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The Developing Role of the Private Sector in Health Care and Provision of Drugs

Action Programme on Essential Drugs

World Health Organization
Geneva

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Explanatory Note

Several topics were proposed to the Management Advisory Committee (MAC) in 1993 as themes for detailed discussions in future MAC meetings. The developing role of the private sector in health care - often referred to as privatization - was considered to be a timely theme, with particular emphasis on drug supply systems. The aim of the discussions would be to explore the theme of privatization from the point of view of the role and the responsibility of the public sector.

It was remarked in the proposal that privatization is not only changing behaviour but also allocation of resources. There is the added risk that the public sector, as represented by ministries of health, may waive certain responsibilities in the process of privatization perhaps due, in part, to weak institutional capacity and lack of management skills to monitor the private sector. However, the public sector has a continuing, very strong, role to play in setting norms and functions and in establishing guidelines.

It was decided to adopt for detailed discussion during MAC(6) in March 1994 the theme of the role of the private sector, including implications for financing and coordinating of activities. In reviewing the roles of the state, the linkages between national drug policies and health policies and strategies should be examined.

Executive Summary

As privatization policies are implemented in the health sector in developing countries, increasing concern has been expressed by public health specialists and government administrations on the potential consequences from greater involvement of the private sector in provision of drugs. These could include economic and geographical inequities, higher drug costs and inadequate attention to regulatory control and quality assurance.

The document focuses on two regions of the developing world: Sub-Saharan Africa and Latin America. They were selected because the realities of these two regions, where large proportions of the population live in poverty, are reasonable sub-samples of evolutionary processes taking place.

In an attempt to present a comprehensive conceptual framework, the two systems - health care and provision of drugs - are looked at from the viewpoint of their inter-relationships. The role of the prescriber, as an agent for the patient/consumer, is considered as a major link between the two systems.

Objectives of equity, cost containment, economic behaviour of prescribers and quality assurance of pharmaceuticals are considered as dependent on the characteristics of health care systems as on the specific characteristics of drug supply systems.

The significance of privatization is looked at from the perspective of the role of the state which may employ inappropriate incentives and controls in relation to private actors. Certain forms of direct public intervention may not only be a disincentive to private actors but may lead to inefficient and inequitable use of resources.

The experience of the two selected regions is reviewed, particularly in respect to the effects of revised policies under which states, with formerly centralized systems, may begin to waive obligation for some of their functions. The risks in a rapid abdication of certain roles by the governments in Africa and the weaknesses of the private actors assuming some of those functions are compared with the stronger emphasis on deregulation in Latin America and the strengths of private actors present there.

It can be argued that both empirical evidence as well as conceptual inference permit a conclusion that there is an important role to be played and, in fact, is already played by private actors in drug supply systems. They can contribute towards the goals of national drug policies (NDPs) of supporting equity, cost-containment and quality assurance.

It is argued that for the state to reap full benefit from the potential of private sector participation there is need for significant changes in public intervention, from direct execution to normative functions.

For the immediate future, the course of the public/private collaboration in the drug sector in developing countries looks uncertain and irregular.

A certain number of relevant questions should be addressed:

a) How can prescribers' actions serve as incentives for sound economic behaviour in both public and private institutions?

b) How best can the state enhance market mechanisms, such as competition, to help in cost/control?

c) Must certain public interventions for the attainment of health goals conflict with private initiatives/goals?

d) How should private beneficiaries return public investment?

e) How can the role of the consumer be progressively strengthened?

1. Introduction

1.1 Private intervention in provision of drugs in the public sector

The international debate in recent years on increased private participation in the health sector has focussed on issues of medical care delivery and finance as well as on new roles to be assumed by national government agencies. Concerns about equity in social policies has brought to the forefront the need for a systematic debate on the mix of public/private intervention in medical care and provision of drugs. An important reason for the debate is that the financial aspects of the drug sector provide telling evidence of how various health institutions spend budgets, control costs, and ensure equitable access.

Equitable access to basic drugs is one of the main components of the WHO strategy of Health For All. Further, the provision of essential drugs is one of the eight components of Primary Health Care (PHC). In the first instance in the early 1980s, the WHO Action Programme on Essential Drugs (DAP) was primarily concerned with the question of how to ensure availability of drugs for expanding health networks within limited budgets. By mid-decade the Programme's focus had evolved towards an emphasis on rational drug use and continued to evolve to meet the transformations wrought by changing social and economic environments in Member States.

