Meeting Report


Manila, Philippines
18–20 November 2009

World Health Organization
Western Pacific Region
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REPORT

EXPERT CONSULTATION ON THE REGIONAL FRAMEWORK
FOR ACTION ON ACCESS TO ESSENTIAL MEDICINES
IN THE WESTERN PACIFIC (2010-2015)

Convened by:

WORLD HEALTH ORGANIZATION
REGIONAL OFFICE FOR THE WESTERN PACIFIC

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NOTE

The views expressed in this report are those of the participants in the consultation and do not necessarily reflect the policy of the World Health Organization.

This report has been prepared by the World Health Organization Regional Office for the Western Pacific for governments of Member States in the Region and for those who participated in the Expert Consultation on the Regional Framework for Action on Access to Essential Medicines in the Western Pacific (2010-2015), held in Manila, Philippines, from 18 to 20 November 2009.
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1. INTRODUCTION

1.1 Background

The Regional Strategy for Improving Access to Essential Medicines in the Western Pacific Region 2005-2010 (hereafter referred to as the Regional Strategy) provides operational and practical guidance to Member States in promoting access to affordable medicines of acceptable quality and ensuring their proper use.

In 2008, an in-depth assessment of the progress of the strategy implementation was undertaken in six countries in the Region. The review found that the Regional Strategy has served well as an operational and practical guide to countries and also to WHO for developing actions to improve access to essential medicines. Countries have made considerable progress in most of the Regional Strategy areas. However, the challenges of ensuring access to quality and affordable essential medicines still remain evident and need to be addressed further.

Based on the development of international and intercountry activities in implementing the Regional Strategy, an Expert Consultation Meeting was held to review these activities in 2009. Experts were also expected to discuss the proposed Regional Framework for Action on Access to Essential Medicines in the Western Pacific (2010-2015) (hereafter referred to as the Framework for Action) which will complement and provide continuation of actions already outlined in the Regional Strategy and include new sector developments.

1.2 Objectives

The objectives of the consultation were:

(1) to review the implementation of the Regional Strategy for Improving Access to Essential Medicines in the Western Pacific region (2005-2010);

(2) to identify challenges and recommended appropriate measures to further improve access to medicines as outlined in the Regional Strategy;

(3) to discuss and provide input on the draft version of the Regional Framework for Action on Access to Essential Medicines in the Western Pacific (2010-2015).

1.3 Temporary advisers

The 15 temporary advisers were from Australia, Cambodia, China, Japan, Lao People’s Democratic Republic, Malaysia, Philippines, Solomon Islands, Tonga and the United States. There were two consultants (those who had undertaken the six country reviews in 2008), one observer and eight secretariat members from WHO Regional Office for the Western Pacific, WHO Regional Office for South-East Asia, WHO Representative Offices in China, the South Pacific and Vietnam and WHO Headquarters.
1.4 Organization and Contents of the Workshop

The consultation was divided into three main sessions: (1) review of the implementation of the Regional Strategy; (2) Topics of particular interest; and (3) Review of the Framework for Action with discussions.

1.6 Opening remarks

Dr Shin Young-Soo, Regional Director, WHO Western Pacific Regional Office, welcomed all participants to the consultation. He said that as the participants are experts in the area of medicines, their input to the Regional Framework for Action on Access to Essential Medicines is important since it will be WHO's guide for the next six years. He then highlighted some of the main issues for consideration during the consultation.

He pointed out that Western Pacific Region (WPR) is extremely diverse in terms of demographics, disease patterns and economic development. WPR covers not only the country with the world's largest population but also those countries that have only a couple of thousand inhabitants. Some of the countries in the Region have the best standards for their medicines systems. Others are undertaking major health sector reforms but lag behind in applying very basic standards to ensure access to medicines, at least for the poor and the vulnerable. From the regional perspective, WHO policies must be tailored to best serve Member States.

Dr Young-Soo reminded the experts that over the past five years, WHO's work in the area of essential medicines has been guided by the Regional Strategy for Improving Access to Essential Medicines in the Western Pacific Region (2005-2010) which was endorsed in 2004 during the fifty-fifth session of the Regional Committee for the Western Pacific, and has served as a guide for action for WHO and Member States.

He mentioned that reviews show that countries have made considerable progress in most of the Regional Strategy areas as they have developed national medicines policies, updated essential medicines lists, developed clinical guidelines, strengthened regulatory systems and improved medicine supply systems. However, he reminded the participants that remaining challenges must be addressed in ensuring equitable access to quality medicines that are used rationally, especially in countries with weak health systems and low public expenditures on health and medicines. Areas that continue to require attention include strengthening the regulatory framework for medicines financing, bolstering inspection capacities, improving supply chain management, and promoting good governance.

He listed some of the problems of access to essential medicines that are frequently encountered in the Western Pacific Region. Prices of many essential medicines continue to be high. Procurement often is inefficient and fragmented, and prepayment mechanisms are lacking, thus making medicines often unaffordable. Some countries still have weak regulatory systems to ensure the quality of medicines and safeguard public health. The irrational selection and use of essential medicines must improve, not only to increase efficiencies of the system, but also to provide the best and most cost-effective treatment to the people who most need it.
Dr Shin said that the input from the consultation, the first part of a wide consultative process, will help to refine the strategic directions outlined in the draft Regional Framework for Action on Access to Essential Medicines in the Western Pacific (2010–2015).

1.7 Appointment of Chairperson, Vice-chairperson and Rapporteur

The consultation meeting elected Dr Chroeng Sokhan from Cambodia as Chairperson and Professor Kazuko Kimura of Japan as Vice-Chairperson. Dr Jane Robertson of Australia was elected Rapporteur.

2. PROCEEDINGS

2.1 Introduction: consultation objectives and expectations

Dr Santoso introduced the objectives and expectations of the consultation, and outlined the structure of the meeting. He mentioned that during the first part of the consultation, the implementation of the Regional Strategy for Improving Access to Essential Medicines in the Western Pacific region, 2005-2010 will be reviewed, followed by presentations on topics of particular interest such as primary health care and health system strengthening; regional health care financing strategy; good governance in medicines; regional medicines price information exchange; health care reforms affecting medicines sector and Global Medicines Strategy 2008 – 2013. The last part of the consultation will be to discuss the draft Framework for Action for Action on Access to Essential Medicines in the Western Pacific region (2010-2015).

Dr Henk Bekedam challenged the participants to help find a new energy to tackle familiar issues, noting that it was important not to simply issue and offer more of the same. Dr Bekedam reflected on the high out of pocket costs for medicines in most countries of the Region, the pivotal role and perverse incentives that exist when prescribing more medicines that leads to improved income and the consequences of this for rational use of medicines. He highlighted the problems of counterfeiting, the need to recognize this as a criminal activity and the difficult nexus between health care regulation and policing issues in this area. Dr Bekedam identified the need for indicators that would be acceptable to Government and provide a sound basis for objectively assessing meaningful progress in medicines issues, and for monitoring over time.

2.2 Regional Strategy for Improving Access to Essential Medicines in the Western Pacific Region (2005 -- 2010) – overview

Dr Santoso stressed that lack of access to essential medicines is an unfinished agenda and that improving access to affordable essential drugs in developing countries is one of the Millennium Development Goals targets. He mentioned that common causes of morbidity & mortality in poor countries can be prevented or treated with available essential medicines. Dr Santoso presented a review of the regional strategy 2005-2010, how it was developed through an extensive consultation process with countries and international experts. He summarized the eight key areas of the Regional Strategy and reported on the support WHO had provided to countries under these eight areas. Dr Santoso then questioned what the impact on access has been of all the interventions. He referred to various existing WHO survey tools using
indicators such as the WHO level I and II indicators, household surveys and the WHO/HAI methodology for price surveys. He showed some examples of level I indicators that had improved in the Region during the period 2003-2007.

In his summary of the way forward, Dr Santo so said the WHO will continue its commitment to collaborate with Member States and partners to improve access to essential medicines towards universal coverage under the renewed focus on Primary Health Care. Other priority areas for collaboration are pharmacy enforcement to deal with counterfeit and sub standard products and medicines financing to reduce out of pocket expenditures. He also stressed the need for demonstrating the impact of interventions using measurable indicators for access. Dr Santoso also referred to the need to respond to special programmes including medicines for children, commenting that reducing child mortality with improved medicines access was a real possibility. He ended his presentation by stating that the Framework for Action on Access to Essential Medicines 2010 – 2016 is a continuation of the Regional Strategy and will serve as a strategic direction in WHO’s collaboration with Member States.

Discussion:

Members of the consultation identified a number of additional areas to discuss in relation to the Regional Strategy. These included controls of advertising of both pharmaceuticals and nutraceuticals (Professor Edelina dela Paz), the impact of the internet on rational medicines use, and the potential for internet medicines to interfere with country medicine regulatory systems (Professor Kazuko Kimura).

Dr Dennis Ross-Degnan emphasized the importance of differentiating between public and private sector systems. In many countries, the private sector provided the majority of medicines to the population and there were fewer interventions to target activities in this sector. In addition, Dr Ross-Degnan suggested the importance of considering medicines for acute and chronic conditions separately, with fewer strategies to manage access issues over a long period of time for chronic disease. While there is an important role for global indicators, Dr Ross-Degnan suggested the need for a country level focus, with more informative country profiles and development of indicators that could be monitored and discussed publicly at the country level.

