EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

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

Brussels, 3 January 2022

Minutes

Meeting of the Medical Devices Coordination Group[1] (MDCG) 6/12/2021

1. Opening, adoption of the agenda

The Commission welcomed the MDCG members to the meeting and it was reminded that the members from Member States in MDCG IVD sub-group were invited to attend the discussions under agenda point 5 on IVDR implementation.

The minutes of MDCG meetings of 18 and 19/10 were endorsed prior to this meeting through written procedure and published on the Commission's Registry for expert groups.

The agenda was adopted with the following additions by the Commission: a new point 5.4 on COVID-19 and IVDs and a short point under AOB on reprocessing and one additional point on custom made class III medical devices under AOB as suggested by a MS.

The Chair noted the big number of deliverables since last MDCG meeting of 19 October, 2021, for example the following (not an exhaustive list):

- Adoption and publication of EUDAMED Implementing Act
- The organisation by the Commission of three workshops on UDI, IVD Clinical evidence and on AI Regulation
- Two new designations NBs under MDR (NANDO)

In addition a big number of documents have been published on Commission's website Overview | Public Health (europa.eu):

- MDCG-2021-25 Application of MDR requirements to 'legacy devices' and to devices placed on the market prior to 26 May 2021 in accordance with Directives 90/385/EEC or 93/42/EEC
- MDCG-2021-26 Questions and Answers on repackaging & relabelling activities under Article 16 of Regulation (EU) 2017/745 and Regulation (EU) 2017/746
- Updated Joint Implementation Plan for medical devices under IVDR
- Eudamed UDI/Devices and Notified Bodies and Certificates modules - Relevant documents and information
- Published information regarding notifications on reprocessing of single-use devices
- Ongoing Guidance development table
- Rolling Plan
- Updated list of 2021 planned meetings of MDCG and subgroups

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

- Updated information on the applications for designation as a notified body

2. Follow up on MDCG governance

2.1 Feedback from MDCG members and next steps

The Commission and MDCG members continued their exchange of views from previous meetings on how to ensure optimal governance and improve their collaboration based on the experiences gained so far since the entry into force of MDR / IVDR. Commission noted that the suggested way forward was based on ideas previously submitted by some MDCG members. Most of the speakers welcomed the opportunity and supported the actions suggested, including to form a Coordination Group to support the work of MDCG, including preparing meetings and monitoring work. MDCG members were invited to indicate their interest in being part of this group, also considering the investment and workload associated with it, by 20 December 2021. A rotating system for participation may be considered at a later stage depending on the interest expressed in active participation. In addition, the added value of the role of co-chairs in some MDCG sub-groups was confirmed. MDCG members (and sub-group members) were invited to indicate their interest to co-chair the subgroups on standards, PMSV, B&C and Annex XVI by 10 January 2022. MDCG also supported a more structured collaboration with NBCG –Med (Notified Bodies Coordination Group) and agreed to allocate part of next MDCG meeting in arch to planning and priority setting, including endorsement of the Annual Work Programmes of the MDCG subgroups.

2.2 New Work Item Proposal (NWIP) template – ***for endorsement***

MDCG endorsed a revised version of the template further to some comments received. It should be noted that the template might require further elaboration in the context of the SoP development. The aim of this template is to formalise the work initiation and follow up in the relevant MDCG sub-groups or Task Forces.

Implementation MDR / IVDR

3. Market surveillance and vigilance

3.1 Question and answers on Article 13 & 14 of Regulation (EU) 2017/745 and Regulation (EU) 2017/746 – ***for endorsement***

MDCG endorsed this Q&A on requirements related to importers and distributors under Regulation (EU) 2017/745 on medical devices (MDR) and Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR) that has been developed by a Task Force under the MDCG sub-group on Market Surveillance, with the exception of two questions that need to be further discussed before MDCG endorsement.

3.2 Framework for a European market surveillance programme (EMSP) – exchange of views

The Commission presented a set of questions for discussion and feedback by MDCG for the development of a collaboration framework for a European market surveillance programme. The framework was developed and consulted by members of the MDCG sub-group on market surveillance. At present the scope is limited to MDR but this will change after the date of application of IVDR. MDCG provided input and this will be considered for a revised version that will be presented for endorsement in Q1 2022.

MDCG decided the establishment of a new Task Force on harmonised evaluation procedures under MDR Art 94 MDR. Ireland will take the lead and other interested national competent authorities are invited to liaise directly with them.

