9-2004

Purchasing Pharmaceuticals (Health, Nutrition and Population (HNP) Discussion Paper)

Ulrika Enemark
Aarhus University

Anita Alban
EASE International

Enrique Seoane-Vazquez
Chapman University, seoanevazquez@chapman.edu

HNP DISCUSSION PAPER

Purchasing Pharmaceuticals

Ulrika Enemark, Anita Alban, Enrique C.S. Vazquez

September 2004

PURCHASING PHARMACEUTICALS

Ulrika Enemark, Anita Alban,
Enrique C.S. Vazquez

September 2004

Health, Nutrition and Population (HNP) Discussion Paper

This series is produced by the Health, Nutrition, and Population Family (HNP) of the World Bank's Human Development Network (HNP Discussion Paper). The papers in this series aim to provide a vehicle for publishing preliminary and unpolished results on HNP topics to encourage discussion and debate. The findings, interpretations, and conclusions expressed in this paper are entirely those of the author(s) and should not be attributed in any manner to the World Bank, to its affiliated organizations or to members of its Board of Executive Directors or the countries they represent. Citation and the use of material presented in this series should take into account this provisional character. For free copies of papers in this series please contact the individual authors whose name appears on the paper.

Enquiries about the series and submissions should be made directly to the Editor in Chief. Submissions should have been previously reviewed and cleared by the sponsoring department which will bear the cost of publication. No additional reviews will be undertaken after submission. The sponsoring department and authors bear full responsibility for the quality of the technical contents and presentation of material in the series.

Since the material will be published as presented, authors should submit an electronic copy in a predefined format as well as three camera-ready hard copies (copied front to back exactly as the author would like the final publication to appear). Rough drafts that do not meet minimum presentational standards may be returned to authors for more work before being accepted.

The Editor in Chief of the series is Alexander S. Preker (apreker@worldbank.org); For information regarding this and other World Bank publications, please contact the HNP Advisory Services (healthpop@worldbank.org) at: Tel (202) 473-2256; and Fax (202) 522-3234.

ISBN X-XXXXXX-XX-X

1818 H Street, NW
Washington, DC 20433

Health, Nutrition and Population (HNP) Discussion Paper

Purchasing Pharmaceuticals

Ulrika Enemark [a], Anita Alban [b], Enrique C.S. Vazquez [c]

[a] Associate Professor, Institute of Epidemiology and Social Medicine, Aarhus University, Aarhus, Denmark
[b] Senior Health Economist, EASE International, Copenhagen, Denmark
[c] Assistant Professor, Ohio State University - College of Pharmacy, Columbus, USA

Paper prepared for the World Bank's Resource Allocation and Purchasing Project

Abstract: This paper discusses the purchasing of pharmaceuticals as a key component of cost-effective and equitable healthcare delivery. Pharmaceuticals account for a high, sometimes the dominant share of health expenditures in developing countries, but the desired health outcomes can only be achieved if the adequate medicines reach the right people and are used in the correct way. This requires purchasing arrangements that take into account the information asymmetry between patients and providers, ensure selection of effective, safe and affordable medicines and set economic incentives in a way that encourages rational drug use. The organizational and institutional frameworks define the roles of the various public and private stakeholders and establish the rules and regulations for registration, import, prescription and distribution of pharmaceuticals within which active purchasing can take place. While there is a trend towards more active purchasing arrangements for pharmaceuticals, the move from passive to active purchasing, using up-to-date information systems to link inputs and outcomes, and pooled purchasing arrangements to optimize the use of limited resources, has been slow.

Keywords: resource allocation and purchasing, health care financing, pharmaceuticals, access

Correspondence Details: Ulrika Enemark, Institute of epidemiology and social medicine, Aarhus University, Building 264, Universitetsparken, 8000 Aarhus C, Denmark. Tel: +45 8942 3124, Email: ue@soci.au.dk; Anita Alban, EASE International, Sankt Peders Straede 21, 1453 Copenhagen K, Denmark, Tel: +45 3316 4616, Fax:+45 3316 4636, Email aa@easeint.com Web www.easeint.com; Enrique C.S. Vazquez, The Ohio State University, College of Pharmacy, 500 West 12th Avenue, Room 129 B, Columbus, Ohio 43210, USA. Tel: 614 292 3907, Fax: 614 292 1335, E-mail: pharmacoeconomics@osu.edu

Table of Contents

FOREWORD

Great progress has been made in recent years in securing better access and financial protection against the cost of illness through collective financing of health care. This publication – *Purchasing Pharmaceuticals* by Ulrika Enemark, Anita Alban and Enrique C.S.-Vazquez – is part of a series of Discussions Papers that review ways to make public spending on health care more efficient and equitable in developing countries through strategic purchasing and contracting services from nongovernmental providers.

Promoting health and confronting disease challenges requires action across a range of activities in the health system. This includes improvements in the policymaking and stewardship role of governments, better access to human resources, drugs, medical equipment, and consumables, and a greater engagement of both public and private providers of services.

Managing scarce resources and health care effectively and efficiently is an important part of this story. Experience has shown that, without strategic policies and focused spending mechanisms, the poor and other ordinary people are likely to get left out. The use of purchasing as a tool to enhance public sector performance is well documented in other sectors of the economy. Extension of this experience to the health sector is more recent and lessons learned are now being successfully applied to developing countries.

The shift from hiring staff in the public sector and producing services "in house" from non governmental providers has been at the center of a lively debate on collective financing of health care during recent years. Its underlying premise is that it is necessary to separate the functions of financing health services from the production process of service delivery to improve public sector accountability and performance.

In this Discussion Paper, Enemark, Alban and Vazquez stress the important role that pharmaceuticals play as a critical input to the proper functioning of the health services. Most curative and many preventive health services depend on pharmaceuticals. Patients perceive availability of pharmaceuticals in a facility as an indicator of the quality of health services, and drug availability helps explain overall utilization of health services. Despite significant progress in increasing the number of people with access to essential medicine over the past decades, a substantial share of the world's population still lack access to reliable supplies of essential medicines.

Alexander S. Preker

Lead Economist
Editor of HNP Publications

ACKNOWLEDGEMENTS

The authors of this paper are grateful to the World Bank for having published it as an HNP Discussion Paper.

INTRODUCTION

The overall aim of this paper is to contribute to the understanding of Resource Allocation and Purchasing (RAP) arrangements as regards pharmaceuticals in developing countries. The specific objective of this paper is to examine the strategic questions that arise, when pursuing an active purchasing and resource allocation strategy for drugs, as well as the actual practice and experience from applying different RAP strategies to promote access of the poor to essential drugs, i.e. availability of affordable essential drugs of good quality and appropriate and efficient use of drugs.

Drugs are a critical input to the proper functioning of the health services. Most curative and many preventive health services depend on drugs. Patients tend to perceive availability of drugs in a facility as an indicator of quality. The availability of the relevant drugs at the time of need is an important determinant for the utilisation of health services (see for example Nolan and Turbat 1995).

Two decades ago health sectors in many developing countries were facing a number of problems, an important one being irregular and insufficient supply of drugs, which forced patients to buy drugs in the private market or to pay unofficial charges in health facilities to avoid rationing. To ensure funding of a stable supply of drugs it was recommended that the principle of cost recovery be incorporated into an agenda for financing publicly provided health services in developing countries (World Bank 1987). User fees on drugs either in terms of cost sharing or cost recovery is therefore now widespread in developing countries, constituting financial barriers to access for the poorest.

Despite progress in increasing the number of people with access to essential medicine over the past decades, a substantial share of the world's population still lacks access to reliable supplies of basic medicines. While this is estimated to be the case for more than one third worldwide, it is the case for more than half of the population in the poorest parts of Africa and Asia (WHO 2000). Thus, "drug shortages continue to undermine the service quality and jeopardise the performance of the health system as a whole" (World Bank 2003). One challenge for reaching the MDGs as well as for in general significantly improving health in the poorest parts of the world is to improve the accessibility to essential drugs to patients, in particular to poor and vulnerable groups.

Many factors influence whether poor people can obtain affordable essential drugs of good quality. Increased access to drugs depends on effective resource allocation and an efficient purchasing system, that is on rational selection and use of medicines, adequate and sustainable financing, affordable prices and reliable health and supply systems. In most developing countries people pay directly out of pocket for drugs, thus access to drugs is particularly sensitive to cost of drugs. Consumers that are faced with high prices and lack of information are at risk of choosing ineffective or even harmful self-medication.

There are a number of constraints in reaching affordable essential drugs to the end-users, with bottlenecks appearing at each of the following steps from invention to consumption: Research,

development, production, selection, procurement, distribution, prescribing and consumption, see also Table 1 for major obstacles. There are a number of important issues regarding reaching affordable essential drugs to the poorest that arise at the research and development stage, issues related to pricing of patented drugs in global markets, patenting, intellectual property rights, macroeconomic constraints, limitations on foreign exchange etc, which the individual country health systems cannot easily, if at all, influence. These are areas in which international stewardship is needed to represent the interests of consumers in low income countries. While we do not dispute the importance of these issues, not least in an increasingly globalized world, the focus here is on the resource allocation and purchasing arrangements only.

Table 1. Obstacles to reaching poor people with drugs – blue marks for drug system

Support to self care	Clinical Care	Outreach
Household level * Low availability of ED – especially in rural areas * Expensive drugs * Knowledge asymmetry * Inadequate national regulations of drugs * Difficulties in controlling the drug market	At hospitals * Low availability of ED * Resource constraints for drugs (fixed costs high) * Insufficient procurement system * Inefficient storage system * Poor drug management * Fraud * Low availability of skilled staff * Limited R&D * Weak QA * Weak M&E	PHC * Long distances * Poor physical infrastructure * Low availability of drugs * Low availability of trained staff/ staff shortage * Insufficient logistics drug system * Poor management * Fraud * Inefficient QA of drugs * Low social accountability of drug schemes * Low motivation of staff * Drug packages does not match local need * Weak M&E

Source: Based on the framework of Marginal Budgeting for Bottlenecks (Soucat et al. 2003).

A core functional component in health systems is financing, both in relation to revenue collection and pooling of funds and in relation to the resource allocation and purchasing arrangements that guide the uses of financing. Thus, Resource Allocation and Purchasing (RAP) is a health system function in which collective (pooled) resources are allocated (actively/strategically or passively) to providers of health services. Such collective policies on resource allocation and the actual purchasing undertaken by ministries, by insurance schemes and providers, determine how resources are distributed and used both across regions and population groups in need of care. Such arrangements are, through their purchasing and resource allocation functions, suited to address such constraints to access of the poor to essential drugs as:

- inefficient resource use as reflected by the prevalence of irrational consumption of drugs as well as irrational prescription stimulated by unaffordability, adverse incentives and weak regulation;
- lack of affordability for the poor due to high user payment and high access cost when drugs are not available in remote areas;
- high cost of drugs reflecting lack of competition between suppliers, brand drugs preferences, weak regulation and inefficient supply systems.

The second section gives an overview over the context in which resource allocation and purchasing arrangements for pharmaceuticals operates in developing countries. The third section briefly outlines the strategic issues in purchasing and resource allocation of pharmaceuticals. The fourth section looks at the key questions and available evidence on a range of strategies that have been used to address the problems in resource allocations and purchasing in developing countries. Finally, the fifth section makes a brief assessment of where the health systems are as regards active purchasing in the area of pharmaceuticals, and the sixth section outlines the main issues and options to consider in pharmaceutical policy as regards purchasing and resource allocation as well as suggested further research in this area.

PHARMACEUTICAL RAP IN DEVELOPING COUNTRIES

CONTEXT

In developing countries, resource allocation and purchasing takes place within a range of constraints and barriers that forms part of the equation to reach essential drugs to poor people to improve their health status. The policy options in the area of pharmaceuticals in developing countries are affected by the characteristics of the wider socio-economic systems and the health finance and delivery systems. It is important to keep some of the constraints in these systems in mind, when looking at strategic options in the pharmaceutical sector.

Developing countries are generally characterized by a low level of organization, large informal sectors, weak tax collection systems, weak regulation and poor enforcement of the regulation that exist, rigid civil service rules, poor pay for civil servants, weak financial management systems and sometimes very rigid budgetary systems in the public sector. Furthermore, the public sector is often also characterised by a mainly reactive managerial culture resulting from decades of crisis response. These general weaknesses influence the current operation as well as the alternative strategic options in the health sector, including pharmaceuticals. For example the low level of formal sector employment is a substantial challenge to the implementation of social health insurance schemes, and rigid civil service rules and poor pay constrain the development of innovative approaches to attract qualified health sector staff to under serviced areas.

The health sector in developing countries is often characterised by lack of sufficient funding, inadequate supply of human resources, inadequate human resource planning and development,

under management as well as fraud and corruption[1] resulting in inefficient use of available funding and resources. In addition, the manoeuvring within the budget constraint is limited by the fact that staff represents a fixed cost that usually take the lion's share of the limited resource available, e.g. 70% in Tanzania. Further, a key characteristic of the health sector in developing countries is the relative importance of the private sector both in terms of not-for profit and for profit providers. Especially the private for profit sector also tends to be fairly disorganised.

These general health sector weaknesses affect the strategic options available in the area of pharmaceuticals. For example, lack of organization of the private sector limits the options for coordination and collaboration with private sector providers on drug policy implementation, and lack of human resources and general systems development may make large increases in drug supply meaningless, i.e. there has to be qualified staff to prescribe and dispense medicine and functioning diagnostic facilities to assist in reaching a decision on the appropriate medication.

