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EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Medical Products and Innovation
Medical devices

Brussels, 17 April 2023

Minutes

Meeting of the Medical Devices Coordination Group[1] (MDCG) with stakeholders

17/04/2023

1. Opening, adoption of the agenda

The Chair welcomed the participants to this full day meeting with national competent authorities and stakeholders. The draft agenda was adopted without any modifications.

The Commission recalled the latest achievements in the field of medical devices since the last MDCG meeting:

- **March 2023** – Adoption of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and *in vitro* diagnostics
- **March 2023** – Finalisation and publication of the Q&A document on practical aspects related to the implementation of Regulation (EU) 2023/607
- **March 2023** – Publication of two Delegated Regulations amending the MDR and IVDR as regards the frequency of complete re-assessments of notified bodies
- **March 2023** – IMDRF meetings in Brussels (27-28 March)
- **February 2023** – 2nd revision of MDCG 2020-16 on Classification Rules for IVDs
- **February 2023** – Publication of Q&A on vigilance terms and concepts as outlined in Regulation (EU) 2017/745
- Listing in NANDO of 1 new notified body for the MDR (18 March) and 2 new notified bodies for the IVDR (16 & 18 February)

2. Transition to MDR/IVDR – *for information and discussion*

2.1 Regulation (EU) 2023/607 of the European Parliament and of the Council amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

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

The Commission recalled the recent publication of the Q&A document on practical aspects related to the implementation of Regulation (EU) 2023/607. It was noted that the Regulation has implications on existing implementing acts (e.g. Common Specifications for Annex XVI products) and guidance documents (e.g. MDCG 2020-3, 2022-4, 2021-25), which ought to be revised to align with the provisions set out in Regulation (EU) 2023/607. In addition to the documents already mentioned by the Commission, stakeholders highlighted the need to align MDCG 2020-6 guidance on clinical evidence needed for MDs previously CE marked under (AI)MDD with the new Regulation as well as all guidance documents referring to 'legacy devices'. It was also highlighted that the number of 'legacy devices' to be registered in EUDAMED could potentially increase significantly due to the extended transition period exceeding the timeline by when registration of devices will become mandatory according to current planning.

In terms of additional elements that should be clarified in an updated version of the Q&A document, stakeholders for instance raised: changes regarding the legal manufacturer and its qualification as a significant change; appropriate surveillance of the legacy device to be conducted by the MDD or MDR notified body; applicability of MDCG 2022-18; the impact on certificates of free sale and whether the foreseen 'self-declaration' from manufacturers will be sufficient to prove the validity of devices' certificates in this regard; implications on EUDAMED and UDI; cancellation of written agreement between notified body and manufacturer; cases where substitute devices are in lower risk class not requiring notified body involvement. Stakeholders were invited to submit these questions and provide draft answers to the Commission in writing.

Further, stakeholders called for a clear communication strategy to be put in place on the extended validity of certificates. It was suggested that the Commission provides information to third countries, e.g. through updated factsheets and at the occasion of the next IMDRF meeting (Sept. 2023 in Berlin).

2.2 **Implementation of MDCG position paper MDCG 2022-14**

The Commission provided a state of play on the multiple actions listed in MDCG 2022-14. For more information, please refer to the presentation.

During the meeting, stakeholders underlined the importance of notified bodies to leverage already existing evidence, of structured dialogues to be put in place and of EUDAMED to be functional. Notified bodies informed that dedicated trainings are being made available for manufacturers on the technical documentation to be provided for certifying medical devices and *in vitro* diagnostics. Some stakeholders called for greater momentum to implement the actions under MDCG 2022-14. Some Member States called for caution and careful planning and prioritisation of the activities under MDCG 2022-14 as these require extensive resources to be implemented.

