CONTINUITY AND CHANGE

Implementing the third WHO Medicines Strategy
2008–2013

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Abbreviations

ADR  Adverse drug reaction
AMR  Antimicrobial resistance
ARV  Antiretroviral
ATC  Anatomical Therapeutic Chemical classification
ASEAN Association of South-East Asian Nations
DDD  Defined Daily Dose
DG  Director-General
DTC  Drug and therapeutics committee
EAC  East African Community
EML  Essential Medicines List
GFATM  Global Fund to Fight AIDS, Tuberculosis and Malaria
GMP  Good manufacturing practices
HAI  Health Action International
HIV/AIDS  Human Immunodeficiency virus/acquired immunodeficiency syndrome
IMPACT  International Medical Products Anti-Counterfeit Taskforce
INN  International Nonproprietary Name
IPR  Intellectual property (rights)
MDG  Millennium Development Goal
MOH  Ministry of Health
MSF  Médecins Sans Frontières
MTSP  Medium-Term Strategic Plan for 2008-2013
NGO  Non-governmental organization
NMP  National Medicine Policy
NRA  National (drug) regulatory agency
OWER  Organization-wide expected result
PANDRH  Pan American Network for Drug Regulatory Harmonization
PHC  Primary health care
PQP  Prequalification Programme
SADC  Southern African Development Community
SO  Strategic objective
STG  Standard Treatment Guideline
T&CAM  Traditional medicine/complementary and alternative medicine
TRIPS  Trade-Related Aspects of Intellectual Property Rights
UEMOA  Union Économique et Monétaire Ouest-Africaine
UN  United Nations
UNICEF  United Nations Children’s Fund
UNFPA  United Nations Population Fund
WHA  World Health Assembly
WHO  World Health Organization
Executive summary

The mission of WHO’s programme on essential medicines and pharmaceutical policies is to support the achievement of the health-related Millennium Development Goals (MDGs) by assisting governments and organizations to ensure equitable access to effective medicines of assured quality, and their rational use by prescribers and consumers. This implies a strong emphasis on principles of equity, solidarity 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.

This implementation plan for the third WHO Medicines Strategy (2008–2013) presents a careful balance between continuity and change. On the one hand, many of WHO’s obligations have been fulfilled for decades and need to be continued, while on the other, the plan addresses recent notable developments. These include 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/UNAID survey methodology, without which medicine prices, availability and affordability could not have been measured in over 50 countries as part of MDG monitoring.

As well as responding to general trends and challenges in the global pharmaceutical situation, WHO’s strategic plan reflects the prevailing development landscape, which is considerably more complicated now than it was just a decade ago. Of note in this respect are the MDGs mentioned above, WHO’s overall strategic direction for 2008–2013 (which is set out in its Medium-Term Strategic Plan), the changing aid architecture and UN reform, and recent World Health Assembly resolutions.

Those aspects of WHO’s medicines work that are widely perceived as being areas in which WHO has a comparative advantage will be continued. Examples include the development and promotion of global norms and quality standards and medicine-related information and evidence; the work on intellectual property rights and medicine prices; and capacity building at country level, especially in the area of national medicine regulation. Linked to this concept of continuity are a number of WHO’s products which need to be developed on a regular basis, such as new International Nonproprietary Names for many new active pharmaceutical substances to be marketed, and systematically assessing priority medicines for UN procurement through the Prequalification Programme. Other important deliverables are based on international treaty obligations (e.g. scheduling of controlled medicines) or because they are essential for generic production (e.g. global quality standards and international chemical reference standards).

There are also a number of policy areas in which the need for change is recognised. For example, innovative public health thinking is required to ensure medicine benefits as part of health insurance, social protection and the promotion of primary health care; transparency and good governance; the rights-based approach to improving access to essential medicines; and regional collaboration in medicine regulation. In short, medicines work will increasingly be presented as one of the six pillars of health systems. A series of indicators and targets for country progress and WHO’s expected results are presented in Annex 1.

The need for essential medicines is as urgent now as it was in the past. The achievement of the MDGs and the renewal of primary health care are unthinkable without WHO’s norms and standards, policy guidance and technical support in this area. This strategic implementation plan provides practical guidance to WHO and all interested stakeholders on how the benefits of the essential medicines concept and WHO’s expertise and longstanding experience can be used to promote universal access and patient-centred health care for all.

[Signature]

Dr Hans V. Hagerziel
Director
Department of Essential Medicines and Pharmaceutical Policies
Achievements

Box 1

The second WHO Medicines Strategy (2004–2007) was widely recognized as WHO’s lead strategy in the field of medicines. This strategy document was used in the promotion and development of national medicines policies, and the prioritization of country-level activities. It was also used as a guide for fundraising, for the identification of new targets and activities, and for the development of regional strategies and plans. It was generally appreciated as a good introduction to the work and priorities of WHO in the medicines area, and as an advocacy document.

An internal review in 2007 identified the following particular achievements in the period 2004–2007:

- Increased number of countries with a national medicine policy and implementation plan
- Rapid expansion and performance of the World Health Organization’s (WHO) Medicines Programme
- Increased number of countries using the database on national medicines policies
- Development of a comprehensive database on pharmaceutical management, in many countries
- Large number of global norms and standards for traditional medicine developed

Box 2
Important achievements of 30 years of essential medicines (1977–2007)

The concept of essential medicines is one of the most important contributions of WHO. This concept has become a global practice and a successful brand name associated with principles of equity, pro-poor policies, common sense and good governance.

- The concept is supported by sound evidence, and linked to global normative activities.
- WHO remains the leading global conceptual and technical leader in this field with a stable technical programme and a large number of experts.
- The concept has become a guiding principle in most pharmaceutical programmes in developing countries, and is widely supported by UN agencies and NGOs.

Medicine policies

- Clear global leadership is available on developing and implementing national medicine policies; over 100 countries have developed national policies.
- The approach of developing and implementing international norms and standards has been used to develop international norms and standards with a focus on essential medicines.
- The concept of essential medicines has been incorporated into the global health agenda.

Access

- Global access to medicines has improved and is now available to over 50 countries and is now accepted as the WHO standard for measuring access.
- Global standards for essential medicines in emergency and pandemic settings can be developed and implemented.
- Several global and regional initiatives have been launched, including the Global Atten. on Access to Essential Medicines (GAE) and the WHO Medicines Programme.

Quality, norms and standards

- The International Pharmaceutical Bureau has been established as a global reference for the quality of new essential medicines.
- The International Pharmaceutical Bureau has been established as a global reference for the quality of new essential medicines, with an emphasis on the quality of new essential medicines.
- The WHO Medicines Programme has been established as a global reference for the quality of new essential medicines.

Selection and use

- The WHO ICT platform has been established as a global reference for the selection and use of essential medicines.
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- The WHO ICT platform has been established as a global reference for the selection and use of essential medicines.

Traditional medicines

- The role of traditional medicine and its providers in primary health care was recognized in Abuja in 1998. There is an increasing number of countries that have national research institutes or traditional medicine and herbal medicine, and increasing number of countries including traditional medicines in their national essential medicines list.
- By 2007, 48 countries had a national policy on traditional medicine and over 110 countries have mechanisms in place to regulate traditional medicine.
The concept of essential medicines is one of the major public health achievements in the history of WHO. It is as relevant today as it was at its inception over 30 years ago.

Dr Margaret Chan
Director-General of the World Health Organization
Introduction

WHO's concept of essential medicines is as relevant today as it was at its inception over 30 years ago. The fact remains that despite the achievements in health care of 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 the 27 developing countries for which precise data were obtained, the average availability of essential medicines in the public sector was only 34.9%. In 33 countries the lowest-priced generic medicines in the private sector cost, on average, more than twice the price of those in the public sector, and for branded products the costs are generally much higher.1

Box 3
Mission

The mission of WHO's programme on essential medicines and pharmaceutical policies is 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.

Lack of access is not the only problem. A recent United Nations Population Fund (UNFPA) study showed that less than one third of the oral contraceptives used in the world are of the assured quality that is required in industrialized countries. In one Asian country, more than half of the artemisinin combinations for malaria are false. 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 either unnecessary or incorrect, and in about half of cases 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. Now, the need for comprehensive health care and strengthened health systems, in which access to essential medicines is critical, is once again being recognized and actively promoted.

This document describes how WHO intends to fulfill its medicine-related commitments as set out in WHO's Medium-Term Strategic Plan (MTSP) for 2008–2013. Within this MTSP, the medicines work is mainly, but not exclusively, concentrated in Strategic Objective (SO) 11: Access, quality and rational use of medical products and essential health technologies. Within SO 11, there are three Organization-wide Expected Results (see Box 4).

WHO's programme on pharmaceuticals existed for 60 years – as long as WHO itself. During this time many products and services have been created which are now widely recognized as unique core functions of WHO (see Box 5). Many countries, organizations, commercial companies, professionals and patients have come to rely on these core activities, and for this reason they should be protected and continued. While this means that the third strategic implementation plan has a considerable component of "more of the same", it stems not from a lack of imagination but from the need for responsible continuity.

"Essential Medicines has become a global concept and a successful brand name."

Dr Hans V. Hagerzeil
Director
Department of Essential Medicines and Pharmaceutical Policies

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This document therefore presents a careful balance between continuity and change. On the one hand it recognizes those many obligations that have been fulfilled for decades and which need to be continued, and on the other it addresses those areas where there is a clear need for change. The strategy for 2008–2013 thus aims to build on the notable achievements of the last decade, such as the creation of the WHO/UN Prequalification Programme without which it would have been impossible to treat 4 million HIV/AIDS patients, and the development of the WHO/UNAIDS methodology, which has made possible the measuring of medicine prices, availability and affordability 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.

The current strategic plan is not intended to cover all aspects of WHO’s medicine policies in detail. Table 3, page 12, presents a summary overview of the core components of the work, with further details presented in section 6, but some components, e.g. traditional medicine, for which detailed strategies are available elsewhere, are only summarized. The relationship between the WHO Medicines Strategy and the global strategy on innovation, public health and intellectual property is explained on page 17.

Target audience and development process

The aims of this publication are to:

- describe how WHO intends to contribute towards the achievement of the health-related MDGs, the implementation of recent World Health Assembly resolutions, the WHO Medium-Term Strategic Plan for 2008–2013 and the priorities of the Director-General;
- present priorities for action by WHO as a guide for future investment and planning decisions;
- provide a brief and user-friendly advocacy and information tool for stakeholders.

