EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health systems, medical products and innovation
Medical devices, Health Technology Assessment

Minutes of the expert groups

Brussels, 23 April 2021

Minutes

Meeting of the Medical Devices Coordination Group[1] (MDCG) with stakeholders 4/3/2021

1) Opening, adoption of the agenda

COM welcomed participants to this MDCG meeting with stakeholders, which is still virtual due to the COVID-19 pandemic. The agenda was approved and minutes of last meeting held on 20 October 2020 were endorsed prior to this meeting through written procedure and are published in the registry for European Commission's expert groups.

2) Short interventions by stakeholders associations

Some stakeholders' associations – COCIR, MedTech Europe, AESGP and Team-NB – briefly presented the perspectives of their members and informed on their readiness for implementation of the new legislative framework for medical devices. Overall, they confirmed their commitment as regards the MDR date of application (26 May 2021). While identifying potential roadblocks today and until the end of the transition period in 2024, no representatives pointed to any major availability concerns related to the date of application. . However, concerns were expressed in relation to the IVDR date of application (26 May 2022). These included the designation of only four notified bodies so far and long time needed to complete certifications.

Other concerns expressed related to lack of some guidance documents, lack of harmonised approaches by Member States on remote audits following the Commission Notice 2021/C 8/01 uncertainty related to the possible updating of the Mutual Recognition Agreement with Switzerland. COCIR repeated its concerns regarding the draft standardisation request under development, mainly stemming from issues arising from the horizontal legislative framework on standardisation.

3) IVDR Implementation

3.1 Report of activities of IVD MDCG Working Group

COM updated participants on the activities undertaken within the IVD Working Group. Its work programme is aligned with the Joint Implementation Plan (JIP) for the IVDR currently under discussion at the MDCG and also contains some work items related to COVID-19. Main work streams include:

[1] Published in the Register of Commission Expert Groups and Other Similar Entities, code number X03565

- Performance evaluation: large amount of comments received in stakeholder consultation and these are currently being processed, work estimated to be finalised in Q2 2021;

- On transposition of common technical specifications under the Directive to common specifications under the Regulation, the Commission recently submitted a proposal to the Member States and the draft will also be shared with stakeholders as soon as possible;

- On EU reference laboratories, the Commission and Member States continue discussion on practical aspects and the Commission continues its work on the implementing acts on tasks and criteria and on fees;

- On assays in clinical trials, as part of a task force joint with medicines authorities, a document is being prepared for stakeholder consultation, to be followed by a workshop with stakeholders.

Two new task forces have recently started operating: on summary of safety and performance and on in-house devices. Stakeholders will be involved at the appropriate time.

3.2 Key implementation priorities

COM informed about the last version of the summary of actions to be completed by 26 May 2022, from the draft IVDR JIP under development in the MDCG, was shared with the IVD WG. Some timelines still need to be reviewed, but nearly all work items are well under way. Stakeholders will be kept informed on the progress of the JIP (Joint Implementation Plan).

3.3 Monitoring the readiness of the sector

COM informed that they conducted a survey amongst notified bodies, industry and competent authorities to acquire quantitative data about the state of play with conformity assessment of devices on the market according to the IVDR. COM is currently processing the results and will inform of the outcome. They also intent to continue monitoring and repeat the surveys of notified bodies to monitor the trend with the numbers of certificates.

4) COVID-19 tests

4.1 Q&A on conformity assessment and performance on COVID-19 tests

This is an overview document, published on COM website at https://ec.europa.eu/health/sites/health/files/md_sector/docs/covid-19_ivd-qa_en.pdf. It is addressed at the general reader, answering some frequent questions and addressing some common misunderstandings around IVDs which have come to light during the COVID-19 crisis. Participants were invited to disseminate it further.

4.2 Common specifications for COVID-19 tests under IVDR – for information

With the kind assistance of German competent authority, draft common specifications for COVID-19 devices covering RT-PCR, antigen and antibody tests have been developed and a stakeholder consultation has taken place. Comments are currently being processed. It is planned to make the specifications available as guidance while the adoption process is ongoing.

5) Implementation MDR/IVDR

5.1 <u>MDCG Subgroups update</u>

COM gave a brief update on main activities of MDCG Subgroups since the previous meeting of MDCG and Stakeholders. All groups operate with excessive workload and limited resources.

