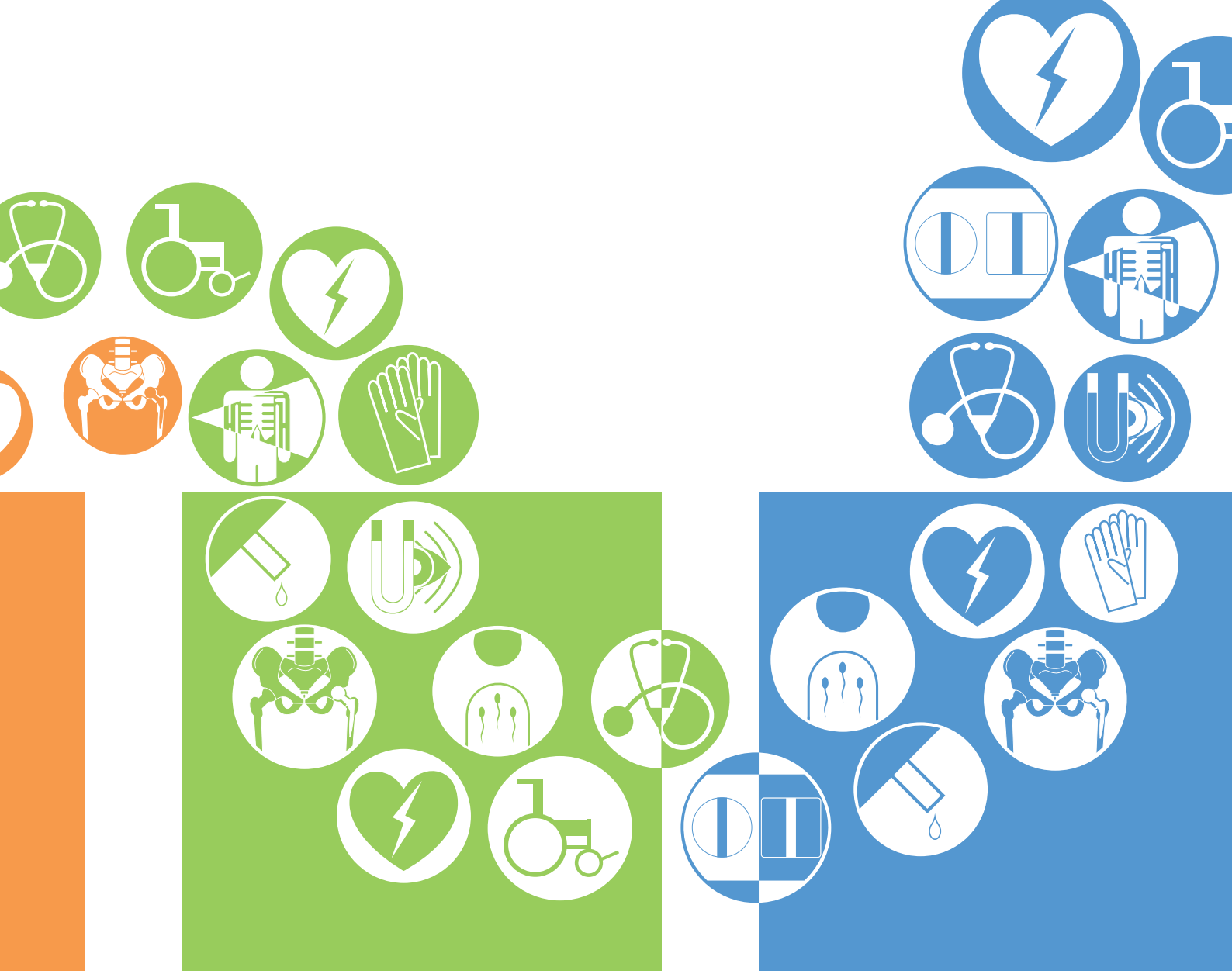

First WHO Global Forum on Medical Devices: context, outcomes, and future actions

World Health Organization

Version 8 April 2011

Designed by L'IV Com Sàrl, Le Mont-sur-Lausanne.