The publication is intended for use by WHO staff, Member States, core development partners, NGOs and other stakeholders in the pharmaceutical sector. The Medicines Strategy 2008–13 represents the culmination of a three-year process which included an analysis of country needs, a review of experiences with the implementation of the previous WHO Medicines Strategy, for 2004–2007, an analysis of programme components which would benefit from change, and several rounds of consultations with an increasing number of stakeholders. Those consulted included all medicine-related WHO staff in country, regional and global programmes, all Member States, WHO departments involved in the development of SG-11 of the MTSG, 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.

Saving lives with the right medicines
Strengths and weaknesses of the medicines programme

The process to develop the present Medicines Strategy started with an external review of the impact of the previous strategy, as well as several rounds of strategic discussions within WHO. An evaluation of programme strengths, weaknesses, opportunities and threats, i.e. a SWOT analysis, also formed an integral part of this process. The key findings of this analysis are summarized below.

Strengths

The programme’s major strength is that the concept of essential medicines is well-known and globally accepted. The concept is generally associated with equity cost-effectiveness, good governance and attention to the needs of the poor and disadvantaged. In addition, WHO in general, and the medicine programme in particular has a solid track record in and a reputation for technical excellence, sound scientific methods, expert staff and extensive global networks. This is supported by WHO’s global mandate and credibility in health matters, WHO’s convening power and established procedures, and WHO’s constitutional mandate to develop and promote global standards on pharmaceuticals and biologicals. Within WHO, the programme has a good reputation for providing systematic support to regional and national programmes, and for effective collaboration with ministries and other partners such as Collaborating Centres and NGOs.

Weaknesses

The major weakness is that several important components of the programme are under-resourced and that over 75% of its funding consists of project-based voluntary contributions, with less than 15% from assessed contributions. Other identified weaknesses include difficulties in accessing the large and growing amount of medicine-related information and evidence that exists, and the perceived lack of systematic programme planning at country level. With regard to national policies, there is insufficient involvement of the private sector and civil society, and insufficient interest for some programme components, such as promoting rational use of medicines. In addition, in recent years little work has been done on ethical medicine promotion.

Opportunities

There are many opportunities and they reflect both the need for continuity and for change. For example, there is a growing need for global quality standards for new essential medicines, e.g. for HIV/AIDS, malaria, tuberculosis, neglected diseases and medicines for children. The need for prequalification of priority medicines for UN procurement is also growing, and medicine pricing surveys in over 50 countries have generated a demand for policy advice on how to reduce prices and promote affordability, and how to ensure universal availability in situations where most medicines are paid for out-of-pocket. A major opportunity is the renewed interest in strengthening health systems, based on primary health care as the fundamental approach to promoting universal access, and the increasing demand for evidence-based policy advice in general. In both cases the programme has built up a solid reputation and its strong links with many other WHO departments increases its potential. Its recent move to the Health Systems Cluster and its expanding network of more than 40 National Programme Officers provide the necessary scope for greater country-level impact in all areas of WHO’s work in medicines.

Threats

The major threat, although not new, is a general preference for quick solutions to programme delivery. This has given rise to many separate medicine procurement and supply mechanisms and, more recently, to single-disease focused pharmacovigilance systems. In turn, this development has led to an increasing number of international players in the medicine field, resulting in a more complex scenario as discussed in section 3.
Trends, challenges and gaps in the global pharmaceutical situation

Implementation of the third WHO Medicines Strategy must address the following emerging trends and challenges in the global medicines situation. First of all, there is growing consensus among the international community that disease-oriented programmes need the backing of comprehensive health systems to provide those services that are common to all diseases, such as the selection of essential medicines, registration, quality assurance, procurement, supply and rational use. In much the same way, it is recognized that many of the new global funding mechanisms for essential medicines will benefit from the global health policy direction, global standards and technical support that WHO can provide. At the same time, the growing number of players and partnerships, which are complicating the strategic and operational landscape, are in need of a multi-stakeholder (“MOH-plus”) approach and greater coordination at country level using existing mechanisms. The Director-General’s stated priorities to promote PHC and improve the health status of the people of Africa and women mean that there is a need to renew the focus on PHC provision and in particular on the public sector and essential medicines, with an increased emphasis on the need for prevention and treatment of chronic and non-communicable diseases.

In most countries, as greater involvement of the private sector has replaced an earlier reliance on governmental health-care services, there is a growing need for social health insurance and medicine reimbursement schemes, and also for effective regulation. With regard to policy and technical issues, there is definitely heightened interest in medicine quality and quality assurance systems among governments and medicine funding agencies, and increasing demand for practical global standards and for technical support to national regulatory agencies. In turn, this increase in support can also promote more rapid regulatory uptake of newly developed essential medicines. There is an increased need for, and interest in, programmes to combat counterfeit medicines and to promote good governance in the pharmaceutical sector. The global debate on intellectual property has been shifting from global discussions on the effects of the WTO TRIPS Agreement towards technical support to countries and practical implementation of existing provisions and recommendations. Recent WHA resolutions on medicine pricing, intellectual property rights, rational use and better medicines for children all infer the need for fundraising and recruitment to expand WHO’s work in these areas.

Besides these challenges, there are also several gaps in current pharmaceutical systems. Despite a clear WHA resolution in 2007, the scope for reducing medical and economic waste through more rational use of medicines is generally insufficiently recognized. Much more effort therefore needs to be made to highlight the great potential benefits of improving rational use – presenting the costs of promoting rational use as part of medicine procurement costs, and counterbalancing promotional messages with independent medicine information.

There are three categories of patients with serious problems in accessing essential medicines. The first important group is children, for whom insufficient age-appropriate medicines exist, or for whom existing medicines are insufficiently accessible in low- and middle-income countries. The second group comprises those in need of centralised medicines, such as opioid analgesics for terminal care or substitution treatment of substance abuse. A third group is the many farm labourers, and other adults and children, who suffer from rabid dog bites or snake bites and for whom therapeutic sera are not available, largely because of market failure in the supply of safe blood and blood products in low- and middle-income countries. What these patient categories have in common is their lack of a strong political voice to make their needs known, which puts the responsibility on WHO and the public health community to speak out for them. The same also applies for essential medicines for neglected diseases in general.
The strategic landscape in 2008

In addition to responding to the general trends and challenges summarized above, the WHO Medicines Strategy also reflects the prevailing strategic landscape, which is considerably more complicated than it was just a decade ago. The main features now include the MDGs, WHO's overall strategic direction for 2008–2013, the changing aid architecture and UN reform, and the priorities of WHO's Director-General. Each of these is briefly considered below.

**Medicine-related Millennium Development Goals**

Three out of the 8 MDGs, all of MDG targets and 18 of 48 MDG indicators are health-related. Most health targets cannot be reached without better access to safe, affordable and budgetary medicines. Table 1, which lists the medicines-related MDGs targets and indicators, shows that access to essential medicines in developing countries is a target in itself. It also shows that special efforts are needed in the field of essential medicines for child survival, reproductive health, HIV/AIDS (including condom use), malaria and tuberculosis. In addition, developing fair pricing and financing systems, and addressing the needs of least-developed countries are specifically mentioned as separate targets.

**The WHO Medium-Term Strategic Plan for 2008–2013**

In 2006 and 2007, WHO undertook an organization-wide exercise to define its medium-term strategic plan (MTSP) for the next six years. Within this plan, which was adapted by the World Health Assembly in May 2007, the work of WHO is described in a wider sense as the activities and commitments of the Member States and the WHO Secretariat. Within the plan, 13 strategic objectives (SOs) have been formulated. One of these, SO 11, includes the medicines area, together with vaccines and health technologies. The strategic plan is further detailed in organization-wide

<table>
<thead>
<tr>
<th>MEDICINE-RELATED MDGs</th>
<th>MEDICINE-RELATED HEALTH TARGETS</th>
<th>MEDICINE-RELATED HEALTH INDICATORS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Goal 4: Reduce child mortality</td>
<td>Target 5: Reduce by two thirds between 1990 and 2015, the under 5 mortality rate</td>
<td>13. Under 5 mortality rate</td>
</tr>
<tr>
<td>Goal 5: Improve maternal health</td>
<td>Target 6: Reduce by three quarters between 1990 and 2015, the maternal mortality rate</td>
<td>14. Maternal mortality rate</td>
</tr>
<tr>
<td>Goal 6: Combat HIV/AIDS, malaria and other diseases</td>
<td>Target 7: Halve by 2015 and begin to reverse the spread of HIV/AIDS</td>
<td>15. HIV prevalence among pregnant women aged 15–49 years</td>
</tr>
<tr>
<td></td>
<td>Target 8: Halve by 2015 and begin to reverse the incidence of malaria and other major diseases</td>
<td>16. Prevalence and death rates associated with malaria</td>
</tr>
<tr>
<td></td>
<td>Target 9: Achieve universal access to treatment for all malaria cases</td>
<td>17. Prevalence and death rates associated with tuberculosis</td>
</tr>
<tr>
<td></td>
<td>Target 10: Reduce the proportion of tuberculosis cases detected and cured under DOTS by 2015</td>
<td>18. Proportion of tuberculosis cases detected and cured under DOT</td>
</tr>
</tbody>
</table>

*This single indicator for access to essential medicines has recently been replaced by a mix of separate indicators for governance structure, taxation, pricing, manufacturing and delivery (see Annex 1).*
Box 4

Medicine-related strategic objective and organization-wide expected results for 2008–2013

Strategic Objective 11:
To ensure improved access, quality and use of medical products and technologies

Organizational-Wide Expected Results:
11.1 Formulation and monitoring of comprehensive national policies on access, quality and use of essential medical products and technologies adopted and supported
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 adopted and supported
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

expected results (Box 4) which describe, and to a certain extent define, the overall strategic directions in the field of medicines. This strategic implementation plan is intended to provide more detail within the overall WHO strategic direction already adopted by the Member States. The link between the four objectives and seven components of earlier WHO Medicines Strategies and the three OWERS of the WHO Medium-Term Strategic Plan and the current strategy, is shown in Table 2.

