

2. Improving access to psychotropics

WHO has defined a framework for “access to essential medicines” (WHO, 2000). This four-part strategy is intended to guide and coordinate activities to improve access to medicines. The framework comprises:

- (i) Rational selection;
- (ii) Affordable prices;
- (iii) Sustainable financing; and
- (iv) Reliable health and supply systems.

These four elements are interrelated and influence each other. Different stakeholders have vital roles in making these elements facilitate, rather than obstruct, access. A mental health policy should balance the various goals and objectives, providing a complete and consistent system within which access to essential psychotropics is fully integrated.

This chapter presents options to improve access to psychotropics by discussing the enabling factors of the four access components. Improvements will depend on existing structures and their effectiveness, the balance between public and private sectors, and the findings of an initial assessment, as outlined in Chapter 4 of this module.

Based on experiences gained in various national health systems of countries with different levels of development, eight enabling factors can be identified:

1. Mental health policies should contain well-defined strategies for improving access to essential psychotropics.
2. Legislation should be supportive of access, rather than obstructing it.
3. Selecting what is most needed for good quality mental health services is the start of any improvement in access. Identifying the most needed drugs and developing standard treatment guidelines go hand in hand. A careful selection of essential psychotropics is also the basis of good supply management and training.
4. Prices of psychotropic medicines have to be affordable to users and health systems, keeping in mind their often chronic use. Adopting best procurement practices will ensure that best prices for good quality products are obtained.
5. Sustainable financing is a key condition for continued purchase of what is needed to treat mental disorders.
6. Effective, efficient and reliable health and supply systems are needed to deliver psychotropics with minimal waste. This includes safeguarding the quality and safety of medicines, and it is important that doctors and consumers trust the medicines they use.
7. Good quality mental health care requires more than information and prescriber training about psychotropic medicines - their appropriate use is a basic condition.
8. Systematic assessment and monitoring are essential for continuous maintenance and improvement.

These eight themes need to be reflected in any sound plan to improve access to psychotropic medicines. Themes 1 and 2 are key conditions for any improvement effort, and are discussed in Chapter 2, subsections 2.1 to 2.3. Themes 3 to 6 deal with the practical, “how-to” questions of improving access, and are discussed in subsections 2.4 to 2.7.

Being the ultimate goal of any medication use, theme 7 is discussed separately in Chapter 3. Theme 8, on assessing access, is explained in Chapter 4. Finally, to assist in planning, Chapter 5 provides a seven-step approach to improving access to psy-

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chotropics. Chapters 4 and 5 also provide hypothetical country examples in assessing systems and designing improvements.

2.1 Making access an integral part of a mental health policy

Access to safe and efficacious psychotropics should be an integral part of a policy to provide effective care to PWMDs (Alarcon and Aguilar-Gaxiola, 2000; Gureje and Alem, 2000). This requires not only a statement on the desirability of adequate availability of psychotropic medicines, but also a comprehensive plan of action on how to improve access to those medicines. Formulation of mental health policies containing details about access to medicines is especially important for countries that have few resources for mental health.

The overall goals mentioned in the access section in mental health policies may be fairly general; specific objectives may differ according to priorities that are determined after the initial assessment, but they should include at least the following:

- To remove obstacles to access (e.g. legislative barriers);
- To make essential psychotropic medicines available and affordable to those who need them; and
- To improve the quality of medical and pharmaceutical services, including prescribing and dispensing practices, and to promote the correct use of this category of medicines by health workers and the public.

Furthermore, the access section should clearly specify the following:

- Identify the major issues and objectives regarding access to psychotropics;
- Define the respective roles of the public, private (for-profit) and NGO (not-for-profit) sectors in the financing and provision of these medicines;
- Identify organizational arrangements in the public, private and NGO sectors to meet the objectives of access;
- Set an agenda for capacity building and organizational development; and
- Provide guidance for prioritizing expenditures and making decisions on resource allocation.

Box 1. Collaboration between hospital authorities and consumer organizations in increasing access to psychotropics in Hong Kong Special Administrative Region of China

Due to increases in costs of new psychotropic medicines, a major hospital in Hong Kong Special Administrative Region of China (Hong Kong SAR) felt obliged to decrease the budget for psychotropic medicines. There is regular interaction between the hospital and a group of NGOs and consumer representatives, and the latter advocated the urgent need for improving access to these medicines. Following meetings with the hospital authorities, it was decided to substantially increase the drugs budget, develop clear treatment guidelines and aim for improved use of these medicines, as there was general awareness of the need for cost containment.

Source: Deborah Wan, CEO, New Life Psychiatric Rehabilitation Association, Hong Kong, 2002, personal communication

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The views of a wide array of stakeholders should be taken into account when designing policies on improved access to psychotropics (Baker, 2001). PWMDs (sometimes called consumers), family members, professionals and other interested parties can play a decisive role in convincing decision-makers to design good policies (see box 1). Designing and implementing mental health policies and plans is further explained in another module in this series (module on Mental Health Policy, Plans and Programmes), while specific WHO resources may be used to supplement the chapter on improving access to psychotropics (see, for example, WHO, 2001b).

