In spite of WHO's promotion of national medicines policies, problems of access to essential medicines remain, especially in developing countries of the Region. In response to concerns expressed by Member States at the fifty-third session of the Regional Committee, and given the public health importance of access to medicines, WHO has prepared a draft regional strategy for improving access to essential medicines in the Western Pacific Region, 2005-2010 which was presented to the fifty-fourth session of the Regional Committee in September 2003. Most Member States supported the draft strategy in principle, but some concerns were expressed. In order to address these, it was agreed that a small group consultation meeting involving some Member States and experts should be convened to review the draft strategy. A meeting was held in the Regional Office in February 2004 and the draft strategy was revised. The revised draft was then distributed to all Member States for their final comments. The draft regional strategy is attached as Annex 1.

The overall objective of the regional strategy is to provide operational and practical guidance to Member States and WHO on improving access to essential medicines. It covers rational selection; rational use; affordable prices; access; trade globalization and the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS); sustainable financing; supply and management systems; quality; and monitoring and evaluation.

The Regional Committee is requested to discuss and endorse the draft regional strategy on improving access to essential medicines in the Western Pacific Region, 2005-2010.
1. CURRENT SITUATION

Lack of access to essential medicines remains a serious public health problem in many countries of the Western Pacific Region. Access to essential medicines includes availability and affordability, which are influenced by a number of related factors such as rational selection and use, pricing, financing and supply systems.

There is irrational use of medicines by health care providers and consumers in many countries of the Region. Irrational use jeopardizes access to essential medicines because limited resources are wasted on unnecessary medicines.

The price of many essential medicines remains too high in relation to local purchasing power in many countries. Affordable prices are essential if access to medicines is to be improved. In many countries in the Region, most financing for medicines is "out-of-pocket" payment and public funding for essential medicines remains low. Several countries still face difficulties in ensuring a stable supply of essential medicines. Uneven distribution is common and rural and remote areas are often left without essential medicines.

Trade globalization and the implementation of the WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) mean that addressing problems of access, especially to newly patented essential medicines such as HIV/AIDS medicines, is now an urgent priority. Intellectual property rights, innovation and public health were discussed at the Fifty-sixth World Health Assembly in May 2003. 1

2. REGIONAL STRATEGY

In response to concerns expressed by Member States at the fifty-third session of the Regional Committee, and because of the public health importance of access to medicines, WHO has prepared a draft regional strategy for improving access to essential medicines in the Western Pacific Region, 2005-2010 (Annex 1). The objective of the regional strategy is to provide operational and practical guidance for Member States and WHO on improving access to essential medicines.

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1 Resolution WHA56.27.
The draft strategy was developed through a process of wide consultation with experts and counterparts and comments from WHO technical programmes and national and international experts were incorporated. The strategy was reviewed in detail at a consultation on improving access to essential medicines in the Western Pacific Region in Penang, Malaysia, in July 2003. It was presented to the Regional Committee at its fifty-fourth session in September 2003. Most Member States supported the draft strategy in principle, but some concerns were expressed. In order to address these, it was agreed that a small group consultation meeting involving some Member States and experts should be convened to review the draft strategy. A meeting was held in the Regional Office in February 2004 and the draft strategy was revised. The revised draft was then distributed to all Member States for their final comments.

3. ACTION PROPOSED

The draft regional strategy for improving access to essential medicines in the Western Pacific Region, 2005–2010 proposes strategies for key areas, with accompanying actions for both WHO and Member States. The Regional Committee is requested to discuss and endorse the draft regional strategy.
# DRAFT REGIONAL STRATEGY FOR IMPROVING ACCESS TO ESSENTIAL MEDICINES IN THE WESTERN PACIFIC REGION

## 2005 – 2010

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DRAFT REGIONAL STRATEGY FOR IMPROVING ACCESS TO ESSENTIAL MEDICINES IN THE WESTERN PACIFIC REGION
2005 - 2010

1. BACKGROUND

Essential medicines save lives and improve health, but only if they are available, affordable and properly used. Essential medicines are medicines that satisfy the health care needs of the majority of the population. Equity in access to essential medicines is a fundamental human right. They should be available at all times in adequate amounts, in the appropriate dosages and at a price that individuals and the community can afford.

Over the past 25 years WHO has strongly advocated the essential medicines concept as part of national medicines policies. Despite this, regular access to medicines is denied to over one third of the world’s population, most of whom live in developing countries. Serious problems of access to essential medicines are still frequently encountered in countries and areas in the Western Pacific Region, despite the existence of national medicines policies, national essential medicines lists and standard treatment guidelines (Box 1).

A focused strategy for improving access to essential medicines in the Western Pacific Region is badly needed. The Region bears a significant part of the global burden of important diseases such as tuberculosis, malaria and childhood illnesses. Deaths and illnesses caused by all these diseases can be significantly reduced by simple essential medicines. For example, about 1000 people in the Region die of tuberculosis every day, despite the existence of an effective cure. There are more than 1 million deaths of children under five years of age every year in the Western Pacific Region. Approximately 700 000 of these are caused by diarrhoea, acute respiratory infections (in particular pneumonia), measles, malaria and dengue fever, with malnutrition as an important underlying condition. In the Western Pacific Region, an estimated 1.2 million people are living with HIV/AIDS.
Box 1. Progress towards improving access to essential medicines in the Lao People's Democratic Republic, Mongolia and Tonga

The revised national medicines policy, 2000, in the Lao People's Democratic Republic aims to improve access to essential medicines through revolving funds. These funds exist at all levels of the health system: hospital, health centre and village. They are integrated with Ministry of Health directives and conform to the national essential medicines list; follow the practices of rational medicines use; and assure medicines quality, prices and services. Revolving funds should not generate profit; the customer charge is 125% of cost and the funds are managed by local health staff. The Food and Medicine Directorate in the Ministry of Health has responsibility for revolving funds management. In August 2001, revolving funds were in place in 94% of hospitals, 83% of district hospitals, 86% of health centres and 11% of villages. The extent of revolving funds in remote areas needs to be determined (the aim is to reach 5000 villages) and the exemption system reviewed. Financing is from users, the government and donors, but many funds find it difficult to replenish their resources.

