 Measures for promoting rational drug use 63
Table 11 Instruments to promote access, rational drug use and drug quality: potential feasibility and effectiveness 65
Table 12 Arguments for public sector pharmaceutical production 67
Table 13 Factors influencing viability of local pharmaceutical production 70
Table 14 Capacities required to contract with and regulate the private sector 74

List of figures

Figure 1 Consumers, payers and health care providers 12
Figure 2 Percentage distribution of household health-care-seeking behaviour, Burkina Faso 34
Figure 3 Source of care for acute illnesses in Sri Lanka 35
Figure 4 Ratio of brand to generic price, Indonesia 53
Figure 5 Estimated annual value of exports for 80 countries 67

Abbreviations and Acronyms

CEE	Central and Eastern Europe
CHW	Community health worker
CMS	Central medical stores
DAP	Action Programme on Essential Drugs
DCC	Drug Control Council (Zimbabwe)
DPO	Drug Procurement Office
DRA	Drug regulatory authority
EDP	Essential Drugs Programme
FDA	Food and Drug Administration, USA
GATT	General Agreement on Tariffs and Trade
GDP	Gross domestic product
GMP	Good manufacturing practices
GNP	Gross national product
ICH	International Conference on Harmonization
IFPMA	International Federation of Pharmaceutical Manufacturers Associations
MEDS	Mission for Essential Drugs and Supplies (Kenya)
MOH	Ministry of Health
NDP	National drug policy
NFP	Not-for-profit
NGO	Nongovernmental organization
NIS	Newly Independent States
NMD	Norwegian Medicinal Depot
OECD	Organization for Economic Co-operation and Development
ORS	Oral rehydration salts
PBM	Pharmaceutical benefits management
PNDP	Philippine National Drug Policy
PPBE	Postpartum breast engorgement
PPI	Pharmaceutical price index
QUM	Quality use of medicines
TRIPs	Agreement on Trade-Related Aspects of Intellectual Property Rights
USA	United States of America
WHO	World Health Organization
WTO	World Trade Organization

Executive summary

In many countries, the relative roles of the public and private sectors are undergoing change. This is true for the pharmaceutical sector as well as for the overall health sector. It is essential that changes in public-private roles are designed so as to promote drug accessibility and rational drug use.

This document is targeted at policy-makers and managers at country, regional and international levels. It draws on experience and analysis to provide a practical guide to how public and private roles may affect drug accessibility and rational drug use.

Questions on public-private roles

This document addresses seven main questions:

1. How is the pharmaceutical market organized and what makes it different from other markets?

2. What are the essential responsibilities of the state in the pharmaceutical sector?

3. What is the current public-private mix in pharmaceutical markets?

4. Can market mechanisms help to improve efficiency and ensure access to essential drugs in the public sector?

5. What mechanisms best promote the availability, affordability and rational use of drugs in the private sector?

6. What role should the government play in the manufacture of pharmaceuticals?

7. What capacities are needed to manage changing roles and how can these capacities be enhanced?

Principles for assessing public-private roles

The changes in public-private roles in the pharmaceutical sector are interlinked with broader changes occurring in the macroeconomy, through health sector reform, and in the structure of the pharmaceutical industry. This context is described in this section. In addition, four principles are proposed for assessing public-private roles in the pharmaceutical sector:

- equity of access;
- efficient use of resources;
- rational use of drugs;
- drug quality.

Pharmaceutical markets: structure and performance

Pharmaceutical markets differ from markets for most other commodities, and even from markets for health care. This partly relates to the fact that drugs are a rather special commodity. Used appropriately they can save lives and improve health; used inappropriately they can be very harmful. Private drug markets are likely to suffer from a number of problems (known as market failure) including:

- informational imbalances between different actors in the sector;
- lack of competition created by patent protection, brand loyalty and market segmentation;
- external benefits in drug consumption.

In addition, unregulated drug markets will also create substantial inequity, particularly in terms of access to drugs. The special nature of drugs and of health care has led to complex market structures. To offset market failure governments have often engaged in drug financing and delivery — although not always with the desired effect. Private for-profit and not-for-profit actors also play key roles in the market.

Essential state responsibilities

Government intervention is required for pharmaceutical markets to function effectively. This section sets out the minimum functions for which government must take responsibility in the pharmaceutical sector. These are:

- policy-making (developing, implementing and monitoring national drug policies);
- drug regulation (licensing and inspecting premises and manufacturers, registration of drugs, control of marketing and independent drug information, and postmarketing surveillance);
- professional standards (education and licensing standards for pharmacists, doctors and other health professionals, developing and enforcing codes of conduct);
- access to drugs (subsidizing essential drugs for the poor and for communicable diseases, supplying drugs through government health services and ensuring universal access);
- rational use of drugs (establishing standards, educating health professionals and supporting public and patient education).

The public-private mix in drug markets

In terms of the pattern of public and private roles globally, data confirm the importance of the private sector in pharmaceutical production and supply, particularly in developing countries. In many countries of Asia, Latin America and the Middle East, over three-quarters of pharmaceutical expenditures are privately financed. Moreover, drugs in these countries account for a much larger proportion of total health care expenditures (often around 40%) than in established market economies.

Market mechanisms in public drug supply

Can market mechanisms help to ensure access to essential drugs in the public sector? This section describes ways in which market mechanisms have been used to strengthen public drug supply systems. These mechanisms include:

- autonomous drug supply agencies;
- direct delivery contracts;
- primary distributor systems.

Despite widespread efforts to reform old-style central medical stores there is very little empirical evidence on which to base policy decisions. While market mechanisms may be appealing strategies for reform, since they leave overall responsibility for drug supply in the public sector, there are a number of questions about their potential effectiveness which need to be addressed, namely:

- Will real competition take place?
- Can drug quality and service quality be maintained?
- Will efficiency actually improve?
- Can governments effectively negotiate and monitor contracts?
- Will there be sufficient financing?
- Will there be wider unforeseen consequences?

Policy-makers need to address these questions in the context of their own country before implementing such market mechanisms.

Promoting public health needs through the private sector

Provision of drugs through the private sector may conflict with principles of equity (both availability and affordability), rational use and drug quality, safety and efficacy. Government has a range of instruments that it may use to promote public health principles through the private sector. These include instruments that:

- affect the market structure (such as licensing and registration) of information and education (such as setting standards, directly providing information and regulating promotional practices);

- control prices (both producer and distribution prices, and retail margins);
- set incentives (financial and otherwise);
- address financing (such as community drug schemes and health insurance schemes).

There are often complex interactions between these instruments. This section describes these various instruments and analyses experiences with using them. Some instruments (such as legislation on drug registration and drug promotion, policies promoting generics, and continuing education) are essential elements of national drug policies. Others (such as provision of price information, training, and standard treatment protocols) are relatively straightforward instruments which are likely to be very useful to governments. A further set of potentially useful, but rather complex instruments (including incentive setting and financing schemes) are identified. Finally, for some instruments (such as regulation of producer prices for non-patent drugs and regulation of retail margins) too little evidence is available to be conclusive about their effects.

Pharmaceutical production and public-private roles

Of all the arguments for direct public sector involvement in pharmaceutical production, only a few are supported by strong empirical evidence. Although governments' objectives in establishing state production of drugs are often commendable, few governments have been able to realize these objectives. This does not mean that government cannot play an important role in strengthening local production capacity. However, the government's role is often best fulfilled by creating a stable economic and political environment, an efficient regulatory environment and favourable tax and duty structures. For governments that already have substantial involvement in the state production of drugs, the situation is rather more complex. Privatization may have costs as well as benefits and, depending on the local context, less drastic measures (such as contracting-out of management or liberalization of the sector) may be preferable.

Capacity-building and the process of change

No matter how well designed and well considered policies to change public-private roles are, they will falter if there is insufficient capacity to implement them, or if the process of implementation is insensitive to the interests of the people and groups who will be affected by them. Successful reform of public-private roles often does not mean reducing the role of government but rather transforming it. Government must learn to carry out new functions (such as contracting or establishing autonomous institutions) or alternatively improve and expand existing functions (such as regulation). Reform programmes need to forecast (and if necessary create) the capacities required to implement reforms successfully. Changes often take place at politically opportune moments rather than as a result of careful planning and consensus-building. It is essential, therefore, that monitoring, evaluation and the flexibility to adjust reforms be built into the reform programme.

Managing public-private roles

The final section of the paper provides a framework for governments that are planning reform of public and private roles. It addresses the questions:

- What are the key elements to consider in the design of a strategy?
- How can such a strategy be monitored and evaluated?

This section also draws the main substantive conclusions from the review of the evidence: what works, what does not work, and what we need to know more about.

1. Public and private roles in the pharmaceutical sector

Health is a fundamental human right. Access to health care, including essential drugs, is central to realizing this right. Public, private for-profit, and private not-for-profit sectors play a variety of roles in financing and providing health services. In many countries, these roles are now undergoing considerable change. This is true for the pharmaceutical sector as well as for the overall health sector.

Despite many notable successes in expanding access to low-cost essential drugs during the last two decades, problems persist. In the public sector of many countries funding for health care is insufficient and the available resources may not be well managed; drug stockouts are common, drug deliveries often late and inadequate. In both public and private sectors there are problems of drug quality and irrational drug use. The picture varies between regions and countries, and even within countries. For instance, in Europe the principal concern is often cost containment [79] whereas in sub-Saharan Africa improving the accessibility of drugs is a much greater concern.

Several of the proposed solutions to these problems involve changing the public-private mix in the pharmaceutical sector. For example, greater use of market mechanisms is often advocated as a means to improve public sector efficiency [135,136]. Promotion of the private sector may be seen as a means to bring extra funds into the pharmaceutical sector and to improve availability of drugs.

Though both the public and private sectors have long played an active role in health, efforts to look systematically at interactions between them are relatively recent. Since the early 1990s, WHO [84,120,122,123,125], the World Bank [49,85,136] and a number of academics [11,12,14,27,75] have explored the role of the private sector and market mechanisms. This exploration is part of broader health reform efforts aimed at improving equity, efficiency and quality of health care services.

One of the earliest country level efforts to look at potential contributions of the private sector was made by the Action Programme on Essential Drugs (DAP) in Africa in 1987 [19]. More recently, a discussion paper prepared for the DAP Management Advisory Committee considered the role of the private sector in health care and the provision of drugs [124].

The purpose of this document is to provide an overview of public and private roles in the pharmaceutical sector, a description of relevant concepts, options for managing public-private roles, and examples of relevant experience. The target audience is policy-makers and managers at country, regional and international levels. This is primarily a discussion document; for many of the issues considered here, experience to date and variations in national circumstances do not support a specific position. However, where there is sufficient experience to draw strong conclusions, the document describes them. Discussions of public-private interactions in health often involve pre-existing opinions for or against public or private sector strategies. For example, it is a common belief that the public sector is more equitable while the private sector is more efficient. Experience suggests that reality is more complex. Readers are encouraged, therefore, to open their thinking to the benefits and limitations of both the public and private sectors.

1.1 Some definitions of public-private roles

There are two distinct approaches to changing public-private roles. On the one hand, a government may actively seek to increase (or decrease) private roles. Sometimes, the range of strategies used to do this is referred to as privatization. On the other hand, a government may introduce "market forces" or "market mechanisms" into its own operations while maintaining public financing and provision of services.

Privatization approaches

The main approaches to privatization have included transfer of ownership, contracting out of services, and creating an enabling environment for the private sector [84,103,134].

- **Transfer of ownership:** Privatization is properly defined as the transfer of ownership from the public to the private sector. This includes divestiture or sale of specific assets such as health insurance organizations, hospitals, drug supply warehouses (central medical stores) or other health care entities.

- **Contracting-out services:** Provision of specific services such as storage, transportation, or computer information services may be contracted to private for-profit or private not-for-profit organizations.

- **Creating an enabling environment for the private sector:** Financial incentives, regulatory changes and other incentives may stimulate private sector growth. Such incentives may be targeted to achieve specific drug policy objectives. For example, duties may be removed on pharmaceutical raw materials for essential drugs, registration of generic drugs may be expedited to promote their sale in the private market, or essential drug services of NGOs may be exempted from certain taxes.

These are active approaches to sustaining or increasing private activity in the health sector. In addition, some countries have experienced "passive privatization" whereby the role of the private sector has grown not because of a shift in government policy but because the quantity or quality of government health services could not meet the rising demand for health care.

Introducing market mechanisms

Such policies are designed to capture private sector efficiencies while maintaining public sector control. Policies introducing market mechanisms include:

- **Introducing private management features in public services** [26,100]**:** Public sector employment is sometimes characterized by low pay, pay that is unrelated to performance, inflexible personnel policies and cumbersome administrative procedures. Public sector management improvements promote performance-based pay, more flexible personnel policies and streamlined administrative procedures.

- **Creating internal markets in public services** [84,91,103]**:** The United Kingdom and several other European countries are using provider payment arrangements to create public or internal markets. Providers are encouraged to improve quality and efficiency by competing for patients. Internal markets may offer consumers the right to choose and may provide financial incentives for public health providers.

1.2 Questions on public-private roles

This document considers seven questions regarding the appropriate roles of the public and private sectors:

1. How is the pharmaceutical market organized and what makes it different from other markets?

2. What are the essential responsibilities of the state in the pharmaceutical sector?

3. What is the current public-private mix in pharmaceutical markets?

4. Can market mechanisms help to improve efficiency and ensure access to essential drugs in the public sector?

5. What mechanisms best promote the availability, affordability and rational use of drugs in the private sector?

6. What role should the government play in the manufacture of pharmaceuticals?

7. What capacities are needed to manage changing roles and how can these capacities be enhanced?

The questions are considered in order. Section 2 considers the nature of pharmaceutical markets. From this analysis it is clear that pharmaceutical markets differ from markets for most other goods and services and that, in order for them to operate effectively, government intervention is required. Section 3 describes the essential state responsibilities in the pharmaceutical sector. Section 4 describes the current global pattern of the public-private mix in pharmaceutical markets. Section 5 looks at private mechanisms for public drug supply. Section 6 reviews mechanisms for meeting health needs through the private sector. Finally, Section 7 explores the arguments and evidence on the role of the state in pharmaceutical manufacturing. In Section 8 the document considers the implications of reform in public-private roles for government, and in particular government capacity to manage new roles and the process of change. Section 9 presents conclusions.

The remainder of this section considers further the context of public-private roles in the pharmaceutical sector and the principles that help assess those roles.

1.3 The context of change

Consideration of public and private roles in the pharmaceutical sector is taking place in the context of three closely linked issues: health sector reform, rethinking the role of the state, and globalization.

Health sector reform

Reform programmes in the pharmaceutical sector need to take account of what is happening in the broader health sector. In this context, it is essential to separate the *principles* and *objectives* of health reform from the *alternative means* for reform.

"Reform" is meant to be a change for the better. Principles for health reform include universal access to essential health services, solidarity, and pluralism to allow individuals a choice of various service options [5]. Thus, the objectives of health reform are equity of access, quality of services, efficiency, and acceptability to consumers. These objectives are sought through reforms in the organization, financing, delivery and regulation of health services.

As part of the reform process, health sector policy-makers in many countries are actively seeking ways to increase the role of private providers and to work more effectively with the private sector. In addition, shifts in the public-private mix are part of a larger package of health sector reform which may also include [26]:

- improving the performance of the civil service (including reducing staff numbers, revising salary scales, and providing clearer job descriptions and appraisals for staff);
- decentralization, both to local government and through the establishment of autonomous bodies;
- improving the functioning of ministries of health through organizational restructuring and strengthening of management;
- broadening health finance options (user fees, community finance, etc.);
- introducing managed competition.

Thus, privatization, decentralization and other such changes are among the *means* which governments may choose in order to implement health reforms; yet these measures should not be seen as the objective of reform.

Rethinking the role of the state

Debate about the proper role of government vis-à-vis the private sector has a long and venerable history, but since the 1980s the debate has been heightened both by the rise of the "new right" which strongly advocates a reduced role for government and by the failure of centrally-planned economies to ensure economic security for their populations. Strong governments in some European and North American countries systematically moved back the borders of the state, privatizing many state-owned industries and reshaping the welfare state and the way that government does business. The full effects of these reforms and their impacts on service delivery and the welfare of the population are only just becoming apparent [100].

Middle-income and lower-income countries have also reconsidered the role of the state. In formerly centrally-planned economies, market ideologies were often espoused with enthusiasm and very rapid privatization occurred. Many other low-income and middle-income countries were pushed by both fiscal constraints and donor conditionalities towards a package of measures which made the private sector the central engine of growth and trimmed back public sector involvement in all aspects of the economy.

Although initially privatization was targeted at state-owned enterprises, social sectors have increasingly been drawn into the debate. In the social sectors outright privatization has rarely appeared appropriate. Instead, governments throughout the world have experimented with greater use of contracting measures and the introduction of market mechanisms into the public sector [92,103,115]. In many countries interest in the relative roles of the public and private sectors in health care has drawn attention to the large numbers of existing private providers and has raised questions both about the quality and efficiency of their services and about the implications of their operations for equity.

Globalization and implications for the pharmaceutical sector

Rethinking public-private roles is taking place at a time when the pharmaceutical sector is already undergoing major transition [40].

Intellectual property protection

The Uruguay round of GATT discussions provided for worldwide patent protection. The research-based industry claims that this will further stimulate research and will have a positive impact on direct foreign investment and the transfer of technology to countries without an innovative pharmaceutical industry of their own. However, local industries which previously prospered claim that lack of competition will result in higher prices for new drugs and that drugs will be imported rather than produced locally [29,40].

Globalization of the world economy

The spread of free trade areas has made importation of products considerably easier. Many countries have recently jettisoned long-standing tariff structures that supported local manufacturing industry (see Box 1). There are increasing efforts (such as the International Conference on Harmonization (ICH)) to harmonize standards for quality, safety and efficacy which will further contribute to globalization.

Industry consolidation

During the 1990s there has been a wave of mergers, acquisitions and strategic alliances among pharmaceutical companies. This process of consolidation has been accompanied by a streamlining of operations, including the closure and concentration of research facilities.

Generic products

The end of patent protection on many high-selling drugs has also changed the face of the industry as generic products become of increased importance, even to multinational corporations. Today most major companies have generic product lines.

Box 1. Trade liberalization and deregulation: effects on the pharmaceutical sector in Latin America [61]

In Latin America, a long period of inward-oriented growth, during which the behaviour of firms and institutions was shaped by signals from the domestic market and by import substitution incentives, is slowly coming to an end. Trade liberalization, deregulation, privatization and more careful management of fiscal and external accounts are inducing far-reaching changes. Most Latin American governments are rejecting the use of tariffs to strengthen domestic industries, anticipating that market forces will bring a more rapid rate of modernization and upgrading of domestic production. The health sector is by no means exempt from these changes. Import substitution policies allowed countries such as Argentina, Brazil and Mexico to develop strong pharmaceutical and chemical industries; as much as 55% of the domestic consumption of final drugs was supplied in Argentina by domestically-owned firms. This share was 20-25% in the case of Brazil and Mexico where local subsidiaries of multinational corporations managed to control a larger share of the market. Some 25-40% of intermediate pharmaceutical raw materials were locally produced by these three countries. Three basic features characterized the institutional framework of the pharmaceutical industry of Argentina, Brazil and Mexico during the post-war period. These were:

- lack of full patent protection;
- high import tariffs for pharmaceutical raw materials;
- advantages in product registration for locally owned firms.

As a result, locally owned small and medium-sized family enterprises rapidly expanded during the period 1950-1980. The 1980s saw the start of a series of structural reform measures in these countries which radically changed the institutional framework:

- product patents were introduced largely due to GATT agreements;
- trade liberalization and market deregulation affected pharmaceutical pricing and reduced the advantages in registration previously given to local producers.

Although these reforms should have resulted in greater competition in the pharmaceutical market, the price of drugs has increased rapidly in recent years. Between 1988 and 1992 real drug prices in Argentina, Brazil and Mexico increased by 16.6%, 24.2% and 44.5% respectively. The impact of these price increases on affordability and social security systems has yet to be fully evaluated.

The composition and conduct of the industry is also changing; locally owned firms have discontinued small-scale raw material production for their own needs but are more likely to import raw materials. Licensing agreements between domestic firms and large multinationals have become more common. It is unclear what effect these changes will have in the long term on the availability of generics and prices of drugs in the market.

1.4 Principles for assessing public-private roles

Public-private roles in the pharmaceutical sector must be considered both in the context of a particular country's perspective on the importance of solidarity in health care and in the context of the overall goals of national drug policies.

Solidarity

Differences between countries in responsibility for drug financing and distribution reflect in part different societal values [45]. In some societies individual freedom is given great importance and in these societies the market is seen as the most appropriate way to distribute goods, even for essential

services such as health care and drugs. In other societies there is much more emphasis on the good of the community as a whole and these societies tend to give government a much greater role in the production and allocation of goods.

While for many goods an individualistic approach is appropriate, for health care and essential drugs there are strong ethical and pragmatic arguments for an approach based more on the collective good and on solidarity [22].

- **Ethical arguments include:**

– equity means fairness, and health care should be allocated on the basis of need;
– health, health care and essential drugs are basic human rights that should be accessible to all.

- **Pragmatic arguments include:**

– disregarding equity is socially destabilizing;
– jeopardizing the health of the poor will have spill-over effects for everyone in society;
– neglecting health among part of the population will damage long-term productivity.

Solidarity recognizes the interdependence of people's lives [24]. Policies in the pharmaceutical sector jeopardize the nation's health if they ignore this interdependence.

National drug policy aims

The central aim of any national drug policy is to ensure access to and rational use of drugs which are safe, effective and of good quality.

Public-private roles in the pharmaceutical sector should, therefore, be designed to:

- ensure equitable access to drugs and, in particular, to essential drugs;
- ensure efficiency in the use of resources for drugs;
- promote rational use of drugs in both the public and the private sectors;
- ensure enforcement of standards for quality in both the public and the private sectors.

Equitable access

Public-private roles in the pharmaceutical sector should ensure equitable access to drugs and, in particular, to essential drugs.

Equity addresses two questions: Who pays? Who benefits? It reflects the solidarity principle that health care should be provided according to need and

financed according to the ability to pay [114]. From a public health perspective, this is a fundamental principle for considering public-private roles.

Equity can be examined from a number of different perspectives [77], but for the pharmaceutical sector the most critical perspectives are:

- Who pays? Contributions should be made according to ability to pay. Therefore the wealthier should contribute more than the poor.

- Who benefits? Those with greater need should benefit more than the less needy. *Equitable access* means that essential drugs, when needed, are available to and affordable by all.

The financial cost of seeking care includes the costs of time and travel, and the costs of purchasing drugs. In order for drugs to be *financially accessible*, the total of these costs must be such that it does not unduly burden a family. *Geographical accessibility* refers to accessibility to the full range of essential drugs throughout the country.

In assessing whether there truly is equitable access to drugs, policy-makers need to ask: "When a person at any level of society is sick and needs a drug, does that person receive an adequate quantity of a therapeutic product at a cost that does not unduly burden the family?"

Policies that increase access in the public sector and policies that improve affordability and availability of drugs through the private sector both contribute to equitable access.

Efficient use of resources

Public-private roles in the pharmaceutical sector should ensure efficiency in the use of resources for drugs.

Efficiency is concerned with the cost of producing a given output. Efficiency (in this sense "technical efficiency") is improved if greater output can be achieved for the same cost or if the same output can be achieved at a lower cost.

It is often asserted that the private sector is "more efficient" than the public sector. Yet efficiency in the private sector is neither guaranteed nor proven. Market forces are unlikely to result in an efficient outcome where there is little or no competition. If, for example, consumers can obtain drugs only from one private outlet, then prices (and possibly costs) at this outlet may rise and/or the quality of service may decline. The imbalance of information between consumers and providers of drugs may also adversely affect efficiency.

Improvements in efficiency depend on the existence of more efficient alternatives and on the flexibility and performance pressure(usually

competitive) to pursue these more efficient alternatives. Reform efforts should aim to achieve these conditions in both the public and the private sectors.

Rational use of drugs

Public-private roles in the pharmaceutical sector should promote rational use of drugs in both the public and the private sectors.

Problems with the irrational use of drugs have been widely described, usually on the basis of studies in the public sector. These problems include general overprescription of drugs (polypharmacy), overuse of antibiotics, overuse of injections, underuse of effective products such as oral rehydration salts, and use of dangerous or ineffective drugs.

In the private sector these problems may be exacerbated by strong economic pressures, lack of information or lack of training. Clinicians may prescribe too many drugs, expensive drugs or inappropriate drugs because of perceived patient expectations, drug company promotional efforts or because they gain directly by dispensing the drugs they have prescribed. Private drug outlets may try to maximize their income with more costly recommendations and dispensing — often on the basis of incorrect or inadequate knowledge of the drugs they are selling [113]. For consumers, high drug prices and lack of information lead to ineffective or harmful self-medication or to the purchase of insufficient quantities of antibiotics and other necessary drugs [37,52,53,66].

Efforts to promote rational drug use must address economic barriers, as well as informational and social barriers, to the effective use of medicines.

Drug quality

Public-private roles in the pharmaceutical sector should ensure enforcement of standards for drug quality in both the public and the private sectors.

The quality of drugs is of equal concern in both public sector and private sector drugs supply systems. The state has a central role in establishing and enforcing quality standards, and these standards should be uniform in both sectors. The same standards of quality are applicable both to drugs procured for government health services and to drugs in the private market. The continued success of established drug companies depends in part on their reputation for quality. Thus, it is in the long-term interests of private industry to maintain standards of quality.

