Continuity and Change
Implementing the third WHO Medicines Strategy 2008-2013

The World Health Organization’s (WHO) concept of essential medicines is as relevant today as it was when it was launched over 30 years ago. Despite achievements in health care over the last three decades, nearly 30,000 children are dying every day from diseases that could easily be treated if they had access to a basic range of essential medicines. In many developing countries the average availability of essential medicines in the public sector is less than 35%.

In 33 countries the lowest-priced generic medicines in the private sector cost more than twice the price of those in the public sector, on average; and for branded products the cost is generally much higher.¹

Lack of access is not the only problem. Less than one third of the oral contraceptives used globally are of the assured quality required in industrialized countries. In one Asian country, more than half of the artemisinin combinations for malaria are fake. Moreover, even when medicines are available and of assured quality, they are not always used appropriately. In many countries up to half of all prescriptions are unnecessary or incorrect, and half of all patients do not take their medicines as prescribed.

In 1978, the Alma-Ata Conference identified the availability, quality and rational use of essential medicines as one of the key components of primary health care (PHC). The need for essential medicines is as urgent now as it was then. The achievement of the Millennium Development Goals (MDGs) and the renewal of primary health care are not possible without WHO’s norms and standards, policy guidance and technical support in this area.

The publication Continuity and Change — Implementing the third WHO Medicines Strategy 2008-2013, describes how WHO will fulfill its medicine-related commitments in WHO’s Medium-Term Strategic Plan (MTSP) for 2008-2013. Within the MTSP, the medicines work is mostly concentrated in Strategic Objective (SO) 11: Access, quality and rational use of medical products and essential health technologies.

The strategic implementation plan presents a careful balance between continuity and change. On the one hand, much of WHO’s work in this area has been ongoing for decades and needs to be continued, while on the other, the plan addresses those areas where there is need for change.

Target audience and process

The strategic implementation plan provides practical guidance to WHO and stakeholders on how the essential medicines concept and WHO’s expertise can be used to promote universal access and patient-centred health care for all. The strategy describes how WHO contributes towards the achievement of the health-related MDGs, the implementation of recent World Health Assembly (WHA) resolutions, the WHO Medium-Term Strategic Plan for 2008-2013.

Plan for 2008-2013 and the priorities of the Director-General. It presents priorities for action by WHO as a guide for future investment and planning decisions, and serves as a user-friendly document for stakeholders. Continuity and Change - Implementing the third WHO Medicines Strategy 2008-2013, was developed through a consultative process involving a review of experiences and achievements as well as country needs with a broad range of stakeholders. Those consulted included medicine-related WHO staff in country, regional and global programmes, Member States, other WHO departments, UN agencies involved in pharmaceutical programme support, public-interest NGOs, the research-based and generic pharmaceutical industries, and interested governmental and private donor organizations.

**Balance between continuity and change**

WHO's work in the area of pharmaceuticals has existed for 60 years - as long as WHO itself. During this time many products and services have been created which are widely recognized as core functions of WHO. Countries, organizations, industry, health-care providers and patients rely on these core services. For this reason certain activities must be continued.

The strategic implementation plan builds on achievements of the last decade such as the WHO/UN Prequalification of Medicines Programme, without which it would not have been possible to treat 4 million HIV/AIDS patients, and the WHO/Health Action International (HAI) survey methodology, without which medicine prices, availability and affordability could not have been measured in over 50 countries as part of MDG monitoring. In view of the increasing global need for essential medicines more such innovative initiatives are needed.

**Continuity**

WHO will continue to deliver on those areas where we provide a unique service, have a comparative advantage or fulfil international treaty obligations:

- global norms and quality standards
- medicine-related information and evidence
- intellectual property rights
- medicine prices
- capacity building at country level, especially in the area of national medicine regulation
- International Nonproprietary Names for every new active pharmaceutical substance
- assessing priority medicines for UN procurement through the WHO/UN Prequalification of Medicines Programme
- scheduling of controlled medicines
- global quality standards and international chemical reference standards.

**Change**

There are also a number of policy areas in which the need for change is recognized:

- innovative public health thinking on the inclusion of essential medicines as part of health insurance, social protection and the promotion of primary health care
- transparency and good governance in the pharmaceutical sector
- promoting a rights-based approach to improving access to essential medicines
- enhanced regional collaboration in medicine regulation.

