“FOR MILLIONS OF PEOPLE THE RIGHT TO THE ENJOYMENT OF THE HIGHEST ATTAINABLE STANDARD OF PHYSICAL AND MENTAL HEALTH, INCLUDING ACCESS TO MEDICINES, REMAINS A DISTANT GOAL”
A WORD FROM THE DIRECTOR, DEPARTMENT OF ESSENTIAL MEDICINES AND HEALTH PRODUCTS

Global health is increasingly challenged by powerful forces such as demographic ageing, rapid urbanization, change in lifestyles caused by economic progress and the related growing burden of noncommunicable diseases, a steady rise in sub-standard/spurious/falsely-labelled/falsified/counterfeit medical products, coupled by an increasing number of players in the global health arena. In this context, the availability of clear and consistent evidence-based policies, advice and technical assistance to guide countries in their efforts to ensure access to safe and quality medical products and their rational use, become all the more important.

During the 2012–2013 biennium, WHO assisted more than 100 countries in the formulation and implementation of national policies and strategies for improving evidence-based selection and rational use of essential medical products, and supported over 120 countries to develop national plans and build capacities to regulate and ensure the quality and safety of medicines, diagnostics, medical devices, vaccines and biologicals. These efforts have been guided by the third WHO Medicines Strategy 2008–2013 and by requests from Member States for support in implementing actions agreed to in World Health Assembly and Executive Board resolutions. Fortunately, WHO draws on a strong network of collaborating partners in ministries of health, national regulatory agencies, academia, research and scientific institutions, regional economic groups, national and international nongovernmental and civil society organizations, United Nations agencies, international technical experts and a network of 50 national professional officers in governments worldwide.

Moving ahead under the 12th General Programme of Work 2014–2019, the Department of Essential Medicines and Health Products is responsible for one of six WHO leadership priorities: Access to medicines and health technologies and strengthening regulatory capacity. I would like to extend my sincere appreciation to all partners who have contributed during the past biennium and I look forward to engaging with existing and new partners in the development and implementation of the Strategic Action Plan for Essential Medicines and Health Products in 2014–2019.
### 2012–2013 highlights

- **100+ Countries** supported to formulate and implement policies on access, quality and use of essential medicines and health technologies
- **100+ Countries** responding to the first Global survey on medical devices
- **161 Countries** with national lists of essential medicines
- **583 Innovative Health Technologies** identified by yearly calls
- **90+ Innovative Pharmaceutical Ingredients, medical devices and vaccines**
- **147 EMP staff** in WHO HQ and regions
- **144 Member countries** in the WHO Medicines Safety Programme
- **101 National vaccine regulatory systems** assessed by WHO
- **100+ Countries** participating in the International Conference on Drug Regulatory Authorities
- **80+ Countries** supported in selection and use of priority diagnostic equipment
- **8900 International Nonproprietary Names (INNs)** given to pharmaceutical substances in total
- **25 The article in the Universal Declaration of Human Rights** stating that “Everyone has the right to a standard of living adequate for the health, and well-being of himself and his family”

### Access

**Supporting national policies for essential medicines and health products**

Essential medical products include chemical and biological medicines, vaccines, blood and blood products, human cells and tissues, biotechnology products, diagnostics and medical devices. On average, WHO Member States spend about half of their total health expenditure on medical products and up to 90% of the population in developing countries purchase health commodities through out-of-pocket payment. Improving access to and regulation of these essential health commodities is a prerequisite for universal health coverage and to the achievement of international goals relating to the unfinished agendas for maternal and child health, communicable diseases targeted by the Millennium Development Goals, and equally crucial in the face of fast growing burdens of noncommunicable diseases and a rapidly ageing world population.

**Choosing and using essential medicines correctly.** The concept of essential medicines is one of the major public achievements in the history of WHO. Essential medicines are selected with regard to disease prevalence, safety, efficacy and comparative cost-effectiveness. The rational use of medicines, including reducing antimicrobial resistance, are areas that require urgent attention and the WHO Model list of essential medicines guides countries in their rational selection and use. The WHO model list has been updated every two years since 1977 and in April 2013 the WHO Expert Committee on the Selection and Use of Essential Medicines adopted the 18th version. To assist countries in developing national lists of essential medicines and making use of the WHO model list, the WHO Model formulary was launched in 2002 as a guide for prescribers and pharmaceutical policy-
makers. In 2012, the National formulary of India was made into a mobile phone application, and downloaded not only in India but by another 50 countries.

