Minutes of the expert groups

Brussels, 16 May 2022

Minutes
Meeting of the International Matters Sub-group[1]
Brussels 9 March 2022

1. Welcome and Approval of the agenda

The Chair welcomed the attendees to the meeting, which was organised by web streaming due to the current rules related to COVID-19. The draft agenda was approved with the following additions under AOB:
Medtech Europe: Switzerland, Free Sales Certificates (FSC) and potential regulatory impact from the situation in Ukraine.
Team NB: MRA with Australia.

2. Nature of the meeting

Meetings of the MDCG and its sub-groups are not public; they are intended only for MDCG members and observers.

The EU's positions for the IMDRF-21[2] Management Committee (MC) meeting scheduled for 22-23 March 2022 were discussed. For the same reasons as mentioned above IMDRF meetings are also web streamed. Stakeholders were invited to contribute in the morning session. Following this session, the Commission and Member States analysed the outcome of the morning discussions. The overview of the decisions taken is presented in these minutes.

3. List of agenda points discussed

International Matters WG Annual Work Programme: the group approved the annual work programme further to some reflections and exchanges. The Chair informed that annual work programmes of all MDCG sub-groups would be presented to MDCG for endorsement at its meeting scheduled for 21-22/3/2022.

Update from the Commission: there was a very brief presentation, mainly for new participants, on the functions of IMDRF and MDSAP (Medical Device Single Audit Programme) and the way of coordination at EU level and collaboration in these contexts.

Debrief on IMDRF-20 Management Committee (MC) 9-16 September 2021 (web-meetings) and IMDRF-21 Management Committee (MC) meeting (web-meetings) on 27 January 2022: The Commission provided a summary of the last IMDRF MC meeting and teleconference, which were both held virtually. . The IMDRF-DITTA Joint Virtual Workshop on Unique Device Identification (UDI) was held on 9/9/2021 of medical devices with 770 registered stakeholders for the virtual workshop. At the Open Stakeholder Forum held on 14/9/2021 there were 758 registered representatives from regulatory authorities, industry and

[1] Published in the Register of Commission Expert Groups and Other Similar Entities, code number X03565
[2] International Medical Device Regulators Forum

the research community. The Commission provided a brief overview of the decisions taken by the Management Committee, including an approval of a new work item "Clinical Evidence for IVD Medical Devices – Key Definitions and Concepts", closing the Medical Devices Clinical Evaluation (MDCE) and IVD Classification working groups, a 60 days public consultation on the machine learning enabled medical devices – artificial intelligence, minor revisions of some MDSAP documents, a brief statement on responding to pandemics and continue discussing and updating the implementation table. During the January meeting a long list of topics, some of them administrative were examined, including updates on current work items, NCAR secretariat update and potential topics for the joint IMDRF-Industry workshops.

Draft Agenda of IMDRF-21:
The Chair provided an overview of the main agenda points for next IMDRF meeting and informed that the topic standards for software was in the agenda of the joint workshop IMDRF-DITTA. The Chair also noted that due to the Russian invasion of Ukraine, there could be modifications to the planning of the meeting.

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

a) **Regulated Products Submission**: slow progress, more interaction with MDCG NBO and no decision expected at IMDRF-21.

b) **Medical Device Adverse Event Terminology**: the group continues to work on maintenance terminology; no decision expected at IMDRF-21;

c) **Good Regulatory Review Practice (Essential principles and Principles of labelling)**: work is ongoing; decision required at IMDRF-21 about an agreement for 60 day public consultation on a doc drafted in relation to reporting;

d) **Personalised Medical Device**: work is ongoing with participation from EU representatives; no decision expected at IMDRF-21;

e) **Medical Device Cybersecurity**: decision required at IMDRF-21 for a public consultation period;

f) **Artificial Intelligence Medical Devices**: decision required at IMDRF-21; the ongoing work with participation of EU representatives resulted in a document which is ready to be put on public consultation;

g) **Clinical Evidence for IVD Medical Devices**: new group; meeting in March cancelled; waiting for further updates.

New Work Item Proposals

The participants noted the possibility for the position of co-chair from an EU representative at the group Adverse Events Terminology and the proposal from for an update of the guidance SaMD (Software as a Medical Device).

Update on the Single Audit Programme (MDSAP): the recent updates of SOPs document were elaborated mainly because of alignment with ISO 13485 and other international standards and they do not constitute major substance changes. The Chair informed on the issuing of new guidance and potential cooperation with PAHO.

IMDRF – EU Chairmanship 2023

The Chair informed that the Commission has started discussing and reflecting internally on the forthcoming EU Chairmanship of the IMDRF in 2023. The current planning includes continuing with the existing formats and structures (meetings in March and September) including joint meetings with stakeholders. They also noted that they welcome feedback/ideas/suggestions also in writing after the meeting. The main stakeholders' association attending the meeting welcomed this opportunity and some stated that they would contribute after consulting their partners in other jurisdictions.

Turkey: the Chair confirmed the alignment of their legislation to the MDR which was achieved in May 2021 and to the IVDR in September 2021; The alignment is officially recognised via statements of the EU-Turkey Customs Union joint committee and a relevant document will be published soon on DG SANTE website.

Israel: the Chair informed on some positive news recently received concerning the work of the Israeli government on a draft amendment of their legislation that would allow recognition of certificates issued by all notified bodies designated in all Member States. When more information becomes available, this will be shared with the group.

United States: the ad-hoc informal digital health think tank established by FDA continues to meet with the participation of HC, DE, DK, EU and recently with TGA as well; discussions are focused on AI; tackling of certain issues creating a mapping for regulatory standards for AI; focus on transparency of information to be provided to the user; no concrete deliverable planned.

Taiwan: Team NB informed that six notified bodies are recognised until now in the context of the Technical Cooperation Programme and more will follow soon. A meeting is scheduled to take place in April in Taiwan. There are no specific additional auditing requirements.

AOB:

Switzerland: the Chair reiterated that the EU always made clear that in absence of a deal on the Institutional Framework Agreement, a full update of the EU-Swiss MRA could not be considered, including the medical devices chapter. The consequences of the non-updated EU-Swiss MRA medical devices chapter are described in the Commission 'Notice to Stakeholders: Status of the EU-Switzerland mutual recognition agreement (MRA) for medical devices' published on 26 May 2021. The Notice also highlights that the part of this MRA chapter covering trade of in-vitro diagnostic medical devices, only continues to apply until the date of application of Regulation (EU) 2017/746 on in vitro diagnostic medical devices.

MRA with Australia: no news since previous meeting of the sub-group;

Ukraine situation and regulatory impact; industry noted potential challenges on transferring medical devices without CE marking through EU to Ukraine; national competent authorities in the meeting were not aware of any such situations but asked to be contacted directly in case any problems arise.

Free Sale Certificates (FSC): industry representatives reiterated that FSCs are essential for trade outside EU and they noted a fragmented approach as regards the issuing FSC. Taking into consideration that a Task Force (TF) under CAMD elaborated some work mainly towards best practices / common approaches to address some of the challenges, industry will share some information with the TF. It was also noted that MDCG has not identified this work as one of its priorities until now.

List of participants: BE, CZ, DK, DE, EE, ES, FR, HR, IT, CY, LU, AT, PL, PT, RO, SL, FI, SE; IC, TR; AESGP, Biomed Alliance, COCIR, EAAR, EUROM VI, EUROMCONTACT, European Society of Cardiology, MedTech Europe, Team NB.