CONTINUITY AND CHANGE

Implementing the third WHO Medicines Strategy

2008–2013

World Health Organization

WHO/EMP/2009.1

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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
IP(R)	Intellectual property (rights)
MDG	Millennium Development Goal
MOH	Ministry of health
MSF	Médecins Sans Frontières
MTSP	Medium-Term Strategic Plan for 2008–2013
NGO	Nongovernmental 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
TM/CAM	Traditional medicine/complementary and alternative medicine
TRIPS	Trade-Related Aspects of Intellectual Property Rights
UEMOA	Union Economique 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/HAI 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 every new active pharmaceutical substance 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 recognized. For example, innovative public health thinking is required on essential 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.

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

Achievements

2004–2007

Box 1
Impact of the second WHO Medicines Strategy (2004–2007)

The second WHO Medicines Strategy (2004-2007) was widely recognized 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.

An external 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 WHO/UN Prequalification Programme
- Innovative standard methodology used in a 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 developed

1977–2007

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

The concept of essential medicines (previously: "essential drugs")

- "Essential Medicines" has become a global concept 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 undisputed global conceptual and technical leader in this field with a stable technical programme and a large number of 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 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 in the area of medicines (e.g. early recognition of the impact of the WTO TRIPS Agreement on medicines, the WHO/UN Prequalification Programme, the WHO/HAI medicine price survey methodology, and the concept of access to essential medicines as part of the fulfilment of the right to health)

Access

- Several global and regional price information services are available
- Standard indicators for assessing availability, price and affordability have been used in over 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
- Recently, the international community has agreed on a global plan of action to promote innovation, public health and intellectual property rights with a focus on medicines for developing countries

Quality, norms and standards

- Global assignment of International Nonproprietary (generic) Names (over 100 new INNs per year)
- Standard procedures for WHO quality norms and standards, with a 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
- By the end of 2007, 84 countries participated in the global pharmacovigilance network, with over 4 million case reports submitted to the global database in Uppsala (see figure opposite)
- WHO/UN Prequalification project for priority medicines, diagnostics and commodities for HIV/AIDS, tuberculosis, malaria and reproductive health; the programme includes major capacity building of national regulatory agencies, quality control laboratories and selected manufacturers. By the end of 2007, 156 individual products and related manufacturing sites were prequalified (65 of these were prequalified in the previous two years). In 2007 alone, 13 training sessions were held in 9 countries

Photo: Irene R. Lengui, L'IV Com Sàrl

Selection and rational use

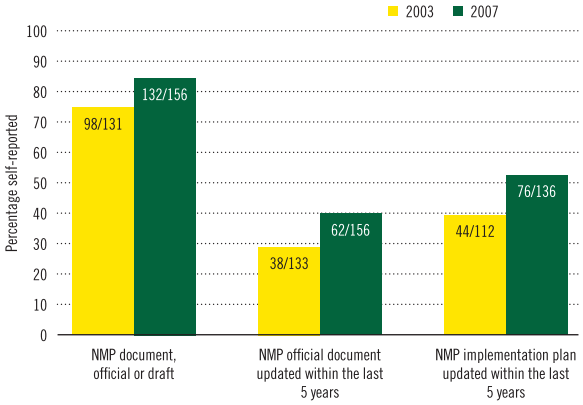
- WHO Model List of Essential Medicines, updated every 2 years since 1977, is a global model process and model product; 1st Model List of Essential Medicines for Children (2007)
- 79% of countries report a national list of essential medicines updated in the last 5 years; and 64% report national treatment guidelines updated within the last 5 years
- Standard indicators for the use of medicines are universally applied in resource-poor settings
- Global database created, giving 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. 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

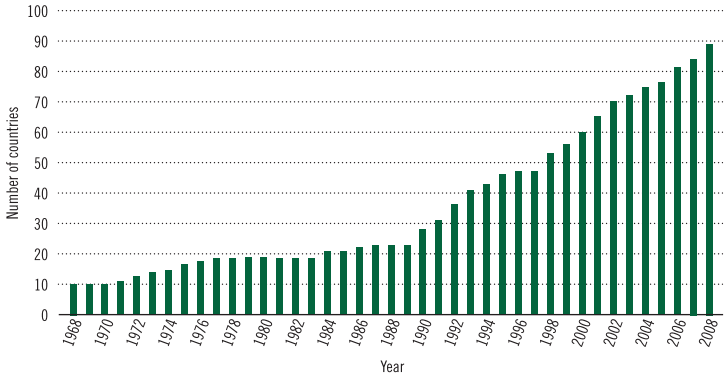
> The concept of essential medicines is one of the major public health achievements in the history of WHO. It is as relevant today as it was at its inception over 30 years ago.
>
> Dr Margaret Chan
> Director-General of the World Health Organization

Progress in national medicine policies: A national medicine policy is a key government commitment to a goal and a guide to action. WHO has performed global surveys of the pharmaceutical sector every fours years since 1999. The number of countries with a national assessment, a national medicine policy and a policy implementation plan is increasing over the years (See Annex 1 for details)

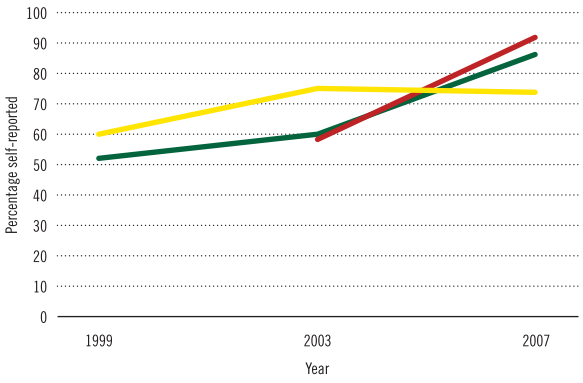


- The proportion of countries with a NMP has increased between 2003 and 2007.
- Even more importantly, the number of countries with NMP and implementation plans updated within the last 5 years has also grown.