2. Pharmaceutical markets: structure and performance

How is the pharmaceutical market organized and what makes it different from other markets?

Drugs are a special commodity. Used appropriately they can save lives and improve health; used inappropriately they can be harmful and even fatal. Drugs are not only costly inputs into health care services, but their availability tends to promote trust in those services. Although often self-prescribed and self-administered the reasons behind the efficacy of drugs remain a mystery to the average consumer. It is not surprising that the pharmaceutical market differs substantially from other markets.

This section describes and analyses the structure of pharmaceutical markets and identifies the key actors in them. It then explores the ways in which pharmaceutical markets differ, both from regular markets and also from health care markets.

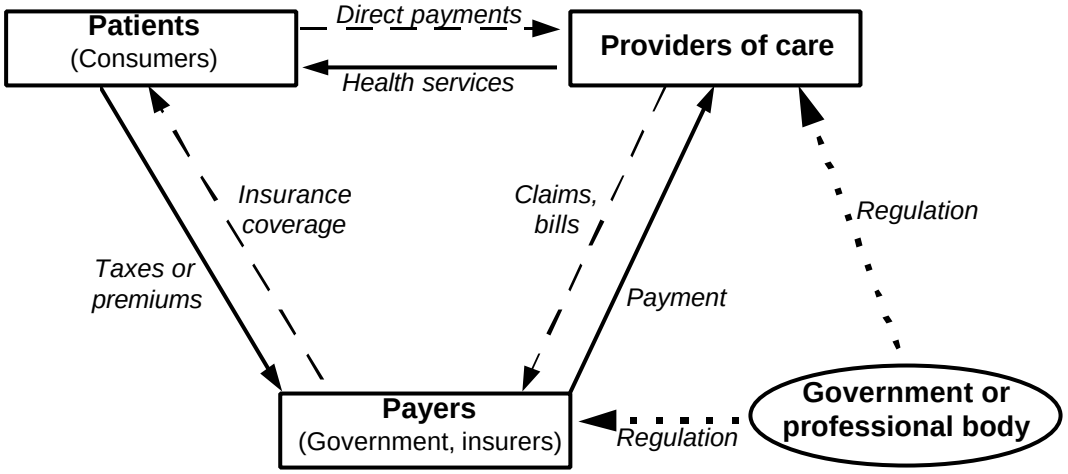
2.1 Drug financing and distribution systems

Much of the special nature of markets for health care stems from the triangular relationship between the consumers, the providers of health care and the agencies that finance it or pay for it (Figure 1). Patients often do not pay directly for health care; instead they pay taxes to the government or premiums to an insurance agency which in turn channels funds to the providers. In most standard markets, prices play a central role, providing signals to both consumers and suppliers. If prices go down, consumers will demand more; if prices go up, then consumers will demand less. As patients in health care markets often do not bear the full cost of care, prices cannot perform the same central role of bringing supply and demand into balance.

Although some systems of "third party payment" exist in virtually all countries, they tend to be much less prevalent in poorer countries where consumers continue to pay for a substantial amount of health care directly out of their own pockets. Consequently the types of problems encountered in countries with substantial insurance schemes are quite different from those where such schemes have limited coverage. Where insurance is common, a key concern is often how to contain costs. In countries with very limited insurance, however, much more attention is paid to the question of affordability.

This triangular relationship exists also in the pharmaceutical market. In many cases, patients receiving drugs will not pay the full price or they will pay but then be reimbursed by an insurance scheme.

Figure 1: Consumers, payers and health care providers (adapted from [81,122])



Many reforms in OECD countries have been based on the separation of the financing and the provision of health care [34,103]. In order to improve efficiency, governments have attempted to stimulate greater competition between providers, both public and private. The state has, however, retained control over finance. Competition, rather than public or private ownership *per se*, is seen to be important.

A separation between financing and distribution functions is also illuminating in the pharmaceutical sector (Table 1).

Public financing includes government budgets (central, regional and local) and compulsory social health insurance programmes. *Private financing* includes out-of-pocket payments by individuals and households, private health insurance, community drug schemes, cooperative schemes, employers' schemes, and financing through other nongovernmental entities.

Public distribution includes wholesale distribution and retail dispensing by government-managed drug supply and health services as well as distribution through state-owned enterprises (state corporations). *Private distribution* includes private for-profit wholesalers and retailers, and not-for-profit essential drugs supply services.

Table 1. Systems for financing and distributing drugs

Distribution / Financing	Public	Private
Public	(1) Government CMS to government providers	(2) Many social health insurance reimbursement systems and contracted-out drug supply systems
Private	(3) User fees at government health services	(4) Fully private systems

Adapted from [13]

The four quadrants of Table 1 represent four basic models of pharmaceutical financing and distribution. Each model carries inherent advantages and disadvantages.

Fully public centralized system (model 1)

Drugs are financed, procured and distributed by a centralized government unit. This has been the standard approach in many countries in Africa, Asia, Europe and Latin America.

This approach may offer insufficient incentives for technically efficient behaviour by the distributor, and the total amount spent on drugs is constrained by the government budget. On the other hand, government involvement in both financing and distribution means that fully public systems can potentially be very equitable ones and monopsony ("single buyer") power in purchasing helps procure drugs at low cost.

Social health insurance reimbursement system (model 2)

Public funding from central budgets and social health insurance premiums is used to reimburse pharmacies or patients themselves for drugs provided through private pharmacies. This approach has been followed in recent years in many western European drug distribution systems and in North America and Australia. Publicly funded drug supply systems which are largely contracted-out to the private sector also fit into this quadrant.

The model may capture some of the benefits of the supposedly superior efficiency in distribution of the private sector, but probably at the cost of higher administrative expenditures. Limited finance may also be a problem.

User fees at government health services (model 3)

Drugs are supplied by government medical stores or state-owned wholesalers and dispensed by government health facilities, but paid for (in whole or in part) by patient fees. This was the case for a time in many former centrally-planned economies. In the 1990s, this approach is being used by China and by government health services in Africa, Asia and Latin America which have implemented user fees for drugs.

Few developing countries manage to raise substantial amounts through such user fee schemes [30], however the amounts raised may have a positive impact that is disproportionate to their size. Such schemes often have adverse implications for equity [45]. In the pharmaceutical sector a special concern is the impact on rational drug use. If providers have a direct financial incentive to prescribe more drugs, or to prescribe more expensive drugs, then this may adversely affect rational drug use.

Fully private (model 4)

Patients pay the entire cost of drugs, purchasing from private retail pharmacies and drug sellers which now exist in nearly every country in the world, accounting in some cases for over 90% of drug distribution. This fully private approach probably accounts for the majority of non-prescription drug sales. Outside market economies that have higher levels of social and private health insurance, this approach probably represents the major source of payment for prescription drugs in most countries.

The fully private system may be technically efficient, but it is therapeutically inefficient. Although the profit incentive may enable private drug suppliers to deliver drugs to the patient at low cost, there are often substantial problems with the provision of low quality drugs, inappropriate drugs and incomplete courses of treatment. These problems mean that the cost may be high for the health benefit gained. A fully private system is also likely to impede access for those with lower incomes who are unable to pay for drugs.

Mixed systems

Most countries have a combination of two or more of these models in operation. Private financing and private provision exist to a greater or lesser extent in nearly every country. With the current pluralistic approach that many countries are taking in the provision and financing of health care, different models may be found for different groups in the population. For example, fully public financing and supply may be used for the poor and for the treatment of communicable diseases, social health insurance for civil servants and those in formal employment, and the fully private model for populations and categories of drugs not covered by the other systems.

2.2 The pharmaceutical market: structures and actors

The pharmaceutical market in most countries is a complex and heterogeneous array of agencies, organizations, companies and individuals. Within the pharmaceutical supply system a number of subsystems exist, including those related to drug development, regulation, production, distribution, prescribing and dispensing (Table 2). Different actors — or stakeholders — are involved at different stages of this process and include actors from the public sector, the private not-for-profit sector, and the private for-profit sector. Government regulation may be directed at any or all of these different points in the supply system. This makes regulatory choices highly complex.

Table 2. Public and private actors in the pharmaceutical market

Function	Public sector	Private not-for-profit	Private for-profit
National drug policy	• Ministry of Health (focal point)	• Professional associations • Consumer groups	• Pharmaceutical companies

ß	• Other government ministries	• Health care providers	• Health care providers
Drug development ß	• National research institutes • Government research grants • State universities	• Private universities • Private foundations • Research institutes	• Research-based pharmaceutical companies
Drug registration & regulation ß	• National drug control authority	• Consumer organizations (e.g. monitoring promotion)	• Selected contract services (e.g. quality control testing)

Table 2. Public and private actors in the pharmaceutical market (continued)

Function	Public sector	Private not-for-profit	Private for-profit
Production/ importation ß	• State importation monopolies • State-owned production • Central medical stores	• NFP essential drugs production • NGO / mission essential drugs services	• Local multinational factories • Locally-owned factories
Wholesale distribution ß	• Central medical stores • State wholesalers • Regional distribution	• NGO / mission essential drugs services	• Private large-scale wholesalers • Private informal wholesalers
Drug information ß	• National formulary and treatment guidelines • Hospital and university drug information centres	• Drug information centres • Consumer groups	• Media • Industry
Prescribing/advising ß	• Government hospitals • Government health centres, dispensaries • State-owned pharmacies • Publicly-supported CHWs	• Mission hospitals • Mission clinics • CHWs	• Private hospitals • Private clinics • CHWs with user fees • Injectionists
Dispensing/retail sale ß			• Pharmacies • Dispensing clinicians • Other drug outlets
Consumption by population	Households / consumers		

Drug development and production

Drug manufacturers may or may not be involved in innovative research. They may be wholly locally owned, or they may be owned by multinational companies, or they may have partly local and partly multinational ownership. There are a few examples of NGO drug production, such as Gonoshasthya Kendra pharmaceuticals in Bangladesh.

The nature of the manufacturer will affect its attitude to policies for changing public-private roles. The international research-based industry strongly opposes price controls as its profitability depends on the launch of innovative new products at good prices. For local firms producing generics, price controls may be less of an issue as they are active in what is already a fairly competitive market. Attitudes towards good manufacturing practice may also differ substantially between actors.

Drug regulators

The central reference point for regulation will generally be a national drug regulatory authority. Such an authority will usually incorporate a department responsible for drug evaluation, registration and control of standards for

production, importation and marketing, an inspectorate division and quality control laboratories. However, it is quite common for some of these functions to be formally or informally delegated to other organizations. In the USA a private not-for-profit organization is responsible for setting drug standards which are then enforced by the Food and Drugs Administration (FDA) [4]. In Sri Lanka the committee that approves pharmaceutical products is based in the Department of Pharmacology at Colombo University [117].

Besides those organizations formally involved in regulation, consumer organizations, the media, professional organizations, manufacturing and trade associations and, where relevant, insurance schemes can all play a key role in ensuring the effectiveness of regulation. It is in the interest of these groups to cooperate. Although they may hold very different views of what regulation is appropriate, the desire for a clear and effective regulatory framework is common. Deregulation is sometimes seen as a means of favouring the private pharmaceutical sector, but deregulation can in fact lead to an erosion of that sector's credibility and to unmanageable competition among unqualified suppliers.

Drug wholesalers

Drug wholesalers may also be publicly or privately owned. Public drug wholesalers may have a monopoly or partial monopoly position. Several not-for-profit organizations have drug wholesaling operations (Box 2).

Drug information, prescribers and retailers

Drug prescribers may be anything from well-qualified specialists in hospitals down to unlicensed "quacks". Retail outlets may be operated by qualified pharmacists, pharmacy assistants or technologists, or untrained drug sellers. In countries where there are now user fees in the government health care sector, a growth in "one-stop pharmacies" has been observed; these employ doctors, clinical officers or nurses both to prescribe and to provide drugs [15].

Drugs may also "leak" from poorly managed or poorly funded government health care systems. Thus, in a number of countries it is not uncommon for publicly funded drugs to be sold by government officers working privately [7].

Nongovernmental organizations

NGOs — sometimes known as the "third sector" — play an important role in the financing and provision of health services in many countries. The share of health services and health financing provided through the private not-for-profit health sector varies considerably between countries, but in low-income countries it can amount to as much as 50% of curative services [13,44]. India (Community Development Medicinal Unit), Kenya (MEDS), Nepal, Nigeria (CHANPHARM) and Uganda (Joint Medical Stores) are among the countries in

which NGOs operate essential drugs supply services. Box 2 describes the origin and operation of MEDS in Kenya.

Besides having a direct role in financing and provision, "third sector" agents such as consumer organizations, trade associations and professional associations may critically influence the policy and regulatory framework. Through lobbying, such organizations may affect government policy and legislation. Through the adoption of voluntary codes of conduct they may affect the behaviour of the actors whom they represent. They may also perform a watchdog role by monitoring the implementation of policies and regulation.

For all of the actors in the pharmaceutical market it is important to look not only at whether they are publicly or privately owned, but also in more detail at their capacity, technical skills, motivation (for-profit or not-for-profit) and the immediate environment within which they operate.

Box 2. The Mission for Essential Drugs and Supplies (MEDS): an NGO essential drugs service in East Africa

NGO drug services

Beginning in the late 1970s, coincident with the introduction of the essential drugs concept by WHO, mission health associations in some countries began to organize essential drugs supply services. NGO essential drugs services generally develop and then strictly follow their own essential drugs list, based on the WHO model list. NGOs obtain drugs from the national parastatal (where one exists), external suppliers or local manufacturers. Financing usually comes from a combination of external donations, local donations and user fees.

Despite some financial and organizational difficulties, NGO essential drugs services have generally been very successful. The problems that have occurred relate to sudden currency devaluations which have temporarily disrupted supply and to matters of quality control of drugs for some organizations.

The example of MEDS [70,71]

The Mission for Essential Drugs and Supplies programme was established in 1986 by two Kenyan religious organizations, the Catholic Secretariat and the Christian Health Association, to supply good quality essential drugs at a reasonable cost to church-managed health units throughout Kenya. These units constitute roughly 36% of the country's rural health services.

MEDS supplies drugs to more than 300 hospitals, health centres and dispensaries. The MEDS programme has the approval of the country's Ministry of Health but is autonomous both from the church organizations that set it up and from the government. It has been financed by governmental and nongovernmental organizations in three European countries by means of a revolving fund, by its Kenyan sponsor organizations, and by its clients' drug purchases. It has received consulting advice from WHO/DAP.

One of MEDS' methods for keeping drug prices down while keeping supplies constant has been bulk buying from local producers; about 70% of MEDS' drug items are of local origin, and still more would be purchased locally if local prices were competitive for drugs of comparable quality. Thirty per cent of the drugs have been imported from Zimbabwe and Europe (requiring foreign currency). The cost of importing drugs into Kenya has been increased by value added tax and by a levy of 1.5%, even on donated drugs.

In early 1993, a serious situation emerged with the sudden free float of the Kenyan shilling, leading to immediate price rises of up to 50%. MEDS tried to keep its own price rises to 10% the following month, but with considerable difficulty. One measure taken was implementation of 30-day payment terms on the units being supplied, as these were the terms imposed on MEDS by importers and wholesalers.

Bulk purchasing has involved the maintenance of sizeable storage and distribution facilities, in addition to quality control operations and sales to at least four international NGOs for their local operations. A management staff of 15 administrators has been assisted by 15 warehouse personnel. Hospitals and health centres are charged a fixed price for the costs of transport, paying on 90-day terms. When some hospitals failed to pay for the drugs and transportation costs, new orders were refused until accounts were paid.

MEDS has provided training for programme staff and health facility personnel on the rational use of essential drugs. Training of health facility personnel is especially important, as the programme's success depends on the proper and efficient use of available drug resources. Training, initially supported by the Ministry of Health and foreign funding (both later withdrawn), uses up a large proportion of MEDS' resources, and many local training needs remain unmet. In 1993, the staff training team comprised nine people, three of them medical professionals; 227 personnel were trained that year. A 1993 evaluation showed that drug consumption by the units declined after training, and that there was a switch to ordering from the essential drugs list.

2.3 Pharmaceutical market failure

Government involvement in the pharmaceutical market has traditionally been far more extensive than in markets for most other goods. Not only the extent of government intervention matters, but also the form. Governments can inform, regulate, mandate, finance and provide [85]. As many governments consider changing the relative roles of the public and private sectors, it is worth reviewing the underlying reasons for different government interventions. Economic theory provides a useful framework.

Economic reasoning suggests that in "perfect markets" willing buyers and sellers should be left to transact their business without government interference as the market will lead to an optimal solution. However, the necessary conditions for a perfect market are rarely fully met and pharmaceutical markets are likely to be plagued by market failure. The main forms of market failure in pharmaceutical markets are considered below, together with possible government responses.

Informational imbalance

For commodities such as cabbages and candies, producers, sellers and consumers are all equally aware of the quality of the product and its value for money. However, if one party to a transaction knows more than the other about product quality this creates space for markets to fail. In the pharmaceutical sector information about quality, safety, efficacy, value for money and the specific appropriateness of individual drugs often varies between the parties involved.

The extent of market failure

Informational imbalance (or asymmetries) probably constitutes the most serious form of market failure in the pharmaceutical sector. As in the health care sector generally, the consumer (or patient) often knows less than the prescriber or dispenser. However, there are also substantial informational differences between other actors in the sector.

Several types of informational problems occur:

- **Drug efficacy:** Most actors will be less well informed than the manufacturer about the efficacy of the drug. This is a problem in virtually all contexts. Prescribers and consumers must depend (at least partially) on the manufacturer for information about the effects of the drug.

- **Drug quality:** There may be substantial questions about the quality and safety of the drug. This is a critical issue in countries with weak regulatory authorities where unsafe drugs are often marketed.

- **Appropriateness of the drug:** Patients tend to know less than the prescriber about the appropriateness to their needs of specific drugs.

Consequences and responses

Informational imbalance between the prescriber / dispenser and the patient allows the prescriber / dispenser to give misleading advice in order to increase profits. Lack of knowledge about a particular product on the part of the prescriber may be reflected in irrational prescription patterns. Some manufacturers may manipulate this lack of information by providing distorting information so as to enhance their own sales and profitability.

Government has a range of tools with which to respond to these problems. These tools include quality regulation, regulation of promotional practices (preventing practices which provide inaccurate or biased information), provision of information and training (to both consumers and prescribers), strengthening of professional ethics to prevent prescribing for profit, and licensing and registration of virtually all actors in the sector. Professional associations and drug manufacturers' associations may also take measures, such as voluntary codes of practice, to prevent the worst consequences of information differences.

Failure of competition

When there are many buyers or sellers of a commodity the actions of any single actor do not affect anyone else. However, if there are few buyers or sellers then these few may be able to exercise market power. In the case of sellers this is *called monopoly power*, in the case of buyers it is known as *monopsony power*. Market power enables sellers to charge higher prices than they would in a situation of perfect competition.

The extent of market failure

Unlike the overall health care sector, the pharmaceutical sector suffers substantial problems related to the failure of competition. High initial investment costs mean that average production costs reduce only when a large quantity of a drug is produced. However, with international trade, it is rarely the case that a true monopoly of this sort exists. Instead market power is created through:

- **patent protection**, which exists in order to encourage research and development;
- **brand loyalty** created through marketing which generates market power even after patents expire;
- **market segmentation,** especially by therapeutic subclass;
- **gaining control over key inputs,** thus preventing other firms from competing effectively;

- **implicit collusion** between firms through, for example, price-fixing.

An alternative perspective suggests that, due to the special characteristics of drugs, competition takes undesirable forms. In particular, because of the life-saving nature of many drugs and the fact that patients do not pay for them directly in many countries, there is unlikely to be substantial price competition but rather competition in product quality, innovation and brand awareness.

Consequences and responses

The most obvious consequence of the failure of competition is higher prices than would be expected in a competitive market. The two main responses are to create more competition in the market and to regulate prices or profits. Both of these responses are evident in the pharmaceutical market. Governments have tried to create more competition through the regulation of promotional practices and through generic substitution policies. Price controls are also common.

Externalities

Health services such as immunization and the treatment of contagious tuberculosis or sexually-transmitted diseases have benefits for people who consume the services, but they also have external benefits (termed 'externalities' by economists) to other people.

The extent of market failure

Externalities are widely prevalent in the health and pharmaceutical sectors. They occur with treatment for all communicable diseases or in the provision of vaccines against such diseases.

Consequences and responses

If consumption of services with externalities is left to the market, then the level of immunization or treatment will be less than what is desirable from a social perspective. Public health will suffer and both individual and collective health costs may rise.

Subsidizing the services with externalities is the standard response to this problem. By reducing the price for at least some consumers, the government can increase consumption of a drug and hence boost demand. It is not necessarily the case that goods with externalities need to be provided free of charge. The appropriate level of subsidy will depend on how far the level of (unsubsidized) consumption falls short of the optimal level.

Equity

Equity, strictly speaking, is not a form of market failure. There is no assumption in economics that perfect markets will lead to equitable situations. But equity is a central policy objective of many governments. Governments often target the

poor and the underserved, although in practice they may not succeed in this goal.

Equity is also an important objective for some private not-for-profit organizations. In sub-Saharan Africa, mission facilities have historically been located in remote rural areas in order to serve the very poor [44].

Private for-profit organizations generally do not have equity as an objective. Their profit-oriented nature may even directly conflict with financial and geographical equity.

Access to pharmaceuticals in the private for-profit sector is granted on the basis of willingness to pay. Those unable to afford drugs will be denied access to them. Moreover private for-profit providers locate where willingness to pay is greatest, which tends to be in urban areas. Poorer rural areas will remain underserved.

Yet the poor in many countries rely on private for-profit drug sellers and pharmacists. Why is this so?

- **Drugs may appear less expensive in the private sector:** Private sector drug sellers may be more willing to sell drugs in small and affordable quantities although people will not be cured without taking a full course of treatment and may even suffer adverse effects (such as increased drug resistance).

- **There is limited access to public sector drugs:** Although in principle the public sector is in a good position to ensure equitable access to drugs, in practice political pressure and other threats to government effectiveness result in inequity. A large share of drug budgets may be allocated to urban referral hospitals rather than to rural dispensaries, for instance. Sometimes referred to as the "inverse care law", the result may be that those with greater needs receive less care [17].

- **People will find money to pay for private sector drugs if there is no access in the public sector:** This often means borrowing money, which may have adverse long-term effects on the welfare of the household.

Equitable access to essential drugs can be achieved only by government subsidy of the drug costs of the poor. Government may choose to provide these drugs itself, or alternatively there are a number of means (such as vouchers or reimbursement systems) whereby subsidies can be targeted at the poor who seek drugs from private outlets.

Government may also consider ways to make the private for-profit sector more geographically equitable, such as by offering incentives or subsidies to locate in more remote areas. Such incentives have a cost. This cost needs to be compared

to that of the government extending its own services and providing drugs directly.

3. Essential state responsibilities

What are the essential responsibilities of the state in the pharmaceutical sector?

Purely private markets for pharmaceuticals are unlikely to be either efficient or equitable. This is apparent from the preceding discussion. Thus, government needs to improve the operation of private markets by establishing a clear policy and regulatory framework. Regardless of how involved the private sector is in the financing and distribution of drugs, it is up to the state to ensure that a set of core functions are performed. These essential state responsibilities include policy-making, drug regulation, establishing professional standards, ensuring access to essential drugs and promoting rational drug use (Table 3). These functions constitute the minimum for which the state must take responsibility.

The state may choose not to implement all of these responsibilities itself; it may delegate some functions to other actors in the pharmaceutical sector. For example, professional bodies may be involved in setting educational standards and developing codes of conduct. The appropriateness of the state's delegating any of the tasks described below to others will depend on capacity in both public and private sectors and on the availability of suitably qualified and motivated agencies. Regardless of who performs these functions, the state must assume responsibility for ensuring that they are performed, and that they are performed effectively.

3.1 Policy-making

National drug policies are guides to action. They provide a framework for the evolution of the pharmaceutical sector [118]. Within the context of national health policy (stated or implicit), national drug policies promote access, rational use and quality of drugs.

National drug policies should be developed with the broad involvement of the full range of public, private for-profit and private not-for-profit organizations or individuals discussed in Section 2.2. However, the ultimate responsibility rests with the state for ensuring that a policy exists and that it is implemented.

3.2 Drug regulation

Concern for public health and welfare requires a degree of regulatory control over drug quality, safety, efficacy, and use [57,64,118]. An example of how

increasing deregulation may have a negative impact on health and welfare is described in Box 3.

Table 3. Essential state functions in pharmaceutical markets

1. Policy-making

- Development and routine review of national drug policy, including elements of policy on:
  - government financing of drugs (how much of what?)
  - affordability (including policies on price regulation and price competition)
  - rational drug use
  - drug quality
- Legislative, regulatory, and programmatic initiatives for policy implementation
- Policy monitoring and evaluation

2. Drug regulation

- Licensing and inspection of importers, wholesalers, pharmacies and other drug outlets
- Licensing and GMP inspection of manufacturers
- Registration of drugs (safety, efficacy, quality)
- Control of marketing and independent drug information
- Post-marketing surveillance (safety, efficacy, quality)

3. Professional standards

- Setting educational standards for pharmacists, doctors and other health professionals
- Licensing of pharmacists, doctors and other health professionals
- Developing and enforcing codes of conduct

4. Access to essential drugs

- Subsidizing the costs of essential drugs for the poor
- Ensuring the geographical accessibility of essential drugs
- Supplying essential drugs to government health facilities
- Ensuring appropriate levels of consumption of drugs and vaccines for communicable diseases

5. Rational use of drugs

- Ensuring availability and dissemination of unbiased information
- Continuing education of health professionals
- Public and patient education

Drug regulation depends on the existence of a legislative framework which defines which organization has the authority to regulate and over which areas it has regulatory control. Within this legislative framework the appropriate regulatory authority must then issue specific regulations to cover both public and private sectors and should specify the sanctions to be taken in the event of failure to conform. Effective enforcement of sanctions is imperative if regulations are to have credibility.

