In spite of WHO’s promotion of national medicines policies, problems of access to essential medicines remain, especially in developing countries of the Region. This is an issue of global importance, as recognized by the Fifty-sixth World Health Assembly in May 2003 (Annex 1). 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, 2004-2009 (Annex 2).

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; sustainable funding; supply and management systems; quality; access; trade globalization and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS agreement); 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, 2004-2009.
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.

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

The prices of many essential medicines remain too high in relation to local purchasing power in many countries in the Region. 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. Public funding for essential medicines remains low in many countries. Furthermore, several countries still face difficulties in ensuring a stable supply of essential medicines. Uneven distribution of medicines is common and rural and remote areas are often left without essential medicines.

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

Improving access to essential medicines is therefore becoming an increasingly important area of work for WHO in the Region.

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,
2004-2009 (Annex 2). The objective of the regional strategy is to provide operational and practical guidance for Member States and WHO on improving access to essential medicines.

The draft strategy was developed through a process of wide consultation with experts and counterparts. Comments from WHO technical programmes, national counterparts and international experts have been incorporated into the attached draft strategy. 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.

The draft regional strategy for improving access to essential medicines in the Western Pacific Region, 2004–2009 proposes strategies for key areas, with accompanying actions for both WHO and Member States.

3. ACTIONS PROPOSED

The Regional Committee is requested to discuss and endorse the draft regional strategy on improving access to essential medicines in the Western Pacific Region, 2004-2009.
The Fifty-sixth World Health Assembly,

Having considered the report on intellectual property rights, innovation and public health;¹

Considering that available data indicates that of some 1400 new products developed by the pharmaceutical industry between 1975 and 1999, only 13 were for tropical diseases and three were for tuberculosis;

Aware that the developed countries represent nearly 90% of global pharmaceutical sales, whereas of the 14 million global deaths due to infectious diseases, 90% occur in the developing countries;

Concerned about the insufficient research and development in so-called “neglected diseases” and “poverty-related diseases”, and noting that research and development in the pharmaceutical sector must address public health needs and not only potential market gains;

Mindful of concerns about the current patent protection system, especially as regards access to medicines in developing countries;

Recalling that, in accordance with the Declaration on the TRIPS Agreement and Public Health (Doha Declaration), the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) does not and should not prevent Members from taking measures to protect public health and, in particular, to promote access to medicines for all;

Noting that the TRIPS Agreement contains flexibilities and that in order to use them adequately, Member States need to adapt national patent legislation;

Reaffirming resolution WHA52.19 on the revised drug strategy, resolution WHA54.11 on WHO medicines strategy and resolution WHA55.14 on ensuring accessibility of essential medicines;

Considering that Member States should urge the pharmaceutical industry to reinvigorate its efforts to develop innovations that add real therapeutic advantage in treating the world’s major killer diseases, especially in developing countries;

¹ Document A56/17.
Recognizing the importance of intellectual property rights in fostering research and development in innovative medicines and the important role played by intellectual property with regard to the development of essential medicines;

Taking into account that in order to tackle new public health problems with international impact, such as the emergence of severe acute respiratory syndrome (SARS), access to new medicines with potential therapeutic effect, and health innovations and discoveries should be universally available without discrimination;

Further considering the continuing efforts of WTO Members to reach a solution for paragraph 6 of the Doha Declaration which recognizes that “WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement”;

Reasserting the need to accomplish target 7 of Millennium Development Goal 6 and target 17 of Millennium Development Goal 8;

Noting resolutions 2001/33 and 2003/29 of the Commission on Human Rights on access to medicines in the context of pandemics such as HIV/AIDS,

1. URGES Member States:

   (1) to reaffirm that public health interests are paramount in both pharmaceutical and health policies;

   (2) to consider, whenever necessary, adapting national legislation in order to use to the full the flexibilities contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS);

   (3) to maintain efforts aimed at reaching, within WTO and before the Fifth WTO Ministerial Conference, a consensus solution for paragraph 6 of the Doha Declaration, with a view to meeting the needs of the developing countries;

   (4) to seek to establish conditions conducive to research and development that spur the development of new medicines for diseases that affect developing countries;

