The European Association
Medical Devices - Notified
Bodies

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IMDRF, March 9th 2015 REPORT		
Present :	Hans-Heiner Junker Francoise SCHLEMMER	

1. Welcome

Erik Hansson from the Commission welcomes the participant and presents the running of the meeting.
First of all, it is important to notice that the Commission decided to change the responsibilities of the directorates. The MD department move to another unit, the new unit stays with Sabine Lecrenier as chief of the unit and Eric Hansson deputy chief of the unit.
The directorate is named GROW "Growth – Internal Market, Industry, Entrepreneurship and SMEs ..." with Mrs Elżbieta Bieńkowska as Commissioner.
The new directorate is a merger from the former DG enterprise, DG internal market and DG Sanco.
DG Sanco becomes a smaller DG now.
The department will move in another building in the next few months.

IMDRF is a voluntary group who is aiming to increase convergence among the countries around the world as far as regulatory is concerned. There are 2 representatives from the Commission and 3 from the member states (France, Germany and Ireland).
There are also official observers (WHO, APEC, ...).
There also affiliates organisation in the field of regulatory.
There are working groups who have mandates on specific activities. They are responsible for the development of documents.
During the meeting there are part where all stakeholders are invited and some part reserved for regulators only.

2. Debrief on the IMDRF Management Committee (MC) meetings in Washington and MC teleconference held on 14.01.2015

The main outcomes of the Washington meeting was for MD single use.
A new item on audit report, Medical Device Single Audit Program (MDSAP) Pilot.
N14 document rev 4 was endorsed for publication.
There is also a work item for harmonized standard.

A list of these standards was proposed by Mathias Neuman. The presentation was adopted for the European side and published on the IMDRF web site.
A document regarding software was adopted but there was a request to further inclusion of comments.
QMS software as MD was adopted.

In the margin of this meeting, EC representatives took the opportunity to speak with the Australian representatives on the MRA. The intention is to speak on this topic at the Japan meeting.

During the January teleconference, the Japanese specify that they want to work on a strategic plan during the next meeting.

3. Presentation of the Draft Agenda of IMDRF-7 (as proposed by Japan)

On the agenda for this meeting, there are among others discussions regarding the development since the last meeting.
The work item will be discussed.
It is planned to have a presentation: MedDRA. Medical Dictionary for Regulatory Activities ...
Registration of Pharmaceuticals for Human Use (ICH) developed MedDRA,
Conclusion of the use of the questionnaire.
Overview on the progress
There will be 2 workshops (MDSAP and software as a MD)
The 3rd day will be a close session with decision from the regulators.

4. IMDRF Work Items – Presentation of the state of play and discussion

4.1. Review of the NCAR system

Presentation by Jean-François ROCHE of DG GROWTH - Health Technology and Cosmetics Unit, European Commission.
The N14 document outlines a revised structure for making the information exchange more effective.
IMDRF N14 rev 4 document was endorsed for public consultation by IMDRF in Washington.
Main changes:
- More accurate definition of the role of NCAR secretariat
- Clarification of wording (ch 6.1) on report exchange for confidential and non-confidential documents.

Next steps:
1. March-mid April: drafting of implementation materials on reporting criteria.
2. Mid-April - October (pilot phase)

Participation limited to IMDRF MC Members who already participated to the GHTF exchange program
Use of implementation materials for new members
Twinning between a new and a former participant

3. November - April 2016 (full implementation)
Progress report (IMDRF IX)
Possible proposal for an extension

4.2. Medical Device Single Audit Program

The IMDRF recognizes the value in developing a global approach to auditing and monitoring the manufacturing of medical devices to ensure safe medical devices.

Final Documents

IMDRF MDSAP WG N3 – "Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition"
IMDRF MDSAP WG N4 – "Competency and Training Requirements for Auditing Organizations"
IMDRF MDSAP WG N5 – "Regulatory Authority Assessment Method for the Recognition and Monitoring of Medical Device Auditing Organizations"
IMDRF MDSAP WG N6 - "Regulatory Authority Assessor Competency and Training Requirements"
IMDRF/MDSAP WG/N11 - MDSAP Assessment and Decision Process for the Recognition of an Auditing Organization
IMDRF/MDSAP WG/N22 - MDSAP: Overview of Auditing Organization Assessment and Recognition Decision Related Processes

Proposed Documents

IMDRF/MDSAP WG (PD1)/N8R2 – "Medical Device Single Audit Program (MDSAP): Guidance on Regulatory Authority Assessment Methods of Auditing Organization's Processes"
IMDRF/MDSAP WG (PD1)/N24R2 – "Medical Device Single Audit Program (MDSAP): Medical Device Regulatory Audit Reports"

Some of the proposed documents (N24) could be adopted in Tokyo and others at the management committee of Kyoto in September (N8).
Documents were sent to prepare this meeting.
The objective of this programme is the development of a standard set of requirements for auditing organizations performing regulatory audits of medical devices manufacturers' QMSs.
In this aim 4 guidance's were adopted.
Outside the exact scope, the US launched a single audit pilot project. This project nevertheless builds on the MDSAP IMDRF guidance's.
The EU objectives is a participation as observer with no regulatory implication.
The EU decided this because of the on-going revision of the EU legislation and the energy already involved in the joints assessments.

Nevertheless, this have some advantages such as the fact that the EU NBs are involved as observers which allow to get useful information, gain expertise as assessors in the possibility of a future full participation.