Evidence. Across regions, there is growing interest in evidence-based selection and use of medicines. The South-Pacific Conference on National Medicines Policy, held in Sydney in May 2012, set the future agenda for medicines policy development, including financing, regulation and rational use, while the Regional framework for action on access to essential medicines in the Western Pacific 2011–2016 prioritizes goals for the pharmaceutical sector and presents strategies to improve access to essential medicines at regional and country levels. The Ministerial Summit on the Benefits of Responsible Use of Medicines, held in the Netherlands in October 2012, reviewed the significant “missed potential” in the way medicines are used.

Medicines for children. Under the Better Medicines for Children Initiative launched in 2007, WHO has made considerable progress in making paediatric medicines available in child-friendly formulations and correct dosage, and a number of tools are now available to countries and UN agencies to help prioritize medicines and medical devices for children, as well as maternal health. In April 2013, WHO published the 4th version of the Essential medicines list for children and WHO has assisted Ghana and India in developing national essential medicines lists and worked with manufacturers in Ghana and Kenya to improve capacities for the manufacture and prequalification of paediatric antimalarial medicines. WHO also provided technical leadership to the formulation of the 13 recommendations of the UN Commission on Life-Saving Commodities for Women and Children and their implementation in eight path-finder countries.

Controlling prices. As up to 90% of the population in developing countries purchase health commodities through out-of-pocket payment, there is need for more systematic and efficient policies for cost containment. In 2012, WHO launched the Guideline on country pharmaceutical pricing policies to aid development of national policies on pricing and ensuring sustainable supply systems and pricing data are now available for 50+ countries applying the WHO/HAI survey tool. The increasing incidence of medicines shortages for which low- and middle-income countries are at heightened risk, is another access-related challenge and WHO has started work to improve management of global stock-outs, including documenting existing mitigation practices.

Pain relief. Childbirth, injuries, noncommunicable and chronic diseases, combined with a rapidly ageing world population gives rise to a need for improved access to pain relief and palliative care. In fact, WHO estimates that 5.5 billion people (83% of the world’s population) live in countries with low to non-existent access to medicines controlled under international drug conventions. Although necessary, drug control regulations and governmental structures, if overly restrictive and inefficient, can hamper access to medicines for therapeutic use. WHO develops internationally recognized standards and tools for treatment with controlled medicines and works with countries to address the barriers to opioid availability. In 2012, WHO published Guidelines on treatment of persisting pain in children and an associated package with brochures and tools as a guide to health care workers, while two other WHO guidelines for treatment of acute and persisting pain in adults are work in progress.

Medical devices. There are an estimated 1.5 million different medical devices, in more than 10,000 types of generic device groups available worldwide. Advances and challenges in improving equal access to medical devices worldwide are discussed in this report.

UN Political Declaration of the High-level Meeting of the General Assembly on the Prevention and Control of Noncommunicable Diseases

Noncommunicable diseases, primarily cardiovascular diseases, cancers, chronic respiratory diseases and diabetes, affect all age groups, kill more than 36 million people every year, nearly 80% in low- and middle-income countries and are the leading causes of death in all regions except Africa.

EMP provides tools to improve access to medical products to prevent, treat and rehabilitate noncommunicable diseases:

- 18th WHO Model list of essential medicines (2013)
- WHO Treatment guidelines for noncommunicable diseases
- WHO List of medical devices for chronic obstructive pulmonary disease
- WHO Prequalification of medicines, diagnostics and vaccines
to these were shared in the 2nd Global Forum on Medical Devices held in November 2013. Of the 161 countries responding to the first Global survey on medical devices, 55 countries did not have a regulatory authority, 87 countries did not have a national health technology policy and 93 countries did not have national lists of approved medical devices for procurement or reimbursement. Such feedback triggered a number of activities such as a Medical Device Clearinghouse, the launch of calls for innovative health technologies which have resulted in a yearly Compendium of innovative health technologies for low-resource settings and a series of country training workshops in the 18 modules of the first WHO Medical Devices Technical Series.

