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In 2004, the *Regional Strategy for Improving Access to Essential Medicines in the Western Pacific Region (2005–2010)* was endorsed by Member States to provide practical and evidence-based guidance for developing actions to improve access to essential medicines and strengthen pharmaceutical systems. Depending on the local context, countries chose specific areas on which to focus and adapted their implementation plans according to their national objectives.

In spite of the progress made over the years, access to essential medicines of assured quality still poses problems for countries in the Western Pacific Region. In high-income countries, problems are related to rational use and cost containment, while in low- and most middle-income countries, ensuring access to essential medicines, especially for the poor and the vulnerable, remains a major public health problem.

After food, medicines account for the second-largest household expenditure. A substantial portion of the population in low- and lower-middle-income countries may have to make difficult choices as they have to pay out of pocket for their vital medicines. In the Western Pacific Region, catastrophic medicine payments can entrench individuals and families in poverty. Recent price surveys show that even the lowest-priced generics are often unaffordable for the poor.

The increasing need for essential medicines due to the growing burden of diseases is stretching country pharmaceutical systems and budgets. Thus, more resources are required for reliable and timely delivery of quality assured medicines as well as their appropriate utilization. To address the growing need, governments must ensure efficient use of resources that the system and the people can afford. They should protect the public from substandard and counterfeit medicines, increase access to medicines while containing costs, and ensure efficiency of supply chains and rational use of medicines.

Countries in the Western Pacific Region have taken a comprehensive approach to prioritizing goals for the pharmaceutical sector and identifying strategies to attain them. They have used the *Regional Strategy for Improving Access to Essential Medicines in the Western Pacific Region (2005–2010)* as a practical guide for developing and implementing actions in a synergistic way.
To ensure continuation and reinforce the strategies and actions outlined in the Regional Strategy and to highlight new and emerging challenges that call for action, the **Regional Framework for Action on Access to Essential Medicines in the Western Pacific (2011–2016)**, hereafter called the Framework for Action, was developed through a consultative process with experts and representatives of Member States. The following are the objectives:

1. to provide strategic direction and guidance for WHO collaboration with Member States;
2. to ensure continuation and reinforce the strategies and actions outlined in the *Regional Strategy for Improving Access to Essential Medicines in the Western Pacific Region (2005–2010)* and include new and emerging issues that call for action; and
3. to serve as a basis for response to the challenges faced by countries in the development and implementation of actions.

The Framework for Action will serve as a basis for country collaboration in improving access to essential medicines. The Framework is organized under the following headings:

1. policy and access to essential medicines;
2. regulation and quality assurance; and
3. rational selection and use of medicines.

The first component on policy and access to essential medicines addresses issues of medicines policy and coordination, adequate financing, affordable prices, procurement and supply management, access to medicines, intellectual property rights and international trade agreements.

The second component on quality assurance addresses issues of regulatory control, substandard medicines and counterfeit medicines.

The third component on rational selection and use of medicines addresses the issues of evidence-based selection of essential medicines and rational use of medicines.

A set of core indicators are proposed which countries can adapt to their context to monitor implementation and evaluate progress. Along with these indicators, a “traffic light” system has been devised to provide “feedback at a glance” and to alert Member States to areas that may require more attention. This system is being introduced on a pilot basis; it is anticipated that it will be refined on a regular basis as feedback will be received from countries.

WHO in the Western Pacific Region will use the Framework for Action to guide its work on essential medicines at the regional level as well as its collaborative work with countries and partners for the period 2011–2016. Simultaneously, based on the national context, countries may use the Framework for Action as policy options to guide their strategic planning and collaboration with WHO.
Background

1.1 Access to essential medicines in the Western Pacific Region

Sustainable and effective pharmaceutical systems are crucial for health service delivery and primary health care. The complexity of these systems require that medicines are of good quality, safe and effective, that they are available at all times in all levels of health care, are affordable and are properly used by providers and consumers.

In the Western Pacific Region, access to essential medicines of assured quality still poses problems for many countries. While high-income countries are tackling the increasing problems of rational use and containing costs, most low- and middle-income countries continue to face difficult challenges in ensuring access to essential medicines, especially for the poor and the vulnerable. Access to essential medicines in majority of these countries remain to be a major public health concern.

After food, medicines account for the second-largest household expenditure. A substantial portion of the population in low- and lower-middle-income countries may have to make difficult choices as they have to pay out of pocket for their vital medicines. In the Western Pacific Region, catastrophic medicine payments can entrench individuals and families into poverty. Recent price surveys show that even the lowest-priced generics are often unaffordable for the poor.

Access to essential medicines is a key development challenge. Despite the progress made in achieving health-related Millennium Development Goals (MDG), around 1500 children under the age of 5 die every day of illnesses that are easily treatable with low-cost essential paediatric medicines. Almost 95% of these deaths occur in six countries in the Region (Cambodia, China, the Lao People’s Democratic Republic, Papua New Guinea, the Philippines and Viet Nam). On the other hand, around 100 maternal deaths occur every day in the Region with huge disparities across and within countries (urban-rural, rich-poor). Postpartum haemorrhage, the main cause of maternal death, could be prevented with the proper administration of oxytocin, a low-cost essential medicine. While the Region is likely to achieve the MDG targets related to tuberculosis, access to
antiretroviral treatment for HIV/AIDS is still around 31% despite a fast scale-up in recent years. On top of all these, access to medicines for chronic diseases also remains a major problem. Collectively, noncommunicable diseases—cardiovascular diseases, cancers, diabetes and chronic respiratory diseases—have overtaken communicable diseases as the leading health burden in the Region. Of the estimated 26,500 people in the Region who die every day from noncommunicable diseases, 20,000 come from developing countries.9 Considering that the majority of the population in low- and most middle-income countries do not have any social health protection and have to pay out of pocket for their medicines, control of chronic diseases is beyond the reach of those most in need.