It may sometimes be difficult to make explicit recommendations, as access to psychotropics is largely determined by groups and systems outside the control of the mental health authorities. However, it is essential for a mental health access policy to be fully in harmony with the overall national health and medicines policies of a country (WHO, 2001c).

A policy, however well formulated, is worth little if it is not translated into a programme of action. Countries need not only to develop and officially adopt policies or plans of action, but also to implement them effectively. A “culture of monitoring” should be fostered, whereby results of monitoring are used to inform policy action. The methodology for this monitoring should be in line with the methodology explained in Chapter 4 of this module: Assessing a psychotropic drug access system.

2.2 Legislation supporting access

Box 2. Over-the-counter use of benzodiazepines: Impact of a change in legislation on medicines in Brazil

Over-the-counter sales of benzodiazepines was a serious problem in Brazil in the mid-1980s. Since the 1960s, low doses of benzodiazepines combined with antispasmodics (marketed as antidistônicos) could be obtained freely, even though a prescription was required by law. In addition, antidistônicos accounted for over 25% of prescribed benzodiazepines, despite the fact that the clinical evidence for these combinations is doubtful.

In the second half of the 1980s, the Ministry of Health designed new legislation strengthening the requirement for a prescription. And in 1989, antidistônicos were fully withdrawn from the Brazilian market. After the new legislation came into force, sales of benzodiazepines without a prescription declined considerably, but not totally, even though it was recognized that this practice should be discontinued completely.

Source: Kapczinski et al., 2001.

WHO (2001c) estimates that, at present, almost a quarter of the countries in the world have no mental health legislation. About half of the existing laws were formulated in the past decade, but nearly one-fifth date back over 40 years. Most existing laws on medicines do not include appropriate specifications on psychoactive medications. Bringing legislation in line with modern thinking on mental health will be a major challenge, but also a priority in making mental health care more effective (see box 2). A review of the main regulations applying to the mental health and pharmaceutical sectors in a country may lead to proposals to amend them, so that they are better adapted to existing realities and can be better enforced. Both sectors may need to be reformed to ensure improved access to essential psychotropics.

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Bringing legislation in developing countries in line with modern thinking on mental health is a major challenge, but also a priority for effective mental health care.

Box 3. Preparing mental health treatment guidelines for primary health care workers in Zimbabwe.

During the mid-1980s the Zimbabwe Essential Drugs Action Programme developed an innovative approach to promoting access to essential drugs. This involved conducting a survey among staff working at primary health care facilities and asking what support they needed. In addition to regular essential drug supplies, staff requested locally appropriate training and reference materials to assist them in their daily work. In addition to requesting training modules on ordering and stock control, dispensing and health centre management, they asked for simple clinical materials that would provide guidance on patient assessment and treatment. To satisfy these demands, representative groups of health workers from all over the country were gathered to review, revise and field test materials produced for them. One of the modules was on Mental Health. A controversial issue was whether nurses could initiate treatment with antidepressant medications. While it was clear that psychotic patients would be taken to district hospitals for treatment initiation, there was a consensus among reviewers that depressed patients, usually women, would not go to distant district hospitals. When the module was published and distributed through workshops, the recommendation that nurses initiate treatment of depression followed by referral created heated discussions. To resolve this issue, a second review group composed of different health workers reviewed the entire module and decided to keep the original recommendation. The Mental Health module later became one of the most requested of the 15 modules produced!

Source: Laing & Ruredzo, 1989.

Legislation should enhance, and not obstruct, adequate access to essential psychotropics. It should ensure that appropriate pharmaceuticals are available at all times in mental health care delivery. The products should be of acceptable quality, safe and efficacious, and not merely available, but also distributed and used.

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Legislation should define the responsibilities and authority of all actors in the access system: who can produce or import medicines, who can store and sell them, which institution is responsible for monitoring and enforcing regulations, and who can prescribe the various types of products. Where there is a policy of integration of mental health care into general primary health care services, essential psychotropics must not only be available at these levels, but primary health care workers, and not just medical doctors, should be trained and authorized to administer them at these levels (WHO, 2001a). Primary health care workers, usually nurses, may be empowered to assess patients, initiate treatment with essential psychotropic medicines, dispense them, and follow up with their patients. Depending on the national policies, these actions may occur under the supervision of a doctor, but if a doctor is not available, unenforceable regulations should be strongly resisted. (See box 3). Details on designing appropriate mental health legislation is provided in another module in this series (see module on Mental Health Legislation and Human Rights).

2.3 International trade agreements and access

Affordability of medicines is likely to be affected by a number of international trade agreements. The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) is one of the most disputed agreements WHO, 2001e).

