

# WHO Medicines Strategy 2008-2013

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## Status of this document

*This is a working draft of the WHO Medicines Strategy for 2008-2013, intended to reflect essential components of earlier inputs and to invite further comments. It presents the main components of the strategy as currently proposed. After review by all major stakeholders the final document will be submitted for endorsement by the Director-General.*

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## Achievements

### Box 1

#### **Impact of the previous Medicine Strategy (2004-2007)<sup>1</sup>**

In the period under review the WHO Medicines Strategy was widely recognized and used as WHO's long term strategy in the field of medicines. The strategy document was used in the promotion and development of national medicine policies, and the prioritization of country level activities. It was also used as a guide for fundraising, for the identification of new targets and outcomes, 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.

The external review in 2007 identified the following particular achievements in 2004-2007:

- Increased number of countries with a national medicine policy and implementation plan
- Rapid expansion and performance of the WHO/UN prequalification programme
- Innovative standard methodology and large number of national medicine pricing surveys
- Increased number of national programmes with full-time staff (national programme officers)
- Development of the good governance programme in pharmaceutical management, in many countries
- Large number of global norms and standards for traditional medicine

### Box 2

#### **Summary achievements of 30 years of essential medicines (1977- 2007)**

##### The concept of essential medicines

- Essential Medicines has become a universal concept and 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 undisputed global conceptual and technical leader in this field; there is a stable technical programme with a strong number of highly qualified and respected experts
- The concept has become the guiding principle in most pharmaceutical programmes in developing countries, and is widely supported by UN, bilateral agencies and NGOs

##### Medicine policies

- Clear global guidance is available on developing and implementing national medicine policies; over 100 countries have developed national medicine policies
- Thousands of professionals from developing and developed countries have been trained in medicine policies, quality assurance, good manufacturing, pricing surveys, supply, promoting rational use, etc
- In the last decade there have been several examples of innovative public health thinking and medicine policy initiatives (e.g. impact of TRIPS, prequalification, medicine prices survey methodology, right to health)

##### Access

- Several global and regional price information services are available
- Standard indicators for assessing availability, price and affordability are available, have been used in 50 countries and are now accepted as the global WHO standard for measuring access
- Global standards for essential medicines in emergencies and donations widely respected and used

##### Quality, norms and standards

- Global assignment of International Nonproprietary (generic) Names (over 100 new INN's per year)
- Standard procedures for WHO quality norms and standards, with focus on new essential medicines
- International Pharmacopoeia has become the primary global reference for the quality of new essential medicines; continuously updated and published in hard copy, CD and on-line

<sup>1</sup> Andy Gray and Fatima Suleman. Assessment of implementation, impact and process of the WHO Medicines Strategy 2004-2007. Geneva: WHO, 2007. Document TCM/PSM/2007.\*\*\*

- WHO / UN prequalification project for priority medicines, diagnostics and commodities for HIV/AIDS, tuberculosis and malaria, reproductive health; the programme includes major capacity building of national regulatory agencies, quality control laboratories and selected manufacturers
- Global pharmacovigilance network, with targeted projects for new essential medicines in resource-poor settings (malaria, HIV, children)

#### Selection and rational use

- WHO Model List of Essential Medicines, updated every 2 years since 1977, has become a global model process and model product; first Model List of Essential Medicines for Children (2007)
- Over 150 countries have national lists and over 130 have national treatment guidelines
- Standard indicators for assessing medicine use are universally applied in resource-poor settings
- Global database and strong evidence for interventions to promote rational prescribing

#### Traditional medicine

- The role of traditional medicine and its providers in Primary Health Care was recognized in Alma Ata in 1978. The use of traditional medicine has increased dramatically worldwide
- There are an increasing number of countries with a national research institute on traditional medicine and herbal medicines; an increasing number of countries include traditional medicines on 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 medicines.

## Introduction

WHO's concept of essential medicines remains as relevant today as it was at its inception over thirty years ago. For example, nearly 30,000 children die every day from diseases which could easily be treated if they had access to a basic range of essential medicines. But there is not only a problem of lack of access. In a recent UNFPA study, 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 fake. Even if medicines are available and of assured quality, in many countries up to half of all prescriptions are unnecessary or incorrect. In addition, in about half of cases the patients do not take the medicines as prescribed.

In 1978 the Alma Ata conference identified the availability, quality and rational use of essential medicines as one of the components of primary health care. Now, after three decades of disease-oriented, vertical approaches, the need for comprehensive health care and strengthened health systems has become apparent again.

This document describes how WHO intends to fulfil its medicine-related commitments in the WHO 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 this SO, there are three Organization-wide Expected Results (Box 3). This document also describes how WHO intends to support the achievement of the health-related Millennium Development Goals (MDGs) - (page 6). 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.

## Target audience, development process

The WHO Medicines Strategy is intended for use by WHO staff, Member States, core development partners, NGOs and other stakeholders in the pharmaceutical sector. It was developed through a two-year process which included an analysis of country needs, a review of the experiences with the implementation of the previous WHO Medicines Strategy, an analysis of programme components which would benefit from change, and several rounds of consultations with an increasing number of stakeholders. Those consulted include all medicine-related WHO staff in country, regional and global programmes, all Member States, WHO departments involved in the development of SO-11 of the MTSP, other WHO departments, UN agencies involved in pharmaceutical programme support, public-interest non-governmental organizations, the research-based and generic pharmaceutical industries, and interested governmental and private donor organizations.

### Box 3

#### Objectives of the WHO Medicines Strategy

1. Describe how WHO intends to contribute towards the achievement of the health-related Millennium Development Goals, the implementation of recent World Health Assembly resolutions, the WHO Medium-Term Strategic Plan for 2008-2013 and the priorities of the Director-General
2. Within this strategic landscape, present priorities for action by WHO as a guide for future investment and planning decisions
3. Provide a brief and user-friendly advocacy and information tool for stakeholders

### Box 4

The concept of essential medicines is one of the major public health achievements in the history of WHO. It is as relevant for the world of today as it was at its inception 30 years ago.