2. REQUESTS the Director-General:

   (1) to continue to support Member States in the exchange and transfer of technology and research findings, according high priority to access to antiretroviral drugs to combat HIV/AIDS and medicines to control tuberculosis, malaria and other major health problems, in the context of paragraph 7 of the Doha Declaration which promotes and encourages technology transfer;

   (2) by the time of the 113th session of the Executive Board (January 2004), to establish the terms of reference for an appropriate time-limited body to collect data and proposals from the different actors involved and produce an analysis of intellectual property rights, innovation, and public health, including the question of appropriate funding and incentive mechanisms for the creation of new medicines and other products against diseases that disproportionately affect developing countries, and to submit a progress report to the Fifty-seventh World Health
Assembly and a final report with concrete proposals to the Executive Board at its 115th session (January 2005);

(3) to cooperate with Member States, at their request, and with international organizations in monitoring and analysing the pharmaceutical and public health implications of relevant international agreements, including trade agreements, so that Member States can effectively assess and subsequently develop pharmaceutical and health policies and regulatory measures that address their concerns and priorities, and are able to maximize the positive and mitigate the negative impact of those agreements;

(4) to encourage developed countries to make renewed commitments to investing in biomedical and behavioural research, including, where possible, appropriate research with developing country partners.

Tenth plenary meeting, 28 May 2003
A56/VR/10

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DRAFT REGIONAL STRATEGY FOR IMPROVING ACCESS TO ESSENTIAL MEDICINES IN THE WESTERN PACIFIC REGION
2004 – 2009

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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, particularly 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 in 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. Challenges and progress towards improving access to essential medicines in the Lao People’s Democratic Republic, Mongolia and Tonga

The 1996 revised national medicines policy 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 medicine use; and assure medicine 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 medicine 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 drugs 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 medicine registration is being carried out. Efforts are also being made to ensure compatibility between the essential medicines list and clinical guidelines.

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 Agreement on Trade-Related Aspects of Intellectual Property (TRIPS agreement). 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 counterparts and international experts have been incorporated. It was finally reviewed in detail at a consultation on improving access to essential medicines in the Western Pacific Region in Penang, Malaysia, in July 2003.

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 essential medicines.

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 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. sustainable financing
5. supply and management systems;
6. quality;
Annex 2

7. access to medicines, trade globalization and the TRIPS agreement; 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 cheap, of low efficacy and quality, for the poor and that they restrict professional freedom of prescribing.

- 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.

Strategies

- Focused advocacy and training for 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 and systematic process to the formulation, evaluation and revision of the essential medicines list, involving relevant stakeholders at different levels of the health care system.
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- 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 as the basis for 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.

**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.

**WHO**

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

- Continue to publish a regional newsletter, *Essential Drugs and Medicines Policy*. Develop other means of networking that take advantage of information technology, i.e. WHO essential medicines library, website and databases.

- Develop model curricula on the essential medicines concept and national medicines policy in undergraduate and continuing education programmes, and promote its adoption and use by Member States.
Annex 2

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

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. 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.

Issues and challenges

• There is a widespread belief that training and developing standard treatment guidelines are enough to improve 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 medicine 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 non-compliance 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.

- Use of standard treatment guidelines and formularies linked to essential medicines lists in public and private facilities.

- Supervision and monitoring of medicine 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 medicine use.

- Promotion of therapeutics and medicines committees in hospitals.

- Implementation of ethical criteria for and regulation of pharmaceutical promotion.

- Development and implementation of appropriate strategies to contain antimicrobial resistance.

**Actions**

**Member States**

- Draw up and implement a comprehensive rational drug use strategy.

- 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 medicine 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.

- Improve the adherence and continuity of antiretroviral treatment.
Annex 2

- Seek partnerships, particularly with nongovernmental organizations and academic institutions to promote rational drug use.

- Develop and implement a national strategy to contain antimicrobial resistance.

WHO

- Support countries to formulate, implement and evaluate comprehensive rational drug use strategies.

- Support the development and field-testing of interventions on drug use practices, combining educational, managerial and regulatory interventions.

- Identify best practices for effective rational medicine use interventions and work with countries to replicate them.

- Support countries to formulate and implement standard treatment guidelines and formularies linked with essential medicines list.

- Draw up guidelines for supervision and monitoring of medicine use practices.

- Develop materials for consumer education and empowerment on rational use of medicines.