In joining the World Trade Organization (WTO), Members must adhere to all 18 specific agreements (one of which is TRIPS) annexed to the Agreement establishing the WTO. TRIPS establishes intellectual property standards for WTO Members, historically based on the standards of developed countries. It requires patent protection for all products

and processes for a minimum duration of 20 years, without any special consideration for pharmaceuticals, and this needs to be reflected in WTO Members' legislation. However, as patent protection awards exclusive rights to an invention, it may prevent generic competition and thus also prevent low-cost generic medicines from becoming accessible to populations.

There are, nevertheless, certain legal safeguards provided under TRIPS, such as compulsory licensing and parallel import of medicines of considerable relevance to public health, which should be reflected in national legislation.

- > Compulsory licensing enables a government to license the use of an invention to a third party or government agency without the consent of the patent-holder.
- > Parallel importation entails the importation of a patented product marketed in another country with or without the patent-holder's consent.

Box 4. Key issues relating to TRIPS implementation

- > TRIPS requires patent protection for all products and processes, with a minimum duration of 20 years, without any special consideration for pharmaceuticals.
- > TRIPS permits Members some discretion in enacting and amending their laws and regulations, which can help promote public health goals.
- > WTO free trade provisions can stimulate generic competition and reduce the prices for off-patent drugs, but TRIPS may also significantly delay the introduction of new generic drugs, depending on how national patent legislation is designed and implemented.
- > Developing countries should be cautious about enacting legislation more stringent than the TRIPS requirements ("TRIPS-plus").

Source: WHO, 2001e

These two safeguard measures are intended to enable governments to tackle public health crises.

TRIPS cannot prevent countries from requiring generic labelling and allowing generic substitution.

A new development is "TRIPS-plus", which refers to efforts to: (a) extend patent life beyond the 20-year TRIPS minimum; b) limit compulsory licensing in ways not required by TRIPS; and c) limit exceptions which facilitate a prompt introduction of generics. Countries are advised to be cautious about enacting legislation that is more stringent than the actual TRIPS requirements.

WHO's perspectives on access to medicines and patent legislation are presented in box 4.

2.4 Selecting the most needed psychotropics

Careful selection of essential psychotropic medicines is a prerequisite for establishing a sustainable psychotropics supply system, or a sound insurance reimbursement system (WHO, 2002b). Selecting a limited number of essential psychotropic medicines is economical and entails fewer risks of duplication, confusion and mistakes.

Prescribers, dispensers and consumers are more easily able to remember therapeutic effects and adverse reactions, and do not have to cope with too many different dosage regimes and confusing nomenclature. Furthermore, careful selection facilitates bulk purchase and easier management of medicines (storage and distribution). It also allows for a more rational and efficient approach to training in prescribing and dispensing. Because of its considerable impact on the quality of care and the cost of treatment, a carefully considered selection of medicines is one of the most cost-effective means of improving mental health services. For example, evidence shows that newer psychotropics may have some advantages, but they are not always more effective, and usually much more expensive.

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Essential medicines used to be selected on the basis of consensus between experts as to which medicines should be available in health care systems. WHO has a Model List of Essential Drugs, including psychotropics, which has been updated on a bi-annual basis for the past 25 years. Medicines are specified by international non-proprietary name (INN), or generic name, without reference to any brand name or specific manufacturer (WHO, 1997a). In the 2002 and 2003 updates of the WHO Model List, medicines have been selected by defining treatment guidelines on the basis of available evidence of effectiveness (e.g. information from the Cochrane collaboration; see www.cochrane.org). Based on these guidelines, the essential medicines needed for treatments have been defined. The 2003 update of the WHO Model List of Essential Medicines (WHO, 2003a) includes nine medicines for the satisfactory management of mental disorders and eight anticonvulsants/anti-epileptics (see box 5).

Box 5. Psychotherapeutic drugs on the WHO Model List of Essential Drugs (EDL 2002: 9 drugs in 17 dosage forms)

Section 24. Psychotherapeutic drugs

- 24.1 Drugs used in psychotic disorders
chlorpromazine tab, 100mg; syr, 25mg /5ml; inj, 25mg /ml in 2-ml amp
fluphenazine inj, 25mg (decanoate or enantate) in 1-ml amp
haloperidol tab, 2mg, 5mg; inj, 5mg in 1-ml amp
- 24.2 Drugs used in mood disorders
- 24.2.1 Drugs used in depressive disorders
amitriptyline tab, 25mg (hydrochloride)
- 24.2.2 Drugs used in bipolar disorders
carbamazepine scored tab, 100mg, 200mg
lithium carbonate caps or tab, 300mg
valproic acid enteric coated tab, 200mg, 500mg (sodium salt)
- 24.3 Drugs used in generalized anxiety and sleep disorders
diazepam scored tab, 2mg, 5mg
- 24.4 Drugs used in obsessive-compulsive disorders and panic attacks
clomipramine caps, 10mg, 25mg (hydrochloride)