Although in monetary terms, drugs may not represent the highest health expenditure (salaries often rank higher), supply of drugs is a critical and important component of the escalation in total health care costs, world-wide. Expenditure on drugs has become one of the preferential targets of cost-control measures in industrialised countries and in least developed countries the inefficient use - or misuse - of scarce foreign currency can bring public health networks to a virtual standstill.

The fact that many countries (including some industrialised ones) have adopted a national drug policy is recognition that there is a need for public intervention in the provision of pharmaceuticals. The state needs to assume responsibility, in particular for public health, and to ensure the safety, efficacy and quality of drugs.

Although economic theory does not demonstrate a "correct" mix of public and private sectors, the aim here is to help address the difficult question of what equilibrium between government intervention and private intervention can ensure the greatest equity of access to good quality drugs at the lowest cost.

Both sides have clear interests: private providers/manufacturers have been traditionally present and have a major function in research while the public sector cannot abdicate its regulatory role in an intricate market. The complexities are increased by the diversity of the actors in the medical care and drug supply systems (private for-profit, private non-profit, non-governmental organizations, private and public insurance organizations, professional associations, federal and state law-makers, etc.) and by the quite different country-specific practical experiences. Attempts to draw general conclusions can be misleading.

2. Conceptual approach

2.1 Greater privatization interactions between the health care and the drug supply systems

Privatization in social sectors is not easily described: the word can be used with different meanings or applied to specific aspects of a problem. The need for state intervention in the pharmaceuticals market can be summarised as follows:

a) private (for profit) providers: a profit-added price may act as a barrier to consumption by those most in need. As demand does not equate with need, the "market failure" may call for state intervention, to redress the market;

b) public intervention: attempts to correct inefficiencies in the systems; however, public interventions can also become inefficient and inequitable;

c) distinctive features of the pharmaceuticals market: technically complex supply systems, and interest groups able to press for higher prices.

The pharmaceutical supply system is a special type of market in which the trade requires an "intermediary-agent", i.e. the doctor/prescriber. Because of this, the operation of the drug supply system is inextricably linked to the functioning of the prescriber within the health care system.

An analysis is needed of the different interpretations of "privatization":

a) privatization in the provision of health care, implies a role in both "provision" and "financing". The simultaneous consideration of provision and financing is an important aspect that is sometimes forgotten, with unfortunate policy consequences. Recent moves towards privatization in medical care have sometimes resulted in increasing private expenditures and decreasing public expenditure;

b) privatization in medical care may have important effects on patterns of drug expenditure, use and accessibility. These consequences stem from the functioning of prescribers in different institutional and ownership settings;

c) privatization in the drug supply system, per se.

Lastly, when appraising privatization in an area of such public importance, there is also a reflection of the search for a changing role for the public sector.

In discussing appropriate public/private mixes in developing countries, the historical processes should be borne in mind by which many of the country-specific combinations have been shaped in industrialized countries. In Europe, various combinations of public and

private mixes in drug provision and financing have evolved through two centuries of adjustments between the interests of the public and private sectors.

The differences and disadvantages of developing countries undergoing a similar historical process must be taken into consideration. Sub-Saharan Africa, in particular, has had insufficient time to develop these adjustments. State intervention often has not enabled the poorest segments of populations to benefit from efforts to provide them with better health care services; it has been, in fact, the better-off members who have reaped the benefits.

By comparison with sub-Saharan Africa, most countries in Latin America demonstrate a more intricate historical process and social organization. This applies, as well, to the health care and drug supply systems. On average, Latin American countries have a higher health care coverage than in sub-Saharan Africa. This higher coverage is coupled with a more extensive and longer presence of private providers of modern medical care and supplies of pharmaceuticals. Their health care systems show a strong presence of health insurance, including some classic forms of publicly-organized health insurance such as labour union-based plans.

2.2 Use of drugs in various health care settings

The prescription of one or more drugs is the most frequent outcome of a visit to a medical practitioner. This reinforces the concept of the "agency relationship" between the often uninformed consumer and the prescriber/the decision-maker on behalf of the consumer. The consumption of drugs and their costs are thus often more dependent on the functioning of the prescriber than on the consumer.