The growing burden of diseases and the new patterns by which they occur has continuously raised the demand for life saving essential medicines. This phenomenon is stretching country pharmaceutical systems and budgets. More resources are required for reliable and timely delivery of quality assured medicines as well as their appropriate utilization. To address this, governments must ensure that resources are efficiently used; essential medicines are affordable to both the health system and the people; substandard and counterfeit medicines are prevented from entering the supply system; financing systems are sustainable in ensuring that costs are contained and medicines are appropriately and rationally used.

Many countries in the Western Pacific Region have taken a comprehensive approach in prioritizing their goals for the pharmaceutical sector and in identifying strategies to attain them. Actions that have been implemented so far, such as the protection of the public from substandard and counterfeited medicines, containing medicines costs, ensuring efficiency of supply chains and rational use of medicines need to be strengthened and sustained. The *Regional Strategy for Improving Access to Essential Medicines in the Western Pacific Region (2005–2010)* has been used as a practical guide for developing and implementing country actions in a synergistic way.

### 1.2 Issues and challenges

The situation on access to essential medicines varies widely from one country to another. A few countries in the Region are successful in implementing pharmaceutical policies though some have advanced regulatory systems that are among the best examples in the world. However, many still lag behind in applying basic standards and face many challenges in improving access to quality-assured medicines. Support is still needed to accelerate the efforts in addressing issues in the areas of policy and access, quality assurance and rational selection and use of medicines.

**Policy and access**—In the last 10 years, most countries in the Region have taken comprehensive and systematic approaches to guide their actions by developing and/or revising their National Medicines Policy (NMP). Of the 25 countries from the Region that participated in the WHO Country Pharmaceutical Situation Survey in 2007, 15 had official NMP documents, three had a NMP in draft form and seven had no NMP
Eight countries had revised their NMP in the last five years. However, existence of a NMP does not mean much if it is not implemented. Many countries in the Region still strive to implement a NMP in a coherent way. Availability of sufficient and adequately trained human resources to implement activities remains a challenge especially in low- and most middle-income countries. Harmonizing and coordinating activities related to implementation of NMP with other health systems building blocks are essential to facilitate effective implementation.

**Table 1.** National Medicines Policy in the Western Pacific Region (2007)

<table>
<thead>
<tr>
<th>Status of National Medicines Policy (NMP) document</th>
<th>Low-income countries</th>
<th>Middle-income countries</th>
<th>High-income countries</th>
<th>Total number of countries</th>
</tr>
</thead>
<tbody>
<tr>
<td>Official NMP document</td>
<td>Cambodia, Lao People’s Democratic Republic, Mongolia, Solomon Islands, Papua New Guinea, Viet Nam</td>
<td>Fiji, Malaysia, Philippines, Tonga, Samoa</td>
<td>Australia, Japan, Republic of Korea, New Zealand</td>
<td>15</td>
</tr>
<tr>
<td>NMP updated in last five years</td>
<td>Lao People’s Democratic Republic, Solomon Islands</td>
<td>Fiji, Malaysia, Philippines, Samoa</td>
<td>Japan, Republic of Korea</td>
<td>8</td>
</tr>
<tr>
<td>Draft document</td>
<td>Cook Islands</td>
<td>Kiribati, Palau</td>
<td></td>
<td>3</td>
</tr>
<tr>
<td>No document</td>
<td>Nauru</td>
<td>China, Marshall Islands, Niue, Vanuatu</td>
<td>Brunei Darussalam, Singapore</td>
<td>7</td>
</tr>
</tbody>
</table>

**Figure 1.** Progress in the development and/or revision of National Medicines Policy in the Western Pacific Region, 2003–2007

Out-of-pocket payments for health in the Asia Pacific region are much higher than in other parts of the world. Without adequate financing for procurement and distribution
of medicines, availability of essential medicines cannot be ensured. Public funding of medicines per capita varies between countries and between country income levels (Table 2). In some low- and middle-income countries, public spending on medicines is extremely low. A price survey conducted from 2004 to 2006 revealed that, in five countries in the Western Pacific Region, the mean availability of 15 medicines surveyed was only 43% in the public sector. Low availability of essential medicines in the public sector, where medicines are generally provided at a low cost or free of charge, means that basic needs of patients cannot be met; as a consequence patients have to purchase higher-priced medicines from the private sector, most often paying out of pocket. 

Availability of medicines in the public sector is influenced also by procurement practices and the supply management system. The Price Information Exchange for Selected Medicines (www.piemeds.org), a web-based tool established by the WHO Western Pacific Regional Office, provides comparative information on procurement prices that countries can use when negotiating with suppliers. This information-sharing platform has revealed great variability in procurement prices in the public sector even when medicines were sourced from the same suppliers. National centralized procurement systems generally yield better prices than fragmented procurement systems. Some models of decentralized government systems in the Region have been reported to negatively affect medicines financing and procurement. In many countries in the Region, weak infrastructure and verticalization of supply systems based on narrowly funded projects continue to disrupt timely delivery of essential medicines in health facilities. A few countries in the Region still use revolving funds as a strategy to cover medicines costs and generate revenue.

The number of countries in the Region that have developed policies to promote the use of generic medicines has increased. By 2007, most of the countries in the Region were implementing generic substitution in the public and private sectors and some had made it an obligatory requirement (Figures 2 and 3). However, preference for using branded medicines still remains high, which has cost implications. Policies to promote generics are difficult to implement if there is no incentive for prescribing and dispensing low-cost generic medicines. Such incentives are relatively common in high-income countries where they are found in both the public and private sectors, but more needs to be done in low- and middle-income countries.

Table 2. Public spending on medicines per person per year (2007), US$

<table>
<thead>
<tr>
<th></th>
<th>Average</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>High income (data from 5 countries)</td>
<td>147.04</td>
<td>38.8</td>
</tr>
<tr>
<td>Middle-income (data from 10 countries)</td>
<td>20.41</td>
<td>4.4</td>
</tr>
<tr>
<td>Low-income (data from 8 countries)</td>
<td>14.11</td>
<td>0</td>
</tr>
</tbody>
</table>
International agreements related to intellectual property rights can have a negative impact on access to medicines. Policy-makers in many, though not all, countries of the region often have insufficient understanding of the TRIPS flexibilities and safeguards that can be used to protect access to medicines. This is further aggravated by the rapidly changing global intellectual property environment.