*Dr Margaret Chan, Director-General of the World Health Organization*

## Strengths and weaknesses of the Medicines Programme

The external review of the impact of the previous Medicines Strategy, as well as several strategic discussions within WHO, have included a SWOT analysis. The key points are summarized below.

### Strengths

The major strength of the programme 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 have a solid track record and reputation of 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 of systematic support to regional and national programmes, and of effective collaboration with ministries and other partners such as NGOs and collaborating centers.

### Weaknesses

The major weakness of the programme is that it is under-resourced and stretched (both financially and with regard to staff) in most subject areas and in all three levels of the organization (HQ, regional and country offices). A large and growing amount of information and evidence is available but is not always easily accessible. There is also a perceived lack of systematic planning at country level. With regard to national policies, there is insufficient involvement of the private sector and civil society, and insufficient

donor interest for some components of the work plan such as promoting horizontal health systems at country level.

#### Opportunities

There are many opportunities. For example, there is a growing need for global quality standards of 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 growing; and the medicine pricing surveys in over 50 countries have now 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 out of pocket. A major opportunity is the renewed interest in strengthening health systems based on Primary Health Care as the basic approach to promoting universal access and the increasing demand for evidence-based policy advice in general. In both cases the programme has a solid reputation and great potential. The expanding network of over 30 national programme officers presents opportunities for greater country level impact in all areas of WHO's work in medicines.

#### Threats

The major threat, although not new, is the donor's preference for quick solutions and for a disease-oriented approach to programme delivery. Examples are the many separate medicine procurement mechanisms, vertical medicine distribution systems and, more recently, disease-focused pharmacovigilance systems. Several large global programmes within and outside WHO have started their own medicine groups, e.g. on medicine pricing and procurement, without the necessary recognition of WHO's global normative functions and existing programmes.

## **Trends, challenges and gaps in the global pharmaceutical situation**

The new WHO Medicines Strategy must address the following trends and challenges. First of all, there is increasing recognition that vertical programmes also need horizontal health systems for issues which are common to all disease programmes, such as selection of essential medicines, registration, quality assurance, procurement, supply and rational use. This also applies to the many new global funding mechanisms for essential medicines that need global health policy direction, global standards and technical support from WHO. At the same time, the increasing number of players and partnerships complicate the strategic and operational landscape and need a multi-stakeholder ("MOH-plus") approach and coordination at country level.

The priorities of the Director-General on promoting PHC and improving the health status of the people of Africa and women imply the need to re-shape PHC, to renew the focus on the public sector and essential medicines. Increasing involvement of the private sector also implies an increased need for social health insurance and medicine reimbursement schemes, and the need for effective regulation. With regard to policy and technical issues, there is definitely more interest in medicine quality and quality assurance systems, which implies the need for practical global standards and support to national regulatory agencies. There is also an increased need for, and interest in, programmes to combat counterfeit medicines and promote good governance. Interest in intellectual property is shifting from global TRIPS discussions towards technical support to countries and practical implementation of existing provisions and recommendations. Recent WHA resolutions on medicine pricing, intellectual property, rational use and better medicines for children imply the need for fundraising and recruitment to expand work in these areas.

Besides these challenges, there are also several gaps in current pharmaceutical systems. The potential to reduce medical and economic waste through more rational use of medicines is insufficiently recognized by donors and national governments, despite a clear WHA resolution in 2007. More advocacy is needed to present the costs of promoting rational use as part of medicine procurement costs. There are also three

categories of patients with serious problems in accessing essential medicines. The first are children, for which insufficient age appropriate medicines exist, or for which existing medicines are insufficiently accessible in low- and middle-income countries. The second group refers to those in need of controlled medicines such as opioid analgesics for terminal care or substitution treatment of substance abuse. The third group consist of the many farm laborers, women and children who suffer from rabid dog bites or snake bites, and for whom the therapeutic sera are not available, largely through market failure and as part of the larger problem of lack 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 Strategic Landscape in 2008

Apart from the general trends and challenges summarized above, the WHO Medicines Strategy should also be responsive to the total strategic landscape, which is considerably more complicated than a decade ago. Main strategic determinants now include the Millennium Development Goals, WHO's overall strategic direction for 2008-2013, the changing aid architecture and UN reform, and the DG's priorities. Each of these are briefly presented below.

### Medicine-related Millennium Development Goals

Three out of eight Millennium Development Goals (MDGs), 8 of 16 MDG targets and 18 of 48 MDG indicators are health-related. Most health targets can not be reached without medicines (Table 1). From this table it can be seen that access to essential medicines in developing countries is a target in itself. 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 trading and financing systems, and addressing the needs of least-developed countries are specifically mentioned as separate targets.

Table 1

**Medicine-related Millennium Development Goals (MDGs), health targets and indicators**

Medicine-related MDGs	Medicine-related health targets	Medicine-related health indicators
Goal 4: Reduce child mortality	Target 5: Reduce by two-thirds, between 1990 and 2015, the under-five mortality rate	13. Under-five mortality rate 14. Infant mortality rate
Goal 5: Improve maternal health	Target 6: Reduce by three-quarters, between 1990 and 2015, the maternal mortality ratio	16. Maternal mortality ratio
Goal 6: Combat HIV/AIDS, malaria and other diseases	Target 7: Have halted by 2015 and begun to reverse the spread of HIV/AIDS	18. HIV prevalence among pregnant women aged 15-24 years 19. Condom use rate of the contraceptive prevalence rate
	Target 8: Have halted by 2015 and have begun to reverse the incidence of malaria and other major diseases	21. Prevalence and death rates associated with malaria 22. Proportion of population in malaria-risk areas using effective malaria prevention and treatment measures 23. Prevalence and death rates associated with tuberculosis 24. Proportion of tuberculosis cases detected and cured under DOTS
Goal 8: Develop a global partnership for development	Target 12: Develop further an open, rule-based, predictable, non-discriminatory trading and financial system	
	Target 13: Address the special needs of the least developed countries	
	Target 17: In cooperation with pharmaceutical companies, provide access to affordable, essential drugs in developing countries	46. Proportion of population with access to affordable essential drugs on a sustainable basis (as defined by WHO)

## The WHO Medium-Term Strategic Plan for 2008-2013

In 2006 and 2007 WHO went through an organization-wide exercise to define its medium-term strategic plan (MTSP) for the next six years. Within this plan<sup>2</sup>, which was adopted 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 plus the WHO Secretariat. Within the plan, 13 strategic objectives 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 expected results (Box 5) which describe, and to a certain extent define, the strategic directions in the field of medicines. The WHO Medicines Strategy is intended to provide more detail within the overall WHO strategic direction already adopted by the Member States.

