

Mental Health Policy and  
Service Guidance Package

# IMPROVING ACCESS AND USE OF PSYCHOTROPIC MEDICINES

*“Psychotropic medications are effective treatments for mental disorders when used in conjunction with psychosocial interventions. Attention to rational selection of drugs, affordability, sustainable financing and the availability of reliable health and supply systems will ensure that these treatments are available to those in need.”*



World Health  
Organization



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Organization**

## WHO Library Cataloguing-in-Publication Data

Improving access and use of psychotropic medicines.  
(Mental health policy and service guidance package)

1. Psychotropic drugs - supply and distribution 2. Essential drugs - supply and distribution 3. Mental disorders - drug therapy 4. Drug utilization 5. Drug costs 6. Drug and narcotic control - methods 7. Guidelines I. World Health Organization

ISBN 92 4 154641 7

(NLM classification: QV 77.2)

Technical information concerning this publication can be obtained from:

Dr Michelle Funk

Department of Mental Health and Substance Abuse

World Health Organization

20 Avenue Appia

CH-1211, Geneva 27

Switzerland

Tel : +41 22 791 3855

Fax : +41 22 791 4160

E-mail : [funkm@who.int](mailto:funkm@who.int)

Suggested citation : *Improving access and use of psychotropic medicines*. Geneva, World Health Organization, 2005 (Mental Health Policy and Service Guidance Package).

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This publication contains the collective views of an international group of experts and does not necessarily represent the decisions or the stated policy of the World Health Organization.

Printed in China

## Acknowledgements

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The Mental Health Policy and Service Guidance Package was produced under the direction of Dr Michelle Funk, Coordinator, Mental Health Policy and Service Development, and was supervised by Dr Benedetto Saraceno, Director, Department of Mental Health and Substance Abuse, World Health Organization.

The World Health Organization expresses its gratitude to Dr Hilbrand Haak, Consultant for Health and Development in the Netherlands for preparing this module.

### **WHO Editorial and technical coordination group:**

---

Ms Marthe Everard, World Health Organization, Headquarters (WHO/HQ), Dr Hans Hogerzeil, (WHO/HQ), Dr Michelle Funk (WHO/HQ) and Dr Benedetto Saraceno (WHO/HQ).

Dr Crick Lund, University of Cape Town, Republic of South Africa, finalized the technical editing of this module.

### **Technical assistance:**

---

Dr Jose Bertolote, (WHO/HQ), Ms Natalie Drew (WHO/HQ), Dr José Miguel Caldas de Almeida, WHO Regional Office for the Americas (AMRO), Dr Thérèse Agossou, WHO Regional Office for Africa, (AFRO), Dr Vijay Chandra, WHO Regional Office for South-East Asia, (SEARO), Dr Ahmad Mohit, WHO Regional Office for the Eastern Mediterranean, (EMRO), Dr Wolfgang Rutz, WHO Regional Office for Europe, (EURO), Dr Xiangdong Wang, WHO Regional Office for Western Pacific Region (WPRO) AND Dr Catherine Le Galès-Camus (WHO/HQ).

### **Administrative and secretarial support:**

---

Ms Adeline Loo (WHO/HQ), Mrs Anne Yamada (WHO/HQ) and Mrs Razia Yaseen (WHO/HQ).

Layout and graphic design: 2S ) graphicdesign  
Editor: Praveen Bhalla

**WHO also wishes to thank the following people for their expert opinion and technical input to this module:**

<b>Dr Jo B. Asare</b>	Ministry of Health and Psychiatric Hospital, Accra, Ghana
<b>Dr Corrado Barbui</b>	Department of Medicine and Public Health, University of Verona, Italy
<b>Dr Claudina Cayetano</b>	Director, Mental Health Program, Ministry of Health, Belmopan, Belize
<b>Professor Emilio C. Cermignani</b>	Assistant Professor of Pharmacology, Cátedra de Farmacología, La Plata, Argentina
<b>Dr Dolors Capellà Hereu</b>	Servei de Farmacologia Clínica, Barcelona, Spain
<b>Dr Alex Cohen</b>	Department of Social Medicine, Harvard Medical School, Boston, USA
<b>Dr Douma Djibo Maïga</b>	Ministry of Public Health, Niamey, Niger
<b>Professor Helen Herrman</b>	Department of Psychiatry, University of Melbourne, Victoria, Australia
<b>Dr Ahmed Mohamed Heshmat</b>	Ministry of Health and Population, Cairo, Egypt
<b>Dr Lars Jacobsson</b>	Department of Psychiatry, Faculty of Medicine, University of Umea, Sweden
<b>Dr Dale L. Johnson</b>	President, World Fellowship for Schizophrenia and Allied Disorders, Toronto, Ontario, Canada
<b>Dr Nancy Jones</b>	WHO Consultant, Mental Health Planning for Cambodia, Seattle, USA
<b>Professor Zurab I. Kekelidze</b>	Deputy Director, Serbsky National Research Centre for Social and Forensic Psychiatry, Moscow, Russian Federation
<b>Dr Pirkko Lahti</b>	Executive Director, Finnish Mental Health Association, Helsinki, Finland
<b>Dr Richard Laing</b>	Associate Professor, International Health, Boston University School of Public Health, Boston, USA
<b>Dr Philippe Lehmann</b>	Director, Swiss National Health Policy Project, Bern, Switzerland
<b>Dr Itzhak Levav</b>	Adviser on Research, Policy and External Relations, Mental Health Services, Ministry of Health, Jerusalem, Israel
<b>Dr Alberto Minoletti</b>	Director, Mental Health Unit, Ministry of Health, Santiago, Chile
<b>Dr Paul Morgan</b>	SANE, South Melbourne, Victoria, Australia
<b>Dr Eva Ombaka</b>	Ecumenical Pharmaceutical Network, Nairobi, Kenya
<b>Dr Vikram Patel</b>	Sangath Centre, Goa, India
<b>Dr Michael Phillips</b>	Associate Professor, Beijing Hui Long Guan Hospital, Beijing, China
<b>Dr Rampersad Parasram</b>	Principal Medical Officer, Ministry of Health, Port of Spain, Trinidad and Tobago
<b>Dr Khaled Saeed</b>	Associate Professor, Institute of Psychiatry, Rawalpindi, Pakistan
<b>Dr Aive Sarjas</b>	Head, Department of Social Welfare, Ministry of Social Affairs of Estonia, Tallinn, Estonia
<b>Professor Shen Yucun</b>	Director, Institute of Mental Health, Beijing University, Beijing, China
<b>Dr Daya Somasundaram</b>	Department of Psychiatry, University of Jaffna, Sri Lanka

<b>Dr HWANG Tae-Yeon</b>	Director, Department of Psychiatric Rehabilitation and Community Mental Health, Yongin Mental Hospital, Kyonggi Province, Republic of Korea
<b>Dr Timi Tuori</b>	Ministry of Health and Population, Cairo, Egypt
<b>Ms Deborah Wan</b>	New Life Psychiatric Rehabilitation Association, Hong Kong, China
<b>Professor HAO Wei</b>	Mental Health Institute, Changsha, Hunan, China
<b>Dr Pude Yang</b>	Beijing Hui Long Guan Hospital, Beijing, China
<b>Dr ZOU Yizhuang</b>	Vice Director, Beijing Hui Long Guan Hospital, Beijing, China

In addition, WHO gratefully acknowledges the generous financial support of the Governments of Italy, the Netherlands and New Zealand.

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This module is part of the WHO Mental Health Policy and Service guidance package, which provides practical information to assist countries to improve the mental health of their populations.

### **What is the purpose of the guidance package?**

The purpose of the guidance package is to assist policy-makers and planners to:

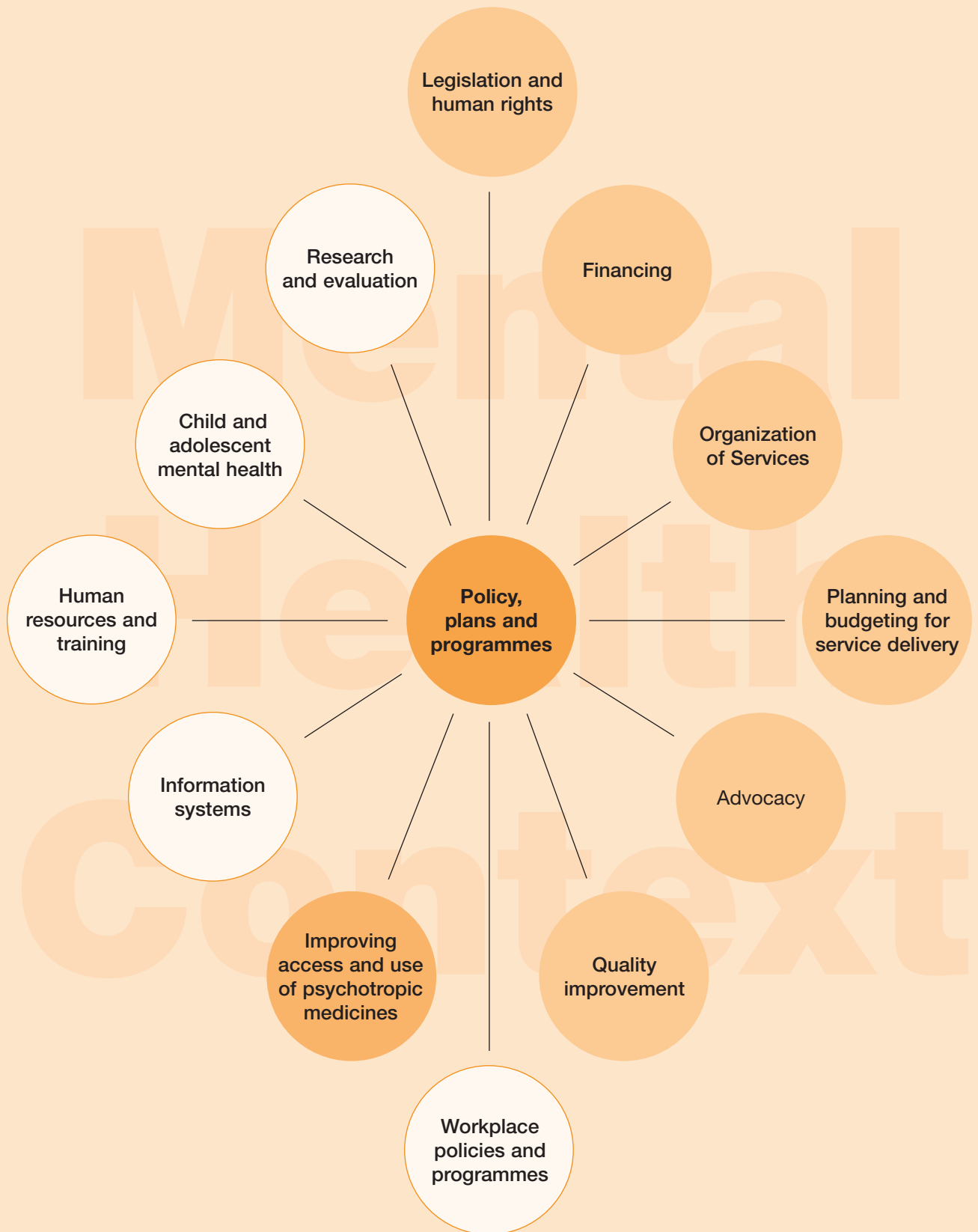
- develop policies and comprehensive strategies for improving the mental health of populations;
- use existing resources to achieve the greatest possible benefits;
- provide effective services to those in need;
- assist the reintegration of persons with mental disorders into all aspects of community life, thus improving their overall quality of life.

### **What is in the package?**

The guidance package consists of a series of interrelated user-friendly modules that are designed to address the wide variety of needs and priorities in policy development and service planning. The topic of each module represents a core aspect of mental health.

The guidance package includes the following modules:

- > The Mental Health Context
- > Mental Health Policy, Plans and Programmes
- > Mental Health Financing
- > Mental Health Legislation and Human Rights
- > Advocacy for Mental Health
- > Organization of Services for Mental Health
- > Improving Access and Use of Psychotropic Medicines
- > Quality Improvement for Mental Health
- > Planning and Budgeting to Deliver Services for Mental Health



● still to be developed

The following modules are planned to be included in the final guidance package:

- Mental Health Information Systems
- Human Resources and Training for Mental Health
- Child and Adolescent Mental Health
- Research and Evaluation of Mental Health Policy and Services
- Workplace Mental Health Policies and Programmes

### **Who is the guidance package for?**

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The modules will be of interest to:

- policy-makers and health planners;
- government departments at federal, state/regional and local levels;
- mental health professionals;
- groups representing people with mental disorders;
- representatives or associations of families and carers of people with mental disorders;
- advocacy organizations representing the interests of people with mental disorders and their relatives and families;
- nongovernmental organizations involved or interested in the provision of mental health services.