The changing aid structure, United Nations reform and country support

The development community increasingly recognizes that the current way international aid is delivered, including the entry of many new partners on the scene, often leads to distorted health sector plans and budgets, loss of national ownership, high administrative overheads for donors and recipients, unnecessary duplication and variations in policy guidance and quality standards at country level.

In response, through the Paris Declaration of 2005, many major donors have pledged that aid should be based on one national plan and promote national ownership, and that donor funds should focus on performance and results, with mutual accountability based on donor coordination, joint planning and one monitoring system. Other aid initiatives, besides the continuation of sector-wide approaches, include the poverty reduction strategic plans and medium-term expenditure frameworks. Put more simply, the intention is to provide more aid, better aid, and to improve coherence. In line with these pledges some of the major bilateral donors and the World Bank are increasingly shifting away from programme support towards sector or general budget support; and some UN agencies are doing the same. There is a crucial role for WHO in guiding the alignment of these national aid coordination frames to support national public health goals.

Table 2: Links between earlier WHO Medicines Strategies and the WHO Medium-Term Strategic Plan

<table>
<thead>
<tr>
<th>OBJECTIVE</th>
<th>COMPONENTS</th>
<th>ORGANIZATION-WIDE EXPECTED RESULTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Policy</td>
<td>1. National policy guidelines</td>
<td>11.3 Comprehensive policies on access, quality and use of essential medical products and technologies adopted and supported</td>
</tr>
<tr>
<td>Access</td>
<td>3. Financing</td>
<td>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 adopted and supported</td>
</tr>
<tr>
<td>Quality</td>
<td>5. Quality and standards</td>
<td>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</td>
</tr>
<tr>
<td>Rational use</td>
<td>7. Rational use by prescribers and consumers</td>
<td></td>
</tr>
</tbody>
</table>

The strategic landscape in 2008
The priorities of the Director-General

In the course of her campaign and transition period WHO’s Director-General, Dr Margaret Chan, met with a large number of Member States, UN agencies and other stakeholders. Drawing on their observations, expectations and recommendations, she formulated two fundamental needs, two strategic components and two operational principles for her five-year tenure (2007–2012).

Fundamental needs: Health development and health security

Health development should be linked to the MDGs, pro-poor policies and fairness in health. This implies greatest attention to priority diseases (HIV/AIDS, tuberculosis and malaria), chronic diseases, those with the largest burden of disease, such as women and children (reproductive health, immunizations), and the people of Africa. Health development as a poverty-reduction strategy implies that health services must reach the poor and underserved. Health security does not only cover emerging diseases; health security at community level also means regular access to basic health care and essential medicines.

Strategic components: strengthening health systems and evidence-based policy guidance

Primary health care is the chosen strategy to strengthen health systems and reach those with the highest burden of disease. This is the only way to ensure fair, affordable and sustainable access to essential care across a population. The underlying values are equity, universal access according to need, provision of affordable and comprehensive care, and local ownership. These values and approaches will be advocated among partners and be supported by evidence-based policy advice; and progress will be measured to improve accountability.

Operational principles: managing partnerships and improving performance

WHO must channel the new political enthusiasm and help to direct the unprecedented level of global funding for health towards the needs of developing countries. WHO will promote integrated service delivery and set the global health agenda based on technical evidence. Rather than attempt to “do everything”, however, WHO will focus on an coordinating role, focusing on activities it is uniquely well suited to perform. Within WHO, emphasis will be put on political and technical accountability, and on measuring WHO’s performance and impact on people most in need. WHO will also be an active partner in the process of UN reform.

WHO’s medicine programme fits very well within these strategic approaches. With its focus on equity, sustainability and comprehensive health care, the concept of essential medicines is perfectly in tune with the new approach to strengthening comprehensive health systems through primary health care delivery. The same is true of WHO’s strong tradition of evidence in pharmaceutical products and policies, rooted in the numerous Expert Committees, expert panels and well established consultation procedures to develop global norms and standards. There is also an excellent basis for further expanding partnerships with other UN agencies, NGOs and other stakeholders.
Strategic directions and priorities for 2008–2013

Continuity versus change

As indicated earlier this third WHO Medicines Strategy recognizes the dual need for continuity and change. Several components of WHO’s medicine work are generally seen as areas in which WHO has a comparative advantage, and which need to be continued. These are:

- development and promotion of global norms and standards and medicine-related information and evidence
- intellectual property rights and medicine prices
- capacity building at country level, especially in the area of national medicine regulation.

In several areas continuity in WHO’s medicines work will be realized in practice by maintaining the well-established systems which ensure the regular updating and dissemination of a number of information products and services, as shown in Box 5. Examples include the assignment of a new International Nonproprietary (generic) Name to every new active pharmaceutical substance to be marketed, and the need to assess priority medicines for UN procurement through the prequalification scheme. In these cases WHO’s decisions are eagerly awaited by manufacturers and consumers, as unnecessary delays can have enormous commercial and financial implications. Timely assessments and reporting are therefore vital for WHO’s reputation. Other deliverables are equally important, as they are based on WHO’s international treaty obligations (scheduling of controlled medicines) or because they are essential for starting generic production (global quality standards and international chemical reference standards).

There are also a number of areas in which the need for change is recognized. Subject areas which require new or additional attention are:

- essential medicine benefits as part of health insurance, social protection and the promotion of primary health care
- transparency and good governance

Box 5

Unique global normative products that need to be delivered on a continuous basis

- International Nonproprietary Names for all new active pharmaceutical ingredients (100–120 per year)
- Antiretroviral Therapeutic Classification and Defined Daily Dose (DDD) for all new active pharmaceutical ingredients (100–120 per year)
- Classification of new active pharmaceutical ingredients under various international treaties for the control of dependence-producing substances (5–5 per two years)
- Global quality standards (International Pharmaceutical Association) and international chemical reference standards for all new essential medicines (5–10 standards per year)
- Global standards on quality and safety of blood products, in-vitro diagnostics and other biologics (5–10 standards per year)
- WHO/UN procurement of priority medicines for HIV/AIDS, tuberculosis, malaria and reproductive health (80–100 products per year)
- International Conference of Drug Regulatory Authorities (Biannual, with over 100 Member States)
- Pharmaceuticals Newsletter on recent regulatory decisions by Member States (monthly)
- WHO Drug Information with summaries of regulatory decisions and proposed INNs (quarterly)
- WHO Model List of Essential Medicines, including essential medicines for children (every two years)
- WHO Model Formulary (every two years)
- The World Medicines Situation (every five years)

- the rights-based approach to improving access to essential medicines
- promotion of regional and subregional structures and collaboration

With regard to process, there is a need for improvements to:

- programming at country level
- the ways in which progress and impact are measured
- planning and allocation of WHO’s human resources across the various levels of the organization
- within-WHO coordination in the field of medicines
- resource mobilization, especially for country programmes.
## Setting of priorities for action

The strategic direction and approaches to be adopted for the core components of WHO’s medicines work are summarized in Table 3. All of these components were included in the Medium-Term Strategic Plan (MTSP) for 2008–2013. Programme activities are listed in the first column. The second column in the table describes the strategic direction and activities which will be continued and the third column lists the areas of new strategic focus.

Priority-setting is linked to the strategic landscape discussed in the previous section, by indicating for each of the core components the extent to which the activities listed are linked to WHO’s constitutional and treaty obligations, will support the MDGs, are reflected in MTSP indicators, are supported by recent WHA resolutions, and fit within the Director-General’s stated priorities. The more of these criteria that apply, the higher the priority of the activity.

### Table 3: Summary of WHO’s strategic directions for medicines 2008–2013

<table>
<thead>
<tr>
<th>PROETY</th>
<th>CONTINUE …</th>
<th>NEW FOCUS ON …</th>
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<tbody>
<tr>
<td><strong>National medicine policies</strong>&lt;br&gt;Priority: MDG 4.1–4.4, MTSP Indicators, DG, WHO/60.27, WHO/61.20, WHO/61.14, WHO/62.19, WHO/64.11</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 or priority areas</td>
<td>Comprehensiveness of HIC, medicine reimbursement as part of social security, country-based integration with health systems; harmonization of national policies among regional blocs; policies for simple pharmacovigilance in post-approval surveillance</td>
</tr>
<tr>
<td><strong>Information and planning</strong>&lt;br&gt;Priority: DG</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 surveys, DFG-data, HIC global data reporting mechanism, standard household surveys, supply chain assessment] to create a package of country data and improve planning and monitoring of country programmes; focus on one or two geographical indicators</td>
</tr>
<tr>
<td><strong>Access to essential medicines</strong>&lt;br&gt;Priority: MDG 4.1–4.4, MTSP Indicators, DG, WHO/60.11, WHO/61.14, WHO/62.17, WHO/62.12, WHO/64.43</td>
<td>Promoting the use of standardized methods to measure access (price, availability, affordability) by all stakeholders; procurement and supply management training</td>
<td>Improve assessment to promote availability and affordability; need forecasting; access to essential medicines as part of the fulfiment of the right to health</td>
</tr>
<tr>
<td><strong>Transparency and good governance</strong>&lt;br&gt;Priority: MDG 4.1, DG</td>
<td>Providing technical support to countries and regional economic blocks</td>
<td>Developing and promoting new policy guidance on transparency and good governance in pricing, procurement and regulation, for example, as entry point to strengthening and harmonization of national health systems through good governance</td>
</tr>
<tr>
<td><strong>Intellectual property rights</strong>&lt;br&gt;Priority: MDG 4.1, WHO/60.27, WHO/61.24, WHO/62.10, WHO/63.14, WHO/66.14, WHO/66.16</td>
<td>Providing technical support to countries and regional economic blocks</td>
<td>Promoting the full implementation of the TRIPS and access; new approaches to medicines policies</td>
</tr>
<tr>
<td><strong>New global funding mechanisms</strong>&lt;br&gt;Priority: DG</td>
<td>Providing country support to prepare the (IS component) for funding proposals for GAVI</td>
<td>Policy advice and technical support to global funding mechanisms, and to promote stronger coordination at country level</td>
</tr>
<tr>
<td><strong>Medication benefits as part of (social) health insurance</strong>&lt;br&gt;Priority: MDG 4.1–4.4, MTSP Indicators, DG</td>
<td>Supporting evidence-based selection of medicines for insurance schemes</td>
<td>Identifying and promoting best practices in health insurance and medication reimbursement schemes, in support of national access and HIC</td>
</tr>
<tr>
<td><strong>Comprehensive supply systems</strong>&lt;br&gt;Priority: MDG 4.1–4.4, MTSP Indicators, DG</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 approaches to supply systems</td>
</tr>
<tr>
<td><strong>Traditional medicines (TM)</strong>&lt;br&gt;Priority: MTSP/WHO/63.13, WHO/62.19</td>
<td>Developing global guidance and technical support on evaluating national policies on Traditional medicine products and practices</td>
<td>Integrating TM within national health systems and HIC programmes; promoting research and development, training and good manufacturing practices</td>
</tr>
</tbody>
</table>
**Priority:** 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