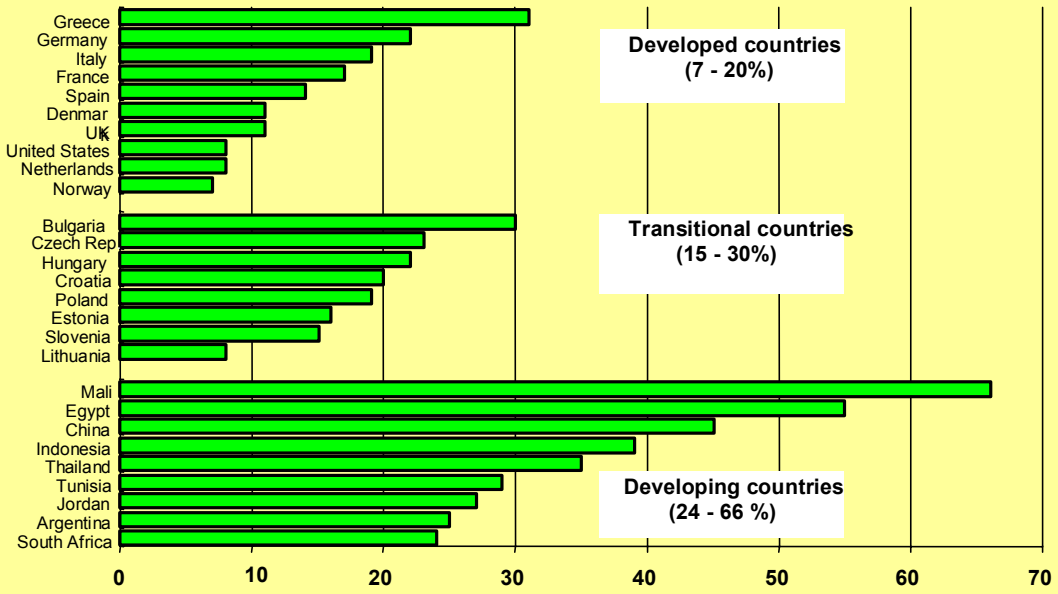
DRUG MARKET CHARACTERISTICS

There is a surprising lack of systematic collection of information on pharmaceutical expenditures and especially trends are therefore difficult to establish. A brief overview over the special characteristics of the consumption of drugs and flow of funds for pharmaceuticals in developing countries may be obtained by looking at a few indicators.

Relative importance of drug expenditures: The importance of drugs for the health sector is illustrated by the fact that drug expenditures constitute a greater share of total health expenditures in developing countries, e.g. from 24% in South Africa to 66% in Mali, see Figure 1 , and that the poorer the country the larger is the share of total health expenditures spent on drugs (WHO 2000).

[1] "In Uganda an inventory of problems with the drug supply system listed theft and resale at all levels of delivery. A World Bank report in 1999 found that 70% of drugs were diverted from the public system for private resale" (WHO Health system, Profiles Database 2003).

Figure 1. Pharmaceutical spending, as % of total health spending



Source: WHO, 2002

Distribution between sources of funding: A comparative study by WHO found that private spending on drugs constitutes a larger share of total pharmaceutical expenditures in developing countries than in developed countries (WHO 2000). With only few exceptions the majority of pharmaceutical expenditures are being privately financed. Private expenditures on drugs in developing countries typically amount to 45-90 % of all spending on drugs (WHO 2000). This share for private financing is larger than for the health sector generally, see Table 2, reflecting both a higher willingness to pay and a higher emphasis on copayment to mobilise resources.

Table 2. HEALTH EXPENDITURES AND DRUGS ON THREE CONTINENTS (in order of HDI/poverty)

Country	% Total HE Of GDP	USD HE per capita	% Gov. HE of GDP	% Priv. HE of GDP	% Access to ED	USD Priv. HE of total
Mozambique	4.3	9	2.7	1.6	50-79	36.6
Tanzania	5.9	12	2.8	3.1	50-79	53.0
Bangladesh	3.8	14	1.4	2.4	50-79	63.6
Nepal	NA	NA	0.9	NA	0-49	NA
Kenya	8.3	28	5.2	1.1	0-49	77.8
Ghana	4.2	11	2.2	2.0	0-49	46.5
Honduras	6.8	62	4.3	2.5	0-49	36.9
Bolivia	6.7	67	4.9	1.8	50-79	27.9
Peru	4.8	100	2.8	2.0	50-79	40.8

Sources: UNDP, HDR, 2002 and WHO, 2002

Distribution between financing agents: The high level of private financing might suggest that spot market transactions are highly prevalent and that pooled purchasing are less frequent. While this is no doubt true to large extent, some of the private expenditures may actually be channelled through or refunded by private financing schemes and as such may qualify as a pooled purchasing transaction. The available data can, however, not tell us to what extent pharmaceutical expenditures are controlled, or channelled through, financing agents. For total health sector spending most developing countries have an insignificant share of private insurance as well as social security financing. However, in Latin America and the Carribeans, private insurance and social security financing is relatively high, as is the case for a few Asian countries. In Sub-Saharan Africa protection by social insurance coverage is still very limited, although some countries have or plan to introduce such systems, e.g. Kenya and Ghana. (WHO 2003, Poullier et al. 2002). Whether a similar pattern exists for drugs is not known.

Market shares by providers: The private sector is the major drug retailer in developing countries as regards number of outlets as well as value of drugs sold (Velasquez, Madrid and Quick 1998). As evidenced in a number of studies on health care seeking behaviour of households, it is quite common in many developing countries to revert to self-medication or to turn to pharmacies for advice, and even more so among low income groups (WHO 2000, Ensor and San 1996, Paphassarong et al 2002)[2]. In the latter study from Laos, interviews with licensed pharmacists indicated that about half of the customers describe their symptoms and request a drug to address them, while almost half ask for a specific drug and only very few actually bring a prescription. Similarly, Mayhew et al. (2001) estimate that in Accra, Ghana, 60% of pharmacy clients come to the pharmacy without a prescription. Thus, seeking care is more commonly a question of buying medicines than of consulting a qualified health care worker.

[2] Ensor and San (1996) in a study from Vietnam found that while 46% of people ill in lowest income quintile used a drug store as only source of care, only 35% did so in the highest income quintile. Similarly, a smaller study from Laos found that households of low socio-economic status had a higher use of private pharmacies or petty vendors and were more likely to use these as the only source of health care than households of high socio-economic status (Paphassarong et al. 2002).

Household expenditure on drugs: Private financing contributes significantly to the total drug financing and, not surprisingly, the major part of household health care expenditures is spent on drugs (WHO 2000). That the economic impact of drugs for illness can be significant is illustrated in an example from Thailand, see Table 3.

Table 3 Economic impacts of HIV/AIDS on rural households, Thailand

Spending on medical treatment	US$ 974
Hospital care (in/out)	US$ 441
Drugs.	US$ 242
Private clinics	US$ 196
Traditional healers	US$ 86
Traditional herbs	US$ 50
Local health centers	US$ 50

Note: Annual income = approx. US$ 1 000

RAP ARRANGEMENTS FOR PHARMACEUTICALS

A large part of pharmaceuticals in developing countries are paid out-of-pocket to private sector providers, pharmacies or drug sellers. Some drugs are, however, financed through pooled funding, either government or another third party payer that may act as purchasing and resource allocation agent. This section briefly describes the RAP arrangements particularly relevant to/prevalent in developing countries.

Some RAP arrangements have been developed particularly for the area of pharmaceuticals, typically in response to a number of problems in making drugs available in health facilities. More often, however, pharmaceuticals are considered as part of a health service package and as such the RAP arrangements for pharmaceuticals are part of general health service RAP arrangements, i.e. in some cases pharmaceutical RAP arrangements could be regarded as a sub-function of general health service RAP arrangements, while in other cases resource allocation and purchasing of pharmaceuticals would be completely integrated, i.e. as purchase of a package from an HMO type organization.

Agents that purchase and allocate resources in the area of pharmaceuticals based on pooled financing include:

- *Central government agencies*
- *Local government:* With the increasing decentralisation of health services in many countries, the local government assumes an increasing role in making allocations and purchases for the health sector, including pharmaceuticals
- *Social or national health insurance schemes:* Social insurance schemes are generally based on compulsory membership for formal sector employees and often open for voluntary membership of informal sector workers.
- *Drug Insurance Plans:* Separate drug insurance schemes exist mainly in Latin America.
- *Public sector drug revolving funds:* Public sector drug revolving funds have typically been set up at district level to ensure the availability of drugs in the government health

system. E.g. the national Cash and Carry Program in Ghana, which is essentially a revolving drug fund in which the fee per drug item charged to users is related to the procurement cost of the item, marked up with fixed percentages by central and regional medical stores, and decentralised district pilot schemes in Kenya and Tanzania and others.

- *Community drug financing schemes*: A number of community financing schemes were set up specifically with a view to improving the local supply of medicines. Starting with the launching of the BAMAKO initiative in West Africa by UNICEF, similar schemes have now been implemented also in other parts of Africa and some places in Asia and Latin America. Some of these schemes are pure drug financing schemes, whereas others have broader financing aims. Prepayment through Mutual Health Organizations with voluntary membership also belong to this category.
- *Employer provided health care*
- *NGOs*

There are quite often several RAP arrangements at work at the same time, e.g. decentralisation may have taken place for some pharmaceuticals, but not for all, e.g. vertical programmes. In Sub-Saharan Africa and most other developing countries non-governmental schemes only partially cover the population and operate side by side with a tax funded public system.

Whether the RAP arrangement is specifically aimed at drugs or at health services generally, the issues that arise are in many ways very similar. While the trade off between spending on drugs and other interventions is not an issue in pharmaceutical specific RAP arrangements, it is an issue that will have to be considered in relation to the general health service RAP arrangements. An organizational issue to consider is that the separation of specific drug financing schemes from general health service schemes, provides incentives for cost shifting that may not be optimal from a societal point of view, as the trade off between drugs versus other treatment options will not be made.

But what are then the relevant considerations for RAP arrangements with regard to drugs when keeping in mind the effects on health, protection against impoverishment and social inclusion? And what are the experiences in this regard in practice?

STRATEGIC ISSUES IN RAP AND PHARMACEUTICALS

To improve access to pharmaceuticals, every society must make important decisions regarding the use of scarce resources. Several questions must be answered:

1. What resources should be devoted to drug therapies versus other health care and non-health care goods and services?
2. What drug therapies should be available in the health care system?
3. What combination of resources should be used to make these drug therapies available ?
4. Who should receive the drug therapies?

The first two questions are related to the allocation of resources and the basic social goal is to achieve allocative efficiency and maximize social utility. The first question concerns the best possible combination of resources, not only in the health care sector, but also across the different sectors of our society. The second question relates to the decision of what specific drug therapies should be available.

The third question deals with productive efficiency. Drug therapies can be made available in many different ways. For example, drug production can take place at the local, national or multinational level with different scales of production and technical inputs. Also, drug therapies can be available at different levels of care (i.e. primary, specialized care): prescribed, dispensed and evaluated by different health care professionals.

The fourth and last question deals with equity or distributive justice. Drug therapies are available for specific population groups. In developing countries, an important part of the population cannot access essential drugs needed for treatment of diseases with negative effects on the health of patients when left untreated.

While the predominant modality for purchasing of drugs in many developing countries is the individual patient buying from a private pharmacy, drug seller or a shop, some third party payment and collective resource allocation and purchasing arrangement exist in virtually all countries. A RAP arrangement may operate at various levels depending on its nature, i.e. community drug schemes may operate at a different level from a national governmental scheme.

As is the case for purchasers of health care generally, active purchasing of pharmaceuticals requires that the purchaser acts strategically in order to maximize the achievements of the resources available. The general questions (Preker et al. 2002) pertain to

a) who benefits from the purchases,
b) what services are acquired,
c) who can provide the service,
d) which incentives are provided by the mechanism for payment and
e) at what price to purchase.

Some of these questions raise general issues that are no different whether the product to be traded is a drug therapy or other health services, while other issues are particular to the area of pharmaceuticals.

WHO BENEFITS? (FOR WHOM TO BUY)

The RAP arrangement acts as an agent for a group of principals on whose behalf drugs are purchased and allocated. For a RAP arrangement using collective finances a key question becomes who should benefit? Who is the constituency on whose behalf drugs are to be purchased and what redistribution between members is relevant, i.e. to what extent should inequities be addressed? In principle the question of who benefits is general and the issues regarding drugs do not differ from the issues that pertain to health services more broadly.

Due to the nature of drugs, which compared to other health service elements are less bound to location and person, i.e. are transportable and transferable (as opposed to, say, medical advice or diagnostics like X-ray) moral hazard is more pertinent in the field of pharmaceuticals. A frequent example is the exempted pregnant mother who receives loads of free drugs for all sorts of ailments – which she redistributes to other family members.

Further, inappropriate use of medicine, i.e. wrong medicine or dosage for condition and cost-ineffective drugs, is probably more common than other sorts of inappropriate use of health services. The irrational use of drugs in the public sector amounts to over prescription, polypharmacy, overuse of antibiotics and injections, under use of effective products like ORS and use of dangerous or ineffective drugs (see also for example Al Serouri et al. 2002). These problems are exacerbated in the private sector under influence of strong economic pressures, lack of information and training, perceived patient expectations, drug company promotions and financial gains from dispensing.

Irrational use of drugs is potentially harmful to the individual as well as the community to the extent that incomplete treatment increases risk of transmission as well as of development of drug resistance, e.g. incomplete treatment courses for TB, see Box 1 for illustrations of the financial implications of drug resistance. It furthermore reduces the quality of care and is a waste of resources. The source of irrational drug use may be the prescriber as well as the consumer of medicine.