Self-regulation by industry or coregulation involving industry and consumer groups is increasingly promoted as a means to complement public sector regulatory capacity. However, such approaches can be fraught with difficulty. Considerable effort is still required to find the best blend of regulatory inputs.

Box 3. China: when government lets go of the reins [21,25,67,107,138]

The context

During the period 1960-1983 China established a "Cooperative Medical System" which brought at least basic health care services to almost the entire population. Rural doctors were paid on a work points system by the local commune. The commune also purchased some care from higher-level facilities for its population.

As the system of communal agriculture in China broke down, so did the old ways of financing and providing health care. By the end of the 1980s the Cooperative Medical System had collapsed in about 90% of Chinese villages. About three-quarters of finance for health care in China came from user fees. Rural doctors generally no longer saw themselves as government employees but as independent private practitioners. At the same time, government controls on higher-level facilities were relaxed; hospitals were given greater managerial autonomy and control over their own finances.

The impact on health and health care

The reforms in China have had an extremely negative effect on access to health care services, particularly in rural areas. It is now estimated that 700 million Chinese have no prepayment or insurance coverage and must thus pay out-of-pocket for virtually all health services. Household surveys have documented a large number of untreated sick people. For example, a national household survey in 1988 showed that 25% of the rural population who needed referral to a hospital were not admitted, largely due to financial problems [25]. Health care expenditures also appear to be a major factor in causing poverty. In a survey of 1013 poor households, nearly 50% of them cited illness as the principal cause of poverty [67].

The declining financial accessibility of health care services has also affected health status. Immunization coverage began to decline towards the end of the 1980s and there have been several recent unexpected outbreaks of immunizable diseases. Both child and infant mortality declined steadily until the 1980s, but the decline in these indicators then stopped and even showed a slight upward drift. This is despite recent rapid macroeconomic growth.

The impact on the pharmaceutical sector [107]

Prior to 1980 health stations stocked only a small number of essential drugs. Since that time, rural doctors have been granted the right to prescribe all drugs except narcotics and major tranquillizers. They have not been provided with extra training to match these new powers.

Health stations in poorer counties often appear to stock more drugs than those in wealthy ones. This probably reflects economic necessity; drug sales are the easiest way to make money. Health facilities have the right to manufacture drugs and an increasing number of small health stations are producing traditional remedies in order to generate revenue.

Several studies have reported inappropriate drug use — the use of injectables rather than oral preparations, and the use of second-line and third-line drugs where simple ones would do.

Ensuring an effective regulatory framework for the pharmaceutical sector is a major challenge for governments. Many countries have a legislative framework but inappropriate or outdated regulations. Equally or more commonly, regulations exist but enforcement agencies do not have the capacity to implement them. The issue of regulatory capacity is discussed further in Section 7.

3.3 Professional standards

In addition to ensuring the quality of drugs, the state is also in the best position to ensure the quality of the health professionals who prescribe, administer and dispense drugs to patients. The state, therefore, has a responsibility to maintain adequate and appropriate educational standards for pharmacists, doctors and other health professionals, to ensure through the licensing process that these standards have been met, and to ensure that codes of conduct are developed and implemented. Professional associations or councils generally play a key role in each of these functions.

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3.4 Access to essential drugs

Recognition of health as a fundamental human right brings with it the responsibility of the state to ensure access to health care, including essential drugs. This does not mean that the state should necessarily finance and provide all drugs. A share of drug needs — in many countries a very large share — may be met through private financing and supply mechanisms. However, the state has a responsibility to ensure that together the public and private sectors make essential drugs accessible to the entire population.

The poor bear a larger part of the burden of disease than do the affluent. In order to ensure equitable access to essential drugs for the poor, government will need to subsidize their drug costs. Government may also wish to subsidize the costs of essential drugs for high priority groups such as children.

For tuberculosis, sexually transmitted and other communicable diseases there are high costs to society if full drug therapies are not geographically and financially accessible to all. In order to ensure effective control programmes for these communicable diseases government may need to subsidize their costs. The issue of making drug prices affordable is dealt with in detail in Section 6.3.

Geographical accessibility of essential drugs may be promoted through the public and/or private sector. Regardless of the strategy or mix of strategies

chosen, government should ensure the availability of essential drugs in public health care facilities. Without such drugs the credibility of the public sector is damaged, other inputs such as staff time are wasted and inappropriate drug consumption patterns may be encouraged.

A variety of mechanisms are available to promote geographical accessibility in the private sector (see Section 6.2).

3.5 Rational drug use

Free markets require full and accurate flow of information between buyers and sellers. Informational imbalance between drug producers and health care providers, and between health care providers and patients, is a major contributor to failure in the pharmaceutical market. Irrational use of drugs may stem both from lack of knowledge on the part of the providers and from the use of guile to mislead less informed consumers in order to increase profits.

Efforts to promote rational drug use aim to ensure that independent and unbiased information is available and that this information is actively used by prescribers, dispensers and patients. In addition, the state has a role in ensuring that professional ethics are not misplaced in the pursuit of profit. Measures for promoting rational drug use are described more fully in Section 6.5.

4. The public-private mix in drug markets: a global picture[1]

What is the current public-private mix in pharmaceutical markets?

Any discussion of policies changing the balance of public and private roles in the pharmaceutical sector needs to be rooted in an understanding of what the current mix is. The relative roles of the public and private sectors can be measured in many ways. In this section we explore the mix with regard to:

- production;
- national expenditure;
- distribution systems;
- household expenditure.

4.1 Production

Pharmaceutical development and production is a major private sector activity for many countries. Several OECD countries and some low- and middle-income countries such as Argentina, Brazil, China, Cuba, Egypt , India, Indonesia, Mexico and Sri Lanka have quite substantial private, and in some cases public, drug manufacturing plants with important innovative capabilities.

The public-private mix in drug production depends mainly on the industrial policy of each country, economic conditions, market, and varied other factors. In addition, it is a question that may substantially change in the future with the globalization of the economy and the effects of the recent international agreements on trade and intellectual property rights (TRIPs).

Box 4 summarizes data available for the Newly Independent States of the former Soviet Union. Country situations obviously vary immensely. In small and low-income countries in particular, a state-owned pharmaceutical production plant may be the only drug manufacturer.

[1] More detailed information on global pharmaceutical expenditures can be found in *Global comparative pharmaceutical expenditures. Health economics and drugs*. [131]

Box 4. The public-private mix in drug production: expenditure and distribution in the Newly Independent States

[Primary data provided by participants at WHO European Regional Seminar on Pricing and Reimbursement] [139]

Production

All of the Newly Independent States (NIS) have some pharmaceutical production capacity, although this varies between states such as Georgia and Ukraine which have substantial capacity and the smaller Asian republics, many of which have just one production plant which is publicly-owned. In Armenia and Georgia there has been fairly rapid privatization of production. The pace has been slower elsewhere.

	ARM	BLR	GEO	KAZ	KGZ	MDA	TJK	TKM	UKR	UZB
No. of local production plants		10	6	18	14	1	1	1	1	21
% private plants	80%	33%	67%	0%	0%	0%	0%	0%	10%	0%

National expenditure

There is a substantial variation in drug expenditure per capita in the NIS from a high of US$ 26.32 per capita in Armenia to a low of US$ 0.52 in Tajikistan. To some extent the differences reflect variation in GNP per capita, but there are also unexplained variations. For example, Armenia has a very high drug expenditure per capita compared to the other states although its GNP per capita is close to the mean of the group. In virtually all the NIS the proportion of expenditure is very high compared to global figures (see Table 4).

	ARM	BLR	GEO	KAZ	KGZ	MDA	TJK	TKM	UKR	UZB
Drug market US$ millions	97	164	56	185	11	55	3	13	317	91
Drug exports per capita US$	26.32	15.89	10.42	10.75	2.55	12.74	0.52	3.38	6.12	4.18
% private	98.0	67.2	61.1	100	99.4	97.0	96.5	67.5	88.7	100
GNP per capita US$	680	2160	-	1160	630	870	360	-	1910	960

Distribution

Different rates of privatization are evident between countries in wholesale and retail markets. Armenia is notable in having very high rates of private sector participation in both wholesale and retail markets. In Belarus the wholesale market is dominated by the private sector but the majority of retail outlets remain in the hands of the state. This pattern is reversed in Uzbekistan.

	ARM	BLR	GEO	KAZ	KGZ	MDA	TJK	TKM	UKR	UZB
Wholesale										
Number of distributors	15	307	110	155	25	133	1	7	39	20
% private	80	98	68	84	75	0	0	0	0	0
Retail										
Number of pharmacies	1090	1334	1507	7731	608	702	507	406	6809	2537
% private	84	19	97	2	35	21	7	11	1	53

Key: ARM - Armenia, BLR - Belarus, GEO - Georgia, KAZ - Kazakstan, KGZ - Khyrgystan, MDA - Moldova, TJK - Tajikistan, TKM - Turkmenistan, UKR - Ukraine, UZB - Uzbekistan.

4.2 National expenditure

Drug expenditure must be viewed in the overall context of health expenditure.

National health expenditure

Table 4 summarizes data on estimated health and pharmaceutical expenditures by region for 1990.

Per capita expenditure on health varies greatly, from US$ 36 for sub-Saharan Africa to nearly US$ 1675 per capita in established market economies.

Globally, approximately 60% of health expenditures are from public sources (primarily taxes, plus social health insurance premiums). In established market economies the average is rather higher at about 77%.

In many developing countries private spending as a percentage of total spending is considerably higher than in the established market economies. This is particularly noticeable in Asia, where public sources account for less than half of all spending on health. This reflects both low national social insurance coverage as well as low general government revenue expenditures on health.

Table 4. Health expenditures by region (1990)

		Health expenditures		Health expenditures by source (%)		
Region (N)	N	Total per capita (US$)	As % of GDP	Public	Private	Aid flows
Established market economies	25	1675.2	7.73	77.0	23.0	-
Middle Eastern Crescent	32	189.1	4.27	55.0	42.9	2.9
Economies in transition	19	150.3	4.27	72.7	27.3	-
Latin America and Caribbean	33	118.1	5.30	54.9	37.4	7.6
Asia and Pacific islands	33	60.2	4.01	40.9	48.1	11.0
Sub-Saharan Africa	47	35.7	4.86	33.4	37.6	28.8

Source: Ref. [82]

Note: mean values listed here are arithmetic means and therefore differ from original reference.

National pharmaceutical expenditure

Comparative information on pharmaceutical expenditures by region is presented in Table 5. These data, and country-specific data reported separately [131], suggest the following:

- **Per capita drug consumption varies greatly among regions and countries:** As with total per capita health expenditures, drug expenditures vary up to 17-fold between regions, and figures also vary enormously within regions.

- **Private spending on drugs accounts for a greater share of total pharmaceutical spending in developing countries:** Among established market economies, private spending on drugs averages less than 40% of total pharmaceutical expenditure, while more than 60% of pharmaceutical costs are paid through public budgets and social insurance (over two-thirds when figures from the USA are excluded). In contrast, in many countries of Asia, Latin America and the Middle East, over three-quarters of pharmaceutical expenditures are privately financed. Exceptions include countries such as Bhutan and Papua New Guinea, where private sector coverage is low and public supply predominates.

- **Spending on drugs accounts for a greater share of total expenditure on health in lower-income countries:** Among the 19 European and other established market economies for which data are available, the median expenditures for pharmaceuticals is 13% of total health expenditures. Only in Greece and Portugal, with lower per capita health expenditures, is more than 25% of total health expenditure devoted to drugs. In contrast, pharmaceutical expenditures represent 35% of total public and private health expenditures in Thailand, 39% in Indonesia, 45% in China, and 66% in Mali [131]. Comparison of per capita pharmaceutical expenditures and per capita health expenditures suggests that drugs may account for over 50% of total expenditure on health in a number of African countries.

Thus, the share of GDP spent on pharmaceuticals is similar in different regions. But in developing countries private spending plays a relatively greater role in drug expenditures and drugs take a higher share of total expenditure on health.

Table 5. Pharmaceutical expenditures by region (1990)

		Pharmaceutical expenditures		Pharmaceutical expenditures by source (%)	
Region	N	Total per capita (US$)	As % of GDP	Public	Private
Established market economies	25	137.5	0.6	59.8	39.6
Middle Eastern Crescent	32	26.8	0.7	26.0	74.0
Economies in transition	19	19.5	-	-	-

Latin America and Caribbean	33	26.4	0.9	28.5	71.5
Asia and Pacific islands	33	11.8	0.6	18.6	81.4
Sub-Saharan Africa	47	7.8	0.9	33.2	66.8

Source: Ref. [9,131]
Note: This work combines data from 140 countries with estimates developed by the authors to adjust for missing data. More recent data on transitional economies is available (see Box 4).

4.3 Drug distribution systems

It is often difficult to obtain data on the number of private drug distribution points in countries. The data which are available, together with anecdotal evidence, suggest that the private sector, particularly in low-income countries, is the major drug retailer both in terms of the value of drugs sold and in terms of the number of outlets.

In 1994 the estimated numbers of private pharmacies in Kenya and Zambia were 290 and 150 respectively [15,16]. These figures, however, include only registered and licensed sellers of prescription drugs. Drugstores, shops selling drugs and street vendors are far more numerous and often sell prescription drugs, although they entirely escape Ministry of Health information systems.

Data on the proportion of public and private involvement in the retail and wholesale pharmaceutical markets in the Newly Independent States are shown in Box 4. However, these figures are again likely to exclude unlicensed drug sellers.

When comparing public and private drug distribution systems, geographical coverage must be carefully considered. In low-income countries with difficult terrain, dispersed populations and relatively few trained pharmacists, formal private distribution channels serve primarily the few urban centres. This is the situation in many African countries. For example, in Kenya 47% of pharmacies are in Nairobi, and three wealthy provinces account for 71% of all pharmacies in the country [15]. It is also the case in some Asian countries such as Nepal and Papua New Guinea.

Outside formal distribution channels, drugs may be widely distributed through shops, drug sellers of various sorts and other informal channels. However, the range, quality and storage conditions of drugs distributed in these ways are highly variable.

Government health systems aim to provide primary health care coverage, including essential drugs, to all parts of the country. In practice, financial, logistical, political and other factors lead to inadequate supply of essential drugs in a number of countries. Remote areas often experience the greatest shortages.

4.4 Household expenditures and sources of drugs

Data on household expenditure complement those from other sources. Such data provide insights into both utilization patterns and the level of private out-of-pocket expenditure.

At the individual and household level, drugs represent the major out-of-pocket expenditure on health. A survey from Mali found that 80% of household expenditure on health was for modern drugs, 13% was for traditional medicine, 5% was for provider fees, and 2% was for transportation costs [35]. In Côte d'Ivoire and Pakistan more than 90% of household health expenditure was related to drugs [136]. Drugs or traditional products represent 62% of financial costs per treatment episode in Burkina Faso, with 17% for provider fees and 21% for transport and other living expenses incurred while seeking care [39].

Among 14 countries of Latin America and the Caribbean, drugs represented 35% of direct private expenditures on health. Figures ranged from slightly under 15% in the Cayman Islands and Uruguay to 44% in Peru, 45% in Guatemala, 46% in Colombia and 47% in El Salvador [94].

Household expenditure on drugs is closely tied to household income. In Ghana, for example, annual per capita drug expenditure varied from US$ 1.45 per person in the lowest-income households to $ 3.32 in middle-income households to $ 8.50 in the highest-income households [137].

Self-medication with privately purchased drugs often represents the most common treatment after home remedies. Household surveys indicate that drugs purchased from local drug sellers or pharmacies are used to treat approximately 53% of illness episodes in Burkina Faso (Figure 2). In an urban setting in Sri Lanka nearly 64% of the first actions taken by households in treating an illness were self-medication with western or traditional drugs (Figure 3). Studies on general and low-income populations in Kenya [97], Nepal [73], Rwanda [33], Thailand [108] and elsewhere [1,55] show similar high rates of medication with drugs acquired in the private sector. Even for potentially life-threatening illnesses such as malaria, self-medication through privately purchased drugs is common in both Africa and Asia [39,86].

Thus, at the household level as well as at national level, private purchase of drugs plays a major role in many countries, even for low-income populations.

Figure 2. Percentage distribution of household health-care-seeking behaviour,
Burkina Faso [104]

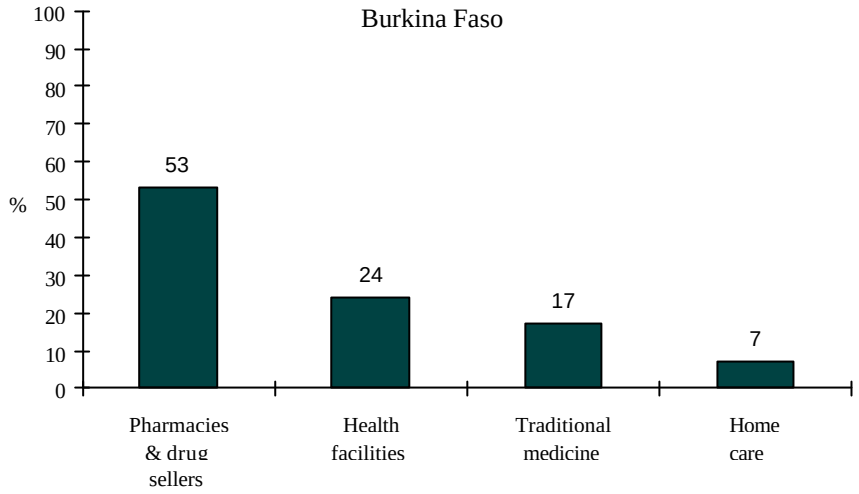
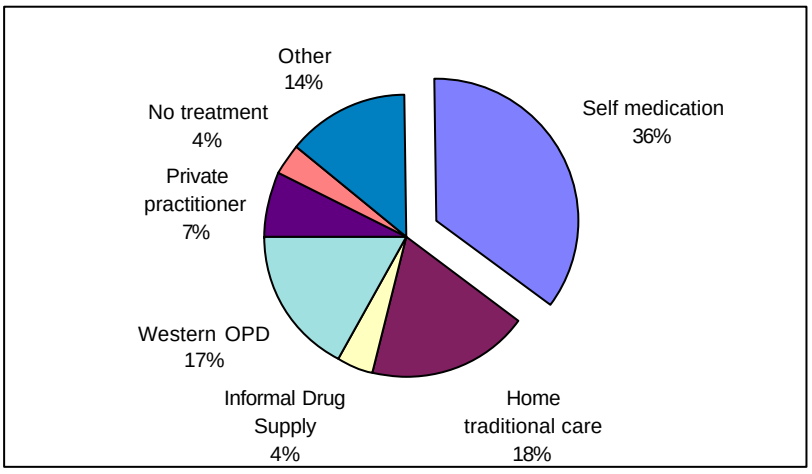


Figure 3. Source of care for acute illnesses in Sri Lanka [112]



4.5 Summary points

- Policies to change the balance of public and private roles in the pharmaceutical sector are likely to be most appropriate when based on an understanding of existing public-private mix.

- Public-private roles can be analysed in terms of:

– production facilities;
– national level expenditure;
– distribution systems;
– household expenditure.

- Different measures are likely to be appropriate depending on the policies under consideration.

- Available data indicate the great importance of private purchases of pharmaceuticals, especially in developing countries. In developing countries a larger proportion of expenditure on health comes from private sources and a larger proportion of that expenditure also goes on drugs.

5. Market mechanisms in public drug supply

Can private sector mechanisms help to improve efficiency and ensure access to essential drugs in the public sector?

In many countries a large share of clinical health services continues to be provided through government health facilities. Among the decisions that governments in these countries face regarding the pharmaceutical sector, the most complex and the most costly often concern the financing and supply of drugs for government health services. In some countries public sector drug supply is well-financed and administratively efficient. In other countries the drug supply system is unreliable and shortages are common; such systems suffer from inadequate funding, outdated procedures and a variety of other problems.

The failure of government drug supply systems to provide adequate and efficient services is often seen to be symptomatic of fundamental problems in the public sector, including:

- public sector rigidities, particularly bureaucratic staff regulations;
- lack of incentives for efficient behaviour;
- unclear institutional relationships and responsibilities;
- political interference;
- lack of managerial autonomy, responsibility and accountability;
- absence of competition;
- inadequate financial resources.

Drug supply systems need to achieve three main objectives:

– **a high level of service**, as measured by low rates of shortages and stockouts;
– **efficiency**, as measured by having low total costs for a given level of service;
– **quality**, in terms of delivering drugs of satisfactory quality.

Can market mechanisms be used to improve public sector efficiency and service levels and thereby improve access to essential drugs through government health services?

In recent years, a variety of attempts have been made to introduce private sector management methods and elements of competition into public health services in developed [90,91] as well as developing [11,12,120,122,125]

countries. These attempts were based on the belief that the key issue was not public ownership, but rather the nature of management and the market environment within which the organization operates.

Market mechanisms are often implemented parallel with or subsequent to decentralization measures. Decentralization may pave the way for market mechanisms by giving different public units control over their own budgets which they can use to purchase goods and services. Furthermore, certain types of market mechanism (such as the establishment of autonomous agencies) entail a degree of decentralization.

User fees for drugs and revolving drug funds introduce an element of private financing into public health services. Experiences with such schemes are described elsewhere [32,81,106]. The focus of this section is on market mechanisms in public sector drug supply systems.

5.1 Organization of the supply system

At least five different methods exist for supplying drugs to governmental and nongovernmental health services:

- **Central medical stores (CMS):** This is a conventional drug supply system, in which drugs are procured and distributed by a centralized government unit. It is possible to decentralize this system by having medical stores at provincial or state level.

- **Autonomous supply agency:** This is an alternative to the CMS system in that drug supply is managed by an autonomous or semi-autonomous drug supply agency.

- **Direct delivery system:** This is a decentralized, non-CMS approach in which drugs are delivered directly by suppliers to districts and major facilities. The government drug procurement office tenders to establish the supplier and price for each item, but the government does not store or distribute the drugs.

- **Primary distributor (“prime vendor”) system:** Another non-CMS system, in which the government drug procurement office establishes a contract with a single primary distributor ("prime vendor"), as well as separate contracts with drug suppliers. The prime vendor is contracted to manage drug distribution by receiving from suppliers, storing and distributing all drugs to districts and major facilities.

- **Fully private supply:** In some countries, drugs are provided by private pharmacies in or near government health facilities. With such an approach,

measures are required to ensure equity of access for the poor, those with the greatest medical need, and other target populations.

Key features of these systems are outlined in Table 6. The systems vary considerably with respect to the role of government, the role of the private sector, and incentives for efficiency. Mixed systems in which different categories of drugs are supplied through different mechanisms are also possible. Box 5 describes how one country, Norway, while maintaining strict regulation of the pharmaceutical sector, has liberalized its centralized system to permit competition from private drug wholesalers.

Table 6. Comparison of supply systems for government and institutional health services

	Description	Responsibilities		
		Contracting suppliers	**Storage & delivery**	**Monitoring drug quality**
Central medical stores	• Conventional supply system • Drugs procured and distributed by centralized government unit	CMS	CMS	CMS, DRA
Autonomous supply agency	• Bulk procurement, storage and distribution managed by autonomous or semi-autonomous agency	Autonomous agency	Autonomous agency	DPO, autonomous agency, DRA
Direct delivery system	• Decentralized approach • Tenders establish the supplier and price for each item • Drugs delivered directly by supplier to districts, major facilities	DPO	Suppliers	DPO, DRA
Primary distributor ("prime vendor")	• DPO establishes contracts with drug suppliers and separate contract with a single prime vendor • Prime vendor warehouses and distributes drugs to districts, major facilities	DPO	Prime vendor	DPO, prime vendor, DRA
Fully private supply	• Private wholesalers and pharmacies manage all aspects of drug supply with government facilities	Procurement and distribution by private enterprises		DRA

CMS: Central medical stores
DPO: Drug Procurement Office
DRA: Drug regulatory authority

These supply systems are described in greater detail in a separate DAP paper on innovative mechanisms for public drug supply [132] and in other recent publications [81].

Central medical stores

The CMS approach has been the standard approach in many countries. In this approach, the state is both the owner and the manager of the entire supply system. Its advantages are clear: government maintains control over the entire system and bulk procurement is likely to lower costs. But the approach is demanding in terms of human resources, physical infrastructure and management and communication systems. In addition, there are often few incentives for efficient behaviour and the CMS is vulnerable to political interference.

Difficulties in managing this highly centralized system have led a number of countries to consider alternative approaches that involve greater private sector participation. One approach is to maintain the CMS model while contracting-out specific services such as port clearance or transport.

Autonomous supply agency

Establishing an autonomous or semi-autonomous drug supply agency is a more drastic, but potentially more successful approach. It has been adopted in Benin, Haiti, Sudan, Uganda and Zambia, among other countries. The aim of autonomous supply agencies is to achieve the efficiency and flexibility often associated with private enterprises, while maintaining sufficient public sector supervision to ensure that essential drugs are provided at reasonable prices and with adequate control of quality.

