EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health systems, medical products and innovation
Medical devices, Health Technology Assessment

Brussels, 4 July 2022

Minutes

Meeting of the Medical Devices Coordination Group[1] (MDCG) 19-20/5/2022

1. Opening, adoption of the agenda

The Chair welcomed the MDCG members to the meeting and introduced the draft agenda. The draft agenda was endorsed with the addition of one point under AOB from an MDCG member on Eudamed and two info points by the Commission on Regulatory committee and collaboration with WHO.

The minutes of MDCG meetings of 21-22 March 2022 were endorsed prior to this meeting through written procedure and published on the Commission's Registry for expert groups.

2. MDCG governance - *for discussion*

The Commission noted that a significant amount of work is ongoing in collaboration with MDCG with the objective to improve governance aspects

2.1 Standard operative procedures (SoP)

Following previous exchanges a draft SoP has been developed by the Commission and two MDCG members volunteered to contribute and already provided comments. The draft SoP will be send to MDCG for consultation and possible comments.

2.2 Coordination group to support the work of MDCG

The coordination group – CG – established by MDCG to support its work, ensure a more participatory approach and strategic discussions has already met five times and discussions are ongoing with the seven MDCG members who volunteered to be part of the CG. After each meeting MDCG is informed on the outcomes. The Commission also informed on their meeting with the HMA Core Group and reminded that they still need a volunteer from a competent authority to co-chair the MDCG PMSV expert group.

3. *In vitro* diagnostics medical devices

3.1 Guidance for IVD legacy devices - *for endorsement*

MDCG endorsed the guidance prepared by the MDCG IVD expert group which aims at clarifying continuation of placement on the market of devices which were certified under

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

the Directives. It follows the same approach as for the guidance MDCG 2021-25 previously endorsed by MDCG on "legacy devices" under MDR.

3.2 Template for summary of safety and performance - for endorsement

MDCG endorsed the summary of safety and performance prepared by the MDCG IVD, as laid down in Article 29 of the IVDR, which is also a work item listed in the IVDR Joint Implementation and Preparedness Plan.

3.3 EU reference laboratories

The Commission presented the state of play of the designation of EU Reference laboratories in the field of *in vitro* diagnostic medical devices including the outcomes of a dedicated workshop they had previously organised with the participation of interested candidates. Main next steps are expected to be the publication of the call for expression of interest in English and the evaluation based on the selection criteria. Adoption and publication of the two relevant implementing acts is expected to be finalised in the following weeks.

3.4 Common specifications for class D IVDs

MDCG received prior to the meeting the draft common specifications for class D IVDs. A great number of comments were received after public consultation integrated in the draft. The Commission provided a short state of play in preparation for the Regulatory Committee foreseen for 9 June, in which the Member States will be invited to vote on the act.

3.5 Joint implementation and preparedness plan

The Commission informed on small editorial changes on the Joint Implementation and Preparedness Plan for the IVDR, mainly due to the date of application of IVDR and corresponding timelines. Following circulation to the MDCG of the updated plan for two weeks scrutiny, the new version would be published.

4. Post market surveillance and vigilance

4.1 Manufacturer Incident Report (MIR) form and transparency document - *for endorsement*

MDCG endorsed the Revised MIR form (7.3.0.) and they agreed that the Post-Market Surveillance and Vigilance (PMSV) sub-group will discuss further the possibility of making available in national languages adverse event terminology, based on the experience gained with the translation of the EU medical device type nomenclature (EMDN).

MDCG endorsed as well the MIR Transparency document. Some MDCG members perceived limitations in transparency approach of the document and noted that it may be feasible to extend further the disclosure of the information registered in MIR reports. It was agreed to insert the following footnote to the endorsed MIR Transparency document: "This document may be subject to revision(s) following horizontal discussion on Transparency".

5. Notified Bodies under MDR / IVDR

5.1 MDCG recommendation on the draft designation of a notified body - *for endorsement*

Following description of the outcome of the relevant joint assessment process, MDCG issued a positive recommendation for the designation of a notified body under Article 35(9) of Regulation (EU) 2017/746, according to which the applicant notified body should be designated within the scope proposed by the designating authority.