Box 1: Common generic drugs are not always effective anymore – new drugs are expensive

Irrational use of drugs may result in development of drug resistance. When common generic drugs are not effective, the financial implications can be significant as the cost of an effective course of treatment increases:

Antibiotics for gonorrhea:
50-90 times the price of generic penicillins

Antimalarial drugs:
chloroquine $0.10 per treatment
Coartem® $4/pp developing country (40 times the cost of chloroquine)
Malarone® $45 per treatment (450 times the cost of chloroquine)

Antituberculosis:
$15 for DOTS
$300 for treatment of multi-drug resistant TB (20 times the cost of DOTS)

Source: WHO, 2002

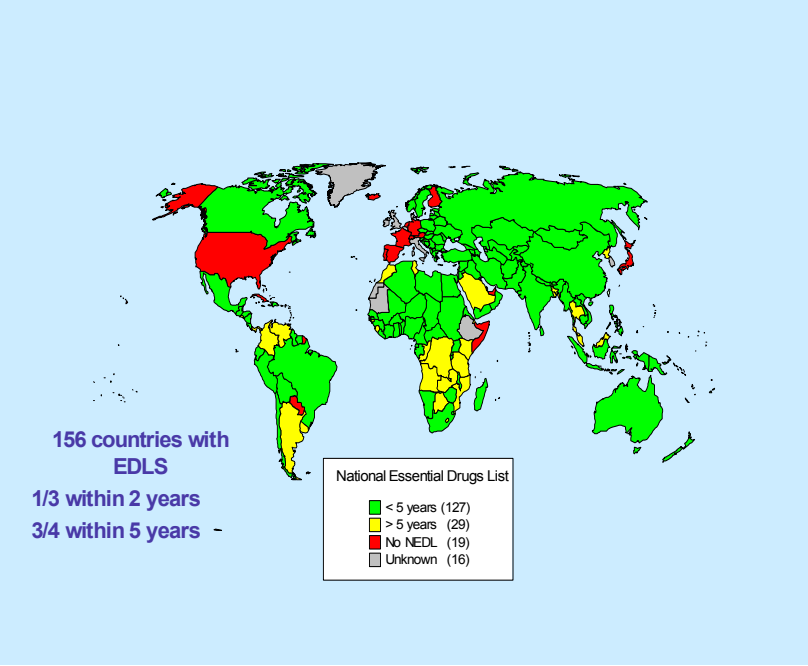
In conclusion, when targeting beneficiaries, due consideration should be given to the question of financial access for the poorest, moral hazard and the appropriateness in actual use of drugs. Demand side interventions may be targeted directly at the patients or at the agent demanding pharmaceuticals on behalf of the patient.

WHAT TO BUY?

The RAP agent is managing a limited resource pool and it is important to prioritize which drugs to buy to achieve maximum benefit. WHO's model essential drugs list suggests which drugs are essential in most countries for addressing the basic health needs. Worldwide, 156 countries have

adopted an essential drugs list, see also Figure 2. The strategic issues include to what extent the model list applies to the local setting in which the RAP agent operates. For example, the viability of small community financing schemes may be threatened if they were to include low-frequency, high-cost drugs, which may include drugs for chronic conditions like diabetes, on their list of drugs reimbursed unless some sort of reinsurance arrangement is set up. Long term/chronic conditions are not insurable by voluntary (private) insurance schemes because there is not uncertainty/risk attached to the expenses related to the disease. Low frequency high-cost drugs might not be affordable even through insurance if pooling is limited or income is low.

Figure 2. Number of countries with a national EDLS, December 1999



Source: WHO, 2002

When adjusting the essential drugs list to the local situation, a strategic issue is which criteria to use for expanding or reducing the list. In a number of developing countries essential health packages have been or are under development with a view to concentrating the use of pooled funding on cost effective health care. Following the World Development Report 1993 (World Bank 1993) much emphasis has been put on cost effectiveness analysis in selecting the contents of the package. Such analyses, however, rarely allow disaggregation between particular sub-groups of beneficiaries, such as the poor. Rather, it is often simply assumed that the packages will be relatively more beneficial to the poor. Similar problems pertain to the Essential Drug Lists. Inclusion may be based on cost effectiveness considerations, but rarely on assessment of the pro-poor target (WHO 2001).

If it is decided to use a positive list for drugs, the issue arises as to how the use of essential drugs on the list can be ensured.

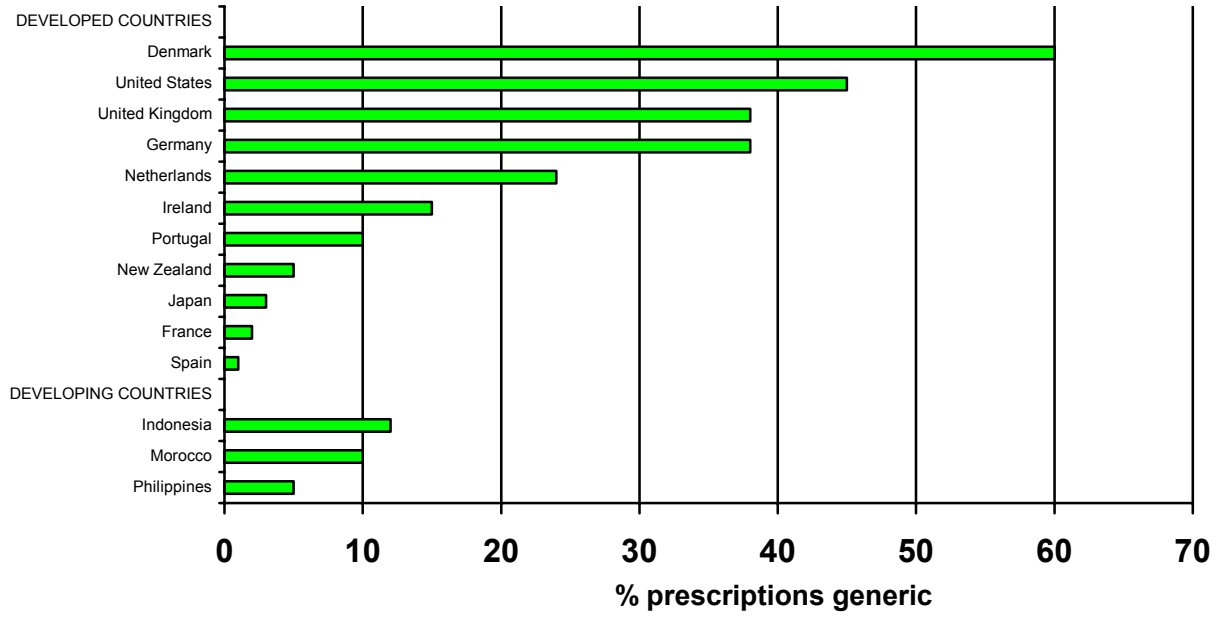
FROM WHOM TO BUY?

The strategic issues related to choice of where to buy the drugs depend on the level at which the RAP agent is operating. The real choices of a small community financing scheme differ from the real choices of a large government agency. The RAP agent may choose to directly purchase and distribute drugs for patients to acquire from the agent's own distribution system, which is what large RAP agents often do. Alternatively, the RAP agent may choose to "contract" with local retailers regarding drug delivery, sometimes weakly and indirectly only - through restrictions on where beneficiaries can get drugs.

The retail market for drugs is a market characterized by a large number of individual transactions. On the demand side, there is a large number of individuals, while the supply side is characterized by a relatively large number of retailers, some of which are unauthorized. The retail market in most developing countries is therefore probably generally highly, at least relatively, competitive (although in remote areas this may not be the case). With predominant information asymmetry regarding quality, the competitive environment poses a risk for the quality of drugs supplied.

At the same time the wholesale and production level is characterized by few large suppliers of drugs, i.e. is oligopolistic by nature, thus allowing for profit seeking through high prices of drugs sold to the retail level. Increasing competition and buying from producers of generic rather than branded drugs can reduce this, a phenomenon which is, however, more prevalent in developed than in developing countries, see figure 3, although the use of generics has been increasing in developing countries.

Figure 3. Percentage of drugs prescribed being generic by mid-1990s.



Source: WHO 2000.

The combination of the high risk of high prices transferred to the retail level and the competitive environment putting pressure on quality poses a special need as well as challenge for the regulatory environment to ensure affordable prices and good quality.

HOW TO PAY?

The incentives embedded in the payment systems adopted will influence the efficiency and equity in use of drugs. Several payment systems may need to be considered to adapt to local circumstances and objectives.

The treatment may be seen as a three-step procedure: prescription, acquirement and consumption of drugs. Therefore the payment system adopted for general health services, i.e. for consultations that may result in prescriptions, will influence drug use depending on the inherent incentives for prescribing. An additional complication is that in a number of developing countries the prescribing and dispensing unit is often the same[3], which potentially provides very strong financial incentives for prescribing.

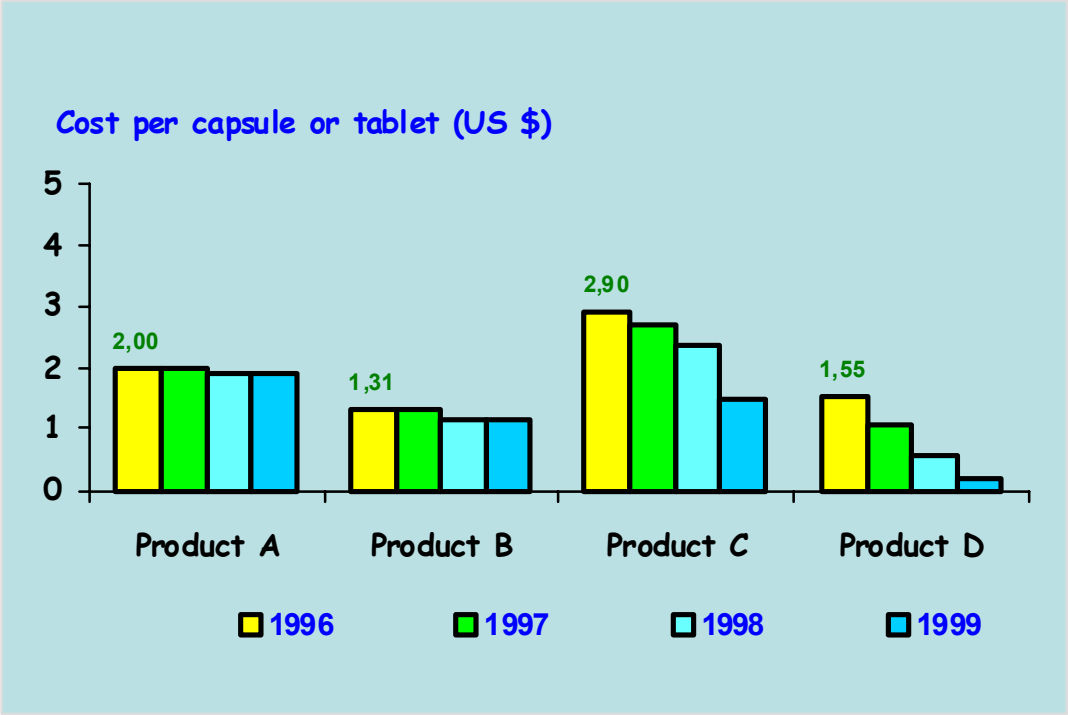
Another strategic issue is whether the reimbursement of expenditures is made to the patient based on reclaims or channeled directly to the provider with no outlays by the patient.

[3] Whereas in developed countries, the individual role of the pharmacies as agent for the consumer has largely disappeared, it still exists in many developing countries, where the patient often rely on self-medication, perhaps based on advise ("prescription") from a pharmacist.

AT WHAT PRICE?

Increasing the affordability of drugs requires that purchases be made at the lowest prices for the same quality. Prices may be regulated through restrictions on the price margins for wholesale and retail of drugs. Competition is, however, also very effective in reducing prices, see the example of anti-retrovirals in Figure 4.

Figure 4. Competition is highly effective in reducing prices - the example of antiretrovirals



Source: UNAIDS, 2000

All RAP arrangements may harvest the benefits from competition by buying generic rather than brand drugs. It will be important, though, to have quality control mechanisms in place. Further a more competitive environment may be created by broadening the potential providers for contracting to include both public and private sector providers, see also *From whom to buy*. Finally, a choice has to be made whether to engage in price negotiations to make a price agreement part of a service contract. The ability of RAP agents to influence the price is likely to vary with their size and their scope, with larger RAP agents, such as government agencies and social insurance schemes obviously having more bargaining power.

CORE POLICY RAP STRATEGIES TO INCREASE ACCESS TO DRUGS

The purpose of this section is to present the key questions in resource allocation and purchasing of pharmaceuticals and the available evidence on a range of strategies that have been used to address the problems related to access to drugs in developing countries.

People in developing countries use many different sources for obtaining drugs. This practice complicates the management, regulation and monitoring of the pharmaceutical sector. The

strategies basically entail measures that will work towards enabling the functioning of the market through incentives, regulation and information.

The strategic options may be categorized into three main categories, i.e. demand side interventions, supply side interventions and pricing and incentives, although there is overlap between the categories.

DEMAND SIDE INTERVENTIONS

Two major constraints that are addressed through demand side interventions are the financial access barrier and the irrational use of drugs. Options for reducing the economic and financial cost of accessing drugs include a) subsidies for target groups, b) reaching sufficient drugs to remote areas (which will reduce transport costs of users) and c) improvement in rational prescription as well as d) improvement in rational use of drugs.

Subsidizing drugs for target population groups

The question of whom to serve is in principle no different for drugs than for health services generally. All RAP arrangements aim to ensure availability of (defined) drugs to all potential users covered by the RAP arrangement. Further recognizing that access is relatively more difficult for some and that increased access and utilization is desirable for certain groups, such groups may be specifically targeted through subsidization of drugs.

There is widespread agreement that access of the poor should be ensured through waiving of fees. Further it is commonly argued that subsidies, in the form of exemptions, should be directed at merit services and services with external effects[4], i.e. ensuring use of drugs for high priority services (MCH, FP) and drugs for diseases of public health importance (such as TB) (e.g. Bitran and Giedion 2003). While these groups are often exempted in principle, they are not always exempted in practice (McPake et al. 1992, Gilson et al. 1995). In Ghana, where about 30% of the population is classified as extremely poor, the average proportion of outpatient visits that are granted exemptions purely on the grounds of poverty is way below 1% (Adams 2002). The percentage may, however, be deceptive as a number of poor people will also be covered under the other broad categories of exemptions.

Government agencies, whether central or local, tend to provide subsidies for health services, including drugs. For drugs there is often a relatively high level of copayment, but exemptions and waivers are given to certain target groups (Russell and Gilson 1995). These target groups are often broad and the practical implementation is often that patients rather than services are exempt. For example Kagera Hospital in Tanzania exempt more than half of the drugs dispensed, because the patients are either pregnant, under five or suffer from chronic diseases. These patients are exempted from all payments irrespective whether it is drugs related to, say, a chronic disease or a common cold. A general feeling often encountered is that many of the patients

[4] Merit goods/services are those that governments consider more valuable than consumers and therefore subsidize. Externalities are a market failure, while merit goods imply an imposition of preferences from the government to the consumers.

exempted can actually pay. Similarly, public sector drug revolving funds tend to follow national guidelines and provide exemptions and waivers for certain groups, including the poor.