*The strategic implementation plan reflects WHO’s mission on essential medicines and pharmaceutical policies:*

"To support the achievement of the health-related Millennium Development Goals by assisting governments and organizations to ensure equitable access to effective and safe medicines of assured quality, and the rational use of medicines by prescribers and consumers. 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, as described in the WHO Constitution and the Universal Declaration of Human Rights."
### Summary of WHO’s strategic directions for medicines 2008-2013

The strategic implementation plan is not intended to cover all of WHO’s medicine activities in detail. The table below presents a summary of the core activities in relation to the MTSP organization-wide expected results (OWERs), as well as MDGs, WHA resolutions, and the Director General’s (DG) priorities.

#### OWER 11.1 Formulation and monitoring of comprehensive national policies on access, quality and use of essential medical products and technologies advocated and supported

<table>
<thead>
<tr>
<th>Priority</th>
<th>Continue</th>
<th>New focus on</th>
</tr>
</thead>
<tbody>
<tr>
<td>National medicine policies</td>
<td>Promoting the establishment, implementation and monitoring of national medicine policies to reflect government commitment and guide national action; update and create new policy guidance documents on priority issues</td>
<td>Comprehensive PHC; medicine reimbursement as part of social security; country-level integration with health systems; harmonizing national policies among regional blocs; policies for simple pharmaceutical systems in post-emergency situations</td>
</tr>
<tr>
<td>Information and planning</td>
<td>Improving pharmaceutical survey indicators and household surveys to measure performance of the national pharmaceutical system</td>
<td>Better link with existing sources of information (national health accounts, IMS-data, HIV global price reporting mechanism, standard household surveys, supply chain assessments) to create a package of country data and improve planning and monitoring of country programmes; new focus on sex-disaggregated statistics</td>
</tr>
<tr>
<td>Access to essential medicines</td>
<td>Promoting the use of standardized methods to measure access (price, availability, affordability) by all stakeholders; procurement and supply management training</td>
<td>Separate assessments and activities to promote availability, price and affordability; need forecasting; access to essential medicines as part of the fulfillment of the right to health</td>
</tr>
<tr>
<td>Transparency and good governance</td>
<td>Providing technical support to counties and regional economic blocs</td>
<td>Developing and promoting new policy guidance on transparency and good governance in pricing, procurement and regulation; use this as an entry point to strengthen comprehensive health systems and promote good governance</td>
</tr>
<tr>
<td>Intellectual property rights</td>
<td>Providing country support in preparing the HS component in funding proposals for GFATM</td>
<td>Promoting the link between innovation, IPR and access; new approach to medicine patents</td>
</tr>
<tr>
<td>New global funding mechanisms</td>
<td>Providing country support in preparing the HS component in funding proposals for GFATM</td>
<td>Policy advice and technical support to global funding mechanisms, and on promoting donor coordination in country</td>
</tr>
<tr>
<td>Medicine benefits as part of (social) health insurance</td>
<td>Supporting evidence-based selection of medicines for insurance systems</td>
<td>Identifying and promoting best practices in health insurance and medicine reimbursement schemes, in support of universal access and PHC</td>
</tr>
<tr>
<td>Comprehensive supply systems</td>
<td>Improving tools on assessing supply systems; identifying and promoting best practices in supply management</td>
<td>The role of the private sector, transparency, and regulatory approach to supply systems</td>
</tr>
<tr>
<td>Traditional medicine (TM)</td>
<td>Developing global guidance and technical support on establishing national policies on TM/CAM products and practices</td>
<td>Integrating TM within national health systems and PHC programmes, promoting research and development, training and good manufacturing practices</td>
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</tbody>
</table>

#### OWER 11.2 International norms, standards and guidelines for the quality, safety, efficacy and cost-effective use of medical products and technologies developed and their national and/or regional implementation advocated and supported

<table>
<thead>
<tr>
<th>Priority</th>
<th>Continue</th>
<th>New focus on</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nomenclature</td>
<td>Programme to assign INNs (generic names) and other classification systems</td>
<td>Developing and refining methods to assign names to biological products</td>
</tr>
<tr>
<td>Controlled drugs</td>
<td>Fulfilling treaty obligations on scheduling of controlled medicines</td>
<td>Improving access to controlled medicines listed on the Model List of Essential Medicines</td>
</tr>
<tr>
<td>Quality standards</td>
<td>Fulfilling constitutional obligations to develop norms and standards for pharmaceuticals and biologicals (Expert Committees)</td>
<td>Missing essential medicines for priority diseases and children, and tools for assessment of regulatory and supply agencies</td>
</tr>
<tr>
<td>Prequalification</td>
<td>Prequalification of priority medicines (HIV, TB, malaria, reproductive health); field sampling and testing of medicines procured by UN; capacity building of national regulatory agencies and manufacturers</td>
<td>Prequalification of quality control laboratories, raw materials, bioequivalence centres; methodological advice to other areas (diagnostics, RH commodities, vaccines), and capacity building</td>
</tr>
</tbody>
</table>
**WHO Policy Perspectives on Medicines**