### CIPER 11.2

<table>
<thead>
<tr>
<th>Priority</th>
<th>Continue</th>
<th>New Focus on</th>
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<tbody>
<tr>
<td>Normatives&lt;br&gt;Priority: Contribution, HTSP Indicator; &lt;br&gt;Ministry of Health</td>
<td>Programmes to assign WHO (generic names) and other classification systems</td>
<td>Developing and refining methods to assign names to biological products</td>
</tr>
<tr>
<td>Controlled drugs&lt;br&gt;Priority: International treaty obligations, &lt;br&gt;MEDG 9.6, WHA 74.23</td>
<td>Refining treaty obligations or scheduling of controlled medicines</td>
<td>Improving access to controlled medicines listed on the World List of Essential Medicines</td>
</tr>
<tr>
<td>Quality standards&lt;br&gt;Priority: Contribution, MEDG 4.5-5.2, HTSP Indicator; &lt;br&gt;WHO &amp; ICM, WHA 71.11, WHA 72.12, WHA 73.2, WHA 74.15</td>
<td>Refining or establishing obligations for the quality of medicines</td>
<td>Establishing guidelines for priority diseases and children, and tools for assessment of regulatory and supply arrangements</td>
</tr>
<tr>
<td>Prequalification (ITQ)&lt;br&gt;Priority: MEDG 4.5-5.4, HTSP Indicator; &lt;br&gt;WHO &amp; ICM, WHA 73.14</td>
<td>Prequalification of medicines (KEN laboratories, national, regional, community health orders), field sampling and testing of medicines processed by the national regulatory agencies and manufacturers</td>
<td>Prequalification of quality control laboratories, new drugs, biocompatibility tests, methodological studies of other areas (open systems, AIT components, methods), and capacity building</td>
</tr>
<tr>
<td>Pharmacovigilance&lt;br&gt;Priority: MEDG 4.6, DG, WHO/66.34 and 67.13</td>
<td>Global standaradisation of ADR monitoring programmes, with WHO ADR Centre</td>
<td>Disease-specific cohorts for priority diseases (pediatrics, HIV, childhood medicine), active sharing and coordination of new global interest in pharmacovigilance, with focus on developing countries</td>
</tr>
<tr>
<td>Combating counterfeit medicines&lt;br&gt;Priority: WHA 71.1, WHA 72.13, WHA 73.19</td>
<td>Strengthening regulatory capacity to promote quality, safety and efficacy of medical products</td>
<td>Developing specific normative and policy guidelines, and support Member States in ensuring the quality of available medicines, and in combating the use of counterfeit drugs</td>
</tr>
<tr>
<td>Traditional medicines&lt;br&gt;Priority: HTSP, WHO/84.11; WHO/85.11</td>
<td>Global standards and support on quality, safety and efficacy of traditional medicines and products</td>
<td>Promote regulation of practitioners</td>
</tr>
<tr>
<td>Blood products and related biologicals&lt;br&gt;Priority: Contribution, HTSP Indicator; &lt;br&gt;MEDG 6, WHA 65.20</td>
<td>Global standards for blood products and related biologicals</td>
<td>Regulation of blood and blood products, access to vaccines and other blood components, and quality assurance</td>
</tr>
</tbody>
</table>

**Strategy directions and priorities for 2006-2013**

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

### CIPER 11.3

<table>
<thead>
<tr>
<th>Priority</th>
<th>Continue</th>
<th>New Focus on</th>
</tr>
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<tbody>
<tr>
<td>Selection&lt;br&gt;Priority: MEDG 4.5-5.4-5</td>
<td>Evidence-based WHO Model List of Essential Medicines (general, children); Essential Medicines Library, including WHO Model Formulary</td>
<td>Better guidance for decision-making, methodology guidelines on evidence-based selection for other WHO departments; expert meetings for selected groups of countries and regions</td>
</tr>
<tr>
<td>National use of medicines (NRM)&lt;br&gt;Priority: MEDG 4.5-5.4-5, HTSP Indicator; &lt;br&gt;WHO &amp; ICM, WHA 71.11, WHA 72.11, WHA 73.11, WHA 74.17, WHA 75.17, WHA 76.18</td>
<td>Global database of statistics on national use of medicines; training in NRM</td>
<td>Education of WHO/NLM, promoting national NRM programmes based on situation analysis, multi-stakeholder approaches, comprehensive health systems, national NRM body and use of proven interventions, promote adherence to donors' treatment, promote NRM training in basic sciences</td>
</tr>
</tbody>
</table>
Strategic direction in selected priority areas

In a number of technical areas important global trends, the current strategic landscape and/or the potential benefit of integrating medicines work into health systems, require a careful reorientation of WHO’s strategic direction. In this chapter a number of these priority areas are presented in more detail, and for most of them separate, more detailed strategic documents are available or are in preparation.

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

Evidence and information for medicine policies

Background and main challenges

Over the last few decades WHO and its many partners in government, academia and civil society have generated a large amount of medicine-related information in the form of research reports, norms and standards, statistical and survey data, policy guidance, reference documents and training materials. While much of this information is highly relevant and of excellent quality, it is not always readily available to those who would benefit from it most. There is therefore a need to ensure the continued development, validation, external review and targeted dissemination of medicine-related materials, which should be regularly updated and available in different languages. It is very important to ensure that all information relevant to a particular country is easily accessible in a format that supports a transparent, evidence-based approach to policymaking and priority-setting.

Strategic direction

Focusing initially on the country level, WHO will define common needs for medicine-related information and by comparing needs with what is currently available in most countries, will identify gaps in information provision. This will allow data identification and collection to be undertaken with all potential partners, including countries, other departments, other UN agencies and WHO Collaborating Centres. The development of standardized methods, analytical tools and reporting systems is envisaged as an ongoing process. At every stage in the development cycle, countries will be encouraged to participate, provided with technical and material support, and involved in data analysis, report writing and dissemination. The various web-based information sources within and outside WHO will, as far as possible, be rationalized and linked.

In terms of information management and planning, WHO’s primary objective is to systematically improve the collection, processing and analysis of medicine-related information that is uniquely available within its Medicine Department (such as pharmaceutical sector surveys, national medicine policies and national medicines lists) and link these to medicine-related information routinely collected by other groups, such as WHO/Evidence and Information for Policy (EIP), national health accounts, standard household surveys, WHO/MAI medicine pricing surveys and IMS Health data. The ultimate goal is to create one central WHO/Medicines web site entry-point with links to all medicine-related country information relevant for planning purposes and for measuring progress. The intention would then be to feed this information into the World Medicines Situation reporting cycle.
Essential medicines for renewed primary health care

Background and main challenges

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 WHO Model List of Essential Medicines. Likewise, 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.

Strategic direction

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 provision of 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 primary care and the necessary referral systems. In this regard, additional emphasis will be placed on the needs of district hospitals.

With the increased emphasis on human rights and social justice in the last decade, universal access to essential medicines has become one of the key indicators used to assess national commitment and progress towards the progressive realization of the right to the highest attainable standard of health, and the achievement of the MDGs. The intention is also to empower patients and consumers. In addition, universal access to health care depends on the real and perceived quality of care (patient-centred, convenience, rational use, medicine availability and price). Approaches to promoting rational use of medicines by prescribers and consumers are strongly supported by scientific evidence of effective interventions, and these will be promoted through national programmes (see page 21).

Careful selection of a basic package of essential medicines and a good economic analysis of costs are needed to promote cost-effective use of resources. Medicine price information from over 50 countries has shown the high prices of medicines and a high level of taxes and margins; but it has also shown the financial advantages of generic policies and the benefits of strengthening the public sector. Where feasible WHO is thus committed to promoting, in collaboration with health systems experts, tax-based systems or subsidized health insurance schemes for a basic package, including essential medicines, as the most equitable approach for achieving universal access and the best incentive to promote the rational and cost-effective use of resources.

Another important aspect of health systems is the need for human resources. Most discussions focus on the lack of doctors and nurses, with little attention paid to similar problems with pharmacists and the other staff needed to procure, supply and dispense medicines. Greater emphasis will be put on including the needs for pharmaceutical staff in human resource development plans, as well as programmes of task-shifting, and other activities aimed at strengthening human resources in countries.

A health systems approach to strengthening medicines supply

Background and main challenges

Most health programmes depend on access to affordable, quality medicines. Hence, health systems strengthening and strengthening medicines supply systems are integrally linked. The application of robust methods for guiding the selection of medicines – through national essential medicines lists, and in some countries, through health insurance schemes – has contributed to improvements in supply. Yet despite the ongoing efforts of WHO and its partners, for instance in mapping existing medicines supply systems and developing new assessment tools and training materials, many challenges remain, as shown in Box 6. Corruption, a major obstacle in much development work, also pervades many medicines management systems. For this reason, the new WHO Good Governance for Medicines Programme includes a technical package to promote transparency, accountability and good governance in medicines procurement and pricing.

Strategic direction

The overarching goal in this area of WHO’s work is improved planning and coordination of all activities
in medicines management. At country level, mapping of supply systems will be continued. Integrated supply management will be encouraged for diseases that are the greatest health burden, taking account of the long-term needs. The aim is also to replicate successful global interagency collaboration at national level, and to link this with UN reform where possible. Within WHO, the aim is to better coordinate the development of tools and collaboration with regions and countries between departments.