### **How to use the modules**

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- They can be used **individually or as a package**. They are cross-referenced with each other for ease of use. Countries may wish to go through each of the modules systematically or may use a specific module when the emphasis is on a particular area of mental health. For example, countries wishing to address mental health legislation may find the module entitled Mental Health Legislation and Human Rights useful for this purpose.
- They can be used as a **training package** for mental health policy-makers, planners and others involved in organizing, delivering and funding mental health services. They can be used as educational materials in university or college courses. Professional organizations may choose to use the package as an aid to training for persons working in mental health.
- They can be used as a framework for **technical consultancy** by a wide range of international and national organizations that provide support to countries wishing to reform their mental health policy and/or services.
- They can be used as **advocacy tools** by consumer, family and advocacy organizations. The modules contain useful information for public education and for increasing awareness among politicians, opinion-makers, other health professionals and the general public about mental disorders and mental health services.

## **Format of the modules**

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Each module clearly outlines its aims and the target audience for which it is intended. The modules are presented in a step-by-step format so as to assist countries in using and implementing the guidance provided. The guidance is not intended to be prescriptive or to be interpreted in a rigid way: countries are encouraged to adapt the material in accordance with their own needs and circumstances. Practical examples are given throughout.

There is extensive cross-referencing between the modules. Readers of one module may need to consult another (as indicated in the text) should they wish further guidance.

All the modules should be read in the light of WHO's policy of providing most mental health care through general health services and community settings. Mental health is necessarily an intersectoral issue involving the education, employment, housing, social services and criminal justice sectors. It is important to engage in serious consultation with consumer and family organizations in the development of policy and the delivery of services.

Dr Michelle Funk

Dr Benedetto Saraceno



IMPROVING  
ACCESS AND USE  
OF PSYCHOTROPIC  
MEDICINES



Mental and behavioural disorders account for a large proportion of the global burden of disease, but only a minority of those suffering from such disorders receive basic treatment. Relatively few people with mental disorders consult a physician. In developing countries, health systems often are not able to provide even the most essential mental care.

In the World Health Report 2001 (WHO, 2001a), a series of recommendations were made on how to improve care for people with mental disorders. The recommendations include improving access to a limited selection of “essential psychotropic medicines”. These are medicines that satisfy the priority mental health care needs of a population. They are selected with due regard to public health relevance, and based on evidence of their efficacy, safety and comparative cost-effectiveness. They can be used for the treatment of symptoms of mental disorders, to shorten the course of many disorders, reduce disability and prevent relapse. Not all “effective” pharmaceutical therapies are “essential”.

The experiences of many countries demonstrate that improvements in the supply and use of medicines are possible. Systematic knowledge on strategies to improve access to medicines is also available. Yet over one-third of the world’s population currently lacks regular access to essential medicines. Whereas psychotropics have many aspects in common with other essential medicines, there are also several aspects that need special consideration when improving access.

### **Improving access to psychotropics**

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Access of populations to essential psychotropics is determined by:

- (i) a rational selection of medicines;
- (ii) making prices affordable;
- (iii) ensuring sustainable financing; and
- (iv) availability of reliable health and supply systems.

Each one of these can enable or prevent effective treatment from reaching those who need it.

In addition to the four determinants mentioned above, four other issues are of key importance. These relate to

- (i) presence of strong mental health policies, which clearly define a strategy to achieve improved access;
- (ii) mental health legislation that enhances, rather than obstructs, access;
- (iii) appropriate use of psychotropic medicines to achieve high quality mental care; and
- (iv) systematic assessment and monitoring for continuous maintenance and improvement of access to care.

All eight issues need to be considered in any plan aimed at improving access to psychotropic medicines.

Mental health policies should clearly define the major issues and objectives of access to psychotropics. They should also define the respective roles of public, private (for-profit), and NGO (not-for-profit) sectors in the financing and provision of these medicines; identify organizational arrangements to meet access objectives; set an agenda for capacity building and organizational development; provide guidance to prioritize expenditure; and make decisions on resource allocation. A policy, however well formulated, is worth little if it is not translated into a programme of action. Countries should not only develop and officially adopt policies or plans of action, but also effectively implement them.



Legislation should define the responsibilities and authorities of all actors in the system, and their responsibilities: who can produce or import medicines, who can store and sell medicines, which institution is responsible for monitoring and enforcing regulations, and who can prescribe the various types of products.

International trade agreements, particularly the one on Trade-Related Aspects of Intellectual Property Rights (TRIPS) - and probably the most disputed agreement - may affect the affordability of medicines in the future. TRIPS provides for a minimum period of 20 years for patent protection for products and processes; it may therefore prevent low-cost generic medicines becoming accessible to populations. Legislation should be put in place which would make full use of the TRIPS legal safeguards such as compulsory licensing and parallel imports for medicines of significant public health relevance. Countries are also advised to be cautious about enacting legislation that is more stringent than the actual TRIPS requirements.

Selecting a limited number of essential psychotropic medicines is economical. It is one of the most cost-effective means of improving mental health services. Careful selection facilitates bulk purchase and easier management of medicines (storage and distribution), and allows for a more rational and efficient approach to training in prescribing and dispensing. Decisions about selecting psychotropic medicines may be difficult when expensive medicines have some advantages, such as milder side-effects, but higher costs as compared to older medicines. In such cases, it is important to calculate the cost of the overall treatment, as this may actually prove to be lower for medicines that are more expensive on a tablet-to-tablet (dose-to-dose) basis.

Achieving affordability of prices for essential psychotropics is important in both the public and private sectors, especially as new medicines are often very costly. Affordable prices are not only important for people with mental disorders (PWMDs); other persons may also benefit from effective treatment. Prices of psychotropic medicines vary considerably between countries, without obvious reasons; therefore their pricing cannot be left solely to market forces. Indeed, active government involvement and intervention would even be justified.

A number of strategies exist for lowering the prices of medicines. These include making global drug price information broadly available; using good procurement practices, professional price negotiations, or direct price negotiations with manufacturers; procurement by generic names; stimulating competition through generic policies; and reduction or abolition of import duties or taxes on essential (psychotropic) medicines. Control of profit margins or mark-ups, or comparison with prices in other countries may also be considered. Clear guidelines exist that document the key operational principles for good pharmaceutical procurement. These operational principles are based on four strategic objectives: procurement of the most cost-effective medicines in the right quantities, pre-selection of reliable suppliers of high quality products, ensuring timely delivery, and achieving the lowest possible total cost. Moreover, purchasing medicines in large quantities may result in large discounts.

Financing mechanisms are crucial to the development of sustainable mental health systems and the medicines needed by them. There are five key principles for improving the financing of health care and its requirements for medicines. They centre around governments taking responsibility for financing basic health care delivery and minimizing direct out-of-pocket expenditures by the population, healthy people subsidizing the sick, the well-off subsidizing the poor (especially in mental health, as people with mental disorders are often poorer than others in the society), and optimizing efficiency and cutting waste as far as possible.

Economic access to essential medicines can only be improved when funds for their purchase are readily available, and when high-level political support for rigid adherence to transparent tender procedures can be ensured.

Effective supply systems rely on good design and management. Operational planning and logistic skills are of key importance to cost-effective distribution lines. Logistics teams should be staffed by qualified people. Details on how to set up such systems are now readily available from the standard essential medicines literature.

The quality of medicines on the market in several countries has become a major cause for concern; surveys show that up to 20% or more of sampled medicines failed quality control tests. Failure of effective control mechanisms has led to the presence of fake or sub-standard drugs in countries. Challenges concerning regulations for medicines include licensing and inspection of sales points and professionals, licensing and inspection of manufacturers, registration of medicines, and post-marketing surveillance. Quality must also be guaranteed throughout the distribution chain, in all climates and by all methods of transport.

### **Promoting appropriate use of psychotropics**

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Appropriate use of medicines requires that people receive medications appropriate to their needs, in doses that meet their individual requirements, for an adequate period of time, and at the lowest possible cost to them and their community. Inappropriate treatment may lead to unnecessary suffering and death, iatrogenic disease and hospital admissions. Inappropriate use may also lead to wastage of resources. There are large variations in prescribing psychotropic medicines among countries and health systems in the world, and there is no clear explanation for this. Any medicines, including essential ones, may be used inappropriately; an essential medicines policy is by no means a guarantee for their appropriate use.

Inappropriate use of medicines is caused by a wide range of factors, including lack of adequate knowledge about prescription and use, economic influences at all levels, lack of adequate regulatory systems, cultural factors, community belief systems, poor communication between prescribers and patients, and lack of objective information on the medicines combined with commercial promotion of the medicines. Poor prescribing for mental disorders includes incorrect use of essential psychotropics and incorrect prescribing of non-psychotropic medicines to treat mental disorders. Poor adherence to (correctly) prescribed medications for mental disorders occurs in both developed and developing countries. Factors influencing the use of medicines include their formulation, feeling better after therapy starts, and lack of regular outpatient support and counselling on the need for continued treatment. The most common non-compliant behaviour appears to be underuse of prescribed medicines.

Practices in the use and prescription of medicines reflect human behaviour, and must be understood from a social science perspective rather than a biomedical perspective. Enabling people with mental disorders to successfully initiate and adhere to treatments depends on several factors, relating not only to themselves but also to health care providers, health care systems and the treatments prescribed.

When developing strategies to improve poor prescribing practices (e.g. over- and underprescribing, prescribing the wrong kind of medicine, or expensive brands when lower cost generics are available) or poor adherence to treatment, it is essential first to identify the extent of these problems and the reasons for them. This can be done through quantitative and qualitative research methods. There exist a variety of easily usable tools and methodologies for this kind of research.

Activities to promote a more appropriate use of medicines need to address all the actors concerned: prescribers, dispensers and consumers of the medicines. International training courses on promoting appropriate use of medicines are being organized regularly, and may help in defining strategies to improve the use of psychotropics at the national or institutional level.

Strategies to promote rational use of medicines can be of an educational, managerial or regulatory nature. For an intervention to be effective, it needs to be focused and

targeted at those prescribers who have a particular prescribing problem, or to those consumers who have a particular use or adherence problem. A substantial amount of research has been carried out into effectiveness of various intervention options. A series of examples of educational, managerial and regulatory strategies are presented in this module.

Information supplied by the pharmaceutical industry through mailings, visits by pharmaceutical representatives and industry-sponsored formularies is very often the only type of information available to prescribers. Lack of access to independent information on medicines can result in their inappropriate use. Medicine information centres are an important means of addressing this problem. In addition, bulletins about medicines can provide summarized, comparative, independent and up-to-date information on selected medicines, and preferably include information about the costs of treatment.

Continuing education activities are sometimes heavily supported by pharmaceutical companies. Government support to university departments and national professional associations for providing independent continuing education can be very cost-effective, as this would more likely encourage a focus on essential medicines as opposed to costly brand-name medicines.

Whereas most of the strategies that are implemented in the public sector can also be implemented in the private sector, some interventions are more effective when aimed at the private sector. These include separation of prescribing and dispensing functions. Dispensing practitioners consistently prescribe more drugs than do their non-dispensing colleagues; they also spend less time with patients. Generic policies, pricing policies and a fair dispensing fee structure could help to encourage the use of essential medicines and promote generic prescribing and substitution, provided that such regulations are well enforced.

### **Assessing a psychotropic access system**

An accurate, systematic assessment is a prerequisite for changing any poorly functioning access system. Depending on the needs, a comprehensive structured assessment, a limited assessment, or any combination thereof, can be carried out. The assessment needs to look at several functions of the access system, including policy and legislation, selection of psychotropic medicines, affordability of medicines, sources of finance, pharmaceutical logistics, procurement, product quality, and drug use and prescription.

The choice of the assessment tool will depend on what is sought to be improved and availability of resources.

Careful management of the assessment is absolutely necessary. Quantitative and qualitative data, performance indicators, and special-purpose analyses should be integrated into the overall assessment methodology. Pharmaceutical management, in particular, may need to be surveyed in detail to determine efficiency and possible waste.

Consumption analysis methodologies, such as ABC (a ranking of drugs according to which ones incur the largest budgetary expenditures) analysis and vital, essential, non-essential (VEN) analyses, can be revealing.

Data collected during the assessments will need to be analysed, with dedicated time and resources made available for this purpose. Time for report writing needs to be reserved, as well as time for presentation and discussions of the findings among larger audiences.

Finally, a seven-step approach is presented for improving access to psychotropics in a country or institution.

## Aims and target audience

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This manual is about how to improve access to essential medicines for mental disorders, often referred to as “essential psychotropic medicines” or “essential psychotropics”. It presents practical ways for governments, mental health departments, essential medicines programmes, non-governmental organizations (NGOs), and others to close the gap between the need for essential psychotropics and access to them. It thus deals with the availability of psychotropic medicines, their affordability, their financing and their appropriate use.

The manual is intended for use by policy-makers and public health professionals of national ministries of health (or health offices) and large administrative divisions of countries (regions, states or provinces) in charge of planning improvements in mental health systems.