Extensive political and socioeconomic changes in Mongolia in the 1990s led to an increase in counterfeit medicines and a lack of objective information on medicines. In a 1998 survey, using WHO indicators (a basket of 10 medicines), stock shortages ranged from 0 to 80 days. Variations in prices within the country also limit the effectiveness of attempts to improve access to essential medicines. Irrational medicines use and prescribing is widespread and injections are widely used. Mongolia's parliament approved a national medicines policy in 2002. A new medicines law was adopted in 1998.

Tonga's efforts to improve access to essential medicines are very much centred on procurement and supply issues, which are made more acute by the fact that the country's 36 inhabited islands are widely scattered. Medicines are procured only once a year, which creates problems with deliveries, storage and shortages. The main island and urban areas have the best access to medicines and the referral hospital has all the necessary medicines available. However, irrational prescribing is widespread. Tonga is now addressing these and other issues in its first national medicines policy, adopted in 2000. Procurement procedures are being revised, training for prescribers is being carried out, guidelines are being issued, and medicines registration is being carried out. Efforts are also being made to ensure compatibility between the essential medicines list and clinical guidelines.
Annex 1

The strategy is designed to reinforce national medicines policies and existing tools and guidelines such as essential medicines lists and standard treatment guidelines. It also examines such issues as sustainable financing and pricing mechanisms and analyses the effects of trade globalization and the WTO Agreement on Trade-Related Aspects of Intellectual Property (TRIPS). It proposes strategic options and actions to improve access to essential medicines.

The draft strategy was developed through a process of wide consultation. This included a review of country experiences at a regional workshop on evaluating the implementation of national medicines policies in Phnom Penh, Cambodia, in November 2002. Comments from WHO technical programmes as well as from national and international experts have been incorporated. The document was reviewed in detail at a consultation on improving access to essential medicines in the Western Pacific Region in Penang, Malaysia, in July 2003 and presented to the fifty-fourth session of the WHO Regional Committee for the Western Pacific in September 2003. Member States supported the framework of the strategy, but asked for another round of consultations. It was agreed that a small working group meeting should be convened. A meeting involving representatives of Member States and experts was held at the Regional Office in February 2004 to review and revise the draft strategy.

2. THE REGIONAL STRATEGY

The overall objective of the regional strategy is to provide operational and practical guidance to Member States and WHO on improving access to affordable essential medicines of acceptable quality and to ensuring that they are appropriately used by those who need them.

The regional strategy is based on the essential medicines concept. This concept is more valid than ever, in both public and private sectors, following the emergence of epidemics of HIV/AIDS, drug-resistant malaria and tuberculosis, as well as the persistence of diseases with high morbidity and mortality, such as acute respiratory infections and diarrhoea.

The implementation of the strategy by Member States will depend on the existing health care system. It will need to take into account national priorities, legislation and administrative framework, and resources.
The regional strategy covers "Issues and challenges", "Strategies", and "Actions" by Member States and by WHO under the following headings:

1. rational selection;
2. rational use;
3. affordable prices;
4. access to medicines, trade globalization and TRIPS;
5. sustainable financing;
6. supply and management systems;
7. quality; and
8. monitoring and evaluation.

3. ISSUES AND CHALLENGES, STRATEGIES AND ACTIONS

3.1 Rational selection

Twenty-five years after the first WHO Model List of Essential Medicines (formerly Model List of Essential Drugs) was produced, model lists have been adopted by the majority of WHO’s Member States (156 countries globally and 27 of 37 countries and areas in the Western Pacific Region). However, implementing these lists in health care services in order to improve access to medicines remains problematic.

Issues and challenges

- There is a lack of ownership of, acceptance of and confidence in the concept of essential medicines among both health care providers and consumers.
- There are often misconceptions about essential medicines; for example, that essential medicines are for the poor and that they are cheap and of low efficacy and quality. It is also widely believed that they restrict professional freedom of prescribing.
Annex 1

- In many countries, essential medicines lists are rarely used as the basis for pharmaceutical procurement, reimbursement or prescribing. Nor are they stratified according to level of care in many countries.

- Some essential medicines are often not available in the market, as manufacturers are not interested in producing them.

**Strategies**

- Focused advocacy and training for policy-makers, health care providers, consumers and health care managers, in public and private sectors, to reinforce the essential medicines concept using an evidence-based approach.

- A participatory approach to and systematic process for the formulation, evaluation and revision of the essential medicines list, involving stakeholders at different levels of the health care system.

- Inclusion of the essential medicines and national medicines policy concepts in the undergraduate curricula of health care professionals as well as in the continuing education programme.

- Monitoring the use of the essential medicines list as the basis for procurement, reimbursement by insurance schemes, and prescribing, taking into account different levels of health care.

- Information exchange among Member States on national medicines policies and other issues related to essential medicines.

- Create incentives for production and distribution of essential medicines.

**Actions**

**Member States**

- Undertake focused advocacy and training for policy-makers, health care providers, consumers and health care managers, in both public and private sectors, on the essential medicines concept in primary health care and hospital facilities.