Professor Shanlian Hu emphasized the importance of pricing and reimbursement issues, the need to reduce out of pocket costs (related to improved systems of health insurance) and the need to focus on human resource issues and capacity building within the medicines sector. Dr Klara Tisocki noted the importance of innovative methods for capacity building. To date there has been emphasis on training and workshops, but measurable improvements in health care systems as a consequence of these were small.

Dr David Lee Chin suggested that WHO needed to recognize the different needs of large and small countries. Without this, it was likely the issues of small countries would be lost and swamped by the issues of larger countries. Professor Rebullida spoke of the challenges to the role of Ministries of Health posed by decentralization of medicines services and responsibilities. Ms Nazarita Tacandong commented that while noting the difficulties and challenges, it was important to not lose sight of the successes that have occurred, particularly in the areas of combating counterfeit and substandard medicines.
2.3 Progress in the Pacific Island Countries, 2004-2009

Ms Lkhagvadorj Vanchinsuren reviewed activities in the Pacific Island countries. She outlined the objectives of the PIC activities, which are to enhance accessibility, quality and use of essential medicines and other pharmaceuticals. She gave examples of the progress made in the eight key areas of this joint EC/ACP/WHO partnership project covering: (1) national medicines policies; (2) international trade agreements; (3) affordability and financing; (4) drug supply and management system; (5) quality, safety and efficacy; (6) effective regulations and quality assurance systems; (7) rational prescribing and dispensing by health professionals; and (8) rational use by consumers. Ms Lkhagvadorj Vanchinsuren concluded that this collaborative partnership programme had a significant impact on the pharmaceutical sector development in the Pacific Region. However, while there had been substantial progress in the period 2005-2009, the challenge was to sustain this effort and this would require country-specific support for countries large and small.

In response to this presentation, Ms Karmen Bennett commented on the diversity among the PIC and that the medicine issues were different to those elsewhere in the region (e.g. counterfeit medicines were less of a problem). She highlighted the important role of indicators to standardize and improve performance.

2.4 Review of Strategy implementation in selected countries

Ms Margaretha Helling-Borda and Mr Truls Eriksen presented the results of their six country reviews on the use and implementation of the 2005-2010 Regional Strategy. They outlined background, preparations and the methodology for undertaking the reviews that took place in October 2008 and included Cambodia, China, Lao PDR, Malaysia, Mongolia and the Philippines.

The two consultants found that in most countries the Regional Strategy was well known among top level staff in the Ministries of Health dealing with pharmaceuticals, but not further down in the organizations. Some countries had used the Strategy to prepare operational plans. Mongolia used it as basis for input to its new Health Sector Master Plan and Implementation framework. In China, in 2007-2008, the Regional Strategy served and continues to serve as a guide in the National Medicines Policy work under the Health System Reform where access to essential medicines is a core element under the new rural health insurance scheme. In Malaysia it served as input for preparing the National Medicines Policy, in Cambodia for development of operational plans, in Lao PDR and the Philippines many of the recommended Regional Strategy activities had been conducted.

The presenters gave examples from the six countries of strengths and weaknesses under the following eight areas or elements of the Regional Strategy (1) rational selection (2) rational use (3) affordable prices (4) access to medicines (5) trade globalization and TRIPS Agreement (5) sustainable financing (6) supply and management system (7) quality and (8) monitoring and evaluation.

The reviewers concluded that experience with the current Regional Strategy (2005-2010), encompassing qualitative and quantitative reviews, showed that in spite of considerable progress in some areas, the problem of access and availability to essential medicines still remains. The Regional Strategy had served as an operational and practical guide to countries and to WHO. It was considered easy to follow and it was felt that it should
not be changed too much since people now are familiar with it. But the health scene has changed since 2004 when the Regional Strategy was approved and new issues have emerged. These include the need for planning and coordination, emphasis on enforcement of regulations, inclusion of children’s medicines in the essential medicines list, and transparency and good governance. These should be included in an updated strategy or Framework for Action.

Specific recommendations had been given to the six countries for improving access to affordable essential medicines. The consultants recommended to WHO/WPRO (1) to offer timely and coordinated management support to countries in the planning phase and in setting priorities (scoring, criteria etc.) for implementation and monitoring of activities; (2) to assist in preparing action plans and; (3) to include indicators for measuring progress and impact. Ms Helling-Borda and Mr Eriksen also recommended that future WHO support should put special emphasis on areas such as: - affordable prices, - supply and management system; -regulatory affairs and enforcement; and on sustainable financing. And finally that WHO/WPRO explore and introduce new mechanisms and modes for effective training, both inside and outside the country; promote the role (functions and knowledge) of pharmacists in the supply and management system; and proactively "market" the Regional Strategy - in countries and with partner organizations.

Discussion:

Members of the expert panel identified progress in some areas subsequent to the review conducted in 2008. They requested further information on the 17 questions prepared by the consultants regarding the use of the Regional Strategy, and the result of the WHO level 1 indicator questionnaire, which provided baseline data for the country reviews.

Members commented on the need for pharmacists to have basic training in financial management (Mr Muhammed Wong Bin Abdullah) and that the new regional strategy needed to recognize other players in the medicines sector (Mr Walebarasialia Tobata). Mr Tobata highlighted the problems of donors pushing their own versions of health care strengthening and that these can sometimes adversely affect local mechanisms for acquiring and managing medicines. Dr Zheng Hong suggested it was also important to recognize the role of traditional Chinese medicines (TCM) in health care and that the selection of TCMs should be subject to the same criteria as western medicines.

In response, Dr Santoso noted that it was not possible to derive a common strategy that would apply to all countries. Rather the emphasis of the Regional Strategy was to provide a framework of the scope of WHO activity and to work with individual countries to develop a collaborative plan that addressed the priorities of the country. Professor Edelina dela Paz supported a role for a regional framework that could be adapted for country needs and suggested a role for NGOs and consumer organizations in identifying country issues.

Ms Karmen Bennett suggested the WHO needed to think differently about how it developed and delivered strategies given the differing country priorities. Countries needed to be able to select from elements in the Regional Strategy that met local needs, with simple, focused strategies for those implementing and delivering health care services. Dr David Lee Chin supported the call for different approaches, commenting that the focus on supply chain management had not translated into substantial improvements in access to medicines or health care outcomes.
2.5 **Renewed primary health care – universal access and Strategic plan for strengthening health systems in the WHO Western Pacific Region**

Dr Dean Shuey started his presentation by defining health systems as systems that consist of all organizations, people and actions whose primary intent is to promote, restore or maintain health. He made reference to some important policy documents such as the World Health Report 2000 and Everybody's business, Strengthening Health Systems to Improve Health Outcomes, WHO's Framework for Action emphasizing that people working on health system strengthening share ownership with all other players of health systems. He elaborated on health systems and primary health care renewal. Primary health care should not be regarded as poor care for poor people. He said that the increased funding from various sources had contributed to putting health system strengthening and primary health care higher on the agenda, although the increased funding was mostly for specific diseases. Dr Shuey commented on the impact of a large number of other partners in the medicine area and the importance of managing these relationships effectively and reminded the expert group that with all the players in the area, at the end was a person or small group required to implement and integrate the activities designed by others. The downside of the increased funding is that health systems come under stress and that there are bottlenecks in health systems as can be seen for supply of medicines.

Dr Shuey described the six health system building block of which Medical products, Vaccines and Technologies is one. He emphasized that the building blocks are not vertical programmes, but in health system strengthening one has to consider all building blocks and that the weakest block of the integrated system may determine the results or outcomes. His key message was that medicines should not be considered in isolation without regard to other parts of the health care system. A key focus of WHO work was universal coverage and universal access as this would deliver best health outcomes.

**Discussion:**

Professor Edelina dela Paz commented that health needed to be seen as a fundamental human right rather than as a financing issue and the Governments carried the prime responsibility for ensuring this right. Dr Shuey responded that the WHO strategy recognized this right but this needed to be treated carefully as human rights was a sensitive political issue in some countries.

Professor Maria Lourdes Rebullida asked whether primary health care was now regarded as an approach or a programme. Dr Shuey responded that WHO was focusing on health system strengthening based on the principles of primary health care, avoiding any suggestion that it was programme to be delivered to poor people in rural settings.

2.6 **Health financing strategy for the Asia Pacific Region 2010 – 2015**

Dr Chris James talked about health financing strategies, noting particularly that there were several aspects to health financing including revenue collection, risk pooling and contributions to ensure purchasing and provision services. Universal coverage is the overarching goal for the new Health financing strategy for the Asia Pacific Region (2010-2015). He stated that the way from a situation with absence of financial protection where out-of-pocket dominates, could be through intermediate stages where a mix of prepayment, social assistance and safety-nets are developed, such as community based health insurance,
cooperative medical services and health equity funds. He explained that universal coverage can be achieved by using tax based financing, social health insurance and a mix of other prepayment schemes including private insurance. He mentioned that data from the Region showed that pharmaceutical expenditures are mostly high out-of-pocket payments. Dr James concluded his presentation by referring to the Health financing strategy for the Asia Pacific Region (2010-2015), which have eight strategic areas: (1) increase investment and public spending on health; (2) increase the use of prepayment and risk pooling; (3) strengthen safety-net mechanisms for the poor and vulnerable; (4) improve aid effectiveness; (5) rationalize health expenditures; (6) improve provider payment methods; (7) improve evidence & information for policy-making; and; (8) improve monitoring & evaluation of policy changes. He also described some of the indicators proposed in the strategy, some of which could be modified and used to measure impact of medicines financing.