2.3 **IVDR – conformity assessment of class D devices**

In terms of the general transition of the sector towards the IVDR, stakeholders reported a positive trend in applications and conformity assessments for IVDs. It was, however, also noted that systemic concerns about notified bodies capacity remain, that many SMEs have yet to sign a contract with IVDR notified bodies, and that the time to certification remains unpredictable and often very long. The leveraging evidence from previous assessments under the IVDD also remains difficult and the quality of the data submitted for conformity assessments very low,

especially in the case of applications by SMEs. Notified bodies informed that a framework for leveraging evidence from conformity assessments performed by notified bodies under the Directive will be developed for IVDs and that a dedicated training session on technical documentation will be organised for SMEs later in 2023. On performance study applications, stakeholders reported inconsistent assessments and procedures in Member States. Performance studies conducted in multiple Member States and combined trials (clinical trial of a medicinal product and performance study of an IVD) pose problems, resulting in delays. This matter will continue to be dealt with in the MDCG IVD WG.

On conformity assessment of class D devices, stakeholders called for the swift designation and operationalisation of European Union reference laboratories (EURLs). The Commission noted that the evaluation following the call for applications is ongoing and that the designation depends on capacity of candidates and quality of applications. It may be that some devices are not covered by an EURL even in the medium or long term if there is no sufficient capacity of laboratories that satisfy the criteria laid down in the IVDR. Stakeholders asked for more transparency in the designation process of EURLs. The Commission also noted that the absence of EURLs is not a legal barrier to certifying class D devices. All agreed that EURLs should be an enabling and not blocking factor in the certification of class D devices.

In this context, the Commission informed that it is looking into the next steps needed to make EURLs operational. In particular, it is considering a transition period in the designating act, with the designation coming into effect at its end. Further consultation was envisaged with Member States and stakeholders on the activities to take place during this transition period and on its length.

It was also recognised that for some class D devices, testing is particularly important to ensure their safety and appropriate performance, especially those that underwent batch testing already under the Directive. Notified bodies reported to be looking into other ways to test or otherwise confirm the performance of such class D devices when there is no designated EURL. The Commission proposed to explore how it and the Member States could support notified bodies in these activities.

Notified bodies invited manufacturers to submit applications at the latest by the end of 2023 for class D devices and other devices for which the end of transition period is 26 May 2025.

2.4 **Orphan devices**

The Commission and taskforce chair provided an update on the on-going work of the taskforce. Please refer to the presentation for more detailed information on the discussions held in the taskforce. As regards the next steps, some Member States expressed the need for MDCG to orientate the work of the taskforce. For that purpose, competent authorities should first agree on the scope and the objectives of the taskforce before further work is being conducted on the suggested work packages, having regard in particular the needs of patients and healthcare professionals. Several Member States stressed the importance of the work on orphan devices, which would have to be conducted in line with the spirit of the Regulations and without dilution of the requirements. Member States and stakeholders suggested that certain aspects of the current working definition for ‘orphan devices’ should be further considered. In this context, some Member States also called for more considerations to be given to devices intended for children and for unmet medical needs. Notified bodies and Member States called for possible ‘certification with conditions’ to be developed separately from the orphan device topic. Industry stakeholders pointed out that the EU was the only major jurisdiction without specific regulatory

pathway for unmet medical needs; regulators should clarify the level of clinical evidence needed for orphan devices.

As a next step, the taskforce will hold a closed session with only competent authorities to further discuss the work to be conducted by the taskforce and propose the way forward.

2.5 **Gaining momentum in designation process of notified bodies**

The Commission provided updates on the planned supporting measures for designating notified bodies, which include training support, additional guidance, increased transparency and process changes. It was noted that corrective and preventive actions review timelines are decreasing and that all parties must continue to work together to speed up the process of designating notified bodies, whilst preserving the level of requirements to be met under the Regulations.

2.6 **Support to SMEs and fostering innovation**

The Commission reported on its work in providing tailored services for SMEs through the Enterprise Europe Network and noted the intention to use the Network to enhance the planned actions on notified body capacity and manufacturers' preparedness.

