



**IMDRF** International Medical  
Device Regulators Forum

## OUTCOME STATEMENT

### of the IMDRF-12 MANAGEMENT COMMITTEE

*19 to 21 September 2017*

The twelfth meeting of the Management Committee (MC) of the International Medical Device Regulators Forum (IMDRF) took place in Ottawa, Canada, from 19 to 21 September 2017. The meeting was chaired by Canada. The MC consists of regulators from Australia, Brazil, Canada, China, the European Union (EU), Japan, the Russian Federation, Singapore, and the United States of America (USA). Representatives of the World Health Organization (WHO) and the Asia-Pacific Economic Cooperation Life Sciences Innovation Forum Regulatory Harmonization Steering Committee (APEC LSIF RHSC) participated as Official Observers and the Asian Harmonization Working Party (AHWP) and Pan American Health Organization (PAHO) participated as Affiliate Organizations.

On the first day, the MC discussed the progress achieved on the current work items:

- a. National Competent Authority Report (NCAR) - EU
- b. Software as a Medical Device (SaMD): Clinical Evaluation - USA
- c. Regulated Product Submission (RPS) - Canada
- d. Medical Device Patient Registries - USA
- e. Medical Device Adverse Event Terminology - Japan
- f. Good Regulatory Review Practices - – Review and Update of GHTF Essential Principles - USA
- g. Improving the quality of international medical device standards for regulatory use - EU

In the afternoon, there was an open session including MC members, Official Observers, Affiliate Organizations and Invited Observers. Brief updates were provided by:

1. Official Observers
  - a. WHO
  - b. APEC LSIF RHSC
2. Affiliate Organizations
  - a. AHWP
  - b. PAHO

### 3. Invited Observers

- a. Mexico
- b. Pan African Harmonisation Working Party
- c. South Korea

### 4. Industry

- a. Global Medical Technology Alliance (GMTA)
- b. Global Diagnostic Imaging, Healthcare IT & Radiation Therapy Trade Association (DITTA)

A number of NWIPs were discussed by the MC during the afternoon open session.

On the second day, an open Stakeholder Forum was held. The Forum included approximately 180 participants representing regulators, industry, and the research community. In the morning, participants had an opportunity to hear regulatory updates from Australia, Brazil, Canada, China, EU, Japan, Russia, Singapore, and USA and update reports on IMDRF's current work items. The morning closed with a Questions & Answers Session.

In the afternoon of day two, Australia presented a NWIP on patient specific devices. This was followed by a panel discussion on real world evidence. The panel explored the challenges, opportunities and the complexity of medical device real world evidence issues in the context of the current trends in medical technology.

Stakeholders and participants had an opportunity to hear updates about the work of:

1. DITTA
2. GMTA
3. APEC
4. WHO
5. AHWP
6. PAHO

The second day was closed with an IMDRF General Questions and Answers Session and concluding remarks by the IMDRF Chair.

On the third day of the meeting, the MC discussed feedback from the public Stakeholder Forum, and made decisions and discussed current and new Work Items, and membership (see Annex).

IMDRF-13 is proposed to be held in Shanghai, China, in March 2018. Details on the venue and on the Stakeholder Forum will be communicated on the IMDRF website.

## ANNEX

### DECISIONS BY THE IMDRF MANAGEMENT COMMITTEE

In summary:

- The MC continued discussions on the development of detailed criteria and procedures for new IMDRF membership.
- The MC approved the proposed document, "Tools for Assessing the Usability of Registries in Support of Regulatory Decision Making", of the Patient Registry Working Group for a two-month public consultation period.
- The MC approved the Final N41 document, "SaMD: Clinical Evaluation" of the SaMD Working Group and decided to close the SaMD Working Group at this time.
- The MC approved the Final N43 document "Terminologies for Categorized Adverse Event Reporting (AER): terms, terminology structure and codes (Annex B-D)" of the Medical Device Adverse Event Terminology Working Group.
- The MC approved Edition 2 of the N14 document, "Medical Devices: Post-Market Surveillance: National Competent Authority Report Exchange Criteria and Report Form" and agreed to create a webpage on the IMDRF website containing links to the recall notification sections of participating IMDRF members' websites. The MC also decided to close the NCAR Working Group.
- The MC approved the proposed NWIP "Patient Specific Devices" (Australia to chair).
- The MC approved with revisions the proposed New Work Item Extension on Improving the Quality of International Medical Device Standards for Regulatory Use.
- The MC approved, with necessary revisions, the NWIP "Harmonized Unique Device Identifier (UDI) Application Guide" (EU to chair).
- The MC agreed to defer the discussion of the NWIP "Clinical Evidence for *in vitro* diagnostic medical devices" until the next IMDRF MC, where it is proposed to have a discussion on the regulatory approach and guidance needed in this area.

*Ottawa, Canada*

*21 September 2017*