- Notified Body Oversight (NBO): met on 5/2 to discuss COVID-19 exceptional circumstances and Commission Notice 2021/C 8/01; Task Force on Art. 117 MDR met a few times with the participation of EMA (European Medicines Agency) to discuss update of the Q&A on combination products drafted by EMA and on a number of fundamental issues related to combination products; progress have been made on certification activities under Art. 16 MDR/IVDR (joint TF with the Market Surveillance WG), the TF on appropriate surveillance to be carried out by NBs according to Art. 120(3) MDR, the TF on designation process and the TF on explanatory note of IVDR codes (Joint TF with IVD WG). For guidance on batch release, it has been sent for consultation of IVD WG and MDCG stakeholders. In addition, NBO will also attend a meeting with NBs on 11/03 on practical aspects related to the clinical evaluation consultation procedure.

- CIE: Clinical Investigation application template (in the absence of Eudamed) finalised, ready to be sent to MDCG for written endorsement; Q&A on Clinical Investigations, also finalised to be sent soon to MDCG for written endorsement; CIE WG support to Eudamed development, active, input provided to the development team.

- Borderline & Classification (B&C): guidance on borderline with medicines to be sent to stakeholders for comments soon, guidance estimated to be finalised by May 2021; guidance on classification of medical devices to be finalised also by May 2021.

- New Technologies: horizon scanning will be reinstated; also actively following the COM internal development of a horizontal AI legislation (artificial intelligence) and is actively participating in the IMDRF (International Medical Devices Regulators Forum) work item on AI; qualification of smart hardware (e.g. wearables) work has been initiated.

- Market surveillance: developing guidance on economic operators including on authorised representatives, a Q&A on Importers & Distributors, Art.16 re-packaging & re-labelling activities (Joint TF - Task Force - with NBO), and in-house devices (Joint TF with IVD WG). Work to 'Enhanced Cooperation & Coordination on Market Surveillance Activities' also continues, notably harmonisation & training initiatives under the Joint Inspectors Group (JIGs), development of the European Market Surveillance Programme & planned regular teleconferences. Two Task Forces are in an advanced stage to provide input to develop the Eudamed Market Surveillance module.

- Annex XVI products: TF established within the Annex XVI WG has finalised the draft of the main body of the common specifications and the draft implementing act on reclassification of active devices without an intended medical purpose. TF is still working on the Annexes of the common specifications, mainly to include requirements for the risk management process. All the drafts will be presented during the upcoming meeting of the Annex XVI WG, planned on the 8th March 2021.

- EUDAMED: currently working on draft Implementing Regulation on Eudamed, discussions on the development progress of Eudamed modules and on the necessary requirements, on outstanding issues regarding the use of Eudamed and finalisation of a guidance on alternative technical solutions until Eudamed is fully functional, which is already published.

- UDI: preparations ongoing for the launching of UDI Helpdesk; finalisation of the data set to be provided for the UDI/Device module of Eudamed. The work items are in advanced status (Storage-handling conditions and Critical warnings + clinical size and measure unit); facilitation of the implementation of the UDI by economic operators and the work items related are ongoing (elaboration of Guidance on integration of UDI into QMS and elaboration of FAQ on UDI regulatory questions).
  Application of the UDI system to specific devices, in particular the elaboration of the concept of Master UDI-DI and the adaptation of UDI rules for specific devices.

- Nomenclature: the first official version of the European Medical Device Nomenclature in Italian is available with thanks to the Italian Ministry of Health who has the lead on this project. Work ongoing is currently focused on translations into all EU languages. A first draft in English is currently under elaboration and is expected for publication prior to the date of application. As for the other EU languages, they will be rolled out as soon as they have been finalised and validated. Work is currently also ongoing with authorities on the elaboration of guidance regarding the allocation of EMDN codes to individual UDI-DI and on setting up the governance structure. In addition, work is currently ongoing on the harmonisation of terms to identify devices on the implant card.

- PMSV: the draft PSUR (Periodic Safety Update Report) guidance has been already largely completed following intensive work of the PSUR Task Force. It is planned to be adopted by beginning of May. A PSUR workshop, for industry and stakeholder organisations, is scheduled to take place soon for providing to operators the possibility to express their views on the draft guidance which will be circulated in advance of this event. Main objective to inform operators on requirements and timelines for the preparation and the submission of their first PSURs.