Countries in the Region have taken actions to promote transparency in the pharmaceutical sector. Through the programme on Good Governance for Medicines (GGM) they are raising awareness on the risk of abuse in the public pharmaceutical sector and promoting good governance and transparency to ensure that medicines
reach the people. Six countries in the Region are taking up the challenge to improve transparency. Malaysia, Mongolia and the Philippines have made significant progress.

**Quality assurance** — With the expansion of the burden of diseases, the increasing need for access to treatment and the significant number of suppliers in the global medicines market, countries continue to face challenges to regulate the pharmaceutical sector. Most countries in the Region have established medicines regulatory authorities and quality assurance systems. In fact, with the exception of a majority of Pacific island countries, all countries in the Region have mechanisms for marketing authorization in place (Figure 4, Table 3).

Even though most countries in the Region have medicines regulatory authorities, their functionality vary at different levels. Weak regulatory systems coupled with weak and nontransparent enforcement of standards may result in the production, distribution and sale of medicines of doubtful efficacy, safety and substandard quality that can endanger the public. Products contaminated with diethylene-glycol, melamine and contaminated heparin are examples of substandard and spurious products that have penetrated the global market. Countries need to strengthen their capacity to safeguard public health by enforcing regulations in the pharmaceutical sector.

In spite of intensified collaboration between the medicines regulatory authorities and law enforcement agencies at national and international levels, the production, distribution and sale of counterfeit medicines continue in the Region. Apart from being a major public health problem, counterfeiting is a serious criminal act. Yet only few criminals are effectively prosecuted as law enforcement is weak. Samples of artesunate collected in remote Mekong areas were found to be counterfeits, without active ingredients, causing catastrophic effects on the poor and rural populations. International and national actions so far have not been able to deal adequately with the problem. A mechanism was established at the regional level to exchange information among
Table 3. Quality assurance in the Western Pacific Region (2007)

<table>
<thead>
<tr>
<th>Countries</th>
<th>Low-income countries</th>
<th>Middle-income countries</th>
<th>High-income countries</th>
<th>Total number of countries</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Provision of marketing authorization</strong></td>
<td>Cambodia, Lao People’s Democratic Republic, Mongolia, Papua New Guinea, Viet Nam</td>
<td>China, Kiribati, Malaysia, Philippines, Tonga</td>
<td>Australia, Brunei Darussalam, Japan, New Zealand, Republic of Korea, Singapore</td>
<td>16</td>
</tr>
<tr>
<td><strong>Marketing authorization list publicly available</strong></td>
<td>Cambodia, Lao People’s Democratic Republic, Mongolia, Papua New Guinea, Viet Nam</td>
<td>China, Kiribati, Malaysia, Philippines</td>
<td>Australia, Brunei Darussalam, Republic of Korea, Singapore</td>
<td>13</td>
</tr>
<tr>
<td><strong>Computerized system for registered products</strong></td>
<td>Cambodia, Lao People’s Democratic Republic, Mongolia, Papua New Guinea, Viet Nam</td>
<td>China, Malaysia, Philippines</td>
<td>Australia, Brunei Darussalam, Japan, New Zealand, Republic of Korea, Singapore</td>
<td>14</td>
</tr>
<tr>
<td><strong>Number of products with marketing authorization (2007)</strong></td>
<td>Median [25th, 75th percentile] 4508 1624 9666 Cambodia, Lao People’s Democratic Republic, Mongolia, Viet Nam</td>
<td>Median [25th, 75th percentile] 14 547 1000 36 899 China, Kiribati, Malaysia, Philippines, Tonga</td>
<td>Median [25th, 75th percentile] 9431 7602 30 647 Australia, Brunei Darussalam, New Zealand, Republic of Korea, Singapore</td>
<td>14</td>
</tr>
<tr>
<td><strong>Adverse drug reactions (ADR) monitored</strong></td>
<td>Mongolia, Viet Nam</td>
<td>China, Fiji, Malaysia, Philippines</td>
<td>Australia, Brunei Darussalam, Japan, New Zealand, Republic of Korea, Singapore</td>
<td>12</td>
</tr>
</tbody>
</table>

countries and to alert them of detected cases of counterfeit medicines. Collaboration between regulatory and law enforcement agencies in Mekong areas has resulted in the confiscation of millions of counterfeited tablets. However, as these types of criminal acts continue, often moving counterfeit products across national boundaries, more action is needed throughout the Region to address this complex issue.

**Evidence-based selection and use**—Efforts to improve access to essential medicines are hampered if medicines are not selected, prescribed and used rationally. Overuse, underuse and misuse of medicines undermine therapeutic benefits and waste resources. Evidence has shown that using a variety of simple methods to guide and monitor the
use of medicines results in better medicines use, more efficient use of resources and better management, which ultimately leads to better health outcomes.14

Almost all countries in the Region have Essential Medicines Lists (EMLs). National EMLs need to be updated regularly to reflect changing therapeutic needs and options for treating the majority of diseases with essential medicines. Essential medicines should be selected based on evidence of comparative efficacy, safety, effectiveness and cost, and through a transparent process. Figure 5 shows the progress that countries have made since 2003 in updating their EMLs.

EMLs must also include paediatric formulations. Table 4 shows that the number of paediatric formulations as compared to the total number of medicines listed in the EML is low, and that the disparity between the low income and high income countries are wide. There is a global need for safe, effective and accessible children’s medicines, without which Millennium Development Goals 4 and 6 cannot be achieved. This is particularly important in the Western Pacific Region where around 1500 children die every day of diseases that can be treated by low-cost, effective essential medicines. Countries must ensure both the inclusion of paediatric formulations in their national EMLs, and that systems are in place to make paediatric medicines available and properly used.