Discussion:

Dr Dennis Ross-Degnan noted the challenges in defining the place of medicines in the overall health financing framework, with medicines policies often neglected within insurance schemes. Schemes covering catastrophic expenditure were mostly focused on hospital care and it requires innovative thinking about how to integrate medicines into benefit packages. Insurance is a system issue. It is also important to recognize the value of routinely collected data from insurance schemes that Governments can use for calculating indicators for monitoring the medicines sector.

Professor Edelina dela Paz expressed some concerns about the focus on insurance schemes, commenting that WHO needed strategies to encourage Governments to increase health budgets. Dr Chris James responded that insurance needed to be considered in its broadest sense. Social health insurance schemes were only one option - insurance schemes could be explicit or implicit through taxation.

Professor Maria Lourdes Rebullida commented on moves towards privatization of health facilities, with increasing use of fee for service arrangements. These user fees were affecting those below the poverty line and were a barrier to accessing care. Dr Socorro Escalante noted that while strategies might focus on increasing Government financing of health care, there was often little scope within country budgets to increase health spending. There is also more devolution of responsibilities for financing health care to local hospitals, where medicines and diagnostic services were regarded as profit centres. Sustainable health care financing was a key issue for consideration by this expert consultation.

2.7 Transparency and good governance in medicines

Professor Maria Lourdes Rebullida spoke of Good Governance in Medicines (GGM) in WPRO. The GGM initiative is intended to enhance transparency and accountable procedures in all aspects of medicines registration, selection and procurement, to focus on integrity and arrest corrupt behavior. The programme was initiated in WPRO but was adopted by WHO for global implementation. Professor Rebullida stated that the goal of the programme is to curb corruption in pharmaceutical sector systems through the application of transparent and accountable administrative procedures and the promotion of ethical practices among health professionals. She mentioned that the GGM framework is a general guide that allows countries to find best approaches in introducing and undertaking the programme based on their national context. Several countries in the regions are implementing the GGM
programme: Cambodia, Lao PDR, Malaysia, Mongolia, Philippines, Papua New Guinea, which are at different implementation phases, which she described in detail.

Professor Rebullida described the facilitating factors for successful implementation of the GGM initiatives some of which are: (1) political commitment; (2) committed focal stakeholders in the Ministry/Department of Health; (3) proactive stakeholders, such as from academic institutions and non-government organizations; (4) steering committee, integrity committee, technical working committee in place; (5) funding from Government budget; (6) GGM activities as part of the work of the government units; and (7) polices and legislation in place.

Discussion:

Asked to define corruption, Professor Rebullida commented that this differed between countries and was defined culturally and by local laws, however, in general, corruption referred to any behavior that waylaid public funds from medicines use for personal gain. A number of members of the consultation asked whether there was evidence that this focus on ethics and integrity had delivered demonstrable benefits in improving medicines supply and access. It was acknowledged that such improvements were difficult to assess.

2.8 Regional Medicines Price Information Exchange in the Western Pacific

Ms Dardane Arifaj presented information on a pilot project for a Regional Medicines Price Information Exchange in the Western Pacific. She mentioned that although some regional projects on collecting/monitoring of medicine prices exist, cross-regional comparison is not yet possible. Although price information of AIDS, TB and Malaria medicines exists, information on prices of medicines for chronic diseases and paediatric medicines is not always readily available. Guided by the Regional Strategy, WPRO is piloting a project on regional medicines price information exchange.

Ms Arifaj stated that the objective of the regional medicines price information exchange is to provide comparative information on procurement prices across the region which countries can use to influence their policies on price regulation and in negotiating with suppliers. She explained that initially procurement prices for 31 medicines have been collected through responses to questionnaires that also included additional data. She was encouraged by the good response from countries. However, some problems related to data quality were encountered such as: incomplete information; manual recording (illegible entries); unit price not per smallest unit (syrups, injections, inhalers); price of alternative dosage forms recorded; confusion as to who is the manufacturer versus supplier; volume procured; and currency reported.

Discussion:

Members of the expert consultation contributed a number of suggestions for improving the usefulness of such an information exchange, but expressed some concerns about the quality of the data provided, as it was not clear what the basis of the prices provided by countries was. The International Commercial Terms (INCO) used need to be specified. For comparison between countries, "ex-works" price (i.e. the price invoiced or quoted by a seller which includes charges only up to the seller's factory or premises) may be the price to compare. Wide variability in medicines prices within facilities and countries also limited the
usefulness of these data for comparing prices. Ms Arifaj responded that based on the experience and inputs, the Regional Medicines Price Information Exchange will be modified.

2.9 Health reforms affecting medicines sector

2.9.1 China

Dr Sun Jing presented a comprehensive overview of health system reform in China. She introduced her topic by describing the Global Trends of the Health System Reform where the core aims are to achieve equity, efficiency and effectiveness and where major trends include (1) universal coverage of essential services and providing social safety net for the poor; (2) central government’s ultimate responsibility; (3) decentralization approach; and (4) public and private partnership.

Dr Sun Jing examined the medicine sector as part of the overall Health System Reform and discussed the building blocks of the health system: (1) service delivery; (2) health workforce; (3) health information system; (4) health systems financing; (5) medical products, vaccines and technologies; (6) leadership and governance. She stressed that the key objectives of the reform in the medicine sector are availability, affordability, quality, safety and efficacy and cost-effectiveness.

Health System Reform in China is basic health care focused and includes four sub-systems: (1) basic public health service system; (2) basic medical service system; (3) basic medical security system; and (4) essential medicine system. The Chinese government’s is committed to achieve universal coverage of safe, efficient, convenient and affordable basic health care.

Dr Sun Jing discussed issues, challenges, strategies and activities under the essential medicine system which is divided into seven major elements or areas: (1) rational selection and use; (2) sustainable financing -one (supply side – increase government funding and remove perverse incentives); (3) sustainable financing -two (demand side – better benefit package to reduce out of pocket spending); (4) affordable prices; (5) quality assurance system; (6) supply system; and (7) monitoring and evaluation. She concluded her expose by saying that a set of core medicine indicators has been included as part of the monitoring and evaluation of the overall Health System Reform in China, that regular data collection and analysis of price, availability, affordability and use of medicines will be undertaken, and that a government fund has been established to support independent policy research.

Discussion:

Dr Dennis Ross-Degnan noted that the issues highlighted were issues for the region not just China and that the Regional Strategy needs to touch on all the issues identified. Dr Ross-Degnan noted the importance of coordinating medicine reforms, and this requires collaborating with financing agencies. Most often medicines are issues of Ministries of Health and regulatory authorities, financing rarely encompasses medicines policies. All countries in the region are in different phases of health system reform and it is important that experiences from these processes are shared i.e. cross system learning.

Dr Ross-Degnan further highlighted the importance of understanding access issues at the household level. The WHO household survey framework provides methods for such
surveys and the need for these should be highlighted in the regional plan. It is important to look at changes at the end-user level to understand the impact of health system reforms.

2.9.2 Mongolia

Ms Llhagvadorj Vanchinsuren spoke of health system reform in Mongolia. She said that under the centrally-planned economy in Mongolia before 1990 the health sector was generally funded by the state. Health services were widespread, accessible and free, but hospital centered with poorly developed primary health care. From 1991 transition to a market-oriented economy affected the government's ability to finance and deliver health services and provide social security services. In 1994 a Health Insurance Fund was established, there was a shift from hospital to primary health care and the health care system was decentralized to become the responsibility of provincial governments. With this followed also decentralization of public sector procurement resulting in loss of efficiency, economy of scale and price competition. Ms Llhagvadorj Vanchinsuren showed figures how the private pharmaceutical sector simultaneously had grown dramatically over a ten years period. The private sector expansion and the decentralization of procurement in the public sector, with high prices in both sectors compared with international reference prices, did not improve availability and affordability of essential medicines. Access therefore generally remains low. Nevertheless, said Ms Llhagvadorj Vanchinsuren, a new Health Sector Reform has been approved and many of the activities recommended in the Regional Strategy have been implemented and more are planned under policy, regulatory and technical areas; all this with a very small staff in the Ministry of Health, where the Pharmacy department was established as late as 2003.

Discussion:

Dr David Lee Chin noted the importance of having baseline data from which to assess the impact of reforms. The data from Mongolia provided a cross-sectional view and without baseline data it was difficult to interpret the extent to which privatization and decentralization had impacted on medicines availability and cost. Dr Socorro Escalante noted that decentralization was a critical issue and challenge to medicines access and commented that the framework for action needed to consider this trend. Dr Escalante commented that decentralization was generally a political reform and health care indicators were rarely included in the debate. She highlighted the potential problems of decentralization on procurement, quality of medicines and financing mechanisms. Dr Escalante noted the importance of recognizing and understanding the impacts of decentralization and the need for tools to ensure the quality of medicines being provided in provinces and local hospitals in a decentralized environment.

Ms Margaretha Helling-Borda commented on the importance of political will to support activities in the medicines sector. Dr Klara Tisocki noted the importance of classifying the market in different countries. WHO policies targeted generic policies but the implementation of these was difficult in markets which have a strong culture of branded medicines. Even where policies exist, the low credibility of some regulatory authorities to ensure bioequivalence makes it difficult to change prescribing behaviors. Dr Gilles Forte commented that WHO was committed to promoting generic policies as there was evidence that these improve access and reduce costs of essential medicines. There is an important role for advocacy at the consumer level to ensure patients understand that generic medicines are not inferior and of lower quality.
Dr. Muhammed Farid Wong Bin Abdullah suggested a role for appendices to the regional strategy that provided success stories of privatization and decentralization. Examples of best practice could provide guidance for other countries in the region.