5.2 <u>Notified bodies</u>

COM shared an overview of notified bodies' activities at each stage of the joint assessment/designation process. A total of 53 applications for the MDR and 16 for the IVDR have been received. However, 4 of those applications were received from UK applicants and a further 2 applicants have withdrawn at various stages in the process. COM has received 53 preliminary assessment reports and has completed 47 on-site assessments (with further assessments scheduled). In addition, due to the travel and quarantine restrictions imposed by the COVD-19 pandemic, and therefore the inability to perform on-site assessments, there have been 2 preliminary remote assessments completed (both under the IVDR) in order to prevent delays to the joint assessment process and to allow conformity assessment bodies to progress with their applications. These preliminary assessments will be followed by on-site assessments in accordance with the process established by the Regulations and prior to designation of the

bodies. There are no outstanding assessments to be scheduled to-date. COM stressed that the final stages of the joint assessment process (CAPA plan reviews – JAT final opinion) are progressing well and have not been affected by the COVID-19 pandemic. A total of 23 notified bodies are now designated under the Regulations and published in NANDO (19 MDR & 4 IVDR).

5.3 Eudamed

COM presented the Eudamed state of play and roadmap. It was noted that the roadmap is an ongoing process constantly revised on basis of the advancement on gathering requirements and the progress done.

The actor module is in production since December 2020, the Data Exchange M2M issues have been solved and the Actor module M2M functionalities are currently used. COM announced delay of the deployment of the modules on devices registrations and on UDI & certificates from May 2021 to September 2021. Also, for the UDI/Devices and the Certificates modules, two playgrounds will be deployed, one in March and another in July. COM presented also a detailed list of the March playground functionalities.

For the second set of modules (Vigilance, CI and MS), COM is in the process of gathering requirements and a planning will be possible at a later stage.

5.4 Expert panels

COM announced that the panels for medical devices under MDR are expected to be opened for submissions from notified bodies on 1 April. A lot of work has been invested in order to ensure that, such as the completion of expert's registration and their contracts, establishment of experts' pools, experts' trainings, development of appropriate IT tools, elections of Chairs and vice-Chairs and development of Rules of Procedures for the panels. Data management will be an important aspect of the work of the panels as their work needs to be facilitated but also to ensure secured methods for sharing confidential information.

5.5 International matters

COM briefly updated on various developments on international files:

- Free trade agreements with AUS and NZ: discussions are ongoing and progress has been made for updating them

- Customs agreement with Turkey: technical assessment of Turkish legislation has been completed and agreement is expected to be signed soon, including an administrative agreement on data protection

- Possible update of MRA with Switzerland: discussions are currently ongoing at highest level. Stakeholders were asked to be prepared for a situation of no update prior to the date of application of MDR (26 May 2021)

- UK withdrawal agreement with Northern Ireland protocol: reminder of a useful notice for stakeholders published on 13 March last year available on COM website relevant to some questions received: https://ec.europa.eu/info/sites/info/files/notice_to_stakeholders_industrial_products.pdf

Further information is available at: https://ec.europa.eu/info/relations-united-kingdom/eu-uk-withdrawal-agreement/protocol-ireland-and-northern-ireland_en.

The Trade and Cooperation Agreement agreed at Christmas-time last year, contains a number of provisions aimed at preventing and addressing unnecessary technical barriers and requirements, including through bilateral cooperation, on market surveillance and product safety and the use of standards and conformity assessment procedures. More information is available here: https://ec.europa.eu/info/relations-united-kingdom/eu-uk-trade-and-cooperation-agreement_en.

6 AOB

MedTech Europe expressed their concerns in relation to a Q&A document and guidance document published by the European Medicines Agency (EMA) on implementation of MDR and IVDR, in particular in relation to the treatment of the concepts of devices integral and co-packaged with a medicinal product. COM taking note informed that they are currently collaborating with EMA in the auspices of the Task Force of implementation of Article 117 MDR, in order to update the Q&A document and guidance document. A request to review the matter from a legal perspective was made by MedTech Europe.

Next meeting

The date of the next MDCG meeting with stakeholders (most likely in virtual format) will be communicated to MDCG members as soon as possible.

List of participants

MDCG members: AT, BE, BG, HR, CY, CZ, DE, DK, EE, ES, FI, FR, GR, HU, IE, IT, LU, LT, LV, MT, NL, PL, PT, RO, SI, SK, SE.

Observers: CH, IC, NO, TR.

Commission: SANTE B6, SANTE F5, JRC F2, SANTE A4

Stakeholders' Organisations / associations participating in MDCG Subgroups.