Setting up a public autonomous supply agency may be costly but, if done properly, it provides an opportunity to specify performance indicators and create clear incentives for efficient behaviour. One key question with respect to the performance of such agencies is how autonomous they actually are. In Zambia, for instance, the autonomous agency, Medical Stores Ltd, continued to provide drugs to government facilities on the authority of the Ministry of Health despite non-payment. This led to substantial financial difficulties for the agency.

Direct delivery system

A direct delivery system is a more decentralized approach. A government procurement office contracts with private suppliers, specifying direct delivery to major health facilities or district stores. There are examples of direct delivery systems in Guatemala, Indonesia, Peru and Thailand. This approach is demanding in terms of information flow, monitoring and financial management, but it reduces the need for a centralized distribution structure. The fragmentation of the distribution system between different suppliers may contribute to inefficiencies. For instance, different suppliers may make separate journeys to deliver drugs to the same point.

Primary distributor system

The primary distributor system is similar to the direct delivery system in that drug suppliers are contracted through the usual government procurement procedures but a second type of contract is then made with a single distributor or prime vendor. The prime vendor is responsible for stocking and distributing drugs — at least as far as major health facilities and district stores. Prime vendor systems operate in some parts of South Africa and the USA.

This system guards against duplication of supply systems but may also create risks for government by placing the entire supply system in the hands of a single private sector agent.

One potential modification to the direct delivery or prime vendor system is the use of *pooled procurement* or *group purchasing*. This describes a system in which groups of smaller countries, hospitals within countries, or other health services join together to combine their procurement activities. A procurement

coordination office is established. Each member (country, hospital or health service) provides information on the drugs and quantities needed. The needs are combined and a single contract is awarded for each item. For groups of countries, pooled procurement usually depends on a direct delivery system; drugs are delivered directly to each member and payment is made directly to the supplier by each member. For hospital and other health services, pooled procurement may be implemented through a supply agency formed by the members or through a prime vendor contract.

Box 5. Norway: increasing supply competition in a highly regulated environment

Background

Norway, with a population of 4.3 million, is the second most sparsely populated country in Europe. This has resulted in a political focus on geographical availability and equity which has strongly influenced the development of the pharmaceutical sector. Total pharmaceutical sales in 1995 were approximately US$ 1 billion Compared to other European countries, Norway has relatively low drug expenditure; 7.3% of health care expenditure is on pharmaceuticals and this percentage has been decreasing.

The drug market in Norway is also characterized by unique measures which limit the number of pharmaceutical products available in the country to just over 2000. These measures are aimed at improving rational drug use by enabling both prescribers and consumers to be better informed, and by protecting consumers from unnecessary drugs. Among the measures are a need clause (drugs are assessed not only from scientific and technical viewpoints, but also in relation to medical need in the country), a restrictive attitude towards fixed combinations of drugs, and a five-year limit to the approval and registration of products.

Effects of liberalization

Until early 1994, the right to import and distribute medicines to pharmacies was restricted to a government monopoly, the Norwegian Medicinal Depot (NMD), which operated with fixed wholesale margins. In response to European Union legislation, there is now competition from two new private wholesalers. One of these is co-owned by pharmaceutical companies and pharmacies, while the other is owned by the Swedish state-owned pharmacy company. Together, these new wholesalers have taken less than 20% of the market to date.

NMD has responded positively to competition. It has reduced its operating costs and maintains a relatively low margin (6%). In addition to these three organizations, some 40–50 importing firms are licensed as wholesalers for their own products only to ensure equity and competition. Norwegian wholesalers are required to supply all drugs that are requested and to deliver everywhere in the country within a time limit.

At the retail level, prescription pharmaceuticals are dispensed exclusively through a network of 350 pharmacies. Most of these are private, but 24 are hospital pharmacies which are owned by the county or state. A further 1250 drug outlets sell over-the-counter drugs. Pharmacies can be owned only by professional pharmacists, and health authorities regulate where these pharmacies are to be opened according to a five-year national plan. In areas where pharmacies may have insufficient business to be profitable, the state has created tax benefits and subsidies to ensure equity and availability.

Summary

Norway is a country which smoothly combines private production and mixed public-private financing with strict and comprehensive government regulation on all aspects of pharmaceutical production and sale. Within this context, measures to enhance competition in the supply of pharmaceuticals appear to have met with success.

5.2 Desirability of using market mechanisms

Experience with alternative approaches to public drug supply is limited. Good analyses of their long-term performance and sustainability are lacking. However, expanding on questions raised with respect to contracting-out health services in general [69,74], the following questions must be considered in assessing the feasibility of using market mechanisms in public drug supply:

- **Will real competition take place?** Both the direct delivery system and the prime vendor system rely on competition to stimulate efficiency. If the private sector is poorly developed then contracting-out may simply replace a government service monopoly with a private one - with no visible cost saving or service improvement.

- **Can drug quality and service quality be maintained?** Contractors may try to cut corners in order to reduce costs. This may adversely affect both the quality of the service (as measured by the rate of shortages and stockouts) and the quality of the drugs delivered.

- **Will efficiency actually improve?** If lower costs are achieved at the price of lower quality then the result in terms of improved efficiency is ambiguous.

- **Can government effectively negotiate and monitor contracts?** The benefits of competitive contracting will not be reaped unless government has adequate negotiating and monitoring capacity. Contract specification must cover the quality of the service in adequate detail and must include sanctions against contractors who break quality standards. Contracted services must be monitored to ensure that they are provided as specified in the contract. Government may operate under constraints in capacity that prevent it from carrying out these tasks effectively.

- **Will there be sufficient financing?** Alternative supply arrangements may result in greater quantities of drugs being provided for a given budget but they will not solve problems of inadequate financing. Late payment of contractors by government is often the main reason given by private sector companies for not wanting to bid for government contracts. So the question of adequate funding may also affect the level of competition.

- **Will there be wider unforeseen consequences?** Establishing a long-term contract with a private sector company may drive other companies out of the market, resulting in less competition in the future. Tying up a substantial amount of funds in one contract may distort resource allocation in the pharmaceutical sector as a whole. Government officials responsible for contracting need to be aware of the system-wide and long-term effects of the contracts they negotiate.

Just how suitable the models described in Section 5.1 are to a particular country or region depends critically on an analysis of the current problems and institutional conditions there, particularly with respect to the six questions outlined above. Although at this point the evidence is insufficient to reach firm conclusions, some rules of thumb about appropriate policy options can be drawn.

- The efficiency of a direct delivery or prime vendor system depends on a well-developed private sector. In countries without a developed private sector these supply solutions do not make sense, at least in the short term. Instead efforts should focus on improving the efficiency of existing public supply systems and perhaps creating the type of business environment that may attract private firms to enter the market.

- If an existing CMS is beset by problems that can be traced to overly rigid government regulations (such as inability to hire and fire staff, or forced reliance on an ineffective transport pool) then a public autonomous supply agency may provide some advantages. However, without true government commitment to the idea of an autonomous agency and without adequate mission statements and terms of reference, an autonomous supply agency may suffer from problems very similar to those of the CMS.

- Different models place different types of demands on government capacities. Where CMS and autonomous supply agency models require substantial physical infrastructure (to procure, store and deliver drugs), the direct delivery and prime vendor systems require capacity to negotiate, contract and monitor contracts. A government should consider which aspects of its capacity are strongest.

- The success of contracting arrangements and the type of contracts which are appropriate may depend considerably on the nature of the organization contracted to provide the service. Not-for-profit organizations are more likely to share objectives similar to those of the government. If a not-for-profit organization such as MEDS (see Box 2) is the prime vendor, government monitoring procedures may not need to be as rigid as if a for-profit company is contracted.

5.3 Summary points

- Recent reforms have shifted drug supply systems away from the conventional CMS model to models incorporating market mechanisms.

- To date there has been no proper evaluation of the advantages and disadvantages of different supply system models in different (particularly low-income) settings. Thus, empirical evidence on which to base policy-making is limited.

- Policy choices about the appropriate public sector supply system must be rooted in country-specific analysis. Such analysis should cover:

  – the nature of problems in the existing drug supply system;
  – the make-up of the private sector and its capacity to offer drug supply services;
  – government capacity in terms of infrastructure, skills and institutional capacity (see Section 7.1).

- Specific proposals for reform need to be backed up by a feasibility study which should aim to assess the comparative cost, efficiency, reliability and quality of current and proposed services.

6. Promoting public health needs through the private sector

***What mechanisms best promote the availability, affordability and rational use of drugs in the private sector*?**

In many low-income countries over half of all drugs are sold through the private pharmaceutical market. Private pharmaceutical purchases are the major source of drugs for the population. Whether this is a matter of policy or simply a matter of practice, it is important to ask what mechanisms best help promote health through these private pharmaceutical expenditures.

This section first summarizes public health concerns regarding the private pharmaceutical sector and then discusses the instruments available to governments wishing to intervene in the market. It goes on to discuss in more detail approaches to the four different types of concerns identified.

6.1 Public health concerns

There are at least four ways in which provision of drugs through the private sector may conflict with the principles of national drug policies. The first two of these concerns relate to equity (availability and affordability), the third to rational drug use and the fourth to drug quality.

- **Availability (geographical access):** The full range of essential drugs should be available throughout the country. Are private pharmacies or other licensed drug outlets accessible to the majority of the population?

- **Affordability (financial access):** Drugs that are needed should be obtainable at a price that is affordable to the majority of the population. How do the poor gain access to drugs?

- **Rational use:** Drugs should be prescribed, dispensed and consumed in a therapeutically rational manner. Are private health providers, pharmacists, pharmacy aides and other drug dispensers providing good advice on consumer purchases? Are patients and consumers buying therapeutic quantities of prescribed or recommended drugs?

- **Drug quality, safety and efficacy:** Drugs should be registered, imported, and produced according to accepted standards of quality, safety, and efficacy. Are only properly registered drugs of good quality available in the private market?

Government has a number of mechanisms by which to help promote availability, affordability and rational use of drugs in the private sector. Table 7 provides an overview of possible options.

Table 7. Measures to promote access, rational drug use and drug quality in the private sector

	Availability	Affordability	Rational drug use	Drug quality
Affecting market structure				
• Drug registration				X
• Licensing of importers, wholesalers and retailers	X		X	X
• Registration of drug outlets	X		X	X
• Dispensing clinicians	X		X	
• Generic substitution		X		
Providing information and education				
• Setting standards of undergraduate training			X	
• Continuing education for professionals			X	
• Training of drug sellers			X	
• Development of standard treatment guidelines			X	
• Public and patient education		X	X	
• Regulation of drug information and promotion		X	X	
• Provision of price information		X		
Controlling prices				
• Regulation of producer and distribution prices		X		
• Regulation of retail margins		X		
Setting incentives				
• Incentives for wholesalers and retailers	X			
• Accreditation schemes			X	
Increasing financing				
• Community drug schemes	X	X	X	
• Health insurance schemes		X	X	

Key: X denotes that this measure may be used to affect the target variable

Government supervision of the private pharmaceutical market involves complex and often contentious issues. Governments must carefully explore and understand the options open to them before acting:

- **Several of the identified instruments will help achieve more than one objective:** For example, regulation of drug marketing may prevent market segmentation and the development of market power, and may also promote rational drug use.

- **For some mechanisms there may be conflict between different objectives:** Allowing clinicians to dispense may enhance geographical accessibility but at the same time may provide an incentive to overprescribe. Price regulation may discourage some producers from entering the market, thus possibly reducing availability.

- **Some mechanisms are easier to implement than others:** Substantial problems may be encountered in price regulation [105]. Providing price information may be easier to do but may (arguably) be less effective in maintaining low prices.

Government may be particularly concerned about improving drug availability and affordability in the private sector in situations where government health services do not exist or are not able to provide drugs to the poor, medically needy, geographically isolated or otherwise underserved populations. In countries where a large proportion of the population is poor and government health services lack sufficient resources, ensuring universal access to drugs is particularly challenging.

6.2 Availability (geographical access)

Essential drugs should be available throughout the country. Efforts to improve availability include:

– licensing and incentives aimed at the distribution network;
– reliance on dispensing clinicians;
– establishment of community drug schemes.

The third option is discussed in Section 6.4 as it is also important in improving affordability.

Licensing of importers, wholesalers, retailers

Availability of essential drugs is frequently a problem in sparsely populated rural areas.

Licensing of private wholesalers may attempt to increase drug availability through:

- **National coverage clause:** This is a licensing condition which requires that the wholesaler agrees to distribute to drug outlets in all geographical areas.

- **Full assortment clause:** This licensing condition requires each wholesaler to provide the full range of a specified list of essential drugs.
- **Location regulations:** Licensing conditions may also aim at encouraging better geographical distribution of pharmacies by specifying minimum distances between an existing pharmacy and a proposed new one.

Though such provisions may promote equity, they may conflict with existing agreements between producers and wholesalers and thus face opposition. Such provisions may also substantially reduce the number of registered wholesalers, which in turn would reduce competition.

Using some examples from Africa, Box 6 shows how private pharmacies and drugstores tend to be concentrated in urban areas. To encourage new pharmacies and licensed drug sellers in relatively underserved areas, guidelines may be established for the minimum distance between drug outlets or limits may be placed on the number of drug outlets in a given town or district.

Box 6. Geographical equity of private drug distributors: evidence from francophone Africa

In seven countries in francophone Africa, considerable disparities exist in the way in which the commercial private pharmaceutical sector is geographically distributed (see table). The lowest number of inhabitants per pharmacy can be found in the region of the capital city.

Geographical inequities tend to be less in countries where the private sector has been developed for a long time, as in Benin, Cameroon and Senegal. Regulations on the setting up of pharmacies may also reduce inequities in the distribution of pharmacies.

Country	Year	Inhabitants per private drugstore in capital city region	Rural areas with the highest number of inhabitants per private drugstore
Benin	1992	12 118	648 330
Cameroon	1994	14 128	210 172
Guinea	1992	8 649	78 878
Madagascar	1992	9 740	122 969
Mali (public and private sectors)	1994	7 084	587 877
Niger	1994	33 822	1 727 873
Senegal	1994	9 210	118 640

Adapted from [28].

Incentives for wholesalers, retailers

As an alternative to licensing restrictions, financial incentives can help to expand services to remote and underserved areas. Australia, Cameroon and Norway are among the countries which have tried such incentives. In Norway higher taxes on pharmacies in more profitable areas are used to cross-subsidize those operating in less economically viable areas. The experience in Norway

appears to have been largely positive (see Box 5). Incentives which have been used or suggested include:

- pharmacy cross-subsidy systems;
- higher retailer margins or high reimbursement rates in remote areas;
- tax reductions for providing services in specified areas of the country;
- tax credits or refunds for transport costs to rural areas.

Tax refunds and other such incentives are likely to be only as effective as the administrative systems that oversee them.

Dispensing clinicians

Doctors, clinical officers and nurses in private practice both prescribe and dispense drugs to their patients in many parts of the world, including Germany, India, Japan, the Netherlands, South Africa and rural areas of the United Kingdom. Clinicians dispense to their patients partly as a service, but also because they have learned that patients are often much more willing to pay for drugs than simply for consultation. In some countries, general practitioners derive 60% of their income from the drugs they dispense. This creates an obvious and measurable incentive to overprescribe [60,78].

At the same time, dispensing clinicians do provide a service. In areas with few pharmacists, clinicians should be more informed about drugs than drug sellers are. In principle, clinicians should also be concerned with proper drug selection and with drug quality. In addition, they should be less likely to dispense subtherapeutic quantities. This is particularly important with antibiotics, antimalarials and other anti-infectives for which drug resistance is a concern.

Allowing a clinician to dispense drugs creates such strong incentives to overprescribe, however, that it should be accepted only in rural and other underserved areas where there is no reliable source of drugs. Even then, dispensing clinicians should sell drugs at cost and not for a profit. Alternative ways to increase access to drugs without encouraging overuse should be explored. Box 7 describes in more detail the role of dispensing doctors and summarizes principles that may be included in legislation regulating them.

Box 7. Practices of dispensing doctors - drug use and health economics [111]

History and experience with dispensing doctors

Prior to the 11th century all dispensing was carried out by doctors. Thereafter pharmacists became recognized and started taking over dispensing. This development continued in most countries where doctors were paid a consultation fee. In countries where doctors' livelihood depends on the sale of drugs, dispensing by doctors is still common. In India, Japan and Pakistan, for example, up to 80% of the doctors dispense drugs. In other countries, dispensing doctors constitute only a minority of 5–10 %. However, the number of dispensing doctors is increasing.

A review of available studies from South Africa, the United Kingdom, the USA and elsewhere indicates that dispensing doctors have, in comparison to non-dispensing doctors, been found to prescribe more drugs (and fewer generic drugs) annually per patient, issue more prescriptions but in lower quantities,

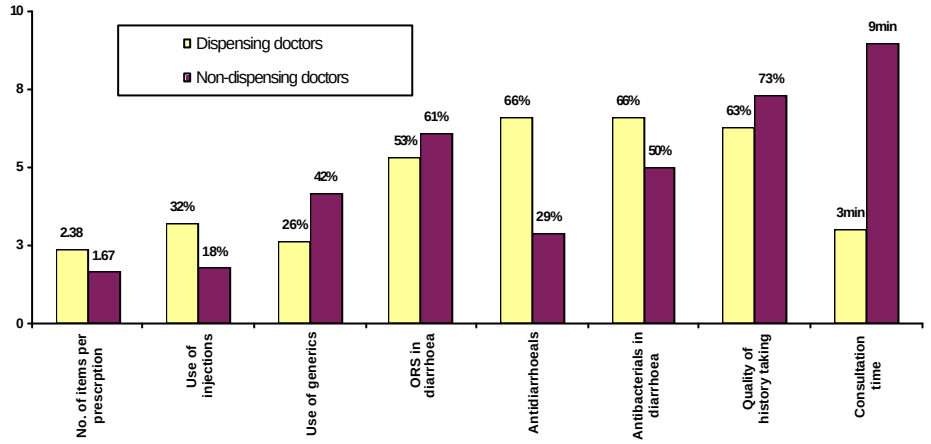
have older patients, and have fewer years in practice. The average number of visits per patient per year was found to be higher among the patients of dispensing doctors.

Dispensing doctors in South Africa

The figure below provides a comparison of dispensing doctors and non-dispensing doctors in South Africa. In 1996, the new national drug policy of South Africa stated that dispensing doctors could be permitted only where separate pharmaceutical services were not available. In these cases the dispensing doctors or dispensing nurses must be registered, must be trained in dispensing, must obtain annual renewal of the registration, must be inspected, and must apply good dispensing practices and show transparency in their pricing structure.

(continued overleaf)

Box 7. Practices of dispensing doctors - drug use and health economics (continued)



Legal principles governing dispensing doctors

Laws on dispensing doctors vary greatly between countries and between states or provinces within countries. Principles which may be included in legislation on dispensing doctors include:

- **Rurality:** Physicians may dispense in rural areas where there are no pharmacies. The law in, for example, the Netherlands, the United Kingdom and Zimbabwe allows dispensing by doctors if no pharmacy is available within a mile or 5 km from the patient's home, or in some cases, from the doctor's practice.

- **Emergencies:** Physicians may dispense in emergencies. The law in five states of the USA allows dispensing only in limited situations, such as medical emergencies. In Denmark this would occur during an out-of-hours visit to a patient where treatment might be required.

- **Quantity limits:** In the USA, the Federal Trade Commission requires that no more than a 72-hour supply of medicine should be dispensed by doctors. In Germany, since 1993, the law has allowed doctors to provide treatment at home before and after a stay in hospital in order to shorten expensive hospital stays.

- **Not-for-profit or cost/price regulation:** The amount physicians may charge for dispensing medication may be limited. Australia, with only 69 dispensing doctors, legislates that the dispensing doctors shall not make a profit.

- **Procedural requirements:** Dispensing may be limited to the physicians' own patients and may be required to follow the same regulations as those mandated for pharmacists — e.g. regarding labelling, record-keeping, packaging and storage (South Africa and USA).

- **Delegation of dispensing:** The dispensing may be undertaken only by trained staff related to the physician's practice. Some laws require that dispensing should be done by the physician personally.

- **Patient choice:** The principle is to protect patients' freedom of choice in deciding whether to purchase the prescription drugs from the physician or from the pharmacy.

- **Registration:** The law in Zimbabwe and in 13 states of the USA requires dispensing doctors to be registered for dispensing.

Conclusion

Experience to date does not suggest one best solution for the dispensing of drugs. Access is a central objective, but whether this can best be achieved by having drugs dispensed by the prescribing doctor or by satellite pharmacies is not certain. However, experience indicates:

– to safeguard the patient, dispensing must be regulated and the regulation implemented;
– much more knowledge must be obtained about the health, social, and economic benefits and costs of different solutions if appropriate policies and laws are to be formulated.

6.3 Making drug prices affordable

Cost can be a major barrier to adequate treatment. There are two different approaches to improving pharmaceutical affordability in the private sector:

– lowering prices (this relates to supply);
– financing schemes to spread the cost (this relates to demand).

This section considers the policies that affect prices. Section 6.4 addresses financing strategies.

Price regulation is common to countries at many levels of development but the motivation for its implementation differs somewhat between developing and developed countries. In those countries where a substantial proportion of the population is covered by health insurance schemes — and patients generally do not bear the full cost of drugs — price controls are seen as part of a cost containment strategy. In countries without substantial health insurance, where consumers bear much of the cost of pharmaceuticals themselves, price controls are viewed mainly as a means to increase affordability.

Regardless of the purpose of price regulation, the basic mechanisms are the same.

Price information

Policy-makers, health professionals, people in the drug distribution chain, and consumers need complete, accurate and up-to-date information on drug prices. When they have information about drug prices and generic drugs, consumers can exert pressure on prescribers and dispensers to control prices.

Methods for communicating price information include:

– listing of price or relative price information in therapeutics manuals;
– listing of price information in pharmacies (e.g. Philippines);
– printing retail prices on drug packages;
– regular publication of a pharmaceutical pricing guide or manual (e.g. Colombia);
– publication of selected pharmaceutical prices in local newspapers or other media (e.g. Argentina).

Price information is increasingly being included in national drugs and therapeutics manuals and guidelines. Price information may be given as relative price levels (such as the relative price bands in the *British National Formulary*), as price comparison bar charts for selected therapeutic categories (such as the Kenyan or Zimbabwean *Clinical Guidelines*), or simply as the current price for each drug.

In India, Pakistan and other parts of Asia, the maximum retail price system has not only been an approach to price control. The requirement that the maximum retail price be printed on drug packages means that the system also provides price information directly to the consumer. In the Philippines — where the national drug policy has encouraged price competition through generic substitution rather than price control — the prices of selected generic drugs are regularly publicized in the media [41].

In Colombia, efforts to promote generic prescribing included publication of a WHO-supported price comparison guide. The guide proved popular and its publication was soon taken over by the Ministry of Health. Because the guide was effective in drawing consumer attention to the price advantage of local products, publication of the guide was eventually taken over by the local manufacturers' association and thus its regular publication became sustainable without public support. In the USA, though prices are largely uncontrolled, price competition is encouraged through regular publication of wholesale drug prices.

Price comparisons over time and between countries can be useful to monitor pharmaceutical price differentials and the effects of various drug policies. Such comparisons can be complex and confusing, however. A pharmaceutical price index, based on the same principles as consumer price indices for monitoring inflation, is one approach to making such comparisons. WHO has described such a method for calculating the value of a "basket of drugs" [23].

For comparison purposes, world market prices for several hundred essential drugs are published annually by Management Sciences for Health [80]. In addition, bulk prices for several dozen active pharmaceutical raw materials are published by the International Trade Centre in conjunction with WHO [56].

Price competition through generic substitution

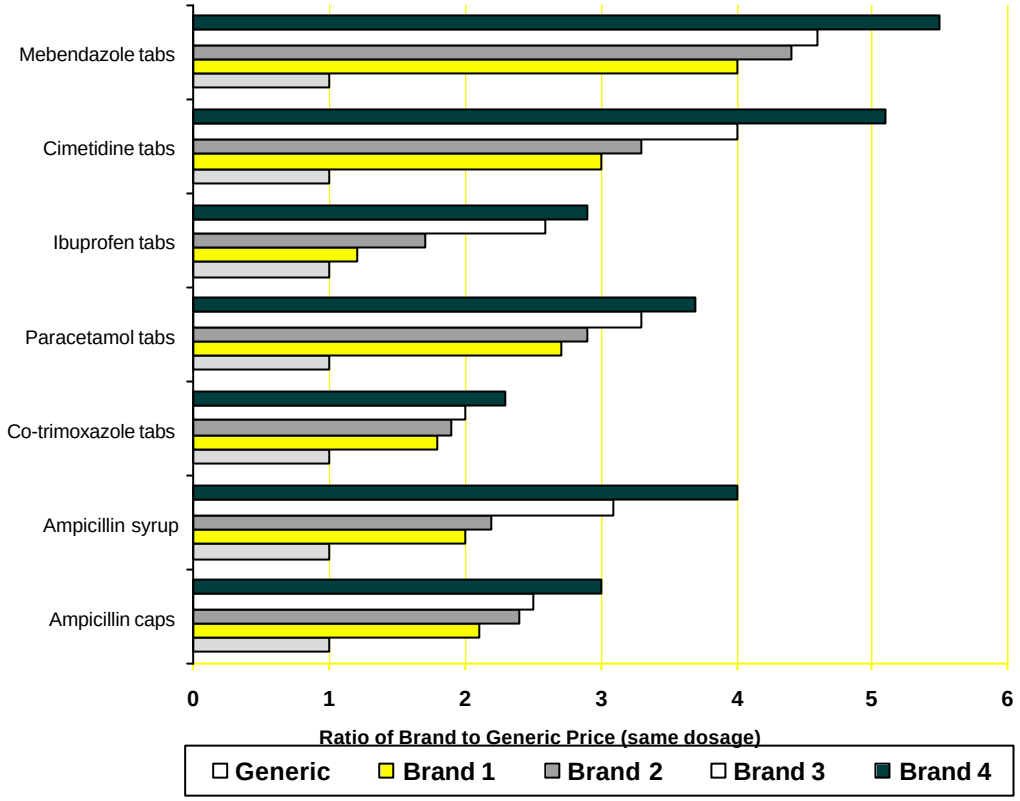
Competitive bulk procurement by generic name is a central feature of most essential drugs programmes. Many large hospitals and health services in high-income countries operate on this basis. In the private market, price competition can be encouraged through prescription and dispensing by generic name.