- Facilitate exchange of information on rational medicines use through the publication of a regional newsletter, Essential Drugs and Medicines Policy, and through electronic communication networks.

- Undertake intercountry and country meetings on hospital therapeutics and medicine 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.

- 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 the mark-up system, 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. Companies therefore set their prices as high as possible.
- 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 and knowledge on options for making prices affordable (i.e. price competition or price control).

Strategies

- Identification and dissemination of best 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 the 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).
Annex 2

- 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 based on the essential medicines concept.
- 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 generic medicines to providers and consumers.
- Establish and implement price monitoring, and participate in regional and global monitoring.
- Provide price information to providers and consumers.
- Encourage collaboration among stakeholders involved in pricing and reimbursement schemes.

**WHO**

- Identify existing pricing policies and practices.
- 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.
- Formulate guidelines for pricing of medicines and provide support for pricing policies.
- Provide support to countries for implementation of and improvements to policies on generic medicines.
- Promote the concept of differential pricing between developed and developing countries.
3.4 Sustainable financing

Sustainable financing for medicines purchases 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.

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 required from consumers are often excessive.

- Information on public and private sources of funding for essential medicines is not readily available. Financial analysis of pharmaceutical expenditures in order to promote cost-efficiency and increase government allocations cannot, therefore, be undertaken.

- There are often conflicting incentives to promote cost-efficiency or rational use in health institutions and pharmacies. It is common for health facilities to use pharmaceutical sales to generate revenue.
Annex 2

- Insufficient awareness of the implications of out-of-pocket payments.

**Strategies**

- Identification of policies and practices on essential medicines financing.
- Improvement in knowledge and skills in order to be able to advocate best policies and practices. Increase financial skills in ministries of health and increase skills and knowledge of health and essential medicines in ministries of finance.
- Establishment of information systems on existing sources of funding and expenditures on essential medicines. Financial analysis of pharmaceutical expenditures to identify areas where cost-efficiency measures are needed.
- Application of cost-efficiency measures to pharmaceutical financing and expenditures, especially in the public sector.
- Promotion of cost-effective financing of essential medicines through, for example, public financing, insurance schemes and community financing.

**Actions**

**Member States**

- Review the impact of current health care and pharmaceutical 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.
- Undertake regular analysis of medicines expenditures and exercise cost-efficiency measures, especially in the public sector.
- Hold national meetings to bring together essential medicines, health and finance stakeholders to address key financing measures to ensure that national medicines policy is a part of health policy and financing.
- Maintain sufficient public financing for essential medicines, 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.

WHO

• As part of broader health financing strategies, particularly in relation to social health insurance, identify suitable medicines financing policies.

• 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 tools to assess Member States’ current medicines financing policies and practices and undertake analysis.

• Develop guidelines on cost-efficiency and containment of expenditures on medicines.

• Support capacity building in pharmaceutical financial analysis, planning and management,

• Provide support for the analysis of medicine financing and expenditures in order to improve cost-efficiency, especially in the public sector.

• Identify best practices that can be used by Member States to improve financing and to undertake cost-efficiency measures.

3.5 Supply and management systems

Several countries in the Region still find it difficult to ensure a consistent supply of essential medicines. This has an impact on access. 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, leaving rural and remote areas 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 for 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, 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, 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.

- Procurement of pharmaceuticals is not based on essential medicines lists in many countries. 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 in many countries. The WHO Certification Scheme is often not used when procuring imported products (Box 4).

- Transportation and distribution in difficult geographical areas (i.e. in very large or island countries) can result in long lead times and changes in the quality of medicines because of adverse climatic conditions.
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 the 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 should routinely request certificates under the scheme as one of several measures to ensure product quality.
Strategies

- Coordinated medicine 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 drug 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. For countries without manufacturing capacity, use of WHO pre-qualified products (Box 5) and manufacturers for HIV/AIDS, tuberculosis and malaria drugs in procurement.

- Identifying best practices on pharmaceutical supply systems and procurement in systems that have been decentralized and reformed, clarifying the roles of central and local governments and the roles of public and private sectors.

- Promoting good and ethical pharmaceutical practices (procurement, distribution, storage and pharmacy) in public and private sectors.
Box 5. Pilot procurement quality and sourcing project: access to antimalarial, antituberculosis and HIV/AIDS drugs and HIV/AIDS diagnostics of acceptable quality

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

The pilot procurement project aims to facilitate access to drugs of acceptable quality through assessment of compliance with WHO recommended standards. It was begun by WHO in collaboration with UNAIDS, UNICEF, UNDP and UNFPA.