As part of these efforts, WHO plans to identify a package of evidence-based interventions that can be used by all partners to improve their supply management systems. These interventions will take account of WHO’s role in countries, the private sector, health insurance systems and different levels of income. Further development of this package will be supported by establishing an international expert panel on medicines supply issues. Based on this package, countries will be assisted individually with solid policy guidance on good governance and transparency, regulatory review and quality assurance as part of procurement procedures, the management and regulation of supply systems, human resources planning and management, the role of public authorities, and donor coordination. By adopting this strategic approach WHO will optimize its capacity, mandate and good reputation to provide leadership in evidence-based medicines supply policies, enhance its existing expertise in selection processes, quality assessment and registration of medicines; and strengthen its expanding network of national programme officers.

Public health, innovation and intellectual property

Background and main challenges

In an increasing number of low- and middle-income countries, stronger patent protection as part of implementation of the WTO TRIPS Agreement is creating a financial barrier to universal access to new essential medicines, such as second-line ARVs. In addition, the lack of an economically viable market does not encourage the development and marketing of some categories of essential medicines, notably those for neglected diseases and for children, and therapeutic sera against rabies and snake bites. This has led to an increase in targeted public investment in the development of “missing” essential medicines, usually through public-private product development partnerships. This poses interesting questions on the patentability of publicly funded developments.

During 2007 and 2008 an Inter-Governmental Working Group formulated, and the World Health Assembly later approved, a global action plan to promote innovation, public health and intellectual property with a focus on essential medicines needed for neglected diseases and poor populations. This new

Box 6

Challenges in supply management

- The many different partners with their own medicines supply strategies has led to a lack of coordination of supply systems, resulting in duplication, inefficiency and increased costs, especially at the facility level. The national approaches for priority diseases have neglected other important conditions (e.g. chronic diseases, common diseases in children).
- Investment in the health-care sector outside the three main diseases has remained low, especially in Africa, with decreases in national government budgets for general health activities and for general health supply systems.
- Little attention has been paid to the long-term supply strategies, such as the market impact of government interventions and how to develop appropriate social insurance systems. Donors have generally focused on public sector supply for specific diseases, with limited consideration of the role of the private sector.
- The infrastructure and human resources to support medicines supply systems have generally been neglected. Routine information systems are weak and a lack of data availability for assessing medicines performance and evaluating efficiency of medicines. Inadequate improvements in this domain.
- Selection and procurement of products is not always based on appropriate methods. Consequently, there is great linkage between national medicines lists, medicines usually purchased and supplied, and those prescribed to the patients.
- External supply system assessments are often not conducted without asking strategic national medicines policies, previous recommendations and trends over time. This problem is compounded by a lack of follow up and political commitment to implement recommendations.
- Although training has been supported extensively, relevant and sustainable development of human resources to ensure appropriate medicines management has not taken place.
- The lack of the availability of medicines management tools and guidance for users and impact. Disease-specific programmes often duplicate these tools, most are in English only and there is no agreed set of interventions that have been shown to be effective in improving medicines supply.
- The optimal interaction between drug regulatory authorities and medicines procurement systems to ensure quality of medicines throughout the supply chain is not well defined. This gap in regulatory guidance leads to duplication of human resources, and a lack of coherence between quality assurance activities, and a lack of systematic enforcement and sanctions.
global strategy is designed to foster a sustainable basis for a needs-driven, essential health research and development environment that is relevant to diseases that disproportionately affect developing countries, and to achieve a balance between incentives to innovate, on the one hand, and early access to new essential medicines on the other. The eight elements of the plan of action are:

1. prioritizing research and development needs;
2. promoting research and development;
3. building and improving innovative capacity;
4. transfer of technology;
5. application and management of intellectual property;
6. improving delivery and access;
7. ensuring sustainable financing mechanisms;
8. establishing monitoring and reporting systems.

The relationship between the Global Strategy on Innovation, Public Health and Intellectual Property for 2008–2015 and the WHO Medicines Strategy 2008–2013 is summarized in Figure 1, from which it can be seen that the former does not cover all aspects of WHO’s work in medicines (e.g. nomenclature, quality standards, rational use) and also includes components which are not linked to medicines.

**Strategic direction**

WHO will implement those components of the global strategy for which it has the mandate and the means. For example, the plan includes many medicine-related activities, such as the identification of missing essential medicines for which research and development are needed, systematic research on traditional medicines, expansion of the Prequalification Programme, strengthening regulatory capacity and other measures to promote universal access. Most of these activities are detailed in separate sections of this document. WHO will continue to give technical support to Member States in implementing the Doha Declaration and using TRIPS-compatible flexibilities. New approaches will also be supported, such as voluntary patent pools for selected essential medicine combinations and global access licensing by universities for publicly-funded research. In both cases the new products resulting from such arrangements may benefit from priority assessment by the Prequalification Programme, so reducing the time it takes to make the products available.

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**Figure 1: Relationship between the WHO Medicines Strategy 2008–2013 and the Global Plan of Action for 2008–2015**

**WHO Medicines Strategy**
- Quality norms, standards, medicine policies, prices, PPR, human rights, governance, rational use

**Global Strategy on Public Health, Innovation and Intellectual Property**
- IPR issues, R&D capacity, vaccines, technology, health-care financing

**WHO Essential Medicines**
- R&D gaps, selection, prequalification, traditional medicines, regulatory support, transfer of technology, production, access, supply
POWER 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

Building regulatory capacity

Background and main challenges
Currently, over two-thirds of countries, including most low- and middle-income countries, lack fully-functioning medicine regulatory systems. Yet with increasing privatization and globalization of health care, including the global trade in medicines, the need for regulation is greater than ever before. Several recent events involving counterfeit and substandard medicines (see page 19) serve to underscore the need for strong regulation in order to protect the public. However, many governments do not seem to recognize the potential benefits of a strong medicine regulatory system and do not make the necessary political and financial commitments to secure one. Many regulatory agencies do not apply a risk-based approach and do not systematically select the most cost-effective activities within their limited means.

Strategic direction
Many components of WHO’s work in medicines already include activities that build regulatory capacity. Examples are:

* the global quality norms and standards and regulatory information exchange services provided by WHO (see Box 5);
* assessments of regulatory authorities;
* provision of training and materials on all aspects of regulation (including regulation of traditional medicines) from the regional and global perspective as well as the national (WHO offers many tailor-made national training programmes and individual country support missions);
* expansion of the global Pharmacovigilance Programme;
* the capacity-building component of the Prequalification Programme (which involves numerous hands-on training courses on dossier assessment and product-specific inspection of manufacturing plants and contract research organizations);
* work to combat counterfeiting.

Many of these activities are discussed in more detail in other parts of this document.

A relatively new aspect will be the promotion of regional regulatory cooperation within existing economic blocs in Africa, such as the Southern African Development Community (SADC), the East African Community (EAC) and the Union Economique et Monétaire Ouest-Africaine (UEMOA). Similar cooperation in other continents is more established and will be continued, for example in the Americas through the Pan American Network for Drug Regulatory Harmonization (PANDRH) and the ANDIEAN Group and in Asia (ASEAN). Especially in Africa, with its heavy burden of HIV/AIDS, tuberculosis and malaria and strong reliance on external funders, it is expected that the format used by the Prequalification Programme (especially the WHO public assessment reports and WHO public inspection reports) will constitute a basis for regional harmonization efforts and rapid regulatory uptake of new essential medicines.

WHO/UN prequalification of priority medicines

Background and main challenges
The WHO/UN Prequalification Programme (PQP) was established in 2001 to centrally select ("prequalify") priority medicines for the treatment of HIV/AIDS, tuberculosis and malaria for UN procurement. The National Regulatory Agencies (NRAs) in developed and developing countries are responsible for doing most of the assessments and inspections. UN agencies, international financial bodies and procurement agencies (such as the Global Fund, World Bank, UNICEF and Médecins Sans Frontières (MSF)), and also national disease programmes, use the list of prequalified medicines. Within WHO there is close cooperation with the disease programmes and active participation in standard setting, drug safety, procurement and regulatory support.

The main challenge for the PQP is the increased need for quality assured medicines for the treatment of HIV/AIDS, tuberculosis and malaria, and thus the increasing expectations for the delivery of services provided by the programme. The significant achievements of the last six years have raised the issue of expanding the scope of the PQP to include
products for reproductive health, neglected diseases, diarrhoea and other children’s medicines. The PQP is also expected to address a growing demand for capacity building and technical assistance activities from NRAs.

**Strategic direction**

The primary strategic objective is to increase the number of quality-assured medicinal products for each priority medicine in order to achieve more choice, lower prices and better supply security. Increasingly important is the maintenance of the quality, safety and efficacy elements of products already prequalified. The evaluation work done by the programme and the outcome of assessment and inspection activities are a public good, and will be made available for use by Member States and all interested parties, including NRAs. Regulatory capacity building in less-resourced countries, a target of the programme since its inception, will be further enhanced by providing technical assistance and capacity building to selected, promising manufacturers in developing countries, who are committed to producing medicines that meet international standards.

To further ensure sustainable production of good quality finished products, the PQP plans to undertake separate prequalification of active pharmaceutical ingredients, which will benefit manufacturers in less-resourced countries. In order to increase country capacity for sampling and testing of pharmaceutical supplies, the PQP will continue to prequalify national medicine quality control laboratories, and to support national quality control systems, including comprehensive sampling and testing programmes.

The Prequalification Programme is by its very nature unique, enabling regulators from well- and less-resourced countries to work together. This collaboration contributes to regional and ultimately global harmonization of regulatory activities, building trust and facilitating implementation of mutual recognition processes. Close cooperation with international drug procurement agencies will also be promoted, to ensure that procurement decisions are increasingly based on considerations of quality, and to encourage investment in quality assurance.

**Combating counterfeit medical products**

**Background and main challenges**

Counterfeiting medical products, (including the entire range of activities from manufacturing to provision to patients), is a serious crime that puts human lives at risk and undermines the credibility of health systems. It is impossible to obtain a precise estimate of the proportion of counterfeit cases. However, the number of incidents detected in 2007 alone increased to over 1,500, i.e., an average of more than four cases each day. A collaborative study conducted by WHO, INTERPOL and other stakeholders showed that about half of the samples of counterfeit medicines collected in the Mekong subregion contained no or insufficient amounts of active substances. In addition to direct harm to patients and therapeutic failures, the presence of counterfeit medical products challenges public confidence in the entire health system, affecting the reputation of manufacturers, wholesalers, pharmacists, doctors, private organizations and government institutions alike.