**Continuity and Change — Implementing the third WHO Medicines Strategy 2008-2013**

**Pharmacovigilance**
MDGs 4-6, DG, WHA16.36 and 23.13

- Global spontaneous ADR monitoring programme, with Uppsala Monitoring Centre
- Disease-specific cohort methods for priority diseases (malaria, HIV, children's medicines); active steering and coordination of new global interest in pharmacovigilance, with focus on developing countries

**Combating counterfeit medicines**
WHA41.16, WHA47.13, WHA52.19

- Strengthening regulatory capacity to promote quality, safety and efficacy of medical products
- Developing specific normative and policy guidance, and support Member States in ensuring the quality of available medicines, and in combating the use of counterfeit drugs

**Traditional medicines**
MTSP, WHA56.31, WHA62.13

- Global guidance and support on safety, quality and efficacy of traditional medicines and practices
- Promoting regulation of practitioners

**Blood products and related biologicals**
Constitution, MTSP indicator, MDG 8, WHA50.20

- Global standards for blood products and related biologicals
- Regulation of blood and blood products, access to therapeutic sera (anti-snake venoms, anti-rabies serum)

**OWER 11.3 Evidence-based policy guidance on promoting scientifically sound and cost-effective use of medical products and technologies by health workers and consumers developed and supported within the Secretariat and regional and national partners**

<table>
<thead>
<tr>
<th>Priority</th>
<th>Continue</th>
<th>New focus on</th>
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<tbody>
<tr>
<td><strong>Selection</strong></td>
<td>Evidence-based WHO Model Lists of Essential Medicines (general, children); Essential Medicines Library, including WHO Model Formulary</td>
<td>Better medicines for children; methodological guidance on evidence-based selection for other WHO departments; model lists for selected groups of commodities and supplies</td>
</tr>
<tr>
<td><strong>Rational use of medicines</strong></td>
<td>Global database of studies on rational use of medicines; training in Rational use of medicines</td>
<td>Execution of WHA2007 resolution, promoting national programmes based on situation analysis, multi-stakeholder approach, comprehensive health systems, national body and use of proven interventions; adherence to chronic treatment; training in basic curricula</td>
</tr>
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</table>

**WHO expected results (MTSP 2008-2013)**

The strategic implementation plan also presents a series of indicators and targets for country progress and WHO’s expected results. The table below shows the WHO expected results for 2013.

<table>
<thead>
<tr>
<th>Indicator</th>
<th>1999</th>
<th>2003</th>
<th>2007</th>
<th>Target 2013</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>OWER 11.1: Policy, access</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MTSP 11.1.1: Number of countries receiving support to formulate and implement official national policies on access, quality and use of essential medicines</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>MTSP 11.1.2: Number of countries receiving support to design or strengthen comprehensive national procurement and/or supply systems</td>
<td></td>
<td></td>
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<tr>
<td>MTSP 11.1.3: Number of countries receiving support to formulate and implement national strategies and regulatory mechanisms for blood and blood products</td>
<td></td>
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</tr>
<tr>
<td>MTSP 11.1.4: Publication of a biennial global report on medicine prices, availability and affordability</td>
<td>MDG-8 report 2008</td>
<td>Biennial reports</td>
<td></td>
<td></td>
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<tr>
<td><strong>OWER 11.2: Quality</strong></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>MTSP 11.2.1: Number of new or updated global quality standards, reference preparations, guidelines and tools for improving the provision, management, use, quality and/or effective regulation of medicines</td>
<td>30 per biennium</td>
<td>30 per biennium</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MTSP 11.2.2: Cumulative number of assigned International Nonproprietary Names for medical products</td>
<td>6003</td>
<td>7342</td>
<td>7822</td>
<td>8500</td>
</tr>
<tr>
<td>MTSP 11.2.3: Number of priority medicines that are prequalified for UN procurement</td>
<td>69</td>
<td>156</td>
<td></td>
<td>350</td>
</tr>
<tr>
<td>MTSP 11.2.4: Number of countries whose national regulatory authorities have been assessed and/or supported</td>
<td></td>
<td></td>
<td>A: 52</td>
<td>S: 94</td>
</tr>
<tr>
<td><strong>OWER 11.3: Rational use</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MTSP 11.3.1: Number of national or regional programmes receiving support for promoting sound and cost-effective use of medicines</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MTSP 11.3.2: Number of countries linking public sector procurement to an EML updated within the last 5 years</td>
<td>62/122</td>
<td>51%</td>
<td>51/93</td>
<td>51/69</td>
</tr>
</tbody>
</table>
Implementing the strategic plan

Advocacy

Advocacy will focus on access to essential medicines as part of the right to health, medicine quality, transparency in medicine registration, procurement and pricing, good governance and social justice, and the promotion of rational use of medicines as part of procurement costs.