Community financing schemes on the other hand tend to have a more limited policy on waivers and exemptions and to cross-subsidize for a limited number of poor households only (Atim 1999, Musau 1999). Still while having a policy of waiving the poor the Bamako Initiative schemes in Benin, Kenya and Zambia all failed in protecting the poorest from the burden of payment, in benefiting this group preferentially and in ensuring that their views were heard in decision-making (Gilson, Kalyalya et al 2001). There were exceptions though, as in Benin, cross-subsidization took place from general services to immunization services and child curative care, and one pharmacy provided free drugs to the poor.

Similarly, a review of 82 insurance schemes for the non-formal sector found that very few schemes applied exemptions to those who could not afford to pay premiums (Bennett, Creese and Monasch (1998)). Only 13 of 82 schemes had an in-built exemption policy. One of these (Abota scheme, Guinea) allowed the poor access to drugs (but no other services). Some schemes in Asia reported having separate schemes for the poor paid by the government (Vietnam, Thailand) or subsidized premiums paid by government (Korea, Philippines). The Thai health card system have largely been relatively successful (Gilson et al. 1998).

Some form of central guidance or coordination seems important in any system to ensure coordination and equity across the country. Although, lower level authorities can make more appropriate decisions on the actual exemptions than central level because they are familiar with and represent local needs and socio-economic circumstances. Russel and Gilson (1995) found that in the majority of countries the centre provided guidelines within which sub-national decisions were made. In nearly 60% of countries the center made the decision to allow price reductions or exemptions to protect the poor or vulnerable nationally. Still, there are, however, examples of wide differences in practice across countries, either because no central guidelines exist or because the guidelines have been outdated or are not monitored (e.g. for example Garshong et al 2001). Few countries have clear cut guidelines on who are indigent.

The extent to which waivers and exemptions are implemented in practice is influenced by the risk sharing embedded in payment modalities adopted, i.e. does the risk of financial loss due to exemptions and waivers fall on the provider, who is also often the exempting authority, or with the RAP agent. E.g. the case of Ghana (Box 2).

Box 2: The exemptions system in Ghana

User fees have existed in some form in Ghana since 1969. The fee system was changed and revenues were significantly increased in 1985. In 1993 the Cash and Carry system, a revolving fund for drugs, was introduced. Drugs account for over 70% of the revenue collected. The health facilities rely on the internally generated funds that are retained at the health facility for their daily operating costs as the government cash budget allocated to the facilities is quite low.

Who benefits?

The majority of exemptions date back to 1985 and relate to particular services regarded as being of public health importance. Thus all fees are exempted for leprosy and TB, immunization (except for international travel) and

storage of bodies at request of a state department. For a number of diseases of public health importance, all fees are waived ***except the cost of prescribed drugs***, i.e. meningitis, cholera, malnutrition, typhoid, venereal diseases, rabies and 18 other diseases. Further all fees except the cost of hospital accommodation and catering services are exempted for ante-natal and post-natal services and treatment at child welfare clinics. In 1997, the exemptions were extended to particular groups, e.g. the under five year olds, the elderly (70+) and paupers and indigents. According to the ministerial guidelines only the paupers are exempted from all fees, whereas the exemptions for the under five year olds and the elderly are for specific diseases only. There is considerable confusion on the ground about how to exempt within these wide groups and whether exemptions are for service fees or also for drugs.

Who bears the cost?

The Ghanaian user fee system has been fairly effective in mobilizing resources. Prior to 1997 exemptions granted were very limited. One problem recognized was the adverse incentives facing health facilities in relation to exemptions as exemptions represented lost revenues to the facility. The government therefore made a commitment to reimburse facilities for revenue lost due to implementation of exemptions. Health facilities have to submit a statement of fee revenue lost to exemptions and request for reimbursement.

In practice, the exemptions system is, however, still not functioning effectively. Almost no exemptions have been granted to the poor, although 40% of the population is defined as poor and 27% as extremely poor. The implementation was generally hampered by unclear guidelines, insufficient funds allocated in view of the number of beneficiaries and by bottlenecks in getting refunds to the health facilities for the revenues lost to exemptions. In a system with irregular and constraints in financial disbursements, the revenue from user charges is quite important for the functioning of the health facilities, especially at the lower levels of care.

Some regions experimented with using part of their exemptions allocations to reimburse mission health facilities to implement the government exemption policy, but as funds were short, mission facilities were the first to bear the cost.

Sources: Agyepong (1999), Health Research Unit (2000), Adams (2002), Garshong et al. (2002).

Designing and implementing a system of exemptions is considerably simpler than doing so with waivers. In the context of the very narrow resource constraint in many developing countries, the question is, however, whether waivers for the poor, from charges or premiums, or exemptions for specific services should be given first priority. The experience with implementation of waivers is not too encouraging, although a card system involving local authorities in identification seems to be working best. Critical evaluation of incentives created by policy design is important. International experience has demonstrated that where user fees are retained at facility level and at the same time comprises a significant portion of available funding only little incentive is provided to exempt patients. The general experience is that the success depends to a large extent on the existence of a functioning reimbursement mechanism.

Targeting of geographical areas

Resources tend to be allocated as they have always been rather than according to needs. There may be considerations given to the geographical distribution of drugs. The larger share often tend to go to hospitals. While more needs-based geographical resource allocation criteria for funding of certain recurrent expenditures has been or is being developed, e.g. Ghana, Tanzania, these often do not pertain to salaries and drug budgets. Currently budgets are often historically determined rather than related to need. One way of targeting drugs to the poor could be to ensure that deprived regions get preferential allocations of drugs reflecting their needs for drugs and their expected need for compensation for waivers and exemptions.

The monitoring of allocation of drugs per capita by region is, however, not well developed and in many developing countries is in its infancy, e.g. Tanzania, Mozambique. While targeting more resources at relatively deprived regions is an important step, it should nevertheless also be remembered that wide disparities also exist within the regions and that appropriate targeting of intra-regional resource allocation is as important if the poorest segments of the population are to be reached.

No evaluation of needs-based resource allocation of drugs has been found.

Promoting rational prescribing

Because of the information asymmetry between the patient and the provider regarding how the welfare of the patient will be affected by treatment alternatives, the provider remains in control of the decision over treatment strategy. Prescribers are therefore an important target group for improving rational use of drugs.

Qualified human resources are in short supply in many developing countries, especially in remote areas. Diagnostics and prescriptions meant to be undertaken by doctors, clinical officers or medical assistants, are often done by nurses or other staff that was not trained to do this. Furthermore, staff, especially in remote areas, is often not updated on new drugs on a regular basis. Irrational prescription may therefore flourish due to lack of knowledge.

Where there is no separation between the prescriber and the dispenser of drugs, i.e. in case of a health professional (or the facility he or she represents) also selling the drugs he or she is prescribing or the patient using the pharmacist as his or her only source for "prescribing", the prescriber has an incentive to over-prescribe as the prescription is directly linked to financial gains for the prescriber cum dispenser (Kutzin 1995, McPake et al 1992). The linkage of remuneration to volume and cost of pharmaceuticals introduce perverse incentives. This lack of distinction between the prescribing and dispensing roles is widespread, particularly in Asia, e.g. South Korea where physicians can prescribe and dispense and drugs sales constitute a large share of revenues for private physicians as well as for hospital outpatient departments . Similarly pharmacists can sell any kind of drugs without a doctor's prescription (Yang 1997).

A number of interventions has been undertaken to improve rational prescription (Laing, Hogerzeil and Ross-Degnan, 2001; Oliveira-Cruz, Hanson and Mills, 2001). A majority of these include training or other educational activities of prescribers as well as of drug retailers. Other interventions include the development of standard treatment guidelines, monitoring of prescriptions and encouragement of generic substitution. The evidence of the effects is mixed, but the overall trend was positive results in terms of decreased average number of drugs prescribed, correct selection and dosage of drugs (Oliveira-Cruz et al. 2001). Evaluation of the impact of drug retailer training was positive in all cases in terms of increased knowledge and sales of drugs. See the section on Other incentives regarding use of financial incentives.

Promoting adequate patient use of drugs

Poor people more often than rich people turn to self-medication or traditional healers to save costs or avoid cash demands. This effect is observed despite the existence of exemptions aimed at protecting vulnerable groups (see for example Ching 1995, Mbugua et al 1995, Gilson et al

2001). Inappropriate use of self-medicated drugs or lack of compliance on the part of patients is a problem for achieving the potential gains related to the expenditures on drugs.

Evidence regarding different interventions to promote adequate patient use of drugs was reviewed by Oliveira-Cruz, Hanson and Mills (2001). The main findings were that health education in various forms (provision on information on dosage and mode of administration to patients) and building of trust between patients (and their caretakers) and prescribers (particularly as part of DOTS) were successful interventions for addressing the low compliance by patients and high levels of self-medication.

Additionally, there is a link between the prevalence of self-medication and to some extent lack of compliance, and affordability of medicine. Thus, for TB the reduction in financial barriers to access the medication was also reported to have positive effects on patient compliance with the drug therapy (Homedes and Ugalde 2000).

SUPPLY SIDE INTERVENTIONS

Supply side interventions may be targeted at production, wholesale and retail. Most RAP arrangements would, however, not be engaged in interventions regarding production. Options for supply side interventions to increase access to affordable drugs to poor people, include the use of positive lists in order to constrain resource use to basic and essential medicines, and to keep prices low through use of generic drugs and increased competition. A key issue for the RAP agent is the selection of which drugs to pay for in terms of content and quality as well as the selection of whom to buy from. In this context mechanisms for enforcing the restrictions on purchases to the selected drugs become important.

Strategic selection of drugs to benefit the poor (What to buy?)

One tool available to control costs and make drugs more accessible is an essential drugs list coupled with a generic drugs policy. The development and implementation of standard treatment guidelines and essential drugs lists is generally recognised as an important component of improving drug use in developing countries (e.g. Laing et al 2001). Similarly, it is well recognised that the use of generic drugs rather than brand name drugs, may reduce the costs significantly as these are often sold at 30-50% below the cost of brands (WHO 2002). The majority of drugs in the WHO model Essential Drugs List is out of patent, making general use of generics quite feasible.

One issue that is rarely clarified is what the adoption of an essential drugs list implies for the supply of other drugs. Does it imply that only drugs on the list should be subsidised, while other drugs may be available at full cost to the patient or does it imply that drugs outside this list are to be purchased in private markets? In Bhutan, drugs are provided free of charge when prescribed by an authorised health staff. Only drugs on the essential drugs list can be prescribed unless there are very special circumstances under which the therapeutic committee may accept deviations. Drugs not on the essential drugs list and brand drugs can only be purchased and given free to patients if it is part of a treatment strategy started while being treated on referral abroad (Bhutan relies to a large extent on contracts with hospitals in India for tertiary referral services.). Bhutan buys generic drugs through international competitive bidding and use part of the savings for quality testing of drugs received by high standard laboratories abroad (e.g. Bangkok).

Usochukwu et al (2002) in a study of the Bamako Initiative in Nigeria, which aims at providing basic essential drugs prescribed under generic names, found that 93% of prescriptions were for drugs on the Essential Drugs List and 80% were generics. While these are relatively high percentages, it still signifies that the essential drugs list is not strictly adhered to as some 'unauthorised' drugs are kept in the health facilities.

In a review of 82 insurance schemes for the non-formal sector, Bennett, Creese and Monasch (1998) found that benefit packages were generally weakly defined. Very few of the schemes had a pharmaceutical policy, although one scheme in Tanzania (UMASIDA) contracts care from providers who among other conditions agree to restrict drug use to the WHO-approved essential drugs list and agree to prescribe only by generic name. A local medical doctor hired as technical adviser to the scheme monitors the prescribing habits of providers. Also, one scheme in India (SEWA) adopted selective contracting with providers and use of essential drug list.

Atim (1998) found that only 4 Mutual Health Organizations out of 65 studied in Central and West Africa reported that they were practicing an essential drugs and generics policy. Similarly, Musau (1999) found that cost controls through use of essential drug lists, standard treatment guidelines and generics is not consistently practiced in the 5 East African insurance schemes studied. Only few studies looked at the enforcement of an essential drugs list policy and generic drugs for refunds under the insurance scheme. Atim (1999) examining two community financing schemes in Ghana and Cameroon concluded that no such enforcement took place. In the UMASIDA scheme, see also above, a provider who violates the agreement on essential drugs, will not be reimbursed (Bennett, Creese and Monasch 1998).

One constraint for the implementation of an essential drugs and generics policy is the widespread preference for brand drugs and the perceived linkage between brands and quality. Al Serouri et al. (2002) in a review of cost-sharing and drug revolving schemes in Yemen found that drug policies vary across schemes, with some schemes restricting drugs to the essential drugs list, while others have no such restrictions and with some purchasing generic drugs in the international market and others buying from the local market. However, most of the cost sharing schemes have started using the essential drugs list guidelines, which has resulted in a decrease in the use of injections, IV drips and syrups. Patients perceive this as a deterioration of services and are disappointed with the very limited drug lists and the quantity of drugs provided. Similarly most facility directors perceived the limitations in the list as a deterioration in quality of services. Likewise there was dissatisfaction with the (generic) drugs from India rather than (brand) drugs imported from the Emirates, as the former is perceived to be of poor quality.

The province of Shanghai, China, introduced an essential drugs policy combined with a cap on hospital revenue to contain drug expenditures. Drug expenditure data over a period of five years suggest that this combined intervention resulted in a dramatic and continuing decline in the growth of drug expenditures and per visit drug expenditures (Hu et al 2001).

Essential Drugs Lists must be updated regularly, adapted to local context and vary for different levels of care (WHO 2001). While many countries have adopted an essential drugs list, see also Figure 1, the problem has been to a) regularly update the list, and not just adding, but also

excluding drugs; b) establishing clear criteria for inclusion on the essential drugs lists (including targeting of the poorest), c) adherence to the essential drugs list by prescribers (even in ordering and procurement); d) development of locally adjusted lists. Many countries have, however, now started indicating the level of use for each drug on the essential drugs list, e.g. dispensary, health centre, general hospital or referral hospital (Laing et al 2001). Finally, little attention seems to have been given to increasing awareness and acceptance in communities to stimulate the demand for generics.

Selecting suppliers (From whom to buy?)