Section 5. Anticonvulsants/antiepileptics

- carbamazepine* scored tab, 100 mg, 200 mg
clonazepam scored tab 500 micrograms
diazepam inj, 5 mg/ml in 2-ml amp (intravenous or rectal)
ethosuximide caps, 250 mg; syr, 250 mg/5ml
magnesium sulfate inj, 500 mg/ml in 2-ml amp; 500mg/ml in 10-ml amp
phenobarbital tab, 15-100 mg; elixir, 15 mg/5ml
phenytoin caps or tab, 25 mg, 50 mg, 100 mg (sodium salt);
inj, 50 mg/ml in 5-ml vial (sodium salt)
valproic acid enteric coated tab, 200 mg, 500 mg (sodium salt)

Source: WHO, 2003a

Essential psychotropic medicines may be selected for use in one or more health facilities or for a sector as a whole. In the latter case, the list usually indicates the level of the health care system where each medicine may be used (a so-called “levelled list”).

The process by which psychotropic medicines are selected is of critical importance. It should be consultative and transparent, with explicit selection criteria, and published application procedures. It should also be linked to evidence-based treatment guidelines. A standing committee should be appointed that includes people from different fields, such as medicine, nursing, clinical pharmacology, pharmacy and public health, as well as health workers at the grassroots level. The participation of representatives of consumers’ and patients’ organizations is highly recommended. However, the final selection should be carried out independently. All members of a selection committee should declare possible conflicts of interest. Representatives from other parties should, preferably, not be allowed to attend these meetings, as it is important to ensure that selection processes are independent of commercial influences (WHO, 2001d).

Not all evidence on medicines’ efficacy is equally strong. For example, the result of a meta-analysis of several clinical trials carries more weight than the result of an observational study without controls, and much more than the personal experiences of individual experts. The strength of the evidence defines the strength of the recommendation.

Decision-making may be difficult when more expensive medicines have some advantages, as is the case with some new antidepressant medicines which have similar efficacy and milder side-effects, but higher costs as compared to older antidepressant medicines (WHO, 2001a). In such cases, it is important to calculate the cost of overall treatment, as this may actually be lower for medicines that are more expensive on a tablet-to-tablet (dose-to-dose) basis. The use of simple indicators, such as cost per month of therapy or cost per hospital admission prevented, may also be useful.

An example of how essential psychotropics are selected is provided in box 6.

Costs of overall treatment should be compared (especially when it involves more expensive medicines), and the most cost-effective medicines selected.

Box 6. Cost-effectiveness criteria in selecting atypical antipsychotic medicines in Chile

In the late 1990s, atypical antipsychotic medicines became available. At the time, outpatient care for schizophrenia already existed in most health districts, and consisted of education, support to consumers and their families, and community rehabilitation programmes. Chlorpromazine and haloperidol (both oral and intramuscular (IM)) and fluphenazine decanoate (IM) were available for use, but some persons with schizophrenia did not respond well to these more established medications. To begin with, a few persons with schizophrenia resistant to the common antipsychotics were started on newer drugs. These first few treatments were financed in a variety of ways, including direct payment by the people themselves, funding from local mental health centres and others. Given the good results obtained for this group, the Mental Health Unit of the Ministry of Health decided to design a more comprehensive strategy to make atypical antipsychotics more widely available for use:

1. A list of persons with schizophrenia resistant to traditional antipsychotics was prepared in collaboration with mental health workers throughout the country. About 1,000 people became eligible for treatment with this new (and more expensive) medication.
2. A cost-effectiveness study on the various treatment options was carried out using data from the Cochrane Library. It was concluded that clozapine was significantly superior to the established drugs for resistant cases of schizophrenia, and that this drug should be made available to the identified group.

3. The Mental Health Unit started a lobbying process to obtain necessary funding to procure adequate quantities to treat this population. Key decision-makers were sent letters which contained the “waiting list for clozapine”, information on the cost of treating the eligible group for a one-year period and a brief overview of the literature review on clozapine (from the Cochrane review). Follow-up meetings were held to explain the benefits of clozapine in treatment and rehabilitation programmes for this group.
4. A specially established Committee on Atypical Antipsychotics in the Ministry of Health elaborated clinical guidelines for the use of clozapine. It was decided that clozapine would be available only to persons with schizophrenia resistant to two different common antipsychotics, and that it could only be used at the specialist level.

Source: Alberto Minoletti, Director, Mental Health Unit, Ministry of Health, Chile, 2002, personal

Treatment guidelines and the selection of essential psychotropics should be updated regularly (usually every two or three years) and accompanied by clear policy guidelines on their application for procurement, distribution and use.