The introduction discusses the problems that exist in mental health care delivery in countries. Practical guidance is then provided to improve the various components of the access framework for psychotropics, based on positive experiences in different countries of the world. Although general principles of improving access to psychotropics apply to most systems in the world, the information presented in this module will need to be adjusted for different contexts within countries. Examples and practical information are provided on how access can be improved. The reference section lists a large number of documents of interest to those who are in charge of implementing programmes to improve access. In addition, cross-references are made, where appropriate, to other modules in the Mental Health Policy and Service Guidance Package.

<b>ACHes</b>	cholinergic receptor agonists
<b>AIDS</b>	acquired immune deficiency syndrome
<b>CBR</b>	community-based rehabilitation
<b>CMS</b>	central medical stores
<b>CNS</b>	central nervous system
<b>DDA</b>	Dangerous Drugs Act
<b>EDM</b>	Essential Drugs and Medicines Policy (WHO department)
<b>EML</b>	Essential Medicines List (previously known as EDL = Essential Drugs List)
<b>HAI</b>	Health Action International
<b>HIV</b>	human immunodeficiency virus
<b>IDA</b>	International Dispensary Association
<b>INN</b>	International Nonproprietary Name
<b>INRUD</b>	International Network for the Rational Use of Drugs
<b>IPC</b>	Interagency Pharmaceutical Coordination group
<b>MOH</b>	Ministry of Health
<b>MSH</b>	Management Sciences for Health
<b>NGO</b>	non-governmental organization
<b>PHC</b>	primary health care
<b>PWMDs</b>	people with mental disorders
<b>STG</b>	standard treatment guidelines
<b>TLC</b>	thin-layer chromatography
<b>TRIPS</b>	Agreement on Trade-Related Aspects of Intellectual Property Rights
<b>UN</b>	United Nations
<b>UNICEF</b>	United Nations Children's Fund
<b>VEN</b>	vital, essential, non-essential (pharmaceutical analysis method)
<b>WHO</b>	World Health Organization

# 1. Introduction

Mental and behavioural disorders are estimated to account for 12% of the global burden of disease, but only a minority of persons affected receive basic treatment. This group of disorders includes depressive disorders, affective disorders, schizophrenia, epilepsy, dementia, post-traumatic stress disorder, obsessive and compulsive disorders, panic disorder and primary insomnia (WHO, 2001a). At the global level only a minority of people with mental disorders (PWMDs) consult a physician (Andrews et al., 2000; Kapczinski et al., 2001). Whereas there is evidence from industrialized countries that not all people with mental disorders receive adequate treatment (Andrews et al., 2000), in developing countries health systems are often not able to provide even the most essential mental health care. How many PWMDs in developing countries remain untreated is a matter of speculation, but it is likely that the numbers are huge.

The World Health Organization (WHO) reviewed evidence for effective treatment of mental disorders, and concluded that a combined psychosocial and pharmacological approach is likely to yield the best results. The World Health Report 2001 (WHO 2001a) presents a variety of recommendations on how to improve care for PWMDs, including improving access to a limited selection of essential psychotropic medicines. These medicines should be made available at all levels of health care and should be included in essential medicines lists, with health personnel trained to use them in treating PWMDs.

Improving access to essential psychotropic medicines is a key component in strengthening access to effective mental health care services.

## **What are essential psychotropic medicines?**

Essential psychotropic medicines are “those that satisfy the priority mental health care needs of a population. They are selected with due regard to public health relevance, evidence of efficacy and safety, and comparative cost-effectiveness. They should be available within the context of functioning mental health delivery systems, at all times, in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford” (WHO, 2003a). Essential psychotropic medicines allow for the treatment of symptoms of mental disorders, shorten the course of many disorders, reduce disability and prevent relapse (WHO, 2001a).

A large number of treatments are available for the pharmacological management of mental disorders. Many of these treatments have been shown to be effective in acute stages and in preventing relapses, but much remains unclear about their effectiveness in long-term treatment and in managing everyday mental disorders (Andrews et al., 2000). Hence, not all “effective” drug therapies are “essential”; this may become clear once such factors as effectiveness of long-term applications, advantages over cheaper alternatives and cost-effectiveness are better understood.

Recent cost-effectiveness studies have concentrated on finding the relative advantages of newer classes of medicines over the older and more established ones. For example, newer antidepressants were compared to the older tricyclic antidepressants, and newer antipsychotics to the conventional neuroleptics. Findings indicated that while newer psychotropic medicines have fewer side-effects, they are not significantly more effective, and they are usually more expensive (WHO, 2001a). However, since the newer medicines sometimes have fewer side-effects, they may help improve adherence and

*disorders account for 12% of the global burden of disease, but only a minority of persons affected receive basic treatment.*

*According to WHO, a combined psychosocial and pharmacological approach is likely to be the most effective way of treating mental disorders*

*Not all “effective” drugs are “essential” in managing mental disorders.*

decrease the need for other care and treatment. A more detailed discussion of treatment options and recommendations for the management of mental disorders is presented in annex 1.

There are basically five classes of psychotropic medicines that target specific symptoms of mental disorders (WHO, 2003a):

- (i) Antipsychotics for psychotic disorders;
- (ii) Drugs used in mood disorders (depressive or bipolar);
- (iii) Anxiolytics or tranquillizers for generalized anxiety and sleep disorders;
- (iv) Drugs used in obsessive compulsive disorders and panic attacks; and
- (v) Anticonvulsants/anti-epileptics.

These medicines target the symptoms of diseases, not the diseases themselves or their causes. A more detailed discussion on the selection of particular medicines is presented in Chapter 2.4.

### **What is “access” and why is it important?**

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This module considers access as a framework of four main components:

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

Access to psychotropic medicines is determined by many factors, each of which can enable or prevent effective treatment reaching those who need it. Each of these components is essential, but not sufficient in itself to ensure adequate access. Details on the WHO “access framework” are further explained in Chapter 2 on improving access to psychotropics.

It is estimated that over one-third of the world’s population lacks regular access to essential medicines, while in the poorest parts of Africa and Asia over half the population lack such access (WHO, 2000). There is a similar pattern with regard to access to essential psychotropic medicines. Indeed, there are indications that it may actually be worse (WHO, 2001a).

Epilepsy is the most common serious neurological disorder and one of the world’s most prevalent noncommunicable diseases. Over four-fifths of the 50 million people with epilepsy are thought to be in developing countries, and around 90% of people with epilepsy in developing countries are not receiving appropriate treatment (Scott, Lhatoo & Sander, 2001).

### **Access can be improved**

---

Experiences of countless countries and programmes demonstrate that substantial and sustainable improvements in the supply and use of medicines are possible. Much can be accomplished with reasonable effort, moderate know-how and relatively little additional funding. Clear goals, sound plans, effective implementation and systematic monitoring of performance are essential ingredients and the best guarantee of success. Substantial knowledge is available now on effective strategies to improve access to medicines (WHO, 2001b).

*Access is determined by many factors including regulation, selection, procurement, financing, efficient management, distribution, good prescribing, and, ultimately, appropriate use by consumers*

*Substantial improvements are possible, and much can be accomplished with reasonable effort, moderate know-how and relatively little additional funding*



A vital condition for improving access is strong political commitment to change. Without it, most efforts to improve access may end up as merely cosmetic and may fail to achieve substantial change (WHO, 2001b).

### **Special considerations for essential psychotropics**

Whereas psychotropics have many aspects in common with other essential medicines, there are several aspects that need special consideration in efforts to improve access. These include:

#### *The often chronic nature of mental disorders, requiring long-term treatment*

Mental and behavioural disorders are often chronic, although sometimes there are periods of remission and relapse. Depression follows a chronic course without remission in about 20% of cases (Thornicroft & Sartorius, 1993), especially when adequate treatment is not available. Schizophrenia follows a chronic or recurrent course, with residual symptoms and incomplete social recovery in about one-third of cases. Epilepsy typically arises during childhood and may follow a chronic course.

This chronic nature has particular implications for access to services, staff availability, and costs to patients and families. What matters is not only the cost of an individual treatment or service, but also the likelihood of the treatment having to be repeated over long periods.

#### *Importance of adherence to treatment*

While adherence to medical treatment is important for many conditions, it is particularly so for mental disorders. Compliance with long-term treatment is harder to achieve than that with short-term treatments. Strong involvement of family members is often of critical importance. A further complication is that mental or behavioural disorders themselves are associated with poor compliance with treatment regimes, especially when difficulties with insight and cognitive functioning are present. As a consequence, compliance with medication regimens is lower among patients with mental disorders than among patients with physical disorders (Kampman & Lehtinen, 1999).

#### *Controlled nature of several psychotropics*

Owing to problems of dependence and misuse, some essential psychotropics may be subject to regulations relating to controlled medicines in some countries. This may apply to phenobarbital, for example, but increasingly also to medicines such as chlorpromazine and diazepam. These drugs may be labelled as drugs of abuse and therefore subject to controls under the Dangerous Drugs Act (DDA), such as requiring storage in double-lock cupboards and signatures in a register to record their movement. On the other hand, such drugs may also be labelled as specialist drugs, which may mean that primary health care workers cannot prescribe them. This complicates their application and is an obstacle in all stages of their management, prescription and use.

#### *Dependence and misuse*

Dependence (both physical and psychological) and subsequent difficulty in withdrawing from the drug may occur with anxiolytics and hypnotics, even the mild ones (WHO, 2002a). Sometimes, the dangers are not clear because recognition of dependence is not always easy and the effects are less obvious. A notable result of uninhibited use is that large numbers of patients in countries may take tablets which do them neither much good nor much harm.

*Psychotropic medicines have several aspects that need special consideration in efforts to improve access.*

*Affordability does not depend only on suppliers setting the prices; there are strategies for securing lower prices.*



### *More difficult therapeutic margins*

There is substantial variability in individuals' response and tolerance of many psychotropics. Whereas plasma levels of lithium are a good indicator of both efficacy and toxicity, plasma concentrations of other psychotropic medicines and their metabolites are usually not good predictors of clinical response owing to pronounced inter-individual variation. Thus, two people being treated with, say, an antidepressant, may respond similarly despite markedly different plasma concentrations (VMPF, 1995).

Ranges for effective doses are sometimes difficult to define; in some countries, people with mental disorders are routinely treated with high-dose psychotropics, especially antipsychotic medicines. There can be negative long-term consequences of such treatment practices, for example, toxicity of the central nervous system (CNS) or the risk of sudden cardiac-related death (cardiac conduction abnormalities).

### **Key points**

- Essential psychotropic medicines, in addition to psychosocial management strategies, enable the effective treatment of symptoms of mental disorders, shorten the course of many disorders, reduce disability and prevent relapse.
- Large numbers of people with mental disorders in developing countries remain untreated because of inadequate access to such medicines.
- Substantial and sustainable improvements are possible with limited effort, a moderate amount of know-how and relatively little additional funding.
- Not all "effective" therapies are "essential" and careful selection of psychotropic treatments is of key importance.

## 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-

*The WHO framework for access to essential medicines comprises four elements:*

- Rational selection;
- Affordable prices;
- Sustainable financing;
- Reliable health and supply systems.

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*

*Formulation of mental health policies containing details about access to medicines is especially important for countries that have few resources for mental health.*

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: Kapczynski 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.

*PWMDs, family members, professionals and other interested parties can play a decisive role in convincing decision-makers to design good policies.*

*A policy, however well formulated, is worth little if it is not translated into a programme of action.*

*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.

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

*Legislation should enhance, and not obstruct, adequate access.*

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**

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- > 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**

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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.

*Evidence shows that newer psychotropics may have some advantages, but they are not always more effective, and usually much more expensive.*

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](http://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.

#### **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.

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



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

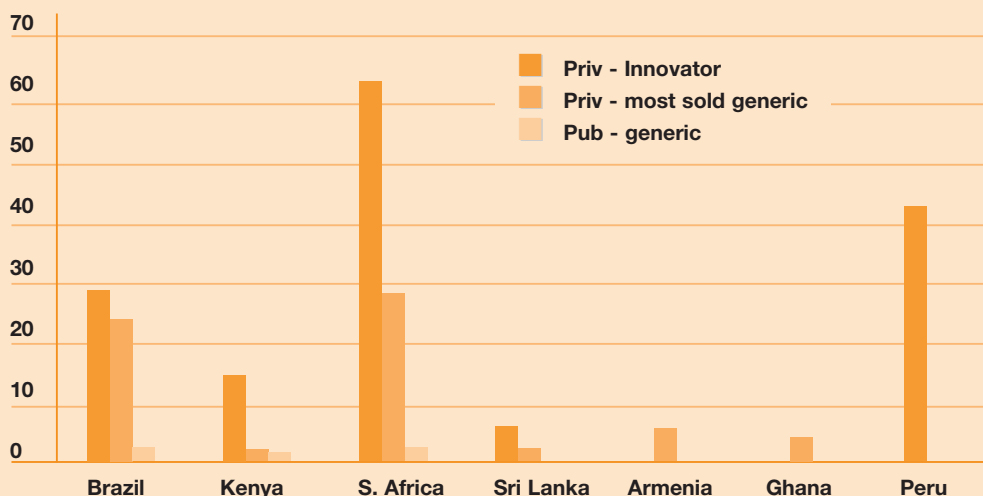
Due to the specific character of treatments for mental disorders (many of them requiring long-term use), expenditure on medicines may constitute a large proportion of overall expenditures in mental health care delivery.