- Introduce the essential medicines concept and the national medicines policy into existing undergraduate curricula and continuing education programmes for health care providers.

- Use the essential medicines list, linked with standard treatment guidelines, as one of the bases for procurement at different levels of care and for reimbursement. Monitor compliance.
• Involve relevant stakeholders at all levels in the development, evaluation and revision of essential medicines list.

• Provide possible incentives for production and distribution of essential medicines, e.g. fast registration, tax exemption, financing mechanism.

WHO

• Develop and field-test advocacy and training materials on the essential medicines concept targeted at policy-makers, providers, consumers and health managers in public and private sectors.

• Continue to publish the regional newsletter, Essential drugs and medicines policy. Develop other means of networking that take advantage of information technology, e.g. WHO essential medicines library, website and databases.

• Develop model curricula on the essential medicines concept and national medicines policies in undergraduate and continuing education programmes, and promote the adoption and use of national medicines policies by Member States.

• Support Member States to develop, revise, implement, monitor and evaluate their essential medicines lists, including their use for procurement and reimbursement.

• Advocate possible incentives and exchange of information on the existing needs of essential medicines and on potential suppliers and manufacturers.

3.2 Rational use

Ineffective and harmful medicine use practices by both providers and consumers are commonly encountered in health care facilities and in the wider community. Such practices include, for instance, the misuse of antimicrobials, the overuse of injections and inappropriate prescribing of many medicines (poly-pharmacy). The reasons for this are complex and require appropriate and consistent interventions. Rational use of medicines means that patients receive medicines appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time and at the lowest cost to them and the community.
Annex 1

**Issues and challenges**

- There is a widespread belief that training and developing standard treatment guidelines are sufficient to improve the rational use of medicines, when in fact a wider combination of interventions is needed.
- There is no comprehensive package of interventions (including educational, regulatory, managerial, financial and systems interventions) to enhance the rational use of medicines in most countries.
- Intervention strategies rarely include evaluations of the impact of the interventions on prescribing and behaviour affecting medicines use.
- Most countries do not continuously monitor and supervise prescribing practices in health facilities. Adherence to standard treatment guidelines is rarely promoted and monitored.
- Prescribing is often driven by profit motives and used for revenue generation. It is largely influenced by promotion of pharmaceuticals and the absence of or noncompliance with ethical criteria for promotion of pharmaceuticals.
- There is increasing antimicrobial resistance in the Region, caused by the uncontrolled availability and widespread inappropriate use of antimicrobials.

**Strategies**

- Development and implementation of a package of rational drug use interventions for providers and consumers, combining educational, managerial, regulatory, financial and systems interventions. This includes a framework for evaluation of impact.
- Use of standard treatment guidelines and formularies linked to essential medicines lists in public and private facilities.
- Supervision and monitoring of medicines use practices in health facilities, including compliance with standard treatment guidelines, essential medicines lists and formularies.
- Consumer education and empowerment on rational use of medicines.
- Networking and exchange of information on rational medicines use.
- Promotion of therapeutics and medicines committees with clear tasks and functions in hospitals.
Implementation of ethical criteria for pharmaceutical promotion, monitoring of pharmaceutical promotion, restriction of unacceptable promotion through regulation and/or voluntary codes of conduct.

Development and implementation of appropriate strategies to contain antimicrobial resistance.

**Actions**

**Member States**

- Draw up and implement a comprehensive rational drug use strategy. Include evaluation plan in any drug use intervention.
- Formulate and use standard treatment guidelines and formularies linked to essential medicines list.
- Undertake supervision and monitoring of medicines use practices in health facilities.
- Undertake consumer education programmes.
- Form hospital therapeutics and medicines committees with clear tasks and functions.
- Take measures to introduce rational drug use and problem-based pharmacotherapy teaching into the curricula of health care providers.
- Seek partnerships, particularly with nongovernmental organizations and academic institutions to promote rational drug use.
- Develop and implement regulations on ethical promotion of pharmaceuticals. Undertake monitoring and provide feedback on promotion.
- Develop and implement a national strategy to contain antimicrobial resistance. Improve the adherence to and continuity of antiretroviral treatment.

**WHO**

- Support countries to formulate, implement and evaluate comprehensive rational drug use strategies. Advocate and support countries to undertake evaluation of drug use interventions.
- Support the development and field-testing of interventions on drug use practices, combining educational, managerial and regulatory interventions.
Annex 1

- Document experiences on effective rational medicines use interventions and work with countries to replicate them.
- Support countries to formulate and implement standard treatment guidelines and formularies linked with essential medicines lists.
- Draw up guidelines for supervision and monitoring of medicines use practices.
- Develop materials for consumer education and empowerment on rational use of medicines.
- Facilitate exchange of information on rational medicines use through publication of the regional newsletter, *Essential drugs and medicines policy*, and through electronic communication networks.
- Undertake intercountry and country meetings on hospital therapeutics and medicines committees and rational drug use.
- Support countries to introduce rational drug use and problem-based pharmacotherapy teaching in the undergraduate curricula of health care providers.
- Advocate the use of ethical criteria for pharmaceutical promotion and provide technical support for monitoring and feedback.
- Support countries and areas to develop, implement and evaluate strategies to contain antimicrobial resistance.

3.3 Affordable prices

Affordable prices are fundamentally important if access to medicines is to be improved. Although the prices of many essential medicines have decreased significantly, they are still too high in relation to local purchasing power in many countries. There are several reasons for high prices, including lack of price competition, lack of transparency in mark-up systems, taxes and tariffs on medicines, the preference of health professionals and consumers for branded products, and the lack of alternative sources for patented medicines.