2.5 Maximizing affordability of psychotropics

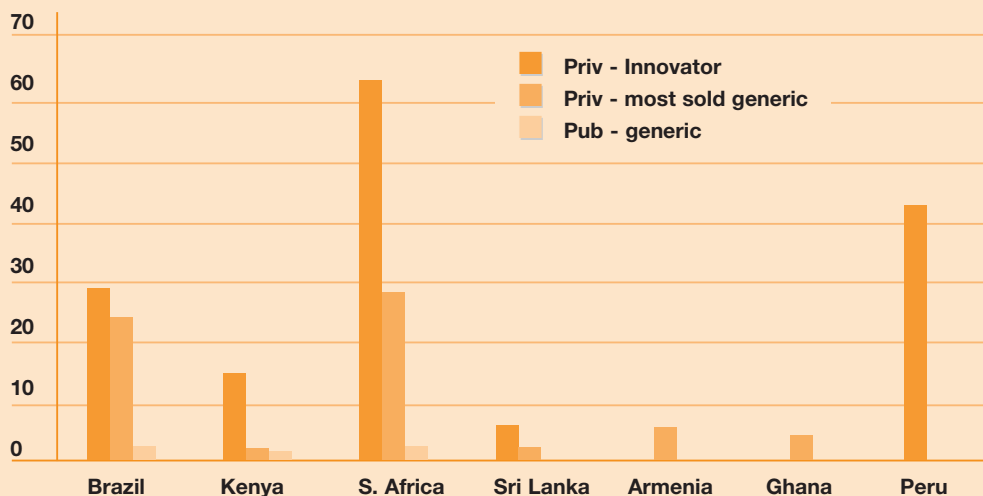
Due to the specific character of treatments for mental disorders (many of them requiring long-term use), expenditure on medicines may constitute a large proportion of overall expenditures in mental health care delivery.

Affordable prices for essential psychotropics are important in both the public and private sectors, especially as new medicines are often very costly. Affordable prices are not only important for PWMDs themselves; other persons, such as family members, may also benefit from effective management of mental disorders in one of their members. Therefore, pricing of essential drugs, including essential psychotropics, cannot be left solely to market forces; it requires active government involvement and intervention.

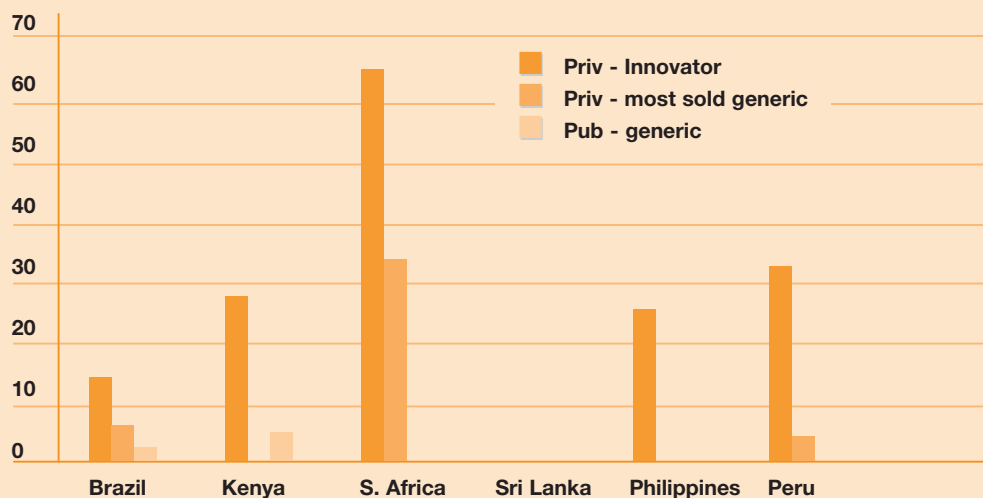
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Box 7. Price variations of amitriptyline in different systems in six countries (prices compared to world market price reference)

Amitriptyline: Prices of innovator brandname drugs 65 times as high as reference price in one country. Generic drugs often close to reference price (=1)



Fluoxetine: Price of innovator brandname drug 6.6 times price Australian PBS reference price in one country. Generic Drugs often lower than reference price (<1)



Source: WHO & HAI, 2002

Prices of psychotropic medicines vary considerably. WHO and Health Action International (HAI) surveyed prices of medicines, including two psychotropic medicines, in a number of low-income countries. Prices of innovator brand-name drugs varied for unknown reasons, while generic drug prices were often equal or lower than reference prices. The findings are presented in box 7.

Affordability does not depend only on suppliers setting the prices; there are strategies for securing lower prices. These strategies have been explained elsewhere (WHO, 2001b), and include:

- > Use of global drug price information;
- > Good procurement practices;
- > Professional price negotiations, or direct price negotiations with manufacturers;
- > Procurement by generic names;
- > Stimulating competition through generic policies and (automatic) generic substitution of medicines;
- > Reduction or abolition of import duties or taxes on essential (psychotropic) medicines;
- > Price regulation; and
- > Control of profit margins or mark-ups, or comparison with prices in other countries ("reference pricing").