The evidence base

WHO’s medicine programme will continue to have a solid foundation of evidence-based standards and policy guidance. The Expert Committee on Medicine Policies will be restarted to focus on scientific evidence on medicine pricing, transparency, and reimbursement schemes. National programmes will have improved access to information through the WHO medicines website’s searchable documentation system.

Collaboration within WHO

Medicine-related activities within WHO disease programmes continue to grow and there is an increasing demand for medicine-related advice and support. Collaboration with these programmes on the selection of essential medicines, quality assurance, regulatory strengthening and medicine pricing will continue. A new focus will be on developing evidence-based treatment guidelines, building comprehensive supply systems and promoting rational use. Efforts will also continue to further standardize WHO’s prequalification of priority medicines, diagnostics, reproductive health devices and vaccines. Work within health systems will focus on primary health care, support to district hospitals, medicines as part of social health insurance in middle-income countries, and on planning human resources for the pharmaceutical sector.

Country support

With an increasing number of countries seeking WHO’s advice and support in organizing their pharmaceutical sector, WHO will use new methods to provide assistance. Where possible, support will be provided to subregional and/or economic blocs. In countries with a real political interest, WHO’s technical support will be through the appointment of dedicated Medicines National Professional Officers and a shift towards better country information, comprehensive multi-stakeholder plans and strengthening the medicines components of WHO’s Country Collaboration Strategies.

The essential medicines programme will be further integrated within the health systems programme at country level.

Partnerships

The programme has many successful partnerships, including the International Conference of Drug Regulatory Authorities, the Interagency Pharmaceutical Coordination group with all UN agencies involved in the pharmaceutical sector, the WHO/UN Prequalification of Medicines Programme, Health Action International, the International Network for the Rational Use of Drugs, and the IMPACT partnership on combating counterfeit medicines. Participation of more countries in such initiatives will be encouraged and supported.

Collaboration will be further strengthened with the Global Fund to fight AIDS, Tuberculosis and Malaria, UNITAID, public-interest NGOs, the research-based and generic pharmaceutical industry, and other bodies engaged in medicines development and delivery.

The relationship with WHO Collaborating Centres will be strengthened, their number increased, and they will be involved in the implementation of the strategy and programme of work.

Human resources for the pharmaceutical sector

The increasing need for human resources and task-shifting in the pharmaceutical area will be addressed, promoting undergraduate training with a focus on good pharmaceutical care. WHO will use its convening power to develop skills-based pharmaceutical training materials and performance assessment tools for non-pharmacist staff providing pharmaceutical services within primary health care. Policy guidance will be developed on setting priorities for human resources in resource-poor settings and small countries. WHO will also work with the International Pharmaceutical Federation (FIP) to define and strengthen the role of the pharmacist; and with the International Union of Basic and Clinical Pharmacology (IUPHAR) to define and strengthen the role of the clinical pharmacologist.

WHO staff and rotational posts

The programme will continue to attract the best global experts in their respective technical fields. It will also strive to achieve gender balance by increasing the number of female experts, especially from developing
countries. If requested by regional offices, efforts will be made to increase technical staff in regional and country offices and in technical areas identified by recent World Health Assembly resolutions. The very successful system of 3 or 6-month rotational posts for experts from developing countries used by the Prequalification and Selection Units will be expanded to include 6-month rotational opportunities for selected Medicines National Professional Officers to regional or headquarters departments. Secondments from developing countries will also be encouraged.

Key documents

Continuity and Change – Implementing the third WHO Medicines Strategy 2008-2013 is available at:
http://www.who.int/medicines/en/

For more information

For more information please visit the Essential Medicines and Pharmaceutical Policies web site at:
http://www.who.int/medicines/en/

Contact us

Email: empinfo@who.int
Contacts in Essential Medicines and Pharmaceutical Policies at WHO headquarters, regional and country offices can be found in Who is Who in WHO Medicines:
http://www.who.int/entity/medicines/about/WhoisWho4Sept09.xls


An external review in 2007 identified the following achievements during 2004–2007:

- Increased number of countries with a national medicine policy and implementation plan
- Rapid expansion and performance of the WHO/UN Prequalification of Medicines Programme
- Innovative standard methodology used in a large number of national medicine pricing surveys
- Increased number of national medicines programmes with full-time staff (WHO Medicines National Professional Officers)
- Development of the Good Governance for Medicines Programme in pharmaceutical management
- Large number of global norms and standards for traditional medicine developed.

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