EMLs are generally used as a basis for public procurement and guidance for prescribing. However, they are often not harmonized with treatment guidelines. Quality prescribing must be based on evidence of safety, efficacy and cost. In some cases, less than half of patients are treated according to the treatment guidelines for the common diseases seen in primary care settings. Provider payment schemes often create incentives for irrational prescribing and excessive prescribing. As shown on Figure 6 some countries use medicines revenues to pay salaries of staff.
Independent and objective information on medicines for providers and consumers is generally lacking and unethical practices in medicines promotion continue. Serious antimicrobial resistance may emerge in many countries in the Region. By 2007, only nine countries reported to have a national strategy for containment of antimicrobial resistance. Antibiotics continue to be sold over the counter in 15 countries in the Region, mostly in low-income countries (Figure 7).

In order to promote regional collaboration, more effective ways of sharing experiences and information between countries are needed. Adequate data that are necessary for drawing evidence are generally lacking for making informed decisions, developing interventions and implementing effective changes in the pharmaceutical system. To

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**Table 4. Essential Medicines List in the Western Pacific Region, 2003–2007**

<table>
<thead>
<tr>
<th>EML</th>
<th>Low-income countries</th>
<th>Middle-income countries</th>
<th>High-income countries</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Cambodia, Cook Islands, Lao People’s Democratic Republic, Mongolia, Nauru, Solomon Islands</td>
<td>355 344 367</td>
<td>352 320 3145</td>
</tr>
<tr>
<td></td>
<td>Cambodia, Cook Islands, Lao People’s Democratic Republic, Mongolia, Nauru, Solomon Islands</td>
<td>26 15 31</td>
<td>59 26 60</td>
</tr>
<tr>
<td></td>
<td>China, Kiribati, Malaysia, Niue, Palau, Philippines, Vanuatu</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Figure 6.** Revenue from sales of medicines used to pay salaries (2007)

![Revenue from sales of medicines used to pay salaries (2007)](image)
address this, specific operational research is needed, in addition to effective monitoring systems that use appropriate indicators. Most countries have not yet developed monitoring systems and indicators for measuring improvement of access to essential medicines. However, both WHO and countries need to measure progress and impact of interventions, a challenge that needs immediate attention.

The Framework for Action proposes a set of core indicators to monitor implementation and evaluate progress. Along with these indicators, a “traffic light” system has been devised to provide “feedback at a glance” and to alert Member States to areas that may require more attention. This system is being introduced on a pilot basis and is anticipated to be refined in the future.
2.1 Purpose of the Framework for Action

In 2004, the *Regional Strategy for Improving Access to Essential Medicines in the Western Pacific Region (2005–2010)*, hereafter the Regional Strategy, was endorsed by Member States to provide practical guidance for developing actions to improve access to essential medicines and to strengthen pharmaceutical systems. Depending on the local context, countries chose specific areas on which to focus and adapted their implementation plans according to their national objectives.

The Regional Strategy covered the period from 2005 to 2010. To ensure continuation of the strategies and actions outlined in the Regional Strategy and to include new issues and areas that need reinforcement, the *Regional Framework for Action on Access to Essential Medicines in the Western Pacific (2011–2016)*, hereafter referred to as the Framework for Action, was developed. The issues that emerged after the introduction of the Regional Strategy and the continuing challenges met by countries which this new Framework for Action seeks to address include the following: (1) essential medicines as a core building block of health systems strengthening for renewed primary health care; (2) essential medicines benefits as part of health insurance and social protection; (3) rights-based approach to improving access to essential medicines; (4) better medicines for children; (5) intercountry information sharing to promote regional collaboration; and (6) transparency and good governance.

The objectives of the Framework for Action are:

1. to provide strategic direction and guidance for WHO 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)* and include issues that need to be reinforced; and
3. to respond to country needs and challenges in the development and implementation of actions, based on agreed guiding principles.

The WHO in the Western Pacific Region will use the Framework for Action to guide its work at the regional level as well as its collaborative work with countries and partners for
the period 2011–2016. Simultaneously, based on the national context, countries should consider using the Framework for Action options to guide their strategic planning and collaboration with WHO.

### 2.2 Development of the Framework for Action

The Framework for Action has been developed in the context of promoting stronger collaboration between WHO and its Member States; thus, it does not separate actions for WHO and for countries as was done in the Regional Strategy. Instead, basic guiding principles were identified for each area and from which recommended actions were based.

WHO and countries are expected to align their collaboration and identify their joint actions based on the stated principles.

The Framework for Action is organized under the following headings:

1. Policy and access to essential medicines
2. Regulation and quality assurance
3. Rational selection and use of medicines.

The three technical components introduced in the Framework for Action are consistent with those in the *WHO Global Medicines Strategy (2008–2013)* and in WHO 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 levels. Activities specified under the components are relevant to the regional context.\(^\text{15}\)

The Framework for Action takes into consideration findings from in-depth reviews undertaken in six countries in 2008;\(^\text{16}\) country situation reports using level I and level II indicators;\(^\text{17}\) comments from Member States; and input from an expert and inter-country consultation held in Manila.\(^\text{18, 19}\) Finally, it was submitted to the sixty second session of the World Health Organization Regional Committee for the Western Pacific for final comments in October 2011. It reflects on the health-related MDG where access to essential medicines is a target in itself.\(^\text{20}\) This implies a strong emphasis on principles of equity and sustainability, the needs of the poor and disadvantaged, and the right to the enjoyment of the highest attainable standard of mental and physical health (often referred to as “the right of health”). 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.\(^\text{21}\) The Framework for Action also synchronizes actions with other strategies such as the *Regional Strategy on Health Systems Based on the Values of Primary Health Care* (where medicines are one of the six building blocks);\(^\text{22}\) and the *Health Financing Strategy for the Asia Pacific Region (2010–2015)*.\(^\text{23}\)
3.1 Policy and access to essential medicines

WHO will continue to support effective promotion, development, revision and implementation of policies to improve access to medicines. In line with the needs identified by countries, new developments in global health, MDGs 4, 5, 6 and 8, and the Director-General’s priorities, WHO will promote a new focus to:

- emphasize the integration of National Medicines Policy within health systems and health financing policies;
- promote access to essential medicines as part of the fulfilment of the right to health;
- increase access to and affordability of essential medicines through expansion of prepayment and other risk-pooling mechanisms (thus reducing high out-of-pocket expenditures), and through appropriate pricing and taxation policies;
- promote strategic planning for procurement and supply management of medicines and strengthen coordination with disease-specific programmes;
- strengthen capacity to manage the implications of trade agreements on access to essential medicines; and
- promote transparency and good governance in the pharmaceutical sector.
3.1.1 National Medicines Policy

Guiding principles

(1) The National Medicines Policy should emphasize principles of equity and sustainability in access to essential medicines as a fundamental human right to health.