This asymmetry between the actors in the "market" has led many authors to characterise the drug market as "imperfect" and justifying some form of state intervention.

Patterns of prescription depend on a number of factors such as the type of institution (public, private for-profit or non-profit) and the financial arrangements for payment or reimbursement. Different forms of misuse of drugs can be found at both extremes of institutional settings: hyper-prescription of drugs in liberal health care models, or spoilage of scarce drugs in inefficient public systems.

It is not surprising that almost every effort for cost containment in health care expenditure includes a strong element of control on expenditure on drugs. Health insurance institutions as well as governments have been trying various mechanisms ranging from macro-economic ones - setting limits on reimbursement practices or on profit margins - to micro-economic ones utilizing such processes as prescription review committees and institutional budgets.

Public health systems in many African countries maintain policies of subsidization that are mainly absorbed by the urban middle-class. Urban areas can absorb up to 70% of the national total drug budget, leaving very little for the larger rural populations. Compounding this unsatisfactory situation, ineffective and under-supplied public facilities may lead the urban poor to resort, for example, to unlicensed vendors of drugs of questionable quality.

2.3 Economic situations and drug financing

In developing countries the pharmaceutical market depends on several co-existing financial cycles. These, in turn, depend on economic development of the country/area, e.g. the level of financing of public health networks, which in many African countries are still the main provider of medical care; the overall state of the economy of the country, especially the capacity to produce/import pharmaceuticals and make them available in the internal market; and, the financial capacity of the individual consumers to pay for services either directly or through insurance or tax schemes.

The severe disadvantages of many African countries led to the launching of the Bamako Initiative which includes support for the first supplies of pharmaceuticals. The supply process continues through the revenues generated by local sales of drugs. Assessment of the experience has shown success in some countries in ameliorating drug supplies.

2.4 Public versus private in the drug supply system

Is there a role for private intervention in the drug supply system? The answer seems to be an unequivocal Yes, for various reasons. Practical experience shows that private actors are already present and their search for efficiency can enhance public health goals.

2.4.1 Actors in the private sector

There are many private actors in the drug supply system in any country and in any type of health sector organization:

<u>The Consumers</u> who make dependent choices are open to quality service and willing to pay for it. Typically, in developing countries large proportions of consumers are among the absolute poor. Despite this, poor consumers already pay a large share of total health costs.

<u>The Manufacturers</u> are indispensable for research on new drugs. They form a complex mosaic, working at various technological levels and with different shares of the market. This leads to competition as, for example, between new brand products under patent protection and cheaper generic drugs. There is also potential for competition between local and international manufacturers. State-protected, less-advanced industries in some countries have often displayed poor results due to technological, managerial and financial inadequacies.

<u>Importers and Distributors</u> represented by private agencies (for-profit and non-profit) are increasingly present in developing countries. Their interests and behaviour vary from purely representing multinationals to non-governmental agencies able to purchase/supply drugs at competitive prices. In several African countries, however, capacities are weak from standpoints of technological and logistical infrastructure.

<u>Retailers/Pharmacists</u> have been present in smaller numbers than medical personnel, and are generally concentrated in urban areas. In principle, they could act as a potent force for support of cost-control measures. They can help to contain prescriber-induced demand for new, more expensive drugs. In many African countries, pharmacists are still present in small numbers but are rapidly increasing.

Prescribers/Doctors in many developing countries have a strong, publicly visible profile which can be used to promote higher payment/reimbursement procedures. However, they frequently lack institutional/corporate organization.

Professional/Economic Associations are not yet developed. They could be instrumental, however, for both cost-control and quality assurance.

Health Insurance Agencies are at the forefront of cost-control in industrialised countries where they must lower costs in order to compete for government funding and to attract clients with lower premiums. In most African countries the situation is different; there is low coverage potential for fuelling higher urban expenditure and state-owned schemes are yet in their infancy.

It can be inferred that in different countries/settings there are various contradictions of interests among private actors. These conflicting interests point to the need for consensus since impositions by state institutions can easily provoke adverse reactions. However, the state could derive benefit by giving appropriate incentives with the aim of attaining greater equity and affordability of essential drugs.