The potential cost advantages of generic drug use are illustrated in Figure 4, which compares brand and generic drug prices for a range of common products in Indonesia. Price differentials will vary considerably from market to market depending on a variety of factors. Though generic prices are often 50% or less of the price for the leading brand, generic drug prices in well-developed European markets are more typically 60–70% of brand prices [9].

A large proportion of items on the WHO Model List of Essential Drugs have been off patent for over 20 years. By 1995, 94% of the 200 most widely used drugs in the USA were off patent [38]. Yet large generic drug markets have developed in a relatively small number of countries. In the mid-1970s, Peru's

Basic Medicines Programme tried to promote a list of generic drugs through retail pharmacies. Pakistan in the late 1970s, Nigeria in the 1980s, and Argentina, Colombia and the Philippines in the 1990s are examples of other countries which have attempted to promote generic drugs in the private sector.

Figure 4. Ratio of brand to generic price, Indonesia [119]



Several of these efforts have run into difficulties. Common problems have included logistical constraints in demonstrating drug quality, inadequate preparation of health professionals, failure to address financial incentives at the dispensing point, and the incorrect assumption that public demand already exists for cheap generic drugs. Box 8 describes various efforts to promote the use of generic drugs in the European Union, Indonesia and the USA.

Experiences to date suggest four main categories of factors which influence the growth and stability of the generic drug market in a country (Table 8):

- supportive legislation and regulation;
- quality assurance capacity;
- public and professional acceptance;
- economic factors.
-

Price control: producer prices

Pharmaceutical prices vary widely, even between countries within the same region [8,9,51,79]. For example, among western European countries there is a two-fold variation in the pharmaceutical price index (PPI), despite pharmaceutical prices being carefully monitored and in many cases actively controlled.

Table 8. Generic drug use: some enabling factors

Supportive legislation and regulation

- Abbreviated registration procedures (focus on drug quality)
- Product development and authorization during patent period
- Provisions which permit, encourage or require generic prescription and substitution
- Requirement that labels and drug information contain generic names

Quality assurance capacity

- Development of substitution, nonsubstitution lists
- Procedures to demonstrate bioequivalence
- National quality assurance capability
- National drug manufacturer and drug outlet inspection capability

Public and professional acceptance

- Involvement of professional associations in policy development
- Phased implementation, beginning with permission to substitute
- Required use of generic names in all education and training of health professionals
- Brand-generic and generic-brand name indexes available to health professionals
- Required use of generic names in clinical manuals, drug bulletins and other publications
- Widespread promotional campaigns targeting consumers and professionals

Economic factors

- Public and professional price information
- Reference pricing for reimbursement programmes
- Retail price controls that favour generic dispensing
- Support by social and private health insurance organizations
- Incentives for generic drug industry
- Trade-offs with industry (reduced price regulation, increased patent protection)

There are many approaches to pharmaceutical price control. It is useful to separate control of producer prices from control of distribution margins. Though there are a number of variations, controls on producer prices fall into three main categories [9,79]:

- **Cost-plus pricing:** Prices are negotiated between the manufacturer and the national authority, based on the cost of raw materials, production, marketing and other producer costs, and a reasonable allowance for profit.

- **Reference pricing:** Reference pricing — also known as yardstick, benchmark, comparative or leader pricing — sets or limits the price of an individual drug by comparison with the price of other drugs. **Internal** reference pricing is based on comparison with drugs already on the national market and which have similar therapeutic effects. **External** reference pricing considers the price of the identical or comparable drugs marketed in other countries.

Box 8. Promoting generic drugs

European Union

As of the mid-1990s, generic dispensing differed greatly among the countries of the European Union. In Denmark, generic substitution was possible with the doctor's agreement and generic drugs represented about 60% of prescription volume and 30% of sales value. In Germany, the Netherlands and the United Kingdom, generic substitution was strongly encouraged and 20–40% of prescriptions were dispensed generically. Except for Germany, these countries had low-to-average per capita drug consumption compared to the entire European Union. On the other hand, countries such as Belgium, France and Italy tended to have relatively low generic drug use — often less than 2% of sales value. The wide variation in generic dispensing among these countries — which are generally able to ensure the quality of generic products — illustrates the impact which national policies and different local circumstances can have on generic drug use.

Indonesia

A 1989 ministerial decree made prescribing and dispensing of generic drugs compulsory in public health facilities and encouraged the use of generic drugs in the private sector. The Ministry of Health initiated a campaign to promote generic drug use by health professionals and the community. Production of "logo generic drugs" was led by state-owned manufacturers, but private manufacturers entered the market with government encouragement. By the mid-1990s, 30 pharmaceutical companies (four state-owned and 26 privately owned) were producing generic drugs, nearly 200 commonly used essential drugs were commercially available by generic name, 408 pharmacies were obliged to provide generic drugs, the market in monetary terms had tripled over a five-year period, and generic dispensing had risen to about 15% of prescriptions [3].

Philippines

The Philippine Generics Act of 1988, passed unanimously in Congress, was the first legislation enacted to operationalize the Philippine National Drug Policy (PNDP). The act provided for mandatory use of generic names on labels, advertising materials and prescription slips. It emphasized the need for pharmacists to provide information to clients on generic drugs and their prices, established incentives for manufacturers of generic products, and provided for public and professional information on the Generics Law and on the rational use of drugs.

A consultative process was facilitated by the establishment of the Task Force on Pharmaceuticals, which included health professionals, drug industry representatives, health NGOs, consumer groups and academics. Implementation approaches were sequenced to promote early high-visibility successes and impact. For example, generic labelling was begun with products having single active ingredients; labelling rules were put in place before generic prescribing and dispensing were mandated. The political process leading to enactment of the generics law, though broad-based, required some compromises. Professional and industry lobbying resulted in doctors being allowed to place their choice of brand names in parentheses on prescriptions. No controls on prices were included in the final law. Implementation of some elements of the law was postponed to gain cooperation.

Despite these efforts, acceptance of generic prescribing and dispensing has been slow. This emphasizes the need for a persistent, long-term approach to promoting generic drug use.

United States of America

In the USA, generic dispensing was greatly encouraged by the 1984 Drug Price Competition and Patent Restoration Act (Waxman-Hatch Act), which facilitated registration of generic drugs. However, laws governing generic substitution at the time of dispensing are actually made at the state level. A few states began with laws which permitted, but did not encourage substitution. During the 1980s, states began to enact laws which more and more strongly encouraged generic dispensing, particularly for patients whose prescriptions were financed wholly or in part with public funds. As a result of these laws, reimbursement limitations of private insurance organizations and public awareness, generic dispensing in the USA rose from about 18% of new prescriptions in 1984 to nearly 40% in 1994.

- **Profit-based pricing:** Control of profits or return on capital investment is done on a company-by-company basis, with target profit levels set in part on an assessment of the company's risk. Within overall profit limits, companies are free to set the prices of individual products.

Cost-plus pricing depends on being able to obtain accurate information on production, marketing and other costs. Reported costs can be manipulated through *transfer pricing* and various other accounting practices. Reference pricing is more transparent and requires virtually no financial information from companies (or their accounting systems). Discussions centre on the question of generic and therapeutic substitutability. Profit-based pricing depends on having access to reasonable company financial information.

Countries may use combinations of the above methods. In addition, different formulas or reference points may be used for locally owned firms, local multinational firms and imported drugs.

The above methods are used to set initial prices at the point of registration, importation or marketing of a drug. After initial prices are set, decisions must be made about price increases. These are often linked to other price indices. Particularly during periods of high local inflation or severe exchange rate fluctuations, the timing and level of allowable price increases becomes a major concern both for producers, who seek price increases to weather the economic storm, and for governments, who seek to minimize the economic impact on the population.

Pharmaceutical price control is very common. In a review of selected policy features, the United Nations Industrial Development Organization [9] reported that among 23 industrialized countries all had some form of pharmaceutical price control (11 had limited controls and 12 substantial controls). Among 33 developing countries, only seven had no price controls; eight had limited controls and 18 had substantial controls.

The arguments and the evidence

Despite the widespread use of price controls, there is little agreement on their overall impact. Proponents of pharmaceutical price controls believe that price controls [9,140]:

– lower individual drug prices;
– lower total drug expenditures;
– improve price information for insurers and consumers;
– are necessary because market forces alone cannot ensure competition.

Opponents believe that price controls [9,140]:

– are cumbersome and open to manipulation;
– encourage misleading accounting practices;
– create scarcities (real or artificial);

– have no impact on patient or overall health expenditures because they encourage use of higher quantities of drugs and more expensive drugs;
– reduce innovation and competition;
– are unnecessary for most therapeutic needs if drugs are sold competitively by generic name.

The case for price control is much clearer for new drugs for which no therapeutic alternative exists. Most governments agree that mechanisms must be found to make such drugs available at an affordable price.

Where price regulation has been enforced, it has been shown to control both individual drug prices and increases in drug prices, though not total drug expenditure [42,43,50,79]. Lowering individual drug prices may be offset by prescribing and dispensing greater quantities of drugs or a different (and more costly) selection of drugs (see Box 9).

Most of the empirical evidence on the effects of price controls comes from OECD countries. Countries should be cautious in interpreting the results of these studies:

- **Price sensitivity may vary among countries and among population groups:** Price regulation may have more favourable public health benefits for lower-income countries and lower-income populations.

- **Developed and developing countries have different objectives in price control:** While OECD countries wish to contain total expenditure, developing countries hope that it will increase. Lower prices should enhance affordability and the amount of (appropriate) drugs which are consumed.

- **Developed countries and developing countries may have different capacities to implement price controls:** Price fixing and enforcement may encounter more difficulty in some countries than in others (see Box 9).

- **Disincentives for drug development may be of less concern for many developing countries:** Most drug development is targeted to and supported by developed countries and, at least until the present, very few developing countries have been active in drug innovation (see Section 7). Therefore, developing countries may see the benefit of greater affordability of existing drugs as outweighing the potential adverse effect which price regulation may have on innovation and drug development in their countries.

More information is required to decide on the wisdom of price controls in developing countries. Key questions are:

- **How does prescriber and consumer behaviour change in the face of price controls?** Do lower prices lead to more prescription of needed essential

drugs, or do providers increase profits by prescribing more expensive drugs or unnecessary drugs?

- **What are the potential risks of price regulation?** If prices are set at less than a competitive price there are likely to be shortages of the product and parallel markets with unregulated prices will develop. Alternatively, prices could be set too high, further damaging affordability.

- **Do developing country governments have the capacity to follow up price adjustments and enforce controls?**

Price regulation systems may have unintended consequences; sometimes the opposite of those intended. It is important, therefore, to evaluate carefully the economic reasoning behind price regulation policies and to anticipate the economic responses of producers, distributors and consumers.

Box 9. Experience with price control systems

Colombia [140]

Colombia started to implement total control over drug prices in 1968. Since then, price regulation has gone through a number of phases and forms. Recently the scheme was changed again so as to combine freedom for a wide range of products with price control for a limited number. Since 1992, essential drugs with fewer than five suppliers and so-called "critical drugs" (in total about 20% of the market) have been subject to "monitored freedom" under which the producers or importers can change the maximum selling price to the public, but must inform the Ministry of Development in advance of a price change. The ministry can require manufacturers to present cost analyses in support of price increases and can also override the producer and impose the price level it deems appropriate.

One of the reasons the scheme was changed was that significant differences in prices for the same product occurred as manufacturers submitted different cost justifications. Furthermore, the manipulation of periodic price adjustments by the Ministry of Health introduced a political element and sometimes led to conflict between the producers and the authorities. Those products with prices that did not keep up with inflation often disappeared from the market, creating artificial scarcity.

In 1994, however, the Colombian government dropped the experiment with "monitored freedom" and returned to a system whereby prices to the consumer for monitored drugs had to be less than 3.4 times the production cost of the drug. The principal reason for this turnaround was lack of government capacity to follow up price changes under "monitored freedom".

Germany [133]

Germany has comprehensive health insurance. As part of efforts to improve cost containment under the health insurance schemes, a reference price system for pharmaceuticals was introduced at the beginning of 1993. This resulted in a decrease in expenditure on pharmaceuticals of 20.6% in the first half of 1993. However after this one-time drop, monthly expenditures continued to rise. One effect of reference pricing has been to switch prescribing to expensive products not covered by the system, such as new antibiotics.

There are three stages for the introduction of reference pricing. The first covers identical preparations, the second covers equivalent products or combinations and the third was originally defined as preparations which had pharmaceutical and therapeutic similarity. This has been changed simply to therapeutic similarity. A difficulty with this system is that if one or more products are under patent then the reference price system cannot be applied.

Manufacturers were required to reduce the prices of their non-reference priced drugs by 5% and also the prices of their over-the-counter drugs during 1993 and 1994. The lowered prices were frozen for two years.

An overall budget (by region) for pharmaceutical costs was introduced in Germany at the same time as the reference price system. Up to 280 million Deutschmarks of any expenditure over these budgets had to be paid back by the doctors and any further excess up to 280 million Deutschmarks had to be met by the drug industry. In the following year a similar budget was set, with the excess falling on doctors alone.

Price control: distribution margins

Considerable attention is paid to controlling producer prices. However, a large percentage of the final selling price of drugs is accounted for by distribution margins — mark-ups charged by importers, wholesaler distributors and retail outlets. Table 9 provides information on actual wholesale margins, retail margins and taxes for selected developed countries, and regulated margins in Indonesia. In remote areas, in areas with poorly developed formal distribution

systems, and in countries with limited regulatory control, distribution margins may be much higher than the regulated level.

Table 9. Wholesale margins, retail margins and tax as % of consumer price

	Distribution margins & taxes as % of consumer price (wholesale+retail+tax)	Wholesale margin	Retail margin	Tax
Developed countries [79]				
Belgium	43.4	8.5	29.2	5.7
Denmark	51.2	4.2	29.0	18.0
France	40.5	6.5	28.8	5.2
Germany	51.3	8.6	30.4	12.3
Ireland	42.1	8.8	33.3	0.0
Italy	38.5	7.3	22.9	8.3
Netherlands	41.2	11.8	23.7	5.7
Portugal	28.0	8.0	20.0	0.0
Spain	42.5	7.8	29.0	5.7
United Kingdom	42.5	7.5	35.0	0.0
Developing countries				
Indonesia [119]				
- Brand drugs	36.0	16.0	20.0	0.0
- Generic drugs	27.9	7.9	20.0	0.0

Distribution margins not only add to the selling price of individual drugs, but the structure of distribution margins is critical because it strongly influences dispensing incentives and advice at the point of purchase. There are five basic methods used to determine distribution margins for pharmaceuticals:

- **Cost + fixed percentage:** The most common approach is for wholesalers and retailers to add a fixed percentage to the price they pay.

- **Cost + declining percentage:** Some countries have adopted margins based on a declining percentage — the more costly the drug, the lower the percentage mark-up.

- **Cost + fixed dispensing fee:** To reduce the incentive to dispense higher-cost drugs, some countries have adopted a system of fixed professional dispensing fees. The pharmacist would charge, for example, $1 per prescription plus the wholesale cost of the drug.

- **Cost + differential dispensing fee:** To encourage generic dispensing, some insurance schemes reimburse pharmacies on the basis of drug costs plus a differential professional dispensing fee — for example, $2 for a generic prescription and $1 for a brand name prescription.

- **Maximum allowable price:** The sale price or reimbursement level is fixed for the generic equivalents of certain drugs or for therapeutic categories.

Pricing control mechanisms which use a fixed percentage mark-up may achieve reductions in individual drug prices, but they retain a strong incentive for retailers to dispense more expensive drugs. Such systems entail *lower* mark-ups for generic and/or essential drugs and thus are likely to discourage, rather than encourage, dispensing of these drugs.

Fixed dispensing fees create a double incentive for dispensing lower-cost drugs. First, the pharmacist is likely to sell more drugs when dispensing drugs for which the final price to the customer is lower. Second, the stock-keeping costs of high-priced brand name drugs are considerable. Selling more lower-cost drugs reduces the overall cost of maintaining drug stocks.

Distribution margins include two components: the margin for the wholesaler and the margin for the retailer. The final price paid by the customer represents the sum of the producer's price ("cost" in the above list), the wholesale margin and the retail margin. Different methods exist for combining producer price regulation and regulation of distribution margins. It should be recognized, however, that pricing structures establish incentives that have a major impact on private drug consumption patterns.

6.4 Affordable financing for drugs

The need for drugs and health often cannot be predicted. This makes it difficult to plan household budgets so as to take account of them. Financing schemes, such as prepayment and insurance schemes, may make drugs more affordable. Prepayment schemes smooth expenditure on drugs over time, while insurance schemes share the cost of drugs between both healthy and sick people.

A substantial amount has been written on the theoretical advantages and problems of health insurance [6,72], different types of prepayment and health insurance schemes, problems associated with health insurance schemes in industrialized countries [89], and the practical issues involved in implementing health insurance schemes in developing countries [65,88,101,106]. These issues will not be reconsidered here. This section discusses the possible impact of the establishment of health insurance schemes on the pharmaceutical sector and the role of community drug funds in improving affordability, availability and rational drug use.

Health insurance and pharmaceuticals

Decisions which affect the coverage of health insurance in a country are largely outside the control of national drug policies, essential drugs programme managers, and others concerned primarily with pharmaceuticals. But, as insurance assumes a greater role in many developing countries, it is important to understand insurance concepts and to be involved from the beginning in the planning, organization or regulation of insurance schemes. In many industrialized countries insurance is the principal means of raising finance for

health care and of making health care services accessible to all. However, in developing country settings the proportion of people with insurance is often limited by the extent of the formal labour market.

Insurance schemes which provide coverage for outpatient drugs may do so through private pharmacies, insurer-affiliated pharmacies, in-house pharmacies or pharmaceutical benefit management schemes. The mechanism of drug supply depends in part on whether the insurer functions only as the financier of services or whether, as with managed care, insurance is linked to a specific health provider.

Well-managed insurance schemes - whether public or private, mandatory or voluntary — are always looking for ways to control costs while maintaining quality. Insurance schemes therefore may be innovative in or receptive to programmes that promote rational prescribing patterns, various price control mechanisms, the use of drugs lists, essential and generic drugs, drug utilization review and so on. Insurance schemes with a strong administrative capacity may be crucial allies in improving prescribing practice in the private sector. They are unique in terms of the access that they have to information about private sector behaviour and their market power as large purchasers of health care. Insurance schemes can use financial leverage to gain access to information about private sector prescribing patterns and to influence those patterns.

Insurance schemes may also have a critical impact on drug utilization patterns through the payment mechanisms they use. Prospective forms of payment (such as case-based payment or capitation payments) fix in advance the total amount paid to the provider and therefore it is not in the provider's interest to prescribe unnecessary drugs. In contrast fee-for-service type payment systems may, if they allow mark-ups on drugs, encourage overprescription and prescription of more expensive drugs in order to enhance profitability.

Pharmaceutical benefits management (PBM) schemes are organizations which contract with insurers to provide pharmacy services. Though PBMs would appear to add another middle-man and additional expense, insurers in developed countries which use PBMs find that their efficiency and expertise in the field actually saves money [47].

Community drug schemes

Community drug schemes are locally managed revolving drug funds. In contrast to most commercial drug outlets, community drug schemes try to emphasize the provision of essential drugs, low prices and the direct connection between diagnosis by a health worker and appropriate drug treatment.

Community drug schemes are typically initiated in areas with limited financial or geographical access to drugs. Thus, such schemes address affordability and

rational use as well as availability. In the context of the Bamako Initiative, community drug schemes often have broader objectives. These may include health education, provision of preventive services such as immunization, and raising of sufficient revenue from drug fees to help finance salaries, medical supplies, or other costs.

Considerable experience has accumulated with community drug schemes and other forms of revolving drug funds. This experience provides support to the arguments of both proponents and opponents of such schemes. Schemes that have implemented large fees with no preparation of the public and little improvement in quality have seen significant decreases in utilization; schemes designed with little attention to management and accounting systems have seen substantial abuse and little revenue compared to the cost of fee collection; revolving drug funds established without a reliable source of low-cost drugs have quickly ceased to revolve; and some schemes with drug charges have seen overprescribing [20,31,68,87].

At the same time, NGOs and many communities are turning to community drug schemes in an effort to increase the availability of essential drugs. Critical factors in the design and implementation of community drug schemes include [81,128]:

- adequate protection mechanisms for the poor and other target groups;
- reliable supply of low-cost essential drugs of good quality;
- locally appropriate fee schedules;
- measures to discourage overprescribing;
- good administrative systems for financial management and supply management;
- strict measures to ensure accountability and control of revenue.

Community drug schemes are not easy to implement. Many things can go wrong to undermine the intended benefits. Large-scale successes are limited. Yet sufficient experience has accumulated to suggest that the measures listed above will increase the chance of success.

6.5 Rational drug use

Though competition and economic incentives may lead to *managerial efficiency* in the private sector, they often lead to *therapeutic inefficiency*. Economic incentives for irrational drug use may exist for the prescriber, the dispenser and the consumer who receives the drug. Profit motives and pressure to please the patient may lead to overtreatment of mild illness, inadequate treatment of serious illness, misuse of anti-infective drugs, and overuse of injections [48,52,53,66]. Consumers, on the other hand, often buy subtherapeutic doses of drugs such as antibiotics [37,63,66] and roughly half the time fail to take drugs as recommended.

Any effort to improve the affordability, availability and quality of drugs in the private sector must be accompanied by vigorous efforts to promote rational use of drugs. A wide range of measures exists to promote rational drug use [54,81,129,130]. A selection of these measures is listed in Table 10.

The government has a central role in ensuring that rational drug use activities are planned and implemented as part of a national drug policy. At the same time, efforts to promote rational drug use in the private sector benefit greatly from active involvement by universities, professional associations, the media, educational institutions outside the health sector, consumer organizations and other NGOs. Encouragement and support for these organizations are essential. Given the large proportion of drugs that is consumed through private purchases in many countries, public education through a variety of approaches may prove one of the most effective public health strategies in the long run.

In many countries a high percentage of drugs intended for prescription only is still sold and dispensed directly by untrained drug sellers. Economic factors contribute to the problem, but there is also in many countries a serious lack of trained pharmacists.

Table 10. Measures for promoting rational drug use

Aimed at professionals

- Training in essential drugs concepts, good prescribing and good dispensing in undergraduate curricula for all health professionals
- Continuing education on rational drug use
- Ethical criteria and enforcement of legal controls on drug promotion
- Regulating and training of pharmacy aides and other drug sellers in the informal sector
- Setting standards of practice, developing national treatment guidelines
- Discouraging conflict of interest (e.g. restricting dispensing clinicians)

Aimed at patients and consumers

- Creating a supportive environment for consumer information and education (including funding of relevant NGO groups)
- Orientation of journalists to drug policy and drug use issues
- Media and other public information campaigns (covering, for example, comparative drug information, and consumer-oriented therapeutic information)
- Patient education at health facilities

For example, as of 1985, Nigeria - a country of nearly 100 million people at the time — had roughly 3600 registered pharmacists, of which only 1200 operated retail pharmacies. The country had an estimated 20,000 licensed patent medicine stores and an estimated further 20,000 that were unlicensed [96]. By 1990 Nepal had 5000 registered drug retailers — one drug seller for every 3000 people, compared with one health post for every 12,000 people.

Recognizing this reality, Nepal [58], Nigeria [93] and several other countries have established training programmes to promote safe dispensing by drug sellers. WHO has developed educational materials aimed specifically at improving dispensing practices for diarrhoeal diseases [121] and malaria [126]. Dispensing recommendations for such training include *only* safe and effective essential drugs. In Nepal, work has been initiated to assess the effectiveness of active learning methods for the triad of *safe dispensing*, *correct advice*, and *appropriate referral* for diarrhoeal disease, acute respiratory infections, and anaemia in pregnancy.

It is often assumed that profit-making and safe dispensing are incompatible. Yet for many common illnesses there are pharmaceutical products which are safe, effective and profitable to dispense. Can drug sellers be trained to find profit in good health? Controlled field studies in Indonesia and Kenya [102] demonstrate that drug sellers can successfully be trained to reduce their dispensing of antibiotics and increase their dispensing of oral rehydration salts for simple diarrhoea.

Inappropriate promotional activities are another element of irrational drug use (see Box 10). It is essential that governments regulate the promotional activities of pharmaceutical companies to prevent misleading messages. France implements a special tax on pharmaceutical company promotion expenditure.

