EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Medical Products and Innovation
Medical devices

Brussels, 11 October 2023

Minutes

Meeting of the Medical Device Coordination Group[1] (MDCG)

10-11/10/2023

1. Opening, adoption of the agenda

The Chair welcomed the participants to the closed session with competent authorities only. The draft agenda was adopted with the addition of three AOB points:

- Availability of Cobalt 60
- Performance studies involving routine blood draws
- Language requirements

2. Preliminary discussion on MDCG short- and medium-term priorities – *for information and discussion*

Prior to the open session with the stakeholders, competent authorities exchanged their preliminary views on the short- and medium-term priorities of the MDCG. Competent authorities notably stressed the need to focus efforts on the implementation of the regulatory system to achieve its objectives of ensuring patient safety and support innovation.

3. Follow up from Day 1 – *for discussion*

The MDCG elaborated further on the status of the transition to MDR and IVDR, the tasks assigned to expert panels and the study on regulatory governance and innovation in the field of medical devices.

On the transition to MDR and IVDR, competent authorities held further discussions on the data presented the previous day on applications and certificates from the study "supporting the monitoring of the availability of medical devices on the EU market". Whilst MDCG members noted some improvement in the figures, such as the increase of certificates issued within the last year, concerns remain. For medical devices, competent authorities noted the still low numbers of QMS certificates as well as a high number of changes of certificates after they have been issued. The need to gain a clearer picture of notified body capacity and hold more granular exchanges with notified bodies on the transition was raised. MDCG members also noted that some manufacturers seem to still be waiting before transitioning to the MDR. Additionally,

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

MDCG members noted that no data is currently being gathered systematically on devices that will be discontinued from the market. In this situation, it is difficult to foresee and adequately mitigate shortages that have a serious impact on patient safety. For IVDs, some MDCG members noted the overall increase in number of certificates but stressed that figures for IVDs are more difficult to interpret, as no clear picture exists on the total number of certificates that are expected to be issued. The Chair noted that there are two benchmarks of what could be expected: data from a survey by MedTech Europe[2] on the number of devices yet to transition to the IVDR and the number of certificates issued under the IVD Directive (severalfold more should be expected under the IVDR). The currently issued number of certificates is far below both of them, especially for class D IVDs, which is worrying. For both medical devices and IVDs, MDCG members agreed on the importance of reinforcing the message that all stakeholders must transition to the MDR/IVDR and that applications should not be further postponed as this would generate additional bottlenecks.

On the tasks assigned to expert panels, competent authorities further discussed opportunities of potential areas where the advice and involvement of expert panels could be valuable. Specific areas mentioned include the development of common specifications or device-specific guidance for certain high-risk legacy devices, assessment of the criticality of potentially discontinued devices in the future, advice on market surveillance, and safety issues. The Commission will continue to engage with the European Medicines Agency to discuss the feasibility of the expert panel's involvement in these areas.

On the study on regulatory governance and innovation, the Commission consulted MDCG members on the need to establish a dedicated taskforce on evidence gathering and analysis, which would have the primary task to support the monitoring of this study and ensure that relevant results are yielded. MDCG members in principle agreed with this suggestion.

4. **Priorities of the MDCG 2024** – *for discussion*

The Commission noted that the main aim under this agenda point is for the MDCG to provide guidance to the chairs and co-chairs of the various MDCG subgroups to ensure that the work programmes of the working groups reflect the priorities of the MDCG. As preliminary, very broad priorities the following were mentioned: ensuring the availability of medical devices and IVDs, supporting the transition to the MDR/IVDR notably through implementing the actions listed in MDCG 2022-14, ensuring the development of EUDAMED and supporting innovation. It was agreed that further discussions are needed to refine and finetune the MDCG priorities and discuss which actions need to be put in place to reach those priorities.

For the work of the subgroups, overall guidelines provided to the chairs/co-chairs included to focus efforts on those items that are close to completion, those that are listed in MDCG 2022-14 and those that support the preliminary, broad priorities as mentioned above.

5. **Documents for endorsement** – *for endorsement*

[2] mte_public-report-ivdr-survey_27-feb-2023.pdf. (medtecheurope.org)

5.1 **New Work Item Proposal: Guidance for manufacturers and notified bodies on the application of clinical evaluation requirements to orphan devices in view of their certification in accordance with the MDR**

The New Work Item Proposal was endorsed by the MDCG.

5.2 **New Work Item Proposal: Revision of guidance concerning legacy devices to be aligned with the new transitional provisions**

The New Work Item Proposal was endorsed by the MDCG. It was suggested that the MDCG ad hoc taskforce should consider whether changes to MDCG 2021-25 would be relevant also for MDCG 2022-8 regarding the application of the IVDR to 'legacy devices'.

5.3 **MDCG recommendations on the draft designation of notified bodies under Article 39(9) of Regulation (EU) 2017/745.**

The recommendations on the draft designation of two notified body under the MDR were endorsed by the MDCG.

6. **Position paper MDCG 2022-11 update** – *for discussion*

The Commission presented an updated version of the position paper MCDG 2022-11 "Notice to manufacturers to ensure timely compliance with MDR requirements". Competent Authorities agreed on the approach of addressing the notice to both manufacturers and notified bodies. During the meeting, some MDCG members shared additional suggestions that will be considered for inclusion by the Commission.

7. **Reprocessing of single use medical devices** – *for information and discussion*

The Commission presented an overview of the challenges in the implementation of Art. 17 of MDR on reprocessing single use medical devices due to the differences across Member States. The Commission also informed that there is an ongoing study assessing the implementation of Art. 17 across Member States. Preliminary results of this study are expected to be ready by the end of October 2023.

8. **CAMD – state of play** – *for information from the Chair of the executive group of CAMD*

The Chair of the executive group of Competent Authorities for Medical Devices (CAMD) presented a general update on the state of play of activities conducted under CAMD. Reinforcing the collaboration between CAMD, the Commission and the MDCG was stressed to ensure alignment and avoid any duplication of work.

9. **AOB**

9.1 **Availability of Cobalt 60**

The Commission informed that according to the latest information, no shortage of Cobalt 60 should be observed. The Commission will continue to monitor the situation closely.

9.2 **Performance studies involving routine blood draws**

MDCG members recalled the point raised by stakeholders during the first day on the need to seek authorisation of performance studies involving routine blood draws. It was noted that this is a long-standing issue related to blood draws being considered as 'surgically invasive procedures' on which competent authorities have had heterogeneous views in the past. This topic is to be further discussed during the MDCG IVD working group meeting on 12 October.

9.3 **Language requirements**

To provide all stakeholders, especially SME manufacturers with an overview of language requirements Member States foresee for documents to be prepared by manufacturers (e.g. label, instructions for use, field safety notice etc), the Commission informed that a table will be circulated to MDCG members asking to correct and complete the information with regards to their national legislation. This language requirement table is foreseen to be published on the Commission's website once completed.

Next meeting

The next MDCG meeting is scheduled on 11-12 December 2023.

List of participants

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

Observers: IS, LI, NO, TR

European Commission and Agencies: SANTE D3, SANTE F5, JRC F2, HADEA A2, EMA