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.

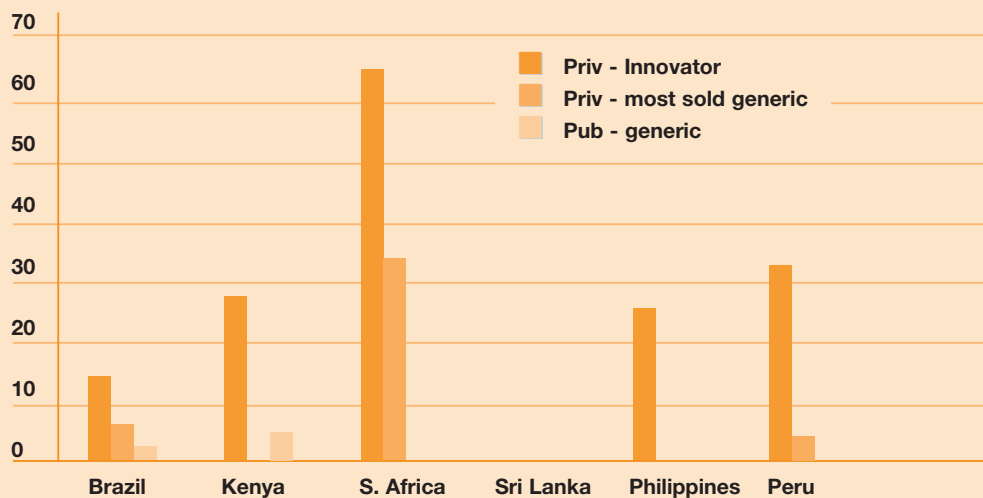
*Affordable prices are important for PWMDs themselves, but also for others, such as families who benefit from effective management of mental disorders of one of their members*

#### 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.

*Affordability does not depend only on suppliers setting the prices; there are strategies for securing lower prices.*

### **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](http://www.ida.nl)), the Supply Division of the United Nations Children's Fund (UNICEF) in Copenhagen ([www.supply.unicef.dk](http://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](http://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.

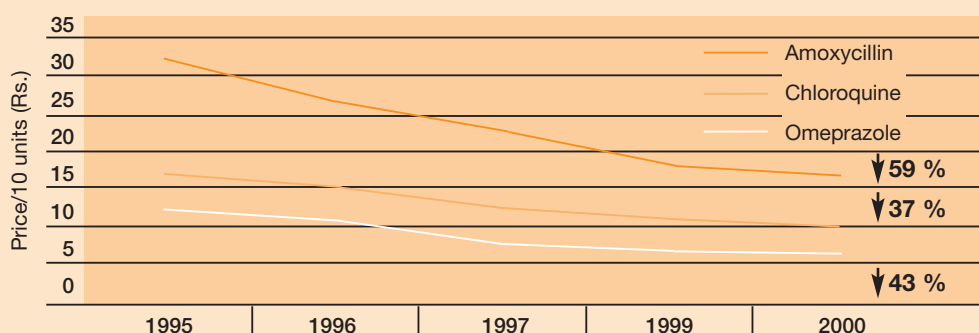
Pre-qualification of suppliers and performance monitoring are indispensable tools to avoid buying pharmaceuticals of poor quality. A wealth of technical information is available from reputable sources (WHO, 1999a, World Bank, 2000) to ensure quality. Market intelligence is of great benefit for procurement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



### 3. Promoting appropriate use of psychotropics

Appropriate use of medicines requires that people receive those that are appropriate to their clinical needs, in doses that meet their individual requirements, for an adequate period of time, and at the lowest possible cost to them and their community (WHO, 2001b).

Inappropriate treatment may lead to unnecessary suffering and death, iatrogenic disease and hospital admissions. In economic terms, inappropriate use may lead to waste of resources and to non-availability of essential medicines in other areas where they may be needed.

An essential drugs policy is no guarantee of appropriate use of medicines. Any medicine, including essential ones, may be used inappropriately, and often is, in both developing and industrialized countries, in the public and private sectors and in the home. All the gains from efficient selection, procurement and distribution can be lost by poor prescribing practices and by lack of adherence to treatment by the patient (WHO, 2002c).

Large variations exist in prescribing psychotropic medicines in various locations in the world (see box 11), and there is insufficient knowledge to explain these differences.

#### 3.1 Factors underlying inappropriate use of medicines

Use of medicines is influenced by a wide range of factors, including lack of adequate knowledge about prescription and use, economic influences at all levels, lack of adequate regulatory systems, cultural factors, community beliefs, poor communication between prescribers and patients, and lack of objective information on medicines, combined with their commercial promotion (Quick et al., 1997; Wang et al., 2000). Practices in the use of medicines reflect human behaviour and must be understood from a social science perspective, rather than a biomedical perspective.

Inappropriate prescription of medications includes poor use of essential psychotropics (e.g. indefinite prescription of benzodiazepines or excessively long use of antipsychotics), and incorrect prescription of non-psychotropic medicines to treat mental disorders (e.g. injectable vitamins for common mental disorders) (Patel et al., 1998, Nunley, 1996).

Poor adherence to (correctly) prescribed medications for mental disorders occurs in both developed and developing countries (Tansella, 2000). A meta-analysis of adherence studies found that people with mental disorders took on average only 58% of the recommended amounts of antipsychotics, ranging from 24% to 96%. People on antidepressants took on average 65% of the recommended amounts, ranging from 40% to 90% (Cramer & Rosenbeck, 1998). Poor adherence includes overuse, abuse, forgetting to take the medications, and alteration of schedules and doses. Factors that contribute to poor use of medicines include dosage forms that are difficult to take, insufficient counselling on the need for continued treatment, and lack of regular outpatient support to ensure correct drug use by patients. Elderly people in acute stages of mental disorders may take more than the prescribed dose to “speed up” their recovery. Forgetting to take a medication is likely when several drugs are required to be taken simultaneously. However, the most common non-compliant behaviour appears to be underuse of prescribed medicines, which may be caused by feeling better after successful treatment (Patel et al., 2003), or lack of regular support that emphasizes the need for continued treatment. When dementia or depression is present, adherence can be particularly poor (Salzman, 1995).

*Inappropriate treatment may lead to unnecessary suffering and death, iatrogenic disease and hospital admissions.*

*Poor adherence to psychotropic treatment is common in both developed and developing countries.*

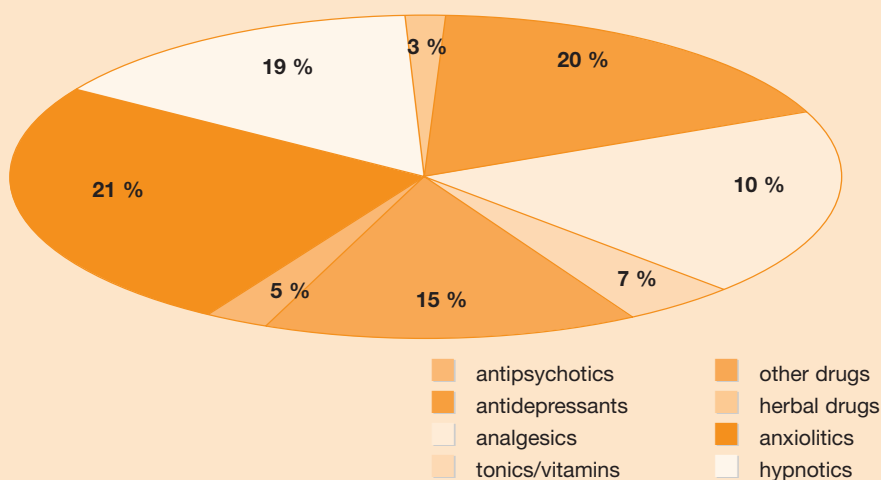


**Box 11. Differences in prescribing practices for psychotropic medicines in primary care centres around the world**

A WHO coordinated study investigated prescribing practices for mental disorders in primary care centres in Berlin, Groningen, Mainz, Manchester, Paris, Santiago, Seattle, Verona, Athens (classified as client-type institutions), and Ankara, Bangalore, Ibadan, Nagasaki, Rio de Janeiro, and Shanghai (classified as clinic-type institutions).

On average 11.5% of practice attendees received a psychotropic medication for a psychological problem, ranging from 29.6% in Santiago to 2.1% in Shanghai. Significant differences were observed with respect to psychotropic polypharmacy (12.6% client, 6.3% clinic), use of tranquillizers (24.2% client, 32.9% clinic), and use of antidepressants (17.3% client, 8.9% clinic).

**Fig 1. Prescribing practices in PHC centres in the world**



Anxiolytics, hypnotics and antidepressants were the most common classes of medicines prescribed, each accounting for approximately 20% of the total. Anti-psychotics, analgesics, tonics and herbal drugs each accounted for 5% -10% of the medications prescribed (see fig. 1). A remarkable finding was the wide spectrum of drugs prescribed for mental disorders. Nearly 80% of the drugs used were of unproven clinical efficacy. Herbal drugs, tonics, analgesics or other unspecified drugs amounted to 35.6% of all prescriptions, and daytime and night-time tranquillizers accounted for another 41.3%.

Prescriptions for antidepressants and tranquillizers (anxiolytics and hypnotics) varied considerably across centres. Whereas in Seattle and Manchester 75.7% and 41.0%, respectively, of depressive disorders were treated with antidepressants, in Santiago and Bangalore the corresponding figures were 35.1% and 12.5%. On the other hand, tranquillizers were used in 2.7% and 12.8% of prescriptions in Seattle and Manchester respectively, and in 45.9% and 27.0% of prescriptions in Santiago and Bangalore. There was a tendency for higher prescription of tranquillizers in clinic-type institutions, and higher prescription of antidepressants and miscellaneous drugs in client-type institutions.

Survey results confirmed that medical treatment in general, and the prescription of drugs in particular, are not related solely to medical or pharmacologic variables but also to psychological, social and cultural factors. Non-clinical factors such as age, gender, education, family status or employment status have an important influence on drug use.

Source: Linden et al., 1999

### **Box 12. Poor client information in Cambodia**

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“Drugs in this country are available without prescription. Everyone has access to small neighbourhood pharmacies and can ask for any drug they wish. Because of this easy access, some psychiatrists will not tell their patients what drug they prescribe. Instead, they give a set number of pills to take. Their rationale for this lack of patient information is that patients may go to the neighbourhood pharmacies and not come back to the psychiatrist, or that they may take the medication improperly”.

*Source: Personal communication with a mental health worker from Cambodia.*

Enabling people with mental disorders to successfully initiate and adhere to treatments depends on several factors, relating not only to themselves but also to health care providers, health care systems and the treatments prescribed. Understanding people’s views on mental disorders and the proposed treatments is an important step to improving the appropriateness of the treatments (WHO, 2001a). Community-based rehabilitation (CBR) approaches, which emphasize the use of local human resources, building community awareness and creating family networks, have been shown to result in significantly better use of psychotropic medicines and better clinical outcomes (Chatterjee et al., 2003).

In some countries, clinicians actively avoid providing clients with information on how to use psychotropics (see box 12).

### **3.2 Investigating the use of medicines**

When developing strategies to improve the prescription or use of medicines, it is essential to learn about the determinants of the problems, and to identify and measure them. Pharmaceutical companies succeed in changing particular habits in the use of medicines because they understand what influences those habits. Interventions to promote better use of medicines often fail because they are based on the notion that simply improving knowledge will improve their use (Quick et al., 1997).

### **Box 13. Indicators commonly used to investigate drug use in health facilities**

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#### **Prescribing Indicators**

- Average number of medicines per encounter
- Percentage of medicines prescribed by generic name
- Percentage of encounters with an antibiotic prescribed
- Percentage of encounters with an injection prescribed
- Percentage of medicines prescribed from essential medicines list or formulary
- Percentage of patients leaving without a medicine being prescribed

#### **Patient Care Indicators**

- Average consultation time
- Average dispensing time
- Percentage of medicines actually dispensed
- Percentage of medicines adequately labelled
- Patients’ knowledge of correct dosage

#### **Health Facility Indicators**

- Availability of copy of essential medicines list or formulary
- Availability of key medicines.

Most indicator input data can also be collected at primary care level. At least 20 facilities should be visited and 30 prescriptions examined at each site, with at least 10 patients observed and interviewed.

Source: WHO, 1993.

A quantitative survey (e.g. a prescription survey, a review of medicine management data, or observation of a particular event of (harmful) prescribing may be a first step towards obtaining a comprehensive understanding. If further investigation confirms that the observed behaviour presents a significant problem, an effort should be made to define the underlying causes clearly. Qualitative research methods can help in understanding why inappropriate prescribing behaviours occur and how they might best be changed (Laing et al., 2001).