Whereas price regulation tends to generate uniform opposition from private producers and distributors, use of generic medicines often develops advocates among specific segments of the pharmaceutical market. The majority of essential psychotropics are available as low-cost generics.

Several countries have adopted policies that encourage generic prescription and dispensing. Large generic medicine markets have started to develop in some countries (especially the United States and Europe). Promotion of the use of generic medicines in the private sector is still difficult because of inadequate information to health professionals and the failure to provide financial incentives at sales points. The assumption that public demand for cheap generic medicines exists and would grow has not so far proved correct. However, competitive bulk procurement by generic name is now a major policy in most essential medicines programmes and in large hospitals in both developed and developing countries.

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Box 8. Poor procurement practices hampering effective community mental health care: The case of Ghana

To achieve a larger coverage of mental health services, Ghana implemented a pilot training programme of non-mental-health personnel, and later volunteers, in remote villages in two districts, with the support of WHO. New mental health care providers were identified from the communities and trained in the management of mental disorders, including the use of selected essential psychotropic medicines. More complicated cases were to be referred to district hospitals, where trained mental health staff were available. Within three months, the number of known cases had increased by 300% as the volunteers created awareness of mental disorders. Since the volunteers were actually living within the communities, they were able to identify cases in their areas, and members of the communities even informed them about cases.

The programme was remarkably successful for a period of time. However when the supply of medicines became irregular attendance rates fell. As prices in the private sector were considerably higher than in the public sector, access to psychotropics was not assured and community members sometimes stopped treatment. It was not only the prices of (often brandname) psychotropics that were an obstacle; community members often could not even afford to pay for transportation to the specialist hospitals further away.

Source: Asare, Chief Psychiatrist, Psychiatric Hospital, Accra, Ghana, personal communication.

Complete, accurate and up-to-date information on prices of medicines can be of great value to policy-makers, health professionals, people in the distribution chain, and consumers or their caretakers. WHO and Management Sciences for Health issue an annual Drug Price Indicator Guide of essential medicines (MSH, 2002), which includes addresses and prices of many reputable suppliers of different medicines, including psychotropics, at non-profit, world market wholesale prices. Several other non-profit medicine wholesalers, such as the International Dispensary Association (IDA, www.ida.nl), the Supply Division of the United Nations Children's Fund (UNICEF) in Copenhagen (www.supply.unicef.dk) and other agencies, supply medicines of good quality at low prices, and provide price information through catalogues and their websites. A comprehensive list of prices for medicines can be found on: www.who.int/medicines/organization/par/ipc/drugpriceinfo.shtml

Poor procurement practices, and therefore poor availability of medicines, can jeopardize efforts to improve mental health care delivery (see box 8). On the other hand, well-prepared procurement systems, access to market information and bulk orders can achieve considerable savings, which can then be spent on further improving health care systems or availability of medicines. Medicine procurement requires expert knowledge and skills.

WHO, UNICEF, the United Nations Population Fund (UNFPA) and the World Bank have issued interagency guidelines with 12 operational principles for good pharmaceutical procurement (WHO, 1999a). These principles are based on four strategic objectives:

- > Procure the most cost-effective medicines in the right quantities;
- > Pre-qualify reliable suppliers of high quality products;
- > Ensure timely delivery; and
- > Achieve the lowest possible total cost.

Complete, accurate and up-to-date information on medicine prices on world markets is available from a variety of sources.

Good procurement involves accurate determination of quantities needed (“quantification”). How to quantify needs at the national, regional or institutional level has been explained in another module in this series (see module on Planning and Budgeting to Deliver Services for Mental Health).

Purchasing medicines in large quantities may result in large discounts, while purchasing medicines in several small consignments may result in excessively high costs. Medicine requirements can be centrally pooled to take advantage of economies of scale. Pooling can take place at institutional, regional, national or inter-country level, or even at a global level. The larger the pooling effort, the greater the potential discounts (see box 9).

The major procurement methods are open tender, restricted tender, competitive negotiation and direct procurement. These vary with respect to their effect on price, delivery times and workload. Generally speaking, the methods of choice are restricted tender and direct procurement from not-for-profit suppliers. The technical details of these methods are well explained elsewhere (Quick et al., 1997). Reliability of payment may be equally or more important in helping to force prices down.