3. **EU4Health actions supporting the implementation of MDR and IVDR** – *for information*

3.1 **Study supporting the monitoring of availability of medical devices on the EU market (HS-p-22-19.04, 06, 07, 08, 09, 10 and 11) (WP 2022)**

The external contractor of the study presented the study objectives, scope of the study, the timeline of planned consultation and survey activities, the datasets to be gathered and a mock-up of the dashboard that will be developed to graphically show the study results. For more information, please refer to the presentation.

3.2 **Grant for capacity building of notified bodies, preparedness of manufacturers (HS-g-22-19.03) (WP 2022)**

The external contractor of this project presented the objectives of the project and the short- and longer-term actions it aims to put in place to further increase the capacity of notified bodies and boost the preparedness of manufacturers. These include providing notified body training on access to immediate technology and improve the quality of file submissions of manufacturers in the short-term and ensuring appropriate matchmaking of notified body capacity with manufacturers demand in the longer term. For more information, please refer to the presentation.

3.3 **Communication campaign on MDR and IVDR (HS-p-22-19.04, 06, 07, 08, 09, 10 and 11) (WP 2022)**

The external contractor presented the actions that are being implemented under this project to promote and disseminate the information and communication material produced by the MDCG and the Commission to all relevant stakeholders. For more information, please refer to the presentation.

3.4 **Study on 'Governance and Innovation' (HS-p-22-19.04, 06, 07, 08, 09, 10 and 11) (WP 2022)**

The external contractor for this study presented the approach that will be taken in gathering information for the study, which will consist of a series of workshops, interviews, surveys, benchmarking, analysis/triangulation and desk research. Preliminary research questions that the study will aim to address were also presented. For more information, please refer to the presentation.

3.5 **Update on 2023 WP – possible actions and next steps**

The Commission gave a brief overview of the processes behind the EU4Health programme, including an overview of on-going or soon to start actions funded under the EU4Health 2022 and 2023 work programmes in the field of medical devices and *in vitro* diagnostics. The Commission also informed stakeholders about the targeted consultation on the current and future Union health priorities, which is open until 8 May 2023.

4. AOB

4.1 **EUDAMED** – *for information*

The Commission provided an update on the current state of development of EUDAMED. Currently, the Commission has delivered 3 modules in production – actors, devices, certificates – and 3 additional modules in the playground – vigilance, market surveillance and clinical investigation. The next functionality steps for EUDAMED to become operational have also been outlined. For more information, please refer to the presentation.

Stakeholders highlighted some of the issues they are facing with the current functionalities of EUDAMED and stressed the importance for EUDAMED to have a 360-degree testing with the involvement of stakeholders. Stakeholders also asked for more flexibility from vigilance triggers and more predictability of timelines of the helpdesk. Stakeholders enquired how national databases can leverage data from EUDAMED once the central database is mandatory to use and fully populated.

Both notified body and industry representatives asked the European Commission to organise a workshop dedicated to the useability of EUDAMED by stakeholders. The European Commission confirmed that this is indeed the intention but highlighted that such exercise would be more useful closer to the readiness date of the central database once most functionalities will have been already implemented.

4.2 **REACH authorisation requirement for DEHP in medical devices (e.g. blood bags)** – *for information*

The Commission informed the MDCG that discussions on extending the sunset date for DEHP in medical devices in Annex XIV of the REACH Regulation are ongoing. The topic will be discussed at the meeting of the REACH Committee on 27 April. Before a possible amendment of the current sunset date can be adopted, a formal vote must take place in the REACH committee followed by a 3 month scrutiny period of the European Parliament and Council of the EU.

List of participants

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

Observers: LI, NO, TR

Commission: SANTE D3, SANTE F5, SANTE R4, JRC F2

Stakeholders' organisations / associations participating in MDCG Subgroups