RAP arrangements have various strategic options for choosing from whom to buy the drugs. This entails a decision about at which level to purchase, retail or wholesale, and whether to use public or private suppliers. I.e. should the RAP agent enter into agreements which allow the patient to collect drugs from local retailers, e.g. SEWA in India, where the only requirement is a medical prescription by an authorised doctor (Ranson 2002), or should the RAP agent itself procure and supply drugs, as is the case in some community financing schemes, e.g. in Yemen (Al Serouri et al 2002), and in most government systems? The potential suppliers of drugs include:

- *Public supply agency*: Until recently the standard approach in many developing countries has been to have a centralized public system such as a government Central Medical Stores supplying drugs to government health facilities and essentially having a monopoly, see also Box 3 for example of Tanzania. Some countries have started a process of transforming the central supply agency into a parastatal or autonomous agency in order to stimulate accountability and more businesslike operations, e.g. Kenya, Ghana. There are also examples of decentralised public supply agencies, for example in Guyana.
- *Producers*: Drugs could be purchased directly from domestic or international producers of drugs. It may be government policy to restrict purchases from international producers, due to constraints on use of foreign exchange, e.g. Mauritania (Audibert et al. 2000), or a policy to protect home industry (e.g., previous to the WTO-TRIPS agreements most developing countries –including India and Argentina- had a policy requiring local manufacture of drugs.)
- *Private supply agency*: This could be either a private for profit supply agency who has specialized in procurement and distribution of drugs, i.e. Crown Agent's, or a non-profit organization such as MEDS (mission based) in Kenya.
- *Private retailers*: The RAP agent may choose to allow patients to buy from any retailer, from retailers licensed by the public authorities (e.g. SEWA, India) or from licensed retailers abiding to certain additional criteria set by the RAP arrangement (e.g. UMASIDA, Tanzania) (Bennett, Creese and Monasch 1998). Sometimes RAP agents purchase drugs for resale from private pharmacies as is the case in Laos (Murakami et al. 2001).

Box 3: Tanzania Drug Supply system

All medical supplies for government health facilities, including drugs purchase with Government of Tanzania funding, are purchased from the Medical Supplies Depot (MSD). This has now been set up as a non-profit autonomous institution.

While the Government of Tanzania is generally pursuing a decentralization strategy and is increasingly decentralizing line ministry budgets and functions, this is not happening for the drugs budget. Resources to be used for drugs by local health care facilities are part of the MOH budget. MOH uses an internal allocation formula for drugs to allocate the available resources to internal accounts from which local government can purchase drugs from the MSD.

The principle for allocation of funds is first to ensure the drugs are allocated for facilities below the district hospital level. MSD uses a 'push' system for allocation to health centers and dispensaries. All health centers receive the same blue kit once a month and all dispensaries receive the same yellow kit once a month. The second priority is to ensure supply of vaccines.

Remaining funds are allocated to hospital accounts with MSD according to a population-based formula, which is however mainly historically determined. For hospitals a 'pull' system (demand driven) is used. Once indicative budget ceilings for the hospital drug accounts have been made, hospitals can order drugs against the national essential drugs list. The hospital has the right to procure from other suppliers if MSD fails to deliver within a specified period of time (max. 2 months). The hospital must adhere to price settings as developed by the MOH.

An important issue is to ensure the quality of suppliers. Regulation is an important tool to ensure quality and equal access, in terms of the quantity and location of pharmacies. This may take place through registration and licensure arrangements and monitoring by regulatory bodies. Insurance schemes may, for example, restrict the financing of members' use of pharmaceuticals to such that have been prescribed and dispensed only by licensed practitioners or pharmacists.

A further strategic question is whether to accept prescribing and dispensing by the same person. The clinics and pharmacies may be licensed to undertake different activities. E.g. in Zimbabwe private practitioners are not allowed to dispense drugs, except under certain circumstances (long distance to nearest outlet) (Bennett et al. 1994), whereas in many other places, for example in Ghana and India, the private clinics are allowed to offer integrated services, i.e. including dispensing of pharmaceuticals. Bennett, Creese and Monasch (1998) found that some Southern African countries have been able to regulate the retail market quite tightly, e.g. Zimbabwe, whereas West African countries are generally less well regulated, e.g. Senegal and Nigeria. A key problem in relation to the regulation of health services and pharmacies is the lack of enforcement, see also Asibuo and Ampofo (2001) for the case of Ghana. The weak enforcement results from lack of human resources, lack of financing and lack of commitment in an environment often focusing much on direct service delivery.

The process of selecting from whom to buy drugs is important. Active competition between public and private sector on price, quality and volume of services at the stage of selecting the providers is likely to reduce prices and result in increasing value for money and affordability. The evidence of effects of shifting to increased competition and the establishment of autonomous supply agencies in developing countries is still limited.

PRICING AND INCENTIVE REGIMES

The nature of the market for pharmaceuticals, e.g. the information asymmetries, the combination of a relatively competitive retail market and a less competitive production and wholesale level, poses a substantial risk of supplier induced demand, irrational prescription, over pricing and unequal distribution. Behavioral changes may be stimulated through financial incentives, penalties or other regulatory measures. The main intervention areas include the design of payment mechanisms, incentives for geographical distribution and control of prices.

Payment mechanisms for health services (How to pay?)

The payment mechanisms for health services may affect the prescription of pharmaceuticals. Success in meeting the users' actual or perceived needs and demand and thereby retain clientele is vital to the economic survival of providers. Given the market and institutional context, which incentives do the various mechanisms for payment provide towards reaching drugs to the poor? To what extent does it provide incentives for efficient use of drugs, for equitable use of drugs (targeting of drugs to certain groups), for use of drugs that are responsive to demand and for drug consumption that effectively improves health status?

Payment for consultation and medicines can either be combined in one fee or split. The joint fee encourages trade offs and reductions in prescriptions. Split fees at least, even when drugs are unaffordable, allow the patient the opportunity to obtain relatively cheap advice. Potentially a split fee would therefore be favorable to improving health of the poor, although it seems that when having to choose between advice or drugs, the majority seem to prefer the drugs. In developing countries the most common practice is to charge for drugs separately as reflected in the high share of pharmaceutical expenditures being privately financed.

Where sources, management of finance and provision of services are separated, the payment for drugs can take place in a variety of contexts relating the RAP agent and providers. Where the finance and management has not been separated, the flow of funds would typically be from the MOH to government providers, and from private insurers to providers. Different payment mechanisms can be used for the different provider institutions such as hospitals, primary health care and pharmacies or for different services delivered within an institution, i.e. typically for example a drug revolving fund arrangement for hospital pharmacy unit. There are three general types of provider payment which have different incentives for prescription of drugs:

- *Budgetary transfer*: Budgets may be allocated in the form of earmarked line-item budget for medicine and supplies, with no reallocation between budget lines allowed (conditional grant). While this mechanism is used to protect the budget, it also does not provide any incentive for efficiency through trade offs across budget lines. Alternatively, global budgets allow reallocation across budget lines in order to optimize resource use. Global sub budget, e.g. Other Charges, including pharmaceuticals also occur.
- *Capitation*: Capitation payment is not so common in developing countries. Prepayment schemes in Rwanda, however, covers a basic package including drugs, and pays health centers for providing this package by capitation (Schneider et al. 2000). Preliminary findings suggest that members seek care earlier, and therefore need fewer drugs and recover faster. However, where capitation payment includes drugs, there is also a risk of

under prescription. Where drugs are not included in the package, prescriptions may be a convenient way to get rid of patients thereby potentially minimizing workload.

- *Fee for service*: This is the most common payment mechanism for private insurance. It provides incentives for increasing the number of services. Apart from the incentive to increase prescriptions, when drugs are actually dispensed by the provider, the prescriptions may be a convenient way to get rid of patients fast and therefore increasing the throughput, and furthermore a tangible symbol that the doctor has understood and taken charge of the problem and a response to patient demand for a technical solution, which should increase the likelihood of patients returning for care.

More complex systems with targeted incentives are likely to have higher administrative costs. In countries with low levels of institutional development, reforms should be limited to simple alternatives such as budget reforms or modest capitation schemes.

In addition to the modality of payment, decisions on the flow of funds are important. There are two major options for channeling payment to providers. The patients may make the payment with full or partial reimbursement later through the RAP agent (indemnity cover), or the payment may be made directly from the RAP agent to the provider. Some community financing schemes rely on third party reimbursement of members, e.g. SEWA (India), others pay providers directly, e.g. UMASIDA (Tanzania) (Bennett, Creese and Monasch 1998). The community scheme's ability to negotiate preferential rates affects the sustainability of the scheme. This role is strengthened through direct payment to the provider by the scheme, and is weakened when the direct relationship is with the patient to be reimbursed, and is outright discouraged when using lump sum of fixed compensation to members, as in an example from Cameroon (Atim 1999).

The payment of drugs by the retail level to the wholesale level also has some implications for prescription behavior and access to drugs. When health facilities just receive drugs through a push system (kit system), accountability is likely to be low as compared to a demand-driven (pull) system in which health facilities order and purchase drugs using either funds held locally (cost sharing funds, decentralized budgets) or in central accounts earmarked for drugs by health facility or by district health services.

Other incentives for rational prescription and dispensing

Financial incentives may also be used to stimulate rational prescription. One strategic option is to separate the prescribing and dispensing function. There are a number of examples where allowing health staff to raise revenues from sales of drugs has resulted in a large increase in drug prescriptions (e.g. Vietnam (Witter 1996), India (Govindaraj and Chellara 2002). Evidence from Zimbabwe clearly shows that dispensing doctors prescribe significantly more drugs per patient than non-dispensing doctors, inject more patients and prescribe more antibiotics and mixtures per encounter (Trap et al. 2002). The presence of the dispensing function does not appear to be related to use of essential drugs and generics. To effectively enforce a regulation that separates these functions is quite a challenge, see also the section on Supply side intervention below.

Musau (1999) found that clinicians tended to prescribe more, even over prescribe, and to prescribe more expensive drugs to members of insurance schemes than to non-members simply because they have insurance coverage. Atim (1999) looked at whether community financing

schemes evaluate the appropriateness of the care provided to members, i.e. prescribing practices, and found that they did not. Examples of schemes that do monitor prescriptions are the SEWA scheme in India and the UMASIDA scheme in Tanzania (Ranson 2002, Bennett, Creese and Monasch 1998).

In Nepal, the effect of different systems of nominal user fees for drugs was evaluated. A system of a user charge per prescription was compared to a system with user charge per drug item prescribed. Efficiency was clearly improved with fewer drugs prescribed per patient , lower costs per prescription, lower wastage due to inappropriate prescribing and larger share of prescriptions adhering to standard treatment guidelines (Holloway et al. 2001, Holloway et al. 2002).

Finally, assuming that the prescriber is the dispenser, or that there is a generics prescription policy allowing substitution by the dispenser, different types of dispensing margins create different incentives for rational prescription and use of generics. Whereas cost plus a fixed percentage mark up encourages dispensing of the most expensive (brand) drugs, a declining mark up percentage with increasing price may reduce this incentive. Mark up with a fixed dispensing fee is neutral, but dispensing of generic drugs may be actively stimulated using a variant of the fixed dispensing fee strategy by allowing a higher fixed fee for generics. Experience with applying such dispensing margins effectively in developing countries is limited, but the economic incentives behind the failure to adhere to known regulations are strong. Respondents in a study among pharmacists and pharmacy owners in Tanzania (Kumaranyake et al. 2003) cite the cost of following regulations in terms of hiring qualified staff and losing revenue by refusing to dispense without a prescription as the main reason for lack of adherence to regulations.

Incentives to locate in remote/uncovered areas

Opening of pharmacies in remote areas may be stimulated with incentives also, e.g. the attempt in Kenya to do so through the establishment of community pharmacies with limited range of drugs in underserved areas (Gilson et al 2001). Incentives could include investment loans, free provision of certain supplies, tax incentives, subsidised purchase of drugs from CMS (joint procurement). Distribution of pharmacies can also be directly regulated: Tanzania in the 1990s legalised private practice for pharmacists (Hongoro et al. 2000) and Ghana has regulations regarding the minimum distance between pharmacies (Asibuo and Ampofo 20001). The legislation restricts registering of new private pharmacies in areas where it is deemed there is an adequate number (distribution) but it is not clear what happens in practice (Kumaranayake et al. 2000). Similarly, the Zimbabwean Medical Services Act of 1998 gives authority to the Minister of health to regulate a wide variety of practices and actors related to the private for-profit sector. No specific measure has, however, been undertaken (Kumaranayake et al. (2000)).

Controlling prices

A number of issues arise in relation to the price at which drugs are purchased on behalf of the patient. Governments can regulate costs ex-factory or by instituting mark-up mechanisms applied to both wholesale and retail facilities. Prices may be set locally or centrally, and prices may be set at actual cost, at actual cost + a mark up (percentage or flat rate) or as a flat rate, e.g. per prescription or per drug item. The choice will have different implications for behaviour, e.g.

example of Nepal above. The implementation of a price control mechanism does not guarantee that it will be followed, that requires that the government is able to monitor and enforce the mechanism. There is little systematic research on the rates of domestic markups and how well markups are enforced (Levison 2003).

In Nepal, the official mark-up is 16%; however, due to lack of surveillance and high demand, retailers receive as much as 100 % mark-up (Levison 2003). Lack of price guidelines and control may further result in large variation in fees charged across the country, e.g. in Kenya (see also Gilson et al 2001). The Cash and Carry system in Ghana essentially requires all government institutions to pay for the drugs they collect from the Regional Medical Store (RMS) at time of collection. The RMS in turn will pay for the drugs they collect at Central Medical Store (CMS). To ensure sustainability the fee per drug item charge to users is related to the procurement cost of the item marked up with fixed percentages. According to guidelines there should be a mark up on CMS procurement cost of 46% when reaching the patient, corresponding to 33% of RMS purchasing costs from CMS. A study of drug prices charged in health facilities in one region of Ghana, however, revealed that in practice the mark up varies a lot between facilities (from 11% to 275% by drug item) and on average is higher than the 33% (Nyanator et al. 2002). This is especially the case for hospitals. It appears that these sometimes procure drugs from the private market, where prices are higher. Facilities claim to have operational problems and an easy and attractive solution is to increase drug prices[5].