Progress in pharmacovigilance: The global centre for monitoring side-effects of medicines is located in Uppsala, Sweden. Since 1990 the number of countries participating in the programme is strongly increasing. WHO and the Uppsala Monitoring Centre are actively involved in training large numbers of national experts from developing countries. Besides routine spontaneous reporting, new monitoring techniques include cohort event monitoring, targeting specific diseases such as HIV/AIDS or malaria

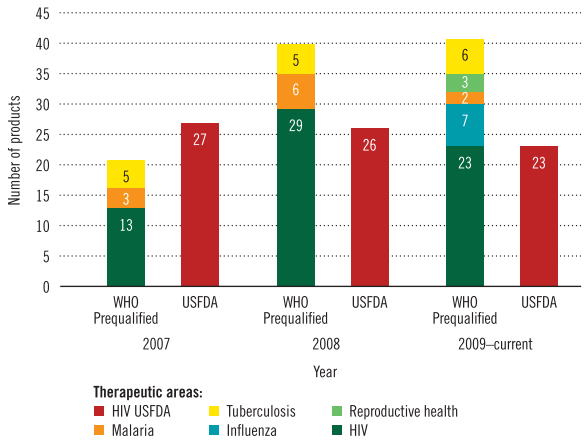


Progress in medicine supply systems: An increasing number of countries use a national list of essential medicines for national procurement, and supply free medicines for HIV/AIDS. However, the number of countries with active generic policies seems stable, a topic that will need more attention in the future

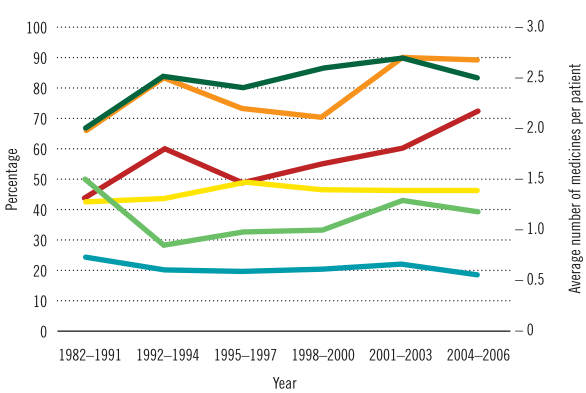


- Public sector procurement largely limited to national EML
- HIV/AIDS medicines provided free in public facilities
- Generic substitution allowed in private pharmacies

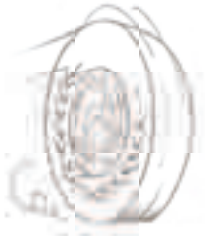
Products added to the WHO List of Prequalified Medicines, per year



Progress in rational medicine use: While some key indicators for rational use are improving, much more needs to be done to prevent suboptimal treatment and economic losses due to irrational prescribing and medicine use



- % medicines prescribed by generic name
- % medicines from Essential Medicines List
- % patients with an antibiotic prescribed
- % patients with an injection prescribed
- % patients treated according to clinical guidelines
- Average number of medicines per patient



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 fake. Moreover, even when medicines are available and of assured quality, they are not always used appropriately; in many countries up to half of all prescriptions are 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 fulfil 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 this SO, there are three Organization-wide Expected Results (see Box 4).

WHO's programme on pharmaceuticals has 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. Hogerzeil
> Director
> Department of Essential Medicines and Pharmaceutical Policies

1 Delivering on the Global Partnership for Achieving the Millennium Development Goals. MDG Gap Task Force Report 2008. New York: United Nations, 2008; 35-44

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/HAI survey 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 SO-11 of the MTSP, 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.

Strengths and weaknesses of the medicines programme

The process to develop the present Medicines Strategy included 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 medicine use. 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.

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 controlled 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, 8 of 16 MDG targets and 18 of 48 MDG indicators are health-related. Most health targets cannot be reached without better access to safe, effective and affordable 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 trading 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[1], 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 (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

1 WHO Medium-Term Strategic Plan 2008–2013. Geneva: World Health Organization; 2007. A/MTSP/2008–2013

Table 1: Medicine-related Millennium Development Goals, 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 (directly observed treatment, short-course)
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)[1]

[1] This single indicator for access to essential medicines has recently been replaced by a set of separate indicators for government commitment, selection, price, financing and availability (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

Organization-Wide Expected Results:
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

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

WHO MEDICINE STRATEGIES 2000–2007		WHO MEDIUM-TERM STRATEGIC PLAN 2008–2013
OBJECTIVES	COMPONENTS	ORGANIZATION-WIDE EXPECTED RESULTS
Policy	1. National medicine policies 2. Traditional medicine	11.1 Comprehensive policies on access, quality and use of essential medical products and technologies advocated and supported
Access	3. Financing 4. Supply	
Quality	5. Quality norms and standards 6. Regulatory support	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
Rational use	7. Rational use by prescribers and consumers	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 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 a 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 now 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)
- Anatomical Therapeutic Chemical (ATC) 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 (3–5 per two years)
- Global quality standards (International Pharmacopoeial monographs) 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 biologicals (5–10 standards per year)
- WHO/UN prequalification of priority medicines for HIV/AIDS, tuberculosis, malaria and reproductive health (40–50 products per year)
- International Conference of Drug Regulatory Authorities (biennial, 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.

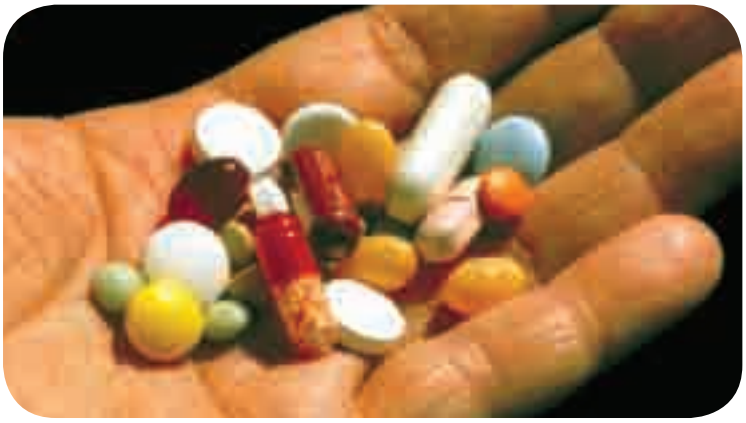
Setting of priorities for action

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 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