Box 10. Problems with rational drug use in the private sector

Medreps in Bombay [59]

Medreps are central to the functioning of the prescription drug market in Bombay. Their job is to persuade doctors to prescribe the drugs of the pharmaceutical company whom they represent. As much of their pay is related to their performance, they are under considerable pressure to get prescriptions. Pharmaceutical companies often spend US$18-20 per month per doctor on marketing costs. This covers the provision of samples, mailings, incentives and gifts, invitations to conferences and personal "thank you" cards for having prescribed products.

Medreps say that they help doctors satisfy patients by offering them "suites" of products that address patients' immediate needs and concerns. Pharmaceutical companies' market research departments identify the sets of symptoms and health concerns which people group together. By encouraging doctors to meet these perceived health needs and expectations, companies reinforce existing, often questionable, patterns of pharmaceutical behaviour, presenting them as normative.

6.6 Drug quality, safety and efficacy

Government is responsible for ensuring the quality, safety and efficacy of drugs in both the public and private sectors. The main means at its disposal for doing this are:

- registration of drugs based on quality, safety and efficacy, with cost and appropriateness to the local health system also being factors in some countries;

- licensing and inspection of importers, wholesalers and retailers;
- licensing and inspection of manufacturers to ensure enforcement of good manufacturing practice in all production facilities.

An effective system of drug quality regulation will also entail a programme of post-marketing surveillance whereby the safety and utilization patterns of drugs in the market is monitored.

The actions required to ensure drug quality are the same for both public and private sectors. However, the enforcement of regulations in the private sector is likely to be considerably more complex than in the public sector. This is particularly the case where government regulatory capacity is relatively weak and a substantial proportion of private sector drug outlets are unlicensed.

6.7 Summary points

- Ensuring that the private pharmaceutical sector provides safe and efficacious drugs, which are accessible to all the population and are used in a rational manner, is an extremely complex role. Governments have a wide range of mechanisms to use in fulfilling this essential role, but complex interactions between mechanisms, political sensitivities and limited government capacities make it a difficult task.

- Table 7 sets out a range of possible instruments which government may use to intervene in the sector. Table 11 reconsiders these instruments and classifies them according to their potential feasibility and effectiveness.

Table 11. Instruments to promote access, rational drug use and drug quality: potential feasibility and effectiveness

Essential instruments - to be used by all governments

- Prohibition of dispensing clinicians, except in underserved areas
- Generic substitution and pro-generic policy
- Drug registration
- Monitor the quality of undergraduate training for health professionals
- Public and patient education
- Regulation of drug information and promotion
- Continuing education for health professionals

Uncomplicated and useful instruments - recommended to governments

- Provision of price information
- National coverage and full assortment clauses in licensing of wholesalers
- Location regulations for wholesalers and retailers
- Training of drug sellers
- Development of standard treatment guidelines (at least for common diseases)

Complex but potentially useful instruments

- Incentives for wholesalers and retailers to deliver/locate in underserved areas

- Regulation of producer prices for drugs under patent
- Community drug schemes
- Health insurance schemes
- Accreditation schemes

Instruments on which more information is required

- Regulation of producer prices for non-patent drugs
- Regulation of retail margins

7. Pharmaceutical production and public-private roles

What role should the government play in the manufacture of pharmaceuticals?

Medicines to meet national health needs can be procured through:

- local public sector manufacture;
- local private manufacture (national companies);
- local private manufacture (subsidiaries of foreign companies);
- imports.

There are virtually no countries whose needs are met entirely through local manufacture (public or private). Even among high-income countries with well-developed production capacity, imports are often equivalent to over 50% of consumption [9]. In part this reflects drugs which are later re-exported, but much of this importation is of specific products which are not economically produced locally. Examples of high-income countries which, as of 1989, relied heavily on importation of pharmaceuticals included Austria, Iceland, the Netherlands, Norway and New Zealand [9].

Essential roles of the state in local pharmaceutical production include licensing and regular inspection of manufacturing premises and registration of drug products. Whether production is private or public, the first priority is that products are of good quality (GMP).

In addition to regulation to ensure quality, government policies and regulations influence the business environment for local pharmaceutical production. Rapidly changing global trade arrangements are likely to change the structure of pharmaceutical markets as products flow more easily between countries [62].

7.1 Arguments for and against public sector pharmaceutical production

Brazil, China, Egypt, India, Indonesia, Nepal, Sri Lanka and a number of former centrally-planned economies are examples of countries with large state-owned and usually state-managed production. A number of other governments have started and then discontinued government production or are attempting to upgrade existing state production facilities.

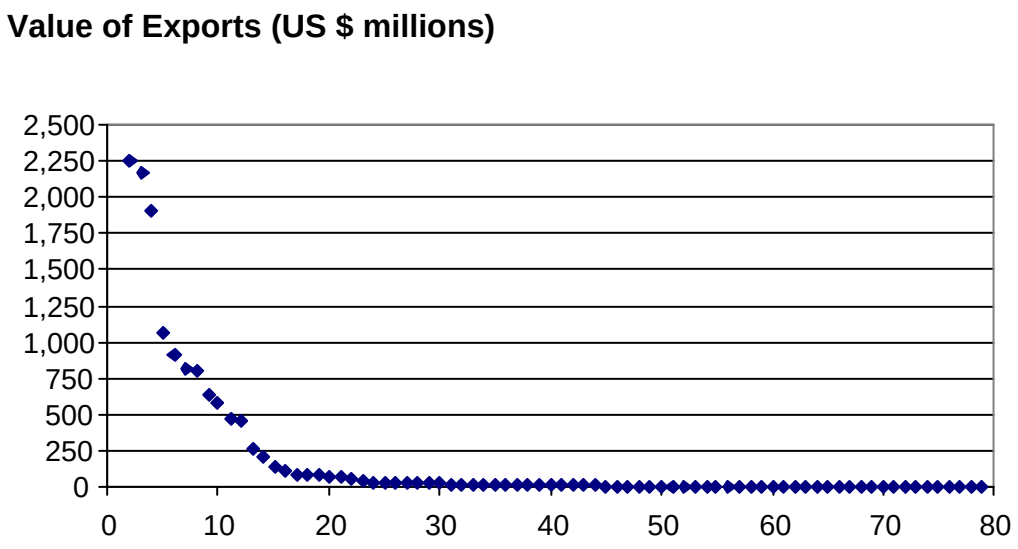
Table 12 summarizes the arguments for direct public sector involvement in pharmaceutical production and also assesses the evidence for each argument.

Table 12. Arguments for public sector pharmaceutical production

Arguments	Evidence
• To save money from pharmaceutical production at lower cost	Profit margins on bulk generic drugs (the usual government requirement) are low. Public production must be as efficient as large-scale private manufacturing if real savings are to be made.
• To save foreign exchange	Modern drug production requires raw materials which typically account for 50-70% of production cost. Raw materials are generally purchased on the international market. Processing of these raw materials requires equipment which will need to be imported. Foreign exchange savings may therefore be small.
• To export drugs to earn foreign exchange	Very few developing countries have developed a successful pharmaceutical export business, as shown in Figure 5. As of 1990, among 80 countries producing pharmaceuticals, only 16 countries had exports over US$ 100 million. These 16 countries accounted for 95% of global exports. Fifty of the 80 producing countries had either no export market or markets below US $20 million per year.
• To achieve self-sufficiency	As of 1990, among approximately 100 developing countries producing pharmaceuticals, less than 20 were producing active ingredients. Many countries have dropped import substitution policies in favour of participating in the international market.

Figure 5. Estimated annual value of exports for 80 countries, 1990

Each diamond represents one country (based on data in ref. [9])



Thus, as Table 12 shows, there is limited evidence to support direct public sector involvement in pharmaceutical production. Many of the problems commonly associated with the public sector, such as political involvement in

decision-making, shortage of funding and inefficient operation, have frequently led to production problems in publicly-owned pharmaceutical companies (see Box 11).

While governments may be ill-advised to consider establishing new state-owned pharmaceutical production facilities, the question of how to handle existing facilities is more complex. Sale of government production units to the private sector is likely to result in better prices only if adequate technical know-how is available in the private sector and if competition exists. If privatization negotiations do not explicitly set out what sort of products firms should produce, then there is a danger that the product range of the privatized company drifts from essential drugs to higher-priced and less essential products.

In the short term government may explore less radical options such as opening up government-owned production to competition or giving autonomy to state-owned pharmaceutical enterprises. In order for competition to be effective, public sector producers must compete on the same basis as private producers, i.e. they should not receive special subsidies.

Despite the existence of several studies evaluating the privatization of state-owned enterprises [2,36], there has been little evaluation of the position of publicly-owned pharmaceutical producers and what measures would best enhance their efficiency.

Box 11. Public sector production of pharmaceuticals - some difficult challenges [81]

- One Latin American ministry created an "in-house" pharmaceutical factory to produce essential drugs for its own health care system. There was little connection with the ministry's market, however, and the product line drifted into over-the-counter preparations and beauty aids, largely missing its original purpose.
- In another semi-autonomous government laboratory, production of essential drugs is usually two or three years behind schedule, throwing ministry purchasing into turmoil and resulting in higher prices because of emergency purchases.
- A parastatal company in East Africa faced multiple problems in producing drugs at competitive prices. Inadequate capitalization and inadequate foreign exchange allocation left the firm unable to purchase enough raw materials to operate at the break-even level of 60% of capacity. For the drugs which were produced, containers of inadequate quality — metal tins without aluminium coating — were all the local suppliers had, and these had to be lined with plastic bags, adding to production costs. Plastic containers were tried, but the lids fitted poorly as a proper mould could not be obtained locally at reasonable cost. The cardboard used for boxes to pack intravenous fluids collapsed when stacked, and the containers broke when transported over rough roads. When the government attempted to purchase drugs on tender from the company, it could not meet the competitive prices on the market. As a result of the structural adjustment programme the company has been put up for sale.
- For political reasons, a Latin American government was obliged to purchase a non-functional private facility as a means of expanding its production capacity. Originally constructed to produce small quantities of a large number of sterile injectable products, it had never functioned because inadequate water supply rendered it useless as a production facility. In addition the plant lacked the production capacity, types of equipment and storage capacity to produce the priority items required by the ministry.

7.2 The government's role in strengthening local production capacity

Although governments often engage in pharmaceutical production in order to develop a local industry, local production is obviously quite distinct from public production. As many countries have moved away from import substitution policies the arguments for local production have been weakened. The WTO may also make the case for local industry less strong. Yet there are still reasons why local production may be desirable, particularly in terms of developing local capacity, creating jobs and achieving some independence from international suppliers.

The viability of local pharmaceutical production will be influenced primarily by the size of the market (population and income levels), the existence of other production capacity in the region, the size and local procurement preferences of the public sector market, physical infrastructure (cost and reliability of water, power and other resources), and human resources (pharmacists, chemists and other technical specialists and skilled production staff).

Government policy may also have an important impact on the viability of local production. Table 13 outlines some of the regulatory and legal provisions, investment and industrial development factors, economic incentives and

disincentives, and import controls which may directly or indirectly influence local production.

Government policies as a whole may actively support or be neutral towards local pharmaceutical production. An intentional policy of discouraging local production is uncommon, though it is not uncommon for policies and regulations unintentionally to discourage local production. For example, the combination of high import duties on packaging material and low duties on finished pharmaceutical products may make locally produced drugs more expensive than imported finished products. Certain policies may encourage all production, while other policies may provide differential preference for indigenous or essential drugs.

Many national procurement procedures, as well as standard procurement procedures for financial institutions such as the World Bank, provide for local preference in public tendering. Typically the local supplier is given preference as long as the bid price is within 10-15% of the overseas price (adjusting for currency differences and including insurance and freight). Since Ministry of Health drug procurement is usually limited to essential drugs, this means that local manufacturers are encouraged both by volume and by a price advantage to concentrate production on essential drugs.

To further support local production of essential drugs, some governments lower or remove duties on raw materials for these drugs. In addition, ministries of health in Colombia, Ecuador, Nepal, Venezuela and a number of other countries have helped to arrange training in good manufacturing practices for local private producers. This is of direct benefit in terms of the quality of drugs on the local market. It also contributes to the firms' competitiveness in the regional and global pharmaceutical markets.

Policy-makers should be aware of the range of possible production options. Distinctions are commonly made between:

- primary production (manufacture of the raw materials used in pharmaceutical production);
- secondary production (processing of finished dosage forms from raw materials or intermediate products);
- tertiary production (packaging and labelling of finished products from primary and secondary sources).

Table 13. Factors influencing viability of local pharmaceutical production

Regulatory and legal provisions

- Ease of registration, registration preference
- Patent protection of products and processes
- GMP standards and enforcement of standards
- Generic labelling, prescribing and dispensing laws and practices

Investment and industrial development environment

- Tax or other investment incentives
- Industrial development funds (access to start-up capital)
- Ownership requirements (limits on foreign ownerships, requirements on local ownership)
- Repatriation of profits (foreign investors)

Economic incentives and disincentives

- Price controls
- Access to foreign exchange
- Export incentives

Duties and import controls

- Active pharmaceutical ingredients (versus finished products)
- Inactive pharmaceutical ingredients and other raw materials
- Packaging materials
- Specialized pharmaceutical equipment
- Non-specialized equipment

Source: Adapted from [81]

The capacity for tertiary production is often developed first by countries and can help build the requisite skills and experience for other levels of production. The local manufacture of liquid preparations (intravenous solutions, oral liquids) is likely to be more economically viable than other preparations due to the high transportation costs of these substances.

Local production capacity may also be enhanced by encouraging the development of joint ventures and licensing agreements between local and multinational firms. This has occurred in many East and South-East Asian countries [9]. Local subsidiaries and joint ventures can result in transfer of technology and technical skills. On the other hand, governments may be concerned that multinational profits do not remain in the country and therefore place controls on such ventures. In India and several other developing countries there are controls on the share of the domestic market which foreign-owned firms can take.

7.3 Summary points

- There is limited argument or empirical evidence that government need be directly involved in the production of pharmaceuticals.

- Countries with state-owned pharmaceutical manufacturing firms often face difficult questions about how to ensure the efficiency of these firms. In noncompetitive markets, privatization (divestment) may not be the best strategy. Governments need to explore a range of different options such as stimulating competing manufacturers and contracting-out management functions.

- Governments can play a key role in encouraging the development of manufacturing capacity in the local private sector. The most effective way of doing this is probably to encourage the development of a stable economic and political environment, an efficient regulatory environment, and favourable tax and duty structures.

8. Capacity-building and the process of change

What capacities are needed to manage changing roles and how can these capacities be enhanced?

No matter how well designed and well planned policies to change public-private roles may be, they will falter if there is insufficient capacity to implement them or if they are implemented in a manner that is insensitive to the interests of the people and groups who will be affected by them. Policy-makers cannot afford to focus on the content of policies to the exclusion of the process of policy development and implementation.

This section addresses firstly the question of capacity to implement new public and private roles and, secondly, the policy environment and how this might help or hinder the process of change.

8.1 The nature of capacity and capacity constraints

There is often an implicit assumption that reform in public-private roles will reduce the burden on government. However the role of government may not be reduced but rather transformed. For example, in shifting from a government operated CMS model to a direct delivery system, government trades functions of storing and delivering drugs for functions of negotiating and contracting with the private sector. Moreover, explicit recognition of the relative roles of both public and private sectors contributes greater complexity to managing the pharmaceutical sector. Governments cannot afford to focus exclusively on public sector pharmaceutical supply but instead are responsible for managing a multidimensional system.

Often the new roles which government must take on are unfamiliar ones. To what extent do governments have the capacity to fulfil these roles?

The reforms discussed here have implications not only for roles of the public sector but also for those of the private sector. For many of the reforms to be successful, substantial capacity is required in both private for-profit and private not-for-profit sectors.

New roles, new capacities

What are the new capacities which the changing public-private mix requires? On the whole, government capacities directly to deliver goods and services — whether they be drug manufacturing or supply — are likely to be of less importance. Instead, government roles in policy-setting, coordinating other actors, negotiating and implementing contracts, monitoring, regulating and providing information all become more important.

Different types of reform require different types of capacity [95] so it is impossible to set out a definitive list of required capacities. Table 14 illustrates the aspects of capacity which might be required to negotiate and implement successful contracts and to regulate private sector drug supply.

Table 14. Capacities required to contract with and regulate the private sector

	Negotiating and implementing public contracts with private companies	**Regulating drug distributors in the private sector**
1. Individual skills	• *Capacity to define objectives and performance indicators* for the delivery agency • *Negotiating and legal skills* to design contracts • *Economic analysis* to assess whether contracting is more efficient than in-house provision	• *Legal, conceptual and political skills* to design an effective regulatory system • *Pharmaceutical knowledge* to ensure safety of drugs in market and GMP practice in production plants
2. Organizational capacities	• *Information systems* required for monitoring • *Adequate accounting and financing systems* for timely payment of contractor • *Private sector capacity* to deliver, plan and cost services	• *Information systems* maintaining up-to-date information on licensed producers, wholesalers, retailers and pharmacists • *Reliable and comprehensive inspection system* to ensure drug quality, appropriate storage etc.
3. Institutional capacities	• *Effective legal system* to enforce contracts • *No political interference* in awarding contracts	• *Effective legal system* to take sanctions against organizations / individuals breaking regulations • *High ethical standards* in inspection unit (terms of service and ethical practices which encourage reliable inspection and avoid illegal payments)

Governments often already possess some of the new skills and capacities required but these need to be reoriented in order to fulfil a new function. Moreover, the level of demand on certain scarce capacities, such as negotiating and legal skills, is likely to increase. For instance, the number of inspectors working for the drug regulatory agency will need to increase with the size of the private sector.

If government lacks capacity in certain of these areas, the not-for-profit private sector may play a critical role in supplementing government action. Consumer groups are often active in monitoring the price and quality of drugs on the market and, when necessary, provoking drug regulatory authorities into action (see Box 12). An active civil society or *third sector* may also help guard against some of the problems stemming from weak institutional capacities. NGOs and the media can be efficient "whistle-blowers" on lax inspection agencies or improper awarding of contracts. Not-for-profit groups may also be allies in capacity-building. The Churches' Action for Health is currently field-testing a management training scheme for pharmacy technicians in Kenya, and the Commonwealth Pharmaceutical Association has developed a distance training course in management. Box 12 describes how NGOs have contributed to drug regulation in India and the USA.

Box 12. NGO roles in contributing to regulatory capacity

NGO protest in India [18]

During the 1980s a number of voluntary groups, NGOs and consumer forums in India launched campaigns to demand controls on drug prices and bans on harmful and irrational drugs. These NGOs enlisted industry insiders in order to document precisely how some companies distort information about drugs. The NGO networks were also able to provide objective and unbiased information on drugs. The federal drug authority acted on this information to ban some toxic drugs (including a high-dose estrogen-progesterone combination). In some cases, such as in Maharastra in western India, NGOs have run independent checks on the quality of products on the market and have helped the Indian authorities weed out spurious or obsolete products.

Consumer Groups in the USA: Public Citizen and bromocriptine [76]

In June 1989 in the USA the FDA recommended that the indication of postpartum breast engorgement (PPBE) be deleted for all drugs marketed for this condition, including bromocriptine. An expert review had concluded that these drugs were largely ineffective and unnecessarily risky. The FDA wrote to companies asking that they voluntarily withdraw the indication of PPBE. All but one company did so. Bromocriptine continued to be prescribed to 300,000 women per year for the indication of PPBE.

In September 1993, the health group of the Public Citizen organization filed a citizen's petition with the FDA calling for the removal of the PPBE indication for bromocriptine. The FDA stated that this indication for the company's product would be withdrawn, but action was delayed. Soon Public Citizen announced a lawsuit against the FDA, charging "unreasonable delay". The following day the FDA announced that it intended to withdraw approval of the indication. A day later the drug company announced that it was withdrawing this indication for the drug.

Health Action International (another NGO) passed the documentation compiled by Public Citizen to its members in many different countries. Thus NGOs all over the world rapidly drew public attention to this issue through the press and directly raised it as an issue with regulatory authorities.

The role of NGOs

NGOs do not have the statutory power to regulate but it is evident that they may be important partners for government. The flexibility, innovation and ability of NGOs to network internationally mean that they may play a critical role in supporting government regulatory authorities in achieving social objectives.

Capacity constraints

There is little concrete evidence on capacity in the pharmaceutical sector to take on new roles. However, lessons can be drawn both from what is known about the existing pharmaceutical sector and from evidence concerning changes in the health sector.

Analysis of contracting in the health sector suggests that while there may be potential efficiency savings from contracting-out services, these efficiency savings are often compromised by inadequate negotiating skills in government, resulting in high prices for government [74].

An interregional WHO meeting concluded that "c*ountries often felt that although they have the authority to monitor (private sector behaviour) they do not have the capacity*" [120]. The literature from the pharmaceutical sector supports this conclusion. For example, Nigeria established in 1990 a special task force to clamp down on counterfeit drugs and illegal drugs-sellers. Two-million dollars were spent on new drug-testing equipment but the federal task force in Lagos still had no vehicles of its own and many of its state offices did not have telephones [10].

Where rapid growth in the private pharmaceutical sector takes place, government is often unable to invest in regulatory authorities at the same pace and the capacity of the regulatory authority is outstripped. This was certainly the case in India [46]. Lack of finance for regulation may mean that regulatory authorities have difficulty in attracting the scarce skills required in order to regulate effectively. This is particularly so since the skills required will also be sought after in the private sector, and there is commonly a considerable salary differential between the two sectors. In this context, experience with self-financing registration authorities (see Box 13) is particularly interesting.

A key problem in regulation is *regulatory capture* whereby the regulatory authority serves the interests of the agencies it is trying to regulate more than those of the consumer. This is particularly a problem in specialized industries such as pharmaceuticals where staff of the regulatory authority and industry are likely to have similar professional training and perhaps similar values.

Box 13. Self-financed drug registration [127]

The self-financing of drug registration is now being introduced in some developing countries. Formerly, it existed only in industrialized countries such as France, Sweden, the United Kingdom and the USA.

The example of Zimbabwe

One developing country example of a drug registration agency that charges fees is Zimbabwe's autonomous Drug Control Council (DCC). The DCC has now become entirely self-sustaining. Its staff, composed of five people, is appointed by the Ministry of Health, though the DCC acts as an independent agency. It charges registration fees of US$ 300 for imported drugs. Fees are lower for drugs imported and repacked in Zimbabwe and lower still for drugs manufactured there. Retention fees are slightly over half of the original registration fee.

Some of the money the DCC collects is apparently now used to support inspection laboratories which are housed in the same building. The inspection operations therefore depend at least in part on the

registration agency, although separate charges are still made for inspections. Even the government's central stores are charged for the inspection of government-distributed drugs. However, Zimbabwe's inspection capabilities are still insufficient; there are only two drug inspectors for the whole country.

Other countries that charge registration fees

Charges for registration are now becoming common practice in anglophone Africa and in some francophone African countries. Fees for registration are now charged in Cameroon, Namibia and South Africa, as well as in Zimbabwe. Once a drug has been registered, a retention fee of US$ 50 per year is usually charged; with 2000 products registered, this brings in around US$ 50,000.

Brazil's high registration fee

One country, Brazil, has now set a very high initial registration fee. This is US$ 10,000, which may be a standard sum for some developed countries but not for a developing one. In Brazil, a commission is also working on establishing a registration agency that is separate from the government and on charging a smaller and more flexible yearly retention fee.

8.2 Approaches to enhancing capacity

Training programmes, both basic education and continuing education, are the standard response to problems of capacity. But adequate capacity is unlikely to be developed by these methods alone. More innovative approaches are required:

- Many of the new skills required, such as negotiating skills, can be acquired only through experience. Organizations and individuals practising these skills, such as drug purchasing offices negotiating direct delivery or prime vendor systems, need the opportunity to reflect on and evaluate their experiences. International organizations may play a role in facilitating this.

- Capacity may be enhanced by increasing collaboration between the public and private sectors through, for example, the exchange of personnel between private firms and regulatory agencies and the use of private sector databases to help with regulatory efforts. To prevent conflict of interest, however, there need to be clear guidelines and structures for such exchanges.

- There are high fixed costs associated with many aspects of pharmaceutical regulation, and small countries will always find these difficult to bear. International collaboration may be a means to reduce the regulatory burden on individual countries. It could take the form of regional drug inspection agencies or mutual recognition agreements between drug inspection agencies.

- Legal, economic, planning and management skills in ministries of health need to be strengthened and augmented to manage new public-private roles. Traditional training programmes could contribute in this area.

8.3 The process of change

There is no right way in the transition process. Policy-makers need to tailor the process so as to best suit the conditions of their country and the particular aspect of pharmaceutical sector reform with which they are dealing.

Some countries have had relatively rapid and far-reaching reform programmes. This has been the case in the countries of Central and Eastern Europe (CEE) and the Newly Independent States (NIS) during the 1990s, which have increased the private sector role, and in Bangladesh (starting in 1982), Sri Lanka (1970) and the Philippines (1986) which placed tighter regulations on the private sector [99,110]. Elsewhere the reform process has been slower and more incremental.

Both rapid and slower-paced reforms share some similarities. Reforming public-private roles is unlikely to be a once-and-for-all event. Reforms are complex and dynamic. They involve a large number of actors (see Section 2.2) who will have different perspectives on the reforms and will try to influence the reform process. Implementation, monitoring and evaluation of reforms will most likely reveal deficiencies and the need for further change.