The procedure for assessing the acceptability, in principle, of drugs consists of the following procedures:

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

Manufacturers who wish to supply drugs 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 can be used as 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 pilot procurement quality and sourcing project: “Access to antimalarial, anti-tuberculosis and HIV/AIDS Drugs and HIV/AIDS diagnostics of acceptable quality” can be found at:
http://www.who.int/medicines/organization/qsm/activities/pilotproc/pilotprocmain.shtml
Annex 2

**Actions**

**Member States**

- Implement a coordinated medicine 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.

**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 bulk procurement and collective multi-country price negotiations for procurement of essential medicines.

- Promoting 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.

- Monitor prices of selected essential medicines and facilitate information exchange on prices and sources for medicines procurement. For countries without manufacturing capacity,
promote the use of WHO pre-qualified products and manufacturers for HIV/AIDS, tuberculosis and malaria drugs.

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

3.6 Quality

Counterfeit medicines are a serious concern for several countries in the Region. Effective medicines regulation and enforcement, promulgation of deterrent legislation, confiscation and destruction of counterfeit medicines and strong political will are needed if counterfeit medicines are to be combated.

**Issues and challenges**

- 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 drugs in many countries.

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

**Strategies**

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

- Formulation and implementation of comprehensive strategies for combating counterfeit and substandard medicines involving relevant stakeholders, including private manufacturers.

- Adoption and further strengthening of legislation, regulations and inspection.
Annex 2

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

- Assessment of the extent of counterfeit medicines in the marketplace.

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

- Training on combating counterfeit medicines.

Actions

**Member States**

- Develop national advocacy material and guidelines on combating counterfeit and substandard medicines for providers and consumers. Increase awareness of counterfeit medicines among policy-makers, law enforcement agencies, providers and consumers through media campaigns.

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

- Share with WHO and other countries the regulatory status of medicines and counterfeit or substandard medicines found in the Region.

- Conduct surveys on counterfeit or substandard medicines.

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

**WHO**

- Provide support to countries in order to improve legislation and inspection.

- Develop advocacy materials on combating counterfeit and substandard medicines for policy-makers, providers and consumers. Promote and facilitate information exchange among Member States, including a rapid alert mechanism, on the regulatory status of medicines and counterfeit or substandard medicines.

- Provide support to countries for surveys on counterfeit or substandard 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.

3.7 Access to medicines, trade globalization and the TRIPS agreement

The World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS agreement, Box 6) makes it obligatory for member countries to apply standards for patent protection for new medicines that are similar to those in major developed countries. The Declaration on TRIPS and Public Health agreed at the WTO Ministerial Meeting in Doha, Qatar, in November 2001 (Doha Declaration) 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 in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all. However, it remains to be seen how the flexibility provided by the TRIPS agreement’s provisions on exceptions, such as parallel imports and compulsory licenses, can be used to protect the public health interests of developing countries. The flexibility of TRIPS is further complicated by bilateral and regional trade agreements.

Issues and challenges

• The globalization of intellectual property rights may reduce access to essential medicines, especially to new patented medicines. The supply of generic equivalents of some patented products may decrease as developing countries move to full implementation of the TRIPS agreement and other international agreements containing obligations on intellectual property. This will create problems, notably for countries with no manufacturing capacity (Box 6).

• Most governments and many ministries of health are unclear about how to safeguard public health in the era of intensive trade globalization.
Under the current World Trade Organization (WTO) Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS agreement), all member countries have to grant patent protection to pharmaceutical products. For industrialized countries the agreement has been applicable since 1996. However, for developing countries a transitional period is granted until 2005, and for least developed countries until 2015.

Under the TRIPS agreement, the production of less costly generic equivalents is no longer possible for patented medicines. However, in the case of public health emergencies and in order to ensure access to essential medicines, countries may use the public health safeguards, namely compulsory licensing, parallel importation and “Bolar provisions”. Compulsory licensing means granting a licence to manufacture a generic equivalent of a patented product, without the consent of the patent holder. Parallel importation is importation, without the consent of the patent holder, of a patented product marketed at a lower price in another country either by the patent holder or with the patent holder’s consent. Bolar provision is early submissions of application for registration of generic equivalent of a patented product before the expiry of patents. In order to utilize the public health safeguard provisions, the provision has to be included in national patent legislation.