Issues and challenges

- Patented and branded products are often expensive because of a lack of competition and patent laws.
- There are large price variations between countries for identical products.
• In many countries, there are no price controls and price mark-ups are not transparent. This may lead to prices that are unaffordable to many people.

• Generic prescribing and dispensing practices are not widely accepted. This means that more expensive brands are often prescribed and dispensed.

• Health professionals and consumers are generally ignorant of price issues.

• Information on taxation of essential medicines, including import duties, is not known in many countries.

• In many countries there is a lack of awareness of and knowledge about options for making prices more affordable (e.g. price competition or price control).

**Strategies**

• Identification and dissemination of practices on pricing policies for essential medicines.

• Price competition through legitimate measures to avoid monopoly and to reduce prices.

• Dissemination of information on pricing controls (including analysis of advantages and disadvantages). Creation of a fair and transparent mark-up system to make medicines more affordable (addressing such aspects as taxes, mark-ups and fees).

• Reductions in taxes, duties and fees on essential medicines.

• Establishment of a regional and local monitoring system on prices of selected essential medicines and participation in a global monitoring system.

• Adoption of policies on generic medicines, and development of appropriate national legislation, in line with international trade agreements.

• Provision of comparative price information to health providers and consumers.

**Actions**

**Member States**

• Formulate pricing policies, including policies on relevant taxes, mark-ups, and reference pricing.

• Formulate and implement policies on generic medicines and promote affordable and quality medicines to providers and consumers.
Annex 1

- Establish and implement price monitoring, and participate in regional and global price monitoring.
- Provide price information to providers and consumers.
- Encourage collaboration among stakeholders involved in pricing and reimbursement schemes.

WHO

- Identify and disseminate existing pricing policies, practices and feasible pricing options.
- Support the development of local price monitoring systems for selected essential medicines and information exchange on prices of essential medicines. Encourage Member States to participate in regional and global price monitoring systems and provide Member States with price information.
- Provide support to countries for implementation of and improvements to policies on generic medicines.

3.4. Access to medicines, trade globalization and TRIPS

The World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) makes it obligatory for member countries to apply standards for patent protection for new medicines. The Doha Declaration on the TRIPS agreement and public health (Doha Declaration) agreed at the WTO Ministerial Meeting in Doha, Qatar, in November 2001 was an important step forward in improving access to medicines. The Doha Declaration affirms that the TRIPS agreement can and should be interpreted and implemented so that it protects public health and, in particular, promotes access to medicines for all. Countries can use the public health safeguards provided in the TRIPS agreement, compulsory licensing and parallel importation, in accordance with their national legislation.

Issues and challenges

- The supply of generic equivalents of some patented products may be affected as WTO Member States move towards full implementation of the TRIPS agreement and other international agreements containing obligations on intellectual property rights.
- Most governments and many ministries of health are unclear about how to safeguard public health in the era of intensive trade globalization.
Developing countries usually do not have enough capacity either for strategic planning or for conducting complex trade negotiations. Ministries of health in developing countries often do not pay sufficient attention to such issues and lack expertise, knowledge and skills. There is a lack of collaboration among the health, trade and other sectors, as these sectors often have different interests.

There is no mechanism for intercountry collaboration to make HIV/AIDS medicines and other essential medicines available and affordable.

**Strategies**

- Exchange of information on the impact of trade agreements on access to essential medicines.
- Exchange of country experiences in dealing with the TRIPS agreement and other agreements, especially with regard to securing public health. Provision of information on the TRIPS agreement and other relevant agreements for informed decision-making by Member States.
- Strengthening of national capacity to deal with trade-related matters that influence access to essential medicines. Use of the TRIPS agreement to improve access to medicines in accordance with national legislation.
- Collaboration between the health and other sectors (e.g. trade, finance, and justice) and other stakeholders (e.g. nongovernmental organizations and universities) in domestic policy preparation to ensure that national health objectives are taken into account when there are any changes to WTO agreements, national, regional or multilateral legislation related to regulations.
- Collaboration among governments in such areas as price negotiations, import and export of essential medicines, reducing regulatory barriers, and developing appropriate policy initiatives on intellectual property.
- International collaboration among international agencies, nongovernmental organizations, pharmaceutical manufacturers and other partners in order to identify and implement ways to ensure access to essential medicines, notably antiretrovirals, at affordable prices.
- Differential pricing of patented medicines.
Annex 1

Actions

Member States

- Review all national policies and regulations that affect pharmaceutical manufacturing and distribution, import and export, including tax, investment, trade and intellectual property regulation. The review should produce a coherent policy and regulatory framework aimed at increasing the supply of affordable quality medicines.

- Amend national intellectual property laws to include the public health safeguards of the TRIPS agreement.

- Establish collaboration between the health and other sectors and nongovernmental organizations in preparing domestic policies in order to ensure that national health objectives are taken into account when multilateral, regional and bilateral trade agreements are negotiated, or national legislation related to trade, health and intellectual property is drafted.

- Monitor policies, legislation and other factors influencing access to medicines in relation to the TRIPS agreement and other multilateral, regional and bilateral agreements that deal with intellectual property and trade globalization.

- Conduct national workshops and other training on trade globalization and access to medicines for health and trade policy-makers.

- Participate in regional associations (e.g. the Association of South-East Asian Nations) and collaborate with other countries to improve access to essential medicines in relation to trade globalization and the TRIPS agreement. Contribute actively to regional information exchange on the TRIPS agreement and other agreements dealing with intellectual property.

- Undertake price negotiation of patented medicines, especially for antiretroviral medicines.

WHO

- Monitor and disseminate information on international developments related to TRIPS, other relevant agreements and trade globalization.

- Support countries to assess their policies on health, trade and intellectual property.