(2) Countries should strive for universal access to essential medicines.

(3) The National Medicines Policy should be developed through a consultative process that ensures the participation of a wide spectrum of stakeholders, partners, civil society, academia and public sector.

(4) The National Medicines Policy should be an integral part of the national health policy and plan.

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

Recommended actions

(1) Plan, develop and revise National Medicines Policy to identify national goals, commitments and actions based on a country’s needs, priorities and resources.

(2) Synchronize National Medicines Policy with health financing policy and other health systems strengthening building blocks.

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

(4) Establish and strengthen monitoring and evaluation of actions in implementing National Medicines Policy.

(5) Promote a synergistic approach with disease-specific, reproductive and child health programmes on the selection of essential medicines, quality assurance, procurement and supply management and rational medicines use.

(6) Foster collaboration with relevant professional organizations, partners, civil society and the private sector on promoting and implementing National Medicines Policy.

(7) Promote information-sharing among countries through interregional meetings, conferences and projects, web-based communication, and printed technical materials.

(8) Promote coordination and information-sharing between national and local levels in decentralized systems.
3.1.2 Affordable prices

Guiding principles

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

(2) Transparent competition will help to improve availability and affordability of medicines.

(3) Import duty and tariffs should not represent barriers to access to essential medicines.

(4) Generic competition is an effective mechanism to increase affordability. Policies that encourage generic prescription and generic substitution should be implemented.

Recommended actions

(1) Exchange information and evidence on mechanisms for and impact of price-setting and on direct and indirect price control policies.

(2) When appropriate, assess interventions to regulate mark-ups at the ex-factory level, or at the level of importers, wholesalers and retailers.

(3) Increase efficiencies in public sector procurement by applying good procurement practices, purchasing generics and aggregating volumes to negotiate better prices.

(4) Implement policies that encourage generic prescription and generic substitution, including financial incentives, in both the public and private sectors.

(5) Support efforts to increase the awareness of health professionals and the public about potential cost-savings when using generics and provide information on medicines prices.

(6) Exchange information on medicines prices among countries in the Region and encourage cross-country comparative information-sharing on price trends (e.g. regional Price Information Exchange at www.piemed.com).

(7) Support mechanisms that contribute to reducing prices of branded medicines.
3.1.3 Adequate financing

Guiding principles

(1) Countries should strive for universal access to essential medicines.

(2) Medicines financing policies should be synchronized with national health financing policies.

(3) Out-of-pocket payments for essential medicines should not be used as the main mechanism for financing medicines, for replenishing revolving funds or for financing other parts of the health system.

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

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

(6) Medicines financing mechanisms should not create incentives that lead to prescriber-induced demand.

Recommended actions

(1) As part of National Medicines Policy, review essential medicines financing strategies based on the principles of equity to access, affordability, cost-containment and sustainability.

(2) Develop and implement strategies that reduce out-of-pocket payments for essential medicines.

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

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

(5) Advise on policies that can contain costs by applying a combination of measures that influence the supply side (e.g. evidence-based essential medicines selection and formulary development, use of EML for procurement and reimbursement based on generics) and the demand side (e.g. treatment guidelines harmonized with EML/formulary, generic prescription policies and control of inappropriate medicines promotion and unethical marketing practices).
3.1.4 Medicines procurement and supply system

Guiding principles

(1) Disease-specific medicines supply systems should be coordinated and where possible integrated into one essential medicines supply system.

(2) Assessments of supply systems by donors and development partners should be harmonized with the national monitoring and evaluation system to reduce unnecessary duplications.

(3) Training activities and efforts to evaluate their impact on the efficiency of the medicines supply system should be coordinated.

(4) Medicines procurement should follow the national EML and treatment guidelines.

(5) Public medicines procurement and supply systems should follow transparent processes to avoid unethical practices.

(6) Medicines procurement and distribution systems should ensure continuous availability of medicines at all levels of the health care.

Recommended actions

(1) Strengthen collaboration and information-sharing between those responsible for medicines supply management and those responsible for disease-specific programmes to increase efficiencies in demand forecasting and to ensure that adequate supplies are provided at all levels of health care.

(2) Synchronize public medicines procurement with the national EML and treatment guidelines.

(3) Strengthen capacity of medicines procurement authorities to apply transparent and good procurement practices and to monitor availability and prices of medicines.

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

(5) Support the development of human resources, infrastructure and logistics capacity to ensure appropriate management of the medicines supply system at all levels of health care.

(6) Strengthen collaboration between the national medicines procurement agency and the medicines regulatory agency to reduce the risk of sourcing medicines of poor quality.

(7) Strengthen information systems to improve planning, monitoring of suppliers’ performance and evaluation of efficiency in procurement and supply chain management.

(8) Integrate data collection for indicators about the medicines supply system into the routine health management information system.
3.1.5 Intellectual property rights and international trade agreements

Guiding principle
Trade agreements and intellectual property rights should not be an impediment to access to essential medicines and to the achievement of public health goals.

Recommended actions
(1) Disseminate information on international developments related to intellectual property rights and trade globalization and their potential impacts on access to medicines, and facilitate the exchange of country experiences.

(2) Advocate the inclusion of the public health safeguards of the Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS) in national intellectual property laws and regulations and support countries to amend legislation accordingly.

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

(4) Support national workshops and training on access to essential medicines and intellectual property rights and international agreements for health and trade policy-makers.

(5) Promote and support 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 according to national context.

(6) Advocate for countries to learn how to use the “TRIPS flexibilities” in order to protect access to medicines and, upon request, support countries’ efforts to use these flexibilities.