OWER 11.1 Formulation and monitoring of comprehensive national policies on access, quality and use of essential medical products and technologies advocated and supported		
PRIORITY	**CONTINUE …**	**NEW FOCUS ON …**
National medicine policies Priority: MDGs 4-5-6-8, MTSP/indicator, DG, WHA39.27, WHA43.20, WHA49.14, WHA52.19, WHA54.11	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 blocs; policies for simple pharmaceutical systems in post-emergency situations
Information and planning 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, HIV global price reporting mechanism, standard household surveys, supply chain assessments) to create a package of country data and improve planning and monitoring of country programmes; new focus on sex-disaggregated statistics
Access to essential medicines Priority: MDGs 4-5-6-8, MTSP/indicator, DG, WHA54.11, WHA55.14, WHA WHA57.14, WHA62.12, EM/RC54/R8	Promoting the use of standardized methods to measure access (price, availability, affordability) by all stakeholders; procurement and supply management training	Separate assessments and activities to promote availability, price and affordability; need forecasting; access to essential medicines as part of the fulfillment of the right to health
Transparency and good governance 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
Intellectual property rights Priority: MDG 8, WHA56.27, WHA59.24, WHA59.26, WHA60.30, WHA61.26, WHA62.16	Providing technical support to countries and regional economic blocs	Promoting the link between innovation, IPR and access; new approach to medicine patents
New global funding mechanisms 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
Medicine benefits as part of (social) health insurance 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
Comprehensive supply systems 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
Traditional medicine (TM) Priority: MTSP, WHA56.31, WHA62.13	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



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

PRIORITY	CONTINUE …	NEW FOCUS ON …
Nomenclature Priority: Constitution, MTSP/indicator, WHA46.19; EB115/11	Programme to assign INNs (generic names) and other classification systems	Developing and refining methods to assign names to biological products
Controlled drugs Priority: International treaty obligation, MDGs 6-8, WHA 58.22	Fulfilling treaty obligations on scheduling of controlled medicines	Improving access to controlled medicines listed on the Model List of Essential Medicines
Quality standards Priority: Constitution, MDGs 4-5-6-8, MTSP/indicator, DG, WHA47.11, WHA47.17, WHA50.3, WHA62.15	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
Prequalification (PQ) Priority: MDGs 4-5-6, MTSP/indicator, DG, WHA57.14	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
Pharmacovigilance Priority: MDGs 4-6, DG, WHA16.36 and 23.13	Global spontaneous ADR monitoring programme, with Uppsala Monitoring Centre	Disease-specific cohort methods for priority diseases (malaria, HIV, children's medicines); active steering and coordination of new global interest in pharmacovigilance, with focus on developing countries
Combating counterfeit medicines Priority: WHA41.16, WHA47.13, WHA52.19	Strengthening regulatory capacity to promote quality, safety and efficacy of medical products	Develop specific normative and policy guidance, and support Member States in ensuring the quality of available medicines, and in combating the use of counterfeit drugs
Traditional medicines Priority: MTSP, WHA56.31, WHA62.13	Global guidance and support on safety, quality and efficacy of traditional medicines and practices	Promote regulation of practitioners
Blood products and related biologicals Priority: Constitution, MTSP indicator, MDG 8, WHA50.20	Global standards for blood products and related biologicals	Regulation of blood and blood products, access to therapeutic sera (anti-snake venoms, anti-rabies serum)

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

PRIORITY	CONTINUE …	NEW FOCUS ON …
Selection Priority: MDGs 4-5-6-8, MTSP/indicator, DG, WHA60.20	Evidence-based WHO Model Lists of Essential Medicines (general, children); Essential Medicines Library, including WHO Model Formulary	Better medicines for children; methodological guidance on evidence-based selection for other WHO departments; models lists for selected groups of commodities and supplies
Rational use of medicines (RUM) Priority: MDGs 4-5-6-8, MTSP/indicator, DG, WHA47.13, WHA47.16, WHA51.9, WHA51.17, WHA58.27, WHA60.16	Global database of studies on rational use of medicines; training in RUM	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

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.

OWER 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 policy-making 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/HAI 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 on 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 principles 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

1. The many different partners with their own medicines 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 outside the three main diseases has remained low, especially in Africa, with decreases in national government budgets for general essential medicines and for general health and supply systems.
3. Little attention has been paid 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 performance and evaluating 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 linking strategic national medicine policies, previous recommendations and trends over time;. This problem is 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. Very few of the many supply management tools available are evaluated for usefulness 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.
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 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:

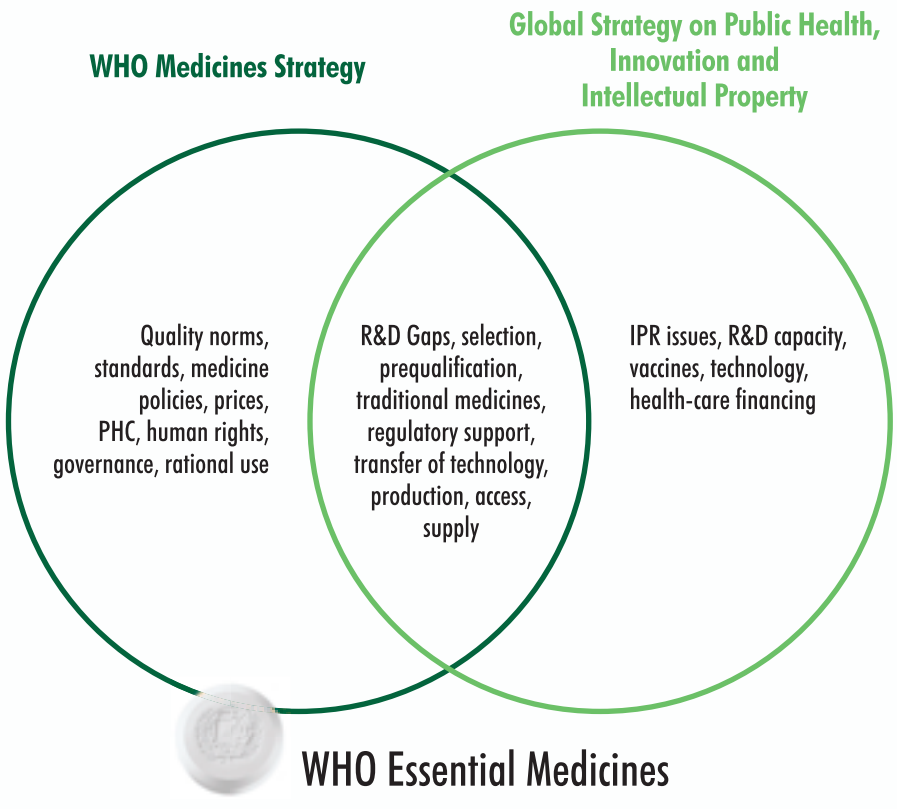
1. prioritizing research and development needs;
2. promoting research and development;
3. building and improving innovative capacity;
4. transfer of technology;
5. application and management of intellectual property;
6. improving delivery and access;
7. ensuring sustainable financing mechanisms;
8. establishing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

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



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

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 ANDEAN 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 is 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.

