



CONTINUITY AND **CHANGE**

Implementing the third WHO Medicines Strategy

2008–2013

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2008 2013

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Contents

Abbreviations	iv
Executive summary	1
Achievements	2
1. Introduction	4
2. Strengths and weaknesses of the Medicines Programme	6
3. Trends, challenges and gaps in the global pharmaceutical situation	7
4. The strategic landscape in 2008	8
Medicine-related Millennium Development Goals	8
The WHO Medium-Term Strategic Plan for 2008–2013	8
The changing aid structure, UN reform and country support	9
The priorities of the Director-General	10
5. Strategic directions and priorities for 2008–2013	11
Continuity versus change	11
Setting priorities for action	12
Summary of strategic directions for 2008–2013	12
6. Strategic direction in selected priority areas	14
OWER 11.1:	14
Evidence and information for medicine policies	14
Essential medicines for renewed primary health care	15
A health systems approach to strengthening medicine supply	15
Public health, innovation and intellectual property	16
OWER 11.2:	18
Building regulatory capacity	18
WHO/UN prequalification of priority medicines	18
Combating counterfeit medicines	19
OWER 11.3:	
Promoting the rational use of medicines	21
Traditional medicine	22
Working within one WHO, supporting regions and countries	23
7. Strategic tools	24
Advocacy of good public health and ethical values	24
Evidence base	24
Within-WHO collaboration	24
Country support	24
Partnerships and WHO Collaborating Centres	25
Human resources for the pharmaceutical sector	25
WHO staff and rotational posts	25
8. Conclusion	26
Annexes	27
Annex 1: Progress indicators and targets	28
Annex 2: Selected World Health Assembly and Executive Board resolutions on medicines, 1963–2009	30
Annex 3: Country support in the field of Essential Medicines, 2008–2009	32

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

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

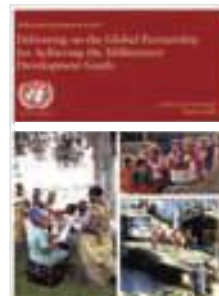
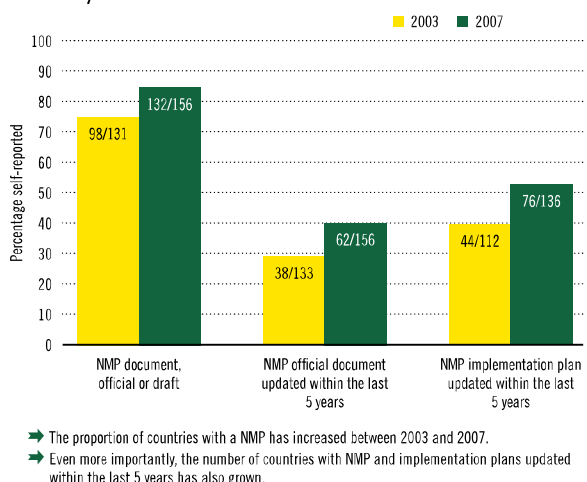


Photo: Irene R. Lengui, L'IV Com Sàrl

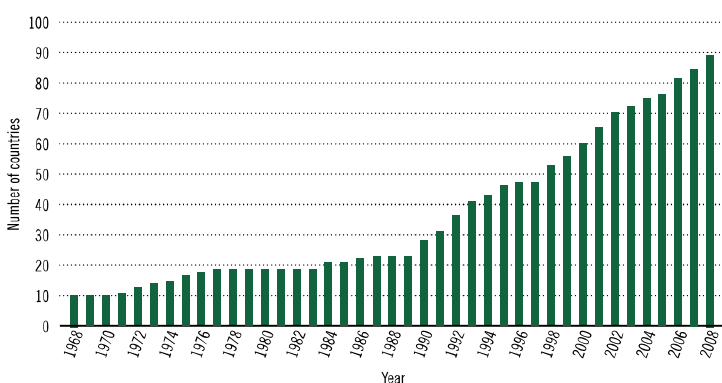
The concept of essential medicines is one of the major public health achievements in the history of WHO. It is as relevant today as it was at its inception over 30 years ago.

Dr Margaret Chan
Director-General of the World Health Organization

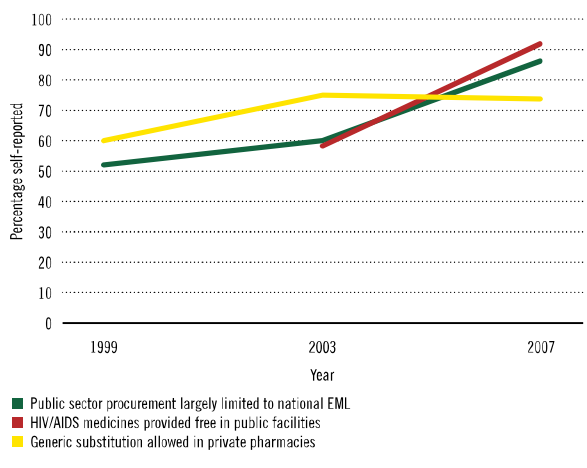
Progress in national medicine policies: A national medicine policy is a key government commitment to a goal and a guide to action. WHO has performed global surveys of the pharmaceutical sector every four years since 1999. The number of countries with a national assessment, a national medicine policy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



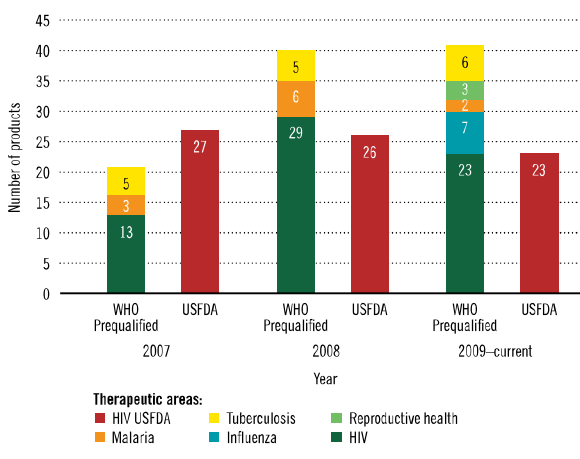
Progress in pharmacovigilance: The global centre for monitoring side-effects of medicines is located in Uppsala, Sweden. Since 1990 the number of countries participating in the programme is strongly increasing. WHO and the Uppsala Monitoring Centre are actively involved in training large numbers of national 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



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

