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) 24-25/10/2022

1. Opening, adoption of the agenda

This was the first physical (hybrid) meeting since COVID pandemic. The draft agenda was adopted with the addition of three points under AOB, regarding HERA preparedness mode activities, supporting actions under EU4Health for MDR/IVDR implementation and information on blood bags shortages in a MS.

The minutes of MDCG meetings of 24-25 August 2022 had been endorsed prior to this meeting through written procedure and published on the Commission's Registry for expert groups.

2. Transition to MDR/IVDR

Capacity and availability focus of discussions

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

MDCG expressed its appreciation for the extensive work which is ongoing by the Coordination Group of MDCG (CG) supported by the Commission. A lot of different work strands and actions included in MDCG 2022-14 are under discussion and significant progress has been noted for most of them.

In several meetings, the CG had discussed the possibility of using market surveillance measure in accordance with Article 97 MDR as a possible 'bridging' measure for avoiding disruption of supply of legacy devices for which the MDD or AIMDD certificate has expired or expires before issuance of the necessary certificate under the MDR. There is strong interest in finding a uniform and consistent approach to the application of Article 97 MDR by competent authorities in those situations. A relevant draft document is being developed.

MDCG members overall welcomed the draft paper, which would only need clarification of some remaining issues. During the discussion, it was highlighted that Art. 97 MDR is a new market surveillance tool that did not exist under the Directives. Competent authorities should apply in a workable way and with an internal market perspective. At the same time, it was stressed that application of Art. 97 MDR was no sustainable solution for dealing with the certification bottleneck towards May 2024. Besides the content of the paper, also

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

communication about the approach, especially its timing, was discussed. MDCG members were asked to provide any written comments on the draft paper by 27 November 2022.

The Commission will continue supporting the work on the various actions included in MDCG 2022-14 position paper, including to find a uniform approach to Article 97 MDR, in close collaboration with MDCG. The Commission also confirmed its readiness to continue supporting cooperation on assessment practices for national derogations upon request of MDCG members.

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

MDCG 2022-14 position paper and all its actions included was broadly supported by MDCG members. However, several MDCG members noted that they considered that additional measures were necessary to prevent shortages of devices by the end of the transition period in May 2024.

MDCG took note of a non-paper on MDR based on a common initiative from France, Ireland and Germany and formally supported by six other countries. While stating their commitment to full and effective implementation of MDR, they consider the need for a targeted amendment of MDR, mainly aiming to extend the transitional provisions. The non-paper was supported by several other MDCG members as they consider these proposals would mitigate risks of shortages of devices with (AI)MDD certificates not yet certified under MDR.

The Commission confirmed its view that the actions included in MDCG 2022-14 position paper will make a real difference. At the same time, it is attentive to the concerns expressed by MDCG members, Member States, Member of the European Parliament and stakeholders. As requested by EPSCO Council in June 2022 the Commission will report back to the next EPSCO Council on 9 December to present clear orientations regarding the way forward for consideration of Health Ministers.

MDCG member from DE leading the taskforce on orphan devices provided a short update on the ongoing work and informed on a dedicated workshop with stakeholders scheduled for 26 October 2022.

3. MDCG priorities for 2023 – *for discussion*

While recognising the great output and deliverables by MDCG since its establishment towards the end of 2017, with more than 100 guidance and other documents produced, the Commission proposed a discussion and general agreement on work priorities for 2023.

Following the concerns expressed by EPSCO in June 2022, on potential disruption of supply of devices and the endorsement of MDCG position paper 2022-14 which contains 19 mitigating actions, a lot of resources have been and will continue to be dedicated on these, which essentially impacts other work strands. To mitigate potential shortages of critical devices was agreed to be the first priority for MDCG in 2023. At the same time, it was recognised that there are other important work streams that require efforts and resources in 2023, such as the obligation for EU to chair IMDRF (International Medical Device Regulators Forum), continue intensively Eudamed development, ensure designation of EU Reference Laboratories under IVDR, adoption of key tertiary legislation (standards, UDI, CSs) and initiate calls for reflections

on how to ensure a sustainable framework for medical devices in medium/long term, including issues linked to innovation, competitiveness and safety coordination.

It was agreed that pursuing work on all these priorities, including investing adequate resources both from NCAs and the Commission, is likely to have an impact on other work strands currently ongoing or included in the Work Programmes of MDCGs working groups. It was considered justified to delay or put on hold some of the work that is not directly linked to the identified priorities.

MDCG decided to continue this discussion on priorities at the level of the CG (Coordination Group) and invite them to come back with their proposals to MDCG.

