IMDRF International Medical Device Regulators Forum

INTERNATIONAL MEDICAL DEVICE REGULATORS FORUM

Annual Report, 2013

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Introduction

The International Medical Device Regulators Forum (IMDRF), created in 2011, is a voluntary group of medical device regulators from around the world who have come together to build strong foundational work of the Global Harmonization Task Force on Medical Devices (GHTF) and aims to accelerate international medical device regulatory convergence.

The founding members of the IMDRF are representatives from the medical device regulatory authorities of Australia, Brazil, Canada, European Union, Japan and the United States. Three international organizations are invited as affiliate organizations: the WHO, the APEC and the AHWP.

In 2012, the first Chair of IMDRF was held by the Therapeutic Goods Administration of Australia. Two annul meetings (IMDRF-1 and IMDRF-2) took place respectively in Singapore (in February 2012) and in Sydney (in September 2012).

In 2013, the IMDRF Chair and Secretariat rotated to the European Union (held by DG "Health and Consumers" of the European Commission). The EU Chair organized two annual meetings: IMDRF-3 in Nice, France (21-23 March 2014) and IMDRF-4 in Brussels, Belgium (12-14 November 2014).

These meetings were successful in bringing together all members of the IMDRF and agreeing on a number of important outcomes of ongoing work items and future collaboration.

This document presents the most important achievements of IMDRF for the year 2013, including the expansion of the Management Committee to two new members: China and Russian Federation, the definition of internal rules of procedure (the Terms of Reference and the Standard Operating Procedures were finalized) and the deliverables related to specific Work Items.

It has been a pleasure and a privilege to chair the IMDRF during 2013. I wish the US Delegation all the best in their role as chair of the Forum in 2014.

Despina Spanou

Director for Consumer Affairs

European Commission

1. Finalization of the Terms of Reference and of the internal Standards Operating Procedures

During its chairmanship, the European Union took over the wave started by the Australian chair to clarify the functioning of the Forum and to enhance its efficiency. In order to agree on a number of issues especially concerning membership, the operation of working groups and the process around working items, the EU chair created a subcommittee in charge of revising the IMDRF Standard Operating Procedures.

The updated Terms of Reference and the revised Standard Operating Procedures were endorsed during 2013 by the Management Committee.

The Terms of Reference and SOPs are available on the website: www.imdrf.org.

2. New members

In 2013, the IMDRF agreed to enlarge its Management Committee membership. Two regulatory authorities formally joined as full members after participating as observers in the first meetings.

China confirmed officially its membership during the IMDRF-3 meeting in Nice and the Russian Federation during the IMDRF-4 meeting in Brussels.

3. Achievements on the Work Items

3.1 UNIQUE DEVICE IDENTIFICATION (LED BY DG SANCO, EU)

This Work Item aims at laying the foundations for a globally harmonized approach to UDI Systems.

As requested in the Roadmap presented during the IMDRF-2 meeting in Singapore, the UDI Working Group delivered a first draft UDI Guidance 2.0 to the Management Committee in the IMDRF-3 in Nice for consideration and decision on a possible posting on the IMDRF website for public comments. The draft UDI Guidance 2.0 was open for public consultation on the IMDRF official website in April 2013 with deadline for comments on 31 August 2013. The UDI WG received more than 300 comments from stakeholders. On the basis of these comments, the WG presented a revised UDI Guidance 2.0 to the MC in the IMDRF-4 held in Brussels for acceptance. The proposed UDI

Guidance was adopted as a final document (IMDRF/WG/N7:2013) by the Management Committee.

3.2 THE REVIEW OF THE NCAR SYSTEM (LED BY DG SANCO, EU)

The National Competent Authorities Reporting Exchange Program (NCAR) facilitates the exchange of relevant post market safety information on medical devices with global distribution. The aim is to trigger rapid adoption of field safety corrective actions (FSCAs) in all concerned jurisdictions to avoid death or serious deterioration of health, when relevant.