Many factors help to create an environment in which the manufacture and trade of counterfeit medical products can thrive. These include: governments’ unwillingness to recognize the existence or gravity of the problem; inadequate legal frameworks and insufficient legal sanctions; weak administrative and coordination mechanisms, not geared to fighting counterfeit medical products; ineffective controls on the

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manufacture, importation and distribution of medical products; poor collaboration among authorities and institutions involved in regulation, control, investigation and prosecution (such as health authorities, police, customs, judiciary); ineffective collaboration and exchange of information between the public and private sectors; and insufficient international collaboration and exchange of information. A number of socio-economic factors, such as inadequate access to health services, and fragmented and unreliable supply channels that create opportunities for informal operators, and extraterritorial trade zones, also contribute to the problem.

Strategic direction
The problem of counterfeit medicines is generally seen within the context of substandard medical products (see section on regulatory capacity building). WHO will remain within its public health mandate as patent and trademark disputes must not be confused with counterfeiting of medical products. Medical products (whether generic or branded) that are not authorized for marketing in a given country but authorized elsewhere are also not considered counterfeit. Substandard batches or quality defects or non-compliance with Good Manufacturing Practices/Good Distribution Practices in legitimate medical products must not be confused with counterfeiting.

In 2006, following strong demand, WHO intensified its activities to build coordinated national and international action to halt the production, movement, trade and sale of counterfeit medical products through a WHO-led coalition comprised of international organizations, NGOs, medicines regulatory authorities, enforcement authorities, associations representing pharmaceutical manufacturers, wholesalers, health professionals and patients. Over the coming years, legislative and regulatory infrastructure will be strengthened, regulations will be drafted and implemented, anticounterfeit technology will be developed, law enforcement will be strengthened, and national and international communication will be improved. The web-based Rapid Alert System developed by the WHO Western Pacific Regional Office will be expanded to other regions. A comprehensive approach will be developed to combat the sale of counterfeit medical products through the Internet, encompassing legislative and regulatory measures. Enforcement support will focus on interested countries in Asia and sub-Saharan Africa.
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 programmes

Promoting the rational use of medicines

Background and main challenges

Irrational use of medicines is a major problem worldwide. It is estimated that more than half of all medicines are prescribed, dispensed or sold inappropriately and that half of all patients fail to take their medication correctly. This contributes to enormous health losses and economic waste both at a personal and a national level. In the last few years the number of countries with updated medicines lists and treatment guidelines has been increasing (figure). However, in 2007 about half of all countries were not implementing many of the fundamental, well-known, evidence-based policies that are necessary to ensure the rational use of medicines. The problem is also not limited to developing countries. For example, some industrialized countries allow or consider allowing direct-to-consumer advertising of prescription-only medicines, which is known to lead to overprescribing and irrational use.

1 The figure is based on responses to the 2007 WHO Survey on Non-communicable Diseases and Health Systems. For details, please see the report "WHO Health Systems and Medicines Situation Report 2008".

Strategic direction

Adopting the strategic direction endorsed by the World Health Assembly in 2007, WHO intends to support Member States in facilitating a multi-stakeholder approach towards a national programme to promote rational use of medicines, with the necessary infrastructure including a multidisciplinary national body, involving civil society and professional organizations. The considerable negative health and economic impacts of irrational prescribing will be used as an argument to convince national governments and international funding agencies that promoting rational medicines use contributes to aid effectiveness and should be seen as part of procurement costs. The cost of rational medicines use programmes is often a fraction of the cost-efficiencies in medicines expenditure that they result in. National plans will then be developed, based on assessments of the situation and the underlying reasons for prescribing behaviour. WHO will also strengthen its ties with other UN agencies (e.g. UNICEF, UNDP) and new players in this field such as the Global Fund, in order to assist them in developing and using evidence-based treatment guidelines and essential medicines lists based on sound economic evaluation.

Figure 2: Country interventions to promote rational use of medicines

- Drug use audit in the last 2 years
- National strategy to contain AMR
- Antibiotics DTC non-available
- Public education on antibiotic use
- DTCs in all general hospitals
- Drug information centre for prescribers
- Government DTC for doctors
- Undergraduate doctors trained in EM/STGs
- Public sector procurement limited to EM
- STGs updated in the last 2 years
- EMs updated in the last 2 years

% countries implementing policies to promote rational use

Traditional medicine

Background and main challenges

In the WHO Traditional Medicine Strategy for 2002–2005 the four general objectives of policy, access, quality and rational use have also been applied to traditional, complementary and alternative medicine (TM/CAM). Between 2002 and 2007, a large number of policy documents and international and regional guidelines and quality standards for TM/CAM have been developed (Box 7). In 2007, 48 countries reported having a policy to integrate TM/CAM with the overall health system; 110 countries had regulations for herbal medicines. Based on the progress in the field of TM/CAM a growing number of countries are interested in integrating TM/CAM into national health systems, covering all aspects of TM/CAM as well as herbal products.

New challenges that countries are facing include how to implement this integration into health systems, health insurance coverage of TM/CAM, qualification of practitioners, and evidence-based information to guide policy decisions and capacity building. The global strategy on public health, innovation and intellectual property includes a strong component of research and research capacity building in traditional medicine.

Strategic direction

WHO’s strategic direction is to facilitate the integration of TM/CAM into national health systems, with a focus on better regulation of traditional medicines and practitioners. The collection and use of better evidence on quality, safety and efficacy will be promoted. The contribution of TM/CAM to primary health care will be explored and, where relevant and possible, promoted. Special emphasis will be put on promoting and upgrading the knowledge and skill of TM/CAM providers to ensure patient safety, and to build national capacity in the field of TM/CAM according to identified country needs. Where necessary, countries will be assisted in protecting their indigenous knowledge and relevant intellectual property rights.

Box 7
Examples of standards and guidelines on traditional medicines, 2002–2007

- Global survey of national policies on TM/CAM and regulation of herbal medicines
- Four regional guidelines for minimum requirements of registration of herbal medicines
- Technical guidelines related to safety, efficacy and quality:
  - Guidelines on good agricultural and collection practices for medicinal plants
  - Guidelines on good manufacturing practice for herbal medicines
  - Guidelines on safety monitoring of herbal medicines in pharmacovigilance systems
  - Guidelines on assessing quality of herbal medicines with reference to contaminants and residues
  - Guidelines on developing consumer information on proper use of TM/CAM
  - A series of basic training guidelines for providers of TM/CAM
  - WHO monographs on selected medicinal plants (Prelates 1, 2, 3)
**Working within one WHO — supporting regions and countries**

WHO will work towards strengthening the managerial capacity of country and regional offices and will provide assistance in fundraising and donor relations. Tools will be refined or developed for planning, monitoring and reporting country activities, and their alignment among regional offices will be encouraged in order to facilitate WHO-wide reporting on progress indicators. At all levels of the Organization, staffing needs will be assessed and, where needed, addressed. Secondments, staff rotations and staff development will be encouraged.

The profile and visibility of regional and country work will be increased by inter-regional projects and knowledge sharing, support for data analysis and report writing, senior WHO staff participation in regional and country activities, and by involving regional and country staff in global activities and meetings. Countries will also be supported in periodically assessing the national pharmaceutical situation, linking to global and national goals, such as the MDGs and PHC commitments. The technical capacity of regional and country staff will be further increased by targeted dissemination of core materials, and facilitated access to relevant country information. This will also include dissemination of information on staff training opportunities, such as WHO Technical Briefing Seminars. Specific technical advice on medicine policy issues will be provided through online communications and participation in regional and country activities. The role and capacity of centres of excellence and WHO Collaborating Centres will be strengthened.

Better country programming will be supported by increasing the number of dedicated national programme officers, by improving access to relevant information, and by helping to identify priority areas for development assistance and advice. It is hoped that this approach will enable national governments to obtain maximum benefit from WHO’s technical support. Where relevant, WHO will also work with national partners outside the Ministry of Health, such as other ministries, academia, professional associations, public-interest NGOs and the private sector (the “MOH-plus” approach).

Many subregional economic blocs (such as SADC and ASEAN) are already promoting technical and political collaboration among their participating countries. As these subregional organizations become increasingly effective in promoting regional harmonization, they become increasingly relevant and cost-effective as mechanisms for technical support. WHO will therefore increase its support to such economic blocs, focusing on guiding the harmonization of pharmaceutical policies and regulatory systems.

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*Photo: E. Giampoli, WHO*

National Professional Officers meet with staff from WHO Headquarters and regions in Geneva in October 2009.
Strategic tools

Several tools are available to implement the third WHO Medicines Strategy. The use of some of these tools involves a strategic choice as well and is therefore included in this document.

Advocacy of good public health and ethical values

A long-standing function of WHO, and especially of the former Action Programme on Essential Medicines, has been the advocacy of care public health principles. In the first decades of the programme, these messages focused on promoting the concept of essential medicines in support of equity and basic health care needs as part of Health for All. These principles are now generally understood and accepted. Yet the need to promote public health principles remains, although the nature of the messages has changed. Advocacy will continue to focus on access to essential medicines as part of the fulfillment of the fundamental right to health, the promotion of medicine quality, of transparency in medicine registration, procurement and pricing, of principles of good governance and social justice, and the promotion of rational use of medicines as part of procurement costs.

The evidence base

A second strong point of WHO’s medicine programme has always been its solid foundation on highly standardized procedures and a scientific approach to develop evidence-based standards and policy guidance. This approach will be continued, and strengthened where needed (e.g., in the area of policy advice on pricing policies). The work of the five WHO Expert Committees, the three expert advisory groups and the global databases on medicine prices and medicine use studies will be continued. The Expert Committee on Medicine Policies will be re-started to focus on scientific evidence on medicine pricing, transparency, and reimbursement schemes. The accessibility of all available information to national programmes will be strengthened by improving the WHO/medicines web site and its document-search facilities.

Within-WHO collaboration

The many medicine-related activities within WHO disease programmes are both a source of concern and a further proof that there is an increasing demand for medicine-related advice and support. Collaboration with some of the disease-oriented programmes on the selection of essential medicines, quality assurance, regulatory strengthening and medicine pricing is already very structured and advanced. The new focus of the collaboration will be the development of evidence-based treatment guidelines, comprehensive supply systems and promoting rational use. Efforts will also continue to further standardize WHO’s many different methods for prequalification of priority medicines, diagnostics, reproductive health devices and vaccines. Technical collaboration within the Health Systems group will focus on PHC, support to district hospitals, medicines benefits as part of social health insurance in middle-income countries, and on planning human resources for the pharmaceutical sector.