2.4.2 Intervention by the State

In the drug supply system serving the health sector interventions can take the form of:

a) financing to increase the opportunities of the lower socio-economic strata by such means as progressive taxation, subsidies to public sector services/goods, or fiscal protection to local manufacturers;

b) regulation of prices to allow for consumption by the lower strata and selection and registration of products authorized in the domestic market, including provision of drug information;

c) direct provision is an area where state intervention is more controversial. There has been increasing discussion that direct supply by the state should take place only when public sector services/goods do not attract the intervention of private actors.

3. Empirical evidence

3.1 The public/private mix in health care and drug supply in developing countries

3.1.1 Africa: expanding and uncontrolled privatization

Many sub-Saharan countries have experienced massive public intervention in the health sector after independence. The reasons common to most of them were a limited presence of private actors, a legacy of a strong public role, and the need for solid public intervention in

support of development strategies to induce greater technological capacity and alleviation of poverty.

Public intervention came under great strain during the global economic downturn in the 1980s in health care delivery where demand continued to grow as populations increased and the economic crisis created new numbers of dependents. At the same time, the budgets of the public sector were reduced resulting in insufficient resource allocation crippling the effectiveness of services and lowering morale among poorly-paid staff who also migrated to the private sector.

Though many countries in Africa have pioneered the development and implementation of national drug policies (importing/ distribution agencies, rationalisation of prescribing practices, subsidisation for the poor, etc.), the functioning of public pharmaceutical supply systems has also demonstrated failures at various steps of the drug provision cycle.

3.1.2 "Prescriptions" for the crisis: pressing for privatization

As the crisis in the health and drug supply sectors was considered in tandem with the problems of domestic and external financial stability, efforts to correct the situation were undertaken by governments, aid agencies and international bodies.

Some of the suggested proposals for change were included in a publication - "Financing Health Services in Developing Countries. An Agenda for Reform" - by the World Bank which was widely disseminated in the late 1980s. The prescriptions put forward by the World Bank included :

a) more private payments at public facilities;

b) incentives to health insurance and private providers of medical care;

c) greater decentralisation and more efficiency in the public sector.

The Bank also highlighted some of the undesirable effects which might accrue from application of these measures: a potential for greater inequalities (geographical and economic); increased concentration of consumption by urban elites stimulated by emerging insurance plans; and poorer quality of services.

For these reasons, the World Bank insisted on the need for *monitoring* the effects of new policies which give a less central role to the public sector. In many countries the cautionary warnings articulated by the World Bank have proven accurate.

On the one hand, privatization in health care and drug supply systems has meant a rapid substitution of actors at many stages: substitution of private for public importers and distributors; insufficient attention to drug regulation and advertising; and, decreased budgets and public subsidies.

As far as drug policies specifically are concerned, the consequences can present the same degree of harshness: increased inequalities; greater money barriers for the poor using both public and private providers; concentration of expenditure in urban areas by private

providers and insurance plans; and larger shares of available foreign currency being used for more expensive drugs, promoted by both private and public prescribers.

There may occur lesser economies of scale in drug importation due to the operation by new private drug importers who import small quantities of branded products for private health care facilities.

There may also occur larger risks in safety for consumers when drug importation and distribution are subject to ineffective or inadequate state controls.

3.2 Latin America: a focus on de-regulation

An important difference between Africa and Latin America is the strong presence of local manufacturers of pharmaceuticals in Latin America. Although dependency on foreign raw materials and production procedures varies from country to country, the local manufacturing sector displays an important potential for economies in drug supplies, particularly with reference to generics.

3.2.2 De-regulation

The recent trend towards greater privatization in the economic and social sectors has taken a somewhat different shape in Latin America. In part, this stems from a different role played by the state. Public financing is channelled towards both public-owned institutions and powerful insurance plans. Other features are a stronger intervention in fiscal policies protecting local production and drug price controls, as well as a larger presence of private providers. A negative feature, however, has been the crisis in public financing, worsened by large levels of external debt.

Main features in Latin America of privatization policies in the health sector include:

a) high levels of private (direct) payments at public facilities, and insurance co-payments;

b) public financing of health insurance transferred to private insurers;

c) incentives for the establishment of private providers.