A variety of easily usable tools and methods are available to assist in this endeavour. The WHO manual, How to Investigate Drug Use in Health Facilities (WHO, 1993) provides a simple quantitative screening method for identifying and measuring the quality of prescribing and dispensing. The manual includes a summary of indicator surveys on the use of medicines in a number of developing countries (see box 13). Outcomes of indicator surveys can be of use in monitoring improvements of mental health delivery programmes (see also another module in this series: Mental Health Information Systems).

WHO and the International Network for the Rational Use of Drugs (INRUD) organize international training courses on promoting appropriate use of medicines. The materials are useful for investigating the use of psychotropic medicines and selecting strategies to improve their use. The course modules are available for downloading, adaptation and use at national or institutional levels (Boston University, undated. <http://dcc2.bumc.bu.edu/prdu/default.html>).

Information on how to improve the general quality of mental health services can be found in another module in this series (see module on Quality Improvement for Mental Health).

### 3.3 Improving the use of medicines

Strategies to promote more appropriate use of medicines need to address all actors, including prescribers, dispensers and consumers of medicines (WHO, 2002c). As traditional concepts about mental disorders may also affect acceptance and compliance with modern treatment (Kaiser et al., 1998), other actors, such as those selling medicines and traditional healers, also need to be addressed in a comprehensive strategy to improve drug use.

Adequate knowledge is important, but does not always lead to appropriate behaviour. For example, when economic incentives to prescribe more expensive medicines exist, education alone will probably do little to change prescribing practices. If a local health facility has long queues, poorly paid and unfriendly staff, and no drugs, while a fully stocked friendly market vendor is near at hand, more than education will be needed to change consumer drug use practices (Laing et al., 2001). For this reason, it is of critical importance to understand the environment in which medicines are used when planning strategies for change.

WHO promotes three integrated components for appropriate use of medicines (WHO, 2000):

*Quantitative and qualitative surveys are essential to understand the complexities of inappropriate use of medicines.*

*Various easy tools and methods are available to assist in investigating drug use practices.*

*Quality training materials to improve use of medicines are available for free downloading, adaptation and use.*

- > Appropriate use of medicines strategy and monitoring: advocating rational use of medicines, identifying and promoting successful strategies and securing responsible promotion of medicines;
- > Appropriate use of medicines by health professionals: developing and updating treatment guidelines, lists of essential medicines and formularies, continuing professional development and supervision for qualified professionals, and supporting training programmes on the rational use of medicines;
- > Appropriate use of medicines by consumers: supporting the establishment of systems of information on medicines, and empowering consumers to take responsible decisions about their treatment.

Strategies to promote rational use of medicines can be educational, managerial or regulatory. These strategies are discussed in detail elsewhere; a substantial amount of research has been carried out into the effectiveness of various intervention options (WHO, 2002c). Box 14 lists specific recommendations to improve the use of medicines in developing countries.

*Strategies to promote rational use of medicines can be educational, managerial or regulatory.*

#### **Box 14. Ten recommendations to improve the use of medicines in developing countries**

##### **Recommended approaches**

1. Develop, disseminate, utilize and revise national (or hospital-specific) standard treatment guidelines.
2. Develop and revise an essential drugs list (or hospital formulary) based on treatments of choice.
3. Establish representative Hospital Pharmacy and Therapeutics Committees with defined responsibilities for monitoring and promoting quality use of medicines.
4. Implement problem-based training in pharmacotherapy in undergraduate medical and paramedical education based on national standard treatment guidelines.
5. Encourage targeted, problem-based, in-service educational programmes by professional societies, universities and ministries of health, and require regular continuing education for licensing of health professionals.

##### **Promising approaches**

6. Stimulate interactive group processes among health providers or consumers to review and apply information about appropriate use of medicines.
7. Train pharmacists and drug sellers to be active members of the health care team and to offer advice to consumers about health and drugs.
8. Encourage active involvement by consumer organizations in public education about drugs, and devote government resources to support these efforts.

##### **Probably effective, but important gaps in experience exist**

9. Develop a strategic approach to improve prescribing in the private sector through regulation and long-term collaborative arrangements with professional associations.
10. Establish systems to monitor key pharmaceutical indicators routinely in order to track the impact of health sector reforms and regulatory changes.

*Source: Laing et al., 2001.*

For an intervention to be effective, it needs to be focused and targeted at those prescribers who have a particular prescribing problem, or to those consumers who have a particular use or adherence problem. For example, in a training intervention, a general lecture on pharmacology of benzodiazepines is unlikely to change prescribing practices. A focused presentation on the correct treatment of mood disorders, emphasizing preferred treatments and cost considerations and discouraging the use of new and unknown brand products, is far more likely to achieve the desired results. Interventions directed towards consumers are most relevant if they focus on common patterns of inappropriate use of medicines, and cover problems that consumers themselves consider important (Quick et al., 1997). Education programmes should have long-term sustainability.

Careful monitoring and evaluation is necessary to determine which approaches and strategies work best, or whether strategies may have to be changed. Standardized indicators are available for this purpose (WHO, 2001f).

### 3.4 Examples of educational strategies

Prescriber training often focuses on the transfer of pharmacological knowledge, rather than on developing adequate prescribing skills and the ability to assess information on medicines critically. Education of consumers is neglected in many parts of the world. This is of special concern in developing countries, where prescription medicines are widely available without prescription from a variety of sources, and where promotion of medicines is not well regulated and frequently inappropriate. An educational strategy that concentrates solely on formal prescribers will have limited impact on the rational use of medicines in the population (WHO, 2002c). Some countries may want to consider educating pharmacy attendants, as a substantial number of PWMDs may go to them for treatment.

#### *Basic training of health Professionals*

Improving the basic training of health workers and those involved in dispensing medicines is important for achieving more appropriate use of medicines (Abiodun, 1998). Emphasis needs to be placed on problem-solving techniques, critical appraisal skills and good communication with patients. They should also be trained to communicate effectively with patients, to explain correct use of medicines and to answer questions as part of pharmaceutical care. The role of nurses in prescribing and dispensing and in communicating with patients should also be recognized (De Vries et al., 1994).

*Educational strategies are essential to improve the knowledge of both health workers and consumers.*

#### **Box 15. Principles of effective public education for improved use of drugs**

Effective public education is governed by a number of principles, including that it should:

- Be an integral part of any policy on medicines.
- Address all issues relating to use that are important to consumers.
- Recognize cultural diversity and the influence of social factors.
- Encourage informed decision-making and cover basic concepts related to drug action (e.g. which conditions do not require medicines, when to seek medical advice, how to read medicine labels or patient information).
- Involve NGOs, teachers, professional associations and community groups in planning, development and implementation of programmes.
- Have clear and measurable objectives. Changing beliefs and practices requires a stepwise process and sustained efforts.

Source: Fresle & Wolfheim 1997.

#### *In-service training of health workers*

Continuing education, supervisory visits and focused lectures and workshops are effective for increasing knowledge and changing prescribing behaviours. Experience has shown that there is a greater impact on behaviour when specific prescribing and dispensing behaviour is targeted, if groups are small, if known experts are involved in teaching, and if training is followed up with specific feedback on actual prescribing practices (WHO, 2002c; Davis et al., 1995).

#### *Consumer information and education*

Consumer information about medicines is very important for promoting adherence to treatment. It is often a neglected area in improving practices in the use of medicines. Experiences in consumer education are presented in a special WHO report (see box 15). A variety of community groups (e.g. consumer groups, family organizations, community leaders and others) may need to be educated on the improved use of psychotropic medicines. Consumers and family organizations may also need training on attitudes towards the pharmaceutical industry, and how to protect themselves from commercial promotion of medicines disguised as therapeutic information.

*Good quality consumer information is very important for promoting adherence to treatment.*

### **3.5 Examples of managerial strategies**

Managerial strategies can have a positive effect on practices relating to the use of medicines. In all cases, extensive discussions with all staff involved, a careful introduction, and intensive supervision and follow-up are essential for achieving a maximum impact.

#### **Box 16. Improving the use of psychotropics through participatory development of guidelines and education**

To improve the cost-effectiveness of use of psychotropic medications, a process was established to involve all stakeholders in a United States-based public-sector behavioural health managed care plan in the development of formulary guidelines. Guidelines were drafted and presented to all stakeholders in a series of meetings. Stakeholders were also educated about pharmacy cost management issues. The guidelines were modified on the basis of the feedback obtained. Within 10 weeks of implementation of the guidelines, monthly medication costs had declined by 3% from baseline, even though the number of medication users increased by 3% over the same period. The organizers concluded that effective, consensus-driven, medication cost-containment strategies can be implemented through a process of engagement and education of stakeholders.

*Source: Baker, 2001.*

#### *Treatment guidelines and essential medicines lists*

Treatment guidelines covering the most common disorders and adapted to the competence of the health workers are a good starting point for most interventions relating to access. Adherence to treatment guidelines can be promoted by involving end-users in defining them, by providing appropriate training on their use, and by supervision and medical audit (Laing et al., 2001; WHO, 2002c; Guiscafre et al., 1995; Grimshaw & Russell, 1993) (see box 16).

*Treatment guidelines covering the most common disorders are a good starting point for most interventions relating to access.*

#### *Drugs and therapeutics committees*

Drugs and therapeutics committees can play an important role in improving the efficient use of medicines both at national and institutional levels. Such committees should be considered essential to national or hospital-based pharmaceutical programmes. Developing the hospital formulary, performing medication prescription reviews, and



developing educational strategies to improve the management and use of medicines are some important activities of the committees (Laing et al., 2001; WHO, 2002c).

### 3.6 Examples of regulatory strategies

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Strategies to improve the rational use of medicines may fail because they are not backed by well functioning regulatory systems. There are various regulatory strategies that can support educational and managerial strategies to promote a rational use of medicines.

#### *Evaluation of medicines for market approval and scheduling*

A critical evaluation of medicines registered for marketing in a country is important to limit the availability and use of inappropriate medicines in the private sector. Banning of unusual psychotropic combination preparations may be necessary. Making tough decisions about which “over-the-counter” medicines should be made available to consumers and which should be available “on prescription only” are important, provided that these regulations are enforced (which too often is not the case). Regulations may be used to allow trained paramedical workers such as nurses, and in some cases, village health workers, to prescribe certain types of medicines (WHO, 1998b).

#### *Regulating inappropriate promotion of medicines*

Promotion of medicines influences prescribers and consumers. Therefore regulations to control such promotion are vital for improving the rational use of medicines. The WHO Ethical Criteria for Medicinal Drug Promotion (WHO, 1988) can be used as a basis for developing such regulations. Promotion should be in line with national health policies, and comply with national regulations and any existing voluntary standards.

### 3.7 Promoting appropriate use in the private sector

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Most of the examples described above also apply to the private sector. However, a few interventions are more effective when aimed at the private sector (WHO, 1997c). These are briefly described below.

#### *Regulatory measures and law enforcement*

To remove perverse incentives, governments may consider regulatory measures to separate prescribing and dispensing functions. Recent research clearly suggests that dispensing doctors tend to spend less time per patient encounter and prescribe more drugs than do their non-dispensing colleagues. Quality of care - in terms of drug use, patient safety and treatment cost - has been found to be lower with dispensing doctors than with non-dispensing doctors (Trap, Hansen & Hogerzeil, 2002).

Generic policies, pricing policies and a fair dispensing fee structure could help to encourage the use of essential medicines and promote generic prescription and substitution. Regulations on the sale of prescription medicines need to be better enforced. In view of the many vested interests, a stepwise approach is recommended (WHO, 2002c).

#### *Unbiased continuing education programmes*

In many countries, continuing education activities are heavily supported by pharmaceutical companies. Government support to university departments and national professional associations to provide independent continuing education, based on the national treatment guidelines, for example, can be very cost-effective. This support could be financial, or simply making sufficient copies of the national treatment guidelines available (WHO, 2002c).

*Regulatory strategies should provide a necessary back-up for any other intervention to improve access and use of essential psychotropics.*

*Drug use interventions aimed at the private sector are as important as those directed at the public sector. Evidence indicates that they are feasible in both sectors.*

### *Health insurance*

Reimbursements for medicines within health insurance schemes can have a positive effect on rational prescribing in the private sector. When their reimbursement is restricted to a specific list and to published treatment guidelines, patients have a financial incentive to put pressure on the prescriber to stay within the limits of those standards (WHO, 2002c). An example of an intervention concerning the reimbursement of psychotropics in Italy is presented in box 17.