3.3 Procedure for coordinated assessment for vigilance cases – current practices and next steps

The Commission presented to MDCG the existing procedures which include monthly teleconferences with Member States and started back in 2012. These meetings are organised and supported by the Commission. Different cases have been examined over time in these teleconferences some of them were considered more complicated than others resulting in taskforces aimed at enhanced coordination.

One MDCG member presented the perspective from the competent authority point of view especially for the two recent cases that had impact on multiple Member States and collaboration was extremely important.

MDCG discussed possibilities for better coordination at the onset of a critical or particular serious incident and the need for a quick assessment to decide proper action adjusted to national tailored actions. Most MDCG members expressed the view that MDCG should be more active and operational in this area.

Based on the feedback provided the Commission will prepare a working document that will be submitted to MDCG following discussion at subgroup level.

4. Clinical investigation: Substantial modification of clinical investigation under MDR, template – ***for endorsement***

MDCG endorsed the template which was developed in the MDCG sub-group for clinical investigations (CIE). In the absence of the European database on medical devices (EUDAMED), a series of clinical investigation application/notification documents have been created by the CIE and already endorsed by MDCG such as MDCG 2021-8 and MDCG 2021-20 to support clinical investigation procedures with respect to MDR. This template comes to complement those documents.

5. IVDR implementation

The Chair reminded that the IVDR amending Regulation was progressing with the co-legislators and underlined that the discussion in the MDCG should focus on the implementing measures.

5.1 Guidance on general principles of clinical evidence for IVDs – state of play

This is one of the actions listed in the JIP IVDR and a document is in preparation for endorsement first by MDCG IVD sub-group and then by MDCG. The dedicated task force has been working on the guidance for the last 2 ½ years and COVID had a major impact on this work; the name of the guidance changed to “Clinical evidence for IVDs”, following an important work shop that took place last month for the development of the guidance on clinical evaluation with the participation of stakeholders and national competent authorities. The document will now be shared with MDCG CIE sub-group and the draft will be submitted to MDCG for consideration and endorsement. Estimated timing for publication: January 2022.

5.2 EU reference laboratories

COM gave an overview of envisaged timeline and process for selection and designation of EURLs. Two legal acts (tasks and criteria, fees) are now published for feedback following interservice consultation until 17 December. Adoption and publication envisaged for Q1 2022.

Member States should verify the compliance of their candidates with criteria. COM evaluation panel will verify the application of those criteria by the MS as well as deal with EU-level aspects such as overall capacity and preference criteria.

A Member State expressed concern about discounting candidates on the basis of capacity as there is uncertainty associated with those numbers. COM explained that the uncertainty in the minimum estimated capacity will be taken into account during the evaluation.

COM highlighted the interplay between EURLs under IVDR and another set of EURLs put forward in the proposal on serious cross border health threats (to be coordinated by ECDC). These two sets of EURLs will have two complementary sets of tasks, the IVDR EURLs focusing on high-risk IVDs in the context of conformity assessment and the IVDR, and the other EURLs being active in public health more oriented towards research support and monitoring and tackling outbreaks. They could be the same institutions but would play distinct roles. A Member State enquired about possible conflict between the roles of these EURLs. COM noted that so far no concrete problems have been raised; Member States are welcome to raise any specific concerns they identify.

5.3 IVDR Joint Implementation Plan

A slightly revised version was presented, with most recent status of a number of work items updated and alignment with MDCG 2021-4. It was agreed to have a short period for feedback on the changes followed by publication.

A Member State raised an issue related to distance sales: after May 2022 those tests used in other countries outside the EU must comply with the IVDR and could risk becoming unavailable. No knowledge yet as to which and how many devices would be affected. The issue is being considered in the IVD MDCG sub-group. To be seen whether this is an issue of wide relevance and whether or not any action can be taken by the MDCG.

5.4 COVID-19 and IVDs

The Commission informed that the MDCG IVD sub-group intends to update MDCG 2021-21 (Performance evaluation of SARS-CoV-2 tests) following some points raised by manufacturers and to bring it in line with common specifications. MDCG will be consulted early 2022.
On another issue and as MDCG was previously informed a notice to 3rd country manufacturers of SARS-CoV-2 tests has been prepared; consultation of stakeholders has been completed and MDCG will be consulted in the following days.