**Innovation.** In 2012 WHO, with the World Intellectual Property Organization and the World Trade Organization, jointly published a major study on promoting access to medical technologies and innovation. In follow-up to the Consultative Expert Working Group on Research and Development, WHO has adopted a strategic work plan and has, with stakeholders, identified four R&D demonstration projects that can show effectiveness of innovation and provide lessons on coordination and financing mechanisms to address market failures. A global health R&D observatory is also under establishment to guide and prioritize innovation and R&D in medical products. The Priority medicines for Europe and the world report 2013 also presents a public-health-based medicines development agenda and identifies pharmaceutical gaps and priorities for pharmaceutical research for 2014–2020. WHO is also working with countries to build their capacity for local production of medical products, which includes strengthening coherence between health and industrial policies.

**Good governance.** With an annual global expenditure estimated at more than US$ 6.5 trillion and a global pharmaceutical market valued near US$ 880 billion, the health sector is a real target for unethical practices. The WHO Good Governance for Medicines Programme continues to grow in tandem with popular demand for accountability and transparency, and is now operational in 44 countries. An external evaluation in 2012 confirmed its contribution to increased awareness of transparency and good governance at the international level and the principles involved are increasingly recognized as being fundamental to the health sector as a whole.

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**Emp provides tools to improve access to life-saving medicines and health supplies:**

- 4th WHO Model list of essential medicines for children (2013)
- 18th WHO Model list of essential medicines (2013)
- Monographs for formulations of paediatric and reproductive health medicines
- Regulatory pathways for the registration of paediatric antimalarial and tuberculosis medicines
- List of priority life-saving medicines for women and children (2012)
- WHO Recommendations for management of common childhood conditions (2012)
- Development of paediatric medicines: Points to consider in pharmaceutical formulation (2012)
- Interagency list of essential medical devices and medicines for maternal and newborn health
- WHO prequalification of medicines, diagnostics and vaccines
- To date, 75 paediatric formulations and 23 reproductive health medicines prequalified
- Paediatric Medicines Regulatory Network
- Advocacy

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*Every Woman Every Child*

UN Global Strategy on Women and Children’s Health

UN Commission on Life-Saving Commodities for Women and Children

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**Make medicines child size**
REGULATION AND PREQUALIFICATION

International norms, standards and guidelines

**Naming medicines.** Twice a year, the International Nonproprietary Names (INN) Expert Group gathers at WHO to painstakingly consider and create names for new substances used in medicines. The INN is a single name that can be recognized and used globally by doctors, pharmacists, scientists, medicines regulators and patients. Since WHO established the INN programme in 1950, it has allocated some 8900 names.

**Norms and standards.** Availability of safe and quality medical products is one of the cornerstones of health care and has major impact on access and costs. WHO assists countries to develop national plans and build capacities for strengthening regulatory oversight of medical products. The development and approval of norms and standards to regulate the quality, safety, efficacy and cost-effective use of medical products is facilitated by two WHO Expert Committees, WHO Collaborating Centres and partner organizations. By including a wide range of partners in the process of making norms and standards, WHO facilitates consensus both on technical matters and among regulatory decision-makers from countries. In 2013, the WHO Expert Committee on Biological Standards held its 64th meeting and approved another nine written standards and eight reference preparations for ensuring the quality of biological substances used in human medicines (such as vaccines, biological therapeutics, blood products and related in vitro diagnostic devices). The current catalogue of WHO biological standards established by the committee comprises over 70 written standards and 300 international reference preparations, essential for the quality control, regulation and clinical dosing of biological medicines globally. The WHO Expert Committee on Specifications for Pharmaceutical Preparations approved another 50 global specifications, monographs and general texts now published in the *International pharmacopoeia* – a compendium of quality control monographs, or standardized terminology, dosage and drug composition that manufacturers and regulators use for quality control. The history of the *International pharmacopoeia* dates back to 1874 and today, 46 countries publish their own national pharmacopoeias.

**The WHO Prequalification Programme.** In 2013, the three WHO prequalification programmes for diagnostics, medicines and vaccines were brought together under one umbrella and during the biennium WHO has ensured the availability of another 110 prequalified priority HIV/AIDS, malaria, tuberculosis and reproductive health medicines (bringing the total to 371); 43 active pharmaceutical ingredients (bringing the total to 51); 7 quality control laboratories (bringing the total to 29), among these are first prequalified laboratories in Belarus, China, Mexico, Russia and Thailand, adding significant quality assurance capacities in countries with existing and expanding pharmaceutical manufacturing. WHO also prequalified another 16 vaccines (bringing the total to 134), 17 diagnostics and 1 medical device (bringing the total to 27). By engaging national regulatory authorities in the prequalification process, WHO is building capacity for regulators from developing countries and internationalizing the skills of regulators from industrialized countries. Quality assurance officers from all over the world have joined forces with the WHO Prequalification Programme to carry out site inspections and dossier inspections; leading to wider understanding of international quality standards and better communication between countries. The network of regulatory agencies also facilitates harmonization of quality assurance benchmarks and policies for assessing and assuring the quality of an end product.