#### **Box 17. A regulatory intervention to improve the use of benzodiazepines in Italy**

To improve the appropriate use of psychotropics, a new reimbursement law was adopted in Italy in 1994. All registered medicines were classified as follows: Class A for severe and chronic disorders, class B for important therapeutic needs, and class C for the remaining medicines. Medicines in class A became freely available, those in class B required a patient co-payment of 50%, while class C medicines had to be paid fully by the patient. Psychotropic medicines were also classified within this system. This (reimbursement) intervention affected the use of psychotropics. Ademethionine, a non-essential antidepressant, was extensively used before the measure, but sales dropped by almost 50% after enactment of the measure. Despite this, ademethionine remained among the five most commonly sold antidepressants for the next five years. Interestingly, the use of benzodiazepines was not affected by the measure. Its use actually increased by 53% during the period 1989-1999, suggesting that classifying these medicines in class C did not significantly discourage their widespread use.

*Source: Barbui et al., 2001.*

### **3.8 Making available unbiased information on medicines**

An underlying factor in the irrational use of medicines is often the lack of access to independent information about them. Information supplied by the pharmaceutical industry through mailings, visits by pharmaceutical representatives and industry-sponsored formularies is often the only type of information available to prescribers (WHO, 1998c). Information centres on medicines are an important tool in responding to the need for independent information about them (DSE, 1995). Such information centres can be established and maintained by the government, or linked to a teaching hospital. They can also be very effectively run by NGOs, particularly those targeting information to consumers. More information on mental health medicines and treatments is available from the WHO Mental Health website ([www.who.int/mental\\_health/](http://www.who.int/mental_health/)) and the WHO (virtual) Medicines Library ([www.who.int/medicines](http://www.who.int/medicines)).

A variety of printed materials can be used to further promote rational prescribing and use. Bulletins about medicines can provide summarized, comparative, independent and up-to-date information on selected medicines, and, preferably, should also include information about the cost of treatment. Used on its own, printed information may have a limited impact. Printed materials are most useful when used with other, more interactive, interventions, such as discussion groups, problem-based learning and prescription reviews (Gutierrez et al., 1994).

*Information on mental-health-related medicines and treatments is available from the WHO Mental Health website and the WHO (virtual) Medicines Library.*



## Key points

- Poor treatment practices may lead to unnecessary suffering and death, iatrogenic disease and hospital admissions. In economic terms, inappropriate use may lead to waste of resources.
- Many factors can lead to the improper use of medicines: lack of adequate knowledge, economic factors, lack of adequate regulatory systems, cultural factors, community beliefs, poor communication, and lack of objective information on medicines. Commercial promotion of medicines can also have a very bad influence.
- To address problems with prescription or use of medicines, it is essential to start by learning about the determinants of such problems.
- Strategies to promote appropriate use of medicines can be educational, managerial or regulatory.
- Educational strategies can target basic training of health professionals, or they can consist of in-service training of health workers, or PWMDs or their caretakers. Adequate knowledge on prescribing is important, but does not always lead to appropriate behaviour.
- Managerial strategies are a separate category of intervention, and may significantly improve the appropriate use of medicines.
- Regulatory strategies are often necessary to support educational and managerial strategies to promote the rational use of medicines.
- For an intervention to be effective, it needs to be focused and targeted at those prescribers or users who have a particular prescribing or use/adherence problem.
- Drug use interventions in the private sector are as important as those in the public sector.

## 4. Assessing a psychotropic access system

An accurate, systematic assessment is a prerequisite for changing poorly functioning access systems. Assessments are particularly appropriate for diagnosing problems, identifying their causes and prioritizing problems. Following an assessment carried out by an appropriate expert team (local or international), sound strategies to improve access and appropriate use can be developed. The outcomes of the assessment may also be used to monitor progress of short- and long-term action plans that may need to be implemented (WHO, 2002c).

Depending on the needs, different assessments may be carried out:

1. Comprehensive, structured assessments, involving relatively intensive work and a dedicated team;
2. Limited assessments, working mainly with interviews and document reviews; or
3. Any combination of the above two methods.

The choice of the assessment tool will depend on what is sought to be improved and the availability of resources. The main questions when structuring the assessment are:

- What issues need to be addressed in the assessment?
- What potential information sources exist?
- What information should be collected?
- What methods will be used to collect the information?
- What sort of team will do the assessment?
- What is the time frame and cost of the assessment?
- How will the assessment be managed?
- How will the results be presented for use by decision-makers?

The assessment needs to look at several functions of the access system, as outlined in the preceding chapters of this module. These functions include:

*Policy and legislation:* Is an access policy an integral part of the national or institutional mental health policy? Does existing legislation enhance or obstruct access to psychotropics?

*Selection of psychotropic medicines:* Which psychotropics are registered and used in the country or the institution? Is there an essential drugs list and which psychotropics are included? Are generic psychotropics known and used?

*Affordability:* What are the prices of psychotropics in the country or the institution? How do these prices compare to world market prices? Are there hidden costs that drive up the prices?

*Financing:* How are psychotropics financed? What share is paid out-of-pocket by PWMDs? Which other sources of financing exist? Do insurance systems cover the costs of psychotropic treatments?

*Pharmaceutical logistics:* How are psychotropic medicines distributed and stored? Are psychotropics available at the points where they are needed? Are there major losses due to expiration or theft?

*Pharmaceutical procurement:* Is there an effective procurement system that obtains good prices and is able to procure drugs in the right quantities and time frame?

*Product quality assurance:* Are the psychotropic medicines purchased and used in a system of good quality? Are the quality assurance programmes adequate?

*An accurate, systematic assessment is a prerequisite for changing poorly functioning access systems.*

*Drug utilization:* Do prescribers, dispensers and patients use psychotropics appropriately? What are the factors that determine use?

Management of the assessment is an absolute requirement, and must include the following detailed arrangements:

- Logistics planning;
- Selecting sites to be visited;
- Selecting indicator drugs;
- Defining data collection methods;
- Developing and refining data collection forms;
- Selecting and training data collectors;
- Analysing the data;
- Formulating conclusions and recommendations; and
- Presenting the findings.

Performance indicators are a fundamental part of any assessment of access. A number of useful manuals have been developed for assessing and monitoring pharmaceutical systems (WHO, 1993; WHO 2001f), and they include different categories of indicators: background information, structural indicators, process indicators and outcome indicators. The manuals also discuss methodological issues such as sample design, survey logistics and training data collectors. Indicators should be clear, useful, measurable, reliable and valid. An overview of key areas of indicators in the two WHO manuals cited above is provided in box 18.

*Performance indicators are a fundamental part of any assessment of access.*

#### **Box 18. Indicators to assess pharmaceutical systems**

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Indicators can be used to assess existing structures and processes in pharmaceutical systems. The data can help determine problem areas in the various components of the systems, and priorities for action. Key areas for which clear indicators have been developed and tested (“Level 1 indicators”) are:

1. National drugs policy
2. Essential drugs list
3. Legislation and regulatory frameworks
4. Quality assurance of medicines
5. Local production activities
6. Financing to procure drugs
7. Rational drug use

More detailed information can be obtained from the “Level 2 indicators”:

##### *Accessibility of drugs*

1. Availability of key drugs in health facilities, stores or warehouses
2. Stock-out duration in health facilities or stores
3. Percentage of prescribed drugs actually dispensed to patients
4. Affordability of key drugs in health facilities and private retail outlets

##### *Quality of drug management*

1. Adequacy of drug storage in health facilities or stores
2. Presence of expired drugs in health facilities, stores or private retail outlets

##### *Rational drug use*

1. Average number of drugs prescribed in health facilities
2. Percentage of use of a specific drug category in health facilities

3. Percentage of injection use in health facilities
4. Percentage of prescribed drugs that are included in the essential medicines list
5. Percentage of drugs that are adequately labelled in health facilities
6. Percentage of patients who know how to take their drug(s)
7. Availability of treatment guidelines in health facilities
8. Percentage of tracer cases treated according to treatment guidelines

*Source: Extracted from WHO, 2001f*

Quantitative data are useful to describe access systems in numerical ways; for example, the percentage of health facilities that stock a set of key essential psychotropics. Qualitative data provide insights into the state of an access situation and help determine the reasons, such as why key informants believe certain medicines are not easily available. Quantitative and qualitative data, performance indicators and special-purpose analyses should be integrated into the overall assessment methodology.

Quantitative and qualitative data may be obtained from:

*Document review:* A variety of studies have been carried out in most countries on issues relating to the pharmaceutical sector; a review of this literature should be one of the first steps in an assessment. It may be useful to contact international agencies such as WHO, the World Bank, bilateral donors and technical assistance organizations to obtain copies of relevant documents.

*Key informant interviews:* Interviews are a relatively fast way to learn about problems, provided the assessment team is able to identify the people who are most knowledgeable about the situation, and these people are prepared to discuss the situation frankly.

*Collection of data from existing records:* Data from existing records are critically important when reasonably well organized, complete, and current records exist. Relevant records include government publications on budgets and expenditures, medical records, pharmacy dispensing records, records of procurement, warehouse records, and accounting and finance records.

*Prospective field observations:* When information cannot be obtained from a review of records, observation may yield the required information. Surveyors can observe encounters with clients directly and record the interaction and medicines that are prescribed. Client exit surveys may yield additional useful data.

*Other methods for collecting qualitative information:* Other common methods for obtaining useful data include focus group discussions and household surveys.

Detailed surveys of pharmaceutical management may be needed to determine efficiency and possible waste. Consumption analysis methodologies, such as ABC and VEN pharmaceutical analyses, can be particularly revealing (Quick et al., 1997).

Data collected during the assessments need to be analysed, and dedicated time and resources made available for this purpose. This process must be well organized, especially when large amounts of quantitative data are available on costs, purchases, drug consumption and utilization practices. Time should also be reserved for report writing, and presentation and discussion of the findings with larger audiences.

### **Box 19. Assessing poor access to psychotropic medicines in a hypothetical country**

Poor access is due to a variety of unspecified problems, ranging from unavailability of essential psychotropic medicines in the public health care delivery system to circulation of poor quality brand-name products in the private sector. There are many opinions, but few clear ideas on the causes of poor access. Despite a functioning national health insurance system, consumers always pay an additional fee for drugs when collecting medicines from both public and private pharmacies. For mental disorders there is the additional problem that only inpatient treatments are covered, and the capacity of the mental health care delivery system is grossly inadequate. In everyday practice PWMDs or their caretakers shop around for all kinds of treatments with a variety of exotic brand-name medicines. As supplies of these brand-name drugs are unpredictable, PWMDs are treated irregularly and with different kinds of drugs.

To improve this dismal situation, a joint task force was established by the ministry of health (MOH), comprising its own staff, a large NGO that provides mental care, the Medical University, the Medical Association, and the Pharmacists' Association. It was decided to carry out a three-week limited assessment using existing information sources, but giving extra attention to the selection of psychotropics for the public sector, their affordability, and the financing of mental health care and its drug needs. Although it was felt that enough in-country expertise was available for most of the tasks, it was decided to request the assistance of WHO experts in the area of clinical pharmacology (with specific knowledge of psychotropic treatment), and a health economist to provide extra expertise in the areas of drug pricing and financing.

To maximize efficiency, a set of key documents was made available well in advance to each team member. Documents included:

- National Essential Medicines List (most recent edition, 1987);
- National Standard Treatment Guidelines (most recent edition, 1983);
- NGO Standard Treatment Guidelines (most recent edition, 1991);
- Procurement Policy of the Central Medical Store (CMS);
- Price catalogue of the CMS;
- Reimbursement Policy of the National Health Insurance;
- A survey of prices of a basket of drugs (including three psychotropics) in commercial pharmacies in the capital, carried out by a health activists' group in 1999; and
- In the absence of a national drugs policy, copies of the Dangerous Drugs Act of 1939 and the Drug Law of 1953 were added.

The task force decided that within the limited time and resources available, only three rapid surveys could be carried out, the results of which would have to be available at the time of the assessment:

- A price survey of essential psychotropics in the public sector;
- A price survey of essential psychotropics in the private sector;
- A psychotropics prescribing survey in a sample of outpatient departments of mental health institutions.

Team members were asked well in advance whether they would have additional information needs.

To guarantee independence, the MOH decided to use its own resources and not to ask international agencies to fund the assessment, except for the two experts to be made available by WHO. For the team-leader function, it was decided to invite an independent international health expert with considerable experience in strengthening mental health systems in a variety of developing countries. The expert was asked to be fully involved in all stages of preparation and implementation of the assessment.

The three-week assessment by five experts consisted of a range of key informant interviews, studying of documents, analysing survey results, and focus group discussions with PWMDs and their family members held in the five regions of the country.

The assessment ended with a two-day workshop entitled “Better access to Mental Health and Essential Psychotropics: The Way Forward”. The workshop received considerable attention from the local media.

### **Key points**

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- An accurate systematic assessment is a prerequisite for effectively changing poorly functioning access systems.
- Different types of assessments may be carried out: comprehensive structured assessments; limited assessments; or any combination of these two.
- Performance indicators are a fundamental part of such an assessment.
- Quantitative data are useful to describe access systems in numerical ways, while qualitative data may provide insights into the reasons behind poor access.
- Quantitative and qualitative data may be obtained from document reviews, key informant interviews, existing record systems or field observations.
- Detailed surveys of pharmaceutical management of the supply system could help determine possible waste or the degree of efficiency of the system.

