EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Medical Products and Innovation
Medical devices

Brussels, 13 December 2022

Minutes

Meeting of the Medical Devices Coordination Group[1] (MDCG) with stakeholders 24/10/2022

1. Opening, adoption of the agenda

This was the first physical (hybrid) meeting since COVID pandemic. The draft agenda was adopted without any modifications. The minutes of the MDCG meeting with stakeholders of 24 August 2022 had been endorsed prior to the meeting through written procedure and published on the Commission's Registry for expert groups.

- The Commission informed on the latest achievements mainly:
- Annex XVI: positive opinion on the draft Commission Implementing Regulations on common specifications for products listed in Annex XVI to Regulation (EU) 2017/745 (MDR) and on the reclassification implementing act for certain active devices without an intended medical purpose. The adoption procedure is currently ongoing and foreseen to be completed by December 2022.
- EURLs: In line with the Implementing acts on tasks and criteria and on fees adopted and published in June 2022 and the call for applications sent to Member States in July 2022, the laboratories are expected to submit applications to Member States by January 2023 and the Member States are required to submit the applications to the Commission by 31 March 2023. An information package for candidate labs has been published on the Commission website and also a contact list of responsible authorities.
- Common specifications for IVDs: Implementing act adopted in July 2022. Transition period until 2024.
- Guidance documents and position papers published:

* Rev.1 of MDCG 2022-21 on type of device for IVD expert panel – Sep 2022

* MDCG 2022-15 on appropriate surveillance for IVDs – Sep 2022

* Manual on borderline and classification under MDR and IVDR – Sept 2022

* MDCG 2022-14 on notified body capacity and availability – Aug 2022

* MDCG 2022-13 on designation, re-assessment and notification of notified bodies – Aug 2022

* MDCG 2022-12 on harmonised administrative practices and alternative technical solutions until Eudamed is fully functional – July 2022

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

* MDCG 2022-11 on manufacturers to ensure timely compliance with MDR requirements – June 2022

- A dedicated IVD section was added to the Commission's medical devices website.

2. Transition to the MDR and IVDR

2.1 Implementation of MDCG position paper MDCG 2022-14 – state of play

The Commission provided a state of play on the multiple actions listed in the above mentioned MDCG position paper MDCG 2022-14, including an overview of the pending designation process of notified bodies under the MDR and IVDR.

The two presentations are made available together with these minutes.

2.2 Calls for additional measures to avoid shortages of medical devices – exchange of views

Stakeholders' associations / organisations made presentations and presented various challenges they are dealing with as regards the implementation of MDR / IVDR.

Overall, they appreciated the work delivered by the Commission and the MDCG until now including the several actions listed in the position paper MDCG 2022-14. However, there was consensus among stakeholders' associations / organisations that those actions were not enough. In particular, they asked for further legislative amendments especially of the transitional provisions to ensure availability of devices. For that purpose, the transitional periods should be extended (possibly in a staggered and risk-based approach), (AI)MDD certificates should be extended, and the sell-off date be removed. Some associations also asked for the possibility of temporary / provisional MDR certification in order to support necessary significant changes and device innovation. It was stressed that extension of certificates should be done without extra workload on notified bodies.

Besides the challenges directly related to MDR requirements, stakeholders pointed to difficult external factors putting pressure on regulatory compliance and supply chains, such as COVID 19, energy crisis, Ukraine war, and other relevant EU regulations. Some stakeholders also asked for a more coordinated approach by competent authorities as regards derogations.

The Commission thanked all for their contributions. It noted the wide support to MDCG position paper MDCG 2022-14 and acknowledged that the Commission was listening attentively to calls for additional measures. At the same time, it reminded that transition to MDR is a shared obligation between all relevant actors and discussions with MDCG and other relevant stakeholders will continue.

3. **EUDAMED** – state of play

The Commission has delivered the first set of modules (Actors registration, UDI/Devices and NBs and Certificates) in production and the second set of modules (Clinical Investigations and performance studies, Vigilance and post-market surveillance and Market Surveillance)

will remain only in the playground until EUDAMED full functionality and the functionalities will be gradually delivered in quarterly releases.

The Commission gave some statistics on the users and the content in Production, presented the EUDAMED customer service (constituted of two pillars; the Support team and the information Centre), gave a state of play of the Q3 release and presented a revised roadmap at high level, only spotting the relevant features timeline.

The Q3 Playground release 3.2 was successfully deployed on 19 October and the deadline for feedback is early December. A release in Production with some improvements and bug fixing is expected in November.

4. AOB

N/A

List of participants

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

Observers: LI, NO, TR.

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

Stakeholders' organisations / associations participating in MDCG Subgroups