



**OUTCOME STATEMENT**

**of the IMDRF-13 MANAGEMENT COMMITTEE**

*20 to 22 March 2018*

The thirteenth meeting of the Management Committee (MC) of the International Medical Device Regulators Forum (IMDRF) took place in Shanghai, China, from 20 to 22 March 2018. The meeting was chaired by China. The MC consists of regulators from Australia, Brazil, Canada, China, the European Union (EU), Japan, the Russian Federation, Singapore, South Korea and the United States of America (USA). Representatives of the World Health Organization (WHO) as Official Observer, and the Asia-Pacific Economic Cooperation Life Sciences Innovation Forum Regulatory Harmonization Steering Committee (APEC LSIF RHSC), the Asian Harmonization Working Party (AHWP) and Pan American Health Organization (PAHO) as Regional Harmonization Initiatives, also participated.

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

- a. Regulated Product Submission (RPS) - Canada
- b. Medical Device Patient Registries - USA
- c. Medical Device Adverse Event Terminology - Japan
- d. Good Regulatory Review Practices - USA
- e. Standards - USA
- f. Personalized Medical Devices-Australia
- g. Unique Device Identification - EU

And two NWIPs proposed by China were discussed by the MC.

In the afternoon, there was an open session including MC members, Official Observer, Regional Harmonization Initiatives, Invited Observer and Industry. Brief updates were provided by:

1. Official Observer
  - a. WHO
2. Regional Harmonization Initiatives
  - a. APEC LSIF RHSC
  - b. AHWP
  - c. PAHO

3. Invited Observer
  - a. Saudi Arabia
4. Industry
  - a. Global Medical Technology Alliance (GMTA)
  - b. Global Diagnostic Imaging, Healthcare IT & Radiation Therapy Trade Association (DITTA)

A number of procedural issues were discussed by the MC during the afternoon closed session.

On the second day, an open Stakeholder Forum was held. The Forum included more than 300 participants representing regulators, industry, and the research community, etc. In the morning, updates presentations and reports on the regulatory situation in the ten jurisdictions of the MC members and IMDRF's seven current work items were provided. And participants had opportunities to share their views and ideas with presenters in Question & Answer sessions.

In the afternoon of day two, there was a panel discussion on Artificial Intelligence Medical Device. The panel explored the challenges, opportunities and the complexity of Artificial Intelligence issues in the context of the current trends in medical technology.

After the panel discussion, stakeholders and participants had an opportunity to hear updates about the work of:

1. China Association for Medical Devices Industry (CAMDI)
2. DITTA
3. GMTA
4. WHO
5. APEC
6. AHWP
7. PAHO
8. Saudi Arabia

The second day was closed with a Question and Answer session and concluding remarks by the IMDRF Chair.

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

IMDRF-14 is proposed to be held in Beijing, China, on September 18-20, 2018. Details on the venue and on the Stakeholder Open Forum will be communicated on the IMDRF website.

## ANNEX

### DECISIONS BY THE IMDRF MANAGEMENT COMMITTEE

In summary:

- The MC approved the revised Final N9 document, “Non-In Vitro Diagnostic Medical Device Market Authorization Table of Contents (nIVD MA ToC)” of the Regulated Product Submission (RPS) Working Group.
- The MC approved the revised Final N13 document, “In Vitro Diagnostic Medical Device Market Authorization Table of Contents (IVD MA ToC)” of the Regulated Product Submission (RPS) Working Group.
- The MC approved the Final N46 document, “Tools for Assessing the Usability of Registries in Support of Regulatory Decision Making”, of the Patient Registry Working Group and decided to close the Patient Registry Working Group at this time.
- The MC approved the proposed document, “Optimizing Standards for Regulatory Review” of the Standards Working Group, for a two-month public consultation period.
- The MC approved the proposed document, “Definitions for Personalized Medical Devices” of the Personalized Medical Devices Working Group, for a two-month public consultation period.
- The MC approved, with necessary revisions, the New Work Item Proposal “Medical device clinical evaluation” (China to chair).
- The MC approved, with necessary revisions, the New Work Item Proposal “Update the List of International Standards Recognized by IMDRF Management Committee Members”, and agreed to direct the Standards Working Group to undertake this Item (USA and China to co-chair).
- The MC discussed the proposed changes to the IMDRF meeting format by changing the Stakeholder Open Forum from current Day Two agenda to DAY ONE, and to allocate more time to Management Committee’s closed sessions discussion. And the MC agreed to implement such changes since IMDRF-14.
- With respect to the proposed future direction of IMDRF work items, the MC agreed to defer to discuss it further at the next teleconference or face-to-face meeting after needed draft documents prepared by Japan, Australia, Canada , EU and USA having been circulated to MC members and the Secretariat for consideration.
- With respect to the proposed revision of IMDRF Terms of Reference to make the wordings of ToR in alignment with the SOP adopted in November 2017, the MC generally agreed to update the necessary wordings revision of ToR.

- To promote transparency, the MC agreed to update the webpage listing the full names of members of the Working Groups and their main activities on the IMDRF website.
- The MC agreed to explore a possible NWIP pertaining to medical device cybersecurity for consideration at a future MC meeting.
- Singapore has volunteered to serve as the 2020 Chair of the IMDRF.

*Shanghai, China*

*22 March 2018*