**Building regulatory capacities.** In 2012–2013, WHO assessed or provided technical assistance to regulatory authorities in 134 countries. In more than 50 countries, such assistance was provided in synergy with the WHO Prequalification Programme. Simultaneously, more than 50 regulatory guidelines and good practices have been updated and published to support regulatory capacity building in countries. Over the years, WHO has developed a number of tools to assess medicines, diagnostics, medical devices and vaccines and an initiative to harmonize these tools and make joint assessments has just recently been launched.
Essential Medicines and Health Products

Every second year since 1980, WHO has been instrumental in convening the International Conference on Drug Regulatory Authorities (ICDRA) where regulatory authorities from all over the world meet to discuss and define actions for national and international regulation and harmonization of regulatory requirements for medicines, vaccines, biomedicines and herbals. The 15th International Conference of Drug Regulatory Authorities took place in Estonia in October 2012, and was attended by more than 300 participants from over 100 countries. WHO continues to drive the harmonization of regulatory standards across regions and is one of the key agencies providing technical support to the African Medicines Regulatory Harmonization Initiative. As the first to be implemented under this initiative, the East African Community Medicines Regulatory Harmonization project provides a model for harmonization of regulatory requirements in other regional economic groups. It has demonstrated remarkable success, particularly in the area of joint activities (dossier assessments and manufacturing site inspections), work sharing and collaboration. WHO also provides expertise and contributes to advance drug regulatory harmonization through cooperation with the International Conference on Harmonization, the Association of South-East Asian Nations, the Asia-Pacific Economic Forum and the Pan American Network for Drug Regulatory Harmonization and works closely with the regional economic groups in Asia to increase uptake of harmonized procedures for medical devices.

Since the 1990s, WHO has implemented a step-wise capacity-building programme to strengthen the six recommended vaccine regulatory functions and as of end 2013, 35 out of 44 vaccine-producing countries have functional vaccine regulatory systems. WHO has become a member of the Management Committee of the International Medical Devices Regulators Forum and has contributed to advance harmonization in the regulation of medical devices. WHO has now made available information on 49 core health technologies using the Global Medical Devices Nomenclature System (no WHO nomenclature is yet available); technical specifications for procurement of 61 medical technologies; and every year WHO has launched a call for innovative technologies, resulting in a

Health and Ageing

Five years from now, for the first time in history, the number of people aged 65 years and older will out-number children younger than five years of age. The increase in the number of older people is mostly occurring in less developed countries. By 2050, 80% of older people will live in low- and middle-income countries.

EMP addresses the challenges of an ageing world population on global health:

- **Minimizing adverse drug events in the elderly** – the elderly take more medications than younger people; elderly patients often take several medications at the same time (poly-pharmacy); as the body ages the effect a drug has on the body changes (pharmacokinetic and pharmacodynamic alterations) and medication mismanagement increases with age

- **Medical devices for the ageing population** – WHO has prepared a study of medical devices required for 19 chronic noncommunicable diseases for the ageing population and mapping of medical assistive devices for the elderly

- **Improve access to controlled medicines for pain management** - as populations age, more people are affected by chronic diseases such as heart disease, cancer, respiratory disease and dementia, which increase the demand for palliative care. WHO is preparing treatment guidelines for persisting and acute pain in adults and works with partners to identify models to deliver integrated palliative care
2013 compendium of more than 90 innovative technologies for low-resource settings. In the area of **diagnostics**, a first training session on international standards for regulatory requirements for diagnostics was organized in China, bringing manufacturers and regulators together.

**Blood products.** In 2012, WHO organized a first global meeting on improving access to safe blood products. More than 50 experts from blood establishments, manufacturers and regulatory agencies met to discuss ways to improve availability, quality and safety of blood products and reduce the current wastage of human plasma, which, when separated from whole blood could be used as an ingredient for the production of essential medicines. A WHO e-catalogue of more than 100 biological reference standards is also available for regulatory agencies to use in the management of blood products and blood safety-related in-vitro diagnostic tests and as a tool for harmonizing international regulation of blood products as neglected essential medicines.

