# Minutes of the expert groups

Brussels, 9 December 2021

Minutes
Meeting of the International Matters Sub-group[1]
Brussels 7 September 2021

## 1. Welcome and Approval of the agenda

COM welcomed the attendees and introduced the agenda that was adopted by the members. Due to the COVID-19 pandemic development the meeting was web streamed.

## 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-20[2] Management Committee (MC) meeting scheduled for 13-16 September 2021 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

**Update from the Commission**: there was a very brief update mainly for new participants on the functions of IMDRF and MDSAP and the way of coordination and collaboration in these contexts.

**Debrief on IMDRF-19 Management Committee (MC) on 25 March 2021 and teleconference on 24 June 2021**: COM provided a summary of the last IMDRF MC meeting and teleconference. The update included an overview of the pending issue of work item extensions relating to IVDs, the liaison programme on standards, developments on collaboration with WHO on nomenclature and an information point related to Argentina becoming an official observer to the IMDRF.

**Draft Agenda of IMDRF-20**:
COM provided an overview of the main agenda points at the next IMDRF meeting.

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

**a. Regulated Products Submission**: participants discussed future activities and engagement; potential use of ToCs; input from notified bodies expected in the following weeks. No decision expected at IMDRF-20.

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

b. **Good Regulatory Review Practice (Essential principles and Principles of labelling)**: work is ongoing; no decision expected at IMDRF-20.

c. **Medical Device Adverse Event Terminology**: the group continues to work on maintenance terminology; no decision expected at IMDRF-20.

d. **Personalised Medical Device**: work is ongoing with participation from EU representatives; no decision expected at IMDRF-20 and some stakeholders flagged their interest to follow some of the discussions if that would be possible.

e. **Medical Device Clinical Evaluation**: the discussion on potential new work items did not conclude at TC of 24 June 2021 and a decision is expected to be taken at IMDRF-20.

f. **Medical Device Cybersecurity**: work is ongoing with participation from EU representatives; stakeholders participate as well; group working on two drafts on legacy and SBOM sections; a decision is expected to be taken at IMDRF-20.

g. **Artificial Intelligence Medical Devices**: the ongoing work with participation of EU representatives resulted in a document which is ready to be put on public consultation; a relevant decision is expected to be taken at IMDRF-20.

**Decisions at IMDRF – 20**: The group discussed:

**Artificial Intelligence Medical Devices (AIMDs)**: The EU agreed to support the document publication for 60-day public consultation. Additionally, EU to raise to the attention of MC that the Chair proposes a reduction on number of participants, which the EU is not in favour of.

**IVD Classification**: The EU will not object to the NWIE/P. However, it is important to raise concerns regarding the timetables foreseen (too ambitious – there is a need to re-evaluate) and stress the importance of this not being a simple 'mini-update'. Additionally, there is a need to reconsider composition of the group, as it will require both clinical and IVD representation.

**IMDRF membership applications**: Argentina was accepted as an official observer in IMDRF MC further to their previous application.

**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.

**Switzerland**: COM reiterated that following the unilateral decision of the Swiss Federal Council to terminate the negotiations of the EU-Swiss Institutional Framework Agreement (IFA) on 26 May 2021, a full update of the MRA medical devices chapter, which the EU always made clear was not possible in the absence of a deal on the IFA, was not concluded. Consequently, from 26 May 2021 the EU no longer has a valid MRA with Switzerland for non-*in vitro* diagnostic medical devices. Member States representatives raised market surveillance obligations related to Swiss manufactured and no longer valid Swiss certified devices.

**Turkey**: The Customs Union Joint Committee statement of May 2021, confirming Turkey's alignment with the EU Medical Devices Regulation (EU) 2017/745, has enabled the continuation of the EU-Turkey Customs Union for medical devices and its trade facilitating effect. Final steps to conclude Turkey's alignment with the IVDR are being concluded.

**Australia and New Zealand:** work is ongoing for the update of MRAs with the two jurisdictions and includes the updates of the legislative and competent authorities' references in the sectorial chapter, as well as of the "mutual confidentiality agreement".

**United Kingdom**: the MHRA - competent authority of Northern Ireland - will be granted partial access to EUDAMED to the extent necessary for the UK to comply with its obligations under the Protocol on Ireland/Northern Ireland.
Until EUDAMED is fully functional, the Commission will set up specific sub-folders in the CIRCABC platform for the exchange of information between Member States' authorities and the MHRA in respect of Northern Ireland.

**United States**: digital technologies workshop organised in June 2021with EU, DE, DK, AUS, UK, Health Canada; information exchange and exploration of further future collaboration as regards horizon scanning and AI regulations. At present not clear how often the group will meet. UDI: trying to work on a solution for registration of contact lenses in EUDAMED; alignment on issuing entities requirements; non-sterile surgical implants, exploring this further at EU level, exploring if room for collaboration.

**14. Other bilateral relations:** recently received some positive news from Israel and they informed that they are currently introducing legislative changes that will allow to accept certificates from notified bodies designated in all EU Member States.

**15. AOB**

- Product registration by MedTech Europe; EU MDR/IVDR impact on international registrations; CE marking; factsheets for non-EU countries helpful; COM is not pursuing any work on the template free sale certificate as this has not been identified as a priority.

- Taiwan: ongoing discussions for update of old agreement to include MDR/IVDR; information provided by Team NB who are following the discussions; small progress with the publication of first round of assessments.

**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.