## 5. A seven-step approach to improving access to psychotropics

A practical way to improve psychotropics access in a country or an institution would be to follow the seven-step approach outlined below.

### **Step 1: Organizing the process**

A necessary first step is to decide how to organize the process of improving access and the different activities needed to achieve this. At this stage it is also important to identify the interested parties to involve, the resources required, and how these can be obtained. The need for assistance from WHO, donors or countries with relevant experience may also be assessed. This stage can be carried out within a ministry of health, a health institution or a health insurance institution, and with the support of a small committee of selected experts.

### **Step 2: Assessing the psychotropic drug access system**

A thorough assessment of all components of non-functioning access systems is the next step. This process has been well explained in Chapter 4 of this module, and the rationale for examining the different components has been explained in Chapters 2 and 3. The experts to carry out this assessment should come not only from the ministry of health, but also from other disciplines and backgrounds, notably the major mental health institutions and the pharmaceutical sector.

### **Step 3: Identifying main problems and making a detailed analysis**

The assessment carried out in step 2 will allow for a thorough analysis and understanding of the main problems in a psychotropics access system. A detailed analysis of the findings can assist in identifying the major problems and their causes, and potential solutions.

### **Step 4: Setting goals and objectives to improve access**

Once the main problems and their causes have been identified, goals and priority objectives can be defined. For instance, priority objectives may be to improve the selection, affordability and financing of essential psychotropic medicines. Another objective may be to improve the prescribing of psychotropics by health professionals, and use and adherence by PWMDs or the community as a whole.

### **Step 5: Designing intervention programmes and selecting verifiable indicators of progress**

The selection of intervention programmes to achieve the defined objectives is more complex, as it involves choosing from among many different intervention options. The systematic assessment should justify the choices and serve as the basis for decisions. Broad consultation and careful consideration of structural constraints are necessary. Selecting appropriate indicators of progress will enable monitoring and evaluation of the impact of the interventions.

### **Step 6: Implementing the intervention programme**

Any intervention programme needs an overall implementation plan or master plan. The plan may cover a 3- to 5-year period. It should be broken down into annual action plans,

and be developed in collaboration with the institutions involved in its implementation. Key features of a well prepared plan are: defining the activities per component, specifying the responsibilities and major tasks, describing the target outputs and specifying a detailed time frame and budget.

### **Step 7: Monitoring and evaluating the programmes**

Monitoring is a way to continuously review implementation of the activities and to determine whether targets are likely to be met. Evaluation, either midway or at the end of the implementation period, enables an analyses of whether objectives and goals are being or have been met. As explained in Chapter 4, performance indicators are indispensable to objectively measure changes, make comparisons and assess whether the targets are being met. Based on the final evaluation, lessons can be drawn for the future and a new intervention programme designed, or the existing one modified, taking into account the need to avoid any pitfalls of the earlier approach.

#### **Box 20. Applying the seven-step process to the hypothetical country example in box 19**

The assessment of the psychotropic access system proceeded as planned and the two-day workshop on Better Access to Mental Health and Essential Psychotropics: The Way Forward was a lively event. Participants expressed considerable frustration over the poor access to psychotropics, but also a number of good ideas on how it could be improved.

The five experts presented their findings, together with options for improvement, as follows:

1. As the National Essential Medicines List had not been updated since 1987, the medicines currently available for the public sector were not the most appropriate. Mental health staff had clearly lost confidence in using some of them, and, as a result, they prescribed a large variety of brand-name drugs, many of them combination drugs;
2. Mental health staff were generally well trained in pharmacotherapy, most of them in the former colonizing power;
3. Far too many PWMDs were institutionalized for disorders that could be well managed in a community setting. A major reason was that the health insurance policy only reimbursed inpatient treatments of mental disorders. As institutional treatment capacity was limited, most PWMDs went without treatment, or had irregular treatment from a variety of providers and with a variety of medicines;
4. Prices of essential psychotropics were far too high. End-user prices of the 17 essential psychotropics on the WHO Model List of Essential Medicines were, on average, 3.73 times the average international world market price (based on the WHO/MSH Drug Price Indicator Guide). These high prices were caused by sub-optimal procurement practices of CMS, characterized by frequent emergency procurements through international shopping. These high prices had led to financing deficits and chronic shortages of all essential drugs, including psychotropics. This, in turn, opened the country to illegal imports of a large variety of brand-name products of doubtful quality.

The workshop identified as priorities the following problems:

1. Sub-optimal procurement practices of CMS;
2. Inappropriate mental health reimbursement policies;
3. A need for general promotion of the essential medicines concept, especially essential psychotropics.



Based on these priorities, four working groups were established to: (a) set up a Medicines Supply Unit in MOH, with the special task of updating the Essential Drugs and Medicines Policy (EDM) and drug legislation; b) develop a new drug procurement system; c) design a new mental health policy with special emphasis on reimbursement systems for community management of mental disorders; and d) design a plan of action, together with a monitoring programme and a set of performance indicators on mental health management in the country. A small seed grant was provided by the World Bank to start the programme.

### **Key points**

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The following seven-step process offers a practical approach to improving access to psychotropics:

Step 1: Organizing the process;

Step 2: Assessing the psychotropic drugs access system;

Step 3: Identifying the main problems and making a detailed analysis;

Step 4: Setting goals and objectives to improve access;

Step 5: Designing intervention programmes and selecting verifiable indicators of progress;

Step 6: Implementing the intervention programmes; and

Step 7: Monitoring and evaluating the programmes.

## **Annex 1. Examples of treatment for disorders, including their pharmacological effectiveness<sup>1</sup>**

Interventions for the management of mental and behavioural disorders can be classified into three major categories: prevention, treatment and rehabilitation. For most disorders, the best treatment is one that combines psychosocial interventions with appropriate application of medicines. This section is based on treatment recommendations presented in the World Health Report 2001 (WHO, 2001a). While it focuses on effectiveness of medicines, it is not intended to imply that this should be the sole treatment for mental disorders.

- Prevention (primary prevention or specific protection) comprises measures applicable to a particular disease or group of diseases in order to intercept their causes before they affect the individual; in other words, to avoid the occurrence of the condition.
- Treatment (secondary prevention) refers to measures to arrest a disease process already initiated, in order to prevent further complications and sequelae, limit disability and prevent death.
- Rehabilitation (tertiary prevention) involves measures aimed at disabled individuals, for restoring them to their previous situation or maximizing the use of their remaining capacities. It comprises both interventions at the level of the individual and modifications to the environment.

The following examples present a range of effective interventions of public health importance. For some of these disorders, the most effective intervention is preventive action, whereas for others treatment or rehabilitation is the most efficient approach.

As treatment options for mental disorders change rapidly, these recommendations cannot replace a comprehensive study of the most recent literature on management of mental disorders when designing treatment schedules.

### *Depression*

Antidepressants are effective across the full range of severity of major depressive episodes. With mild depressive episodes, the overall response rate is about 70%. With severe depressive episodes, the overall response rate is lower, and medication is more effective than the placebo. Studies have shown that the older antidepressants (tricyclics) are as effective as the newer medicines and less expensive: the cost of the older antidepressants is about US\$ 2-3 per month in many developing countries. New antidepressants offer more effective treatments for severe depressive episodes, with fewer unwanted effects and greater patient acceptance, but their availability remains limited in many developing countries. These medicines may offer advantages to older age groups.

The phase known as “maintenance pharmacotherapy” is intended to prevent recurrences of mood disorders, and is typically recommended for individuals with a history of three or more depressive episodes, chronic depression, or persistent depressive symptoms. This phase may last for years, and typically requires monthly or quarterly visits to health care facilities.

Some people prefer psychotherapy or counselling to medication for the treatment of depression. Evidence from 20 years of research has revealed that several forms of time-limited psychotherapy are as effective as medicines in mild to moderate depressions. These depression-specific therapies include cognitive behavioural therapy and interpersonal psychotherapy, and emphasize active collaboration and patient education.

<sup>1</sup>: adapted from WHO, 2001a

A number of studies from Afghanistan, India, the Netherlands, Pakistan, Sri Lanka, Sweden, the United Kingdom and the United States show the feasibility of training general practitioners to provide this care, and its cost-effectiveness (Sriram et al., 1990; Mubbashar 1999; Mohit et al., 1999; Tansella & Thornicroft 1999; Ward et al., 2000; Bower et al., 2000).

Even in industrialized countries, only a minority of people suffering from depression seek or receive treatment. Part of the explanation lies in the symptoms themselves. Feelings of worthlessness, excessive guilt and lack of motivation deter individuals from seeking help. In addition, such individuals are unlikely to appreciate the potential benefits of treatment. Financial difficulties and the fear of stigmatization are also deterrents. Beyond the individuals themselves, health care providers may fail to recognize symptoms and to follow best practice recommendations, because they may not have the time or the resources to provide evidence-based treatment in primary care settings.

#### *Alcohol dependence*

The prevention of alcohol dependence needs to be seen within the context of the broader goal of preventing and reducing alcohol-related problems at the population level (e.g. alcohol-related accidents, injuries, suicide and violence). The goals of therapy are reduction of alcohol-related morbidity and mortality, and reduction of other social and economic problems related to chronic and excessive alcohol consumption.

The main strategies that have proved to be effective for the treatment of alcohol-related problems and dependence are: early recognition of problem drinking and early intervention, psychological interventions, treatment of the harmful effects of alcohol (including withdrawal and other medical consequences), teaching new coping skills in situations associated with the risk of drinking and relapse, family education and rehabilitation. Epidemiological research has shown that most problems arise among those who are not significantly dependent, such as individuals who get intoxicated and drive or engage in risky behaviours, or those who drink at high-risk levels but continue to have jobs or go to school and maintain relationships and relatively stable lifestyles. Among patients drinking at hazardous levels who attend primary health care clinics, only 25% are alcohol dependent.

Brief interventions comprise a variety of activities directed at persons who engage in hazardous drinking, but who are not alcohol dependent. These interventions are of low intensity and short duration: typically no more than three to five sessions comprising 5-60 minutes of counselling and education. They are intended to prevent the onset of alcohol-related problems. The content of such brief interventions varies, but most are instructional and motivational, designed to address the specific behaviour of drinking, with feedback from screening, education, skill-building, encouragement and practical advice, rather than intensive psychological analysis or extended treatment techniques (Gomel et al. 1995).

For early drinking problems, the effectiveness of brief interventions by primary care professionals has been demonstrated in numerous studies (WHO, 1996b; Wilk, Jensen & Haviighurst, 1997). Such interventions have reduced alcohol consumption and heavy drinking by as much as 30% over periods of 6 to 12 months or longer. Studies have also demonstrated that these interventions are cost-effective (Gomel et al., 1995).

For patients with more severe alcohol dependence, both outpatient and inpatient treatment options are available and have been shown to be effective, although outpatient treatment is substantially less costly. Several psychological treatments have proved to be equally effective, including cognitive behavioural treatment, motivational interviewing and the "Twelve Steps" approach associated with professional treatment. Community

reinforcement approaches, such as that of Alcoholics Anonymous, during and following professional treatment are consistently associated with better outcomes than treatment alone.

Therapy for spouses and family members, or simply their involvement, has benefits for both initiation and maintenance of alcohol-dependence treatment.

Detoxification (treatment of alcohol withdrawal) within the community is preferable, except for those with severe dependence, a history of delirium tremens or withdrawal seizures, an unsupportive home environment, or previous failed attempts at detoxification (Edwards et al., 1997). Inpatient care remains a choice for patients with serious comorbid medical or psychiatric conditions. Psychosocial ancillary and family interventions are also important elements in the recovery process, particularly when other problems occur along with alcohol dependence. There is no evidence to indicate that coercive treatment is effective. It is unlikely that such treatment (whether it follows civil commitment, a decision of the criminal justice system, or any other intervention) will be beneficial (Heather, 1995). Medication cannot replace psychological treatment for people with alcohol dependence, but a few drugs have proved to be effective as complementary treatment for reducing relapse rates (NIDA, 2000).

### *Drug dependence*

The prevention of drug dependence needs to be considered within the context of the broader goal of preventing and reducing drug-related problems at the population level.

The goals of therapy are to reduce morbidity and mortality caused by or associated with the use of psychoactive substances, until patients can achieve a drug-free life. Strategies include early diagnosis, identification and management of risk of infectious diseases as well as other medical and social problems, stabilization and maintenance with pharmacotherapy (for opioid dependence), counselling, access to services and support to achieve social integration.

Persons with drug dependence often have complex needs. They are at risk of HIV and other blood-borne pathogens, comorbid physical and mental disorders, problems with multiple psychoactive substances, involvement in criminal activities, and problems with personal relationships, employment and housing. Their needs demand links between health professionals, social services, voluntary agencies and the criminal justice system.

