IMDRF International Medical Device Regulators Forum

OUTCOME STATEMENT
of the IMDRF-5 MANAGEMENT COMMITTEE
25 to 27 March 2014

The fifth meeting of the Management Committee (MC) of the International Medical Device Regulators Forum (IMDRF) took place in San Francisco, California (USA) from 25 to 27 March 2014. The meeting was chaired by the United States of America. The 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), Asian Harmonization Working Party (AHWP) and Asia-Pacific Economic Cooperation (APEC) also participated.

On the first day, the MC discussed the significant progress achieved on the six on-going work items:

a. Medical Device Single Audit Program (MDSAP)
b. National Competent Authority Report (NCAR)
c. Recognized Standards
d. Regulated Product Submission (RPS)
e. Software as a Medical Device (SaMD)
f. Unique Device Identification (UDI)

In the afternoon, an open session was held that included Management Committee members, Affiliate Organizations and Invited Observers. Brief reports and presentations were provided by:

a. World Health Organization (WHO)
b. Asian Harmonization Working Party (AHWP)
c. Asia-Pacific Economic Cooperation (APEC) Life Science Innovation Forum (LSIF) Regulatory Harmonization Steering Committee (RHSC)
d. Pan African Harmonization Working Party (PAHWP)
e. Pan American Health Organization (PAHO)
f. Ghana
g. Indonesia
h. Kazakhstan
i. Republic of Korea
j. Singapore

k. Malaysia
l. Medical Device Epidemiology Network (MDEpiNET)
m. Global Diagnostic Imaging, Healthcare IT, and Radiation Therapy Trade Association (DITTA)
n. Global Medical Technology Alliance (GMTA)

On the second day, there was an open Stakeholder Forum with more than 150 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 MC 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 held three interactive workshops that included the Medical Device Single Audit Program (MDSAP), Software as a Medical Device (SaMD) and WHO Global Initiatives.

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

IMDRF-6 will be held in Washington, DC 16-18 September 2014. Details of the Stakeholder Forum will be communicated on the IMDRF website, including a theme for possible presentations by stakeholders on that occasion.

ANNEX

PROGRESS ON IMDRF WORK ITEMS

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

- The MC approved the proposed N11 document "MDSAP Assessment Outcomes and Recognition/Re-recognition Decision by Regulatory Authorities" of the MDSAP Working Group (WG) for a two-month public consultation. The MC approved the MDSAP overview flowchart to be posted on the IMDRF website.

- The MC agreed to have a separate teleconference to provide the NCAR WG with recommendations for possible revision of the proposed N14 document "Medical Devices: Post Market Surveillance: National Competent Authority Report Exchange Criteria and Report Form" on NCAR exchange criteria and report form.

- The MC agreed to post on the IMDRF website an updated slide presentation on the study it conducted on recognition of standards by IMDRF members. The MC also agreed to explore possible future New Work Item Proposals regarding standards recognition.

- The MC agreed that the Work Item Extension on "Common Data Elements to describe a Medical Device through its Regulatory Life-Cycle" will start work immediately with a joint subcommittee of RPS and UDI regulators for initial drafting. The MC also agreed that the Work Item Extension on UDID will focus on harmonized formats and definitions of data sets, which will be performed by this joint subcommittee as part of the Common Data Elements Work Item. The joint subcommittee will seek input from the non-regulatory authority members of the RPS and UDI WGs before submitting a proposed document to the MC for public consultation.

- The MC approved the proposed N12 document "Software as a Medical Device: Possible Framework for Risk Categorization and Corresponding Controls" of the SaMD WG for a two-month public consultation. The MC decided to receive public consultation on the proposed N12 document prior to deciding on additional SaMD Work Items.

- The MC did not adopt New Work Item Proposals at this meeting.
  "Processing of used medical systems" – from DITTA and "Integrating patient registries and innovative tools for medical device evaluation" - Medical Device Epidemiology Network – from MDEpiNet

San Francisco, CA (USA)
27 March 2014