5.2 Update on Joint Assessments

The Commission shared an overview of notified bodies' activities at each stage of the joint assessment/designation process and informed that a total of 57 applications for the MDR and 18 for the IVDR are progressing at various stages throughout the joint assessment process. Member States were encouraged to do what is possible to speed up these processes. There have been 58 on-site assessments completed to-date and a number of on-site assessment are scheduled for the coming months. At the time of the meeting, a total of 36 notified bodies were notified in NANDO under the Regulations (29 MDR and 7 IVDR) which was an increase in 3 since the previous MDCG meeting. Member States were also thanked for their continued support to the process in providing national experts.

6. Capacity of notified bodies and availability of devices - *for discussion*

The Commission presented for discussion a variety of topics that may have an impact on capacity of notified bodies and availability of devices, based on feedback received by stakeholders and some MDCG members.

Two MDCG members briefly presented the main challenges and practices followed at national level.

MDCG noted that they very much appreciated the open exchanges with stakeholders at the previous session of "MDCG & Stakeholders", although some alerting figures and info was shared like:

- Only 1000 certificates issued under MDR/IVDR compared to 25000 under Directives
- Discontinuation 30% devices is forecasted
- Long assessment times noted

MDCG noted that a combination of different actions may be needed to mitigate the risks and these should be further explored; the national derogations are considered only as a last resort.

FR leading the dedicated Task Force on NB capacity gave a short state of play of the work under development, mainly the collection of data from industry and data from notified bodies on certification activities.

MDCG also agreed in principle on a Notice to manufacturers which is essentially a letter to manufacturers, calling for timely adherence to MDR requirements. It was agreed to publish the notice following some formatting and linguistic checks.

MDCG took also note of the ongoing work in the special Task Force led by DE dedicated on orphans / niche devices: the TF is in the process of analysing all information received so far on the discontinuation of certain devices.

Based on feedback received by some economic operators but also from some MDCG members on more consistency and clarity in applicability of guidance documents developed by MDCG, the Chair reminded that the main objective for the development of these guidance documents is to facilitate implementation for all concerned actors but they are not legally binding. The Commission asked for feedback in writing for this point after the meeting.

Further to the discussion on all above points, the Commission proposed to use one of the existing Task Forces to examine in detail possible solutions to deal with challenges related to capacity and preparedness MDCG decided to dedicate this task to the newly established CG (Coordination Group) and requested with a view of proposing a list of actions to mitigate the risks and report back to MDCG as soon as possible.

7. Market surveillance - *for information*

The Commission informed on the planned Joint Action (JA) on market surveillance and encouraged participation of competent authorities as a good opportunity not only to increase resources, but also gain expertise on inspections and other operational aspects of market surveillance for their staff. The JA is possible under the EUHealth Programme 2022, focuses on inspections and accommodates the request from MDCG members for increased safety coordination. Finally, it offers the possibility for competent authorities to receive up to 60% funding of the total action budget.

The Commission also informed on a coordination call / meeting on derogations that took place on the 29/4 based on a request by the MDCG Market Surveillance expert group. The objective was to exchange information and experiences on operational level and, discuss challenges and possible solutions and provide feedback to MDCG. On next steps, Commission informed that the outcomes of the discussions, would be reported to the MDCG to determine the further proceedings. MDCG members supported the organisation of further operational calls if needed. The Commission also reminded Member States about their legal obligation to notify adoption of national derogations under Article 59(2) and asked them to use the excel sheet (in CIRCABC) for this purpose.

8. Revision of guidance document MDCG 2019-3 on the Interpretation of Article 54(2), point(b) MDR - *for endorsement*

MDCG did not agree on the endorsement of the revised guidance MDCG 2019-3. The Commission presented the revised version with the objective to reflect better the legal wording and the intention of Article 54(2) point (b) MDR related to the scope of the work of the scientific panels under clinical evaluation consultation procedure (CECP). It also noted that new elements emerging since the first publication of the guidance need to be taken into account, such as the expected peak of expiring certificates end 2023 – early 2024 and the need to rationalise the work of the panels and explore their full potential including by expanding their work with new functions. The input received from the notified bodies shows that not only the wording of the document is not entirely clear but that also its effect is opposite to the intended one. Commission and EMA presented an assessment of the volume of the expected submissions and warned that at the predicted levels the panels will be significantly overloaded and will not be able to deliver on their functions. Furthermore, it will not be possible to manage the predicted volume due to firstly the acute nature of the peak, i.e. the concentration of most of the submission over a 6 months period and secondly due to availability of experts. Additionally limitations in staff and resulting from budgetary procedures need to be taken into account. The only mitigation

available would be to revise guidance MDCG 2019-3 in relation to the treatment of legacy devices under the MDR.