Privatization in drug supply systems, on the other hand, have resulted in:

a) decreased government capacity to maintain its control functions on both prices and drug quality assurance and control. Scarcity of public funds have made enforcement mechanisms inadequate for ensuring compliance with prescription/sales regulations, retail prices, sales promotion and advertising ;

b) increases in total expenditures, due to price deregulation and its influence on prescription patterns;

c) policies of decentralization leading to wider inequities among geographical areas; governments have been obliged to yield their former roles in previously centralised fiscal policies and investment budgets.

A critical appraisal of the two consecutive phases that Latin America has undergone - state intervention followed by policies of liberalisation - displays indications that new actors and opportunities are already in place.

Increasingly, private actors, including non-profit institutions such as health maintenance organizations (HMO)s, pharmacist's associations, non-governmental organizations (NGO)s involved in drug purchasing, distribution and other functions, improve their corporate organization enhancing both competition and achievement of social goals.

There is still room for innovative fiscal policies that maximise the role of local manufacturers, as well as both public and private distributors and retailers (including non-profit), thus widening the opportunities for greater competition and lower prices.

More widespread levels of co-payments by consumers can foster rationalisation of prescription patterns in both public and private institutions. By appropriate competition among insurance plans, cost-control measures can be tried out in demand, supply and financing functions.

4. Looking ahead

4.1 Greater private intervention in drug supply systems: implications for equity, financing and coordination

Some relevant features of the short-term scenarios in developing countries can be foreseen. A protracted crisis of public funding may be forecast due in part to the burden of external debts and the slow pace of recovery of international trade.

Private providers and sources of financing will be called on to play a progressively increasing role even in the situation of improved efficiency of public institutions. Private sources of finance, however, will be limited by widespread poverty. A high degree of dependency on foreign assistance may continue in some developing countries.

There will be an ongoing need for direct public provision of services for the poorest segments of populations and for public health disease control programmes. States must undoubtedly expand their coordinating and regulating capacities, particularly in countries in Africa. Private providers there will also remain relatively few in number.

4.1.1 Further development of national drug policies

Key elements of national drug policies as defined by WHO include drug selection and procurement; supply and logistics; regulation, registration and quality assurance; financing; education and training; and information.

Governments in developing countries, wanting to ensure access to essential drugs for the maximum possible proportion of their populations, must define broad strategic goals along the following lines:

a) achieve maximum cost-control in expenditures on pharmaceuticals ranging from procurement for drug supply systems to the economic behaviour of prescribers;

b) make drug prices economically affordable to the majority of the population and for public health disease control programmes;

c) increase geographical accessibility especially in view of weak communication and trade networks;

d) ensure appropriate prescribing practices and provision of objective information for safe and effective use of pharmaceuticals of good quality.

Strategies for the continuing development of national drug policies must take into account that these goals can only be achieved through a *combination of initiatives* within both the health care delivery and the drug supply systems.

Critical activities in health care systems will include :

(i)
- rational prescribing;
- promotion of co-payments and avoidance of fee-for-service;
- assurance of regular drug supplies to public facilities ;
- appropriate training in pharmacology, therapeutics and health economics for doctors;
- greater numbers and better quality training for all health workers;
- enforcement of regulations and supervision of para-medical personnel;

(ii)
- improved accessibility for low socio-economic strata and appropriate subsidization policies;

(iii)
- quality assurance and safe use of drugs including more stringent enforcement of regulations and information to providers and consumers.

In the drug supply systems and financing, attention must be given to:

(i)
- drug pricing;
- manufacture, importation and retail sale of generic drugs;
- incentives for non-profit importers-distributors ;
- legislation permitting generic substitution by pharmacists;
- adequate control over advertising of pharmaceuticals;
- incentives for competition among insurance companies on efficiency/costs;

(ii)
- improving geographical accessibility and regular drug supplies;
- improving distribution in the public health networks;
- drug regulation and selection mechanisms;

- decentralisation of estimation of needs and improved budget capacities for local purchase;
- improvement in inventory control;
- involvement of private distributors in public sector supply systems;

(iii)
- achieving greater quality assurance and control;
- promoting collaboration between government, industry and international agencies with particular attention to good manufacturing practices;
- enforcing legislation in respect to registration of imported and locally produced drugs;
- collaboration to develop information systems and networks supporting quality control laboratories and inspectors;
- support from pharmacists for monitoring and to improve patient compliance.