Shared care and integration of services are examples of good practices in caring for substance dependents. General practitioners can identify and treat acute episodes of intoxication and withdrawal, and provide brief counselling as well as immunization, HIV testing, cervical screening, family planning advice and referral. Counselling and other behavioural therapies are critical components of effective treatment of dependence, as they can deal with motivation, coping skills, problem-solving abilities and difficult interpersonal relationships. Particularly for opioid dependents, substitution pharmacotherapies are effective adjuncts to counselling. As the majority of drug dependents smoke, tobacco cessation counselling and nicotine replacement therapies should be provided. Self-help groups can also complement and improve the effectiveness of treatment by health professionals.

Medical detoxification is only the first stage of treatment for dependence, and by itself does not change long-term drug use. Long-term care needs to be provided along with treatment of comorbid psychiatric disorders, in order to decrease rates of relapse. Most patients require a minimum of three months of treatment to obtain any significant improvement.

Injection of illicit drugs poses a particular threat to public health. Sharing of injection equipment is associated with transmission of blood-borne pathogens (especially HIV and hepatitis B and C), and has been responsible for the spread of HIV/AIDS in many countries, wherever injecting drug use is widespread. People who inject drugs and who do not get treatment are up to six times more likely to become infected with HIV than those who enter and remain in treatment. Treatment services should therefore provide assessment for HIV/AIDS, hepatitis B and C, tuberculosis and other infectious diseases and, whenever possible, provide treatment for these conditions and counselling to help patients stop unsafe injecting practices.

Drug dependence treatment is cost-effective in reducing drug use (40%-60%), and the associated health and social consequences, such as HIV infection and criminal activity. The effectiveness of drug dependence treatment is comparable to the success rates for the treatment of other chronic diseases such as diabetes, hypertension and asthma (NIDA, 2000). Treatment has been shown to be less expensive than alternatives, such as not treating dependents or simply incarcerating them. For example, in the United States, the average cost for one full year of methadone maintenance treatment is approximately US\$ 4,700 per patient, whereas one full year of imprisonment costs approximately US\$18,400 per person.

### *Schizophrenia*

The treatment of schizophrenia has three main components. First, there are medications to relieve symptoms and prevent relapse. Second, education and psychosocial interventions help patients and families cope with the illness and its complications, and also help prevent relapse. Third, rehabilitation helps patients reintegrate into the community and regain a place in the educational or occupational world. The real challenge in the care of people suffering from schizophrenia is the need to organize services that lead seamlessly from early identification to regular treatment and rehabilitation.

Two groups of medicines are currently used to treat schizophrenia: standard antipsychotics (previously referred to as neuroleptics), and novel antipsychotics (also referred to as second-generation or “atypical” antipsychotics). The first standard antipsychotic medicines were introduced 50 years ago and have proved useful in reducing, and sometimes eliminating, such symptoms of schizophrenia as thought disorder, hallucinations and delusions. They can also reduce associated symptoms such as agitation, impulsiveness and aggressiveness. This can be achieved in a matter of days or weeks in about 70% of patients. If taken consistently, these medicines can also reduce the risk of relapse by half. Currently available medicines appear to be less effective in alleviating such symptoms as apathy, social withdrawal and poverty of ideas. First-generation medicines are inexpensive, costing no more than US\$ 5 per month of treatment in developing countries. Some of them can be administered in the form of long-acting injections at 1-4 week intervals.

Antipsychotic medicines can help sufferers benefit from psychosocial forms of treatment. The newer ones are less likely to induce some side-effects while improving certain symptoms. There is no clear evidence that these newer antipsychotic medications differ appreciably from the older ones in their effectiveness, although there are differences in their most common side-effects.

The average duration of treatment is 3-6 months. Maintenance treatment continues for at least one year after the first episode of illness, for 2-5 years after the second episode, and for longer periods in patients with multiple episodes. In developing countries, response to treatment tends to be more positive, medicine dosages lower and duration of treatment shorter.

In the total care of the patients, the support of the families is important. Some studies have shown that a combination of regular medication, family education and support can reduce relapses from 50% to less than 10% (Leff & Gamble, 1995; Dixon, Adams & Lucksted, 2000; Pharaoh, Marij & Streiner, 2000).

### *Epilepsy*

Effective actions for the prevention of epilepsy are adequate prenatal and postnatal care, safe delivery, control of fever in children, control of parasitic and infectious diseases, and prevention of brain injury (for example, control of blood pressure and the use of safety belts and helmets). The goals of therapy are to control fits by preventing them for at least two years, and to reintegrate people with epilepsy into educational and community life. Early diagnosis and the steady provision of maintenance medicines are fundamental for a positive outcome.

Epilepsy is almost always treated with anti-epileptic medicines. Recent studies in both developed and developing countries have shown that up to 70% of newly diagnosed cases of children and adults with epilepsy can be successfully treated with such medicines, making them seizure-free, provided they take their medicines regularly. After 2-5 years of such successful treatment (cessation of epileptic fits), the treatment can be withdrawn in 60%-70% of cases. The remainder have to continue on medication for the rest of their lives, but provided that they take the medication regularly, many are likely to remain free of seizures; in others the frequency or severity of seizures can be considerably reduced. For some patients with intractable epilepsy, neurosurgical treatment may be successful. Psychological and social support are also valuable (ILAE/IBE/WHO, 2000).

Phenobarbitone has become the front-line antiepileptic medicine in developing countries, perhaps because the cost of other medicines is 5-20 times higher. A study in rural India found that 65% of those who received phenobarbitone were successfully treated, with the same proportion responding to phenytoin; adverse events were similar in both groups (Mani et al., 2001). A study in Indonesia concluded that, despite some disadvantages, phenobarbitone should still be used as the first-line medicine in the treatment of epilepsy in developing countries. Studies in Ecuador and Kenya compared phenobarbitone to carbamazepine and found that there were no significant differences between them in terms of efficacy and safety (Scott, Lhatoo & Sander, 2001). In most countries, the cost of treatment with phenobarbitone can be as low as US\$ 5 per patient per year.

### *Alzheimer's disease*

Cholinergic receptor agonists (AChEs) have generally been beneficial in ameliorating global cognitive dysfunction, and are most effective in improving attention. Treatment with these AChE inhibitors also appears to benefit non-cognitive symptoms in Alzheimer's disease, such as delusions and behavioural symptoms. However findings concerning amelioration of learning and memory impairment, the most prominent cognitive deficits in Alzheimer's disease, have been less consistent. Treatment of depression in Alzheimer's disease patients has the potential to improve functional ability.

### *Mental retardation*

Because of the severity of mental retardation and the heavy burden that it imposes on affected individuals, their families and the health services, prevention is extremely important. In view of the variety of different aetiologies of mental retardation, preventive action must be targeted at specific causative factors. Examples include the iodization of water or salt to prevent iodine-deficiency mental retardation (cretinism) (Mubbashar,

1999), abstinence from alcohol consumption by pregnant women to avoid foetal alcohol syndrome, dietary control to prevent mental retardation in people with phenylketonuria, genetic counselling to prevent certain forms of mental retardation (such as Down's syndrome), adequate prenatal and postnatal care, and environmental control to prevent mental retardation caused by intoxication from heavy metals such as lead.

The treatment goals are early recognition and optimal utilization of the intellectual capacities of the individual through training, behaviour modification, family education and support, vocational training and opportunities for work in protected settings. Early intervention comprises planned efforts to promote development through a series of manipulations of environmental or experimental factors, and is initiated during the first five years of life. The objectives are to accelerate the rate of acquisition and development of new behaviours and skills, to enhance independent functioning, and to minimize the impact of impairment. Typically, a child is given sensory motor training within an infant stimulation programme, along with supportive psychosocial interventions. The training of parents to act as trainers in the skills of daily living has become central to the care of persons with mental retardation, especially in developing countries. This means that parents have to be aware of the learning principles and to be educated in behaviour modification and vocational training techniques. In addition, parents can support each other through self-help groups.

The majority of children with mental retardation experience difficulties in following regular school curricula. They need additional help, and some need to attend special schools where the emphasis is on daily activities such as feeding, dressing, social skills and understanding the concept of numbers and letters. Behaviour modification techniques play an important role in developing many of these skills, as well as in increasing desirable behaviours while reducing undesirable behaviours. Vocational training in sheltered settings and using behavioural skills has led to a large number of people with mental retardation leading active lives.

#### *Hyperkinetic disorders*

The precise aetiology of hyperkinetic disorders and hyperactivity in children, often with involuntary muscular spasms, is unknown. Thus, primary prevention is currently not possible. It is possible, however, to prevent the onset of symptoms that are often misdiagnosed as hyperkinetic disorders through interventions with families and schools. The treatment of these disorders cannot be considered without first addressing the adequacy and appropriateness of diagnosis. All too often, hyperkinetic disorders are diagnosed even though the patient does not meet the objective diagnostic criteria. Failure to make an appropriate diagnosis leads to difficulties in establishing the patient's response to therapeutic interventions. Hyperkinetic symptoms can be seen in a range of disorders for which there are specific treatments that are more appropriate than the treatment for hyperkinetic disorder. For instance, some children and adolescents with symptoms of hyperkinetic disorder are in fact suffering from psychosis, or may be manifesting obsessive compulsive disorder. Others may have specific learning disorders. Still others may be within the normal range of behaviour but live in environments with a reduced tolerance for the behaviours that are reported. Some children manifest hyperkinetic symptoms as a response to acute stress in the school or home. A thorough diagnostic process is thus essential, for which specialist help is often needed.

While treatment with amphetamine-like stimulants is now common, there is support for the use of behavioural therapy and environmental manipulation to reduce hyperkinetic symptoms. Therapies should be evaluated for their appropriateness as first-line treatments, especially where the diagnosis of hyperkinetic disorder is questionable. In the absence of universally accepted guidelines for the use of psycho-stimulants in children and adolescents, it is important to start with low dosages and only gradually



increase to an appropriate dose, under continuous observation. Sustained-action medications are now available, but the same caution regarding appropriate dosage applies. Tricyclic antidepressants and other medications have been reported to be of use, but are not currently seen as first-line medications. The diagnosis of hyperkinetic disorder is often not made until children reach school age, when they may benefit from a more structured school environment or more individualized instruction. In the home environment, parental support and avoidance of unrealistic expectations or conflicts can help reduce hyperkinetic symptoms. Once thought to be a disorder that children outgrew, it is now known that for some people hyperkinetic disorder can persist into adulthood. Recognition of this by the patient can help him (rarely her) to find life situations that are better adapted to limiting the debilitating effects of the untreated disorder.

### *Suicide prevention*

There is compelling evidence indicating that adequate prevention and treatment of some mental and behavioural disorders can reduce suicide rates, whether such interventions are directed towards individuals, families, schools or other sections of the general community. Early recognition and treatment of depression, alcohol dependence and schizophrenia are important strategies in the primary prevention of suicide. Educational programmes to train practitioners and primary care personnel in the diagnosis and treatment of depressed patients are particularly important. In one study of such a programme on the island of Gotland, Sweden (Rutz, Knorrning & Walinder, 1995), the suicide rate, particularly among women, dropped significantly in the year after an educational programme for general practitioners was introduced, but increased once the programme was discontinued.

Ingestion of toxic substances, such as pesticides, herbicides or medication, is the preferred method for committing suicide in many places, particularly in rural areas of developing countries. For example, in Western Samoa in 1982, the ingestion of paraquat, a herbicide, had become the predominant method of suicide. By reducing the availability of this herbicide to the general population a significant reduction in the number of suicides was achieved, without a corresponding increase in suicide by other methods (Bowles, 1995). Similar successful examples relate to the control of other toxic substances and the detoxification of others, such as domestic gas and car exhaust. In many countries, the lack of easily accessible emergency care results in deaths from the ingestion of toxic substances which in most industrialized countries would be suicide attempts that are saved.

In the Russian Federation and its neighbouring countries, alcohol consumption has risen sharply in recent years, and has been linked to an increase in rates of suicide and alcohol poisoning (Vroublevsky & Harwin, 1998), and to a decline in male life expectancy (Notzon et al., 1998; Leon & Shkolnikov, 1998).

Several studies have shown an association between the possession of handguns at home and suicide rates (Kellerman et al., 1992; Lester & Murrell 1980). Legislation restricting access to handguns may have a beneficial effect. This is suggested by studies in the United States, where a restriction on the sale and purchase of handguns was associated with lower rates of suicide using firearms. States with the strictest handgun control laws had the lowest firearm suicide rates, and there was no switching to an alternative method of suicide (Lester, 1995).

As well as interventions that involve restricting access to common methods of suicide, school-based interventions involving crisis management, enhancement of self-esteem, and the development of coping skills and healthy decision-making have been shown to lower the risk of suicide among young people (Mishara & Ystgaard, 2000). It is believed that glamorizing suicide may lead to imitation. Thus the media can assist in prevention



by limiting graphic and unnecessary depictions of suicide and by deglamorizing news reports of suicides. In a number of countries, a decrease in suicide rates coincided with the media's consent to minimize the reporting of suicides and to follow proposed guidelines.

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ISBN 92 4 154641 7



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