MDCG members expressed various concerns mainly on the need for the revision, for the number of devices concerned.

The Commission noted that according to its analysis in the current circumstances the expert panels will not be able to engage in other activities than CECP/PECP.

It was agreed, as a follow-up, that the Commission will ask notified bodies for further information and data.

9. Questions and Answers on the Unique Device Identification system under MDR and IVDR - *for endorsement*

MDCG endorsed the Q&A which is developed based on questions most frequently received about the UDI system. It is considered a living document and the intention is to regularly update it as the analysis of more complex topics will be finalised by regulators. Competent authorities and stakeholders have been consulted.

10. Expert Panels – state of play - *for information*

EMA provided a state of play of the activities of the expert panels with regards the Clinical Evaluation Consultation Procedures (CECP) and the Performance Evaluation Consultation Procedures (PECP). Since the implementation of these activities, 20 CECP applications and 15 PECP applications have been submitted leading to 5 opinions and 15 views respectively. Since November 2021, no new PECP submission has been received by the Secretariat.

The EMA presentation highlighted the fact that the majority (65%) of the devices subject to the CECP so far were legacy devices modified from a previous generation of devices with the same intended purpose. None of these devices were considered as novel by the screening experts hence no opinion were requested for them. Considering the number of certificates that will expire in 2024, the corresponding number of CECP files is estimated at 230 per month between October 2023 and March 2024. This would request the involvement of 460 screening experts each month while the expert panel is made of 70 experts with very limited possibility to increase its capacity.

11. Monitoring and mitigating shortages of critical medical devices in the context of a public health emergency - *for information*

EMA provided an overview on the provisions of the Regulation (EU) 2022/123 on the extended mandate of EMA in the management of critical medical devices that will come into application on 2 February 2023. EMA presented the roles and responsibilities of the Executive Steering Group on Shortages of Medical Devices (MDSSG).

The role of the Member States in monitoring and mitigation shortages of critical medical devices of the public health emergency critical devices list was presented. In addition, the obligations on manufacturers of medical devices, authorised representatives, importers, distributors and notified bodies were also described. A detailed overview was provided of EMA's preparatory work for the implementation of the Regulation, including the establishment of interactions with existing groups responsible for medical devices and an ad hoc drafting group to support the preparatory work.

12. AOB

12.1 One MDCG member expressed concerns about the MVP approach and the M2M service. They pointed out the importance of some functionalities to be included in the MVP scope, especially with respect to M2M, and highlighted that focusing on passing the audit only, could lead to insufficient acceptance and usage of the system, once declared mandatory to use.
The functional specifications should well clarify the MVP approach versus a truly functional Eudamed with sufficient functionalities, safety and usability in view of successful implementation of the MDRs across MS. They also expressed concerns about having a strict timeline for implementation, if this risks lowering the quality of the product delivered. Some MDCG members asked for a planning for the development.
The Commission reminded that the MVP approach follows from the MDR itself and has been agreed by the MDCG. It was also explained that consultation is being conducted within the CIE, Vigilance and Market surveillance WGs, as regards the scope of the MVP for DTX on the last three modules.
In addition, the Commission reminded that a M2M functionality for the upload of devices is already available to economic operators.
A dedicated discussion may need to be scheduled in the context of the MDCG EUDAMED expert group specifically dedicated to M2M.

12.2 The Commission informed on the meeting of the Regulatory Committee that took place on the 26/4, followed by a positive vote on two implementing acts on EURLs now ready for adoption. Also the common specifications of Annex XVI was discussed by the committee but could not be sent to vote due to remaining outstanding issues. Next meeting of the Regulatory Committee scheduled for 9/6 where the plan is to present the CS for IVDs and Annex XVI for a vote.

12.3 The Commission reminded on the World Health Organisation initiative for update "Official use of nomenclature in 180 Member States" and they requested MDCG for a mandate to respond on their behalf; they also informed on the update of the Global Model Regulatory Framework for medical devices and MDCG members were invited to send possible comments.

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: IC, LI, NO, TR.

European Commission and Agencies: SANTE B6, SANTE F5, SANTE A4, JRC F2, and European Medicines Agency (EMA).