4.3. Regulated Products Submission

The Work Item plan strives for 3 goals:

4.3.1. Testing whether the Regulated Product Submission (RPS) Standard developed for medicinal products can be used for medical devices;

The ultimate goal is to fix common premarket requirements for device applications.
The proposal is focused on the adoption of a common structured set of device identification elements that can be used to support electronic regulatory submission of device identification information that could consistently be used as a component of multiple regulatory submission types (pre-market and post-market).
The RPS Standard was adopted in September 2014.
This RPS Standard is currently in the process of becoming an ISO standard (it should normally take around 18 months). Further testing is however ongoing in a view to test and refine the existing RPS standard.
In the view of possible future implementation of this standard within jurisdictions, the Work Group decided to consider the possible endorsement by the Management Committee of a document focusing on benefits arising from adoption of this standard. The draft is currently under preparation and is expected to be submitted during the Management Committee Teleconference in June 2015.

4.3.2. Development of a common, modular Table of Content (ToC) for device applications (IVD and non-IVD).

An IMDRF Pilot of the existing ToCs was considered by the Work Group and a draft Pilot will be prepared for endorsement by the Management Committee at IMDRF-7. This Pilot is expected to last until end of 2016.
As a consequence of this work the timing and process of an internal pilot within the EU (that was agreed in the IMDRF Coordination meeting of July 2014) will be aligned to the IMDRF Pilot. This will allow us to conceive/design it in a way that makes it as complementary as possible to the IMDRF pilot, avoiding duplication of exercises and related waste of energy and resources. The EU regional Pilot could address particularly low-medium risk devices and small-medium manufacturers (that are often not interested to export their products abroad and therefore not likely to be considered by the IMDRF Pilot).

4.3.3. "Common Data Elements to describe a Medical Device through its Regulatory Life-Cycle" (in coordination with the UDI Working Group)

The group started listing common data elements that help identifying devices throughout the overall device lifecycle. A draft list will be submitted to the

Management Committee for endorsement for public consultation at IMDRF-7 (June 2015).

4.4. Software as a Medical Device

This Work item based on two first steps was extended as follows:
1. First step: definitions/qualification;
2. Second step: risk classification criteria to identify different types of software depending on risk.
3. Third step "Quality Management Systems (QMS) for Software as a Medical Device (SaMD)"

As regards the first step, the document on key definitions was adopted at IMDRF-4 in Brussels in November 2013.
As regards the second step, the final document on risk categorization was adopted at IMDRF-6 in Washington. This latter document, while adopted, will be subject to a public consultation so that stakeholders can provide further views on this.
As regards the third step, the document was adopted at IMDRF-6. This focuses on applicability of current QMS standard to SaMD.

The IMDRF SaMD Work Group met in Canada at the end of January in a view to finalise the draft document on QMS for SaMD, which was later submitted to the Management Committee at IMDRF-7 for public consultation. Before the meeting in Canada, the group, already at this early stage of drafting, asked jurisdictions to launch internal informal consultation procedures in a view to get stakeholders 'views on the work done so far. The EU's informal consultation period ended on 8 January 2015.

This group adopted 2 documents. The name of the document is related to the applicability of QMS which is important because there is no new document. It is only a guidance to help a better comprehension to apply the QMS to software activities.

4.5. Medical Patient Registries

Paul Piscoi presented this topic.
The aim of the Working Group is to propose essential informatics principles for data formats, database linkages, query tools, data security and data access so as to optimize national and international regulatory utility of medical devices registries and their ability to integrate mature, established data resources with new tools.
The EU has a mirror group.

The work will be undertaken in two stages
Stage 1 – Principles Document
Stage 2 – Methodology

The Working Group has been composed with participation of USA. (Chair), Europe (UK, DE and COM), Japan, Russia, Canada, Australia, Brazil on the regulators side. More than 9 non-regulatory members (academia, professional organisations) are also a part of the group and representatives from industry are being sought. The group is assisted by MDEpiNet, a "mirror group" that would support the work on the technical side. At EU level there is a Task Force on Medical Registries that agreed to monitor and support this activity.

There were teleconferences up to date and 3 sub-Working Groups were set up, as follows:
• Vision – methodology/infrastructure and existing national and international systems
• Data access, quality and security
• Linkage of electronic patient, device and outcome data sources

The first face-to-face meeting will be organised in Japan in April 2015.
It is asked to EU task force on MD registries (mirror group) to bring input.
Guidelines are ready for publication this month.

There is a request from Industry to participate at the April meeting.

It is to notice that a registry became mandatory in the Netherlands from January 2015.

5. Discussion on EU's contribution to IMDRF Strategic Plan and on future IMDRF Perspectives

- There is a request from Japan to set up a nomenclature of Medical devices for adverse events.
- The ISO TS 19218 nomenclature (ISO/TS 19218-2:2012 Medical devices -- Hierarchical coding structure for adverse events) -- is already existing and as well the US has their own.

It seems that this initiative has not a lot of support.
An alternative could be to support the revision of the ISO.
It is also clear that in the framework of EUDAMED such a nomenclature will be needed and mandatory from next year on. In this case the Japan initiative will not come to a solution in such a short period of time.

The Commission proposes to come back to the stakeholders after the Tokyo meeting.
In case there are some topics that could be proposed to be addressed by IMDRF, the ideas of the stakeholders are welcomes.

6. Next preparation meeting could take place in July (attempt date **July 7th)**