*Box 5*

### Medicine-related Strategic Objective and Organization-Wide Expected Results for 2008-13

#### Strategic Objective 11:

To ensure improved access, quality and use of medical products and technologies

#### Organization-Wide Expected Results (OWERs):

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

## The changing aid architecture, UN reform and country support

There is increasing recognition in the development community 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 of the major donors have pledged that aid should focus on the Millennium Development Goals; 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 and joint planning. Other developments, besides the continuation of sector-wide approaches (SWAPs) include the PRSPs (poverty reduction strategic plans) and MTEFs (medium term expenditure frameworks). In other words, the intention is to move towards more aid, better aid, and better coherence. In line with these pledges some of the major bilateral donors and the World Bank are increasingly shifting from programme support to sector- or general budget support; and some UN agencies do the same. For example, in 27 countries UNFPA participates in SWAPs, and in 10 of those in sector-wide ("basket") funding. There is a crucial role for WHO in guiding the alignment of these national aid coordination frames to support national public health goals.

## The priorities of the Director-General

In the course of her campaign and transition period WHO Director-General, Dr Margaret Chan, has met with a large number of Member States, UN agencies and other stakeholders. Based on their observations, expectations and recommendations, she has formulated the following six strategic priorities for her five-year tenure (2007-2012).

<sup>2</sup> WHO Medium Term Strategic Plan 2008-2013. Geneva: WHO, 2007. A/MTSP/2008-2013

Fundamental needs: Health development and health security. Health development should be linked to the Millennium Development Goals, pro-poor policies and fairness in health. This implies attention to those people with the largest burden of disease, such as women and children (reproductive health, immunizations), priority diseases (HIV/AIDS, tuberculosis and malaria), chronic diseases, 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 implies 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: manage partnerships and improve performance. WHO must channel the new political enthusiasm and unprecedented global funding for health in developing countries. WHO will promote integrated service delivery and set the global health agenda based on technical evidence. WHO will focus on a coordinating role rather than trying to do everything, and focus 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 UN reform.

It is clear that WHO's medicines programme fits very well within these strategic approaches. The concept of essential medicines, with its focus on equity, sustainability and comprehensive health care fits perfectly in the new approach to strengthening comprehensive health systems through primary health care. But the same applies for the 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 to further expand partnerships with other UN agencies, NGOs and other stakeholders.

## **STRATEGIC DIRECTIONS AND PRIORITIES FOR 2008-2013**

### **Continuity versus 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: the development and promotion of global norms and standards and medicine-related information and evidence; the work on intellectual property rights and medicines prices; and capacity building at country level, especially in the area of national medicine regulation.

There are also a number of areas in which the need for change is recognized. Subject areas in which new or additional attention is needed are: (1) essential medicine benefits as part of health insurance, social protection and the promotion of primary health care; (2) transparency and good governance; (3) the rights-based approach to improving access to essential medicines; and (4) promotion of regional and subregional structures and collaboration. With regard to process, there is a need for (5) better programming at country level; (6) better ways to measure progress and impact; (7) better planning of WHO's human resources across the various levels of the organization; and (8) better within-WHO coordination in the field of medicines; and (9) better resource mobilization, especially for country programmes.

## Setting of priorities for action

It is outside the scope of this strategic document to describe in detail all the ongoing and future work of the medicine programme. The strategic direction and approaches for the core components of WHO's medicines work are therefore summarized in Annex 1. All these components are already included in the Medium Term Strategic Plan (MTSP) for 2008-2013.

Priority setting is linked to the strategic landscape described above, by indicating for each of the components listed, to what extent the activities 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 DG's stated priorities. The more of these criteria apply, the higher the priority of the activity. The second column in Annex 1 indicates strategic directions and activities which will be continued; the third column indicates areas of new strategic focus.

## 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 re-orientation of WHO's strategic direction. In the following pages a number of these priority areas are presented in more detail. For most of these subjects separate, more detailed strategic documents are available or in preparation.

## 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 Model List of Essential Medicines. Similarly, renewed PHC in the 21<sup>st</sup> 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, and supported by essential referral systems where needed. PHC services are delivered through public, private-not-for-profit (e.g. faith-based) facilities, and private for profit facilities. However, public funding is largely insufficient (except for the three major diseases) and most services are paid out-of-pocket. The quality of most medicines circulating in developing countries is not assured, and regulation of products and services is very weak. About half of all prescriptions are incorrect and up to half the patients do not adhere to treatment; yet there is little political and professional interest in promoting rational prescribing and preventing the huge medical and economic waste. In short: PHC services are usually scarce, mostly of poor quality and always expensive.

### *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 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 essential medicines for PHC and the necessary referral systems. In this regard, additional emphasis will be placed on the needs of district hospitals.

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

Stronger emphasis on human rights and social justice, as seen in the last decade, strengthens the need for universal access to essential medicines. Access to essential medicines as part of the progressive

realization of the right to the highest attainable standard of health will therefore be promoted as one of the key indicators to assess national progress towards social justice and the achievement of the MDGs. This is also intended to empower patients and consumers.

Universal access to PHC also depends on the real and perceived quality of care (convenience, rational use, medicine availability and price). For example, many consultations are now for chronic diseases for which follow up times are predictable. They should be based on appointments and take into account patient working hours to reduce loss of income. Approaches to promoting rational use by prescribers and consumers are strongly supported by scientific evidence on effective interventions, and these will be promoted through national programmes (see also page 13). Towards the major funders of essential medicines, rational use programmes will be presented as part of aid effectiveness and as a necessary part of procurement costs.