In 2012, a survey on the NCAR Exchange Program has been circulated. At IMDRF-3, the NCAR Working Group presented the findings of this survey. Based on these results, the MC decided that, for the time being, the scope should not to be extended but, rather, be narrowed and focused on the initial mandate according to the historical objective of the programme. In line with this recommendation, the WG suggested a structured two-tier approach for the review of the NCAR exchange program:

- STREAM 1 will focus on significant concerns or potential trends not yet resulting in recalls or Field Safety Corrective Actions. It would encompass serious public health issues, observations from national trend analysis or signal detection and request for assistance/information. Stream 1 is conceived as a two way communication system.

- STREAM 2 will consist in a rapid exchange mechanism for the communication of "serious" recalls and FSCAs. Its added value would be particularly noticeable in case of MFR's failure to inform concerned authorities in a timely manner of serious recalls and FSCAs. STREAM 2 would be faster and more targeted than the current method and only a limited number of high risk issues would be exchanged via this route. Stream 2 will be a one way communication system.

At the IDMRF-4 meeting the Management Committee endorsed this new approach to be launched and completed in 2014.

3.3 MEDICAL DEVICE SINGLE AUDIT PROGRAM (LED BY FDA, US)

The **MEDICAL DEVICE SINGLE AUDIT PROGRAM** (MDSAP) Work Item aims at developing a standard set of requirements for auditing organizations performing regulatory audits of medical device manufacturers' quality management systems. The document will be applicable to competent authority auditing groups/inspectorates, as well as third party organizations that conduct such audits. This action will complement the current ISO13485 revision process under which IMDRF seeks modifications to achieve a harmonized standard amongst its members.

In 2013, the MDSAP Work Group worked on four guidance documents:

- Two documents which define the criteria for Auditing Organizations:
  - N3: "*Requirements for medical devices Auditing Organizations for regulatory authority recognition*";
  - N4: "*Competence and Training Requirements for Auditing Organizations*".

- Two documents which define the framework for assessments of auditing organizations by regulatory authorities:
  - N5 "*Regulatory Authority Assessment Method for the Recognition and Monitoring of Medical Device Auditing Organizations*" and
  - N6 "*Regulatory Authority Assessor Competence and Training Requirements*".

The four documents were submitted for public consultation during spring and summer 2013. In total, more than 1,700 comments were received by the Working Group on these four documents. The WG analysed all of them, but one part belonging to the N5 Guidance has been transferred to 2014 first semester.

Following analyses and inclusion of the comments, the WG submitted the N3, N4 and N6 updated documents, as well as a reduced N5 document for adoption to the Management Committee at IMDRF-4. The Management Committee adopted the four documents as final and two new WI extensions aimed at completing the MDSAP framework:

- the N11 "*Auditing Organizations Assessments, Recognition, and Remediation*" (whose objective is to "grade" nonconformities found by Regulatory Authorities during the assessment of Auditing Organizations under MDSAP and to document the decision process for recognizing an Auditing Organisation or revoking recognition), and
- the "*Regulatory Authority Assessment Method Guidance*" (consisting of the chapter of the N5 document which analysis was postponed to 2014 first semester).

3.4 List of Recognized Standards (led by Germany, EU)

The aim of this Work Item is to create a list of International Standards used for medical device regulatory purposes. During a first phase, members of the Working Group established a list of standards currently used within the MC regulatory authorities.

At the IMDRF-4 meeting, the preliminary results were presented to the Management Committee, which decided to publish the list of Standards commonly recognized by a majority of jurisdictions on the IMDRF website. In the future, the list will be updated as appropriate.

3.5 REGULATED PRODUCT SUBMISSION (LED BY HEALTH CANADA, CANADA)

This Work Item builds on a project underway internationally working towards a messaging standard that supports the electronic transmission of regulatory submissions. This work aims at defining a common 'Table of Contents' (ToC) for medical device regulatory submissions as a first step in defining a common data set.

At IMDRF-3, the Management Committee endorsed the work achieved so far, including the completion of the draft non-IVD Table of Contents for marketing authorization as well as progress on the testing of the RPS standard for medical devices.