2.10 WHO Medicines Strategy 2008-2013

Dr. Gilles Forte presented the WHO Medicines Strategy 2008-2013. He mentioned that in spite of efforts to improve access, there are large gaps in the availability and affordability of medicines in both the public and private sectors as public sector availability of essential medicines covers only one third of needs (34.9%), while private sector availability covers about two thirds (63.2%). Prices vary a lot in both sectors and are higher than international reference prices making medicines unaffordable. He continued to address some of the challenges that countries are facing as more players and partnerships in medicines with specific niches are often unaware of countries’ priorities, thus overstretch expert and decision making capacity in countries.

Moreover, diseases specific programmes and new global funding initiatives with specific delivery mechanisms and substantial funding could be a challenge to health systems strengthening efforts. He shared the objectives of the WHO Medicines Strategy which are: (1) identify common country barriers to sustainable availability and affordability of quality medicines and to their appropriate use; (2) identify approaches and interventions to address these barriers and that take into account WHO expertise, capacity and mandate; (3) identify suitable approaches for WHO collaboration with and support to countries in achieving improved availability and affordability of quality medicines; and (4) identify suitable approaches for collaboration with partners and Global Health Initiatives at country and global level to ensure that country needs are addressed through efficient support.

He mentioned the Framework on which the strategy is in line with such as the Millennium Development Goals 2000-2015, various WHO resolutions and stated priorities by the Director General. Dr. Forte stated that WHO will continue its work in major areas such as: (1) Global standards on quality assurance; (2) International Non Proprietary Names; (3) Controlled medicines; (4) Prequalification of medical products; (5) Selection of medicines; (6) Traditional medicine; and (7) Intellectual Property Rights and public health safeguards. He then went on to describe what WHO would do differently and areas in which WHO will expand its work such as: Transparency, good governance and aid effectiveness; Financing; and Human resources for pharmaceutical sector.

Discussion:

Ms Nazarita Tacandong noted the importance of the International Medical Products Anti-Counterfeiting Taskforce (IMPACT) programme and sought clarification on whether this work would continue. In addition, Ms Tacandong asked if there were plans for assessment of countries currently in Phase III and about to enter Phase IV of the GGM Initiative. Dr. Forte indicated there were plans to align assessment of the GGM alongside the evaluation of the Medicines Transparency Alliance (MeTA) project in 2010. Professor Edelina dela Paz asked if nutraceuticals were likely to be considered by WHO, and asked who should take responsibility for the regulation, advertising and promotion of nutraceuticals. Dr. Forte said he would raise the issue with WHO, but that such a request would carry more weight if it were to come from a member state.
Professor Maria Lourdes Rebullida commented on the large number of questionnaires, surveys and assessment methodologies being used and the burden this imposed at country level. Dr Forte noted this was a concern for WHO as well and there were plans to try to streamline tools and to sequence the surveys to reduce the burden. He noted there was considerable scope to harmonize survey tools with those of other agencies.

Dr Socorro Escalante commented on the need to assess the extent to which price control mechanisms were having an impact on access and affordability. There was a need to know what mechanisms worked best. Dr Ross-Degnan noted that there were a series of systematic reviews being undertaken by Health Action International (HAI) and WHO, and that these should be finished at the end of 2009. These would provide some evidence on the effectiveness of various strategies including insurance and reimbursement schemes, cost plus pricing, internal and external reference pricing.


Dr Santoso and Ms Dardane Arifaj introduced the Regional Framework for Action on Access to Essential Medicines in the Western Pacific 2010-2015.

Dr Santoso started by reiterating his earlier statement that rather than having an updated version of the Regional Strategy, WHO had decided that a Regional Framework for Action would be a suitable guide for continuing WHO’s activities in its work with individual countries to develop a collaborative plan that addressed the priorities of the country. He thanked the participants for their comments on the first draft of the Framework sent to the secretariat before the meeting. He acknowledged that considerable work and input from the participants was still very much needed to make the current draft (2) of the Framework for Action clearer and more concise.

Ms Arifaj then outlined the objectives of the Framework for Action 2010-2015, explained the format, the principles and the clustering of three major interdependent components: (1) policy and access; (2) quality assurance; and (3) rational selection and use, plus monitoring and evaluation. In several detailed slides she compared the structure and content of the eight areas or elements in the current Regional Strategy 2005-2010 with that under the clusters in the draft Framework for Action 2010-2015. She highlighted the need for adopting indicator-based tools to guide implementation of National Medicines Policies, using results to refine implementation plans. Ms Arifaj also drew attention to new activities and issues under the clusters, particularly the inclusion of essential medicines in the context of primary care and health systems strengthening, and the global strategic direction in this area.

Ms Arifaj concluded by inviting the participants to discuss in detail the content under each component and then the indicators. She said that the comments the participants had made on draft 1, sent out before the consultation, were mostly on the introductory pages. Regarding the technical parts there had been minor inputs.

Members of the expert consultation reviewed the draft document in plenary. In reply to the chairperson’s question whether the members wished to break into small groups to divide the work between them, they overwhelmingly felt that the review of the whole draft document should be done in plenary.

Participants made many comments on the introductory text of Draft 2 which is discussed below under 3.2.3. It became clear that the introductory text needed to be rewritten reflecting the comments made at the meeting. Not to lose time, the meeting requested the consultants to rewrite and present a new draft of the introduction before the end of the meeting. This was done, but once more the content and text of these important introductory pages required more work and time. The consultants therefore worked jointly on the text after the meeting. It is now included in draft 3 of the Framework for Action. Parts of this text are found below under 3.2.3.1.

Since time was short the chairman decided to proceed to the section of “Components”.

3.2.1 Components and contents

Members of the expert consultation reviewed the text under the tree major interdependent components; (1) policy and access; (2) quality assurance; and (3) rational selection and use. In their deliberations they took note of Dr Bekedam’s plea at the start of the meeting that there was a need for addressing improvement in access to medicines with renewed focus and energy. To achieve this, the members decided that the Framework must clearly differentiate between, and list separately, principles and activities under each technical component to avoid causing confusion by intermixing them as presented in Draft 2. While reviewing the text under each component, participants started by deciding which text should go under “Principles” (P) and what belonged under “Activities” (A). Once this was done they suggested additions, revisions and elimination of texts. The secretariat took notes of all suggestions for incorporation into Draft 3 of the Framework to Action, which was going to be sent to all participants for review, after the meeting.

3.2.2 Indicators: Implementation, Monitoring and Evaluation

WHO has continued to gather data and information on pharmaceutical situations of member states using indicator based tools to follow up progress or non progress of pharmaceutical works in countries. Among the tools are the Level I monitoring indicators on structures and processes of the pharmaceutical system in countries. Level II indicators are less easily accessible, are more specific and usually require special studies, household surveys or an internal monitoring system especially designed to measure for example number of medicines per prescription, percentage of antibiotics prescribed within a certain health facility or facilities, stockouts during a certain set time period etc.

Draft 2 of the Framework did not include specific indicators. However, Dr Forte and Ms Arifaj had prepared a draft list of about twenty indicators as basis for discussion at the meeting. These indicators were reviewed individually under the three major components and led to lively discussion. It was clear that the topic of indicators is complex.
The meeting had insufficient time to finally agree upon and select a few major indicators that could measure impact of interventions and improvement in access to essential medicines in countries. It was left to the secretariat to do some further work on this, taking into consideration the many comments and suggestions made by the participants who would receive another draft for comments. Considering the importance of the contributions made during this meeting, the following summary of points made during this agenda item is intended to help both the experts and the secretariat in their further deliberations on indicators.

Summary of points made during the discussion on indicators:

**Under Policy and Access (8 proposed indicators)**

- Discussions around the target/use for these indicators. Need for impact indicators; also a role for structure, process, output and availability indicators as WHO has multiple areas of activity in medicines;

- Need to consider availability of data for derivation of indicators;

- Important to use existing indicators where appropriate not develop new unless particularly relevant for focus of activity;

- Group wanted some clarification on relationship with Level 1 indicators. Dr Santoso suggested that impact indicators should focus on access, quality, rational use, also some on financial issues;

- Level 2 indicators are likely to be relevant and countries will be familiar with their derivation. Five relevant indicators; - number of drugs/case; % antibiotics, % injections, % medicines from essential medicines list (EML), % prescribed generic name;

- Need to link indicators to strategy/framework for action;

- Cannot impose indicators on countries (Dr Bekedam) – provide a list of indicators countries might choose from; not new indicators;

- Issue that some of indicators derived from HAI/WHO pricing survey methodology. Need to consider extent to which align with pricing surveys which are difficult to undertake and are expensive so question of sustainability. However have some global acceptance and perhaps need to consider whether one wants indicators to be consistent with global measures;

- First indicator (on draft list) – which suggested measuring availability of 30 medicines. Which ones and is 30 a relevant/appropriate number? Vary with setting? Need to be consistent with EML framework which allows local adaptation rather than prescriptive on which drugs. However defined medicines will allow some comparability;

