Guide to drug financing mechanisms

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1998

WHO Library Cataloguing in Publication Data

Guide to drug financing mechanisms / Jérôme Dumoulin, Miloud Kaddar & Germán Velásquez

1. Pharmaceutical services—economics 2. Drug utilization—economics
3. Drugs—supply and distribution 4. Prescriptions, Drug I. Dumoulin, Jérôme
II. Kaddar, Miloud III. Velásquez, Germán

ISBN 92 4 154509 7 (NLM Classification: QV 737)

Designed by WHO Graphics
Typeset in Hong Kong
Printed in England

97/11666—Best-set/Clays—5500

The World Health Organization was established in 1948 as a specialized agency of the United Nations serving as the directing and coordinating authority for international health matters and public health. One of WHO's constitutional functions is to provide objective and reliable information and advice in the field of human health, a responsibility that it fulfils in part through its extensive programme of publications.

The Organization seeks through its publications to support national health strategies and address the most pressing public health concerns of populations around the world. To respond to the needs of Member States at all levels of development, WHO publishes practical manuals, handbooks and training material for specific categories of health workers; internationally applicable guidelines and standards; reviews and analyses of health policies, programmes and research; and state-of-the-art consensus reports that offer technical advice and recommendations for decision-makers. These books are closely tied to the Organization's priority activities, encompassing disease prevention and control, the development of equitable health systems based on primary health care, and health promotion for individuals and communities. Progress towards better health for all also demands the global dissemination and exchange of information that draws on the knowledge and experience of all WHO's Member countries and the collaboration of world leaders in public health and biomedical sciences.

To ensure the widest possible availability of authoritative information and guidance on health matters, WHO secures the broad international distribution of its publications and encourages their translation and adaptation. By helping to promote and protect health and prevent and control disease throughout the world, WHO's books contribute to achieving the Organization's principal objective—the attainment by all people of the highest possible level of health.

Foreword

In all countries, expenditure on drugs is a critical aspect of health policy. As such, it deserves careful study.

Half of the world's population lacks regular access to drugs that are absolutely indispensable, and in developing countries this proportion is estimated to be more than 60%. Moreover, in many countries economic deterioration during the last 10 years has made it difficult to increase accessibility to drugs.

An unfavourable balance of payments has severely hampered the drug supply in many countries that import drugs or the raw materials to produce them. Many importing countries prefer to allocate scarce hard currency to production and exports while neglecting the purchase of drugs. This situation parallels that in industrialized countries where pharmaceuticals are an important export and are therefore supported by government policies.

Government policies designed to reduce budget deficits have, in most cases, substantially reduced government expenditures for health. Spending on supplies such as drugs declines first, because spending on personnel cannot so easily be reduced. Yet drug shortages can bring health care systems to a standstill. Hospitals and health centres that are well designed and organized lose credibility—and clients—as soon as drugs are no longer regularly available.

Pharmaceutical policies based on the concept of essential drugs illustrate the economic benefits of rationalizing the health sector. Whatever the general economic context, substantial improvement is always possible within the pharmaceutical system. Poor policy and strategy coordination, ineffective procurement, inequalities in distribution, inadequate quality assurance, prohibitive prices and bad use of drugs are more often the rule than the exception. It is thus absolutely necessary to analyse the rationale for expenditure on health and drugs from within, in order to make the best use of scarce resources.

This book continues the research carried out by WHO's Action Programme on Essential Drugs on the issue of financing that began with the document entitled *Access to drugs and finance: basic economic and financial analysis* (*1*). It will be of interest to all who wish to see drugs made more accessible and affordable to all in need, wherever they may live. It will be particularly useful to those who

formulate national drug policies and to those who procure, distribute or dispense drugs.

WHO wishes to thank the three authors for their considerable efforts over a number of years in making this analysis of drug financing possible.

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Acknowledgements

The authors would like to thank the following persons within and outside WHO who have sent their contributions, suggestions and comments: Mr Paul Bouvier-Patron (Institute of Economic Research, Grenoble, France), Mr Pierre Chirac (Revue Prescrire, Paris, France), Mrs Michèle Fardeau (Professor, University of Paris I, France), Mr Yves-Antoine Flori (Lecturer, University of the Sorbonne, Paris, France), Dr Sabine Kopp-Kubel (World Health Organization), and the members of the World Health Organization Task Force on Health Economics and the team of the Action Programme on Essential Drugs.