4. Notified Bodies under MDR / IVDR

4.1 MDCG recommendations on the draft designations of notified bodies – *for endorsement*

Following description of the outcome of the relevant joint assessments process, MDCG issued two positive recommendations for the designation of notified bodies under Article 39(9) of Regulation (EU) 2017/745, according to which the applicant notified bodies should be designated within the scope proposed by the designating authorities.

4.2 Revision of question III.6 of MDCG 2019-6 concerning the meaning of the term "employed" in MDR Article 36(1) / IVDR Article 32 (1) – *for endorsement*

After adding minor editorial changes, MDCG endorsed the above revision which was identified as one of the priority actions in MDCG 2022-14 position paper, aiming at enhancing notified body capacity. The proposed text is the result of several rounds of consultations at MDCG NBO (Notified Body Oversight) sub-group, including feedback from notified bodies and stakeholders.

5. Draft Commission delegated acts – *for consultation*

5.1 Draft COMMISSION DELEGATED REGULATION (EU) …/... of XXX amending Regulation (EU) 2017/745 of the European Parliament and of the Council as regards the frequency of complete re-assessments of notified bodies

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The Commission informed about developments regarding the two draft delegated acts since the presentation of preliminary drafts at the meeting on 24/25 August 2022. Adoption of those acts is one of the actions listed in MDCG 2022-14 position paper. The draft acts presented now are the result of the Commission's interservice consultation and, after translation, will be submitted to the Commission for adoption by the end of November/beginning of December 2022. MDCG expressed their full support for the delegated acts.

Due to the deferral of the timing of complete re-assessment with the involvement of joint assessment teams, the importance of surveillance and monitoring activities by national authorities was highlighted. It was suggested that NBO should look into mechanisms to ensure effectiveness of those national surveillance and monitoring activities.

It was also stressed that the addition of designation codes should be simplified, so that scope extensions could easily be done in between complete re-assessment cycles.

6. In vitro diagnostic medical devices – *state of play of implementation*

MDCG was updated on different actions supporting IVDR implementation.

6.1 Performance studies

MDCG IVD sub-group conducted a survey and is looking into requirements on high-risk performance studies. Some stakeholders have reported heterogeneous processes for authorisation and notification of high-risk performance studies between different Member States, in particular when these studies concern a combined trial with a medicinal product. The sub-group may come up with proposals for potential work items for next year on this topic.

6.2 Common specifications (CS)

MDCG IVD sub-group is engaged in the development of three new sets of common specifications for class D devices with input developed by MedTech Europe (hepatitis E, Toxoplasma and Plasmodium). The aim is to prepare the amendment of the CS implementing act by end of 2023.

In relation to CS for highly virulent influenza, a request for advice was sent to IVD expert panel as to which influenza devices would fall into class D. The process is expected to be finalised by 31 October 2022.

The first draft of CS for arboviruses is also expected by the end of 2022.

6.3 Guidance documents

MDCG was updated on the progress of various guidance documents, the following have been published:

MDCG 2021-22 type of device in context of expert panels: Rev.1 published in September 2022

MDCG 2022-15 appropriate surveillance for IVDs: published in September 2022
Furthermore:

- MDCG 2021-16 classification of IVDs: Rev 2 in preparation, to be proposed for endorsement before the end of the year
- Performance study application/notification forms: review of comments ongoing following MDCG endorsement period

- Draft guidance on in-house devices: in preparation for sub-group endorsement.

The work item on health crisis preparedness is ongoing with a draft paper prepared by the Commission.

6.4 European Reference Laboratories

Following the adoption of the implementing acts on tasks and criteria and on fees in June 2022, the Commission launched a call for applications 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. Exchanges between Member States are ongoing to ensure a common understanding as to the assessment of compliance with criteria. A candidate information pack is also available on the Commission website, as well as a list of contact points of competent authorities that deal with EURLs in each country. A survey conducted among Member States currently indicates ~30 interested labs covering all categories of designation (although not all may eventually submit an application).

The IVDR joint implementation and preparedness plan will be updated to mark the completion or advancement of various work items.

7. Market surveillance

7.1 Guidance on Authorised Representatives MDR/IVDR – *for endorsement*

MDCG endorsed the above guidance which was developed and proposed to MDCG for endorsement by MDCG Market Surveillance sub-group. MDCG IVD and stakeholders were consulted in the development phase.

This guidance document is written for authorised representatives, manufacturers and other economic operators, and intends to provide guidance on relevant requirements under the Regulations. Where clarification is already covered by other MDCG guidance documents, this guidance on authorised representatives includes a reference.