- Advocate and facilitate collaboration between the health and other sectors and nongovernmental organizations in preparing domestic policies to ensure that national health objectives are taken into account when multilateral, regional and bilateral agreements are
negotiated, or when national legislation related to trade, health and intellectual property is drafted.

- Advocate the inclusion of the public health safeguards of the TRIPS agreement in national intellectual property laws and regulations and support countries to amend legislation accordingly.

- Support national workshops and other training on trade globalization and access to medicines for health and trade policy-makers.

- Facilitate exchange of country experiences in dealing with TRIPS and other agreements, especially in protecting public health. Provide information on TRIPS and other relevant agreements to Member States.

- Support collaboration among Member States in such areas as price negotiation, imports and exports of essential medicines, reducing regulatory barriers, developing appropriate policy initiatives on intellectual property. Pursue regional collaboration with relevant partners such as pharmaceutical manufacturers and their associations, nongovernmental organizations and consumer organizations.

- Promote the concept of differential pricing for developed and developing countries.

3.5 Sustainable financing

Sustainable financing for purchases of medicines is critical if essential medicines are to be made accessible. Government commitment for funding essential medicines is crucial, especially in primary health care facilities and for poor populations. In many countries in the Region, most financing for medicines is "out-of-pocket" (Box 2). In several countries, hospitals use the sale of medicines as an important source of revenue.
Annex 1

Box 2. Out-of-pocket financing for health, including pharmaceuticals

The *World health report 2002* revealed an increasing trend towards private financing of health care in the Region. In China, private out-of-pocket financing increased from 53.3% in 1995 to 63.8% in 2000. The same trend could be seen in Viet Nam (from 59.6% in 1995 to 74.2% in 2000) and Cook Islands (from 21.1% to 37.2% in 2000), among others.

In some countries there have been slight reductions in out-of-pocket payments, but these have often been from very high levels, for example in Cambodia (from 79% in 1995 to 75.5% in 2000) and Tonga (56.7% in 1995 to 53.2% in 2000).

The funding allocated to medicines varies between countries and often comes from different sources. However, expenditure on medicines usually accounts for 25% to 50% of total public and private health expenditures in developing countries.

**Issues and challenges**

- Allocations from public sector budgets for essential medicines are insufficient and contributions from consumers are often excessive.

- Many countries lack staff with financing and budgeting skills, which leads to inefficient financial planning and management.

- Information on public and private sources of funding for essential medicines is not readily available. Financial and economic analysis of medicines expenditures in order to promote cost-efficient and cost-effective financing options is rarely undertaken.

- There are often conflicting incentives to promote cost-efficiency or rational use in health institutions and pharmacies. It is common for health facilities and providers to use medicines sales to generate revenue.

- There is insufficient awareness of the reasons and implications of out-of-pocket payments in many countries.

**Strategies**

- Identification of policies and practices on essential medicines financing.
Annex 1

- Increase financial planning skills in ministries of health and improve awareness and knowledge of health and essential medicines in ministries of finance. Encourage collaboration between ministries of health and finance in financial planning and analysis for health.

- Establishment of information systems on existing sources of funding and expenditures on essential medicines. Implementation of financial and economic analysis of medicines expenditures to identify areas where cost containment measures are needed.

- Application of cost containment measures to medicines expenditures, and cost effectiveness analysis in the selection of medicines, especially in the public sector.

- Promotion of fair financing of essential medicines through social insurance schemes and various forms of community financing.

- Identification of effective public subsidy mechanisms for poor segments of the population.

- Human resources development in order to improve financial analysis of medicines financing.

**Actions**

**Member States**

- Review the impact of current health care and medicines financing on access to essential medicines.

- Maintain a coordinated information system on sources of medicines financing and expenditures as part of national health accounts or other national health financing information systems. Promote the use of such information and data on health statistics in order to analyse the impact of medicines expenditures.

- Undertake regular financial and economic analysis of medicines expenditures using cost efficiency and cost effectiveness analytical tools, especially in the public sector.

- Hold national meetings to bring together essential medicines, health and finance stakeholders to ensure that the national medicines policy is a part of health policy and financing.

- Maintain sufficient public financing for essential medicines, through improved financial management, especially for the public sector and primary health care, based on properly quantified health care needs.

- Ensure that essential medicines are covered by social health insurance and create mechanisms for social safety nets.
Annex 1

- Undertake training on budgeting, financial planning and management.

WHO

- Undertake operational research to document the practice and implications of out-of-pocket payment.
- Increase awareness of the implications of out-of-pocket payment for medicines and promote social health insurance to cover the cost of medicines, as part of broader health financing strategies.
- Identify and disseminate policies and practices of Member States in fair medicines financing, and efficient and effective financial management.
- Support countries to establish or maintain coordinated information system on sources of medicines financing and expenditures as part of national health accounts.
- Develop methods and analytical tools to assess and monitor Member States’ current medicines financing policies and practices.
- Support capacity building for financial and pharmacoeconomic analysis. Strengthen planning and management of human and financial resources.
- Provide support for the analysis of medicines financing and expenditures in order to improve cost-efficiency and cost effectiveness, especially in the public sector.

3.6 Supply and management systems

Several countries in the Region still find it difficult to ensure a consistent supply of essential medicines. Because of poor estimations of needs, essential medicines may sometimes be unavailable for unacceptably long periods or may have to be disposed of because they have expired (Box 3). Uneven distribution of essential medicines, with rural and remote areas often left without essential medicines, is also common. Poor storage conditions throughout the distribution system often lead to further wastage and quality problems.
Box 3. Country examples: drug availability in Cambodia, Malaysia and the Philippines

Cambodia has a system that allows comprehensive monitoring of the supply of medicines and their use in health facilities. Using this monitoring system, the Ministry of Health was able to demonstrate 94%-95% availability of essential medicines from 2000 to 2002. However, even such a monitoring system may not guarantee an immediate response if there is a supply problem because of weaknesses in procurement. The system also requires continued supervision.