During summer 2013, the WG decided to articulate its work around a two-phase test plan beginning with a non-IVD ToC for the pilot.

The WG chair explained that the initial phase of testing will involve a single manufacturer and jurisdiction as a proof of concept before expanding to broader industry involvement in Phase 2.

In 2013, the WG has progressed on the development of documented storyboards and test cases with unique device requirements. Four test case scenarios (in Australia, Canada and the US) were completed, the vendor neutral findings were compiled for public posting and the IMDRF comments were submitted to the RPS HL7 ballot.

Regarding the development of Tables of Contents, the group first completed the non-IVDs ToC in the first semester of 2013 and drafted a IVDs ToC in the second semester of 2013. At IMDRF-4, the MC agreed on the publication of this IVDs Table of Content for public consultation. Finally, the MC also adopted an extension of the WI aimed at defining "*Common Data Elements to Medial Describe a Device Through its Regulatory Lifecycle*" through a collaboration between the UDI and RPS working groups; to be launched in the second half of 2014.

3.6 SOFTWARE AS A MEDICAL DEVICE

This Work Item was proposed at IMDRF-3 with the aim to facilitate international regulatory convergence towards a smart and balanced regulatory approach that provides an optimal level of patient safety while fostering innovation and provides patients and providers with continued access to advanced health care technology that is safe.

During the IMDRF-3 meeting in Nice it was decided to submit a modified proposal with a two-step approach and a narrowed scope by 10 April 2013. The first step covers terminology, qualification and classification criteria, while the second step will develop a risk-based approach for determining what regulatory requirements should apply to standalone medical software. The first document has been proposed for public

consultation during summer 2013, modified in consequence and adopted at the IMDRF-4 meeting.

4. The Open Session: a place for stakeholders to meet, network and exchange with regulators

Two Open Sessions for Stakeholders were organized by the EU: the first one, in Nice, France (20 March 2013) and the second one in Brussels, Belgium (13 November 2013). Both of them gathered more than 100 participants representing regulators, the medical devices industry, health professionals, patients and the research community.

The March Open Session offered participants to be heard on any challenges they are facing today. The November Open Session focused on "Innovation for Safety: achievements and challenges".

The feedback from stakeholders was positive regarding both the content and the organization of these Open Sessions that allow effective exchanges of views between regulators and stakeholders.

Open sessions could benefit from further dialogue, through workshops or breakout sessions. The Management Committee agreed to consider the feasibility of these options.

5. Development of the website

Since the launch of IMDRF, the Therapeutics Goods Administration of Australia has been very effectively running its website (www.imdrf.org).

At IMDRF-4, the members of the Management Committee agreed on the following rules for publication of documents:
- regular update of contact points of every jurisdiction and Work Items' sections;
- the list of adopted documents (IMDRF guidance final documents) should be published after each meeting;
- all presentations made on regulatory updates and by keynote speakers should be published after the Open Session;
- progress documents on work items should not be published, as they do not represent a final view of the IMDRF Management Committee;
- attendance lists should not be published due to potential data protection issues that could arise

6. Conclusion

2013 was a very productive year for the International Medical Device Regulators Forum: the structure and operating procedures of the IMDRF were clarified, six guidance documents were adopted, the list of Standards commonly recognized by a majority of jurisdictions was published on the IMDRF website, and one new work item (Software as a Medical Device) was launched. Furthermore the open sessions with stakeholders allowed constructive exchange of views and cooperation between regulators and stakeholders, including industry, the medical community and patients.

In 2013, IMDRF members have proven to be very pragmatic, allowing for work to be taken forward and finalized. The adoption of six final documents shows that the IMDRF is progressing towards its goal of greater regulatory convergence for safer and healthier Medical Devices for all.

In 2014 the US will take the lead on IMDRF. The future meetings have already been scheduled: the IMDRF-5 MC meeting will be held on the 25-27 March 2014 in San Francisco and the IMDRF-6 MC meeting on the 16-18 September 2014 in Washington, DC.

Brussels, 15 December 2013