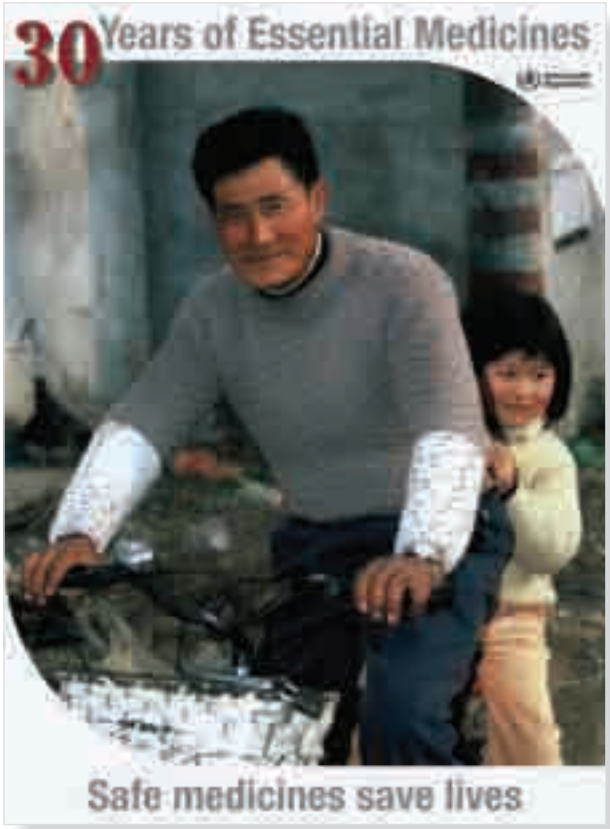
To further ensure sustainable production of good quality finished products, the PQP plans to undertake separate prequalification of active pharmaceutical ingredients, which will benefit manufacturers in less-resourced countries. In order to increase country capacity for sampling and testing of pharmaceutical 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 1500, 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 antimalarial medicines collected in the Mekong subregion contained no or insufficient amounts of active substances.[1] 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

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

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.

Photo: Interpol

Counterfeit medical products are a major public health risk.

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

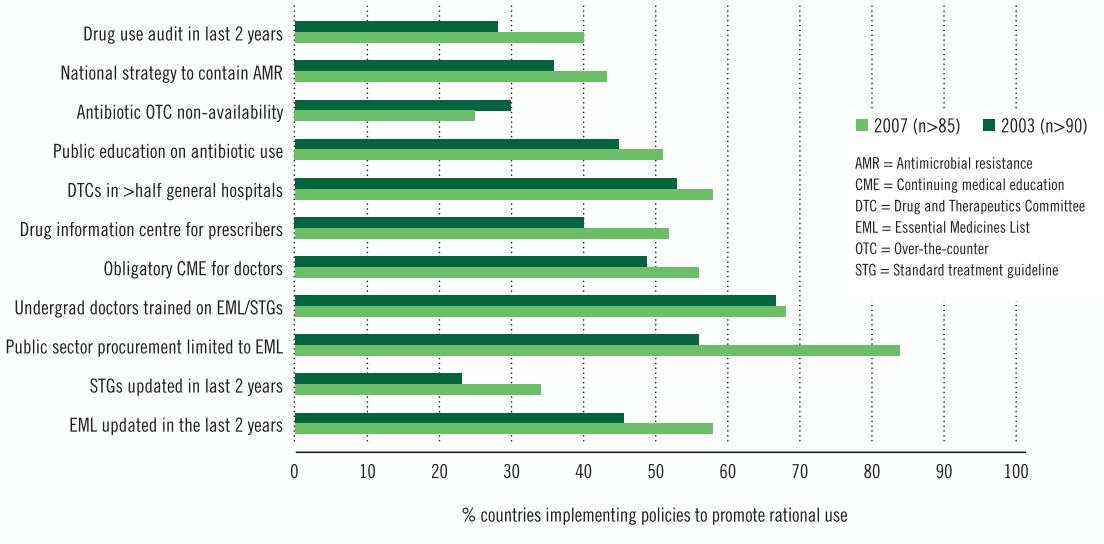
Irrational use of medicines is a major problem worldwide. It is estimated that more than half of all medicines are prescribed, dispensed or sold inappropriately and that half of all patients fail to take their medication correctly. This contributes to enormous health losses and economic waste both at a personal and national level. In the last few years the number of countries with updated medicines lists and treatment guidelines has been increasing (figure).[1] 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 strong increase in percentage in 2007 may partially be explained by the fact that fewer countries responded to the survey, with countries with active medicine programmes being more likely to respond. For full details, please see the next World Medicines Situation Report.

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, UNFPA) 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



Source: Pharmaceutical policy surveys 2003 and 2007.

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 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 (Volumes 1, 2, 3).

The safflower (*carthamus tinctorius*), a plant that has a long tradition of use for medicinal purposes in many parts of the world.

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 on-line 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.

Photo: Eric Georget, WHO

National Professional Officers met 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 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 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 counties 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 pharmaceutical 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 NPOs to regional or headquarters departments. Secondments from developing countries will also be encouraged.

8

Conclusion

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

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

INDICATOR	1999	2003	2007	TARGET 2013
OWER 11.1: POLICY, ACCESS				
MTSP 11-A: Access to essential medical products and technologies, as part of the fulfillment of the right to health, recognized in countries' constitutions or national legislation			4 constitutions	8
MTSP 11-B1: Availability of 30 selected generic essential medicines in the public, private and nongovernmental sectors			Public: 34.9% Private: 63.2%	80% in all sectors
MTSP 11-B2: Median consumer price ratio for 30 selected generic essential medicines in the public, private and nongovernmental sectors			Public: 2.5 Private: >6	Less than 4x world market price
Countries having conducted a national assessment of their pharmaceutical situation in the last 5 years	n.a.	46/89 (52%)	55/83 (66%)	75%
Countries with official national medicine policy new/updated in the last 5 years[1]*	57/128 (45%)	50/125 (40%)	62/118 (53%)	60%
Countries with a national medicine policy implementation plan new/updated in the last 5 years*	39/106 (37%)	41/102 (40%)	71/126 (56%)	70%
Countries with public sector procurement limited to national essential medicines list	71/133 (53%)	71/126 (56%)	74/88 (84%)	95%
Countries that provide HIV/AIDS-related medicines free at public health facilities	n.a.	62/106 (58%)	104/114 (91%)	95%
Countries in which generic substitution is allowed in private pharmacies	87/135 (61%)	87/131 (66%)	100/134 (75%)	85%
OWER 11.2: QUALITY				
MTSP 11-C1: Countries of which the national regulatory authority has been assessed		17	37	70
MTSP 11-C2: Status of national regulatory authority				33% basic 50% med 17% high
Countries participating in the global programme of monitoring adverse drug reactions	53	70	84	100
OWER 11.3: RATIONAL USE				
MTSP 11-E: Percentage of prescriptions in accordance with current national or institutional clinical guidelines			Public: 39.3% Private: 27.5%	50%
Countries with a national list of essential medicines updated in the last 5 years*	117/159 (75%)	81/117 (69%)	107/135 (79%)	85%
Countries with treatment guidelines updated in the last 5 years*	50/90 (56%)	28/85 (33%)	65/102 (64%)	80%
Countries with Drug and Therapeutics Committees in majority of referral hospitals	n.a.	56/99 (57%)	70/121 (58%)	60%
Countries with a national strategy to contain antimicrobial resistance	n.a.	44/117 (38%)	57/133 (43%)	50%