In 2002 a survey in Malaysia revealed that the average percentage availability of essential medicines listed in the public sector was 95.4%, with an average out of stock duration of 6.5 days.

In the Philippines, a study has shown that the availability of essential medicines in the public sector is low: 34.1% in public health facilities and 38.0% in public warehouses.

Issues and challenges

- In many countries, the procurement of essential medicines is carried out by different programmes and organizations, using different methods and quality standards, with no efficient coordination, which leads to inefficiencies and waste.

- Public sector planning, monitoring and management information systems for procurement and distribution are usually inadequate and there are not enough trained people to manage the drug supply. There is inadequate stock management, leading to wastage at various levels.

- In many countries, procurement of medicines is not based on essential medicines lists. There is poor estimation of essential medicines needs at various levels of health care systems. There is a lack of information on prices and sources of good quality medicines.

- The principles of good procurement practices are not widely known or implemented. The WHO Certification Scheme is often not used when procuring imported products (Box 4).

- Transportation and distribution in difficult geographical and remote areas can result in long lead times and changes in the quality of medicines because of adverse climatic conditions. This is aggravated by lack of management, infrastructure and skills.

- Lack of bulk procurement mechanisms often lead to higher cost and lower quality products.

- In many countries, decentralization of the medicines procurement system very often result in inefficiencies, which have an adverse impact on access to medicines.

- The distribution of medicines is often uneven and poorer populations are often not reached.
Box 4. What is the WHO Certification Scheme?

The WHO Certification Scheme is an international voluntary agreement, devised to enable countries with limited regulatory capacity to obtain partial assurance from exporting countries concerning the safety, quality and efficacy of the products they plan to import.

How does the scheme function?

It is a voluntary agreement that requires regulatory authorities of exporting countries to issue certificates when requested by importing countries. The certificates:

- explain whether a special product is approved for use in the exporting country, and if not, why;
- contain details of whether the premises where the product is manufactured are inspected regularly and meet good manufacturing practices standards; and
- attest to the fact that all submitted product information, including labelling, is currently authorized in the certifying country.

What are the scheme's strengths and weaknesses?

Strengths

- The scheme provides evidence that the exporting country has evaluated the products and manufacturers for which certificates are issued.
- It uses a standard format that helps importing countries to obtain all the information they need about products they are importing.
- Use of a standard format obliges the certifying authority to disclose important information to the importing country;
- It promotes information exchange between countries about pharmaceutical products and can lead to harmonization of product information.

Weaknesses

- A certificate is only as good as the certifying authority.
- The scheme relies on the honesty and competence of the issuing authorities.
- The scheme does not cover pharmaceutical products while they are in transit, during which time a product could be relabelled or mixed with other products.

Procurement agencies are encouraged to request certificates under the scheme as part of their overall efforts to ensure product quality.
Strategies

- Coordinated medicines management, planning and monitoring systems in the public sector, including procurement based on good procurement practices, national policies, essential medicines lists and standard treatment guidelines.

- Training in medicines management, including quantification, costing, procurement, distribution and inventory management of essential medicines.

- Information exchange on prices and sources for medicines procurement.

- Bulk and collaborative procurement, collective price negotiations for procurement of essential medicines. Use of WHO pre-qualified products (Box 5) and manufacturers for HIV/AIDS, tuberculosis and malaria medicines in procurement.

- Promotion of good and ethical pharmaceutical practices (procurement, distribution, storage and pharmacy) in public and private sectors.

- Identification of best practices in pharmaceutical supply and procurement in systems that have been decentralized and reformed. Clarification of the roles of central and local governments and the roles of public and private sectors in such decentralized systems.

- Strengthening of system and human resources capacities in medicines supply management in decentralized settings. Advocacy for local government commitment.

- Implementation of a mechanism for social protection that covers essential medicines for poorer populations.
Box 5. WHO prequalification project: access to antimalarials, antituberculosis and HIV/AIDS medicines and HIV/AIDS diagnostics of acceptable quality

Many international, regional and national organizations are involved in the procurement of medicines. The supply of effective medicines of acceptable quality for the treatment of HIV/AIDS, malaria and tuberculosis has become a major concern at both international and country levels.

The WHO prequalification project aims to facilitate access to medicines of acceptable quality by assessing their compliance with WHO recommended standards. It was begun by WHO in collaboration with UNAIDS, UNDP, UNFPA and UNICEF.

The procedure for assessing the acceptability, in principle, of medicines consists of two procedures:

(1) an evaluation of product data and information provided by manufacturers and suppliers; and
(2) inspection of manufacturing sites to ensure that good manufacturing practices are in place.

Manufacturers who wish to supply medicines through this pilot project may express their interest to WHO. After ensuring that submitted documentation related to products and manufacturing facilities is satisfactory, WHO may organize a detailed evaluation of product dossiers and inspection of the manufacturing site. Only products and manufacturing sites that are found to meet the recommendations in the WHO guidelines are published in a list of suppliers. The list is intended to be a tool to guide the selection of suppliers for procurement purposes.

Member States are recommended to use these lists when sourcing products for procurement in order to ensure that medicines of acceptable quality are purchased. This will also facilitate the registration of medicinal products, as the listed products and suppliers already comply with WHO guidelines for registration and good manufacturing practices.