Careful selection of the basic package and good economic analysis are needed to promote cost-effective use of resources. Medicine price information from over 50 countries has shown the high prices of medicines and the high level of taxes and margins; but also the financial advantage of generic policies and the benefits of strengthening the public sector. In most countries, generic medicines are 3-5 times cheaper than the same branded products; and prices in private-for-profit facilities 2-5 times higher than in the public sector. Yet, in many countries the cheaper generic medicines are often out of stock in the public sector. These price and availability variations have a great impact on the affordability of medicines for the poor and disadvantaged, which are mostly paid out-of-pocket. Wherever possible, systems of national or subsidized health insurance for a basic package including essential medicines will therefore be promoted, in collaboration with health systems experts, as the most equitable approach to achieve universal access and the best incentive to promote the rational and cost-effective use of resources.

## 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. WHO and partners have made progress in documenting current supply systems, and in the development of assessment tools and training materials. There are also robust methods for selection of medicines through national essential medicines lists, and in some countries, through health insurance schemes. Corruption has been identified as a major obstacle in development work, including in medicine management systems; and the new WHO programme on good governance includes a technical package to promote transparency, accountability and good governance principles in medicine procurement and pricing. Yet many challenges remain (Box 6).

### *Box 6*

#### **Challenges in supply management**

1. The large number of different partners with their own medicine supply strategy has led to a lack of coordination of supply systems, resulting in duplication, inefficiency and increased workload, especially at the facility level. The selective approach for priority diseases has neglected other important conditions (e.g. chronic diseases, common diseases in children)
2. Investment in the health care sector has remained low, especially in Africa, with decreases in national government budgets for essential medicines, and a decrease in external resource flows in some cases
3. Little attention has been given to 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
4. The infrastructure and human resources to support medicines supply systems have generally been neglected. Routine information systems are weak and a lack of information for planning makes monitoring of performance and evaluation of efficiency challenging. Investment in logistic requirements is deficient.

5. Selection of products for procurement is not always based on appropriate methods. Consequently, there are poor linkages between national medicines lists, medicines actually purchased and supplied, and those prescribed to the patients
6. External supply system assessments are often simply descriptive without linkages between strategic national medicine policies, previous recommendations and trends over time; compounded by a lack of follow up and political commitment to implement recommendations
7. Although training has been supported extensively, coherent and sustainable development of human resources to ensure appropriate medicines management has not taken place
8. Many supply management tools are available but very few are evaluated for usefulness and impact. Disease specific programmes often duplicate them, most are in English only and there is no agreed set of interventions that have been shown to be effective in improving supply of medicines
9. The optimal interaction needed between drug regulatory authorities and medicines procurement systems to ensure quality of medicines throughout the supply chain is not well defined. This gap in normative guidance leads to duplication of human resources, and a lack of coherence between quality assurance activities, and of systematic enforcement and sanctions.

*Strategic direction*

First of all, better coordination of all activities in medicines management will be promoted. At country level, the 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. It will also be tried to replicate the successful global interagency collaboration at the national level, and link this with UN reform where possible. Within WHO, the development of tools and the collaboration with regions and countries will be better coordinated between departments.

In addition, a package of evidence-based interventions will be identified that can be used by all partners to improve supply management systems, taking account the role of WHO in countries, the private sector, health insurance systems and different levels of income. The further development of this package will be supported by the establishment of an international expert panel on medicine supply issues. Based on this package, countries will be assisted individually with solid policy guidance on good governance and transparency, the management and regulation of supply systems, human resources planning and management, and donor coordination. This strategic approach will optimize WHO's capacity, mandate and good reputation to provide leadership in medicine supply policies based on evidence, its existing expertise in selection processes, quality assessment and registration of medicines; and its expanding network of national programme officers.

## **WHO / UN Prequalification of priority medicines**

*Background and main challenges*

The main partners involved in the WHO / UN Prequalification Programme (PQP), doing most of the assessments and inspections, are the National Regulatory Agencies (NRAs) in developed and developing countries. UN agencies, international financial bodies and procurement agencies (such as the Global Fund, World Bank, UNICEF and 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 positive results produced over the last six years have raised the issue of expanding the scope of the PQP, such as products for reproductive health, neglected diseases, diarrhoea, avian flu and children's medicines. The PQP is also expected to address a growing demand for capacity building and technical assistance activities towards NRAs, national medicine quality control laboratories, and manufacturers in developing countries.

*Strategic direction*

The main strategic direction 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 is a public good, and will thus be made available for use by Member States and all interested parties, including NRAs. One important other strategic objective, since the beginning of the programme, has been regulatory capacity building in less resourced countries. More recently this has been expanded with technical assistance and capacity building for selected promising manufacturers in developing countries, committed to come up with production of medicines meeting international standards.

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

The prequalification programme is by nature unique, as regulators from well and less resourced countries work together. This contributes to the global harmonization of regulatory activities, to building trust and implementation of mutual recognition processes. Close cooperation will also be promoted with international drug procurement agencies, to incorporate quality as a prerequisite for procurement decision, and to encourage investments into quality.

## **Combating counterfeit medicines**

### *Background and main challenges*

Counterfeiting medical products, including the entire range of activities from manufacturing to providing them 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 has increased to over 1500, i.e. more than 4 cases each day. A collaborative study conducted by WHO, INTERPOL and other stakeholders has shown that about half of the samples of anti-malarials collected in the Mekong sub-region contained no or insufficient amounts of active substances.<sup>3</sup> 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. WHA resolutions 41.16, 47.13, and 52.19 recognize the threat posed by counterfeit medical products and request WHO to support Member States in their efforts to combat the manufacture, trade and use of counterfeit medical products.

Many factors contribute to creating an environment in which manufacture and trade of counterfeit medical products can thrive. Some of these are: governments' unwillingness to recognize the existence or gravity of the problem; inadequate legal framework and insufficient legal sanctions; weak administrative and coordination measures, not focused on fighting counterfeit medical products; ineffective control on medical products manufacturing, importation and distribution; ineffective 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 public and private sector; and insufficient international collaboration and exchange of information.