[1] The 1999 and 2003 values refer to a 10-year updating period
* For certain indicators numerator and denominator figures differ slightly from those in previous publications due to updated information and standardization of the calculation methods across all 3 time periods

II. WHO expected results (MTSP 2008–13)

INDICATOR	1999	2003	2007	TARGET 2013
OWER 11.1: POLICY, ACCESS				
MTSP 11.1.1: Number of countries receiving support to formulate and implement official national policies on access, quality and use of essential medicines			Advocacy: 74 Support: 56	Advocacy: 100 Support: 78
MTSP 11.1.2: Number of countries receiving support to design or strengthen comprehensive national procurement and/or supply systems			Advocacy: 52 Support: 45	Advocacy: 70 Support: 60
MTSP 11.1.3: Number of countries receiving support to formulate and implement national strategies and regulatory mechanisms for blood and blood products			Advocacy: 43 Support: 13	Advocacy: 60 Support: 20
MTSP 11.1.4: Publication of a biennial global report on medicine prices, availability and affordability			MDG-8 report 2008	Biennial reports
OWER 11.2: QUALITY				
MTSP 11.2.1: Number of new or updated global quality standards, reference preparations, guidelines and tools for improving the provision, management, use, quality and/or effective regulation of medicines			30 per biennium	30 per biennium
MTSP 11.2.2: (Cumulative) number of assigned International Nonproprietary Names for medical products	6003	7342	7822	8700
MTSP 11.2.3: Number of priority medicines that are prequalified for UN procurement		69	156	350
MTSP 11.2.4: Number of countries whose national regulatory authorities have been assessed and/or supported			Advocacy: 52 Support: 94	Advocacy: 70 Support: 125
OWER 11.3: RATIONAL USE				
MTSP 11.3.1: Number of national or regional programmes receiving support for promoting sound and cost-effective use of medicines			Advocacy: 56 Support: 43	Advocacy: 70 Support: 60
MTSP 11.3.2: Number of countries linking public sector procurement to an EML updated within the last five years	62/122 (51%)	51/93 (55%)	51/69 (74%)	85%

III. New indicators for access to essential medicines

Several agencies 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; 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 has been split into several separate, measurable indicators, each reflecting various aspects of access (government commitment, rational selection, affordable prices, sustainable financing, reliable systems). Most of these are already in the WHO Medium-Term Strategic 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 serious a government is in making essential medicines available to all its population.

INDICATOR	TARGET VALUE
GOVERNMENT COMMITMENT	
Access to essential medicines/technologies as part of the fulfillment of the right to health, recognized in the constitution or national legislation	Yes
Existence and year of last update of a published national medicines policy[1]	Yes, and updated within the last 10 years
RATIONAL SELECTION	
Existence and year of last update of a published national list of essential medicines[1]	Yes, and updated within the last two years
AFFORDABLE PRICES	
Legal provisions to allow/encourage generic substitution in the private sector[1]	Yes
Median consumer price ratio of 30 selected essential medicines in public and private health facilities[3]	Below 4x world market reference price
Percentage mark-up between manufacturers' and consumer price[3]	Country-specific value
SUSTAINABLE FINANCING	
Public/private per capita expenditure on medicines[1,2]	Country-specific $ value
Percentage of population covered by national health service or health insurance[1,2]	Country-specific; ultimately 100%
RELIABLE SYSTEMS	
Average availability of 30 selected essential medicines in public and private health facilities[3]	80% (may need country-specific targets)

[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)

Annex 2: Selected World Health Assembly and Executive Board resolutions on medicines, 1963–2009