Country support

The number of countries that are seeking WHO’s advice and support in organizing their pharmaceutical sector (currently over 80 and rapidly approaching 100) is increasing to such an extent that the regional offices and HQ find it difficult to respond to all requests. Where possible, efficiencies will be achieved by reducing the support to individual countries and increasing the support to subregional and/or economic blocs, for example in the area of regional regulatory harmonization or medicines supply strategies. However, in those countries with a real political interest, WHO’s
technical support will be intensified through the appointment of dedicated national programme officers. In those countries, the focus will shift towards better country information, comprehensive multi-stakeholder planning in strategic areas (regulatory support, procurement and supply chain management, rational use, national coordination of development agencies, UN reform) and on strengthening the medicines components of WHO’s Country Collaboration Strategies. Where possible, the medicine programme will actively support UN reform at country level. A special case will be made for setting up basic pharmaceutical systems in countries post-emergencies.

Partnerships and WHO Collaborating Centres

The programme will continue its successful partnerships. These include the bi-annual International Conference of Drug Regulatory Authorities, the six-monthly Interagency Pharmaceutical Coordination group with all UN agencies, the WHO/UN Prequalification Programme with over 50 national regulatory agencies, Health Action International with all its medicine pricing work in over 50 countries, the International Network for the Rational Use of Drugs with over 20 countries, and the more recent International Regulatory Cooperation for Herbal Medicines 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, UNITAID, public-interest NGOs, and the research-based and generic pharmaceutical industry.

A very special type of partnership exists with the many WHO Collaborating Centres. The relationship with these centres of excellence will be further strengthened. Their number will be increased, in close collaboration with the regional offices; and they will be more involved in the implementation of the strategy and programme of work. At country level, the medicine programme will be further integrated within the programme of health systems.

Human resources for the pharmaceutical sector

The increasing need for human resources and task-shifting in the pharmaceutical area will be addressed by the promotion of good undergraduate training with the focus on good pharmaceutical care. In addition, WHO will use its convening power to start a process to develop skills-based pharmacist training materials and performance-assessment tools for various levels of non-pharmacist staff performing pharmaceutical services within PHC. Policy guidance will be developed on setting priorities for such human resources in resource-poor settings and small countries. Work will also be undertaken with the International Pharmaceutical Federation (FIP) to further 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 full gender balance by increasing the number of female experts, especially from developing countries, through active invitations to briefing and training sessions and involvement in research projects, leading to membership of WHO Expert Advisory Panels and WHO Expert Committees. The very successful general Technical Briefing Seminars for WHO staff, UN staff, national counterparts and NGOs will be continued in two languages; in addition, specialist technical briefing seminars will be continued in selected areas, such as prequalification and medicine pricing.

If requested by the regional offices, efforts will be made to increase technical staff in regional and country offices and in technical areas identified by recent WHA resolutions. The very successful system of 3-month or 6-month rotational posts for experts from developing countries (as done already in the Prequalification and Selection Units) will be expanded to include 6-month rotational systems for selected NGOs to regional or headquarters departments. Secondments from developing countries will also be encouraged.
The need for essential medicines is as urgent now as it ever was. The achievement of the MDGs and the necessary elements of renewed primary health care are unthinkable without WHO’s norms and standards, policy guidance and technical support in this area. This strategic implementation plan provides practical guidance to WHO and all interested stakeholders on how the benefits of the essential medicines concept and WHO’s longstanding experience and reputation can be used to promote universal access and patient-centred health care for all.
## Annexes

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<td>32</td>
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</tbody>
</table>
Annex 1: Progress indicators and targets

Introduction

The first and second WHO Medicines Strategy documents introduced and used a set of progress indicators closely linked to the content of the strategy and the structure of the WHO Plan and Budget of that period, presenting values for most indicators for 1999 and 2003, and targets for 2007.

The current strategic implementation plan will be guided and evaluated by an improved set of indicators from two development backgrounds. Firstly, the most robust indicators from earlier strategies have been taken, mostly with their values of 1999, 2003 and 2007. Secondly, several medicine-related Country Progress indicators and selected WHO Expected Result indicators from the WHO-wide Medium-Term Strategic Plan 2008–2013 are used.

The indicators are presented in two separate groups. Country Progress indicators describe progress in the pharmaceutical field for which countries are largely responsible themselves, and for which progress may or may not be related to WHO’s technical and political support. WHO Expected Results indicators are taken from the MTSP and describe outputs for which WHO is largely (although rarely fully) responsible. In a separate table the new set of disaggregated indicators for measuring access to essential medicines at country level is presented, replacing the single access indicator, which proved unworkable in practice.

### I. Country progress indicators

#### Ower 11.1: Policy Access

<table>
<thead>
<tr>
<th>INDICATOR</th>
<th>1999</th>
<th>2003</th>
<th>2007</th>
<th>Target 2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>MeP 11.1-1: Access to essential medicines and technologies, as part of the fulfillment of the right to health, recognized in country constitutions or national legislation</td>
<td>n.a.</td>
<td>4 constitutions</td>
<td>8</td>
<td></td>
</tr>
<tr>
<td>MeP 11.1-2: Availability of 10 selected generic essential medicines in the public, private and non-governmental sectors</td>
<td>Public: 34.9% Private: 43.2%</td>
<td>100% in all sectors</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MeP 11.1-3: Median consumer price ratio for 10 selected generic essential medicines in the public, private and non-governmental sectors</td>
<td>Public: 2.5 Private: &gt; 4</td>
<td>Less than 40% of world market price</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Countries having conducted a national assessment of their pharmaceutical situation in the last 5 years: n.a.

Countries with national medicines policy/plan updated in the last 5 years:

- MeP 11.1-4: 57/133 (43%) 58/135 (43%) 62/178 (35%)
- MeP 11.1-5: 39/101 (39%) 43/100 (43%) 71/124 (57%)
- MeP 11.1-6: 71/133 (54%) 71/130 (55%) 74/114 (64%)

Countries that provide PEPFAR-supported medications free at public health facilities: n.a.

Countries in which generic substitutions are allowed in private pharmacies:

<table>
<thead>
<tr>
<th>Country</th>
<th>2005</th>
<th>2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>Botswana</td>
<td>35%</td>
<td>46%</td>
</tr>
<tr>
<td>Mozambique</td>
<td>30%</td>
<td>43%</td>
</tr>
<tr>
<td>South Africa</td>
<td>30%</td>
<td>40%</td>
</tr>
</tbody>
</table>

#### Ower 11.2: Quality

<table>
<thead>
<tr>
<th>INDICATOR</th>
<th>1999</th>
<th>2003</th>
<th>2007</th>
<th>Target 2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>MeP 11.2-1: Countries of which the national regulatory authority has been assessed</td>
<td>17</td>
<td>37</td>
<td>76</td>
<td></td>
</tr>
<tr>
<td>MeP 11.2-2: Status of national regulatory authority</td>
<td>33% basic 26% good 15% high</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Countries participating in the global programme of monitoring adverse drug reactions:

<table>
<thead>
<tr>
<th>Country</th>
<th>2005</th>
<th>2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>Botswana</td>
<td>55</td>
<td>70</td>
</tr>
<tr>
<td>Mozambique</td>
<td>34</td>
<td>64</td>
</tr>
</tbody>
</table>

#### Ower 11.3: Rational Use

<table>
<thead>
<tr>
<th>INDICATOR</th>
<th>1999</th>
<th>2003</th>
<th>2007</th>
<th>Target 2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>MeP 11.3-1: Percentage of prescription in accordance with current national or institutional clinical guidelines</td>
<td>n.a.</td>
<td>81/112 (73%) 80/112 (72%)</td>
<td>81%</td>
<td></td>
</tr>
<tr>
<td>MeP 11.3-2: Countries with a national list of essential medicines updated in the last 5 years:</td>
<td>70/133 (53%)</td>
<td>59/100 (59%)</td>
<td>50%</td>
<td></td>
</tr>
<tr>
<td>MeP 11.3-3: Countries with treatment guidelines updated in the last 5 years:</td>
<td>84/106 (80%)</td>
<td>84/100 (84%)</td>
<td>84%</td>
<td></td>
</tr>
<tr>
<td>MeP 11.3-4: Countries with Dengue and Chikungunya Committees in majority of referral hospitals</td>
<td>n.a.</td>
<td>59/109 (55%) 78/113 (68%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MeP 11.3-5: Countries with a national strategy to combat antimicrobial resistance</td>
<td>n.a.</td>
<td>44/137 (32%) 47/137 (35%)</td>
<td>50%</td>
<td></td>
</tr>
</tbody>
</table>

1. The 1999 and 2003 values refer to a 10-year updating period.
2. The data and indicators presented in this annex differ from those in previous publications due to updated information and standardization of the calculation methods over all three periods.
II. WHO expected results (MTSP 2008–13)

<table>
<thead>
<tr>
<th>INDICATOR</th>
<th>1999</th>
<th>2003</th>
<th>2007</th>
<th>TARGET 2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>MTSP 11.1.1</td>
<td>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>
</tr>
<tr>
<td>MTSP 11.1.2</td>
<td>Number of countries receiving support to design or strengthen comprehensive national procurement and supply systems</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MTSP 11.1.3</td>
<td>Number of countries receiving support to formulate and implement national strategies and regulatory mechanisms for licensed and non-licensed products</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MTSP 11.1.4</td>
<td>Publications of a biennial global report on medicine prices, availability and affordability</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MTSP 11.2.1</td>
<td>QM</td>
<td>10% per biennium</td>
<td>10% per biennium</td>
<td></td>
</tr>
<tr>
<td>MTSP 11.2.2</td>
<td>Cumulative number of original International Nonproprietary Names for medical products</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MTSP 11.2.3</td>
<td>Number of priority medicines that are prequalified for UN procurement</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MTSP 11.2.4</td>
<td>Number of countries whose national regulatory authorities have been assessed and judged satisfactory</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MTSP 11.3.1</td>
<td>Number of countries reporting progress towards regional and cost-effective use of medicines</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MTSP 11.3.2</td>
<td>Number of countries linking public-sector procurement to an WHO updated within the last five years</td>
<td>42/127 (33%)</td>
<td>51/125 (41%)</td>
<td>55/106 (52%)</td>
</tr>
</tbody>
</table>

III. New indicators for access to essential medicines

Several objectives within and outside the UN system are actively monitoring global progress towards the MDGs. The single indicator on “Access to Essential Medicines” was created by WHO in the mid 1990s and has been used since then, but that measure was exempted at MON indicators. However, we propose a new indicator in line with those and propose a “Guiding principles”.