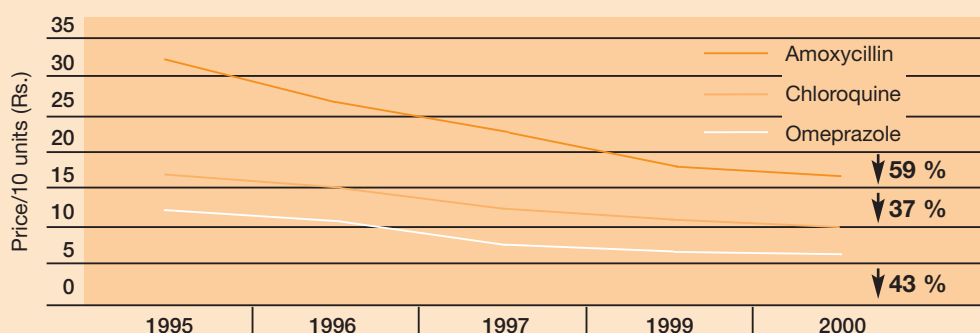
Pre-qualification of suppliers and performance monitoring are indispensable tools to avoid buying pharmaceuticals of poor quality. A wealth of technical information is available from reputable sources (WHO, 1999a, World Bank, 2000) to ensure quality. Market intelligence is of great benefit for procurement of medicines, and can strengthen the buyer’s bargaining power.

By pooling requirements for medicines, economies of scale can be achieved and substantial discounts obtained.

Box 9. Cost reductions through improved procurement in Delhi state, India

Delhi state’s policy is to provide free medicines to all. With a population of 14 million, this is a major challenge. In the past, medicines were ordered individually by each hospital, but supplied to a central warehouse. Hospitals were not aware of the prices of drugs. Moreover, as delivery structures were outdated and overly bureaucratic, by the time the drugs reached hospitals they were often close to or past their expiry dates. Primary health centres were not covered at all by this scheme. As a result, costs of medicines were high, quality was poor, and, generally, stocks were depleted or had been exhausted.

Fig 1. Cost reduction of common drugs through pooled procurement in Delhi State, India



A new procurement system was designed, in which drug volumes were efficiently pooled, leading to huge procurement volumes and stronger purchasing power. Not surprisingly, suppliers also showed greater interest, participating actively in bidding for drug requirements. The new system resulted in a sharp fall in the procurement prices of essential drugs (see fig 1).

The new system also resulted in improved quality of medicines, as a dedicated inspection team visited companies wishing to supply drugs to check adherence to good manufacturing practices. Firms with dubious products were excluded from bidding (one-third of 27 factories inspected were initially rejected). Doctors were encouraged to submit medicines they suspected as being of substandard quality.

Finally, doctors have been requested to prescribe only those drugs that feature on the procurement list. Hospital physicians have been given some additional freedom, as they can prescribe non-listed drugs up to the value of 10% of their drug budget.

Source: Chaudhury, 1999

2.6 Ensuring sustainable financing

Financing the purchase of medicines has become increasingly important in the formulation and implementation of policies on access. The combined effects of economic pressures, continued population growth and the aging of populations, also in developing countries, have made this a difficult task for many countries. Mental disorders are currently among the 10 leading causes of disability in many countries (WHO, 2001a), and many of them are also chronic. Therefore, not only is the direct cost of an individual treatment or service important, but also the possibility of its use over long periods of time.

Financing mechanisms are crucial to the development of sustainable mental health systems and the medicines they need. The challenge is to implement those financing strategies that best ensure equity of access and a continuous supply of medicines. There are five key principles for improving financing of health care and requirements for medicines (WHO, 2001a; WHO, 2001b):

Adequate mechanisms to finance medicines are necessary if success of intervention programmes is to be ensured.

Box 10. Psychotropic medicines are bought through out-of-pocket payments in most low-income countries

According to the WHO Atlas Project, one-third of countries do not have any specific mental health budget, although they presumably devote some resources to mental health. Out-of-pocket payments are the primary method of financing mental health in one-third of countries in the African and South-East Asian Regions. This was not found in countries in the European Region. Private insurance and external grants account for a negligible proportion of costs of mental health care in low-income countries. Whereas social insurance is the primary method of financing in 38% and 29% of high- and higher-middle-income countries respectively, no social insurance exists as the primary method of financing mental health in low-income countries. External grants support mental health as a primary method of financing in only 5%-8% of low-income countries.

Source: WHO, 2001c

- Especially in the poorest countries, governments should finance basic health care delivery, and direct out-of-pocket expenditures by their poor populations should be minimized as much as possible. Such payments may only be required for small expenses on affordable goods or services (see box 10). Various ways exist to generate sustainable financing for health service, such as general taxation, mandatory social insurance or voluntary private insurance. These strategies allow for separation of use of the services and paying for them, an important way to limit perverse incentives for health care providers.

A major objective of a financing strategy should be to reduce out-of-pocket expenditures for psychotropic treatments.