- Indicator with median price ratio – is wrong term – should be ratio to international reference price IRP). Management Sciences for Health-(MSH)
prices might consider, if wanting to be consistent with global, however hard to interpret at local level. May be more relevant to give ratio relative to wage of lowest paid worker (also in HAI methodology) – avoids use of IRP. David Lee commented on limitations of MSH price – might be biased sample of procurement prices;

- Delete indicator regarding HIV (7);
- Rephrase proposed indicator 8 about compulsory generic substitution;

**Under Quality Assurance (3 proposed indicators)**

- Delete Quality Assurance indicators 1 and 2 – too hard to interpret;
- Add indicator on: does country have anti-counterfeiting law? ;
- Add indicator on national surveillance programme for counterfeit drugs;
- Add indicator on national GMP in existence;

**Under Rational Selection and Use (5 proposed indicators)**

- Delete proposed indicator 1(% prescriptions in accordance with clinical guidelines) – too difficult to measure- deleted from INRUD set
- Delete 4 (Drugs and Therapeutics Committees)– too difficult to measure and interpret
- Government commitment – delete 1 – access to EM/Technologies

**Under Affordable prices and sustainable financing**

- Affordable prices proposed 2 -median price ratio covered under policy and access;
- Delete % mark-up – too difficult;
- Add pharmaceuticals as % of total health costs;
- Add a measure relating to out of pocket expenditure
- Consider indicator capturing something about stock outs of EM;
- Examples of indicators from Cambodia and Laos may be useful;
- With development of indicator set; need field for field testing to see if feasible and practical to collect the data you need;
3.2.3 Introductory text of the Framework for Action

As mentioned earlier, the participants felt that considerable work had to be done on the introductory text of Draft 2 of the Framework for Action to make it clearer and presentable in a more logical sequence.

When rewriting the text after the meeting, the consultants considered the many valuable comments provided by the participants during the meeting. These are summarized below as reminders and as important references to the discussions held under this topic:

*Summary of points made during the discussion on the introduction of the Framework:*

- Suggested reshaping of document to make it clear what the document is about, origins i.e. framework based on Global Strategy, what it does, addresses the need for...
- Suggestion of eventual diagram/picture showing relationships between global strategy, resolutions, framework, regional strategy etc.
- Include reference to Alma Ata but in context of revitalization of PHC values
- Section on issues and challenges needs to be shorter and tighter. Re-order and follow sequence of the three major components i.e. aspects of Policy and Access, Quality Assurance and Rational Use
- Change reference to highest proportion of out of pocket payments
- Delete reference to prices – change link to high prices, stress not affordable prices
- Change way decentralization is presented
- Delete reference to cost-effectiveness
- Remove section and lists of emerging issues and challenges and areas for reinforcement
- Refer to principles and actions that arise in response to various challenges
- Comments that reference to access in document does not take account of geographic accessibility or cultural acceptability, focus here is available and affordable
- Need to mention something about ongoing research
- Under objectives – add a section on set of indicators that allow monitoring of progress
3.2.3.1 Revised introductory text (prepared by the consultants after the meeting)

Based on discussions and the above comments the consultants rewrote the introductory text of which the first part and the objectives are found below. The part covering issues and challenges was also rewritten by the consultants, in accordance with suggestions from the meeting, and is included in Draft 3 of the Framework for Action.

Rewritten introductory text: first part and objectives:

"What is the Framework?

The Framework for Action on Access to Essential Medicines in Western Pacific 2010-2015 is a guide for WHO in supporting and collaborating with Member States in improving access to essential medicines.

It addresses the need for improving access to medicines with renewed focus and energy. To achieve this, the Framework outlines principles and activities under three technical components;

- Policy and access to essential medicines,
- Quality assurance,
- Rational selection and use of medicines

The three technical components, introduced in the Framework, follow those in the WHO Global Medicines Strategy 2008-2013 (Strategic Objective 11 “Access, quality and rational use of medical products and essential health technologies”) by which WHO’s work is guided and managed at the global, regional and country level. Activities specified under the components are adapted to the regional context.

The Framework is differently presented than the Regional Strategy 2005-2010. It does not separate actions for WHO and for member states as in the Regional Strategy but lists principles and actions under each technical component.

How will the Framework be used?

- WHO will use the Framework in the development of collaborative, biannual work plans with countries
- Countries will use the Framework in selecting activities for WHO support.
- WHO will actively advocate the Framework in member states, and among partners at regional and country level, in planning and operation of action oriented country support.

How was the Framework developed?

Background:

In 2004 countries endorsed The Regional Strategy for Improving Access to Essential Medicines in the Western Pacific Region 2005-2010 (hereafter the Regional Strategy), which
over the years, served the diversity in this Region well, as an operational and practical guide for developing actions towards improving access to essential medicines.

Among other things, the Regional Strategy provided a comprehensive list of global evidence-based actions for improving major components of the pharmaceutical systems. A few countries in the region have achieved remarkable progress thus setting some of the best examples in the world. However, many still lag behind in applying basic standards that are crucial to ensure universal access to quality medicines that are used rationally.

The Framework for Action on Access to Essential Medicines in Western Pacific 2010-2015:

The Framework was developed as a continuation and updating of the Regional Strategy, including new issues and areas needing reinforcement. It follows the WHO Global Medicines Strategy 2008-2013 and WHO's planning and management systems. However, it does not divert from the principles of the Regional Strategy.

The Framework reflects the findings from the in-depth reviews undertaken in six countries in 2008; country situation reports using level I and level II indicators; comments from member states and input from the expert consultation held on 18-20 November 2009 in Manila.

It supports the health-related Millennium Development Goals (MDGs) where access to medicines is a target in itself. This implies a strong emphasis on principles of equity and sustainability, the needs of the poor and disadvantaged, and the attainment of the highest possible standard of health as a fundamental right. It draws on actions based on the priorities set by the WHO Director-General on health development, health security; and strengthening health systems through primary care under the revived Alma Ata declaration. The Framework also synchronizes actions with other strategies such as the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property; Strengthening Health Systems in the WHO Western Pacific Region; and the Health Financing Strategy for the Asia Pacific region 2010-2015.

Issues and Challenges (not included here, see Draft 3)

"Objectives of the Framework for Action.

In summary the objectives of the Framework for Action on Access to Essential Medicines in Western Pacific 2010-2015 are:

1. to provide strategic direction and guidance for WHO's support to and collaboration with member states

2. to ensure continuation of the actions outlined in the Regional Strategy for Improving Access to Essential Medicines in the Western Pacific Region 2005-2010; with focus on new developments and areas to be reinforced;

3. to respond to country needs and challenges in development and implementation of activities, based on expressed principles, grouped under the following components:

   • Policy and access to essential medicines,
3.2.2 Follow-up action – advocacy

After some discussion, suggestions and recommendations from participants for follow-up actions and advocacy of the Framework for Action, Dr Santoso summarized what would happen after this meeting, gave a tentative time schedule for the development and finalization of the Framework and how it then will be used:

1. WHO will prepare Draft 3 of the Framework (including selected list of indicators as an Annex) and will send this to meeting participants by mid-December 2009.

2. Based on comments received, Draft 4 will be prepared and distributed to meeting participants by mid January 2010.

3. By end January – beginning February 2010, Draft 4 will be distributed to a selected wider audience; responses expected by end February – beginning March 2010.

4. By end March - mid April 2010 there will be a Draft 5.

5. Draft 5 will be the basis for review at a WHO Inter-country Consultation, planned for May- June 2010 after which Draft 6 will be prepared and circulated to participants in this consultation.

6. A final Draft (7) of the Framework will be edited and the final document will be published by end September 2010. This will be used effectively and widely as advocacy for promoting access to essential medicines in the Region. It will be used in the WHO collaboration with Member States when preparing bi-annual action plans from September 2010 onwards, and in dialogues and collaboration with WHO partner organizations.

3. CONCLUSIONS AND RECOMMENDATIONS

3.1 Conclusions

The members of the Expert Consultation on the Regional Framework for Action on Access to Essential Medicines in the Western Pacific (2010 – 2015) held in Manila, Philippines, 18 to 20 November 2009 heard and reviewed the overall use of the Regional Strategy 2005-2010 in member states in the Western Pacific Region and its use and impact in
six selected countries, based on in-depth reviews in 2008. They discussed issues relevant to the goal of universal access to essential medicines after listening to presentation on: (1) renewed primary health care; (2) health financing strategies for the Asia-pacific Region 2010-2015; (3) transparency and good governance; (4) regional medicines price information exchange; (5) health reforms affecting medicines sector; and (6) the WHO global medicines strategy 2008-2013. Lastly, why there was now a need for a Regional Framework for Action on Access to essential medicines in the Western Pacific (2010-2015).

The members reviewed international and inter-country activities in implementing activities of the Regional Strategy 2005-2010, identified challenges, recognized that considerable progress had been made in several countries and proposed appropriate measures to further improve access to medicines as outlined in the Regional Strategy.

The Members of the Expert consultation made valuable and substantial contributions and input in reviewing Draft 2 of the Regional Framework for Action on Access to essential medicines in the Western Pacific (2010-2015). Their contributions will be incorporated and reflected in Draft 3, prepared and distributed by the secretariat by mid-December 2009.

3.2 Recommendations

Based on the discussion the following is recommended and foreseen:

(1) WHO should revise the Framework for Action and attach Indicators as Annex according to the discussions and input from the consultation and send Draft 3 to participants for review, by January 2010;

(2) WHO should then prepare a Draft 4 based on the input, which will be the basis for discussion at an inter-country consultation;

(3) WHO will conduct an Inter-country Consultation to review Draft 4, May-June 2010;

(4) WHO should then prepare Draft 5 and circulate this to participants in the Inter-country consultation and others as appropriate.