The lists and additional information about the WHO prequalification project can be found at: http://mednet3.who.int/prequal
Actions

Member States

- Implement a coordinated medicines management system for planning and monitoring.

- Undertake procurement of medicines for the public sector based on national medicines policies, good procurement practices, essential medicines lists and standard treatment guidelines.

- Undertake training in management of medicines, including quantification, costing, procurement, distribution and inventory management of essential medicines.

- Pursue mechanisms for centralized or collaborative (bulk) procurement and collective negotiations.

- Monitor prices of essential medicines and contribute actively to regional information exchange.

- Develop a social protection mechanism covering essential medicines, such as exemption of a user's fee for the lower income segment.

WHO

- Promote coordination of medicines procurement by different programmes, based on national medicines policies, good procurement practices, essential medicines lists and standard treatment guidelines.

- Pursue mechanisms for collaborative (bulk) procurement and multicountry price negotiations for procurement of essential medicines.

- Promote good and ethical pharmaceutical practices (procurement, distribution, storage and pharmacy) in public and private sectors.

- Support the development and implementation of coordinated management planning and monitoring systems for medicines.

- Provide technical support and training (international and national) in drug management, including quantification, costing, procurement, distribution and inventory management of essential medicines.
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- Monitor prices of selected essential medicines and facilitate information exchange on prices and sources for medicines procurement. Promote the use of WHO prequalified products and manufacturers for HIV/AIDS, tuberculosis and malaria medicines.

- Support operational research to document and to evaluate practices on pharmaceutical supply systems and procurement in public and private sectors in health systems that have been decentralized and reformed.

3.7 Quality

The quality of medicines is an integral part of access. Pharmaceutical products should be fit for their intended use, comply with the requirements of the marketing authorization and should not expose consumers to risks. If this is to be achieved, there must be a system of quality assurance, which incorporates product development, manufacture, distribution and storage. Quality assurance of pharmaceuticals is part of WHO's support for national medicines policies and essential medicines.

In some countries in the Region medicines are still not manufactured according to internationally accepted standards, such as WHO good manufacturing practices. This results in substandard medicines being manufactured, distributed and used.

The most urgent quality issue in the Region is counterfeit medicines. There has been a significant increase in the production, distribution and sale of counterfeit medicines in recent years, particularly for medicines used to treat diseases with high mortality, such as malaria, especially in the Mekong region. Consumers are wasting valuable resources on fake medicines. Effective medicines regulation and enforcement, legislation, confiscation and destruction of counterfeit medicines and strong political will are all needed if dealers in counterfeit medicines are to be deterred.

3.7.1 Counterfeit medicines

Issues and challenges

- Policy-makers, health professionals and the general public tend not to appreciate the size of the counterfeit medicines problem.

- Laws and regulations relating to quality assurance (e.g. drug registration, inspection and quality surveillance) are not properly enforced in many countries.

- In some countries, the number of unlicensed private pharmacies is increasing.
Penalties for breaking laws or regulations are very lenient in most countries. Counterfeiting is commonly considered a trade violation rather than a serious criminal act violating public health.

There is a lack of political commitment to combat counterfeit medicines in many countries.

In many countries there is a lack of collaboration between law enforcement agencies and health officials in combating counterfeit medicines.

The definition of counterfeit medicines varies from country to country, hampering international collaboration.

**Strategies**

- Campaigns against counterfeit medicines, targeting health care providers, policy-makers and the general public.

- Formulation and implementation of comprehensive strategies to combat counterfeit medicines involving relevant stakeholders, including private manufacturers.

- Strengthening, adoption and enforcement of legislation, regulations and inspection.

- Information exchange among Member States, including a rapid alert mechanism, on the regulatory status of medicines and on counterfeit medicines.

- Regular assessment of the extent of counterfeit medicines in the marketplace.

- Intercountry collaboration and collaboration between medicines regulatory authorities and other law enforcement agencies.

- Training on combating counterfeit medicines.

- A common definition of counterfeit medicines.
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Actions

Member States

- Develop national strategies, guidelines and advocacy materials on combating counterfeit medicines.

- Increase awareness of counterfeit medicines among policy-makers, law enforcement agencies, providers and consumers.

- Strengthen collaboration among law enforcement agencies through meetings and training.

- Share with WHO and other countries the regulatory status of medicines and information on the prevalence of counterfeit medicines in the Region.

- Conduct regular assessments on the extent of counterfeit medicines.

- Conduct training on combating counterfeit medicines for law enforcement agencies and drug inspectors.

- Strengthen legislation and regulation, including stronger penalties and a definition of counterfeit medicines in line with the WHO definition. Improve implementation and enforcement of laws and regulations.

WHO

- Provide support to countries so they can improve legislation, regulation and inspection.

- Develop advocacy materials on combating counterfeit medicines for policy-makers, providers and consumers.

- Provide support to countries for an assessment of the extent of counterfeit medicines.

- Support intersectoral and intercountry workshops on combating counterfeit medicines.

- Provide support for training on combating counterfeit medicines for law enforcement agencies and drug inspectors.

- Promote and facilitate information exchange among Member States, including a rapid alert mechanism, on the regulatory status of medicines and on counterfeit medicines.
• Collaborate with other international agencies, such as Interpol, manufacturers’ associations, donors, etc.

• Promote the WHO definition of counterfeit medicines.

### 3.7.2 Substandard medicines

**Issues and challenges**

• Surveys in some Member States show a high incidence of substandard medicines in the market.

• In some countries, manufacturers do not comply with good manufacturing practices because of a lack of human resources or a lack of commitment to invest in improvements to manufacturing facilities.