WHO/HSS/EHT/DIM/11.11

First WHO Global Forum on Medical Devices: context, outcomes and future actions

9 –11 September 2010
Bangkok, Thailand

Acronyms and abbreviations

AGIT	Advisory Group on Innovative Technology
AIDS	acquired immune deficiency syndrome
CD-ROM	compact disc read-only memory
CPG	clinical practice guideline
DALY	disability-adjusted life year
DVD	digital video disc
GBD	global burden of disease
GHTF	Global Harmonization Task Force
HIV	human immunodeficiency virus
HTA	health technology assessment
HTAi	Health Technology Assessment International
HTM	health technology management
ICF	International Classification of Functioning, Disability and Health
IFMBE	International Federation for Medical and Biological Engineering
INAHTA	International Network of Agencies for Health Technology Assessment
ISO	International Organization for Standardization
LED	light-emitting diode
MDG	Millennium Development Goal
NGO	nongovernmental organization
SMS	short message service
TAGHT	Technical Advisory Group on Health Technologies
UN	United Nations
WHA	World Health Assembly

Table of Contents

List of appendices

Boxes, figures and tables

Executive Summary

Medical devices – health technologies that are not medicines, vaccines or clinical procedures – save lives, improve health and are indispensable for the prevention, diagnosis, treatment and management of all medical conditions, diseases, illnesses and disabilities. But medical devices need to be accessible, appropriate for different health-care settings and affordable to populations in need. Since the adoption of resolution WHA60.29 on health technologies *(1)* by the Sixtieth World Health Assembly in May 2007, WHO has been working with partners towards devising an agenda, action plan, tools and reference documents to increase access to appropriate health technologies, particularly medical devices, to achieve one of WHO's strategic objectives of improving access, quality and use of medical products and health technologies.

Convened in Bangkok, Thailand, from 9-11 September 2010, the First WHO Global Forum on Medical Devices *(2)* built on previous work, knowledge and experience in this area, and was a pivotal point in advancing collaborative efforts to improve access to appropriate medical devices globally. Participants included high-level policy-makers from Member States, representatives from patients' organizations, nongovernmental organizations, health professionals, researchers, academic institutions, professional organizations, biomedical engineering institutions, umbrella organizations in the medical devices industry, and UN organizations. Participants from 106 countries attended the three-day Global Forum to discuss and explore existing and potential challenges and opportunities for promoting access to innovative, appropriate, affordable and high quality medical devices. A crucial outcome of the Global Forum was a consensus on the priorities for future action, resulting in agreed recommendations.

This report, the *First WHO Global Forum on Medical Devices: context, outcomes and future actions,* briefly describes the intense activity in the medical device arena leading up to the Global Forum. It outlines and discusses the main outcomes of the Global Forum, and then consolidates the information to focus on future actions for achieving global access to appropriate medical devices, through better regulation, assessment and management processes.

It is proposed that the stakeholders implement all of the priority actions outlined in this report, ideally, before the Second WHO Global Forum on Medical Devices in 2012. The WHO commitment to health technologies, particularly medical devices, is permanent and steadfast and more priority actions will be identified and implemented along the way, as necessary.

In order to increase health coverage, have better health services, and best assist populations in need, it is necessary to make all stakeholders aware of the importance of decisions relating to the design, choice and use of appropriate, safe and effective medical devices, and to act accordingly. All stakeholders, whoever and wherever they are, are accountable for the success or failure of access to appropriate medical devices – a fundamental factor in improving the health of populations.

Introduction

In September 2010, over 300 participants from around the world gathered in Bangkok, Thailand, for the first ever WHO Global Forum on Medical Devices *(2)*. The Global Forum built on three years of intense activity that followed the adoption of the first resolution on health technologies by the World Health Assembly (WHA) in May 2007 (WHA60.29). These activities included: regional meetings on health technology; a baseline country survey on medical devices; development of reference documents and tools on medical device regulations, assessment and management; and a search for innovative technologies for global health concerns. The Global Forum provided a platform for raising awareness of the importance of medical devices, identifying and planning for future, country-driven priorities, and galvanising global support for this crucial health systems component.

High-level policy-makers from 106 Member States (including representatives from United Nations (UN) and nongovernmental organizations (NGO), diverse health professionals from research and academia, as well as umbrella organizations in the medical devices industry), met for three days to learn, share and discuss a previously neglected area of huge importance to global health that requires increasing recognition in the future: access to appropriate, affordable, innovative, and high quality medical devices.

At the Global Forum's inaugural address the Prime Minister of Thailand, Mr Abhisit Vejjajiva, called on delegates, scholars, industry members, representatives from international organizations and donors to jointly commit themselves to "building fairness and reducing inequity to ensure access to affordable, safe and effective medical devices, and to quality health care for all" *(3, Appendix A)*. And in her opening speech the Director-General of WHO, Dr Margaret Chan, challenged participants to maintain the momentum emerging on medical devices following the adoption of the health technology resolution three years earlier: "We are here to help set the agenda for a more rational approach to the acquisition and use of medical devices in their full range of applications," she said. "I believe you will agree: too many people are being excluded from the benefits of medical devices, and this is a challenge we need to address" *(4, Appendix B)*.

The following section outlines the importance of medical devices and sets the scene for the remainder of this report.