Contents

Introduction

Providing a population with safe, effective, good quality drugs at the least possible cost is a major pharmaceutical policy challenge. Many innovations have been tried to increase access to essential drugs.[1] Economic criteria are not yet widely used to formulate and apply pharmaceutical policies; and when they are, their use is generally confined to keeping prices as low as possible. However, pharmaceutical supply is complex and requires a broader economic analysis. Decisions need to be made about purchase strategy and organizational arrangements, and not simply about the less costly of two alternatives. Therefore, pharmaceutical policy-makers should possess some competence in economics, in spite of the fact that the economic characteristics of drugs vary from one to another and there is no fully fledged theory or reliably tested economic instrument to ensure that this sector is properly regulated.

Objectives

The economic objective of a pharmaceutical supply system is to ensure a supply of safe, effective, good quality drugs at the least possible cost to the people who need them. This means that criteria of cost–effectiveness (maximum return on minimum resources) must be combined with criteria of equity (in which all people are

[1] The WHO Expert Committee on the Use of Essential Drugs defines essential drugs as "those that satisfy the health care needs of the majority of the population" [*The use of essential drugs. Seventh report of the WHO Expert Committee.* Geneva, World Health Organization, 1997 (WHO Technical Report Series, No. 867)]. More than 70 countries now have national drugs policies based on the concept of essential drugs; within the context of their national health policies, these countries each maintain a list of essential drugs.

Notwithstanding the above definition, many countries also use a classification system (known as the VEN classification) to set priorities for the selection, procurement and use of drugs according to their health impact. The VEN classification, which is described in more detail on page 10, assigns drugs to one of three categories:
V: *vital* drugs
E: *essential* drugs
N: *non-essential* drugs.

Each of these categories may be on a country's essential drugs list. Drugs for minor illnesses assigned to the non-essential category may still be on the list but may be considered a lower priority for procurement than drugs in the other two categories.

This book uses the term "essential" in two ways—both to describe drugs on an essential drugs list and to describe the second category of drugs in the VEN classification. In each case the context identifies the usage for the benefit of readers.

regarded as equal). The aim pursued here is not the management of pharmaceutical services (*2, 3*) but the overall economic organization of a country's pharmaceutical sector.

The importance of economic criteria and instruments in a world characterized by scarcity and unequal distribution of resources needs hardly be stressed. But however important economic criteria may be, legal, pharmacological, cultural and political criteria also play a role. These guidelines are deliberately confined to the economic aspects, although they do sometimes touch on these other dimensions.

Audience

These guidelines will be of interest to all who are concerned to ensure that adequate supplies of drugs are available for those who need them. They will be of use to pharmaceutical policy-makers at the national level, as well as to all who produce, distribute or dispense drugs. This book is practical. It discusses specific problems, using illustrations which it is hoped will help in making decisions. It does not offer any ready-made solutions, which would be both futile and dangerous, but instead proposes ways to analyse the pharmaceutical sector. For a similar analysis less geared to decision-making, refer to *Access to drugs and finance: basic economic and financial analysis* (*1*).

Concepts

A country's pharmaceutical sector comprises three interrelated systems: the pharmaceutical supply system, the financing system by which the manufacturers and distributors of drugs are paid, and the information system that enables their exchange and utilization. Many studies on drug supply have focused only on the first of these systems. In the last few years, other studies have looked at prices, the financing of drugs and the information supplied by producers. This book analyses all three systems simultaneously and emphasizes their relationships. The circulation of money and information very directly influences the circulation of drugs. And acting on the financing or information systems can often improve access to drugs more effectively than acting on the pharmaceutical supply system. Integration of the three systems is indispensable to economic analysis.

The pharmaceutical supply system is the most straightforward. It runs from the manufacturer to the patient and passes through the following stages:

— procurement (purchase from manufacturers);
— distribution (routing through the pharmaceutical system);
— dispensing (delivery to patients);
— utilization (use of drugs).

Utilization is determined both by prescribers and by patients, who may self-prescribe and who are the ultimate consumers of drugs.