• Medicines regulatory authorities do not have sufficient capacity and skills to provide advice to and inspect manufacturers of medicines and to register medicines. Breaches of good manufacturing practices are not punished and law enforcement is weak.

• Results of quality surveillance, if any, are not used to improve quality assurance.

**Strategies**

• Implementation of good manufacturing practices and collaboration between manufacturers and drug regulatory authorities on improving compliance with good manufacturing practices.

• Building capacities and skills of medicines regulatory authorities in the areas of good manufacturing practices, inspection and product registration.

• Regular surveys on the quality of medicines, followed by appropriate interventions.

• Strengthening, adoption and enforcement of legislation, regulations and inspection.

• International collaboration and information exchange on medicines regulatory affairs, particularly on inspection and medicines registration.

**Actions**

**Member States**

• Strengthen capacity and skills of the national regulatory authorities, particularly in the field of establishing and auditing good manufacturing practices, inspections and drug registration.
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- Strengthen and improve enforcement of legislation and regulations.
- Collaborate with national regulatory authorities in other countries to take advantage of inspections and product evaluations that have already been carried out.
- Conduct quality surveys and evaluation of medicines.
- Participate in international information exchange on the regulatory status of medicines and the prevalence of substandard medicines.
- Collaborate with manufacturers' associations to undertake training programmes in good manufacturing practices and to certify manufacturers.

WHO

- Provide technical support for good manufacturing practices, inspection and drug registration.
- Support training of staff in good manufacturing practices, inspection and drug registration.
- Provide technical support for the strengthening of legislation and regulations pertaining to quality.
- Provide support for the conduct of quality surveys and evaluation of medicines.
- Facilitate information exchange between countries on the regulatory status of medicines and the prevalence of substandard medicines.

3.8 Monitoring and evaluation

In the mid-1990s, WHO published a comprehensive set of indicators to monitor the implementation of national medicines policies, including access to essential medicines. It soon became evident that a core set of indicators was needed if the pharmaceutical situation in a country and implementation of the national medicines policy were to be assessed regularly (Box 6). However, suitable indicators to measure access to essential medicines have not yet been defined or agreed upon.
Box 6. Country examples: use of indicators in Australia, Cambodia and Indonesia

Although Australia does not yet have a nationally recognized set of national medicines policy indicators, the indicators and targets for the “quality use of medicines”, which began in 1992, have been regularly assessed and performance has been reported. Information on achievement or non-achievement has enabled continuity during periods of political change. The indicators used to monitor the “quality use of medicines” component of Australia’s national medicines policy (officially launched in 1999) have also been used to demonstrate successes and gaps in policy development and implementation.

From the start of its national medicines policy in 1995, Cambodia introduced a set of 24 indicators to monitor and supervise medicines supply, storage and distribution, and rational use of medicines. While some indicators have reflected positive trends, such as the percentage of medicines prescribed from the national list of essential medicines (from 92% in 1995 to 98% in 2002) and the percentage of children below the age of five years receiving oral rehydration salts (from 64% in 1995 to 86% in 2002), others, such as those used to assess medicines management, have remained the same, pointing to a need for interventions. Some of the problems in medicines management relate to current government procedures, which allow procurement only once per year, which frequently leads to stocks of some medicines running out and others being overstocked. Other constraints include the lack of a budget to measure the impact of some interventions, such as those used to measure rational medicines use.

Indonesia used indicators to measure the impact of the country’s currency crisis in the late 1990s on the availability and affordability of medicines in both public and private sectors (public and private hospitals, public health centres, private pharmacies). Some findings were reassuring; such as the availability of key essential medicines throughout the crisis and consistently low injection use. Others were disconcerting but not surprising. For example, prescription practices did not improve during the crisis, indicating a need for improvement in private health facilities. The impact on affordability was lower in public facilities, where there is an essential medicines list, than in private facilities, which apply less restrictive procurement policies. Hospitals were affected by the crisis as they rely on sales of medicines to generate profit, which indicates the need for better financing schemes.
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Issues and challenges

- In many countries, there is no regular system to monitor the implementation of the national medicines policy or to measure its impact on access to medicines. Even if data are available, they are rarely analysed or used by policy-makers to help health managers and providers to improve national medicines policy implementation and access to essential medicines.

- The continuity of monitoring the implementation of national medicines policies, including access to essential medicines, is often jeopardized when there is a change from a central to a decentralized system.

- Many countries do not have sufficient capacity to evaluate the impact of interventions designed to improve access to essential medicines.

- Suitable indicators for measuring access are not yet available.

Strategies

- Monitoring and evaluating of the implementation of national medicines policy, particularly with regard to access to essential medicines. Feeding back data derived from assessments of the pharmaceutical sector to stakeholders in order to improve policy implementation.

- Operational research to develop, field test and measure the impact of interventions.

- Establishment of a technical advisory group to provide recommendations for improving access to essential medicines in the Region.

- Further refinement and use of suitable indicators for measuring access to medicines.

Actions

Member States

- Establish systems to monitor and evaluate the impact of the national medicines policy, particularly with regard to access to essential medicines.

- Undertake assessment of pharmaceutical sectors using selected indicators.

- Develop or update the national medicines policy, based on assessments of the pharmaceutical sector.

- Contribute actively to regional information exchange on implementation of the national medicines policy and other interventions to improve access.
WHO

- Support assessments of the pharmaceutical sector and implementation of regular monitoring and evaluation systems for national medicines policies, including operational research to measure the impact of interventions on access, quality and proper use of essential medicines.

- Establish a regional technical advisory group to provide recommendations on measures to improve access to essential medicines in the Region.

- Refine, field-test, disseminate, promote and support the use of practical and suitable indicators to measure access to essential medicines.