**Monitoring safety and use.** The ultimate goal of any regulatory authority is to ensure that the patient receives safe treatment. Globally, most health care is provided in non-hospital settings, where little is known about the burden of unsafe medicines and their use; in some countries, adverse drug reactions rank among the top 10 leading causes of mortality. WHO encourages countries to establish or strengthen national centres for drug monitoring to detect and prevent sub-standard products and adverse drug reactions and in collaboration with a consortium of partners, WHO has developed methods to widen the reporting of adverse drug reactions by also involving consumers. Through its network of 144 Member and Associate Member countries, the WHO Programme for International Drug Monitoring monitors the **safety of medicines use.** The extensive network enables the submission of over 1 million adverse drug reaction reports to a WHO database every year and signals on severe adverse reactions linked to quality failures have resulted in five **Global Drug Alerts.** In 2012–2013 another seven countries joined the programme: Bangladesh, Bolivia, Laos, Papua New Guinea, Qatar, Syria and the United Arab Emirates.

As the number of vaccine doses administered globally and the number of vaccine products available keep increasing, the Global Vaccine Safety Initiative provides a mechanism for monitoring and responding to adverse reactions after **vaccination.** With partners from academia, national regulatory authorities and technical agencies, the initiative has identified close to 100 activities to enhance vaccine pharmacovigilance capabilities in low- and middle-income countries. In Asia, the Global Vaccine Safety Initiative has helped anticipate and investigate events related to the introduction of pentavalent vaccine against diphtheria, tetanus, pertussis, hepatitis B and *Haemophilus influenzae* type b, which upon further investigation, contributed to preventing unnecessary disruption of life-saving immunization activities. Under the **Global vaccine safety blueprint** launched in 2011, WHO and partners work to build national capacity to monitor vaccine safety.

**Sub-standard/spurious/falsey-labelled/falsified/counterfeit (SSFFC) medical products.** The international health community is becoming increasingly aware of the problem of poor quality medical products. The two first meetings of the Member States mechanism on SSFFC medical products health in Argentina (2012) and Geneva (2013) represent a determination on the part of the international community to tackle the growing challenge it poses to public health. WHO has designed, developed and deployed a SSFFC rapid alert system for reporting and monitoring suspected SSFFC cases. This central database allows structured and systematic reporting and a more accurate assessment of the scope, scale and harm caused. The first 200 reports of suspected SSFFC medical products have been received and in response five international drug alerts have already been issued.
CONTRIBUTIONS AND PARTNERS

Total planned budget for the biennium 2012–2013:

78 638 500 US$

Contributions:

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Core funds
Specified voluntary contributions

The Department of Essential Medicines and Health Products is grateful to long-time and new partners for the crucial financial and in-kind support to its work to improve access to medicines and health products in 2012–2013:

Governments and intergovernmental organizations: Canada, People’s Republic of China, European Commission (Directorate General for Development and Cooperation, Directorate General Enterprise and Industry and Directorate General for Research and Innovation), France, Germany, Hong Kong Special Administrative Region, Japan, the Netherlands, Spain, Switzerland, the United Kingdom and the United States of America (Food and Drug Administration, Centres for Disease Control and Prevention and USAID).

Foundations and nongovernmental organizations: Bill and Melinda Gates Foundation, Cancer Pain Relief Committee, Diana Princess of Wales Memorial Fund, the International Association for Hospice and Palliative Care, the International Association for the Study of Pain, the International Children’s Palliative Care Network, the Mayday Fund, the Open Society Institute and the Sabin Vaccine Institute.

Joint collaboration with the Global Fund to Fight AIDS, Tuberculosis and Malaria, the Medicines for Malaria Venture, the Global Alliance for Vaccines and Immunization, the Global Alliance for TB Drug Development, the World Bank, UNICEF, UNFPA and UNITAID.
“THE ANSWERS LIE IN BUILDING OUR COLLECTIVE RESOLVE TO ENSURE UNIVERSAL ACCESS TO ESSENTIAL HEALTH SERVICES AND PROVEN, LIFE-SAVING INTERVENTIONS AS WE WORK TO STRENGTHEN HEALTH SYSTEMS”

Ban Ki-moon, New York, December 2010