Price control in the private sector is equally difficult. Bennett and Ngalande-Banda (1994) found no example of government regulation of private practitioners fees in African countries. There is no reason to believe that governments would be any more successful in controlling prices for private pharmacies. It is extremely difficult to regulate the sector partly due to the diversity of services and partly due to lack of organizations to negotiate with. In terms of price regulation there are very few regulations in Tanzania and Zimbabwe, mostly pertaining to salaries (Kumaranayake et al. 2000). At the market level, there is very little regulation found, except for the sale and import of drugs into the local market.

A key problem is enforcement. Kumaranayake et al. (2000) found that ”current regulations in Tanzania and Zimbabwe 1) focus on individual inputs rather than health system organizations; 2) aim to control entry and quality rather than explicitly quantity, price or distribution; and 3) fail to address the market-level problems of anti-competitive practices and lack of patient rights.” In Costa Rica the price control scheme has been in force for twenty years and its functioning has serious problems due to the difficulties which the authorities face in carrying out the required controls and monitoring of the retailer’s and pharmacist’s profit margins.” (WHO 1995). Further there is limited staff and funding available to enforce mark-up margins and it is especially difficult to monitor and enforce at the lowest level, food stalls.

Price regulation has been used extensively in parts of Asia (Berman 1997). One solution to the problem of enforcement of price control is practiced here. In India drugs are categorised into

[5] The Cash and Carry system constitutes a revolving drug fund financed entirely from user payment, but at the same time sale of drugs also constitute the main source of user fee revenues for the health facilities.

several broad classes to which different degrees of price control applies. The strictest price control is on the most essential drugs, for which the retail price is to be clearly specified on the drug containers for easy reference to the consumer. Similar systems can be found in Pakistan and other parts of Asia. One possible negative effect could be that the strict control on price may discourage production of the essential drugs compared to other less regulated drugs.

The purchasing agencies have a potential role in controlling that regulations are adhered to and a potential role in bargaining for low prices. Bennett, Creese and Monasch (1998) found only one scheme out of 82 insurance schemes for the non-formal sector (ORT scheme in Philippines) that had managed to negotiate favourable prices for essential drugs from local suppliers. Atim (1999) assessed whether community financing schemes evaluated invoices and negotiated prices. Neither of the two schemes studied did so. Musau (1999) found that one scheme in East Africa, the Mburahati Health Trust Fund in Tanzania, that had an essential and generics drug policy, also had a clear pricing policy. The dispensing agent is obliged to use prices according to the price list that is attached to the contract. These prices are based on the use of generic drugs and even if brand name drugs were dispensed, the dispensary can only bill the price of the generic drugs.

Keeping mark-ups too low on the other hand in an attempt to obtain low prices, may also cause problems. Some community financing schemes and drug revolving funds, where appropriate estimates of necessary mark ups, taking into account future inflation and exchange rate development and selling at expected replacement costs including operational costs of storage distribution and loss, were not made, has faced significant problems with sustainability (Gilson et al. 2001).

ORGANIZATIONAL AND INSTITUTIONAL ARRANGEMENTS

Organizational and institutional arrangements set the framework within which RAP arrangements works. RAP agents have different opportunities in a decentralised system that allocates authorities differently than in a centralised system and the existence of pooled purchasing arrangement allows better planning, prices and quality. Drug policies set out the general framework and guidelines and together with the regulatory framework sets out the rules of the game for the sector. In this section we shall briefly outline the issues and experiences.

ORGANIZATIONAL ISSUES

The private retail drug market in developing countries is highly dispersed, relying largely on individual transactions in an open market. Establishment of community financing and other insurance schemes represents an increasing concentration on the demand side, although these schemes are still to effectively function as active purchasing agents, bargaining for drug price and quality and setting restrictions on drug use. Most countries also have some sort of third-party payment system, which often includes drug benefits but requires a copayment and limits drug use to a defined list of drugs. In some countries, separate drug benefit schemes exist. This separation provides cost-shifting incentives that may not be optimal from a societal point of view as cost minimizing health plans may urge providers to prescribe drug intensive strategies financed under the separate drug plan rather than alternatives.

Health care providers and pharmacies may be licensed to undertake different activities. In Zimbabwe, for example, private practitioners are allowed to dispense drugs only under certain circumstances (long distance to nearest outlet) (Bennett and Ngalanda-Banda 1994). In other places, like Ghana and India, private clinics are allowed to offer integrated services including dispensing of pharmaceuticals. The lack of separation between prescribing and dispensing roles, particularly in Asia, gives practitioners an incentive to overprescribe, because the prescription is directly linked to financial gains. In fact, the number of prescriptions written is higher when prescribing and dispensing functions are combined (Witter 1996, Govindaraj and Chellara 2002, Trap, Hansen, and Hogerzeil 2002).

While government RAP agencies are often tied to purchasing from the public sector supply agency, this is not the case for many community financing and insurance schemes. Public sector RAP agencies at decentralized level are also increasingly free to use other sources for procurement. A key question is, however, how the quality of drugs is ensured and whether the benefits of purchasing from smaller supply agents in a competitive environment exceeds the benefits of large-scale procurement through centralized procurement agents with the inherent inefficiencies of monopoly public sector institutions.

The health sector reform process in developing countries often entails a combination of measures like strengthening of the district health services and giving autonomous status to major hospitals as well as to the government medical stores, e.g. Mozambique, Ghana, Tanzania, Uganda, Zimbabwe.

While the pharmaceutical area is yet to be decentralised to the same extent, the reality is that the health services in general are increasingly being decentralised. The impact on reaching drugs to the poor is, however, yet to be evaluated.

Fragmentation of purchasing functions is often a problem. With increasing decentralisation there is a risk of an increased number of smaller decentralised procurement units which could potentially result in decreasing effectiveness. On the other hand the benefits of pooled purchasing has been shared with the private non-profit sector by allowing private providers in many countries (e.g. Ethiopia, Ghana, Tanzania, Uganda, Zambia, Zimbabwe, Malawi) to purchase drugs from government stores (Bennett and Ngalande-Banda 1994).

In Mozambique drug imports are largely financed by donor assistance. In the past the lack of coordination in drug procurement resulted in huge inefficiencies (Pavignani and Durão 1999). The practice was that types and quantities of medicines to purchase was decided only after a donor had allocated a specific amount. This was not satisfactory as it was subject to unpredictable funding, erratic purchasing cycles, difficulties with long term planning and tied donations which resulted in frequent stock outs on one side and expiring drugs on the other side. The decisions on what to buy in which quantities were very much offer driven and drug imports expanded or shrank according to the available external financing and donor priorities. A number of agencies pushed for restructuring based on the MOH's own specification of needs based on agreed criteria. The donor group pooled their funds and responded to the needs according to the government's priority. In Mozambique, a common pool for drugs, *Fundo Comum Medicamentos*

(FCM), has been in operation since 1997-98 and currently 7 donors are making multi-year commitments to and disbursing through the FCM.[6]

The potential benefits of pooled purchasing is also illustrated by the case of multinational purchasing pools for HIV drugs in the Americas, see also Box 4. According to UNAIDS figures, almost 2 million people are living with HIV/AIDS in Latin America and the Caribbean.[7] The Caribbean, with about 500,000 people living with HIV/AIDS, has the second highest HIV prevalence rate after sub-Saharan Africa.[8] The higher prices of antiretroviral drugs to treat HIV/AIDS makes it difficult for patients to pay out-of-pocket for the drugs and for public and private insurance to make the treatment accessible to patients. Prices of antiretroviral drugs to treat HIV/AIDS dropped in Latin America and the Caribbean countries as a result of negotiated agreements between ministries of health and pharmaceutical companies.[9] However, the prices still were high in comparison to generic prices in countries like India. There were also wide differences between countries, with some countries paying up to 10 times more for the same treatment.

Box 4: National and Multinational Purchasing Pools: The Case of HIV Drugs in the Americas

National purchasing pools: Prices of antiretroviral drugs to treat HIV/AIDS dropped in Latin America and the Caribbean countries as a result of negotiated agreements between ministries of health and pharmaceutical companies (1). A PAHO survey compared the prices of drugs purchased in May 2001 and May 2002 by the ministries of health of 14 countries in Latin America and the Caribbean. To calculate the annual cost of treating a person living with AIDS, PAHO selected two of the most common combinations of antiretroviral therapies. On average, the reductions for 3TC/ZDV+NVP were 25 percent (from US $3,701 to $2,746). For 3TC/ZDV+EFV, the prices decreased 54 percent (from $5,506 to $3,737 to $2,499). (1)

However, the prices still were high in comparison to generic prices in countries like India. There were also wide differences between countries, with some countries paying up to 10 times more for the same treatment. These results from the price surveys confirmed the need for mechanisms to facilitate the multinational purchase of antiretroviral drugs (2).

International purchasing pools: The Caribbean Community (Caricom) became the first region in the history of HIV/AIDS to negotiate price reductions. On July 10, 2002, the Caribbean countries and six pharmaceutical companies signed an agreement that significantly reduced the cost of drugs for treating HIV/ AIDS in the region. The negotiated annual price of ARV combinations dropped to $1,100, similar to prices offered to Sub-Saharan countries for brand name ARV (3).

[6] The Fundo Comum Medicamentos has been managed by the central store for drugs and medical supplies, CMAM, with administrative support in financial management from Swiss Development Corporation on behalf of the consortium of donors. The competence demonstrated by central health authorities in running operations is high and a high level of openness among the partners over the years has produced a conducive environment. During 2003 CMAM and SDC will work closely together to build the necessary capacity for transfer of management.

[7] www.unaids.org

[8] PAHO. UN Groups Strengthen Response to HIV/AIDS in the America. Available on the Internet: www.paho.org/English/DD/PIN/pr030611.htm . Accessed on June 28, 2003.

[9] PAHO. AIDS Drug Prices Drop 54% in Latin America, Caribbean. July 18, 2002. Available on the Internet: http://www.paho.org/English/DPI/pr020718.htm. Accessed on June 28, 2003.

The lead of the Caribbean Community was followed in February 2003 by countries of Central America (Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua, and Panama). For those countries in the region participating in the agreement, the annual price of first-line triple therapy was further reduced to between US$ 800 and US$ 1,200 per patient (4).

The third Latin American and Caribbean agreement was signed by Peru, Bolivia, Colombia, Ecuador, Venezuela, Chile, Argentina, Mexico, Paraguay, and Uruguay. In the 10 countries, the prices of first-line therapy (the most common treatment for people living with HIV) will be reduced between 30 percent and 92 percent. Initially, the therapy prices varied from $1,000 to $5,000, but after the negotiation, they will fluctuate from between $350 to $690. The Lima negotiations also included prices of laboratory reagents which are used for diagnosis and follow up. Five manufacturers of reagents offered reductions from 62 percent to 81 percent for the rapid tests for diagnosis, from 13 percent to 33 percent for the ELISA test, from 5 percent to 70 percent for the CD4 count test, and from 22 percent to 82 percent for the viral load test. The agreement will allow the countries to save up to $120 million a year, which amounts to 150,000 annual treatments (5). All the companies meet the quality requirements established by the negotiating countries which are based on standards outlined by the World Health Organization prequalification process.

Brazil's generic development and production policy managed to reduce prices at the lowest levels in Latin America before the regional negotiations. Brazilian prices of 3TC/ZDV+NVP fell from $1,408 to $635 in 2002. Nevertheless, Brazilian prices are higher than generic drug prices in the Lima negotiation suggesting possible savings from the use of multinational purchasing negotiations.

Sources: (1) PAHO. AIDS Drug Prices Drop 54 % in Latin America, Caribbean. July 18, 2002. Available on the Internet: http://www.paho.org/English/DPI/pr020718.htm. Accessed on June 28, 2003. (2) Resolution of the 42nd Directing Council, PAHO. (3) James C. Caribbean deal aims to cut cost of treating AIDS. Drugs Prices to Fall by up to 90%. Section: The Americas; Pg. 10. Financial Times (London). July 10, 2002, Wednesday London Edition 2. (4) PAHO. Prices of AIDS drugs in Central America cut more than half. February 7, 2003. Available on the Internet: www.paho.org/English/DPI/pr030203.htm. Accessed on June 28, 2003. (5) PAHO. New Negotiations Lower Prices of HIV Drugs in 10 Countries of the Americas. June 12, 2003. Available on the Internet: www.paho.org/English/DD/PIN/pr030612.htm. Accessed on June 28, 2003.

An analysis of the Latin American and Caribbean negotiations for HIV drugs suggests that regional pooling procurement benefits not only countries with small size markets, high need, lack of private insurance, and lack of pharmaceutical industry like Central America and the Caribbean, but also large markets with an established pharmaceutical industry like Argentina, Colombia and Mexico. The use of generic manufacturers prequalified by WHO allowed for more price competition and further reduction of drug prices

With increasing decentralization, competitive procurement may also be introduced by local RAP arrangements, either by selection between procurement agents or by own-procurement (local tendering). Increasing the number of smaller procurement units, however, could reduce the drug procurement efficiency.

INSTITUTIONAL ARRANGEMENTS

Many governments in developing countries have developed national drug policies to ensure efficacy, safety and rational prescription mainly in a comprehensive approach including competitive bidding, management control, distribution strategy, educational activities in rational use of drugs, premarket registration, licensing and other regulatory requirements. However, evidence of the impacts of national drug policies on actual use of medicine is weak.

Evidence of the impacts of national drug policies is limited. Ratanawijitrasin et al. (2001) identified only few studies in this area, all of which fairly old and with a relatively weak design. There seems however, to be some indications that combined approaches may have advantages in terms of impact, e.g. simply supplying drugs to health facilities will not necessarily improve drug use.

One important element in increasing access to medicines is to strengthen the national and local level public sector drug supply systems and supply capacity in a way that would support countries to run efficient public sector drug supply systems ensuring the availability of essential drugs at all levels of the distribution chain. Strengthening of drug procurement and supply system including allowing international competitive bidding along side other efforts such as the Bamako Initiative was an important factor behind the relative success of the Benin community financing schemes compared to Zambia and Kenya, where the weaknesses in drug supply and distribution systems persisted, in terms of increasing access to drugs (Gilson et al 2001).