4.2 The state and coordination of public/private interventions

The search for opportunities for a greater private involvement in promotion of national health system goals leads also to the need to review the role of the state.

Without question, governments must retain the responsibility for designing strategies to ensure greater access to essential drugs, stimulating appropriate interventions by different actors and enforcing them and monitoring results.

Cost-control mechanisms combined with incentives for economic behaviour by prescribers, including in public sector facilities, must also be retained as a state responsibility and even reinforced. Last but not least, the state cannot but strengthen the full set of measures for quality assurance and control, from the manufacturing of drugs to prescribing patterns and drug use by consumers.

A main change that seems necessary in public intervention is a move away from massive and direct execution of programmes to a role as designer/coordinator/controller of the various actors involved in strategies leading to greater equity in accessibility of drugs.

The state can explore ways of deriving the maximum benefit from the different mandates of these various actors and promoting private intervention where this has a potential for greater internal efficiency.

It can explore the conflicts of interest that have a potential influence on cost-containment and design incentive policies for national and international manufacturers, pharmacists, prescribers and insurance plans.

Decentralised management in the public health care and drug supply systems can help foster competition.

Public administrations must be aware that limitations in technical and organizational capacities need to be addressed in public as well as private institutions. This may need a long-term strategy in which the state must provide leadership.

New roles for the state may compel not only overcoming concerns and vested interests, but reallocations of resources away from previous activities.

The technical and professional capacities and corporate organization of private actors need strengthening in order to regulate competition and quality and to facilitate dialogue with the public sector.

Incentives for private sector installations must be established that will compensate in some measure for uncertainties through insurance and enlarging private demand. Previous bias of state interventions that created disincentives will need correction as well as fiscal incentives that contribute towards cost-containment.

The main investments that will be necessary to achieve the goals of such capacity-building strategies are in the areas of professional training for both public and private sectors, complemented by revised salary policies that can retain technical staff in the public sector.

4.3 Monitoring future developments: many uncontrolled variables ahead

The call to monitor developments of policies towards greater private involvement in public social sectors is repeatedly heard. The reason is straightforward: the apprehensions that developments will not be equitable match the enthusiasm for increased opportunities for private efficiency. The appropriate involvement of private actors depends on a new approach to the role of the public sector which may face resistance to implementation.

It is assumed that indicators to measure developments must be applied to match the region/country-specific aspects of strategies. The following set is suggested as *illustrations* of the type:

4.3.1 Indicators on total economy/cost-control:

a) national per capita expenditure on drugs;

b) comparison among different institutional/financing settings, i.e. public, private for-profit, private non-profit, insurance, direct private payments, etc., for average per capita expenditure on drugs, average expenditure on drugs per consultation/hospitalisation;

c) results of incentives on the behaviour of public and private entities involved in drug provision (importation, distribution, retail): compare profits/sales volume, unit prices; results of different combinations of sales profit- margins and reimbursement procedures on incentives to cost-control by pharmacists/retailers;

d) compare total costs with volume of drug supplies between public and private sectors: are the rising costs being translated into rising volumes of drugs? What share of costs-volume belongs to essential drugs? What share is spent on generic versus brand name drugs?

e) percentage of government health sector spending on drug supplies; percentage of family income spent on health costs devoted to drugs.

4.3.2 Indicators on increasing socio-economic and geographical equity of access

a) improved access in rural areas; number of providers/distributors/retailers, public and private; N.B.: as geographical coverage will mean presence of technically skilled manpower, this indicator will also reflect the effectiveness of public training policies;

b) availability of subsidised drugs for low socio-economic strata, at least in public health facilities;

4.3.3 Indicators on rational use of drugs:

compare average numbers of drugs per prescription in different prescriber settings;

4.3.4 Indicators on quality assurance and control

examples of public-private collaboration at various stages from manufacturing to consumption.

In conclusion, private intervention can contribute towards the goals of national drug policies in various areas including manufacturing, distribution, dispensing/retail, quality assurance and control, supervision of prescribing patterns, information to the consumers, negotiations of profit margins and reimbursement by insurance plans.

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