Wide-ranging and rapid reform programmes have often been driven by political forces. New governments have come to power and have pushed through a package of reforms in a relatively short space of time. The speed with which such reforms have occurred is part of the secret of their success but may also contribute to their failure. Speed may prevent resistance to the reforms from emerging but it may also jeopardize the content of the reform package. The stages in the transition process in the CEE and NIS (see Box 14) may not appear rational; it would have been sensible to put an effective regulatory framework in place prior to privatizing. Yet such measures may have signified ambivalence and jeopardized the reform process. The strongly political nature of such reforms may also be problematic. In Bangladesh, the Philippines and Sri Lanka, the pharmaceutical reforms faltered when new governments came to power [99].

Box 14. Rapid reform: Central and Eastern Europe and the Newly Independent States [109]

It has been several years since the countries of CEE and NIS started an unprecedented transition process from a centrally-planned economic system towards a market-oriented system with a democratic political structure. This process of change and transition took place in an atmosphere of uncertainty and to some extent anarchy.

The most important element responsible for the changing public-private roles in CEE/NIS countries is the acceptance in almost all places of privatization as a basic vehicle for reform. The discussion in most countries is not whether to privatize, but how and at what speed.

The drug supply system transition process

The introduction of a market-oriented drug supply system is accepted in most of the CEE/NIS countries as an indissoluble part of the general reform process. Prior to the changes, the provision and distribution of drugs were centralized. The system was poorly maintained and coordinated. The transition towards privatization in the CEE/NIS has taken place in phases, starting with the introduction of private ownership all the way through to the development of appropriate regulation of the sector.

Stages in drug supply transition in CEE/NIS

Stage 1 **Implicit introduction of private ownership** in the drug supply system as part of general measures to encourage private initiatives within the framework of economic reform.

Stage 2 **Emergence of a number of private pharmacies** in addition to the existing state-owned systems. These new pharmacies have many forms of ownership and most do not comply with accepted standards of good pharmacy practice.

Stage 3 **Decentralization of the state-owned sector** so that each pharmacy has its own financial account. This is a necessary step prior to privatization. Some countries decentralized before the transition; others are just beginning.

Stage 4 **Phased privatization of the state-owned sector,** depending on the availability of funds and will to privatize. Some countries keep a strategic stake in the sector to guarantee supply and

maintain some pharmacies or a wholesaler under state control.

Stage 5 **Uncontrolled market expansion,** including increased availability of imported drugs, rising prices, margins and profits, uncontrolled sale of drugs, examples of unacceptable and irresponsible behaviour — which finally trigger the need for regulation. This is supported by emerging social dissatisfaction — particularly inequity.

Stage 6 **Setting up of regulating authorities** (functions previously performed by ministries or state-owned wholesalers). The initial focus on privatization is replaced by investment in regulation and control structures. This process needs key professionals and funds.

Stage 7 **Gradual regulation** of the sector in terms of licensing, setting minimum standards, limiting forms of ownership, establishing new pharmacies, and promoting coverage in rural and remote areas.

Reform in former centrally-planned economies has been driven by an ideological vigour uncommon elsewhere. Often in these countries privatization has become the objective of reform rather than a means to an end.

As the problems associated with privatization have become apparent, controls on the private sector have had to be implemented. A more planned approach would obviously have tried to predict the potential problems and implement an adequate regulatory framework prior to privatization. However, reform programmes are commonly driven by political opportunity.

The process of reform in Australia (see Box 15) serves as a useful counterpoint. Recent reforms to promote rational drug use (in both the public and private sectors) in Australia took place against the framework of a relatively well developed national drug policy and in a mature pharmaceutical sector with many well-established interest groups. In this context, very rapid reform was not appropriate and instead the government has pursued a process of negotiation and discussion involving all key actors.

There are various techniques, such as political mapping [98,99] and guides to policy analysis [116], which may allow policy-makers to gain a clearer understanding of the political dimensions of the policies they are implementing and hence make implementation easier. But it is also important that policy-makers and planners clearly locate reforms in a comprehensive sector strategy (so as to avoid ad hoc decision-making) and try, as far as is possible, to predict the full implications of reform.

Change also tends to be costly; new regulations and bureaucratic structures must be established, actors in both public and private sectors need to be convinced of the wisdom of reform, and information campaigns explaining the nature of the change need to be coordinated. The costs of change, both in financial terms and in terms of the motivation and commitment of individuals working in the system, need to be factored in to decisions about reforming public-private roles.

Box 15 . A participatory approach to rational drug use in Australia [83]

Since the 1950s when the Australian government decided to provide life-saving drugs to the entire population, the role of the state has evolved into one of active control over the market for prescription pharmaceuticals. In 1994–1995 government expenditure on subsidized access to drugs was $1.9 billion or about 0.42% of GDP.

Although problems of equity, access, quality and industry viability have been addressed in Australia, the complex and important problem of rational drug 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.

Problem recognition

Many government enquiries during the 1970s and 1980s raised the issue of educating all those involved in prescribing, dispensing and using medicines. Consumer groups became concerned about the toxicity of drugs and the lack of information provided at pharmacies. Campaigns were run by consumer groups to raise awareness of the overuse of benzodiazepines. Pharmacy training underwent change, leading to increased emphasis on education about drugs and communication skills. These trends were strengthened by the formation of a national professional body (the Australian College of Pharmacy Practice). The subcommittee on drug utilization under the Australian medical benefits scheme began to develop and refine databases on drug use; this highlighted particular problems in drug use and led to special programmes to encourage appropriate use.

Government adopts a lead role

By the end of the 1980s there were many groups working within the broad area of rational drug use (including professional groups, consumers and industry) but there was little cooperation and some hostility between groups. Piecemeal programmes were unlikely to have maximum impact. The

government began to fund the development of more programmes, which helped different groups to come together. These included a task force on polypharmacy in the elderly and a conference exploring influences on prescribing.

(continued overleaf)

Box 15. A participatory approach to rational drug use in Australia [83] (continued)

In 1992, Australia adopted a Quality Use of Medicines (QUM) Policy which endorses the WHO definition of rational drug use. Its goal is to optimize the use of medicines to improve the health outcomes of all Australians.

Implementation examples

The implementation of the QUM policy was designed to take full cognisance of the many actors involved in the pharmaceutical sector:

- Meetings with industry have articulated shared objectives in developing industry-sponsored education and promotion
- Two very successful workshops brought workers from all major groups together to discuss academic detailing and consumer education and information.
- A workshop with professional, academic and practising pharmacists was held to develop strategies to maximize their professional contribution to the quality use of medicines.

As a result there have been initiatives in a number of areas, including the development of:

- national prescribing guidelines, a national formulary and consumer information;
- a curriculum in clinical pharmacology for medical schools;
- education programmes encouraging consumers to ask health professionals more questions about medicines;
- several types of academic detailing programmes.

The coordination of a comprehensive policy from a history of separate objectives and programmes requires both time and dialogue to make sure that all actors are comfortable with closer relationships. Partnerships should not lead to subtle forms of cooption but should rather clarify which issues can be resolved through cooperative action and which require tensions to be argued out in a political or regulatory process.

8.4 Summary points

- When deciding on reform packages, governments must forecast the new skills and capabilities they will require in order to operate successfully. If these skills and capabilities are not present, new capacities need to be built — or the reforms need to be reconsidered.

- New roles for government generally require stronger planning, information, management and financial systems to support monitoring of contracted suppliers, regulation of the private sector etc. Ironically weaknesses in these very systems are often part of the reason why reforming public-private roles is considered in the first place.

- The level of funding for regulation needs to increase as regulatory responsibilities expand. This can be achieved both through greater public financing and through more extensive use of regulatory self-financing.

- As a part of reform programmes, governments need to consider how to increase capacity in the private sector. Efforts to build capacity may take the form of skills and systems development for private producers, wholesalers, retailers and professional organizations on the one hand, and support on pharmaceutical issues to consumer groups and the media on the other.

- Change is unlikely to be a once-and-for-all action but is rather an iterative process. Successful reform programmes take this into account; they allow for trial periods, periodic evaluation of reforms and flexibility to adjust the reform path.

- Policy-makers should not lose sight of the ultimate objectives (efficiency, equity, drug safety, rational drug use) in reforming public-private roles. To this end national drug policies provide an overarching and guiding framework.

9. Managing public-private roles

The most appropriate mix of public and private roles in the pharmaceutical sector will depend ultimately on the specific circumstances, preferences and political choices of individual countries. Policy-makers must draw on concepts and experiences from elsewhere, in addition to analysing their own situation in order to develop a strategy.

9.1 Developing a strategy

In each country some mix of public-private activity in the pharmaceutical sector already exists. Public-private roles in the health sector often evolve without guiding policies or strategies. Increased focus on these roles gives countries an opportunity systematically to assess the strengths and constraints of each.

Several considerations are important in developing a strategy for public-private collaboration in the pharmaceutical sector:

- **Analysis of the national development environment:** Within the context of overall social, economic, development and industrial policy, what is the government's stance on the relative roles of the public and private sectors? What has been the experience of the health and other social sectors with the mix of private and public provision and financing?

- **Pharmaceutical sector analysis:** What is the current status of the public pharmaceutical sector with respect to financing, human resources, physical infrastructure, management systems and overall performance? What is the current status of the private sector with respect to these same elements?

- **Comparative advantages of public and private pharmaceutical sectors:** Given the current level of development and performance in the public and private sectors, what are the comparative advantages of each sector? How well is each meeting the objectives of equitable access, efficiency and rational use? Are there likely to be clear-cut benefits in changing the current situation?

- **Phasing of change in the pharmaceutical sector:** If careful analysis suggests a need for change, phased implementation of change may lead to a smoother transition and more lasting benefits.

Section 1 of this document outlined a set of four overarching principles. Changes in public-private roles in the pharmaceutical sector need to be appraised against these principles. The core questions which need to be asked are:

- Is equitable access being favourably or adversely affected?
- Will the organizational changes, and changes in regulations and incentives, bring about greater efficiency in the use of resources for drugs?
- Is more rational use of drugs likely to result?
- Will standards of quality in both public and private sectors be maintained or improved?

Neither purely private nor purely public pharmaceutical systems are likely to be appropriate. The most appropriate solution will most probably lie in between. This means that an incremental approach can often be adopted: publicly-owned drug manufacturers can be put under private management prior to any move to privatize ownership; a poorly functioning CMS may benefit from an improved management structure or greater autonomy prior to considering making contracts with the private sector. Box 16 describes how Tunisia has endeavoured to find an appropriate public-private mix for the pharmaceutical sector .

Box 16. An appropriate public-private mix for the pharmaceutical sector in Tunisia [36]

The context

Tunisia has a population of 8.8 million with a GDP per capita in 1995 of US$ 1768. Health indicators are good. In 1993 the child mortality rate was 30 per 1000 births. Health care spending has increased significantly since 1980, with spending rising faster in the private sector than in the public sector. There has also been an increase in pharmaceutical spending, but pharmaceutical expenditure as a percentage of health care expenditure has significantly decreased over the same period.

Outside the health sector, government policy has been to disengage from all non-strategic economic activities in Tunisia [36].

Public-private roles

Importation. The state has held a drug importation monopoly since the 1960s and there is no intention to modify this system. The centralized purchasing of medicines is seen to have substantial advantages in efficiency, cost and planning.

Production. The private sector plays a major role in production, accounting for 65% of all production in 1994. Six new privately owned companies have been created and the country has 17 production units.

Distribution. Public and private distribution systems coexist in Tunisia. The distribution of pharmaceuticals to public hospitals and dispensaries is the responsibility of a state-owned organization. Distribution to private retail dispensaries is handled by 45 wholesalers, three of which are publicly controlled. The publicly controlled wholesalers achieve a 10% market share and are used to check the availability of drugs on the market. There are 1267 private dispensaries.

Regulation. The state is responsible for registration and for the regulation of the quality of pharmaceutical products. The government is also involved in setting the prices of medicines so as to ensure affordability. This is done through the collaboration of the Ministries of Public Commerce and

Public Health.

Rationales

The state plays an active role in most parts of the pharmaceutical sector in Tunisia. It does so in order to compensate for market failures, to guarantee access to medicines, to guarantee the quality of medicines, to promote the rational use of drugs and to ensure that high ethical standards are present in drug promotion.

It is recognized that the pharmaceutical sector is different from other industrial sectors which are being privatized in Tunisia and therefore requires different treatment.

Discussion of public-private roles has highlighted the substantial contribution made by the private pharmaceutical sector. Because of market failure, a large unregulated private sector is likely to prove problematic. Governments need to have at least a basic regulatory capacity, including:

- legislation and regulations which have been formally reviewed and, where necessary, updated within the last 10 years;
- a functioning drug control authority with a core of qualified staff and an office;
- formal licensing procedures for distributors, manufacturers and individuals, and a functional licensing system with information on all licensed persons and organizations;
- regular inspection, according to agreed guidelines and procedures, of distribution and manufacturing premises.

This minimal regulatory capacity needs to be in place before countries implement policies expanding the role of the private sector. There are of course substantial further regulatory capacities which should be developed over time.

9.2 Monitoring and evaluation

Experiences with changing public-private roles in the social sector have clearly demonstrated that change is *not* always for the better. It is necessary, therefore, that national governments should regularly monitor and systematically evaluate the impact of both planned and unplanned changes. Monitoring and evaluation are necessary to determine whether objectives are being met. Monitoring is especially useful if changes are being made in phases and if there is an opportunity to hasten, delay, or modify implementation on the basis of experience.

Indicators for monitoring national drug policies have been developed by WHO [23]. These indicators include measures relating to background, structure, process and outcome in seven key areas: legislation and regulation, essential drugs selection and drug registration, public sector drug financing, public sector procurement procedures, public sector distribution and logistics, pricing policy, and information and continuing education on drug use.

Outcome indicators are especially important for assessing the impact of change. The WHO manual includes specific impact indicators on the availability and affordability of essential drugs, on quality and on the rational use of drugs.

The public-private mix in the pharmaceutical sector can be measured in terms of:

- overall drug expenditures;
- number of public and private importers, wholesalers and dispensing points; balance of the public and private sectors in drug production;
- sources of drugs consumed at the household level.

Gathering and reviewing information on these measures will provide a picture of how the pharmaceutical sector is evolving.

Evaluations assess the overall impact of policy reform. They may provide the impetus for further reform or for amendments to the initial reform.

One test of the overall effectiveness of the pharmaceutical sector is whether a person at any level of society who is sick and who needs a drug receives an adequate quantity of a therapeutic product for a cost that does not unduly burden the family, and uses the drug correctly. Assessments based on information gathered from national statistics, industry, government health facilities or private pharmacies provide no indication of who is not receiving adequate treatment and whose household is being disrupted by excessive health expenditures.

Household surveys, though costly and time-consuming, provide the best way to assess the ultimate impact of policies on households and individuals. These surveys provide an indication of where people are obtaining health care and drugs and, more importantly, whether significant numbers of people are failing to obtain needed care as a result of problems with affordability or availability.

Qualitative methods, particularly those used in rapid rural appraisal (focus groups, time lines, social mapping etc.), may provide useful information in a more economical way. The results of an assessment of evolving public-private roles in the pharmaceutical sector in Guinea are described in Box 17.

9.3 Unanswered questions

Gaps in our understanding of public and private roles in the pharmaceutical sector are evident. Governments, international agencies and academics must use existing data (where available) or special research efforts to address the following questions:

- **What are the implications of globalization for public and private roles in the pharmaceutical sector?** In particular, how will the GATT and TRIPs agreements affect access to drugs in developing countries and what will their health impact be?

- **How effective have attempts been to introduce market mechanisms into public drug supply systems?** Many such efforts have been made but no considered evaluation of experience has been undertaken to date.

- **What are the advantages and disadvantages of different regulatory strategies?** Regulatory objectives (improving availability, drug quality and rational drug use) may be pursued through a variety of strategies. Which strategies are better? How does this vary with the size and nature of the private sector and the capacity of government?

- **What mix of price competition and price control is best able to make drugs affordable and contain costs?** How do governments' regulatory and negotiating capacities affect the implementation of these different instruments? Although some evidence from industrialized countries is available on this topic, the situation and concerns in developing countries are rather different.

Box 17. Evaluating evolving public-private roles in Guinea

Until 1984 Guinea's pharmaceutical sector — like most other sectors — was characterized by a state monopoly. When the regime changed, the old structures broke down but there was nothing to replace them. There were virtually no drugs in the country. The Guinean government adopted a two-pronged approach:

- **A public primary health care programme** was established which involved the rehabilitation of infrastructure, community involvement, cost recovery, preventive programmes, essential drugs, rational drug use and staff training.
- **In the private sector,** government created substantial profit margins on drugs in order to encourage entrepreneurs to start private pharmacies.

Ten years later the changes are dramatic. Over 80% of subdistricts have functioning health centres. There is a large number of private pharmacies in urban areas, and drugs are available. A 1995 evaluation of the pharmaceutical sector highlighted some successes and continuing problems.

Indicator	Public sector	Private sector	Parallel market
Availability of drugs			
% of a selection of essential drugs available at remote health centres	93%	n/a	n/a
% of a selection of essential drugs available as generics in private pharmacies	n/a	33%	46%
Affordability of drugs			
Cost of treatment of pneumonia case as % of family food cost for 1 day	26%	166%	29%
% of drugs prescribed by generic name	91%	21%	37%
Quality of drugs			
% of drugs failing quality standards	23%	19%	24%
Rational drug use			
% of prescriptions with injections	20%	21%	34%
% of patients knowing dosage schedule of drugs received	86%	79%	30%

- Availability, affordability and rational drug use in the public sector are good.
- Availability and rational drug use in the private sector are good — but affordability is not.
- Due to the limited affordability and geographical inaccessibility of the private sector a large parallel drug market has emerged.
- Availability and affordability in the parallel drug market are good — but rational drug use is not.
- In all three subsectors the quality of drugs is poor.

Challenges ahead

The evaluation highlighted a number of key areas for improvement in the national drug policy. These included:

– encouraging and promoting generics in the private sector;
– strengthening the CMS so as to enable it to buy good quality drugs at competitive prices;
– improving coordination between government departments so as to have stricter control over the

importation and sale of drugs.

- **What strategies are appropriate for governments to deal with existing publicly-owned pharmaceutical manufacturing enterprises?** In particular, what has been the experience with the divestment of government-owned production plants and contracting-out of their management?

9.4 Conclusions

Considering the broader context

- **Macroeconomic and health sector reform set the context for changes in the pharmaceutical sector**. Pharmaceutical policy reform must be viewed in the broader context of socioeconomic change, changes in political ideology, health sector reform and trends towards globalization.

- **Governments must focus on public health goals.** Equity of access, rational drug use and drug quality are the ultimate goals. Altering the relative roles of the public and private sectors is solely a *means* to achieving these goals. Privatization is not a goal in itself.

- **Policies reforming public-private roles need to be rooted in an overall policy framework.** The national drug policy, based on the essential drugs concept, provides such a framework.

The pharmaceutical market is different from other markets

- **The pharmaceutical market requires separate analysis and different treatment from markets for most commodities**. Drugs are different from cabbages and candies. The pharmaceutical market is a far more complex and critical market than markets for most other commodities.

- **Unregulated pharmaceutical markets will not promote efficiency in health care**. Competition, flexibility and the profit motive may make the private sector efficient in a narrow technical sense. But the essential drugs concept and focus on cost-effective treatment may result in greater therapeutic efficiency in the public sector (greater health outputs for a given cost).

- **Unregulated pharmaceutical markets will create inequitable access to drugs.** Equity of access means that essential drugs are affordable and available to the entire population. In a free market access will be based on people's ability and willingness to pay for drugs, not on their need for drugs. Low-income populations, people in remote areas and those requiring certain categories of drugs (e.g. "orphan drugs" and high-cost drugs) will be denied access.

- **Regulating pharmaceutical markets is a highly complex and difficult task**. The problems associated with pharmaceutical markets cannot easily be vanquished by regulation. Even highly sophisticated governments with substantial capacity struggle to regulate effectively. In many instances direct government provision of drugs may be an easier task than regulating a private market.

Cornerstones of a government strategy

- **The state has fundamental responsibilities** to ensure equity of access to drugs, rational drug use and drug quality. In order to assure these the state is likely to be involved in:
  - financing of drugs (particularly for low-income and vulnerable groups, and for drugs and vaccines for communicable diseases);
  - organization and provision of services;
  - regulation of both public and private sectors.

- **Affordability is a major concern in the private for-profit sector**. A high percentage of consumers cannot afford to purchase a therapeutic quantity of drugs when needed. The state must find mechanisms to ensure that essential drugs are affordable. Such mechanisms may try to:
  - influence the price of drugs in the market;
  - establish equitable health financing mechanisms.

- **Greater private involvement does not mean less public involvement**. An increasing role for the private sector means a *different* role for the public sector, *not a decreased* role.

- **Increasing resources for regulation** — especially for registration, licensing, inspection, quality assurance, enforcement and information provision — should be a high priority for most governments. This is particularly so if there is increasing reliance on private pharmaceutical supply.

- **The integration of market mechanisms in the public sector needs to be approached with caution.** While on *a priori* grounds there are good reasons to believe that such mechanisms may reap benefits, there is no empirical evidence to support this. Lack of capacity in both public and private sectors may prevent the successful use of such mechanisms.

- **The establishment of new state-owned and state-managed production facilities has little to recommend it** — and much against it.

- **The private sector is heterogeneous**. Government policies need to distinguish between different actors within the private sector. In particular the potentially key role played by the "third sector" or NGOs should be defined and explored in greater detail.

It is not the purpose of this document to recommend a specific public-private mix for the pharmaceutical sector. As has been seen, the balance of public-private involvement varies widely and a particular combination of roles may function well in one situation or culture, yet may fail to ensure satisfactory accessibility and rational drug use in another. Rather, the purpose has been to stress the importance of flexibility in reviewing the balance of public-private roles and the importance of being forewarned when considering economic, social

or development policies that may affect that balance. The complex issue of public-private roles in the pharmaceutical sector has certainly not been settled. It will continue to be a focus of concern for governments since it involves a great many aspects of society, a great deal of money and, most importantly, the maintenance of health standards for a great many people.

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References

1. Abosede OA. Self-medication: an important aspect of primary health care. *Soc. Sci. Med.* 1984; 19: 699-703.

2. Adam C, Cavendish W, Mistry PS. *Adjusting privatization: case studies from developing countries.* London: James Currey; 1992.

3. Andajaningsih. *Quality, safety and efficacy (QSE) of medicines. Indonesia country report.* Sydney: International Conference on National Medicinal Drug Policies; 1995.

4. Anderson L, Higby G J. *The spirit of voluntarism. The United States Pharmacopeia, 1820-1995.* Rockville, USA: The United States Pharmacopeial Convention, Inc. (USPC); 1995.

5. Antezana F, Velasquez G. *Drugs and health sector reform. WHO Task Force on Health Economics.* Geneva: World Health Organization; 1996. WH0/TFHE/96.2.

6. Arrow KJ. Uncertainty and the welfare economics of medical care. *American Economic Review.* 1963; 53(5): 941-973.

7. Asiimwe D, McPake B, Mwesigye F, Streefland P. The private behaviour of public health workers: the case of Uganda. *In: Private health care providers in developing countries: serving the public interest?* Bennett S, McPake B, Mills A. London: Zed Press; 1997.

8. Balasubramaniam K. *Strategies to ensure availability & affordability of safe and effective drugs of good quality in the Asia-Pacific Region. Conference presentation.* Sydney: International Conference on National Medicinal Drug Policies; 1995.

9. Ballance R, Pogány J, Forstner H. *The world's pharmaceutical industries. An international perspective on innovation, competition and policy. Prepared for United Nations Industrial Development Organization.* Aldershot: Edward Elgar Publishing Limited; 1992.

10. Bartholet J. *The case of the killer aspirin.* Newsweek; 1990.

11. Bennett S, Dakpallah G, Garner P, Gilson L, Nittayaramphong S, Zurita B. Carrot and stick: state mechanisms to influence private provider behaviour. *Health Policy Plan.* 1994; 9 (1): 1-13.

12. Bennett S. *The mystique of markets: public and private health care in developing countries.* London: London School of Hygiene & Tropical Medicine; 1991. PHP Departmental Publication, N° 4.

13. Bennett S, Ngalande-Banda E. *Public and private roles in health: a review and analysis of experience in sub-Saharan Africa.* Geneva: World Health Organization; 1994.

14. Berman P, Hanson K. *Assessing the private sector: using non-government resources to strengthen public health goals. Data for decision-making project.* Boston, MA: Harvard University; 1994.

15. Berman P, Nwuke K, Hanson K, Kariuki M, Mbugua K, Ngugi J, et al. *Kenya: non-governmental health care provision.* Boston: DDM project, Harvard School of Public Health; 1995.

16. Berman P, Nwuke K, Rannan-Eliya R, Mwanza A. *Zambia: non-governmental health care provision.* Boston: DDM Project, Harvard School of Public Health; 1995.

17. Bevan G. *Equity in the use of health care resources. Current concerns. SHS paper N°3.* Geneva: World Health Organization; 1991. WHO/SHS/CC/91.1.

18. Bidwai P. One step forward, many steps back: dismemberment of India's National Drug Policy. *Dev Dialogue.* 1995; 1: 193-222.

19. Biersteker T, Adenika F, Brown GC. *Study of potential for private sector participation in drug supply.* Geneva: World Health Organization; 1987.

20. Blakney RB, Litvack JI, Quick JD. *Financing primary health care: experiences of pharmaceutical cost recovery.* Arlington, VA: PRITECH Project; 1989.

21. Bloom G, Lucas H, Cao S, Gao J, Yao J, Xing-yan G. *Financing health services in poor rural areas: adapting to economic and institutional reform in China.* Brighton: Institute for Development Studies; 1995.