NO.	YEAR	TITLE	SUMMARY
WHA 16.36	1963	**Clinical and pharmacological evaluation of drugs**	Member States to report to WHO any decision to **prohibit or limit the availability** of a drug in use, any decision to refuse the approval of a new drug and any approval accompanied by restrictive provisions. Director-General should transmit this information to countries; evaluate value and feasibility of collecting and sharing INN and formulae of new drugs as well as information on **toxicity**; study the possibility of formulating international basic **principles and requirements for clinical, toxicological and pharmacological evaluation** of drugs; REPORT to EB and WHA17
WHA 23.13	1970	**International monitoring of adverse reactions to drugs**	Develop the pilot project to operational phase aimed at establishment of international system for monitoring adverse reactions with provisions for alerting Member States; from 1972 project will be financed from regular budget but Director-General will explore possibility of financing this through sources other than regular budget. As soon as arrangements are made project will based at WHO HQ in Geneva
WHA 39.27	1986	**The rational use of drugs**	ENDORSES attached **drug strategy**. REQUESTS to publish report on the Nairobi Conference in all official languages and ensure dissemination; implement revised strategy also by seeking extra-budgetary resources; REPORT to WHA41
WHA 43.20	1990	**Action Programme on Essential Drugs**	Strengthen support for the promotion of the **essential drugs concept** as part of the revised strategy; ensure adequate funds and HR are provided for the **Action Programme on Essential Drugs**; REPORT to WHA45 on criteria for promotion (WHA41.17) and progress of the revised drug strategy
WHA 46.19	1993	**Nonproprietary names for pharmaceutical substances**	Member States to ensure that **INNs or equivalent generic names** used in the labelling and advertising of medicines are always prominently displayed; Member States to encourage manufactures to use their corporate name + INN rather than trade-marks for products introduced after patent expired; Member States to develop guidelines on use and protection of INNs and discourage use of names derived from them as trade-marks
WHA 47.17	1994	**Implementation of WHO Revised Drug Strategy-safety, efficacy and quality of pharmaceuticals**	Maintain normative activities that provide **standards to ensure quality**; continue to provide information to support effective regulation, monitor excessive claims in **advertising** and promote **rational use** of drugs; provide support and training to improve countries' **regulatory capacity**; support the biennial international conference of drug regulatory authorities
WHA 47.13	1994	**Implementation of WHO Revised Drug Strategy-rational use of drugs and WHO's Action Programme on Essential Drugs**	Strengthen action leadership and advocacy to mobilize and coordinate global effort; encourage contacts with donors, UN agencies, consumers, industry and NGOs; assist Member States in **ensuring quality of drugs** and combating **counterfeit medicines**; report on current state and progress by periodically publishing the World Drug Situation; REPORT to WHA49 and then biennially
WHA 47.12	1994	**Role of the pharmacist in support of the WHO Revised Drug Strategy**	Support Member States to develop drug **regulatory and pharmaceutical services**; encourage Member States to assess their needs for pharmaceutical services, **manpower and training facilities**; encourage regular publication of the World Directory of Schools of Pharmacy; REPORT to the EB97
WHA 47.16	1994	**WHO Ethical Criteria for Medicinal Drug Promotion**	ENDORSES report of CIOMS/WHO consultation on **WHO Ethical Criteria for Medicinal Drug Promotion**; REQUESTS: disseminate WHO ethical criteria and educational material on them; monitor their implementation; carry out studies on current promotion practice; support countries to regulate promotion; stress importance of universities and of educational programmes; periodical review of criteria; REPORT regularly to the EB
WHA 47.11	1994	**Implementation of WHO's Revised Drug Strategy-GMP**	APPROVES revision of **Good Manufacturing Practices** (GMP) as in 32 and 31 report of EC on Specifications for Pharmaceutical Preparations; AUTHORIZES EB to approve amendments proposed by future EB meetings
WHA 49.14	1996	**Revised Drug Strategy**	Support Member States in NMP and encourage to establish a system of **coordination of strategies**; review effectiveness of WHO criteria for **promotion**; promote WHO **Certification Scheme**; disseminate the interagency Guidelines for **Drug Donations**; review information on **prices of drugs and raw materials; standards** for drug regulatory and quality control mechanisms; development and dissemination of **information** on pharmaceutical products; promote **research** of drugs for rare and tropical diseases; study **impact of WTO** work on national medicine policies and access to drugs; REPORT to WHA51
WHA 50.20	1997	**Quality of biological products moving in international commerce**	Provide clear norms and active leadership to promote quality safety and efficacy of biological and **biotechnological products**; support strengthening of regulatory authorities and laboratories; disseminate decisions of EC on Biological Standardization; serve as central resource for MRAs; review of WHO activities to harmonize, minimize duplication and faster response to scientific developments; review relation between WHO reports and guidelines and WTO agreements
WHA 50.3	1997	**Guidelines for the WHO Certification Scheme**	ENDORSES: guidelines for implementation of WHO **Certification Scheme** and URGES Member States to implement them and request WHO-type certificates
WHA 51.17	1998	**Emerging and other communicable diseases: antimicrobial resistance**	Support countries to control **antimicrobial resistance** through strengthening of laboratory capacity; develop policies for rational antimicrobial use (including food-animal production); collaborate with stakeholders concerned with antimicrobial production and use to sharing knowledge and resources; collect and share information by countries and promote cooperation; information and education for prescribers; promote research of new antimicrobials
WHA51.9	1998	**Cross-border advertising, promotion and sale of medical products using the Internet**	Encourage the formulation of self-regulatory guidelines for **good information practices**; develop guide to educate public on the use of **Internet** to obtain reliable information; urge states to monitor cross-country advertising and sale of pharmaceutical through the Internet and take regulatory action
WHA 52.19	1999	**Revised Drug Strategy**	Support implementation and monitoring of **drug policies**; implement WHO Ethical Criteria for Medicinal Drug **Promotion**; further work on WHO **Certification Scheme** and guidelines for trade; establish model inspection certificate for manufacturing sites and products; provide information on **prices of starting materials**; monitor and analyse public health impact of **trade agreements**; review and update the strategy to reflect new challenges and principles of **renewed health-for-all** policy; REPORT to WHA53
WHA 53.14	2000	**HIV/AIDS: confronting the epidemic**	Support implementation of drug **price monitoring** system to promote equitable access to care; strengthen countries' capacities for monitoring **adverse drug reactions** and misuse of drugs; monitor the pharmaceutical and public health implications of **trade agreements**; pursue dialogue with **pharmaceutical industry** to make drugs accessible to developing countries; use partnerships to make drugs financially accessible and used safely and effectively; promote **research** and development of vaccines, diagnostic tools, and treatment, including traditional medicines