In addition to the ubiquitous factor of corruption, there are a number of socio-economic factors which also support an environment in which counterfeits can flourish. These include national drug policies that prioritize economic over public health aspects of medicine manufacturing; extremely fragmented distribution channels; extraterritorial trade zones which are substantially out of regulatory and enforcement oversight; inadequate access to health services and unreliable pharmaceutical supply channels that create opportunities for informal operators; and illiteracy and poverty

<sup>3</sup> <http://medicine.plosjournals.org/perlserv/?request=get-document&doi=10.1371/journal.pmed.0050032>

*Strategic direction*

Against this background WHO, in 2006, launched IMPACT, the International Medical Products Anti-Counterfeiting Taskforce, which aims to build coordinated action across and between countries to halt the production, movement, trading and selling of counterfeit medical products around the globe. IMPACT is a coalition comprised of all the major anti-counterfeiting players including: international organizations, non-governmental organizations, medicines regulatory authorities, enforcement authorities, associations representing pharmaceutical manufacturers, wholesalers, health professionals and patients.

IMPACT has identified five areas that need to be simultaneously addressed. Legislative and regulatory infrastructure will be strengthened, regulations will be implemented, anti-counterfeit technology will be developed, law enforcement will be strengthened, and national and international communication will be drastically improved. Work plans include disseminating and promoting the documents already developed, expanding the web-based Rapid Alert System developed by the WHO Western Pacific Regional Office in order to make it available to all regions; building a comprehensive approach to combating the sale of counterfeit medical products through the Internet encompassing legislative and regulatory measures; and initiatives focused on the specific needs and problems in sub-Saharan Africa.

**Promoting the rational use of medicines***Background and main challenges*

Irrational use of medicines is a major problem world-wide. 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 them correctly. This contributes to enormous health and economic impacts both at a personal and national level. Many different aspects of health policies and systems involving many different stakeholders influence how medicines are used. More than half of all countries are not implementing many of the well-known evidence-based basic policies, which are necessary to ensure rational use of medicines. For example, in 2003 only about 60% of countries had clinical guidelines updated in the previous five years; just over 70% had a national essential medicines list but only 30% used this list for insurance reimbursement.

A major reason for this lack of implementation is that promoting rational use of medicines has received little political attention, has not been institutionalized within health systems in many countries and is therefore lacking a national structure for developing, coordinating and monitoring policy. Many rich nations have adapted their health systems to address this issue by setting up national systems for medicines selection, prescription monitoring, obligatory continuing medical education, etc. Unfortunately, few low- and middle-income countries have done this.

*Strategic direction*

The following strategic direction was discussed and endorsed by the 60<sup>th</sup> World Health Assembly in 2007. The thrust of WHO's Medicines Strategy 2008-2013 will be 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 health and economic impacts of irrational prescribing will be used as an argument to convince national governments and international funding agencies that promoting rational medicine use contributes to aid effectiveness and should be seen as part of procurement costs. It is estimated that rational use programmes can lead to 50-70% cost-efficiencies in medicine expenditure.

To assist Member States in changing their health systems, WHO will also strengthen its own infrastructure and way of working. This will involve setting up a small team of dedicated senior public health specialists, based mostly in the regions. Their role will be to facilitate the multi-stakeholder process at the national level in selected countries where problems in medicines use will be identified and addressed in coordinated way. A quality improvement cycle will be set up involving the identification and prioritization of problems, implementation policies and interventions to correct the problem followed by evaluation of impact. By facilitation of such activities it is hoped to establish a national process and infrastructure for promoting rational use of medicines and improving quality of care.

A three-step approach will be used. Firstly, a standardized method will be developed for undertaking national situational analysis with regard to how medicines are used and its underlying causes, including the related topics of antimicrobial resistance and PHC. The second step is to implement and evaluate some national plans of action. Thirdly, an external evaluation will be performed after five years to review progress made across the selected countries. At that stage further practical recommendations will be formulated on promoting rational use at a national level, on the type of health systems issues which must be addressed (e.g. service delivery, health workforce, availability of information, availability of essential medicines, financing and good governance), on the role that civil society can play in developing national programmes and infrastructure; and how to expand to more countries.

Many information tools and training courses are available and will be used to support the process, particularly with regard to methods of monitoring medicines use and interventions to promote rational use of medicines. WHO will also continue to support selected research programmes that address known gaps with regard to promoting rational use of medicines such as patient adherence in chronic diseases, quality use of medicines in hospitals, scaling up interventions in primary health care and combating inappropriate drug promotion. Also important is a systematic approach to pre-service training of health personnel.

## 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). In 2002-2007 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 have 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 besides herbal products. New challenges that countries are facing include issues such as how to implement this integration, health insurance coverage of TM/CAM, qualification of practitioners, and evidence-based information to guide policy decisions and capacity building.

### *Box 7*

#### **Examples of standards and guidelines on traditional medicine, 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 practices 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 (Volume 1, 2, 3).

### *Strategic direction*

With regard to policy, WHO's strategic direction is to facilitate the integration of TM/CAM into the 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 the providers of TM/CAM to ensure patient safety; and to build national capacity in the field of TM/CAM according to the identified country needs. Where needed, countries will be assisted in protecting the intellectual property rights on their traditional knowledge.

## Evidence and information for medicine policies

### *Background and main challenges*

Over the last decades WHO and its many partners in government, academia and civil society have generated a large amount of research reports, norms and standards, statistical and survey information, policy guidance, references and training materials. While many, if not most of these, are highly relevant and of excellent quality, there is a need to continue to ensure a transparent and evidence-based process of priority setting, evidence-based development, validation, external review and targeted dissemination of these materials; and to ensure that they are accessible in different languages and are regularly updated. There is also a special need to ensure that all information relevant to a particular country is easily accessible in such a way that it can be used for setting policy directions and programme priorities.

### *Strategic direction*

To this end WHO will first assess the country needs for medicine-related information. This assessment will be compared with the information currently available, and gaps will be identified. Data identification and collection will then be undertaken with all possible partners, including countries, other departments, other UN agencies and WHO Collaborating Centres. Standardized methods, analytical tools and reporting systems will continue to be developed. 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 much as possible, be rationalized and linked.