22. Braveman P. *Equity in health and health care: a WHO/SIDA initiative.* Geneva: World Health Organization; 1996.

23. Brudon-Jakobowicz P, Rainhorn J, Reich MR. *Indicators for monitoring national drug policies.* Geneva: World Health Organization; 1994. WHO/DAP/94.12.

24. Bryant JH. Equity, solidarity and sustainability - critical underpinnings for the future Health-For-All strategy. Interregional meeting on Health-For-All renewal, Geneva, 26-30 August 1996. Unpublished.

25. Carrin G, Ron A, Wang SC, Xuesheng L, Jun Y, Hui Y, et al. *The reform of the rural cooperative medical system in the People's Republic of China: initial design and interim experience.* Geneva: World Health Organization; 1996.

26. Cassels A. *Health sector reform: key issues in less developed countries. Discussion paper N° 1.* Geneva: World Health Organization; 1995. WHO/SHS/NHP/95.7.

27. Cederlof C. *Health and profits - can they ever meet? Using private pharmacies to look at pharmacoeconomics.* Stockholm: Karolinska Institutet; 1993. IHCAR Report 2/93-94.

28. Collective work, Disponibilité des médicaments essentiels. *In: Le secteur pharmaceutique privé commercial en Afrique.* Kaddar M, Bruneton C. Paris: Ministère de la Coopération - Organisation mondiale de la Santé; 1996: 60-61.

29. Correa CM. *The Uruguay round and drugs. WHO Task Force on Health Economics.* Geneva: World Health Organization; 1995. WHO/TFHE/97.1.

30. Creese A L. *User charges for health care: a review of recent experience.* London: Oxford University Press; 1991.

31. Creese A L. Review article: User charges for health care: a review of recent experience. *Health Policy Plan.* 1991; 6 (4): 309-319.

32. Creese A L, Kutzin J. *Lessons from cost-recovery in health. Forum on health sector reform. Discussion paper N° 2.* Geneva: World Health Organization; 1995.

33. Csete J. Health-seeking behavior of Rwandan women. *Soc. Sci. Med.* 1993; 37: 1285-1292.

34. Culyer AJ, Maynard A, Posnett J. Reforming health care: an introduction to the economic issues. *In: Competition in health care: reforming the NHS.* Culyer AJ, Maynard A, Posnett J. Basingstoke: Macmillan Press; 1990: 1-11.

35. Diarra K, Coulibaly S. Financing of recurrent health costs in Mali. *Health Policy.* 1990; 5(2): 126-138.

36. Donaldson D. *Privatization: principles and practice.* Washington, D C: International Finance Corporation; 1995.

37. Dua V, Kunin C M, Vanarsdale White L. The use of antimicrobial drugs in Nagpur, India. A window on medical care in a developing country. *Soc. Sci. Med.* 1994; 38: 717-724.

38. Dukes MNG, Change and growth in generic markets in developed and developing countries. *In: Seminar on medicines and the new economic environment (Madrid, 29-31 March 1995) organized by WHO Action Programme on Essential Drugs and the Universidad Carlos III de Madrid.* Madrid: Universidad Carlos III de Madrid; 1995: 1-19.

39. Ettling M, McFarland DA, Schultz LJ, Chitsulo L. Economic impact of malaria in Malawian households. *Trop. Med. Parasitol.* 1994; 45: 74-79.

40. Fefer E. Future challenges in regulatory control. Unpublished.

41. Galvez Tan J. *The Philippines national drug policy programme. Conference presentation, 8-11 October 1995.* Sydney: International Conference on National Medicinal Drug Policies; 1995.

42. GAO. *Prescription drugs: companies typically charge more in the United States than in the United Kingdom. Report to the Chairman, Subcommittee on Health and the Environment, Committee on Energy and Commerce, House of Representatives. GAO/HEHS-94-29.* Washington, D C: General Accounting Office; 1994.

43. GAO. *Prescription drugs: spending controls in four European countries. Report to the Chairman, Special Committee on Aging, U.S. Senate. GAO/HEHS-94-30.* Washington, D C: General Accounting Office; 1994.

44. Gilson L, Dave Sen P, Mohammed S, Mujinja P. The potential of health sector non-governmental organizations: policy options. *Health Policy Plan.* 1994; 9 (1): 14-24.

45. Gilson L. *Government health care charges: is equity being abandoned? Evaluation and Planning Centre discussion paper, N° 15.* London: University of London School of Hygiene & Tropical Medicine; 1988.

46. Gothoskar SS. Drug control: India. *World Development.* 1983; 11(3): 223-228.

47. Grabowski H, Mullins D. Pharmacy benefit management, cost-effectiveness analysis and drug formulary decisions. *Soc. Sci. Med.* 1997; 4: 535-544.

48. Greenhalgh T. Drug prescription and self-medication in India: an exploratory survey. *Soc. Sci. Med.* 1987; 25: 307-318.

49. Griffin CC. *Strengthening health services in developing countries through the private sector.* Washington, D C: World Bank; 1989. IFC discussion paper N°4.

50. Grupper M. Drug cost containment policies: a new challenge for the future. Unpublished.

51. Haaijer-Ruskamp FM, Dukes MNG. *Drugs and money. The problem of cost containment. 6th edition.* Groningen: WHO Collaborating Centre for Clinical Pharmacology and Drug Policy Science and Pharmaceuticals Unit, World Health Organization, Regional Office for Europe. STYX Publications; 1991.

52. Haak H, Hardon AP. Indigenised pharmaceuticals in developing countries: widely used, widely neglected. *Lancet.* 1988; 2: 620-621.

53. Hardon A, van der Geest S. Hazards of self-medication. *World Health Forum.* 1987; 8: 469-471.

54. Hogerzeil HV. Promoting rational prescribing: an international perspective. *Br J. Clin. Pharmac.* 1995; 39: 1-6.

55. Igun UA. Why we seek treatment here: retail pharmacy and clinical practice in Maiduguri, Nigeria. *Soc. Sci. Med.* 1987; 24: 689-695.

56. ITC. *Pharmaceutical raw materials/essential drugs report. Market News Service.* Geneva: International Trade Centre UNCTAD / GATT; 1995.

57. Jayasuriya DC. *Regulation of pharmaceutical in developing countries: legal issues and approaches.* Geneva: World Health Organization; 1985.

58. Kafle KK, Gartoulla RP, Pradhan YM, Shrestha AD, Karkee SB, Quick JD. Drug retailer training: experiences from Nepal. *Soc. Sci. Med.* 1992; 35(8): 1015-1025.

59. Kamat VR, Nichter M. Monitoring product movement: an ethnographic study of pharmaceutical sales representatives in Bombay, India. *In: Private health providers in developing countries: serving the public interest?* Bennett S, McPake B, Mills A. London: Zed Press; 1997:

60. Kapil I. Doctors dispensing medications: contemporary India and 19th century England. *Soc. Sci. Med.* 1988; 26: 691-699.

61. Katz J, (2.1) The drug industry of Argentina, Brazil, and Mexico after trade liberalization and market de-regulation. *In: Report of an informal consultation on evolving public-private roles in the pharmaceutical sector.* Geneva: World Health Organization; 1997: WHO / DAP / 97.10.

62. Kinnon CM. *WTO: what's in it for WHO?* Geneva: World Health Organization; 1995. WHO/TFHE//95.5.

63. Kunin CM. Use of antimicrobial drugs in developing countries. *International Journal of Antimicrobial Agents.* 1995; 5: 107-113.

64. Kutzin J. *Experience with organizational and financing reform of the health sector. Current Concerns SHS Paper, N°. 8.* Geneva: World Health Organization; 1994. WHO/SHS/CC/94.3.

65. Kutzin J, Barnum H. *How health insurance affects the delivery of health care in developing countries.* Washington, D C: World Bank; 1992: 1-20.

66. Lansang MA, Lucas Aquino R, Tupasi TE, Mina VS, Salazar LS, Juban N, et al. Purchase of antibiotics without prescription in Manila, the Philippines. Inappropriate choices and doses. *J Clin Epidemiol.* 1990; 43: 61-67.

67. Liu Y, Hsiao WCL, Li Q, Liu X, Ren M. Transformation of China's rural health care financing. *Soc. Sci. Med.* 1995; 41(8): 1085-1093.

68. McPake B, Hanson K, Mills A. Community financing of health care in Africa: an evaluation of the Bamako initiative. *Soc. Sci. Med.* 1993; 36 (11): 1383-1395.

69. McPake B, Ngalande-Bande E. Contracting out health services in developing countries. *Health Policy Plan.* 1994; 9 (1): 25-30.

70. MEDS. *Report of the MEDS operations & proposal for 36 months extension of funding.* Nairobi: Mission for Essential Drugs and Supplies, Kenya; 1990.

71. MEDS. *Report of an annual conference.* Nairobi: Mission for Essential Drugs and Supplies, Kenya; 1993.

72. Mills A, Chapter 4. Economic aspects of health insurance. *In: The economics of health in developing countries.* Lee K, Mills A. Oxford: Oxford University Press; 1985: 65-87.

73. Mills A. The household costs of malaria in Nepal. *Trop. Med. Parasitol.* 1993; 44: 9-13.

74. Mills A, Contractual relationships between government and the commercial private sector in developing countries: are they a good idea in health? *In: Private health providers in developing countries: serving the public interest?* Bennett S, McPake B, Mills A. London: Zed Press; 1997.

75. Ministry of Health. *Guidelines for expenditure under health care services fund. Circular Ref. B/13/1/18C/(92), 17 December, 1992.* Nairobi: Ministry of Health; 1992.

76. Mintzes B, Hodgkin C. Chapter 5. The consumer movement: from single-issue campaigns to long-term reform. *In: Contested ground: Public purpose and private interest in the regulation of prescription drugs.* Davis P. Oxford: Oxford University Press; 1996: 76-91.

77. Mooney G. Equity in health care: confronting the confusion. *Effective Health Care.* 1983; 1: 179-184.

78. Morton-Jones TJ, Pringle MA. Prescribing costs in dispensing practices. *BMJ.* 1993; 306: 1244-1246.

79. Mossialos E, Ranos C, Abel-Smith B. *Cost containment, pricing and financing of pharmaceuticals in the European Community: the policy-makers' view.* Athens, Greece: LSE Health and Pharmetrica S A; 1994.

80. MSH. *International drug price indicator guide (updated annually).* Washington, D C: Management Sciences for Health; 1995.

81. MSH / WHO / DAP. *Managing drug supply, 2nd edition.* Hartford, CT: Kumarian Press; 1997. Management Sciences for Health in collaboration with World Health Organization, Action Programme on Essential Drugs. Edited by Quick JD, Rankin J, Laing RO, O'Connor R, Hogerzeil HV, Dukes MNG, and Garnet A.

82. Murray CJL, Govindaraj R, Musgrove P. National health expenditures: a global analysis. *In: Global comparative assessments in the health sector: Disease burden, expenditures and intervention packages.* Murray C, Lopez A. Geneva: World Health Organization; 1994.

83. Murray M. Australian national drug policies: facilitating or fragmenting health? *Dev Dialogue.* 1995; 1: 148-192.

84. Muschell J. *Technical briefing note on privatization in health.* Geneva: World Health Organization; 1995. WHO / TFHE / TBN / 95.1.

85. Musgrove P. *Public and private roles in health: theory and financing patterns.* Washington, D C: World Bank; 1996.

86. Mwenesi H, Harpham T, Snow RW. Child malaria treatment practices among mothers in Kenya. *Soc. Sci. Med.* 1995; 40: 1271-1277.

87. Nolan B, Turbat V. *Cost recovery in public health services in Sub-Saharan Africa. EDI Technical Materials.* Washington, D C: World Bank; 1995.

88. Normand C, Weber A. *Social health insurance: a guidebook for planning.* Geneva: World Health Organization; 1994. WHO/SHS/94.3.

89. OECD. *Financing and delivering health care: a comparative analysis of OECD countries.* Paris: Organization for Economic Cooperation and Development; 1990.

90. OECD. *The reform of health care systems: a review of seventeen OECD countries.* Paris: Organisation for Economic Cooperation and Development; 1994. Health policy studies, N° 5.

91. OECD. *Internal markets in the making: health systems in Canada, Iceland, and the United Kingdom.* Paris: Organisation for Economic Cooperation and Development; 1995.

92. Osborne T, Gaebler H. *Reinventing government. How the entrepreneurial spirit is transforming the public sector.* New York: Addison-Wesley; 1992.

93. Oshiname FO, Brieger W. Primary care training for patent medicine vendord in rural Nigeria. *Soc. Sci. Med.* 1992; N° 35: 1477-1484.

94. PAHO. *Health conditions in the Americas. 1994 edition. Volume 1.* Washington, D C: World Health Organization/Pan American Health Organization; 1994. Scientific publication N° 549.

95. Paul S. *Capacity-building for health sector reform. Forum on Health Sector Reform discussion paper, N° 5.* Geneva: World Health Organization; 1995. WHO/SHS/NHP/95.8.

96. Quick JD. *Report of a consultation on ORS supply and distribution in Nigeria*. Boston: Management Sciences for Health; 1985.

97. Quick JD, Musau SN. *Impact of cost-sharing in Kenya: 1989-1993*. Nairobi: Management Sciences for Health; 1994.

98. Reich MR. *Political mapping of health policy: a guide for managing the political dimensions of health policy*. Boston: DDM Project, Harvard School of Public Health; 1994.

99. Reich MR. The politics of health sector reform in developing countries: three cases of pharmaceutical policy. *Health Policy*. 1995; 32: 47-77.

100. Robinson R, Le Grand J. *Evaluating the NHS reforms.* London: King's Fund Institute; 1993.

101. Ron A, Abel-Smith B, Tamburi G. *Health insurance in developing countries. A social security approach.* Geneva: International Labour Office; 1990.

102. Ross-Degnan D, Soumerai S, Bates J, Goel P, Makhulo J, Sutoto. *Improving diarrhoea treatment practices in Kenya and Indonesia. Conference presentation, 31 October-4 November 1993.* Yogyakarta: Asian Conference on Clinical Pharmacology and Therapeutics; 1993.

103. Saltman R. *Applying planned market logic to developing countries' health systems: an initial exploration. Forum on Health Sector Reform Discussion Paper N° 4.* Geneva: World Health Organization; 1995. WHO/SHS/NHP/95.7.

104. Sauerborn R, Ibrango I, Nougtara A, Borchert M, Hien M, Benzler J, et al. The economic costs of illness for rural households in Burkina Faso. *Trop. Med. Parasitol.* 1995; 46: 54-60.

105. Saxenian H. *Getting the most out of pharmaceutical expenditures.* Washington, D C: World Bank; 1994.

106. Shaw RP, Griffin CC. *Financing health care in sub-Saharan Africa through user fees and insurance.* Washington, D C: World Bank; 1995.

107. Sheng-Lan T, Bloom G, Xue-Shan F, Lucas H, Xing-Yuan G, Segall M. *Financing health services in China: adapting to economic reform.* Brighton: Institute of Development Studies; 1994.

108. Sringernyuang L, Hongvivatana T, Pradabmuk P. *Community health workers and drugs: a case study of Thailand.* Geneva: World Health Organization; 1994. WHO/DAP/94.19.

109. Stobbelaar F, Chapter 2. (2.1). *In: Report of an informal consultation on evolving public-private roles in the pharmaceutical sector, April 1996.* Geneva: World Health Organization; 1997: WHO/DAP/97.10.

110. Stobbelaar F. *Ensuring value for money from pharmaceuticals. WHO European Health Care Reforms, Lubljana Conference Paper, November 1995.* Copenhagen: Deloitte & Touche Management Consultants; 1995.

111. Trap B. *Practices by dispensing doctors related to rational drug use and health economics.* Presented at: International Conference on Improving Use of Medicines: State of the Art and Future Directions, Chiang Mai: Thailand 1997.

112. Tudor Silva K, Amarasiri de Silva MW, Wijekoon Banda TM. Chapter 12. Access to Western drugs, medical pluralism, and choice of therapy in an urban low income community in Sri Lanka. *In: Medicines: meanings and contexts.* Etkin NL, Tan ML. Quezon City, Philippines: Health Action Information Network; 1994: 185-208.

113. Van der Geest S, Whyte SR. *The context of medicines in developing countries. Studies in pharmaceutical anthropology*. Dordrecht/Boston/London: Kluwer Academic Publishers; 1988.

114. Wagstaff A, Van Doorslaer E. Chapter 2. Equity in finance and delivery of health: concepts and definitions. *In: Equity in the finance and delivery of health care: an international perspective.* Van Doorslaer E, Wagstaff A, Rutten F. Oxford: Oxford University Press; 1993: 7-19.

115. Walsh K. *Public services and market mechanisms. Competition, contracting and the new public management.* Basingstoke: Macmillan; 1996.

116. Walt G, Gilson L. Reforming the health sector in developing countries: the central role of policy analysis. *Health Policy Plan.* 1994; 9(4): 353-370.

117. Weerasuriya K. A search for balance: pharmaceuticals in Sri Lanka. Pioneering steps in a receptive environment and subsequent accommodations. *Dev Dialogue.* 1995; 1: 54-95.

118. WHO. *Guidelines for developing national drug policies.* Geneva: World Health Organization; 1988.

119. WHO. *Review of the drug programme in Indonesia: report of a WHO mission, 16 October-3 November 1989.* Geneva: World Health Organization; 1989. DAP/90.11.

120. WHO. *The public/private mix in national health systems and the role of ministries of health.* Geneva: World Health Organization; 1991. WHO/SHS/NHP/91.2.

121. WHO. *Guide for improving diarrhoea treatment practices of pharmacists and licensed drug sellers.* Geneva: World Health Organization; 1993. WHO/CDD/93.43.

122. WHO. *In: Evaluation of recent changes in the financing of health services: Report of a WHO study group*. Geneva: World Health Organization; 1993: 1-74. WHO Technical Report Series, N° 829.

123. WHO. *Public/private collaboration for health. National health systems and policies.* Geneva: World Health Organization; 1994. WHO/SHS/NDP/94.2.

124. WHO. *The developing role of the private health sector in health care and provision of drugs.* Geneva: World Health Organization; 1994. DAP/MAC(6)94.8.

125. WHO. *Improving complementarity of public/private mix in health and human resources. Report of a consultation, Bangkok, 27 June-1 July 1994.* New Delhi: World Health Organization; 1994. SEARO / SEA / HMD / 205.

126. WHO. *The treatment of malaria: information for non-pharmacists selling antimalarial drugs.* Leverkusen: Bayer A. G. 1995.

127. WHO. *DAP documents and interviews with WHO staff members.* 1995.

128. WHO. *Theme paper for discussion: health reform and drug financing: overview of experiences, options and priorities for action.* Geneva: World Health Organization; 1997. DAP / MAC(9)97.7.

129. WHO / DAP. Public education in drug use: a growing need. *Essential Drugs Monitor.* 1994; 18: 1-24.

130. WHO / DAP. Informed therapy. *Essential Drugs Monitor.* 1995; 19: 1-28.

131. WHO / DAP. *Global comparative pharmaceutical expenditures. Health economics and drugs.* Geneva: World Health Organization; 1997. (DAP Series N° 3, in preparation).

132. WHO / DAP. *Competitive mechanisms for public drug supply: options, issues, and cautions (working draft).* Geneva: World Health Organization; 1997.

133. WHO / EURO, Chapter 5. Allocating resources efficiently. *In: European health care reforms: Analysis of current strategies.* Copenhagen: World Health Organization; 1996: 131-188. EUR / ICP / CARE 94 01 / CN01.

134. WHO / SEARO. *Privatization of health care: A SEARO kit.* New Delhi: WHO Regional Office for South-East Asia; 1995.

135. World Bank. *Financing the health sector: an agenda for reform.* Washington, D C: World Bank; 1987.

136. World Bank. *World development report 1993. Investing in health.* New York, NY: Oxford University Press; 1993.

137. World Bank. *Better health in Africa. Experience and lessons learned.* Washington, D C: World Bank; 1994. Report N° 12577-AFR.

138. World Bank. *China: issues and options in health financing.* Washington, D C: World Bank; 1996.

139. World Bank. *World Development Report 1996. From plan to market.* Oxford: Oxford University Press; 1996.

140. Zerda Sarmiento A. *Alternativas de políticas de precios de medicamentos in las Americas: Serie "Economía de la Salud y Medicamentos", N° 1.* Geneva: World Health Organization; 1995. WHO / DAP / 95.6.

Glossary

Term	Meaning	Source
Community financing	Direct financing or co-financing of health care by households in villages or communities, either by payment on receipt of care or by prepayment.	Health Economics: glossary (TFHE/glos./1995)
Competitive market	A market in which no buyer or seller has market power. See "market power".	Schiller, B.R. The Economy Today, Sixth Edition. New York: McGraw-Hill, Inc. 1994
Contracting-out	The practice of the public sector or private firms of employing and financing an outside agent to perform some specific task rather than managing it themselves.	Health Economics: glossary (TFHE/glos./1995)
Cost recovery	Receipt, by a health provider, of income from individuals or the community in exchange for health services. It may be expressed as a percentage of expenditure.	Health Economics: glossary (TFHE/glos./1995)
Drug registration	The procedure of release of a drug for marketing after it has been evaluated by the competent health authorities.	International Federation of Pharmaceutical Manufacturers Associations (IFPMA). Document IFPMA/75
Generic drug	Product marketed under a nonproprietary or approved name rather than a proprietary or brand name. See pioneer drug.	Executive Board, Seventy-third session, Geneva, 11-20 January 1984, (EB73/1984/REC/1 Annex 7, p.60)
Generic substitution	The practice of substituting a product, whether marketed under a trade name or generic name, by an equivalent product, usually a cheaper one, containing the same active principle(s).	Executive Board, Seventy-third session, Geneva, 11-20 January 1984, (EB73/1984/REC/1 Annex 7, p.60)
Gross domestic product (GDP)	The market value of the total final output of goods and services produced in a country over a specified period of time.	Health Economics: glossary (TFHE/glos./1995)
Health financing	Provision of funds or credit for a specified purpose in the health sector. The origin of financing may be external (from abroad) or domestic (private or public).	Health Economics: glossary (TFHE/glos./1995)
Health insurance	A contract between the insured and the insurer to the effect that in the event of specified events (determined in the insurance contract) occurring the insurer will pay compensation either to the insured person or to the health service provider.	Health Economics: glossary (TFHE/glos./1995)
Internal market	Policies which encourage competition or market-like behaviour within the public sector. Examples of internal market policies include performance-related payment mechanisms (e.g. capitation), or policies designed to encourage patient choice of provider. Also called "public market".	Technical briefing note on privatization in health. WHO Task Force on Health Economics, 1995.

Term	Meaning	Source
Managed competition	In the context of health care provision, a concept whereby the market is structured so that the pursuit by consumers of their own best interests has a beneficial effect on the market as a whole, and competition between providers promotes *efficiency* while maintaining *equity*. This market structure can be established by large group purchasers of care, including public programmes and employers.	Health Economics: glossary (TFHE/glos./1995)
Market economy	An economy that relies on market mechanisms (price and sales to signal desired outputs or resource allocations) for basic decisions about WHAT to produce, HOW to produce it, and FOR WHOM to produce.	Schiller, B.R. The Economy Today, Sixth Edition. New York: McGraw-Hill, Inc. 1994
Market failure	An imperfection in the market mechanism that prevents optimal outcomes.	Schiller, B.R. The Economy Today, Sixth Edition. New York: McGraw-Hill, Inc. 1994
Market power	The ability to alter the market price of a product (or service).	Schiller, B.R. The Economy Today, Sixth Edition. New York: McGraw-Hill, Inc. 1994
Parallel importing	Parallel importing is an international wholesale trade in medicines which profits from the existing price divergence. It is the import and distribution from low-price states to high-price states of licensed branded medicines by an organization other than the manufacturer. This practice bypasses the official routes and marketing organizations through which prices are controlled.	Chambers, G., Belcher, P.J., The Consumption of Medicines in the European Union, 1994
Passive privatization	The private sector grows on its own accord, without any related changes in government policy. See privatization.	Technical briefing note on privatization in health. WHO Task Force on Health Economics, 1995
Private sector	That part of the economy in which economic activity is carried out by private enterprise.	Health Economics: glossary (TFHE/glos./1995)
Privatization	Transfer of ownership, in which the state divests itself of public assets to private owners. The primary objective of divestiture is to reduce the scale of government commitments. The term privatization is often applied less accurately to other policies in which non-government actors become increasingly involved in the financing and/or provision of health care services.	Technical briefing note on privatization in health. WHO Task Force on Health Economics, 1995.
Public sector	That part of the economy of a country that comes within the scope of central government, local government authorities and public corporations.	Health Economics: glossary (TFHE/glos./1995)
Quality control	All measures designed to ensure the output of uniform batches of drugs that conform to established specifications of identity, strength, purity, and other characteristics.	WHO. Technical Report Series, No. 567, 1975, p.17

Term	Meaning	Source
Therapeutic equivalence	Pharmaceutical products which, when administered to the same individuals in the same regimen, have essentially the same efficacy and/or toxicity.	WHO. Technical Report Series, No. 722, 1985, p.50
Transfer price	The often artificial price that a daughter company pays to purchase products or materials from a parent or related company abroad. In some cases it is found that well over 50% of the manufacturer's selling price is represented by transfer prices paid to a foreign parent company or manufacturer.	Chambers, G., Belcher, P.J., The Consumption of Medicines in the European Union, 1994
User charges	Also, fees. Charges to be paid by the users of a service.	Health Economics: glossary (TFHE/glos./1995)

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