WHA 54.11	2001	**WHO Medicines Strategy**	Stimulate development of drugs for diseases in developing countries; explore system for monitoring drug **prices**; support drug monitoring systems; study effects of **trade agreements** on public health; support countries to set up regulatory systems for **quality assurance** and compliance with GMP, bioavailability and bioequivalence; work on **traditional medicines**; REPORT to WHA55 on progress of initiatives to expand **access** to essential drugs
WHA 54.10	2001	**Scaling up the response to HIV/AIDS**	Foster research on HIV vaccines, microbicides and new antiretroviral therapies; support surveillance of **adverse drug reactions** and emergence of resistance with ARVs; collaborate with international community and private sector to improve **availability** of medicines for HIV/AIDS
WHA 54.14	2001	**Global health security: epidemic alert and response**	Technical support to state to develop interventions that prevent epidemics and respond to communicable diseases treats; provide technical support to national efforts to contain and prevent **resistance to antimicrobials**
WHA 55.14	2002	**Ensuring accessibility of essential medicines**	Ensure independence of **Expert Committee on the Selection and Use of EMs**; medicines strategy reflects IP and PH issues; promote **differential pricing** of EMs between developed and developing countries; advocate EM as tool for **rational prescribing**; work on database of **prices** of EMs worldwide; pursue all diplomatic and political opportunities to improve **access to EMs**; join and support **NGOs**
WHA 56.31	2003	**Traditional medicines**	Support countries to formulate policies and regulation of **traditional medicine**; methodology to monitor safety, efficacy and quality and ensure exchange of information; seek information on cost-effectiveness of products and provide it to states; collaborate with other organization on protection of **traditional knowledge** and conservation of plant resources; REPORT to the WHA58
WHA 56.27	2003	**Intellectual property rights, innovation and public health**	Support countries in exchange and **transfer of technology**; establish TOR of body to produce analysis of **intellectual property rights**; support states to monitor the public health implications of relevant international agreements; encourage developed countries to invest in biomedical and behavioural **research**
WHA 57.14	2004	**Scaling up treatment and care within a coordinated and comprehensive response to HIV/AIDS**	Improve **access** of developing countries to pharmaceutical and diagnostic products, including strengthening of **prequalification** programme; ensure that prequalification review process and results are made publicly available; provide support to developing countries to improve the **procurement and supply** chain of HIV/AIDS products
EB115.R4	2005	**International nonproprietary names: revised procedure**	The Executive Board, considering the report above, ADOPTS the **revised procedures** (contained in annex 1) for the selection of recommended **INNs** for pharmaceuticals
WHA 58.22	2005	**Cancer prevention and control**	Improve WHO capacity in prevention and control; (…); support research to evaluate low-cost interventions that are affordable for developing countries; explore with International Narcotics Control Board the feasibility of treating pain with **opioid analgesics**; REPORT regularly to WHA
WHA 58.27	2005	**Improving the containment of antimicrobial resistance**	Accelerate implementation of resolutions WHA 51.17 and WHA 54.14; collaborate with partners to scale up effective interventions and sharing knowledge; generate up-date information to be available to Member States and others; gather and share evidence on cost-effective interventions; report to WHA60 and then regularly
WHA 58.34	2005	**Ministerial Summit on Health Research**	ACKNOWLEDGES Mexico Statement on Health Research (Nov 2004); REQUESTS: assess WHO expertise and activities and produce paper to report to 59WHA; engage on programme on health-system research and bridge gap between research and practice; pursue voluntary platform to link **clinical trial registers**
WHA 59.24	2006	**Public health, innovation, essential health research and intellectual property rights**	DECIDES: to establish a IGWG to draw up a **global strategy and plan of action** to be submitted to the WHA61 REQUESTS: convene the IGWG and set resources for it; continue to issue public health-based research and development reports to identify gaps; continue to monitor the impact of IP
WHA 59.26	2006	**International trade and health**	Support countries to frame policies to address the relationship between **trade and health** and to monitor health effect of trade agreements; collaborate with other organizations to ensure policy coherence between health and trade sector; REPORT to WHA61
WHA 60.16	2007	**Progress in rational use of medicines**	Strengthen WHO leadership and support to Member States on **rational use** of medicines (RUM); strengthen coordination of technical and financial support for RUM: promote research on sustainable interventions; promote discussions among authorities, patients and professionals; REPORT to WHA62 and then biennially
WHA 60.20	2007	**Better medicines for children**	Revise and update the WHO **Model List of Essential Medicines** to include **medicines for children**; develop norms and standards for medicines for children; make available guidelines and independent information on dosage and standards; collaborating with other organizations to ensure fair trade in safe and effective medicines for children; REPORT to WHA62 and then subsequently through the EB as appropriate
WHA 60.30	2007	**Public health, innovation and intellectual property**	Provide technical and financial support to **intergovernmental working group** (IGWG) to deliver by WHA61; provide support to countries that want to make use of flexibilities; provide technical and financial support for regional consultative meeting; encourage health-needs driven research; prepare background documents on the 8 elements of the IGWG plan.
EB 121.R2	2007	**Exp. Committee on the Selection and Use of Essential Medicines: establishment of a Subcommittee**	Establishment of a temporary **sub-committee of the Expert Committee on the Selection and Use of EM** to prepare a list of EM for children, determine dosage forms, review feasibility of manufacturing, identify clinical-research gaps. REPORT to the Expert Committee in 2009. Sub-Committee terminates in 2009
EM RC54/R.8	2007	**Medicine prices and access to medicines in the Eastern Mediterranean Region**	Promote networking among countries through a web-based hub, to share information on **medicines prices** and best practices in management; support countries in surveying and monitoring prices; develop guidelines for regional pricing policies, and support countries in implementation and monitoring of policies; make information on best practice from other regions available to countries
WHA 61.21	2008	**Global strategy and plan of action on public health, innovation and IPR**	**Global strategy and plan of action** adopted; coordinate with WIPO, WTO and UNCTD for implementation of plan of action; examine financing of research and development and look for innovative sources of funds to promote research. REPORT Progress at WHA62 and final at WHA63
EB124.R8	2009	**Primary health care, including health system strengthening**	WHO to respect Alma-Ata principles; Strengthen capacity to support Member States on 4 **PHC** pillars; collate countries experiences in implementing PHC; foster coordination of interventions for Health System Strengthening; REPORT to WHA63, then every 2 years
EB124.R9	2009	**Traditional Medicines**	Request to support Member States in the implementation of Beijing Declaration on **Traditional Medicines** (Nov 2008); update WHO traditional medicines strategy; give consideration to traditional medicine in Global Strategy and Plan of Action on IP

Annex 3 : Support to countries/territories in the field of essential medicines, 2008-2009