(7) Disseminate information on the potential implications for access to medicines of “TRIPS-plus” provisions (notably data exclusivity and “linkage” between patent and registration status); where necessary, also support countries in identifying strategies to mitigate the negative impact, if any.
3.2 Regulation and quality assurance

WHO will continue to support medicines regulatory authorities in improving legal frameworks and implementing norms and standards to assure that the production, import, export, distribution, sale 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 intercountry information-sharing. In line with the needs identified by countries, new developments in the field, and MDG 8, WHO will pay more attention to:

- improving medicines safety through an effective post-marketing surveillance system;
- increasing effectiveness in detecting and addressing problems of substandard medicines;
- strengthening collaboration between medicines regulatory authorities and law enforcement agencies in combating counterfeit medicines; and
- ensuring the continuity in the application of internationally accepted norms and standards and quality assurance systems in medicines production and along the entire supply chain.
3.2.1 Medicines regulation

Guiding principles

(1) The medicines market should be effectively regulated and regulations should be actively enforced.

(2) Transparency, good governance and disclosure of conflicts of interest should be key principles of the medicines regulatory authority.

(3) Medicines promotion should be regulated and guided by codes of conduct.

Recommended actions

(1) Strengthen the legal framework to assure that medicines production, import, export, distribution, dispensing, sale use, promotion and clinical trials follow internationally accepted standards.

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

(3) Strengthen monitoring of compliance with good practices in production, distribution, storage and dispensing, to ensure the quality of medicines.

(4) Advocate and support the independence of regulatory decision-making to strengthen the capacity for effective enforcement of laws and regulations.

(5) Support the application of internationally accepted standards in licensing, inspection, quality control and product evaluation to ensure medicines quality.

(6) Support the establishment of functional mechanisms to monitor adverse medicine reactions, and encourage the establishment of medicine safety networks and warning/recall systems in countries to ensure the safety of medicines.

(7) Promote ethical conduct in the promotion and marketing of medicines.

(8) Ensure the availability of independent, unbiased, correct, updated and accessible information on medicines to prescribers and consumers.

(9) Strengthen mechanisms for collaboration with regional and international bodies on medicines regulation.

(10) Support medicines regulatory authorities in providing access to accurate and timely information on licensed manufacturers, suppliers and pharmacies.
3.2.2 Substandard medicines

Guiding principle
All medicines in the market should meet internationally accepted quality standards.

Recommended actions
(1) Provide guidance on procedures and sampling methods for collecting samples for routine detection of substandard medicines.

(2) Support continuous surveillance of the extent of substandard medicines in national and regional markets.

(3) Conduct training and capacity-building for implementation of pharmaceutical norms (particularly good manufacturing practices [GMP]) to reduce the risk of substandard production.

(4) Train staff involved in medicines supply management, prescribers and dispensers on product integrity issues and procedures for detecting and reporting suspected substandard (or counterfeit) medicines.

(5) Develop advocacy materials to increase consumer awareness of substandard medicines and to describe mechanisms for reporting suspected cases.

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

(7) Develop country guidelines for donations, product return and safe disposal of unwanted, damaged and/or expired medicines.
3.2.3 Counterfeit medicines

Guiding principles
(1) Systems should be established for regular surveillance of counterfeit medicines and for timely reporting of counterfeit medicines to national, regional and international monitoring systems to safeguard public health.

(2) Countries should establish a legal framework to combat counterfeit medicines and implement appropriate sanctions against counterfeiting of medicines.

Recommended actions
(1) Develop and implement a national action plan on combating counterfeit medicines, involving multiple stakeholders, which includes effective legislation.

(2) Develop advocacy materials for providers and consumers to increase their awareness of counterfeit medicines and the associated risks.

(3) Encourage the development of innovative technology for the prevention of counterfeit medicines.

(4) Support continuous surveillance of counterfeit medicines in national and regional markets.

(5) Strengthen capacities of laboratory staff, inspectors and law enforcement agents to detect counterfeit medicines.

(6) Strengthen collaboration between medicines regulatory authorities and law enforcement agencies to enforce appropriate laws.

(7) Develop and implement guidelines for rapid recall/withdrawal of medicines suspected or confirmed to be counterfeits.

(8) Facilitate collaboration with international agencies, manufacturers and professional associations on synergizing actions to combat counterfeit medicines and to exchange experiences and best practices.

(9) Support the use of a regional/global reporting system to rapidly alert national medicines regulatory authorities of counterfeit medicines in the Region.
3.3 Rational selection and use of medicines

WHO will continue to support the essential medicines concept, which incorporates regular and evidence-based revisions of national EMLs, reflecting new, safe and cost-effective therapeutic options, and will continue to advocate for rational use of medicines. In line with the needs identified by countries, new sector developments, MDGs 4, 5, 6 and 8, World Health Assembly resolutions and the Director-General’s priorities, in this process, WHO will promote a new focus to:

- prioritize inclusion of children’s medicines in national EMLs;
- provide methodological guidance on evidence-based selection;
- promote transparency in selection of essential medicines; and
- promote innovative approaches to improve rational use of medicines.
3.3.1 Evidence-based selection of essential medicines

**Guiding principles**

(1) The role of the EML should be clearly defined in the National Medicines Policy.
(2) The EML should be part of the basic package for universal health care.
(3) The EML should be available, accepted and used at all levels of health care.
(4) Transparent processes should be used in selecting essential medicines.
(5) Children’s medicines should be included on the EML.
(6) The EML should be harmonized with evidenced-based national standard treatment guidelines.

**Recommended actions**

(1) Build national capacity to promote essential medicines as a cost-effective component of health care and a means to promote health equity.
(2) Provide tools for applying evidence-based methodologies for development or revision of the EML.
(3) Promote and support regular revision and distribution of the EML to incorporate evidence on efficacy, safety, cost, effectiveness, and new therapeutic options.
(4) Advocate for the distribution and use of the EML for public procurement, reimbursement and prescribing at all levels of health care.
(5) Provide guidance for including children’s medicines on the EML and advocate for availability of children’s medicines in the market.
(6) Advise on strategies to engage educational institutions in promoting the essential medicines concept in undergraduate and continuing education programmes.
### 3.3.2 Rational use of medicines

#### Guiding principles

1. Rational use of medicines should be integrated with the national goal of universal access to essential medicines.

2. Quality prescribing should be based on need, evidence of safety, efficacy and cost.

3. National strategies and regulations should be developed to contain antibiotic use and resistance.

4. Policies should be implemented to promote rational and safe use of medicines for children.

5. Policies should be implemented to improve patient adherence to therapies for chronic diseases.

6. Medicines prescribing and use should not be adversely influenced by financial interest. Provider payment schemes should not create incentives for irrational prescribing of medicines.