Of the three provisions, compulsory licensing remains problematic for many developing countries, as not all countries have the capacity or sufficient market for pharmaceutical production of generic equivalents of patented products. Under the agreement, these countries cannot use compulsory licensing to import generic equivalents of patented products from other countries where the original drug is patented. Under the TRIPS agreement, generic equivalents of patented products manufactured under compulsory licensing can only be used predominantly for the domestic market.

The Ministerial Meeting in Doha in 2001 tried to resolve this problem. In the article 6 of the Doha Declaration, it was recognized that WTO members with insufficient or no manufacturing capacities could face difficulties in making effective use of compulsory licensing. The Doha Declaration instructed the TRIPS Council to find a solution to this problem. In spite of several meetings and negotiations after Doha meeting, no solution has been reached. Countries with insufficient or no manufacturing capacity will not be able to import generic equivalents of patented products after 2005, when the agreement is enforced. Even before 2005, political pressures have practically prevented the use of compulsory licensing by developing countries.
There are often international political pressures that prevent countries from using the public health safeguards of the TRIPS agreement to improve access.

- Developing countries have insufficient capacity either for strategic planning or for conducting complex trade negotiations. Ministries of health in developing countries do not pay sufficient attention to these issues and lack expertise, knowledge and skills. There is a lack of collaboration among health, trade and other sectors, which often have different interests.

- There is an absence of intercountry collaboration to make HIV/AIDS medicines and other essential medicines available and affordable.

**Strategies**

- Monitoring of international developments related to regional, multilateral and bilateral agreements.

- 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 national capacity to deal with trade-related matters that influence access to essential medicines. Using the public health safeguards of the TRIPS agreement in national intellectual property laws and regulations.

- 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 World Trade Organization (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. The potential for bilateral or regional agreements on the production or export of generic medicines before patent expiration should be explored.
Annex 2

- International collaboration among international agencies, nongovernmental organizations, manufacturers of generic medicines and other partners in order to identify and implement ways to ensure access to essential drugs, notably antiretrovirals, at affordable prices.

Actions

Member States

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

- 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 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.

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

WHO

- Follow international developments related to TRIPS, other relevant agreements and trade globalization and their impacts.
• Support country assessment in relation to 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 the TRIPS and other agreements, especially in protecting the public health interest. Provide information regarding the TRIPS and other relevant agreements to Member States.

• Support collaboration among governments in such areas as price negotiation, imports and exports of essential medicines, reducing regulatory barriers, developing appropriate policy initiatives on intellectual property. Explore bilateral or regional agreements on the production or export of generic medicines before patents expire. Pursue regional collaboration with relevant partners such as pharmaceutical manufacturers and their associations, nongovernmental organizations and consumer organizations.

3.8 Monitoring and evaluation

In the mid-1990s, WHO published a comprehensive set of indicators to monitor implementation of national medicines policies. It soon became evident that a core set of indicators had to be selected to assess the pharmaceutical situation in a country and to monitor implementation of the national medicines policy regularly (Box 7). However, suitable indicators to measure access to essential medicines have not yet been defined or agreed upon.
Box 7. 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 nonachievement has enabled continuity during periods of political change. The indicators monitoring 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 medicine 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 medicine 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 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 and medicines stores). 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.
**Annex 2**

**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. Even if data are available, they are rarely analysed or used by policy-makers to help health managers and providers to improve implementation.

- Continuity of existing monitoring of implementation of national medicine policy 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.

- Suitable indicators for measuring access are not yet available.

**Strategies**

- Monitoring and evaluating implementation of national medicines policies, particularly with regard to access to essential medicines. Feedback of 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 (TAG) to provide recommendations for improving access to essential medicines in the Region.

**Actions**

**Member States**

- Establish systems for monitoring and evaluating the impact of the implementation of national medicine policies, particularly with regard to access to essential medicines.

- Undertake assessment of pharmaceutical sectors using selected indicators.

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

- Contribute actively to regional information exchange on implementation of national medicines policies 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 for measuring the impact of intervention 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.