The single access indicator has been split into several composite, measurable indicators, each reflecting various aspects of access (government commitment, national selection, affordable prices, sustainable financing, available products). Most of these are already in the WHO Medicines Strategy Plan (MTSP) for 2008-2013, and are being collected by countries and by WHO as part of the MTSP reporting system. Together these indicators present a good measure of how urgent a government is in making essential medicines available to all its population.

<table>
<thead>
<tr>
<th>INDICATOR</th>
<th>TARGET VALUE</th>
</tr>
</thead>
<tbody>
<tr>
<td>GOVERNMENT COMMITMENT</td>
<td></td>
</tr>
<tr>
<td>Access to essential medicines in line with the MDGs</td>
<td>Yes</td>
</tr>
<tr>
<td>Existence and update of national medicines policy</td>
<td>Yes, and updated within the last 18 years</td>
</tr>
<tr>
<td>NATIONAL SELECTION</td>
<td></td>
</tr>
<tr>
<td>Existence and update of national list of essential medicines</td>
<td>Yes, and updated within the last two years</td>
</tr>
<tr>
<td>AFFORDABLE PRICES</td>
<td></td>
</tr>
<tr>
<td>Public expenditure (as percentage of GDP)</td>
<td></td>
</tr>
<tr>
<td>Medicinal prices as a percentage of MDG targets</td>
<td>Below world market reference price</td>
</tr>
<tr>
<td>Percentage of population covered by national health services or health insurance</td>
<td>Country-specific index</td>
</tr>
<tr>
<td>SUSTAINABLE FINANCING</td>
<td></td>
</tr>
<tr>
<td>Public expenditure per capita on medicines</td>
<td>Country-specific index</td>
</tr>
<tr>
<td>Percentage of population covered by national health services or health insurance</td>
<td>Country-specific, ultimately 100%</td>
</tr>
<tr>
<td>RELIABLE SYSTEMS</td>
<td></td>
</tr>
<tr>
<td>Availability of essential medicines in public and private health facilities</td>
<td>80% (from national country-specific targets)</td>
</tr>
</tbody>
</table>

1. Standard WHO/WH� national survey average, weighted average of score based on country results.
2. Standard WHO/WH� indicator of national survey quality, weighted average of score based on national country results.
### Annex 2: Selected World Health Assembly and Executive Board resolutions on medicines, 1963–2009

<table>
<thead>
<tr>
<th>NO.</th>
<th>YEAR</th>
<th>TITLE</th>
<th>SUMMARY</th>
</tr>
</thead>
</table>
| 146 | 1963 | Clinical and pharmacological evaluation of drugs | Report to WMA to advise on methods to limit the availability of new drugs; to determine the validity of new drugs, a new drug in addition to the approval of a new drug by the approval of a new drug by the Committee on the availability of new drugs. 
| 158 | 1965 | International standardization of amines in medicine | Implement the preimplementation plan aimed at establishing an international system for the standardization of amines in medicine. 
| 207 | 1966 | The national use of drugs | Establish a detailed drug strategy. 
| 250 | 1968 | Action Programme on Essential Drugs | Strengthen support for the provision of the essential drugs and programs as part of the national strategy. 
| 353 | 1975 | Nontoxic substances for pharmaceutical purposes | Reduce the potential of new drugs in medicine to be used as nonpharmaceutical substances. 
| 445 | 1977 | WHO Clinical Criteria for Medicinal Drug Promotion | Establish a framework for the development and promotion of new drugs. 
| 528 | 1985 | Quality of biologic products meeting in international commerce | Establish the WHO's Action Programme on International Trade. 
| 563 | 1986 | Guidelines for the WHO Drug Certification Scheme | Establish a system for the certification of biologic products. 
| 579 | 1986 | Emerging and other communicable diseases in international trade | Implement the national strategy on the use of drugs and WHO's Action Programme on International Trade. 
| 591 | 1986 | Cross-border advertising, promotion and sale of medical products using the Internet | Establish the national strategy on the use of drugs and WHO's Action Programme on International Trade. 
| 634 | 1990 | WHO/UNICEF coordinating the activities | Implement the national strategy on the use of drugs and WHO's Action Programme on International Trade. 

*Note: The above table is a partial list and may not include all relevant resolutions.*
<table>
<thead>
<tr>
<th>Code</th>
<th>Year</th>
<th>Title</th>
<th>Text</th>
</tr>
</thead>
<tbody>
<tr>
<td>W14.41</td>
<td>2001</td>
<td>WHO-Medication Strategies</td>
<td>Stimulate development of drugs for disease in developing countries, support efforts for monitoring drug prices, support drug monitoring systems, study effect of trade agreements on public health, support countries to set up regulatory systems for quality assurance and compliance with US standards and harmonization, work on traditional medicines; RUPPD to WHO-MS to collaborate on progress of indications to allow access to essential drugs.</td>
</tr>
<tr>
<td>W14.43</td>
<td>2001</td>
<td>Setting up the response to HIV/AIDS</td>
<td>Focus on research, development, and new pharmaceutical strategies, support achievement of disease targets and approved interventions to improve health and reduce mortality from HIV/AIDS.</td>
</tr>
<tr>
<td>W14.44</td>
<td>2001</td>
<td>Global health security: epidemiological and surveillance</td>
<td>Support countries to develop information that prevent epidemics and rapid communication among countries, provide technical support to national efforts to prevent and respond to outbreaks of bioterrorist attacks.</td>
</tr>
<tr>
<td>W14.51</td>
<td>2002</td>
<td>Reassessing accessibility of essential medicines</td>
<td>Focuses on Independent Expert Committees on the Selection and Use of EIs, needs of countries, EIs and Phe values, presents differential policy of EIs between developed and developing countries, assesses IEs to be used for humanitarian purposes, such as education of prions for the world, countermeasures to prevent, control, and eradicate diseases.</td>
</tr>
<tr>
<td>W14.53</td>
<td>2003</td>
<td>Traditional medicines</td>
<td>Support countries to formulate policies and regulations of traditional medicines, to increase safety, efficacy, quality and assess needs of products, to provide assistance, to collaborate with other countries and organizations to protect traditional medicines and improve quality of traditional medicines; RUPPD to WHO-MS to collaborate on progress.</td>
</tr>
<tr>
<td>W14.57</td>
<td>2004</td>
<td>Setting up research and use within a coordinated and comprehensive response to HIV/AIDS</td>
<td>Improve access of developing countries to pharmaceuticals and diagnostic products, including strengthening of pharmaceutical and diagnostic programs, access to essential medicines, human body therapy, and vocational training.</td>
</tr>
</tbody>
</table>


<table>
<thead>
<tr>
<th>Code</th>
<th>Year</th>
<th>Title</th>
<th>Text</th>
</tr>
</thead>
<tbody>
<tr>
<td>W15.04</td>
<td>2003</td>
<td>International nonproprietary names: mutual recognition</td>
<td>The Committee on Essential Medicines (CEM) to promote and facilitate adoption of WHO-MS.</td>
</tr>
<tr>
<td>W15.22</td>
<td>2005</td>
<td>Cancer prevention and control</td>
<td>Improve WHO capacity to promote and control. RUPPD to provide support to enhance capacity of RUPPD to WHO.</td>
</tr>
<tr>
<td>W15.24</td>
<td>2006</td>
<td>Improving the containment of antimicrobial resistance</td>
<td>Accelerate implementation of resistance. WHO-MS to continue to work with the countries on the national and global level.</td>
</tr>
<tr>
<td>W15.25</td>
<td>2006</td>
<td>Pharmaceutical support for health research</td>
<td>WHO-MS to support the countries in the development of national health research programs.</td>
</tr>
<tr>
<td>W15.26</td>
<td>2006</td>
<td>Public health, innovation, and research and development</td>
<td>WHO-MS to support the countries in the development of national health research programs.</td>
</tr>
<tr>
<td>W16.15</td>
<td>2007</td>
<td>Progress in national control of diseases</td>
<td>WHO-MS to encourage and support the countries to adopt control and surveillance strategies.</td>
</tr>
<tr>
<td>W16.17</td>
<td>2007</td>
<td>Better medicines for children</td>
<td>WHO-MS to support the countries in the development of national health research programs.</td>
</tr>
<tr>
<td>W16.18</td>
<td>2007</td>
<td>Public health, innovation, and research and development</td>
<td>WHO-MS to encourage and support the countries to adopt control and surveillance strategies.</td>
</tr>
<tr>
<td>W17.12</td>
<td>2007</td>
<td>WHO Committee on the Selection and Use of Essential Medicines: establishment of a subcommittee</td>
<td>Establish a subcommittee to facilitate the implementation of the Committee on the Selection and Use of Essential Medicines.</td>
</tr>
<tr>
<td>W17.53</td>
<td>2008</td>
<td>Medicines policy and medicines in the Eastern Mediterranean Region</td>
<td>Promote networking among countries through a regional forum, to share information on national policies and programs, support countries in networking and monitoring progress, and implement a regional framework for the WHO-MS program.</td>
</tr>
<tr>
<td>W18.23</td>
<td>2008</td>
<td>Global strategy and plan of action on public health, innovation, and IT</td>
<td>Establish a strategy and plan of action on public health, innovation, and IT.</td>
</tr>
<tr>
<td>W18.24</td>
<td>2008</td>
<td>Primary health care, including health systems strengthening</td>
<td>WHO-MS to support the countries in the development of national health research programs.</td>
</tr>
<tr>
<td>W18.28</td>
<td>2009</td>
<td>Traditional Medicines</td>
<td>WHO-MS to support the countries in the development of national health research programs.</td>
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</table>
Annex 3: Support to countries/territories in the field of essential medicines, 2008-2009