#### Recommended actions

1. Support the development of a system and building of capacities to promote rational use of medicines at all levels of health care within the framework of national medicines and health policy.

2. Support the review and reform of provider payment mechanisms such that health care workers are not influenced by incentives to prescribe medicines inappropriately.

3. Support studies to generate evidence on the health and economic impacts of irrational prescribing and on the effectiveness of interventions.

4. Encourage the sharing of information and experiences among countries on successful interventions to promote rational use of medicines.

5. Support the development and updating of evidence-based treatment guidelines and their harmonization with the EML.

6. Support the development and testing of interventions that address appropriate and safe use of medicines, especially for maternal and child health, adherence to medicines for chronic illness and antibiotic use.

7. Support the monitoring of prescribing practices in health facilities.

8. Promote strengthening of the performance of drug and therapeutic committees or their equivalent in health care centres, especially in hospitals.

9. Support the strengthening of mechanisms for medicines information-sharing.
(10) Advocate for the incorporation of training modules on rational use of medicines in undergraduate and continuing education programmes for health care workers.

(11) Support the development and application of tools to promote the rational use of medicines by consumers and in the community.

(12) Support the 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 access to essential medicines.

Guiding principles
(1) Countries should implement an indicator-based monitoring of pharmaceutical system structures, processes, outcomes, and impacts.
(2) Countries should use monitoring data to refine approaches in implementing National Medicines Policies.

Recommended actions
(1) Advise on the development and adoption of indicator-based tools to monitor the implementation of National Medicines Policy and strengthen national technical capacities for conducting monitoring.
(2) Support periodical assessments of the national pharmaceutical situation – and advise on their frequency – to measure the impact of interventions on access, quality and rational use of essential medicines.
(3) Support dissemination of, and provide feedback on, assessment results to national policy-makers, health workers, consumer groups, and other stakeholders.
(4) Support the sharing of pharmaceutical situation reports at national, regional and global levels.
Endnotes


5 Op cit. Ref 2.


Regional strategy on health systems based on the values of primary health care. Manila, World Health Organization, 2010 (draft).


For the purpose of this Framework, a counterfeit medicine is one that is deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient (inadequate quantities of) active ingredient(s) or with fake packaging.
# Annex 1: Proposed indicators