In addition to these stages, the following functions are habitually involved:

— selection (choice of the drugs to be procured and distributed);
— quantification (evaluation of the quantities required);
— quality control (verification of compliance with standards).

These functions are carried out during the stages of procurement and distribution.

The financing system is more complex to describe and analyse than the pharmaceutical supply system. Payment may take place at each stage of the pharmaceutical supply system; the intermediate stages (distribution and dispensing) may be financed in different ways; and the final payment may be made by different agents (patients, the community, health insurance or government).

The information system is still more complex since the nature of the information involved may vary considerably. From a basic economic point of view, the following may be distinguished:

Information regarding supply:
— availability of drugs (authorized drugs, drugs in stock);
— usefulness and efficacy of drugs (technical data);
— suppliers' prices and conditions of payment.

Information regarding demand:
— drugs requested by prescribers and by patients;
— quantities required for procurement, distribution and prescription;
— quality of drugs; undesirable side-effects.

Information on the relationship between supply and demand:
— actual consumption in volume and in value;
— shortages;
— current prices.

The pharmaceutical supply system is the principal system. The financing and information systems must ensure that this principal system functions well.

Plan of this book

The topics discussed here are those to which economic methods are most relevant. Quantification has been studied in depth elsewhere (*4*). Utilization is an area of research that is now expanding fast (*5*). It is discussed here only with regard to the economic aspects of prescribing. The main aspects of pharmaceutical supply are therefore examined as follows: selection (Chapter 1), procurement (Chapter 2), distribution (Chapter 3), and prescribing (Chapter 4).

The links between the pharmaceutical supply system, the financing system and the information system are studied with regard to each aspect. Each is examined under three headings: What are the objectives? What processes allow these objectives to be attained? What structures and organizational arrangements are needed to carry out these processes and attain these objectives?

CHAPTER 1

Selection

Selection consists in choosing from the wide array available those drugs to be procured and distributed. Selection proper denotes establishing shortlists for the next two stages of procurement and distribution. Drugs on these shortlists may be chosen by the government within the framework of a national drugs policy or by procurement and distribution agencies. The drugs selected depend on the procurement and distribution policies that a country wishes to pursue.

Objective of selection

It is often necessary to procure and distribute only those drugs that are most needed and efficient. Selection, then, should focus on these high-priority drugs.

Avoid drugs of no therapeutic interest

Of all drugs available, some are ineffective or useless, and others are dangerous but have at least one equivalent safe alternative. Drugs that are of no therapeutic use cannot be justified on either medical or economic grounds. Therefore, these drugs should be eliminated by a general ban. In 1982 Bangladesh banned 1707 products, fully one-third of its total consumption. Of the banned products, 305 were altogether harmful, 134 associations (associations of components offering no additional therapeutic value as compared with their components taken separately) required reformulation and 1268 drugs were useless. Industrial or political problems engendered by such bans must be taken into consideration, but without compromising the goal of the ban.

Reduce the number of drugs

From a purely economic point of view, it is good to keep the number of drugs to be procured, distributed and used as small as possible, as this reduces certain costs and facilitates rational use of drugs. However, this smallest possible number cannot be defined solely from an economic point of view. Costs may be reduced by reducing pharmaceutical spending, by operational improvements, or by both of these measures.

The effect on procurement costs

When fewer different drugs are selected, larger quantities of each drug can be procured. If each drug is produced in larger amounts, economies of scale may be passed on to the buyer. The price paid by the consumer may be lower if larger amounts of the same drug are available. It appears that these effects are rare in the international market since procurement by small importing developing countries accounts for only a small share of the production of export manufacturers. But this effect could be substantial if drugs are produced within the country. An increase in consumption beyond certain thresholds makes national production viable on an industrial scale. The market share of national enterprises in Bangladesh thus rose from 35% in 1981 to 64% in 1991, in an expanding market with falling prices (−41.7% for 25 widely used drugs between 1981 and 1991) (*6*).

The effect on transaction costs

On the international market, lower import prices result not from any increase in the quantity of each drug procured but from concentrating procurement into a smaller number of transactions.