The main approach to information management and planning will be to systematically improve the collection, processing and analysis of information which is uniquely available with WHO (such as the pharmaceutical sector surveys, national medicine policies, national medicine lists) and link these to medicine-related information routinely collected by other organizations such as WHO/EIP, national health accounts, standard household surveys, WHO/HAI medicine pricing surveys and IMS data. The final strategic goal is to create one central WHO/EM website with links to all medicine-related country information relevant for planning purposes and measuring progress. This information will then also feed into the planned World Medicines Situation in 2009.

## Working within one WHO, supporting the regions and countries

### *Background and main challenges*

The main challenge is that the WHO's capacity at headquarters, regional and country level is insufficient, both in terms of human and financial resources. While there is sufficient donor interest in supporting global functions, there is a lack of central funding for country-level medicines programmes and insufficient extrabudgetary donor interest to strengthen horizontal essential medicines programmes in countries. On top of that is a marked lack of political interest, both in countries and in the donor community at large, in promoting integrated supply systems, and rational use of medicines.

### *Strategic direction*

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. In 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 the 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 to 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 medicines policy issues will be provided through on line communications and participation in regional and country activities by HQ staff and experts. 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 better access to relevant information, and by assistance in the identification of 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 partnerships are promoting technical and political collaboration among their participating countries. These partnerships become increasingly effective in promoting regional harmonization, and therefore become increasingly relevant and cost-effective as mechanisms for technical support. WHO will therefore increase its support to such economic blocks, with focus on guiding the harmonization of pharmaceutical policies and regulatory systems and intellectual property rights.

### ***Cross-cutting themes***

The total scope of WHO's medicine work is too wide to be easily described. In an effort to offer another way of looking at the next six years, a few cross-cutting themes are briefly presented here. More detail of each of the topics mentioned can be found in Annex 1.

#### **Priorities of the Director-General**

The medicine-related priorities of the Director-General focus on the health-related MDGs which need medicines. The PHC approach is supported by promoting the concept of essential medicines, equity, the multi-stakeholder approach, comprehensive health systems and human rights. The programme will maintain a strong focus on people most in need in Africa through the essential medicines concept, PHC, regulatory support, prequalification and supply systems. The programme will focus on women through the selection and prequalification of essential items for reproductive health.

#### **Access to essential medicines**

Access to essential medicines will focus on a few selected special groups. The Model List of Essential Medicines for Children will be refined, missing scientific data will be identified and the development and prequalification of new formulations for children will be promoted. New essential medicines for neglected diseases will be promoted by using the requirements for the Model List and the prequalification programme as a guide to innovation. Access to controlled medicines will be promoted by updating the guidelines for pain relief and opioid availability, and by supporting countries in this regard. A new programme will be started to promote access to blood products and related biologicals.

#### **Building the pharmaceutical sector after acute emergencies**

The increasing demand for (re)building the pharmaceutical sector after natural and man-made disasters will be addressed by developing specific policy guidance on essential components of a pharmaceutical programme in resource-poor settings and post-emergency situations. The International Emergency Health Kit and drug donation guidelines will be updated.

#### **Support the pharmaceutical sector in middle-income countries**

There is an increasing demand for evidence-based policy guidance on more complicated technical topics in Middle Income Countries. New emphasis will be put in developing and sharing high-level technical

expertise in topics such as medicine benefits in social health insurance, pricing surveys and policies, good governance and transparency, regional regulatory harmonization and public-health directed policies for local production.

### **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 focus on good pharmaceutical care; and by a new focus on better mechanisms to describe pharmaceutical human resource needs, and on developing skills-based pharmaceutical training and performance-assessments for various levels of non-pharmacist staff to support pharmaceutical services within PHC. Policy guidance will be developed on setting priorities for pharmaceutical human resources in resource-poor settings and small countries.

## STRATEGIC TOOLS

Several tools are available to implement the WHO Medicines Strategy. The use of some of these tools involves a strategic choice as well.

### **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 core 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 promotion of public health principles remains needed, but 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 the promotion of rational use of medicines as part of procurement costs.

### **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 four WHO Expert Committees on selection of essential medicines, on pharmaceutical quality standards, narcotic medicines and biological standardization will be continued and strongly supported. The three expert advisory groups on medicine safety, INN-nomenclature and medicine statistics methodology, 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 website 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. Within WHO, the collaboration will therefore be intensified with the departments of HIV, malaria, child and adolescent health, reproductive health and non-communicable diseases. Efforts will continue to further standardize WHO's many different methods for prequalification of priority medicines, diagnostics, reproductive health devices and vaccines; and to further support the evidence-based development of all clinical guidelines through the WHO Guideline Development Group. Technical collaboration with the Health Systems group will focus on PHC, medicine benefits as part of social health insurance in middle-income countries, and on planning human resources for the pharmaceutical sector. The collaboration with EIP will focus on medicine-related information and evidence, and will also be encouraged at the regional and country level.

### **Country support**

The number of countries that are seeking WHO advice and support in organizing their pharmaceutical sector (currently over 80, rapidly approaching 100) is increasing to such an extent that the regional offices and HQ cannot cope any longer. Where possible, efficiencies will be achieved by reducing the support to individual countries and increasing the support to subregional and/or economic blocks, for example in the area of regional regulatory harmonization or medicine 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, rational use, national

coordination of development agencies, UN reform) and on strengthening the medicine 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 in post-emergencies.

### **Partnerships**

The programme will continue its successful partnerships, such as the bi-annual International Conference of Drug Regulatory Agencies, the six-monthly Interagency Pharmaceutical Coordination group with all UN agencies, the WHO/UN prequalification programme with over 50 national regulatory agencies, the International Network for the Rational Use of Drugs with over 20 countries, and the more recent International Regulatory Cooperation for Herbal Medicines (IRCH) 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, WHO Collaborating Centers, public-interest NGOs, and the research-based and generic pharmaceutical industry.

### **WHO staff and rotational posts**

The programme will continue to attract the best global experts in their respective technical fields. The programme 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, 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 all three 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 the 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 NPOs to regional or headquarters departments. Secondments from developing countries will also be encouraged.