Similarly, Oliveira-Cruz et al. (2001) identified three studies, that are mostly positive on the impact of such reforms, but the evidence base remains weak. Ratanawijitrasin et al. (2001) conclude that ”the question … - Do national drug policies and essential drugs programs improve drug use? – is not answerable at present, due to lack of reliable data.”

The combination of high prices transferred from the concentrated wholesale drug market to the retail level and the pressure put by the competitive environment of the retail market on quality and information asymmetries generates a challenge for the regulatory environment and quality assurance system to ensure affordable prices and standard drug quality. For a successful generic drug policy, continued trust in the quality of drugs is essential. Bhutan is an example of a country that buys generic drugs through international competitive bidding and uses part of the savings for paying for drug-quality testing in high-standard laboratories in Bangkok.

The decentralisation of control over drug budgets have been particularly slow, though. Drug budgets in government facilities are quite often given as conditional grants, i.e. they are earmarked for drugs and medical supplies, and are often tied to purchases with one supply agent, the government medical store, often controlled by the Ministry of Health. While in principle a pooled procurement system if run effectively are likely to be more advantageous, the district medical services might in practice find that a large private sector supply agent, for example for the mission sector (e.g. MEDS in Kenya), are able to provide supplies at competitive prices and qualities.

The decentralisation puts an increasing focus on distribution of resources within the countries and objective and transparent resource allocation mechanisms are receiving increased attention under the realms of the implementation of national Poverty Reduction Strategies. This seems to be resulting in increased allocations to deprived areas, and is potentially a step forward to reaching resources to poor areas, e.g. Ghana, Malawi, although the effects are yet to be properly evaluated.

In some countries the decentralisation has resulted in a weakening of the regional health service, as for example in Tanzania, which threatens the already weak monitoring and supervisory

functions that is important for addressing issues of rational prescription, drug store management etc. Further it potentially weakens the possibilities for monitoring and enforcing adherence to regulations.

Regulation is a key instrument employed by many governments to modify the behaviour of drug systems. The market is characterised by a large number of individual transactions, which makes the regulation regarding entry and quality more important. Further, the high risk of supplier induced demand due to high financial pressures on poorly paid civil servants (McPake et al. 1999), the large information asymmetries in societies with low literacy rates and the lack of effective separation between prescriber and dispenser, some kind of regulation is needed. Regulation may pertain to quality, quantity and price. With a large private and dispersed market with many 'unauthorized' pharmacies and drug sellers and few resources for regulatory activities, there are significant difficulties and cost of enforcement, which would imply that use of incentives may be more effective than regulation. Most low income countries have not yet successfully regulated the pharmaceutical market.

To ensure quality and to provide appropriate incentives for prescription, regulatory control is needed to determine which health professionals are authorised to prescribe and dispense medicines. Licensing may include setting standards for building, equipment and staffing, whereas regulation of actions of providers may include restrictions on the dispensing of certain pharmaceuticals without a doctor's prescription.

There is only little documentation on the effects of regulatory measure regarding pharmaceuticals in developing countries, see however Box 5 for the experience of Laos.

There is a basic legal regulatory framework present in most countries, but it is often weakly enforced (Kumaranayake 1997). Despite the fact that regulations governing the private sector exist in most countries, the enforcement of regulatory controls is often lacking or at best weak. Effective regulation requires sufficient state capacity to collect information, devise sound rules and monitor and enforce compliance. Capacities in these areas are typically weak in developing countries.

Box 5: Regulation of the private pharmacy sector in Laos

The role of the private pharmacy sector: In Laos the private provision of drugs has increased dramatically over the past decades from 32 private pharmacies in 1986 to 1990 in 1999. In 1996 private pharmacies accounted for 75% of the value of drugs sold. Most drugs are purchased without prescription and poly-pharmacy and overuse of antibiotics and injections are widespread. Low socio-economic status groups are very dependent on the private pharmacy sector, which caters for more than half the health care seeking contacts in this group, much higher than for the high socio-economic status groups. The private pharmacy sector are now of such a magnitude, that it is not just considered as a competitor to public sector drug revolving funds, but also as the major source of procurement with 40% of health centers and 89% of district hospitals procuring drugs from private pharmacies.

The regulatory system: The government has slowly been responding to the private pharmacy sector development by building up the regulatory capacity within the framework of a National Drug Policy adopted in 1993. The focus or regulation is on registration and licensing as well as quality.

- Entry: Entry into the pharmaceutical sub-sector is regulated through legal instruments and information. Laos has a licensing system that allows those who wish to sell drugs to do so, depending on their qualifications. There are thus three classes of pharmacies with different dispensing rights depending on

qualifications of the license holder, i.e. pharmacists, assistant pharmacists and pharmacist technicians/any other health personnel.

- Quantity: There is no regulation of quantity and distribution of pharmacies, although there has been a number of attempts to use legal measures to restrict number of pharmacies in the large urban areas. Every time this has been met with strong opposition and the changes could not be sustained. The number of brand names is not regulated.
- Quality tends to be lower in remoter districts. Poor dispensing practices prevail, e.g. retailers lack information about the drugs, drugs are mixed in same package, poor labeling. Quality is regulated through legal regulation and information.
- Prices: Drug prices are not controlled or monitored. There is considerable price variation between pharmacies for four sample drugs. Prices tend to be higher in remoter districts, but there is also considerable price variation within districts.

Enforcement: The incentives for enforcing the regulation is stimulated by 75% of money fines being forwarded to central government and 25% being distributed among the inspection staff.

In 2000, a study of four districts found that a district drug inspector was in place in each district. In addition to licensing procedures some rounds of inspections of private pharmacies had been carried out during the year. The quality of the inspections was, however, not optimal. Registers were, however, relatively updated, but the indicator system for monitoring was weak and data invalid, which limits the possibilities for effective regulation. Drug sellers were generally found to have very little knowledge on the relevant regulation of their activities. So far, the system in Laos has not allowed withdrawal of licenses, thus hampering the possibilities to strictly enforce quality criteria.

Sources: Stenson et al (1997), Murakami et al. (2001), Stenson et al. (2001) and Paphassarang et al. (2002). Financing Programme, London School of Hygiene and Tropical Medicine, UK.

In many Asian countries these efforts at regulating are reported to be largely ineffective, due to totally inadequate capacity for enforcement (Berman 1997) and similar problems are abundant in the African region (Kumaranayake et al. 2000). Registration systems are often terribly outdated and regulatory bodies under staffed and under financed, e.g. India (Berman 1997), Ghana (Asibuo and Ampofo 2001). Further the inability of many governments to regulate retail pharmacies is also well-known: drugs that should be available only with a doctor's prescription are often easily obtainable over the counter (Kumaranayake et al. 2003, Mujinja et al. 2003, McPake et al. 1999). Sometimes regulation is also not clear: In Ghana, the Pharmacy Act stipulates that pharmacists can treat "simple ailments of common occurrence where it is not reasonably practical for the patient to consult a medical practitioner." According to Mayhew et al. (2001) it may easily be argued that sexually transmitted infections (STI) does not belong to simple ailments, yet on the Ghana Essential Drugs List STI-drugs are classified as programme drugs which are not subject to the usual restrictions on the need for a prescription.

As described above, in the section on Controlling prices, difficulties also pertain to enforcement of regulations of price and profit margins in both the public and the private sector. Similarly, drug manufacturing standards are also difficult to enforce and spurious drugs are often widely available (Berman 1997).

MAIN RAP ISSUES FOR REACHING DRUGS TO THE POOR

FROM PASSIVE TO ACTIVE PURCHASING OF PHARMACEUTICALS – WHERE ARE WE?

In many developing countries, the health care insurance and provision functions continue to be integrated, although Ghana and some other countries have worked with soft performance contracts within the government and mission sector. A community drug scheme may both collect premiums and supply the drugs (e.g., RDF Nyamira, Kenya, see also Box 6, pg. 37), and facility-based schemes have no separation between supply and demand side. Few insurance schemes for the informal sector act as active purchasers (Bennett, Creese, and Monasch 1998).

Theoretically, active purchasing should be easier to introduce in the area of pharmaceuticals, because drugs are actually purchased outside the health facilities. In principle, larger RAP agents should be better able than small buyers to exert collective consumer influence over large providers, thereby making more effective purchases ensuring high-quality services and drugs at affordable prices. One way forward could be to encourage networking and associations of small schemes to strengthen their bargaining position.

To separate the health financing and provision functions, the separation of ownership and governance can take place through decentralization of ownership, decentralization of the budget process (e.g., to regional or district health authorities), and creation of semi-autonomous agencies. Decentralization and the establishment of agencies is the current trend in many developing countries, but the process has proven slow (e.g., Kenya, Ghana). Several countries experience a process of re-centralization in the national government of functions related with pharmaceutical that were previously decentralized in local institutions. This re-centralization responds to health care crisis. (e.g. Argentina), and particularly to the HIV crisis that generated the establishment of vertical programs at the national level, instead of local programs using decentralized institutions (E.g. Guyana).

FOR WHOM TO BUY?

A main issue for discussion is how to prioritise waivers versus exemptions under resource constraints. The area of exemptions is fairly well researched although not specifically for drugs. Waivers for the poor may be most effectively implemented, if based on a system of pre-identification and a system in which the health facility is compensated for the loss of revenues incurred due to waivers.

Needs-based resource allocation to target people in remote and under serviced areas (who often tend to be relatively poorer) is a strategy spreading as regards general health services, but is still in its infancy in the area of drugs. There is a need for further analysis and evaluation of the strategic options in this regard.

Rational use of drugs is important. The poor and illiterate are especially at risk of being victimised when it comes to prescriptions as well as consumption. Most evidence concentrate on training and educational activities as well as standard treatment guidelines. These interventions are generally found successful. There is, however, a need to look more at the impact of such

activities especially for the poor. Further the focus in most studies have been on the public sector, while irrational drug use is as common in the private sector.

WHAT TO BUY?

Essential drugs, generics rather than brands, would be the prompt response to the above question. Yet while most governments have an essential drug policy, very few community financing and insurance schemes seem to have one. While community financing in general is an increasingly researched area, the drug policies of community financing schemes appear to have received less attention.

The essential drugs policy appears to have been largely effective in terms of increasing availability of essential drugs in facilities, while it is less clear whether the list as such have changed the access and use of the poor to appropriate drugs. Also, the extent to which the drugs on the list are targeted to the needs of the poor needs further investigation.

With increasing number of financing agents it will be a relevant strategy to strengthen the capacity of community financing and small scale insurance schemes to negotiate, monitor and enforce contractual arrangements that effectively stimulates the use of generics. In this context there seems to be a considerable need for building acceptance and understanding of the concept of essential and generic drugs among the users. There is a need to research the effectiveness of various interventions to overcome this perception of poor quality linked with the two concepts.

FROM WHOM TO BUY?

While government RAP agencies are often tied to purchasing from the public sector supply agency, this is not the case for many community financing and insurance schemes. Public sector RAP agencies at decentralised level are also increasingly free to use other sources for procurement. A key question is, however, how the quality of drugs is ensured and whether the efficiency savings of smaller supply agents in a competitive environment exceeds the benefits of large scale procurement of centralised procurement agents with the inherent inefficiencies of monopoly public sector institutions.

It is further an issue whether at retail level to accept that drugs are purchased from the same person or same facility who made the prescription. While it is known that there are differences in prescribing habits, between dispensing and non-dispensing prescribers, little is known about interventions to separate these functions.

HOW TO PAY?

Payment modalities for health services provide incentives for prescription of drugs. The most common practice for government RAP arrangements is to have budgets earmarked for drugs and medical supplies, often tied to spending with a particular statal or parastatal supply agency. The impact on reaching drugs to the poor of various budget transfer mechanisms has not been evaluated. In relation to this, the implications for reaching essential drugs to the poor of push versus pull supply systems needs to be evaluated.

There is fairly strong evidence that linkage of financial gains of prescription to the prescriber increases the prescriptions and that the degree seems to be related to the strength of the

incentives. Not much evidence is available for alternative payment modalities, although capitation seems to result in lower use of drugs. Whether any of these result in the appropriate level of drug use, particularly to the poor is an open question. In this context issues related to the separation of prescribing and dispensing function is also important to look into.

Various interventions to strengthen the bargaining positions, consequent contractual agreements and methods of monitoring and enforcement of RAP agents in general as well as by whether they provide direct payment to providers or merely provide indemnity cover could also be an issue for further research.

AT WHAT PRICE?

A key issue in relation to price is the lack of effective implementation of price controls due to weak capacities in monitoring as well as enforcement of adherence to regulations. Where price regulations exist, they are therefore rarely effective, neither in the public nor the private sector. One possible solution is the requirement of printing maximum retail prices on packages as practiced in India and Pakistan. But then poor people often buy by the capsules rather than by package… There is a need to explore various ways of strengthening monitoring systems and functioning of the relevant regulatory bodies.

An alternative to price regulation is to make use of increased competition to drive prices down. This requires that a mechanism be in place to ensure that quality standards are met. One way of taking advantage of the competitive effects on price is to increase the use of generic drugs. Although many developing countries already have a generics policy and generics seem to have an increasing share of markets, there is still a need to explore effective mechanisms to broaden the use of generic drugs, such as addressing lack of acceptance among users, perceived quality problems, etc.

Prices may also be reduced through more competitive procurement by centralised procurement agencies (international tendering) or by lower level RAP agents in selection between procurement agents or even by own procurement (local tendering). The impact on prices and access of the poor to drugs, however, needs evaluation.

FUTURE RESEARCH NEEDS

In conclusion, the evidence on effect of interventions focused on the poor and disadvantaged is weak, i.e. more research is needed to tell us which interventions will enable us to more effectively reach this segment of the population. There is limited evidence from developing countries on how regulations are implemented and enforced as well as on their overall effectiveness, i.e. whether the regulation had impact and whether the impact achieved was what was intended. Further, there is little information on the functions of community financing schemes and drug revolving funds with regards to purchasing and resource allocation of drugs, and in particular what works for reaching those drugs to the poor.

