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