EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

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

Minutes of the expert groups

Brussels, 30 November 2021

Minutes

Meeting of the Medical Devices Coordination Group[1] (MDCG)
19/10/2021

1. Opening, adoption of the agenda

The Chair welcomed participants to the meeting and the agenda was adopted with addition of an AOB point. This meeting followed a session with stakeholders on the previous day and a Regulatory Committee meeting also on the previous day.

The minutes of the meeting held on 27-28 May 2021 were endorsed prior to this meeting through written procedure and are published in the registry for European Commission's expert groups.

2. Follow up from the meeting MDCG & Stakeholders

The group recognised and appreciated the great amount of information that was shared at the previous day session with stakeholders but will reflect if it needs to be structured differently in the future. The more active involvement of more representatives from competent authorities will be examined and more structured interventions from stakeholders will be considered in order to ensure more useful meetings and tailor need to all participants.

An MDCG member raised concerns on the technical solutions for EUDAMED on the Machine-to-Machine (M2M) interface requiring significant investment in local infrastructure, processes and resources and the variety of access technologies used across different EU systems.

3. MDR implementation

3.1 MDCG governance – for discussion – *tour de table*

The Commission introduced the topic as a follow up to previous exchanges. Although the establishment of MDCG and the role of all involved actors including the Commission are clearly described in the MDR and IVDR, the system put in place is still new and the discussion on how to improve governance aspects was already initiated by Commission from previous MDCG meetings. Many MDCG members took the floor in an open and interactive manner and many ideas were put on the table. Taking into consideration the heavy workload and available resources it was initially discussed how to best ensure effective coordination and priority setting in order to deliver according to the aim of legislation.
A number of challenges were initially identified such as better coordination between MDCG and MDCG subgroups, work prioritisation and meeting preparations, shortcomings in technical support including availability of national authorities' experts to contribute to guidance

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

development. MDCG members also called for more central coordination as regards certain vigilance and market surveillance activities on critical cases.

There was alignment amongst many delegations who took the floor on the need to have a coordination/ steering group and the need to further elaborate the roles and responsibilities of the MDCG, the national competent authorities and the Commission collectively and individually. A number of MDCG members supported the need for priority focus on coordination of EU level safety issues relating to medical devices.

The Commission welcomed the constructive discussion, invited for contributions in writing and committed to follow up.

3.2 Report of the MDCG *ad hoc* task-force on transitional provisions ('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) – *information from task force*

The task force on transitional provisions was established earlier in the year following an MDCG decision. The report of the MDCG *ad hoc* task-force on transitional provisions was endorsed by the MDCG by written procedure and been forwarded to all MDCG working groups to orientate the development of specific guidance documents where the application of the transitional provisions laid down in Article 120(3) of Regulation (EU) 2017/745 is relevant. At its meeting on 19 October 2021, the MDCG agreed to publish the task-force report as MDCG guidance. Published after the meeting here:
MDCG 2021-25 Regulation (EU) 2017/745 - 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

3.3 Market surveillance and vigilance

3.3.1 Questions and Answers on re-packaging and re-labelling activities under Article 16 MDR and IVDR – ***for endorsement***

MDCG endorsed this guidance which was jointly developed by the MDCG subgroups Market Surveillance and NBO (Notified Body Oversight). It aims to provide guidance to importers & distributors performing relabelling and repackaging activities under Article 16.

After the meeting it was published here:

https://ec.europa.eu/health/sites/default/files/md_sector/docs/md_mdcg_2021_26_en.pdf

3.3.2 European market surveillance programme – *for discussion*

The Commission presented a preliminary approach for an EMSP (European Market Surveillance Programme) framework, including initial reflections on its structure and content. The main objectives are to achieve efficiency and harmonisation of market surveillance in the Union, in accordance with MDR provisions. The presentation pursued a common understanding by competent authorities of the market surveillance requirements and alignment of implementation practices.
The Commission presentation was overall well received and MDCG provided useful comments on potential expansion to more market surveillance activities, vigilance and avoidance of

duplications. Further discussions on EMSP will continue at MDCG Market Surveillance subgroup and at a later stage the document will be presented to MDCG for endorsement.

3.3.3 Procedure for coordinated assessment for vigilance cases – *for a first exchange of views*

The Commission introduced the topic based on different ideas gathered both at various meetings with Member States and in the context of some CAMD discussions. These ideas focus on more structured coordination between competent authorities with the support of the Commission on specific vigilance cases. MDCG asked for the establishment of a system that would allow an agile response and clear criteria for the selection of cases. The Commission invited for more comments in writing and the topic will be discussed again in future meetings.

3.4 Annex XVI – Common Specifications final draft for consultation

MDCG was informed on the latest developments concerning the common specifications (CS) for products without a medical purpose listed in Annex XVI to MDR. The relevant MDCG subgroup reached last month an agreement on the CS. The current CS address the application of risk management, in respect of certain general safety and performance requirements set out in Annex I of MDR. Once the CS become applicable, the MDR will apply to the groups of products listed in Annex XVI.
The implementing act will be adopted by the Commission through an examination procedure, with the assistance of the Committee on Medical Devices. Before the vote, the implementing act will be subject also to the feedback procedure and to the Technical Barriers to Trade procedure (WTO-TBT).