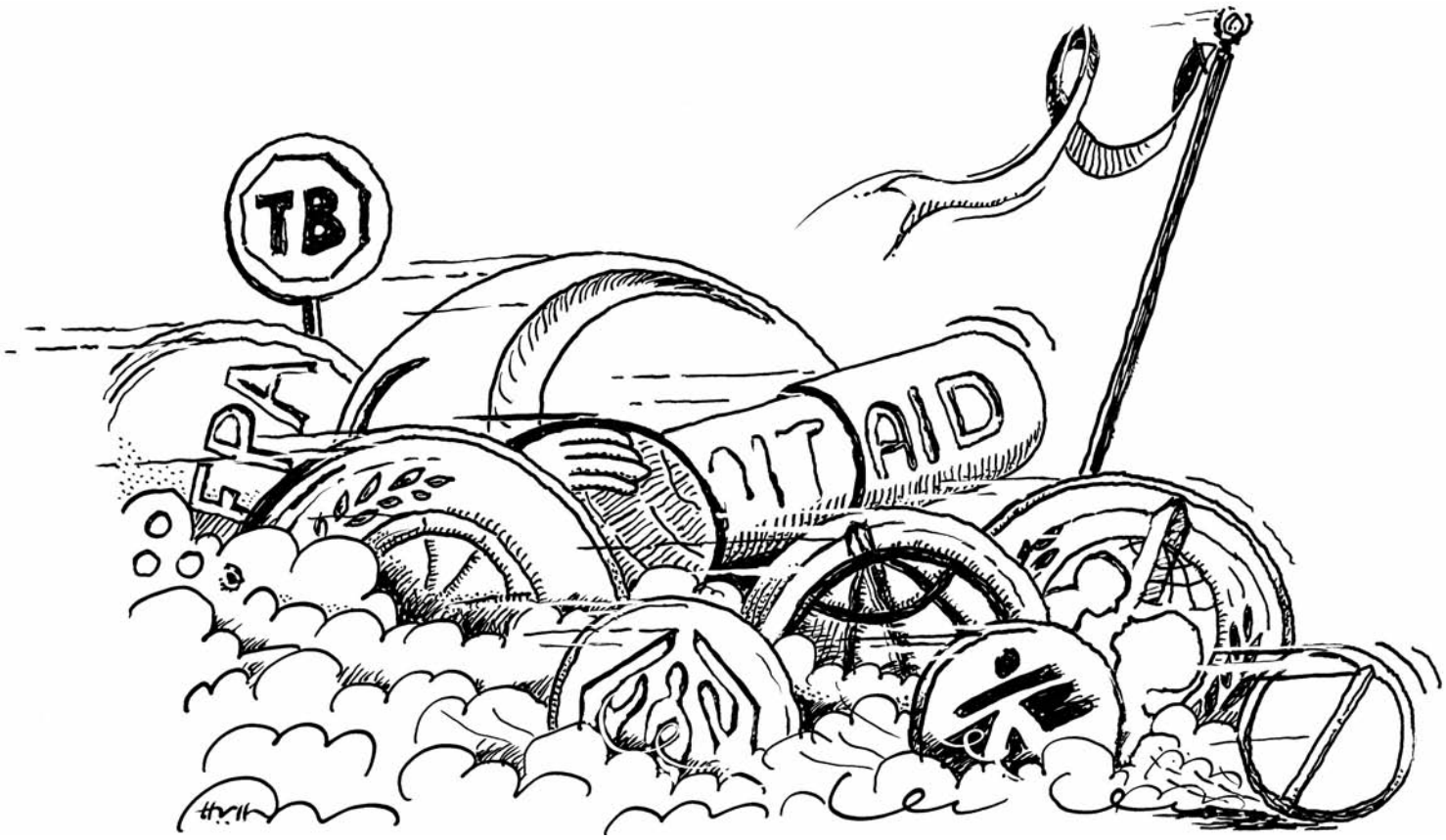
- Part-time WHO medicines adviser
- Full-time WHO medicines adviser
- Advocacy (1–2 nationals attended an international meeting and/or <$25,000 activity budget for this subject in the country)
- Support (3 or more nationals attended an international meeting and/or > $25,000 activity budget for this subject in the country)

NPO National Professional Officer
P National policies on access, quality and use of essential medicines
S Procurement and/or supply systems
B National strategies and regulatory mechanisms for blood and blood products and/or infection control
Q National regulatory authorities have been assessed and/or supported
R Promoting sound and cost-effective use of medical products and/or technologies

	NPO	P	S	B	Q	R
Afghanistan						
Albania						
Algeria						
Andorra						
Angola						
Antigua						
Argentina						
Armenia						
Australia						
Austria						
Azerbaijan						
Bahamas						
Bahrain						
Bangladesh						
Barbados						
Belarus						
Belgium						
Belize						
Benin						
Bhutan						
Bolivia						
Bosnia and Herzegovina						
Botswana						
Brasil						
Brunei Dar						
Bulgaria						
Burkina Faso						
Burundi						
Cambodia						
Cameroon						
Canada						
Cape Verde						
Central Africa						
Chad						
Chile						
China						
Colombia						
Comoros						
Congo						
Cook Islands						
Costa Rica						
Cote d'Ivoire						
Croatia						
Cuba						
Cyprus						
Czech Republic						
Denmark						
Djibouti						
Dominica						
Dominican Republic						
DPR Korea						
DR Congo						
Ecuador						
Egypt						
El Salvador						
Equ. Guinea						
Eritrea						
Estonia						
Ethiopia						
Fiji						
Finland						
France						
Gabon						
Gambia						
Georgia						

	NPO	P	S	B	Q	R
Germany						
Ghana						
Greece						
Grenada						
Guatemala						
Guinea						
Guinea Bissau						
Guyana						
Haiti						
Honduras						
Hungary						
Iceland						
India						
Indonesia						
Iran						
Iraq						
Ireland						
Israel						
Italy						
Jamaica						
Japan						
Jordan						
Kazakhstan						
Kenya						
Kiribati						
Korea, Republic of						
Kuwait						
Kyrgyzstan						
Lao PDR						
Latvia						
Lebanon						
Lesotho						
Liberia						
Libya						
Lithuania						
Luxembourg						
Madagascar						
Malawi						
Malaysia						
Maldives						
Mali						
Malta						
Marshall Islands						
Mauritania						
Mauritius						
Mexico						
Micronesia						
Monaco						
Mongolia						
Montenegro						
Morocco						
Mozambique						
Myanmar						
Namibia						
Nauru						
Nepal						
Netherlands						
New Zealand						
Nicaragua						
Niger						
Nigeria						
Niue						
Norway						
Oman						
Pakistan						

	NPO	P	S	B	Q	R
Palau						
Palestinian SRA						
Panama						
Papua New Guinea						
Paraguay						
Peru						
Philippines						
Poland						
Portugal						
Qatar						
Republic of Moldova						
Romania						
Russian Federation						
Rwanda						
St Vincent & the Grenadines						
Samoa						
San Marino						
Sao Tome & Principe						
Saudi Arabia						
Senegal						
Serbia						
Seychelles						
Sierra Leone						
Singapore						
Slovakia						
Slovenia						
Solomon Islands						
Somalia						
South Africa						
Spain						
Sri Lanka						
St Kitts & Nevis						
St Lucia						
Sudan						
Suriname						
Swaziland						
Sweden						
Switzerland						
Syria						
Tajikistan						
Tanzania						
Thailand						
FYR Macedonia						
Timor Leste						
Togo						
Tonga						
Trinidad & Tobago						
Tunisia						
Turkey						
Turkmenistan						
Tuvalu						
United Arab Emirates						
Uganda						
Ukraine						
United Kingdom						
United States						
Uruguay						
Uzbekistan						
Vanuatu						
Venezuela						
Vietnam						
Yemen						
Zambia						
Zimbabwe						



Department of Essential Medicines and Pharmaceutical Policies
World Health Organization, Avenue Appia, 1211 Geneva 27, Switzerland