EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Medical products and innovation
Medical devices

Brussels, 18 October 2022

Minutes

Meeting of the Medical Devices Coordination Group[1] (MDCG) 25/8/2022

1. Opening, adoption of the agenda

The Chair welcomed the MDCG members to this extraordinary meeting dedicated to notified body capacity and availability of medical devices and IVDs, and introduced the draft agenda, which was adopted with the addition of several points under AOB (see below).

The minutes of the MDCG meeting of 19-20 May 2022 had been endorsed prior to the meeting through written procedure and published on the Commission's Registry for expert groups.

2. Draft MDCG position paper "Transition to the MDR and IVDR: Notified body capacity and availability of medical devices and IVDs" – ***for discussion and endorsement***

The Chair provided a short debriefing of the MDCG meeting with stakeholders on 24 August 2022 where stakeholders had expressed broad support for the draft MDCG position paper, while emphasising the need for more clarity regarding the implementation of the different actions as well as the need for additional measures going beyond the current regulatory framework.

MDCG members expressed their full support for the MDCG position paper which was endorsed with only minor changes[2]. Many MDCG members asked for urgent follow-up and close monitoring of the actions listed, to be ensured by the MDCG Coordination Group. The Chair announced that a draft implementation plan would be circulated to MDCG for comments shortly after the meeting.

While supporting the positive effects on the transition to the Regulation of the actions listed in the MDCG position paper, a number of MDCG members argued that those actions would not be sufficient. Therefore, reflexions on a back-up plans, including possible legislative measures, should be undertaken. While the urgency of mitigating measures was stressed, also the request to manufacturers to undertake all reasonable efforts to transition to the new Regulations was reiterated.

Moreover, while several MDCG members stressed the importance of applying market surveillance measures and national derogations (Articles 59 and 97 MDR) cautiously, many referred to an urgent need to coordinate the approach among Member States regarding the use

[1] Published in the Register of Commission Expert Groups and Other Similar Entities, code number X03565
[2] Published as MDCG 2022-14

of these provisions, especially as regards cases where Directives' certificates expire already in 2022 and 2023.

3. Preliminary draft for Commission delegated acts amending Article 44(10) of Regulation 2017/745 of the European Parliament and of the Council on medical devices and Article 40(10) of Regulation (EU) 2017/746 of the European Parliament and of the Council on in vitro diagnostic medical devices as regards the frequency of complete re-assessments of notified bodies - *for discussion*

MDCG members supported the planned acts, including the envisaged flexibility regarding the timing of complete re-assessment and the transitional provisions regarding ongoing re-assessments. One MDCG member expressed its preference for a temporary character of the change of frequency of complete re-assessments until the current challenges related to notified body capacity were solved.

A Commission representative explained the procedure for the adoption of a delegated act (Commission inter-service consultation; consultation of national experts, i.e. MDCG; adoption by Commission; 3 months objection procedure by Council and Parliament; no urgency procedure). As to a possible return to the frequency for re-assessment as currently laid down in the MDR and IVDR, the Commission representative mentioned that such a change could be done again by delegated act.

Having regard to the broad support for the delegated acts and the expected immediate positive effects of the deferred timing of complete re-assessments in the current situation, MDCG (including the Commission) confirmed their common understanding that the planning for complete re-assessments could already be adapted to the schedule laid down in the draft delegated acts.

One MDCG member enquired whether the joint assessment team (JAT) for the re-assessment had to be composed of the same members as the JAT for the initial joint assessment. The Commission representatives explained that Article 44(10) MDR referred to the same process for setting up a JAT for the complete re-assessment as for the initial assessment prior to designation; the JAT for re-assessment, however, does not have to be composed of the same

MDCG members were given until 2 September 2022 to provide comments in writing.

4. AOB

- Recording of a MDCG member's diverging position

The Chair referred to a note circulated prior to the meeting regarding the way how a MDCG member's diverging position in respect of a MDCG guidance could be handled in line with Article 103(4) MDR. Concretely, it concerns the German and Italian MDCG members' objections to the borderline guidance MDCG 2022-5. The Commission intends to circulate an updated text for the disclaimer in MDCG 2022-5 that will refer to the MDCG minutes which will contain the grounds for the diverging positions.

- EMA's extended mandate regarding monitoring of shortage of medical devices

The Chair informed about correspondence from EMA asking for help to identify experts who could be involved in the preparatory work under Regulation 2022/123 (extended EMA

mandate) to monitor shortages of medical devices. The Chair clarified that this is not a MDCG task or work.

- Joint actions on market surveillance

The Chair informed that the deadline for nominations to the joint actions on market surveillance is 1 September 2022 and encouraged competent authorities to participate.

- Annex XVI MDR products

A Commission representative informed that the Medical Device Committee in its meeting on 6 July 2022 issued 'no opinion' with regard to the draft Commission implementing act on common specifications for Annex XVI products. The Commission representative reminded that the legal deadline for adopting the common specifications has already passed and that the Commission pursues its objective to adopt the common specifications as soon as possible.

Next meeting

The next MDCG meeting is scheduled for 24-25 October 2022.

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: LI, NO, TR.

European Commission and Agencies: SANTE B6, SANTE F5, JRC F2.