

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:

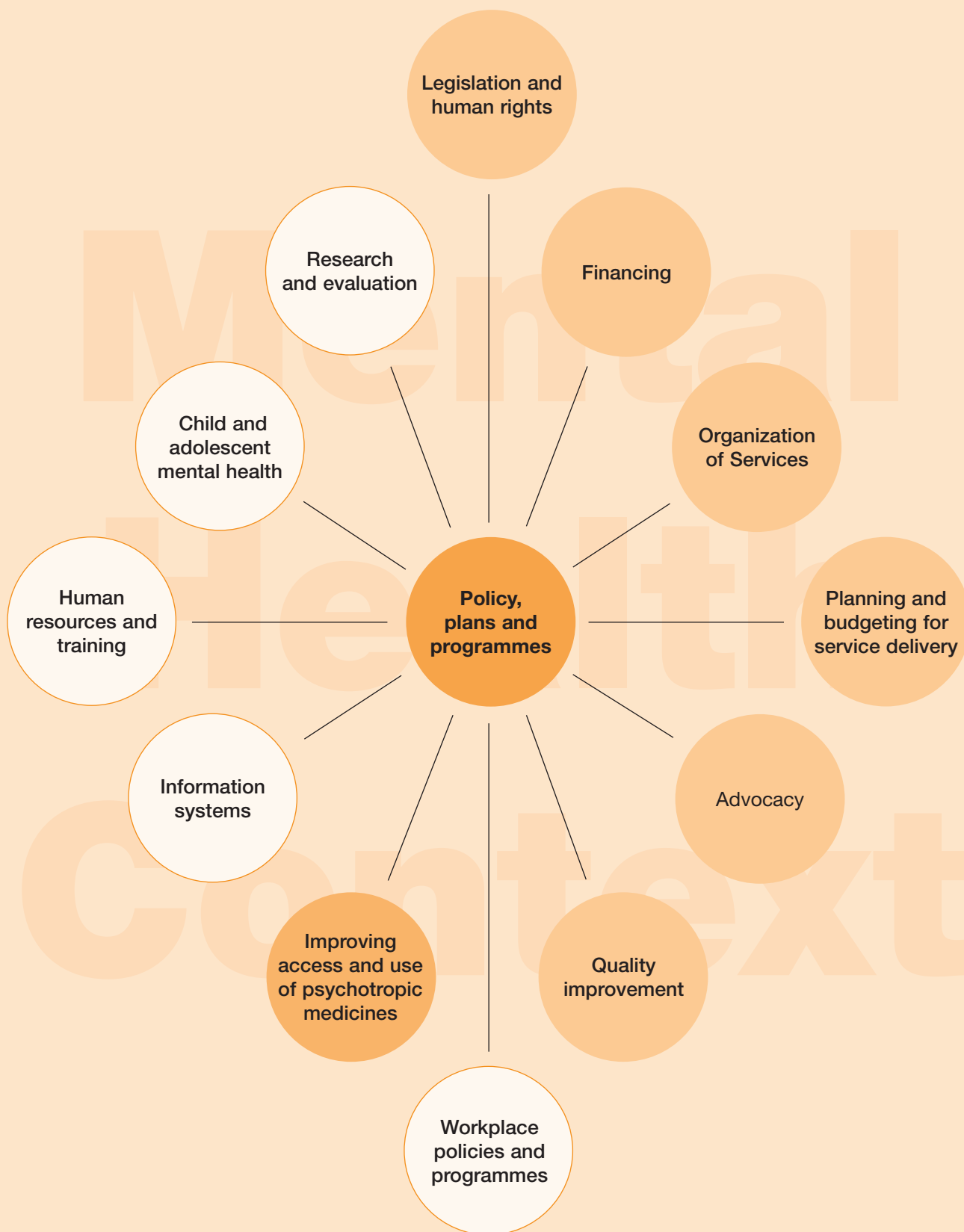
- develop policies and comprehensive strategies for improving the mental health of populations;
- use existing resources to achieve the greatest possible benefits;
- provide effective services to those in need;
- assist the reintegration of persons with mental disorders into all aspects of community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

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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.

## Abbreviations

<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