(5) WHO/PHA should finalize the Framework and send for editing to be published by end of 2010.

(6) WHO should develop collaborative bi-annual plans with countries and use the Framework to effectively and widely advocate and promote universal access to essential medicines in the Region, in countries and among partners.
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AGENDA

1. Opening session
2. Introduction: consultation objectives and expectations
4. Review of Strategy implementation in selected countries
5. Lessons learnt – discussion
6. Renewed primary health care – universal access and Strategic plan for strengthening health systems in the WHO Western Pacific Region
8. Transparency and good governance in medicines
9. Regional Medicines Price Information Exchange in the Western Pacific
10. Health reforms affecting medicines sector
12. Why a Regional Framework for Action on Access to Essential Medicines in the Western Pacific?
14. Draft review – policy and access
15. Draft review – Quality assurance and regulation
16. Draft review – rational use
17. Follow-up action – advocacy
18. Implementation, monitoring and evaluation
19. Conclusions and recommendations
20. Closing session
THE REGIONAL FRAMEWORK FOR ACTION ON ACCESS TO ESSENTIAL MEDICINES IN THE WESTERN PACIFIC 2010-2015

What is the Framework?

Objectives

How will the Framework be used?

How was the Framework developed?

Issues and Challenges

Components

1. Policy and access to essential medicines
   1.1. Medicines policy
   1.2. Sustainable financing
   1.3. Affordable prices
   1.4. Procurement and supply management
   1.5. Intellectual property rights and international trade agreements

2. Quality assurance
   2.1. Regulatory control
   2.2. Counterfeit medicines
   2.3. Substandard medicines

3. Rational selection and use of medicines
   3.1. Evidence-based selection of essential medicines
   3.2. Rational use of medicines

Monitoring and evaluation

Essential medicines in the context of primary care and health systems strengthening (global perspective)
**What is the Framework?**

The Framework for Action on Access to Essential Medicines in Western Pacific 2010-2015 will provide strategic direction for WHO to support member states to strengthen pharmaceutical systems in order to ensure equal access to medicines that are affordable, of assured quality and used rationally. Depending on the national context, countries should consider adopting Framework in their strategic planning and when collaborating with WHO.

**Objectives**

The objectives of the Framework for Action on Access to Essential Medicines in Western Pacific 2010-2015 are to:

1. Provide strategic direction and guidance for WHO to support member states;
2. Ensure continuation of the actions outlined in the Regional Strategy for Improving Access to Essential Medicines in the Western Pacific Region 2005-2010, with focus on new developments and areas to be reinforced;
3. Respond to country needs and challenges in development and implementation of activities, based on expressed principles and grouped under the following components:
   - *Policy and access to essential medicines*,
   - *Quality assurance*,
   - *Rational selection and use of medicines*
4. Actively advocate and promote the Framework in member states and among partners at regional and country level, in planning and coordinating actions for country support.
How will the Framework be used?


- WHO will use the Framework to guide its work at the regional level and in the collaborative work with countries and partners for the period 2010-2015.

- Depending on their local context, countries should refer to the Framework to decide which areas require primary focus that WHO can support.

- WHO will actively advocate and promote the Framework in member states, and among partners at regional and country level, in planning and coordinating actions for country support.

The Regional Framework for Action on Access to Essential Medicines 2010-2015, addresses the need for improving access to medicines with renewed focus and energy. To achieve this, the Framework outlines principles and activities under three technical components;

- Policy and access to essential medicines,
- Quality assurance,
- Rational selection and use of medicines

The three technical components, introduced in the Framework, follow those in the WHO Global Medicines Strategy 2008-2013 (Strategic Objective 11 “Access, quality and rational use of medical products and essential health technologies” by which WHO’s work is guided and managed at the global, regional and country level). Activities specified under the components are relevant to the regional context.
The Framework is differently presented than the previous Regional Strategy 2005-2010. It does not separate actions for WHO and for member states as in the Regional Strategy but lists principles and actions under each technical component; WHO and countries are expected to align their collaboration and identify their joint activities based on the stated principles and actions.

**How was the Framework developed?**

In 2004 countries endorsed The Regional Strategy for Improving Access to Essential Medicines in the Western Pacific Region 2005-2010 (hereafter the Regional Strategy), which over the years, served well as an operational and practical guide for developing actions towards improving access to essential medicines. Among other things, the Regional Strategy provided a comprehensive list of global evidence-based actions for improving major components of the pharmaceutical systems. A few countries in the region have achieved remarkable progress thus setting some of the best examples in the world. However, many still lag behind in applying basic standards that are crucial to ensure universal access to quality medicines that are used rationally.

To guide the work for the next five years, *The Framework for Action on Access to Essential Medicines in Western Pacific 2010-2015* was developed to include new issues and areas that need reinforcement, without diverting from the principles of the Regional Strategy 2005-2010 in order to ensure continuation. It follows the WHO Global Medicines Strategy 2008-2013 and WHO's planning and management systems.

The Framework takes into consideration findings from the in-depth reviews undertaken in six countries in 2008; country situation reports using level I and level II indicators; comments from member states and input from the expert consultation held on 18-20 November 2009 in Manila. It reflects on the health-related Millenium
Development Goals (MDGs) where access to medicines is a target in itself. This implies a strong emphasis on principles of equity and sustainability, the needs of the poor and disadvantaged, and the attainment of the highest possible standard of health as a fundamental right. It draws on actions based on the priorities set by the WHO Director-General on health development, health security; and strengthening health systems through primary care under the revived Alma Ata declaration. The Framework also synchronizes actions with other strategies such as the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property; Strengthening Health Systems in the WHO Western Pacific Region; and the Health Financing Strategy for the Asia Pacific region 2010-2015.

**Issues and Challenges**

Essential medicines *save lives, reduce suffering and improve health only if they are of quality, safe and effective, available in the health care system, affordable and properly utilized by providers and consumers*.

*Demand for regular access* to medicines continues to rise globally. *Access* to quality essential medicines remains a problem in the Western Pacific where approximately 3000 children die every day of illnesses that are easily treatable with a low-cost basic range of essential medicines. Twenty-five percent of the global burden of non-communicable diseases is in this Region. In addition to twenty-four percent of the estimated global tuberculosis prevalence, around 1.3 million people are living with HIV/AIDS,

Problems of access to essential medicines are frequently encountered in the Western Pacific Region. A few countries have a medicine policy that integrates and balances objectives, responsibilities and funding streams of all structures involved in addressing issues on access, quality assurance and rational use of medicines. Improving access to
essential medicines, as a core building block of health systems strengthening, is a major challenge under the renewed emphasis on primary health care and within health sector reforms.

*Expenditure* on medicines is a major issue. Expenditures of medicines are exorbitant and account for over half of overall health expenditures. *Public funding* of medicines generally remains low; medicines financing is mainly *out-of-pocket* thus creating a major burden for the sick and the poor to afford the treatment. The Western Pacific has the highest proportion of out-of-pocket payments among all the WHO regions and financing of medicines needs urgent attention. Options for financing mechanisms (social health insurance, revenue collection, risk pooling, etc.), must therefore be further explored; operational research undertaken and documented on practices and implications of out of pocket payment. *Prices* of many essential medicines are not affordable in relation to local purchasing power.

Difficulties remain in ensuring uninterrupted *supply systems* at all levels of health care; the availability of essential medicines in some countries in the region is low in both public and private sectors, sometimes as low as 50%.

*Procurement* of essential medicines is inefficient and fragmented in many countries in the Region. Some models of decentralized government systems have been reported to negatively affect financing and procurement of medicines. Revolving funds are still means to cover medicines costs and generate revenue.

Sufficient *human resources* required for implementation of activities under medicines policies and pharmaceutical services is an issue which is still not adequately addressed.
Promoting transparency for good governance (Good Governance in Medicines, GGM), identifying vulnerabilities in technical and administrative areas in the pharmaceutical sector, needs to strengthen further.

International rules and agreements on intellectual property rights continue to pose challenges to pharmaceutical supply/access to medicines. This is due to insufficient understanding of intellectual property-obligations and safeguards among health professionals, and aggravated by the rapidly changing global intellectual property 'environment'.

With the burden of diseases and the rising need for access to treatment, and with more suppliers entering the global medicines market, countries are facing bigger challenges to regulate their pharmaceutical sector. They need to safeguard the public health, contain costs while assuring equitable access to medicines, and sustain the supply chains that can be responsive to needs.

Weak regulatory systems and weak enforcement result in the production, distribution and sales of medicines of doubtful efficacy, safety and substandard quality that may endanger the public health. Cases of products contaminated with diethylene-glycol, melamine, contaminated heparin that have penetrated the global market are only a few examples.

In spite of intensified collaboration between the health sector and law enforcement agencies at national and international level, the production, distribution and sales of counterfeit medicines continue in the region. Apart from being a major public health problem, counterfeiting is a serious criminal act but few criminals are being prosecuted as law enforcement is weak. Over half of samples of artesunate antimalarials collected in the remote Mekong areas were found to be counterfeited, without active ingredients, with catastrophic effect on the poor, rural population.
Actions so far have not been able to deal adequately with the problem. As these criminal acts continue, innovative approaches are necessary to tackle the issue.

