



IMDRF International Medical
Device Regulators Forum

OUTCOME STATEMENT
of the IMDRF-4 MANAGEMENT COMMITTEE
12 to 14 November 2013

The fourth meeting of the Management Committee of the International Medical Device Regulators Forum (IMDRF) took place in Brussels (Belgium) from 12 to 14 November 2013. The meeting was chaired by the European Commission (Directorate General for Health and Consumers), assisted by appointed representatives of EU Member States (France, Germany and Ireland). The Management Committee (MC) consists of regulators from Australia, Brazil, Canada, China, the European Union, Japan, the Russian Federation and the United States of America. Representatives of the World Health Organization (WHO) participated as official observers and regulators from Argentina attended as invited observers.

The Management Committee discussed the significant progress achieved on the six on-going work items:

- a. the review of the National Competent Authorities Report Exchange Program;
- b. the roadmap for Implementation of Unique Device Identification system;
- c. the Medical Device Single Audit Program;
- d. the List of Recognized Standards;
- e. the Regulated Product Submission; and
- f. the Software as a Medical Device.

On the second day, there was an open Stakeholder Forum with more than 100 participants representing regulators, the medical devices industry, the medical professionals, patients and the research community. Participants had an opportunity to hear updates on the regulatory situation in the eight jurisdictions of the Management Committee members. In addition, update reports were provided on IMDRF's priority work items and stakeholders had an opportunity to share their views and ideas on the work of the IMDRF.

In the afternoon, stakeholders discussed "Innovation for Safety: challenges and achievements". Five stakeholders' associations representing the patients, healthcare professionals, notified bodies and industry (medical devices and *in vitro* diagnostic medical devices) were invited to explain how they contribute to the improvement of safety and performance of these devices and to identify challenges. All stakeholders agreed that no issue can be solved without common engagement, and that collaborative approach is key to enhance safety.

On the final day of the meeting, the Management Committee discussed matters arising from the open Stakeholder Forum including how to improve the operation of the Forum so that it delivers input to the IMDRF work and adopted the revised Standard Operating Procedures.

In 2014, the Chair will be held by the US FDA. The IMDRF-5 meeting will take place in San Francisco on 25-27 March 2014. Details of the Stakeholder Forum will be communicated on the IMDRF website, including a theme for possible presentations by stakeholders on that occasion. The European Union will publish on the IMDRF website (www.imdrf.org) an annual report covering the work done in 2013.

ANNEX

PROGRESS ON IMDRF WORK ITEMS

The Management Committee noted with satisfaction the excellent progress of the six working groups which presented their ongoing work. In summary:

- The Management Committee adopted the revised Work Program of the NCAR Working Group (WG) encompassing a two-stream approach.
- The revised N7 “Unique Device Identification (UDI) System for Medical Devices” was adopted by the Management Committee.
- The four guidance documents of the Medical Device Single Audit Program WG were adopted. Due to the very large number of comments received on the N5 document, it was agreed to postpone part of document N5 (i.e. the Guidance part) to another Work Item (WI) extension.
 - N3 "Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition";
 - N4 "Competency and Training Requirements for Auditing Organizations";
 - N5 "Regulatory Authority Assessment Method for the Recognition and Monitoring of Medical Device Auditing Organizations";
 - N6 "Regulatory Authority Assessor Competency and Training Requirements".

In addition, two new WI extensions were approved by the Management Committee: the “Regulatory Authority Assessment Method Guidance” (consisting of the extracted part of the N5 document) and a new document on “Auditing Organization Assessments, Recognition and Remediation” (N11).

- Based on the fruitful results produced by the analysis of the recognition of international standards within IMDRF jurisdictions, the Management Committee decided to publish the list of recognized standards on the IMDRF website. The list will be updated as appropriate.
- Regarding the Regulated Product Submission WI, the Management Committee endorsed the draft Table of Contents for IVDs that will be submitted for public consultation in a view of adoption at IMDRF-5. A new WI extension on “Common Data Elements to describe a Medical Device through its Regulatory Life-Cycle” was approved by the Management Committee, to be launched in the second half of 2014.
- The Management Committee recognized the work conducted on the recently launched WI on Software as Medical Device, and adopted the N10 Guidance “Software as a Medical Device (SaMD): Key Definitions”. The Management Committee agreed on the continuation of the work.

The Management Committee decided to hold discussion on the possibility of a new WI proposal on “Guidance on Risk/benefit Determination” at IMDRF-5.

Brussels (Belgium)
14 November 2013