- > The healthy should subsidize the sick. This can generally be achieved through pre-payment mechanisms. Mental health should also be well covered in such schemes.
- > The well-off can subsidize the poor to a large degree. People with mental disorders are often poorer than the rest of the population, particularly in developing countries. Insurance can make the well-off subsidize the worse-off only if both groups are covered.
- > Cost-sharing mechanisms can only contribute to increasing the financing of services if equity principles are respected and care is taken not to exclude the poor from using services due to their unaffordable costs.
- > Efficiency should be optimized and waste reduced as much as possible. No system can provide quality health services if resources are lost as a result of poorly functioning systems. A variety of methods exist to improve efficiency and reduce waste in all stages of medicine supply and use systems. They are explained further in this manual (see subsection 2.7).

Further details on financing mental health services and essential psychotropics are presented in another module in this series (module on Mental Health Financing).

Health insurance is making considerable inroads in many developing countries, and some countries even have special arrangements for rural and low-income populations (WHO, 1998a). Mental disorders are not always covered. Where they are included they may only cover inpatient costs and exclude outpatient consultations, drug costs or day-care services. Yet the latter are the principal forms of health care needed for most mental disorders (Wang et al., 2000). Governments should help the establishment or expansion of health insurance schemes through supportive legislation and subsidies, and ensure that mental disorders are included, especially outpatient treatment and the associated costs of drugs.

Finally, it is of critical importance to understand that economic access to essential medicines can only be improved when funds for the purchase of medicines are readily available, when foreign exchange for international procurement is readily accessible, when reliable payment mechanisms exist, and when high-level political support for rigid adherence to transparent tender procedures can be ensured.

2.7 Improving distribution strategies and safeguarding quality

Designing an efficient system for storing and distributing medicines, medical supplies and equipment is challenging and important to ensure effective supplies. Skills in operational planning and logistics are needed for developing a cost-effective distribution system, and it is important to have a well-qualified logistics team.

The roles of public and private entities involved in arrangements for the distribution of medicines vary greatly. The best systems are probably based on a combination of public and private management (Quick et al., 1997).

Alternative strategies for the supply of medicines to the public are attracting interest. These include formation of an autonomous supply agency, direct delivery, the prime vendor system, various privatized models and mixed systems. These alternative supply systems may be evaluated for their applicability in improving the supply of essential psychotropic medicines. Details about these systems are provided in the standard essential medicines literature (Quick et al., 1997).

Although global standards for the quality of medicines are becoming stricter, their actual quality on the market in many countries has become a cause for major concern. Surveys from a number of developing countries show that 10% - 20% of sampled medicines

Effective supply relies on good design and management of systems to store and distribute medicines.

fail quality-control tests. It is estimated that fewer than one in three developing countries have fully functioning regulatory authorities for medicines (WHO, 2000). Failure of good manufacturing practices can lead to the presence on the market of sub-standard medicines, while failure of effective control mechanisms may lead to the presence of fake or sub-standard drugs. Medicines that are unsafe and ineffective can pose a serious problem for the health of populations.

Ensuring good quality medicines in a country starts at the central level. Challenges involved in the regulation of medicines include licensing and inspection of sales points and of professionals, licensing and inspection of manufacturers, registration of medicines, and post-marketing surveillance (WHO, 1999b).

WHO's Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce (WHO, 1996a; WHO, 1997b) can play an important role in ensuring that medicines are of good quality. The Scheme, to which 112 countries adhere, enables importers to check whether the supplier meets WHO requirements for good manufacturing practices in regularly inspected factories, and whether the medicine is registered in the exporting country.

Quality must also be guaranteed throughout the distribution chain, in all climates and by all methods of transportation. This calls for an adequate inspection system and for quality control that is ideally based in a small laboratory (national or regional), capable of analysing and checking medicines used within the country. Methods such as thin-layer chromatography (TLC) or dissolution tests are now available for rapid screening of drugs for quality.

Surveys from developing countries show that 10%-20% of sampled medicines fail quality-control tests.

Key points

- Adequate access to essential psychotropics is determined by rational selection, affordable prices, sustainable sources of finance, and reliable health and supply systems.
- Access to safe and efficacious psychotropics should be an integral part of a policy to provide effective care to PWMDs.
- However, an access policy is worth little if it is not translated into a programme of action.
- Selecting a limited number of essential psychotropic medicines is economical and reduces the risk of duplication, confusion and mistakes.
- Affordable prices for essential psychotropics are important in both public and private sectors, and for both PWMDs and their families. Pricing of essential medicines, including essential psychotropics, cannot be left solely to market forces.
- Accurate, and up-to-date information on medicine prices on world markets is available from a variety of sources, and of key importance to improving affordability.
- Financing mechanisms are crucial to the development of sustainable mental health systems and the medicines needed to run them.
- By pooling requirements for medicines, economies of scale can be achieved leading to substantial discounts.
- Effective supply relies on good design and management of systems to store and distribute medicines.
- Quality of medicines must be guaranteed throughout the distribution chain, in all climates, and by all modes of transport.