Transaction costs are incurred with every sale or purchase (*7*). These costs comprise seeking possible suppliers, selecting the suppliers to be contracted, negotiating contracts, forward acceptance of orders, and invoicing. These costs are independent of the quantities involved in any one transaction and are proportional to the number of transactions. Table 1 illustrates this principle. Where only a few personnel are competent to carry out transactions, a shorter list of drugs to be procured will allow them to devote more time to each transaction and thus obtain lower procurement prices.

The effect on stock-keeping costs

A smaller number of drugs facilitates stock management. There is less movement in and out and fewer registers and records to be kept. The value of the stock needed and storage depot costs can also be reduced.

The effect on quantification

However one determines the quantity of a drug that is needed (whether on the basis of a population's morbidity or of its past drug consumption), calculations are simpler, more accurate and fairer if fewer drugs are to be considered. Accurate calculation makes it

Table 1. Comparison of transaction costs of two lots of drugs (example)

Determinants of cost	Lot A	Lot B
Drug purchases		
Number of different drugs	5	1
Units of each	1000	5000
Price in US$		
Per unit	1	1
Total price of all units	5000	5000
Transaction cost (US$ 100 per drug)		
Number of drugs × US$ 100	500	100
% of total drug cost	10%	2%

easier to predict the amounts to be procured and distributed, more accurate forecasting means that a smaller inventory needs to be kept and the risk of a depleted inventory is lessened. Fewer disruptions in supply should in turn ensure more continuous distribution and more reliable distribution forecasting.

The effect on information about drugs

When prescribers may choose among 25 different β-blockers, the choice is likely to be made at random, by habit, or under pressure from producers. In all three cases the choice may not be the best. Reducing the variety of drugs procured can improve therapy decisions because the training of prescribers is facilitated, unwanted side-effects are easier to recognize and, above all, opportunities for irrational treatment can be ruled out.

Reducing the number of drugs limits the amount of information to be produced, managed and used at all stages. Prescribers can better master the smaller volume of drug information, and better rationales for treatment and economy can be maintained. The selection of a limited number of drugs improves the entire pharmaceutical system.

Increase the efficiency of available drugs

From a public health standpoint, the selection of drugs should be based in the first instance on efficacy, safety and sufficient quality, and only then on cost. The economic standpoint differs. It uses only one criterion for the classification of all drugs—efficiency. Efficiency is the ratio of costs to efficacy (including the desired therapeutic

effects and the risks inherent in any given quality). While the most effective and least expensive drugs are preferred from the twin standpoints of public health and the economy, the criterion of economic efficiency discriminates between more effective drugs that cost more and less effective drugs that cost less.

The criterion of economic efficiency

Using the criterion of economic efficiency assumes the ability to measure costs and to measure the efficacy of drugs.

Measurement of costs

Costs comprise the prices of drugs and the costs of treatment with the drug in question.

Comparison of drug prices

Drugs that have the same active principle should be designated by their international nonproprietary name (INN). This name enables comparison of the prices of drugs from different suppliers and fosters competition among suppliers. Typically, a drug sold under a brand name is linked with one supplier that has a monopoly on the brand. Prices of brand-name drugs are generally much higher than the prices of the drugs designated by their INNs (Table 2).

One can also compare prices of drugs that differ in form or composition but whose effects are so similar that the drugs may be regarded as identical. Thus drugs in oral suspension are more

Table 2. Comparison of prices of brand-name and generic drugs in Colombia in 1992

Drug and dose		Price (pesos)		Price ratio: Brand name /Generic
		Brand-name	Generic	
Buspirone	10 mg tablets	432.00	291.00	1.48
Ampicillin	1000 mg ampoules	1040.00	700.00	1.49
Amoxicillin	500 mg capsules	352.17	165.60	2.13
Cimetidine	200 mg tablets	262.60	97.02	2.71
Gentamicin	80 mg ampoules	1150.67	421.00	2.73
Mebendazole	100 mg tablets	95.00	33.00	2.88
Diclofenac	75 mg ampoules	773.33	240.00	3.22
Ranitidine	150 mg tablets	537.00	160.00	3.37
Metronidazole	500 mg tablets	1676.00	50.00	33.52

Source: Data taken from *Farma National Catalogue* (*8*)