3.5 'Orphan devices' under the MDR – *exchange of views*

The Commission informed that they have received repeated complaints from industry, mainly from a specific region in Germany, claiming that the MDR would lead to the withdrawal of certain vitally important medical devices. Mainly concerned are allegedly 'niche' products or other long-time used devices for small patient populations, as their manufacturers (mainly SMEs) would not be able to gather the required clinical evidence or would simply not be able to bear the costs for the certification of their products in accordance with the MDR. Main reasons cited are increased costs and longer certification timelines, strengthened MDR requirements regarding clinical evaluation and refusal by ethics committees of clinical investigations on existing proven and tested devices.
Some MDCG members informed that they were aware of similar complaints while others appeared less affected. Some members informed that similar cases brought to their attention they were handled as national derogations under Article 59 MDR. The Commission inquired whether MDCG members could share any additional information that may come to their attention so that national competent authorities can reflect how to respond accordingly.

4. Notified bodies under MDR/IVDR

4.1 MDCG recommendation on the draft designation of a notified body

Following description of the outcome of the relevant joint assessment processes, MDCG issued positive recommendations for the designation of two 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 authority.

As a general remark on the process for endorsement of the MDCG Recommendation on the draft designation of notified bodies, one MDCG member proposed to proceed with written procedure in cases when no diverging opinions between the designating authority and the joint assessment team were raised. It is worth noting that the written procedure will normally include a 2-week consultation period.

4.2 Joint Assessments Progress Report

The Commission shared an overview of notified bodies' activities at each stage of the joint assessment/designation process and informed that a total of 53 applications for the MDR and 17 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 52 on-site assessments completed to-date and currently there are no on-site assessment to be scheduled in relation to the number of preliminary assessment reports received. At the time of the meeting, a total of 29 notified bodies were notified in NANDO under the Regulations (23 MDR and 6 IVDR).

4.3 Notified Bodies – geographical coverage

The Commission added this point on the agenda in the context of challenges currently faced by the medical devices sector with regard to capacity of notified bodies, as some information had been brought to their attention, on how the Regulations could affect peripheral Member States not having notified bodies established in their territory. The 23 notified bodies currently designated under the MDR are based in 11 Member States in total. Concerning the IVDR, the 6 notified bodies currently designated are based in total in 3 Members States. Based on the feedback provided by MDCG members during the meeting the geographical location is not as important for manufactures including SMEs as is limited capacity, language barriers and high fees. The Commission invited for more feedback in writing if relevant.

5. IVDR Implementation

5.1 Discussion of specific IVDR transition issues

MDCG took note of the new Commission proposal on amendment of the IVDR. The Commission expressed hopes for smooth handling of the proposal in the European Parliament and the Council. The MDCG will continue working hard on implementing the IVDR.

MDCG discussed the update of status and timelines of the Joint Implementation Plan. It was decided to include a dedicated discussion on increasing capacity of notified bodies as well as guidance on the meaning of "significant changes" as referred to in Art 110(3) of the IVDR by analogy to the existing guidance under the MDR – MDCG 2020-3. The Commission asked for volunteers from competent authorities to contribute to both work items.

5.2 Common specifications

The common specifications for the following class D devices are expected to be adopted early in 2022: detection and/or quantification of HIV, HTLV, HCV, HBV, HDV, vCJD, CMV, EBV, T. pallidum, T. cruzi, SARS-CoV-2, as well as ABO, Rhesus, Kell, Kidd, and Duffy blood grouping.

The Commission consulted the MDDG on the appropriate length of the transition period for these common specifications. It was agreed for the MDCG Members to provide feedback after the meeting.

5.3 EU Reference Laboratories

The Commission informed on the state of play with the establishment of EURLs, including the next steps with the implementing acts on tasks and criteria and fees. There are key changes to the act on tasks and criteria, including:

- A role for the Member States to verify the compliance with criteria prior to submitting the application
- Accreditation to standard 17025 to be used as a means of presumption of conformity with certain criteria

The Commission also informed on next steps with the call for applications:

- After guidance on batch testing is endorsed, reassessment of required batch testing capacity taking into account possible reduction in batch testing frequency
- Timelines until designation taking into account verification of compliance with criteria by the Member States

6. COVID-19 and IVDs

The Commission informed that the MDCG IVD subgroup continues to invest a lot of time and resources on the coordination between competent authorities on SARS-COV-2 tests. A key milestone was the publication of the guidance on performance evaluation of SARS-CoV-2 tests - **MDCG 2021-21**. A notice on genetic variants has also been published - **MDCG 2021-7**. The IVD sub-group is considering a communication to 3rd country manufacturers as some common errors have been identified such as appointment of multiple authorised representatives. More information will be provided in the following days in writing. Another Commission department is coordinating work on a common list of rapid tests supporting the EU Digital COVID-19 Certificate in collaboration with Member State authorities (the Health Security Committee Technical Working Group). Many representatives in that group are also Members of the MDCG IVD sub-group.

7. AOB

Due to lack of time AOB points were not covered.

Next meeting

The next MDCG meeting is scheduled for 6 December 2021.

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.