Box 6: Nyamira Revolving Drug Fund, Kenya

The Revolving Drug Fund has been jointly developed with the District Medical Store (with support from the Belgian Technical Corporation), and the operations are currently intertwined. Three RAP arrangements for drugs are in operation: government purchasing and resource allocation as regards malaria drugs, the revolving drug fund for Nyamira district as regards all other essential drugs and the cost sharing funds held by the health facilities that can potentially be used also for buying drugs.

Who benefits?

- Beneficiaries include all users of public health facilities in the district.
- Exemption system for the poor is in place, but in practice very few are exempted and no exemption cards have been issued.
- Exemptions are made for patients with malaria (but this was directive from MOH and exemptions are reimbursed in kind).
- Cross-subsidization from cheaper to more expensive drugs.

What to buy? In which form? What to exclude?

- The RDF has developed an adjusted essential drugs list based on the Kenya Essential Drugs List taking into account the local morbidity pattern.
- The drugs listed are generics.
- Drugs have to be locally registered (according to National Drug Policy).
- Quantities purchased are based on a 'pull-system', i.e. purchases are demand-driven.
- Drugs that are appropriate for patients, i.e. focus on rational use of drugs.

From whom to buy?

- The RDF collects payment for drugs consumed in government health facilities in the district. The revenue collections are used to pay for drugs at the District Medical Store. Currently, these functions are intertwined.
- Drugs are (exceptionally) purchased using a private procurement agent.

At what price?

- Fixed price lists developed by RDF/DMS taking into consideration replacement costs as well as principles of cross-subsidization, and a margin to cover operational costs.
- Suppliers are chosen based on national competitive bidding (international tender is not allowed due to government regulations).

REFERENCES

Adams I. Implementation of user fee policy in Ghana: A review of the issues (Part 1). *Bulletin of Health Information.* 2002; 1(2&3): 3-13.

Agyepong IA. Reforming health service delivery at district level in Ghana: the perspective of a district medical officer. *Health Policy and Planning* 14(1): 59-69.

Al Serouri AW, D Balabanova, S Al Hibshi. Cost sharing for primary health care. Lessons from Yemen. Oxfam working papers 2002.

Asibuo S K, Ampofo K K K. Review study of health sector regulation in Ghana. Accra, August 2001.

Atim C. Social movements and health insurance: a critical evaluation of voluntary, non-profit insurance schemes with case studies from Ghana and Cameroon. *Social Science & Medicine.* 1999; 48(7):881-96.

Atim C. Contribution of Mutual Health Organizations to financing, delivery, and access to health care. Synthesis of research in nine West African Countries. Technical Report no. 18. Partnerships for Health Reform, July 1998.

Audibert M, Mathonnat J. Cost recovery in Mauritania: Initial lessons. *Health Policy and Planning* 2000;15(1):66-75.

Bennett S, Ngalande-Banda. Public and private roles in health. A review and analysis of experience in sub-Saharan Africa. Current Concerns. SHS Paper Number 6. World Health Organization 1994.

Bennett S, Creese A, and Monasch R. Health insurance schemes for people outside formal sector employment. Current Concerns, ARA Paper number 16. World Health Organization 1998.

Berman P. Supply-side approaches to optimizing private health sector growth. In: Newbrander, W. (ed): Private health sector growth in Asia. Issues and implications. Wiley & Sons 1997.

Bitran R, Giedion U. Waivers and exemptions for health services in developing countries. The World Bank, 2002.

Ching P. User fees, demand for children's health care and access across income groups: the Philippine case. *Social Science & Medicine.* 1995;41(1):37-46.

Circular to hospitals under the hospital capitalization program. Circular CP1/1999. Pharmaceutical Supplies Unit, Ministry of Health, Tanzania.

Ensor T, San PB. Access and payment for health care: the poor of Northern Vietnam. *International Journal of Health Planning and Management*. 1996;11(1):69-83.

Garshong B, Ansah E, Dakpallah G, Huijts I, Adjei S. A study on factors affecting the implementation of the exemption policy in Ghana. *Bulletin of Health Information* 2002; 1(2&3): 22-31.

Gilson L, Russell S, Buse K. The political economy of user fees with targeting. Developing equitable health financing policy. *Journal of International Development. Special issue.* 1995*,*7(3):369-402

Gilson L, Russell S Rauyajin O, Boonchote T, Pasandhanathorn V, Chaisenee P, Supachutikul A Tantigate N. Exempting the poor: a review and evaluation of the low income card scheme in Thailand. PHP Departmental publication no. 30; London School of Hygiene and Tropical Medicine 1998.

Gilson L, Kalyalya D, Kuchler F, Lake S, Oranga H, Ouendo M. Strategies for promoting equity: experience with community financing in three African countries. *Health Policy* 2001;58(1):37-67.

Govindaraj R, Chellara G. The India Pharmaceutical Sector. Issues and options for health Sector Reform. World Bank Discussion Paper No. 437, 2002

Health Research Unit. National report on exemptions study. Ministry of Health. August 2000.

Holloway KA, Gautam BR, Reeves BC. The effects of different kinds of user fees on prescribing quality in rural Nepal. *Journal of Clinical Epidemiology*. 2001;54(10):1065-71.

Holloway KA, Gautam BR, Harpham T, Taket A. The influence of user fees and patient demand on prescribers in rural Nepal. *Social Science & Medicine*. 2002;54(6):905-18.

Homedes N, Ugalde A. Improving the use of pharmaceuticals through patient and community level interventions. *Social Science and Medicin*e, 2001;52:99-134.

Hongoro C, Kumaranayake L. Do they work? Regulating for-profit providers in Zimbabwe. *Health Policy and Planning* 15(4): 368-377.

Hu S, Chen W, Cheng X, Chen K, Zhou H, Wang L. Pharmaceutical cost-containment policy: experiences in Shanghai, China. *Health Policy and Planning*. 2001;16 Suppl 2:4-9.

Kumaranayake L. The role of regulation: influencing private sector activity within health sector reform. *Journal of International Development*. 1997;9(4):641-649

Kumaranayake L, Hongoro C, Lake S, Mujinja P. Mpembeni R. Coping with private health markets: regulatory (in)effectiveness in Sub-Saharan Africa. In Soderlund N, Mendoza-Arana P (eds). The New Public-Private Mix in Health: Exploring the Changing Landscape. Alliance for Health Policy and System Research/EHO: Geneva 2003 - forthcoming

Kumaranayake L, Lake S, Mujinja P, Hongoro C, Mpembeni R. How do countries regulate the health sector? Evidence from Tanzania and Zimbabwe. *Health Policy and Planning* 2000;15(4):357-67

Kutzin, J. Experience with organizational and financing reform of the health sector. Current Concerns. SHS paper; no. 8. Geneva: World Health Organization, 1995.

Laing R, Hogerzeil H, Ross-Degnan D. Ten Recommendations to improve use of medicines in developing countries. *Health Policy and Planning* 2001;16(1):13-20.

Levison, L. 2003. "*Policy and Programming Options for Reducing the Procurement Costs of Essential Medicines in Developing Countries*." Concentration Paper. : Boston University School of Public Health, Department of International Health. Unpublished.

Mayhew S, Nzambi K, Pepin J and Adjei S. Pharmacists' role in managing sexually transmitted infections: policy issues and options for Ghana. *Health Policy and Planning.* 2001;16(2):152-60

Mbugua J K, Bloom G H, Segall M M. Impact of user charges on vulnerable groups: the case of Kibwezi in rural Kenya. *Social Science and Medicine* 1995;41(6):829-835

McPake B, Hanson K, Mills A. Implementing the Bamako Initiative in Africa. A review and five case studies. PHP Departmental Publication No. 8, London School of Hygiene and Tropical Medicine 1992.

McPake B, Asiimwe D, Mwesigye F, Ofumbi M, Ortenblad L, Streefland P et al. Informal economic activities of public health workers in Uganda: implications for quality and accessibility of care. *Social Science and Medicine*. 1999;49(7):849-65.

Ministry of Health. "Public Expenditure Review - Health Sector in Tanzania. Final Report." Tanzania 2001.

Ministry of Health. "Public Expenditure Review Health Sector Update for 2002. Final report." Tanzania 2002.

Mujinja P, Mpembeni R, Lake S. Awareness and effectiveness of regulations governing private drug outlets in Dar es Salaam: perceptions of key stakeholders. In Soderlund N, Mendoza-Arana P (eds). The New Public-Private Mix in Health: Exploring the Changing Landscape. Alliance for Health Policy and System Research/EHO: Geneva 2003 – forthcoming

Murakami H, Phommasack B, Oula R, Sinxomphou S. Revolving drug funds at front-line health facilities in Vientiane, Lao PDR. *Health Policy and Planning* 16(1): 98-106.

Musau, S. N. Community-Based Health Insurance: Experiences and Lessons Learned from East and Southern Africa. Technical report no. 34. 1999. Partnerships for Health Reform, PHR.

Nolan, B and Turbat, V. Cost Recovery in Public Health Services in Sub-Saharan Africa. World Bank, Washington D.C., 1995.

Nyanator F, Asare FBA, Tayvia H. From the central medical store to the patient – a situation analysis of mark-ups on drugs in the Volta Region. *Bulletin of Health Information* 2002;1(2&3):32-36.

Oliveira-Cruz V, Hanson K, and Mills A. Approaches to Overcoming Health Systems Constraints at the Peripheral Level: A Review of the Evidence. Paper no. WG5:15, 1-121. 2001. Commission on Macroeconomics and Health. CMH Working Paper Series.

Paphassarang C, Philavong K, Boupha B, Blas E. Equity, privatization and cost recovery in urban health care: the case of Lao PDR. *Health Policy and Planning*. 2002;17 Suppl. 1:72-84.

Pavignani E, Durao J. Managing external resources in Mozambique: building new aid relationships on shifting sands? *Health Policy and Planning*. 1999;14:243-253.

Poullier JP, Hernandez P, Kawabata K, Savedoff WD. Patterns of Global Health Expenditures: Results for 191 Countries. EIP/HFS/FAR, Discussion Paper No. 51. World Health Organization 2002.

Preker et al. Resource allocation and purchasing. RAP arrangements that benefit the poor an excluded group. November 2002.

Ranson, MK. Reduction of catastrophic health care expenditures by a community-based health insurance scheme in Gujarat, India: current experiences and challenges. *Bulletin of the World Health Organization.* 2002, 80(8): 613-21.

Ratanawijitrasin S, Soumerai SB, Weerasuriya K. Do national medicinal drug policies and essential drug programs improve drug use?: a review of experiences in developing countries. *Social Science and Medicine*. 2001;53(7):831-44.

Russel, S, Gilson L. User fees at government health services: Is equity being considered. An international survey. PHP Departmental Publication no. 15. London School of Hygiene and Tropical Medicine 1995.

Schneider, P, Diop F, Bucyana, S. Development and implementation of prepayment schemes in Rwanda. Technical Report No. 45, Partnership for Health Reform, March 2000.

Stenson B, Syhakhang L, Eriksson B, Tomson G. Real world pharmacy: assessing the quality of private pharmacy practice in the Lao People's Democratic Republic. *Social Science and Medicine* 2001;52(3):393-404.

Stenson B, Tomson G and Syhakhang L. Pharmaceutical regulation in context: the case of Lao People's Democratic Republic. *Health Policy and Planning* 1997; 12(4): 329-340.

Trap B, Hansen EH, Hogerzeil HV. Prescription habits of dispensing and non-dispensing doctors in Zimbabwe. *Health Policy and Planning* 2002;17(3):288-95.

Uzochukwu BSC, Onwujekwe OE, Akpala CO. Effect of the Bamako-Initiative drug revolving fund on availability and rational use of essential drugs in primary health care facilities in south-east Nigeria. *Health Policy and Planning*. 2002;17(4):378-383

Velasquez G, Madrid Y and Quick JD. Health Reform and Drug Financing: Selected Topics. *Health Economics and Drugs, DAP Series No. 6.* World Health Organization, 1998.

Witter S. 'Doi Moi' and health: The effect of economic reforms on the health system in Vietnam. *International Journal of Health Planning and Management.* 1996;11(2):159-172.

World Bank. Working Together to Accelerate Progress Towards the Health and Nutrition Millennium Development Goals. Washington DC, 2003.

World Bank. Financing Health Services in developing countries: An Agenda for reform. World Bank, Washington DC, 1987

World Bank. World Development Report 1993. Investing in Health. Washington DC 1993.

World Health Organization. Global Comparative Pharmaceutical Expenditures. Health Economics and Drugs, EDM Series No. 3. (EDM/PAR/2000.2) 2000

World Health Organization. How to develop and implement a national drug policy. Second edition Geneva 2001.

World Health Organization. WHO Health System Profiles Database (accessed April 2003 at www.who.int)

World Health Organization. On-line annex tables for World Health Report 2002 (accessed April 2003 at www.who.int/whr/2002/annex/)

World Health Organization. Alternative drug pricing policies in the Americas. Health economics and drugs, DAP Series no. 1 (WHO/DAP/95.6) Geneva 1995.

Yang B. The role of health insurance in the growth of the private health sector in Korea. In: Newbrander, W. (ed): Private health sector growth in Asia. Issues and implications. Wiley & Sons 1997.

HEALTH, NUTRITION,
AND POPULATION

HUMAN DEVELOPMENT NETWORK

THE WORLD BANK

About this series...

This series is produced by the Health, Nutrition, and Population Family (HNP) of the World Bank's Human Development Network. The papers in this series aim to provide a vehicle for publishing preliminary and unpolished results on HNP topics to encourage discussion and debate. The findings, interpretations, and conclusions expressed in this paper are entirely those of the author(s) and should not be attributed in any manner to the World Bank, to its affiliated organizations or to members of its Board of Executive Directors or the countries they represent. Citation and the use of material presented in this series should take into account this provisional character. For free copies of papers in this series please contact the individual authors whose name appears on the paper.

Enquiries about the series and submissions should be made directly to the Managing Editor Joy de Beyer (jdebeyer@worldbank.org) or HNP Advisory Service (healthpop@worldbank.org, tel 202 473-2256, fax 202 522-3234). For more information, see also www.worldbank.org/hnppublications.

THE WORLD BANK

1818 H Street, NW
Washington, DC USA 20433
Telephone: 202 473 1000
Facsimile: 202 477 6391
Internet: www.worldbank.org
E-mail: feedback@worldbank.org