## Annex 1: SUMMARY OF STRATEGIC DIRECTIONS FOR 2008-2013

The following table presents a summary overview of the various programme components, presented under their respective Organization-Wide Expected Results (OWERs) of the Medium Term Strategic Plan (MTSP) for 2008-2013.

**Priority:** The first column indicates to what extent the listed activities are linked to WHO's constitutional and treaty obligations, will support the Millennium Development Goals, are reflected in the global MTSP-indicators, are supported by recent WHA resolutions, and fit within the DG's stated priorities. The more of these criteria apply, the higher is the priority of the activity.

**Continuity:** The middle column indicates constitutional or treaty obligations, long-term commitments and successful strategic approaches which will be continued.

**New strategic focus:** The right-hand column indicates technical areas of new strategic focus.

<b>OWER 11.1 Formulation and monitoring of comprehensive national policies on access, quality and use of essential medical products and technologies advocated and supported</b>		
<i>Priority</i>	<i>Continue ...</i>	<i>New focus on ...</i>
<b>National medicine policies</b> Priority: MDGs 4-5-6-8, MTSP/indicator, DG)	Promoting the establishment, implementation and monitoring of national medicine policies to reflect government commitment and guide national action; update and create new policy guidance documents on priority issues	Comprehensive PHC; medicine reimbursement as part of social security; country-level integration with health systems; harmonizing national policies among regional blocks; policies for simple pharmaceutical systems in post-emergency situations
<b>Information and planning</b> Priority: DG	Improving pharmaceutical survey indicators and household surveys to measure performance of the national pharmaceutical system	Better link with existing sources of information (national health accounts, IMS-data, EIP standard household surveys) to create a package of country data and improve planning and monitoring of country programmes; new focus on sex-disaggregated statistics
<b>Access to essential medicines</b> Priority: MDGs 4-5-6-8, MTSP/indicator, DG	Promoting the use of standardized methods to measure access by all stakeholders	Separate assessments and activities to promote availability, price and affordability; access to essential medicines as part of the fulfillment of the right to health
<b>Transparency and good governance</b> Priority: MDG 8, DG		Developing and promoting new policy guidance on transparency and good governance in pricing, procurement and regulation; use this as an entry point to strengthen comprehensive health systems and promote good governance
<b>Intellectual Property Rights</b> Priority: MDG 8, WHA-2007, DG	Providing technical support to countries and regional economic blocs	Promoting the link between innovation, IPR and access; new approach to medicine patents
<b>New global funding mechanisms</b> Priority: DG	Providing country support in preparing the HS component in funding proposals for GFATM	Policy advice and technical support to global funding mechanisms, and on promoting donor coordination at country level
<b>Medicine benefits as part of (social) health insurance</b> Priority: MDGs 4-5-6-8, DG	Supporting evidence-based selection of medicines for insurance systems	Identifying and promoting best practices in health insurance and medicine reimbursement schemes, in support of universal access and PHC

<b>Comprehensive supply systems</b> Priority: MDGs 4-5-6-8, MTSP/indicator, DG	Improving tools on assessing supply systems; identifying and promoting best practices in supply management	The role of the private sector, transparency, and regulatory approach to supply systems
<b>Traditional medicine (TM)</b> Priority: MTSP	Developing global guidance and technical support on establishing national policies on TM/CAM products and practices	Integrating TM within national health systems and PHC programmes, promoting research and development, training and good manufacturing practices

<b>OWER 11.2 International norms, standards and guidelines for the quality, safety, efficacy and cost-effective use of medical products and technologies developed and their national and/or regional implementation advocated and supported</b>		
<i>Priority</i>	<i>Continue ...</i>	<i>New focus on ...</i>
<b>Nomenclature</b> Priority: Constitution, MTSP/indicator, WHA***	Programme to assign INNs (generic names) and other classification systems	Developing and refining methods to assign names to biological products
<b>Controlled drugs</b> Priority: International treaty obligation, MDGs 6-8	Fulfilling treaty obligations on scheduling of controlled medicines	Improving access to controlled medicines listed on the Model List of Essential Medicines
<b>Quality standards</b> Priority: Constitution, MDGs 4-5-6-8, MTSP/indicator, many WHA resolutions, DG	Fulfilling constitutional obligations to develop norms and standards for pharmaceuticals and biologicals (Expert Committees)	Missing essential medicines for priority diseases and children, and tools for assessment of regulatory and supply agencies
<b>Prequalification (PQ)</b> Priority: MDGs 4-5-6, MTSP/indicator, WHA-2005, DG)	Prequalification of priority medicines (HIV, tuberculosis, malaria, reproductive health); field sampling and testing of medicines procured by UN; capacity building of national regulatory agencies and manufacturers	Prequalification of quality control laboratories, raw materials, bioequivalence centers; methodological advice to other areas (diagnostics, RH commodities, vaccines), and capacity building
<b>Pharmacovigilance</b> Priority: MDGs 4-6, WHA***, DG	Global spontaneous ADR monitoring programme, with Uppsala Monitoring Centre	Disease-specific cohort methods for priority diseases (malaria, HIV, children's medicines); active steering and coordination of new global interest in pharmacovigilance, with focus on developing countries
<b>Combating counterfeits</b> Priority: WHA-***	Acting as secretariat to the International Medicinal Products Anti Counterfeit Taskforce (IMPACT)	Supporting countries in implementing the IMPACT strategy
<b>Traditional medicines</b> Priority: MTSP, WHA-***	Global guidance and support on safety, quality and efficacy of traditional medicines and practices	Promote regulation of practitioners
<b>Blood products and related biologicals</b> Priority: Constitution, MTSP indicator, MDG 8	Global standards for blood products and related biologicals	Regulation of blood and blood products, access to therapeutic sera (anti-snake venoms, anti-rabies serum)

<b>OWER 11.3 Evidence-based policy guidance on promoting scientifically sound and cost-effective use of medical products and technologies by health workers and consumers developed and supported within the Secretariat and regional and national partners</b>		
<i>Priority</i>	<i>Continue ...</i>	<i>New focus on ...</i>
<b>Selection</b> Priority: MDGs 4-5-6-8, MTSP/indicator, WHA-2007,	Evidence-based WHO Model Lists of Essential Medicines (general, children); Essential Medicines	Better medicines for children; methodological guidance on evidence-based selection for other