Even when medicines are available and affordable, very often they are used inappropriately. In many countries in the Region, Essential Medicines Lists are not selected based on the evidence of the comparative efficacy, safety, effectiveness and cost.

Clinical guidelines are mostly not harmonized with the Essential Medicines List. In some cases, less than half of patients get treated according to clinical guidelines for the common diseases seen in primary care settings.

Antibiotics continue to be sold over the counter in 15 countries in the Region causing serious antimicrobial resistance. This practice is more common in low-income countries. Objective information on medicines for health care providers and consumers is generally lacking and unethical practices of medicines promotion continue.

To promote regional collaboration, more effective ways of sharing experiences and information between countries are needed. Data is generally lacking for making decisions, interventions and changes in the pharmaceutical system. To obtain such data, specific operational research is needed, in addition to introducing an effective monitoring system using indicators. Most countries have not yet developed monitoring systems and indicators for measuring improvement of access to essential medicines. This is a major challenge for both WHO and countries which need to measure progress and impact of interventions, a challenge that needs immediate attention.
Components

1. Policy and Access

WHO will continue to support effective promotion, development/revision and actions required for effective implementation of policies to improve access to quality medicines that are used rationally. In line with the new developments in the field, needs identified by countries, MDG goals 4-5-6-8 and Director’s General priorities, in this process, WHO will promote a new focus to:

- emphasize the integration of national medicines policies within health systems and health financing policies;
- promote access to essential medicines as part of the fulfilment of the right to health;
- increase affordability of medicines through inclusion in prepayment mechanisms (such that high out-of-pocket expenditures on medicines are reduced), and through appropriate pricing and taxation policies;
- strengthen procurement and supply management practices to minimize cost, increase efficiencies and improve access;
- build capacity on the practical implementation of existing provisions and recommendations of trade agreements and their implications on access to essential medicines.

1.1. Medicines Policy and coordination

Principles guiding recommended country policies

(a) National medicines policy needs to emphasize principles of equity and sustainability in access to essential medicines as a fundamental human right to health.
(b) National Medicine process should involve in a policy dialogue a wide spectrum of stakeholders, partners, civil society and academia.

(c) Include human resources development as a part of the national medicines policy.

(d) National Medicines Policy should be linked to all health systems building blocks: service delivery, health workforce, information, financing and leadership and governance.

Activities that WHO supports

(a) Support the process of planning, developing and revising medicines policies to identify national goals, commitments and actions based on a country's unique needs, priorities and resources.

(b) Facilitate integration and balance objectives, responsibilities and funding streams of all structures involved in addressing issues on access, quality assurance and rational use of medicines.

(c) Synchronize national medicines policy with health financing policy and other health systems strengthening building blocks.

(d) Strengthen institutional capacity for national coordination of partners and development agencies to align technical assistance with national medicines goals.

(e) Establish and strengthen monitoring and evaluation of actions in implementing medicines policy.

(f) Promote a synergistic approach with disease specific, reproductive and child health programs on the selection of essential medicines, quality assurance, comprehensive supply systems and promoting rational use.

(g) Foster collaboration with relevant professional organizations and bodies on promoting and implementing medicines policy.

(h) Promote information exchange and knowledge-sharing between countries by inter-regional meetings, conferences and projects, web-based communication, and printed technical materials.

(i) In decentralized systems, support strengthening of coordination and information sharing from national to local level.
1.2. Affordable Prices

**Principles guiding recommended country policies**

(a) Universal access to essential medicines.

(b) Medicines should be available at the cost that health system (both public and private) and patients can afford.

(c) Competition to improve availability and affordability of medicines.

(d) Import duty and tariffs should not be barriers to access essential medicines.

(e) Apply policies that encourage generic prescription and generic substitution.

**Activities that WHO supports**

(a) Exchange of information and evidence on price-setting and on direct and indirect price-control policies.

(b) Provide information on pricing policies and, when appropriate, promote combination of interventions to regulate mark-ups at one or more levels: ex-manufacturer level, ex-importer level, wholesale and retail pharmacies.

(c) Support activities to increase efficiencies in public sector procurement by applying good procurement practices, purchasing of generics and volume aggregation to negotiate better prices, if feasible.

(d) Support implementation of policies that encourage generic prescription and generic substitution both in public and private sector.

(e) Support education programs for the health professionals and the public about the generics and provide information on prices.

(f) Exchange information on medicines prices between countries at the regional platform, which in return will provide cross-country comparative information on price trends in the region.
1.3. Sustainable Financing

**Principles guiding recommended country policies**

(a) Universal access to essential medicines

(b) Medicines financing policies should be synchronised with national health financing policies.

(c) Out-of-pocket payments for essential medicines should not be used as the main mechanism to finance medicines, replenish revolving funds and generating revenues from sales in order to finance other parts of the health system.

(d) Essential medicines should be part of the basic package for health care.

(e) Health/medicines financing policies must provide full or partial protection against the costs of essential medicines, especially for the poor and other vulnerable groups.

(f) Medicines policies should not create incentives that lead to prescriber's induced demand.

**Activities that WHO supports**

(a) As part of national medicines policy, review essential medicine financing strategies based on the principles of equity to access, affordability, cost-containment and sustainability.

(b) Support actions that discourage out-of-pocket payments for essential medicines as the main mechanism to finance medicines, replenish revolving funds and generating revenues from sales in order to finance other parts of the health system.

(c) Establish information systems to monitor medicine expenditures, disaggregated by sources, building on existing national health accounts.

(d) Provide technical support and training on medicine financing systems.

(e) Advise on policies that can contain costs by applying a blend of measures that influence supply (evidence-based selection of essential medicines list/formulary, use of essential medicines list for procurement and
reimbursement based on generics) and influence demand (treatment guidelines harmonized with essential list/formulary, generic prescription policies and control of inappropriate medicines promotion).

1.4. Supply Systems

**Principles guiding recommended country policies**

(a) Disease specific supply systems should be coordinated and integrated into essential medicines supply systems.

(b) Minimize duplication of assessments of supply systems.

(c) Coordinate training and measure the impact of training activities on medicine supply system.

(d) Procurement should be tied to EM and STGs.

(e) Medicines public procurement should follow transparent process.

**Activities that WHO supports**

(a) Support strengthening of collaboration and information sharing between programs and supply management to increase efficiencies in demand forecasting and provision of adequate supplies at all levels of health care.

(b) Synchronize procurement with Essential Medicines List and treatment guidelines, following good procurement practices.

(c) When feasible, increase efficiencies in procurement by aggregating volumes to negotiate better prices.

(d) Support development of human resources, infrastructure and logistics to ensure appropriate management of medicine supply system at all levels of health care.

(e) Strengthen relationship between national medicines procurement agency and medicines regulatory agency to reduce risk in sourcing medicines of poor quality.

(f) Strengthen information systems to improve planning, monitoring of supplier's performance and evaluation of efficiency in procurement and supply chain management.
(g) Integrate information of medicine supply system into routine health MIS, using indicators.

1.5. Intellectual Property Rights and international trade agreements

Principles guiding recommended country policies
(a) Trade agreements and IP rights should not be an impediment to access to EM and achievement of public health goals.

Activities that WHO supports
(a) Support countries to include public health safeguards of the TRIPS agreement in national intellectual property laws and regulations.
(b) Disseminate information and facilitate exchange of country experiences on international developments related to TRIPS, other relevant agreements and trade globalisation and their impacts.
(c) Support national workshops and other training on trade globalisation and access to medicines for health and trade policy-makers.
(d) Promote and support, including through international cooperation, national and regional institutions in their efforts to build and strengthen capacity to manage and apply intellectual property in a manner oriented to public health needs and priorities of developing countries.

2. Quality Assurance

WHO will continue to support medicine regulatory authorities in improving legislation and implementing norms and standards to assure that production, distribution, sales and use of medicines are regulated effectively to protect public health; it will continue to strengthen collaboration between regulatory authorities in combating counterfeit and substandard medicines and improve inter-country information sharing. In line with the new developments in the field, needs identified
by countries and MDG goal 8, in this process, WHO will also promote a new focus to:

- Improve surveillance systems to ensure post-marketing medicines safety.
- Advance collaboration between medicines regulatory authorities and law enforcement agencies in combating counterfeit medicines.
- Increase effectiveness in detecting and addressing problems of substandard medicines.

2.1. Medicines Regulation Support

**Principles guiding recommended country policies**

(a) Medicines market should be regulated and regulations actively enforced.

(b) Promote transparency and disclosure of conflict of interests on the requirements, criteria and decisions made by a medicines regulatory authority on medicines registration, renewals and withdrawals.

(c) Support application of best practices in reviewing medicines with long-established chemical entities and medicines containing new chemical entities (including authorization of clinical trials) to ensure medicines efficacy and safety.

(d) Medicines promotion should be guided by codes of conduct.

**Activities that WHO supports**

(a) Support completion of legal framework to assure that manufacture, import, export, distribution, dispensation, sales, use, medicines promotion and clinical trials follow specified standards.

(b) Increase national technical capacity and knowledge sharing in implementing norms and standards in medicines regulation.

(c) Strengthen monitoring of compliance and guidance for manufacturers on best practices in production (GMP), distribution (GDP), storage (GSP) and
good pharmacy practice (GPP) as the quality of medicines may be compromised in any part of the supply system.

(d) Advocate and support regulatory officers to ensure independence and capacity for undertaking their role.