6. EUDAMED update on state of play

The Commission presented the state of play of the Eudamed development and the high level planning for the year 2022.
First three modules (Actor, UDI/Device and Notified bodies and certificates) have been released and currently in use on voluntary basis. No blocking issue reported to date. Change requests and extended functionalities are also in the pipeline for 2022.

Second set of modules (Vigilance, Clinical investigation/Performance study, Market surveillance): requirements gathering at 75% and development started. First release in testing environment foreseen Q1 2022.

Closing of requirements foreseen Q1 2022 with possibility of feedback and change requests until Q3 2022.

MVP development foreseen to be completed Q2 2022.

Audit foreseen for first semester 2023. Notice of full functionality to be published after successful outcome of the Audit.

7. Orphan devices - follow up to the discussion at MDCG 19 October 2021

Several MDCG members participated in the discussion on 'niche'/'orphan' devices. MDCG members noted that various aspects had be looked at in the context of this topic, such as national derogations, clinical evidence, impact on SMEs, etc. There was consensus that it was needed to clearly define the topic, what devices are actually affected and what is the extent of the alleged problem. Information gathered in the framework of the CIE working group hinted to the fact that mainly neo-natal cardiology devices seemed to be affected. A few MDCG members do not consider the possible disappearance of devices due to the transition to the MDR as a problem that would require EU level action; national derogations in accordance with Article 59 MDR would sufficiently address possible public health and patients' needs. Other MDCG members considered that Article 59 would not offer a solution for many cases; more sustainable solutions were needed.

Some MDCG members stressed that the regulatory requirements in the MDR were reinforced for good reasons and it may be justified that certain devices that do not meet the new requirements will disappear from the market. Other MDCG members considered that one should distinguish between the different reasons for which manufacturers discontinue (development of) devices.

Further to the discussion MDCG decided to set up a Task Force with the objective to define the scope, quantify the data and consider whether further discussions are needed. The Chair invited MDCG members to nominate their members by 20 December 2021. After the meeting, Germany confirmed their availability to lead the Task Force.

8. Application of the Clinical Evaluation Consultation Procedure in accordance with Article 54(1), point (b), MDR also to class III active devices that administer/remove a medicinal product, such as active therapeutic closed loop systems that administer/ remove a medicinal product? – orientation discussion

The Chair presented the topic seeking advice from MDCG based on a request by a notified body as to whether also class III active devices that administer and/or remove a medicinal product, such as an active therapeutic closed loop system that administers insulin, should be subject to the CECP in accordance with Article 54(1), point (b), MDR. Those devices fall under rule 22.

Several MDCG members considered that Art. 54(1)(b) MDR, which refers only to class IIb devices, should not be extended to class III devices, even though that might leave a gap regarding class III active devices that administer medicines.

In order to conclude on this topic, the Chair invited comments in writing no later than two weeks after the meeting.

9. International Medical Device Regulators Forum (IMDRF)

The Chair reminded MDCG that the EU is expected to take the chairmanship of the Management Committee in 2023. Australia will be chairing in 2022 and the transition will take place in autumn 2022, while officially start in January 2023. It is expected that meetings will be organised physically by then and the European Commission invited MDCG members to express their interest in writing after the meeting to participate in strategic and other preparatory discussions to allow sufficient preparations in advance.

10. Interplay between MDR/IVDR and proposed Artificial Intelligence Act

The Chair informed on the workshop recently organised with MDCG New Technologies sub-group and DG CNECT. Participants, including stakeholders in the workshop, had the opportunity to ask questions on the proposed legal act on AI which is currently being examined in the context of co-decision.

11. AOB

11.1 Member States' notifications on reprocessing of single-use devices

The Chair informed that the information provided by national competent authorities on reprocessing of single-use devices is published on the Commission website: National rules on reprocessing of single-use devices | Public Health (europa.eu) MDCG members can notify the Commission as soon as the national rules are established, if not already done so.

11.2 Class III custom made devices

One MS raised concerns about the lack of transitional periods for the above mentioned devices under MDR, notably in the context of potential notified body congestion. Other MS were asked to reflect on this and it was suggested to come back to the topic in the dedicated MDCG forum on notified body capacity on 16 December.

Next meeting

The next MDCG meeting is scheduled for 17-18 March 2022 (tbc). A dedicated MDCG forum on notified body capacity will be held on 16 December.

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.

Commission: SANTE B6, SANTE F5, JRC F2, SANTE A4.