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Type</th>
<th>Target 2016</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indicator Type</td>
<td>Regional</td>
<td>Country</td>
</tr>
<tr>
<td>Policy and Access</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 Medicines policy and implementation mechanism in place</td>
<td></td>
<td></td>
</tr>
<tr>
<td>a. NMP official document exists. Write the year of the most recent revision.</td>
<td></td>
<td>revised in last 5 years</td>
</tr>
<tr>
<td>b. NMP implementation plan exists. Write the year of the most recent revision</td>
<td></td>
<td>revised in last two years</td>
</tr>
<tr>
<td>c. NMP implementation regularly monitored/assessed</td>
<td></td>
<td>regular monitoring</td>
</tr>
<tr>
<td>2 Availability of 30 essential medicines in public and private sector</td>
<td>Y/N</td>
<td>70% of countries</td>
</tr>
<tr>
<td>3 Public procurement prices for selected medicines in comparison to international reference price.</td>
<td>Ratio to international reference price</td>
<td>80% of countries below 3x world market reference price</td>
</tr>
<tr>
<td>4 Total pharmaceutical expenditure per capita (public and private)</td>
<td>$ value</td>
<td></td>
</tr>
<tr>
<td>5 Total pharmaceutical expenditure as a % of total health expenditure</td>
<td>%</td>
<td>70% of countries 15–20% of THE</td>
</tr>
<tr>
<td>6 Public expenditure (including public health/social insurance) on pharmaceuticals as % of total pharmaceutical expenditure</td>
<td>%</td>
<td>70% of countries above 50%</td>
</tr>
<tr>
<td>7 Private out-of-pocket expenditure as % of total health expenditure</td>
<td>%</td>
<td>70% of countries less than 50% out-of-pocket</td>
</tr>
<tr>
<td>8 Does a public health service, public health insurance, social insurance or other sickness fund provide partial or full coverage for medicines that are on the EML for outpatients (write % of coverage and % reimbursement)</td>
<td>Y/N</td>
<td>70% of countries all EML</td>
</tr>
<tr>
<td>9 Does a public health service, public health insurance, social insurance or other sickness fund provide partial or full coverage for medicines that are on the EML for inpatients (write % of coverage and % reimbursement)</td>
<td>Y/N</td>
<td>70% of countries all EML</td>
</tr>
<tr>
<td>10 Is revenue from the sale of medicines used to pay the salaries or supplement the income of public health personnel in the same facility</td>
<td>Y/N</td>
<td>80% of countries no</td>
</tr>
<tr>
<td>Indicator Type</td>
<td>Target 2016</td>
<td>Importance of the indicator</td>
</tr>
<tr>
<td>----------------</td>
<td>-------------</td>
<td>-----------------------------</td>
</tr>
<tr>
<td>Action is needed</td>
<td>Needs further improvement/support</td>
<td>Good progress</td>
</tr>
<tr>
<td>No</td>
<td>Yes but document older than 5 years</td>
<td>Yes, document revised at least once in last 5 years</td>
</tr>
<tr>
<td>No</td>
<td>Yes but plan older than 2 years</td>
<td>Yes, plan revised in last 2 years</td>
</tr>
<tr>
<td>No</td>
<td>Yes, once in 2 years</td>
<td>Yes, more frequently than 2 years</td>
</tr>
<tr>
<td>availability 80% or below</td>
<td>availability 80—95%</td>
<td>availability above 95%</td>
</tr>
<tr>
<td>above 5x world market reference price</td>
<td>between 3–5x world market reference price</td>
<td>below 3x world market reference price</td>
</tr>
<tr>
<td>Expenditure on medicines</td>
<td></td>
<td></td>
</tr>
<tr>
<td>25% and above 15% and below</td>
<td>20% — 25%</td>
<td>15% — 20%</td>
</tr>
<tr>
<td>30% and below</td>
<td>30% — 50%</td>
<td>50% and above</td>
</tr>
<tr>
<td>70% and above</td>
<td>50% — 70%</td>
<td>50% and below</td>
</tr>
<tr>
<td>No</td>
<td>Yes but not for all medicines in the EML</td>
<td>Yes, all EML</td>
</tr>
<tr>
<td>No</td>
<td>Yes but not for all medicines in the EML</td>
<td>Yes, all EML</td>
</tr>
<tr>
<td>Yes</td>
<td>Yes but this system is in the process of phasing out</td>
<td>No</td>
</tr>
<tr>
<td>Indicator</td>
<td>Type</td>
<td>Regional</td>
</tr>
<tr>
<td>-----------</td>
<td>------</td>
<td>----------</td>
</tr>
<tr>
<td><strong>Quality Assurance</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>An assessment of the medicines regulatory system has been conducted in the last five years?</td>
<td>Y/N</td>
</tr>
<tr>
<td>12</td>
<td>Legal provisions exist permitting inspectors to inspect premises where pharmaceutical activities are performed</td>
<td>Y/N</td>
</tr>
<tr>
<td>13</td>
<td>Legal provisions exist requiring manufacturers, wholesalers, distributors and dispensers to be licensed</td>
<td>Y/N</td>
</tr>
<tr>
<td>14</td>
<td>Antibiotics are dispensed over the counter without a prescription</td>
<td>Y/N</td>
</tr>
<tr>
<td><strong>Rational Selection and Use</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>15</td>
<td>EML updated in the last three years</td>
<td>Y/N</td>
</tr>
<tr>
<td>16</td>
<td>A survey on rational use of medicines has been conducted. Write the year of the survey.</td>
<td>Y/N, year</td>
</tr>
<tr>
<td>a.</td>
<td>Average number of medicines prescribed per patient (outpatient)</td>
<td>nr</td>
</tr>
<tr>
<td>b.</td>
<td>% of patients in outpatient public health care facilities receiving antibiotics</td>
<td>%</td>
</tr>
<tr>
<td>c.</td>
<td>% of medicines in outpatient public health care facilities that are prescribed by INN (generic) name</td>
<td>%</td>
</tr>
<tr>
<td>d.</td>
<td>% of medicines prescribed in outpatient public health care facilities that are in the EML</td>
<td>%</td>
</tr>
<tr>
<td>17</td>
<td>% of prescriptions complying with the standard treatment guidelines</td>
<td>%</td>
</tr>
<tr>
<td>18</td>
<td>A national programme or committee (involving government, civil society and professional bodies) exists to monitor and promote rational use of medicines</td>
<td>Y/N</td>
</tr>
<tr>
<td>Action is needed</td>
<td>Needs further improvement/support</td>
<td>Good progress</td>
</tr>
<tr>
<td>-----------------</td>
<td>----------------------------------</td>
<td>--------------</td>
</tr>
<tr>
<td>No</td>
<td>Yes but five or more years ago</td>
<td>Yes in the last five years</td>
</tr>
<tr>
<td>No</td>
<td>Partially</td>
<td>Yes for all</td>
</tr>
<tr>
<td>No</td>
<td>Partially</td>
<td>Yes for all</td>
</tr>
<tr>
<td>License</td>
<td>Licensed pharmacies and drug sellers</td>
<td>None</td>
</tr>
</tbody>
</table>

| EML updated more than three years ago | EML updated three years ago | EML updated less than three years ago | Rational Selection | collect information from the MOH | every two years |
| No | Yes more than 5 years ago | Yes in less than 5 years ago | Prescribing practices | collect information from the MOH | baseline and 2016 |
| More than 3 | 2.5–3 | 2.5 or less | Prescribing practices | as in "How to investigate RDU in health facilities" | baseline and 2016 |
| More than 20% | Between 10–20% | Below 10% | Prescribing practices | as in "How to investigate RDU in health facilities" | baseline and 2016 |
| less than 50% | 50–80% | 80% and above | Prescribing practices | as in "How to investigate RDU in health facilities" | baseline and 2016 |
| less than 70% | 70–90% | 90% and above | Prescribing practices and rational selection | as in "How to investigate RDU in health facilities" | baseline and 2016 |
| Less than 50% | 50–80% | 80% and above | Prescribing practices and rational selection | as in "How to investigate RDU in health facilities" | every two years |
| Yes, only government members | Yes composed of government and other partners | System to promote RMU | collect information from the MOH | every two years |
Annex 2

Suggested reading materials

   http://whqlibdoc.who.int/publications/924154547X.pdf


3. *International Health Partnership, country planning cycle database*


5. *Price Information Exchange for Selected Medicines in the Western Pacific Region*
   www.piemeds.com

   http://apps.who.int/medicinedocs/en/d/Js4884e/


   http://www.who.int/medicines/publications/ModelQualityAssurance.pdf


11. *Procurement and Supply Management Toolbox*
    www.psmtoolbox.org

    http://www.wpro.who.int/sites/emp/documents/sample.htm

13. *WHO medicines regulatory package*
14. **Resources on good governance for medicines**

15. **Resources on quality assurance**

16. **Quality assurance terminology database, list of terms and related guidelines**
   http://www.who.int/medicines/services/expertcommittees/pharmprep/TermListcategory.pdf

17. **Rapid Alert System**
   http://www.counterfeitmedalert.info/

18. **Resources on combating counterfeit medicines**

   http://www.who.int/selection_medicines/list/en/


23. **Antimicrobial Resistance Document Centre**

    http://apps.who.int/medicinedocs/en/d/Js6160e/

    http://apps.who.int/medicinedocs/index/assoc/s14877e/s14877e.pdf