(e) Support innovative actions to strengthen the control of the unlicensed medicines outlets.

(f) Support application of best practices in licensing, inspection, quality control and product evaluation to ensure medicines quality.

(g) Support establishment of functional mechanisms to monitor adverse medicine reactions and warning/recall systems to ensure medicines safety.

(h) Apply codes of conduct for ethical promotion and advertising of medicines.

(i) Ensure unbiased, correct, updated and accessible information on medicines to prescribers and consumers.

(j) Strengthen mechanisms for information exchange with international bodies and inter-country collaborations by applying standard reporting mechanisms, inter-regional meetings, conferences and projects, web-based communication and printed technical materials.

(k) Support Medicines Regulatory Authorities to provide access to accurate and timely information on legitimate, licensed suppliers and pharmacies.

2.2. Counterfeit Medicines

Principles guiding recommended country policies

(a) Regular surveillance for counterfeit medicines and timely reporting to national and international monitoring systems to safeguard public health.

(b) Appropriate sanctions against the violation of anti-counterfeit laws.

Activities that WHO supports

(a) Support development of a national action-plan on combating counterfeit medicines, involving multi-stakeholders, including effective anti-counterfeiting laws.
(b) Development of advocacy materials for providers and consumers to increase awareness on counterfeit medicines.

(c) Support for regular assessments of the extent of counterfeit medicines in a country and regional markets.

(d) Increase capacities for detection of counterfeit medicines for laboratories, inspectors and law enforcement agencies.

(e) Advise on strategies for strengthening collaboration between medicines regulatory authority and law enforcement agencies to enforce appropriate laws.

(f) Guidance on establishing an effective system for rapid recall/withdrawal of medicines suspected or confirmed to be counterfeits.

(g) Facilitation of collaboration with international agencies such as INTERPOL, manufacturers and professional associations on synergizing actions to combat counterfeit medicines.

(h) Support in use of regional reporting system to rapidly alert neighbouring countries on counterfeit medicines.

2.3. Substandard Medicines

Principles guiding recommended country policies
(a) All medicines in the market should meet quality standards

Activities that WHO supports
(a) Guidance on procedures and sampling methods for collection of quality samples for routine detection of substandard medicines.

(b) Support training and capacity building for implementation of pharmaceutical norms (particularly GMP) to reduce risk of substandard production.
(c) Training for the staff involved in medicines supply management, prescribers and dispensers on product integrity issues, and procedures for detecting and reporting suspected substandard (or counterfeit) medicines.

(d) Development of advocacy materials for consumers to increase awareness on substandard medicines and describe the mechanism for reporting suspected cases.

(e) Guidance on establishing an effective system for rapid recall/withdrawal of medicines that are suspected or confirmed to be substandard.

(f) Development of guidelines for product return and safe disposal of unwanted, damaged and/or expired medicines.

3. Rational Selection and Use of Medicines

WHO will continue to support Essential Medicines as a forward looking concept which incorporates the need for regular and evidence-based revisions of national lists to reflect new, safe and most cost-effective therapeutic options and will continue to advocate for rational use of medicines. In line with the new sector developments, needs identified by countries, MDG goal 4-5-6-8, Director’s General priorities and WHA resolutions, in this process, WHO will promote a new focus towards:

- Prioritizing inclusion of children’s medicines in national essential medicines lists;
- Providing methodological guidance on evidence-based selection;
- Promoting transparency in selection of essential medicines;
- Promoting innovative approaches to improve rational use of medicines.

3.1. Evidence-based selection of Essential Medicines

Principles guiding recommended country policies

(a) Role of the Essential Medicines list should be clearly defined in the national medicines policy.

(b) Essential medicine list is part of the basic package for healthcare
(c) Essential Medicines list is available, accepted and used at all levels of health care.
(d) Transparent process in selection of essential medicines
(e) Children’s medicines are included on EML.
(f) Regularly updated essential medicines list harmonized with evidenced-based standard treatment guidelines.

Activities that WHO supports
(a) Strategies to build national capacity to promote essential medicines as a cost-effective component of health care and a means to promote health equity.
(b) Provide tools for applying evidence-based methodologies for development or revision of essential medicines list.
(c) Promote and support regular revision and distribution of essential medicines list to incorporate evidence on efficacy, safety, cost, effectiveness, and to incorporate new therapeutic options.
(d) Advocate the use of the Essential Medicines list for public procurement, reimbursement and prescribing.
(e) Guidance on including children’s medicines in essential medicines list.
(f) Strategies to engage educational institutions in promoting essential medicines concept in undergraduate and continuing education.

3.2. Rational use of medicines

Principles guiding recommended country policies
(a) Rational use of medicines should be integrated with the national goal of universal access to medicines.
(b) Promote quality prescribing based on the evidence, safety and efficacy.
(c) Contain antibiotic use and resistance.
(d) Rational and safe use of medicines for children.
(e) Patient adherence to therapies for chronic diseases.
(f) Medicines prescribing and use should not be adversely influenced by financial interest. Provider payment schemes should not create incentives for irrational prescribing of medicines.

**Activities that WHO supports**

(a) Development of infrastructure and capacity building to promote rational use of medicines at all levels of health care within the framework of national medicines policy.

(b) Support provider payments reform such that healthcare workers are not influenced by incentives to incorrectly prescribe medicines.

(c) Studies to generate evidence on health and economic impact of irrational prescribing.

(d) Support sharing of experiences among countries on successful interventions to promote rational use of medicines.

(e) Creation and updating of essential medicines list and harmonization with clinical treatment guidelines

(f) Development and testing of interventions that address appropriate and safe use of medicines, especially use of antibiotics, treatment of children, and adherence to medicines for chronic illness

(g) Support for monitoring of prescribing practices in health facilities.

(h) Strengthening the role of Drug and Therapeutic Committees in hospitals.

(i) Strategies to engage promote rational use of medicines in undergraduate and continuing education programs for health care workers.

(j) Application of tools to promote rational use of medicines for the consumers and in the community.

(k) Development, implementation, and monitoring of regulations on ethical promotion of medicines.
Monitoring and Evaluation

WHO will continue to support countries to regularly monitor and evaluate implementation of national medicines policies and assess levels of access to essential medicines.

Principles guiding recommended country policies
(a) Routine indicator-based monitoring of pharmaceutical system structures, processes, outcomes, and impacts.
(a) Use of monitoring data to refine approaches in implementing national medicines policies.

Activities that WHO supports
(a) Advice on adoption of indicator-based tools to guide implementation of national medicines policy and strengthening national technical capacities for conducting monitoring.
(b) Support for periodic assessments on national pharmaceutical situation to measure the impact of interventions on access, quality and rational use of essential medicines.
(c) Strategies for feedback of assessment results to national policy makers, other, health workers at all levels, consumer groups.
(d) Support for communication of pharmaceutical situation reports at national, regional and global level.
Essential Medicines in the context of primary care and health systems strengthening; global strategic direction

The provision of essential medicines has always been an important component of Primary Health Care (PHC). In this respect the Alma Ata Conference of 1978 drew heavily on the new concept of essential medicines, as launched in 1977 with the first Model List of Essential Medicines. Similarly, renewed PHC in the 21st century will not be possible without essential medicines. Renewed PHC focuses on affordable essential preventive and curative care, close to the people, specifically aimed at promoting equity, universal access and the fulfilment of the MDGs, supported by essential referral systems where needed, within a context of good governance and health-in-all-policies.

The general strategic direction is to make full use of all the scientific and operational evidence to support the renewal and scale-up of national PHC programmes, through the identification and promotion of best practice examples and relevant global guidance. Evidence-based selection of essential medicines remains a cornerstone of PHC, and countries will be supported in making full use of the better evidence in updating their national lists as the basis for the supply, financing, reimbursement, quality assurance and rational use of a limited range of essential medicines for PHC and the necessary referral systems. In this regard, additional emphasis will be placed on the needs of district hospitals.

Regulation systems are slowly improving, but many low income countries still do not have functioning regulatory systems and will be supported in further strengthening them. In view of the increasing reliance on non-public sector delivery channels, countries will also be supported in assessing and regulating the performance of the PHC system, and promoting good governance and accountability. This may include a licensing system for receiving public subsidy for delivering contracted PHC services or products.

Stronger emphasis on human rights and social justice, as seen in the last decade, strengthens the need for universal access to essential medicines. Access to essential medicines as part of the progressive realization of the right to the highest attainable standard of health will therefore be promoted as one of the key indicators to assess national progress towards social justice and the achievement of the MDGs. This is also intended to empower patients and consumers.

Universal access to PHC also depends on the real and perceived quality of care (patient-centered, convenience, rational use, medicine availability and price). Approaches to promoting rational use by prescribers and consumers are strongly supported by scientific evidence on effective interventions, and these will be promoted through national programmes. Towards the major funders of essential medicines, rational use programmes will be presented as part of aid effectiveness and as a necessary part of procurement costs.

Careful selection of the basic package and good economic analysis are needed to promote cost-effective use of resources. Price and availability variations have a great impact on the affordability of medicines for the poor and disadvantaged, which are mostly paid out-of-pocket. Wherever possible, systems of national or subsidized health insurance for a basic package including essential medicines will therefore be promoted, in collaboration with health systems experts, as the most equitable approach to achieve universal access and the best incentive to promote the rational and cost-effective use of resources.

Detailed actions on how to operationalize this integrative approach to primary care and health systems strengthening are addressed in the interdependent components throughout this document.