8. **Update of MDCG 2020/10/1 Safety reporting on clinical investigations of medical devices under (EU) 2017/745**– *for endorsement*

The Commission presented a draft update of MDCG 2020-10/1 Safety reporting on clinical investigations of medical devices under (EU) 2017/745, on behalf of MDCG CIE subgroup. The initial guidance as well as the amendment were developed by MDCG CIE subgroup and deal with safety reporting of events occurring during clinical investigations, in the absence of EUDAMED.
An MDCG member asked for some clarifications therefore MDCG decided to proceed with written endorsement following this meeting.

9. **Expert Panels** – *state of play*

EMA provided a state of play of the activities of the expert panels. As regards the Clinical Evaluation Consultation Procedures (CECP) and Performance Evaluation Consultation Procedures (PECP), 38 CECP applications and 16 PECP applications were submitted since the implementation of these activities leading to 10 opinions and 16 views respectively. Since the last MDCG meeting in May 2022, 7 opinions and 1 view were developed by the expert panels. As regards additional activities, one advice to the MDCG was being finalised by the IVD panel. The implementation of advice to manufacturers is currently being discussed internally at the EMA and with the European Commission. The Commission complemented with information on the expected number of submissions for the period 2022 – 2023.

10. Recording of diverging positions on MDCG guidance – *for discussion and agreement*

10.1 General principles

MDCG discussed and agreed the recording of diverging opinions as regards the endorsement of guidance documents. According to Article 103(4) of MDR, MDCG shalluse its best endeavours to reach consensus. If such consensus cannot be reached, the MDCG shall decide by a majority of its members. Members with diverging positions may request that their positions and the grounds on which they are based be recorded in the MDCG's position. A recent example is MDCG 2022 – 5 'Guidance on borderline between medical devices and medicinal products under Regulation (EU) 2017/745 on medical devices', endorsed and published while two MDCG members maintain their reservations and ask for their recording.

It was agreed that if consensus could not be achieved in writing, in principle a discussion in MDCG should be organised to allow objecting MS to present their view points. When requested, diverging opinions will be recorded as follows: the objection and justifications for the diverging opinions will be published in the minutes of the first available MDCG meeting; a link to the relevant MDCG minutes will be added to the published guidance documents to reflect the recording of diverging opinions.

10.2 Guidance on borderline between medical devices and medicinal products under (EU) 2017/745 (MDCG 2022-5)

MDCG agreed to handle to objections from DE and IT to MDCG 2022 – 5 according to this procedure. The divergent opinions are embedded below.


DE dissenting position MDCG 2022-


IT dissenting position MDCG 2022-5.pdf

11. IMDRF Chairmanship 2023

MDCG acknowledged the huge challenge for EU to chair for 2023 the Management Committee of IMDRF (International Medical Device Regulators Forum). This will be a highly intensive exercise coordinated by the Commission with more active participation by national competent authorities urgently required. It was also recognised that during the last years we were more focused on MDR/IVDR implementation at EU level and now is a good opportunity to reconnect with our international partners in the context of IMDRF. MDCG members were invited to check with their colleagues and reach out to the Commission with possible candidates for participating in the relevant expert groups.

In the meantime, the Commission informed that the first series of physical meetings will take place in Brussels last week of March 2023 and MDCG members will receive invitations to attend, while the second series of physical meetings will take place in Germany late in September 2023.

12. AOB

12.1 Update from HERA

The Health Emergency Preparedness and Response (HERA) informed briefly MDCG on their preparedness mode activities by collecting information on medicines, medical devices and PPEs. Upon request by MDCG more information can be shared at a later stage.

12.2 EU4Health Programme to support implementation of the Regulations on medical device

MDCG received information on funding opportunities and relevant projects and activities that are supported financially by EU4Health program and aim at supporting implementation of the new legislative framework, i.e., on joint inspections, supporting capacity of notified bodies, UDI database development infrastructure, communication campaign, support Eudamed infrastructure, study on governance and innovation and others. It was also noted that organisation of all MDCG related meetings are supported by EU4Health. The program is managed by HADEA (European Health and Digital Executive Agency).

The Commission will keep MDCG informed for any updates but in the meantime national competent authorities looking for funding opportunities could consult the relevant website of the European Digital and HADEA https://hadea.ec.europa.eu/programmes/eu4health_en

12.3 Blood bags potential shortages

PL MDCG members informed about potential shortages of blood bags with citrates based on information collected by national blood centres. One MDCG member suggested that blood bags could be an example for prioritisation of certification by notified bodies in the public interest. Another MDCG member stressed that there should be no automatism between EMA's scientific opinion on the qualification of citrates as medicinal substances and the application of rule 14 to blood bags containing citrates. Member States were asked to report similar concerns related to availability or classification aspects.

Next meeting

An extraordinary MDCG meeting dedicated to the issue of notified body capacity and manufacturers' preparedness is scheduled for 17 November 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 D3, SANTE R4, SANTE F5, JRC F2 and European Medicines Agency (EMA).