DG	Library, including WHO Model Formulary	WHO departments; models lists for selected groups of commodities and supplies
<b>Rational Use of Medicines</b> Priority: MDGs 4-5-6-8, MTSP/indicator, WHA-2007, DG	Global database of studies on rational use of medicine; training in RUM (rational use of medicines)	Execution of WHA2007 resolution, promoting national RUM programmes based on situation analysis, multi-stakeholder approach, comprehensive health systems, national RUM body and use of proven interventions; promote adherence to chronic treatment; promote RUM training in basic curricula

## Annex 2: PROGRESS INDICATORS AND TARGETS

The MTSP includes several medicine-related country progress indicators, as well as specific indicators and targets for the delivery of WHO's expected results related to medicines (box). Some of these indicators are new and procedures to collect and record them need to be further developed. The baseline data were provisionally estimated in early 2007 and may need to be adapted to the actual situation by the end of 2007.

### Indicators and targets for country progress and WHO Expected Results (MTSP 2008-2013)

	Country Progress indicators	WHO Expected Results indicators
<b>OWER 11.1: Policy and access</b>	<u>11.A:</u> Access to essential medical products and technologies, as part of the fulfillment of the right to health, recognized in countries' constitutions or national legislation (target: 50 countries in 2013) <u>11.B:</u> Availability of and median consumer price ratio for 30 selected generic essential medicines in the public, private and nongovernmental sectors (target: 80% availability in all sectors; median consumer price ratio not more than 4x the world market price)	<u>11.1.2:</u> Number of countries receiving support to design or strengthen comprehensive national procurement and supply systems (baseline: 20; target: 25 in 2009 and 35 in 2013) <u>11.1.4:</u> Publication of a biennial global report on medicine prices, availability and affordability (target: global reports in 2009, 2011 and 2013)
<b>OWER 11.2: Quality, safety, efficacy</b>	<u>11.C:</u> Developmental stage of national regulatory capacity (target: national regulatory authority assessed; 33% of countries with basic level; 50% with intermediary-level and 17% with high-level regulatory functions in place by 2013)	<u>11.2.1:</u> Number of new or updated global quality standards, reference preparations, guidelines and tools for improving the provision, management, use, quality and effective regulation of medical products and technologies (target: 30 per biennium) <u>11.2.2:</u> Number of assigned International Nonproprietary Names for medical products (baseline: 8900; target: 200 per biennium) <u>11.2.3:</u> Number of priority medicines, vaccines, diagnostic tools and items of equipment that are prequalified for UN procurement (baseline: 150; target: 250 in 2009 and 500 in 2013) <u>11.2.4:</u> Number of countries whose national regulatory authorities have been assessed, supported and accredited (baseline: 20; target: 30 in 2009 and 80 in 2013)
<b>OWER 11.3: Cost-effective use</b>	<u>11.E:</u> Percentage of prescriptions in accordance with current national or institutional clinical guidelines (target: 70% by 2013)	<u>11.3.1:</u> Number of national or regional programmes receiving support for promoting sound and cost-effective use of medical products and technologies (baseline: 5 programmes; target: 10 programmes in 2009 and 20 programmes in 2013) <u>11.3.2:</u> Number of countries using national lists, updated within the last five years, of essential medicines, vaccines and technologies for public procurement and/or reimbursement (baseline: 80; target: 90 in 2009 and 100 in 2013)

### Measuring progress and impact

The current EM database of country-level pharmaceutical information is insufficiently accurate and not easily accessible. The main approach will be to drastically improve the quality and accessibility of unique EM information (pharmaceutical surveys, national policies, national EM lists) and link this to medicine-related information routinely collected by other organizations such as WHO/EIP, national health accounts, standard household surveys, WHO/HAI price surveys, IMS systems, etc. The final objective is to create one central WHO/EM web site with links to all medicine-related country information relevant for planning purposes and measuring progress.

## Access indicators

Several agencies within and outside the UN systems 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; for that reason it was accepted as MDG indicator 46. However, this single access indicator is now generally seen as inaccurate and meaningless "quantified intuition".

The single access indicator will be split into several separate, measurable indicators, each reflecting various aspects of access (selection, price, financing, supply systems). Most of these are already in the WHO Medium term Strategic Plan (MTSP) for 2008-2013, so have been recognized and are being collected by countries and by WHO as part of the MTSP reporting system. Together these indicators give a good impression on how serious a government is in making essential medicines available to all its population.

## New access indicators

<i>Indicator</i>	<i>Target value</i>
<b>STRUCTURE:</b>	
a. Access to essential medicines/technologies as part of the fulfillment of the right to health, recognized in the constitution or national legislation (MTSP country progress indicator).	Yes
b. Existence and year of last update of a published national medicines policy (1)	Yes, and updated within the last ten years
c. Existence and year of last update of a published national list of essential medicines (1) (MTSP indicator).	Yes, and updated within the last two years
d. Legal provisions to allow/encourage generic substitution in the private sector (1)	Yes
<b>PROCESS:</b>	
e. Public and private per capita expenditure on medicines (1,2)	Country-specific \$ value
f. Percentage of population covered by national health service or health insurance (1,2)	Country specific; ultimately 100%
g. Average availability of 30 selected essential medicines in public and private health facilities (3) (MTSP country progress indicator).	MTSP target 80%; may need country-specific targets
h. Median consumer price ratio of 30 selected essential medicines in public and private health facilities (3) (MTSP country progress indicator).	MTSP target: below 4x world market reference price
i. Percentage mark-up between manufacturers' and consumer price (3). Target: country specific	(target to be refined)

(1) Standard WHO pharmaceutical survey indicator, collected every 4 years (last in 2007) from most countries

(2) Standard information, available from National Health Accounts survey, routinely collected from a large number of countries

(3) Standard WHO/HAI indicator from national medicine pricing surveys, available from 45 countries (2007)