

CONTINUITY AND CHANGE

Implementing the third WHO Medicines Strategy

2008-2013



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Abbreviations

ADR Adverse drug reaction
AMR Antimicrobial resistance

ARV Antiretroviral

ATC Anatomical Therapeutic Chemical classification

ASEAN Association of South-East Asian Nations

DDD Defined Daily Dose DG Director-General

DTC Drug and therapeutics committee

EAC East African Community
EML Essential Medicines List

GFATM Global Fund to Fight AIDS, Tuberculosis and Malaria

GMP Good manufacturing practices
HAI Health Action International

HIV/AIDS Human immunodeficiency virus/acquired immunodeficiency syndrome

IMPACT International Medical Products Anti-Counterfeit Taskforce

INN International Nonproprietary Name

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

he 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

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