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, 23 April 2021

Minutes

Meeting of the Medical Devices Coordination Group[1] (MDCG)
4/3/2021 and 5/3/2021

1) Opening, adoption of the agenda

COM welcomed participants to the meeting, in virtual format due to the COVID-19 pandemic. The agenda was adopted with addition of some AOB points. The minutes of the meeting held on 7-8 December 2020 were endorsed prior to this meeting through written procedure and are published in the registry for European Commission's expert groups.

2) Follow up to the session MDCG & Stakeholders

The Chair noted the useful exchanges with stakeholders of the earlier session of the meeting in particular their expressed commitment for the date of application of the MDR and their concerns on the date of application of the IVDR. Regarding the IVD sector, COM will continue evaluating feedback received by all stakeholders.

The latest developments concerning the draft MDR/IVDR standardisation request were subject to some discussion and questions. Although the use of harmonised standards is voluntary, the Commission noted the risk of not having harmonised standards under the MDR and the IVDR, as they facilitate conformity assessment activities by manufacturers to place devices on the EU market, and are relevant also for notified bodies and market surveillance. MDCG members exchanged views on how they could be more involved in the process of development of the standardisation request and some members expressed concerns that they have not received sufficient information at an early stage. COM informed about the procedures laid down in the Standardisation Regulation (EU) 1025/2012 and the horizontal Committee on Standards, where various sectorial legislation such as medical devices is being examined, and recalled the information and consultation activities carried out with the members and observers of the MDCG Subgroup on Standards during the process. COM invited MDCG members to liaise with their national representatives in the Committee on Standards, in view of the written procedure for their opinion by 12/3, and continue contacts on medical devices specific issues at a later stage for follow-up.

3) Organisation and planning MDCG

3.1 MDCG management aspects

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

COM explained its intention to initiate an exchange of views on optimising the governance structure and functionality of MDCG. It was noted that this was the start of a longer reflection process with MDCG members, based on some questions sent in advance of the meeting also taking into consideration the previously endorsed JIP (Joint Implementation Plan) for the MDR. Initial reactions as expressed at the meeting by some MDCG members were positive with regards to the initiative of the COM but still some analysis needed. The members proposed more active involvement of MDCG in the monitoring of work in the various MDCG sub groups. They also noted that better organisation and coordination is needed between competent authorities in their operational involvement in the various MDCG sub-groups before discussing a more strategic role for MDCG. Comments were invited in writing after the meeting and the discussion will be continued in future meetings.

3.2 MDCG sub-groups Work Programmes – *for endorsement*

In the context of the previous topic of MDCG management aspects and improving its operation, COM had shared before the meeting the annual work programmes (WPs) of ten MDCG sub-groups – out of thirteen in total – and proposed their endorsement. The members of all MDCG sub-groups are nominees from MS competent authorities. In addition, in all sub-groups except NBO (Notified Bodies Oversight) and MS (Market Surveillance), stakeholders participate as observers following their applications to dedicated Calls for Expression of Interest published by COM. It should be also noted that stakeholders are consulted as appropriate on an ad-hoc basis by NBO and MS.

MDCG endorsed the WPs of NBO, PMSV, MS, B&C, New Technologies, UDI, IVD and Nomenclature sub-groups. The CIE WP was endorsed with reservations by two MDCG members who were invited to send additional comments in writing.

WPs of Annex XVI, Eudamed, Standards and International matters will be sent to MDCG after the meeting and their written endorsement will be sought following internal agreement in the respective MDCG sub-groups.

3.3 Implementing acts

COM gave a brief update on the work progress of the following implementing acts which are currently being developed:

- Electronic instructions of use (e-IFU): following discussion in previous MDCG meeting COM proceeded to an expansion of scope medical devices software; scope is limited to MD software; internal procedures currently being followed that will lead to a decision to be taken by the Medical Devices Comitology Committee

- Standardisation: the final publication in the OJEU of references of harmonised standards under the Directives should take place in the next weeks; the draft standardisation request is seeking a positive opinion in the Committee on Standards until 12/3 to allow COM to adopt the Implementing Decision likely by March, to address it to CEN and Cenelec for their acceptance in 1 month time, to start publishing in the OJEU references of harmonised standards under the Regulations;

- Annex XVI: work on Common Specifications progressed a lot but is not yet finalised. Transitional provisions and additional risk management requirements have been added to common specifications. Work on the draft implementing act on reclassification of

active devices without an intended medical purpose has been finalised and an advance draft is available. The documents will be presented and discussed during the upcoming meeting of the Annex XVI WG, planned on the 8th March 2021.

4) Q & A on Custom made devices – *for endorsement*

MDCG endorsed a Q&A document on Custom made devices. The Q&A represents the consensus outcome of intensive exchanges of a dedicated Task Force that was launched at the request of the MDCG at its previous meeting in December 2020.

5) Notified bodies under MDR/IVDR

5.1 MDCG recommendation on the draft designation of a notified body

Following description of the outcome of the relevant joint assessment process, MDCG issued a positive recommendation for the designation of one notified body under Article 39(9) of Regulation (EU) 2017/745, according to which the applicant notified body should be designated within the scope proposed by the designating authority.

5.2 Joint Assessments Progress Report

COM shared an overview of notified bodies' activities at each stage of the joint assessment/designation process. COM has received a total of 53 applications for the MDR and 16 for the IVDR. However, 4 of those applications were received from UK applicants and a further 2 applicants have withdrawn at various stages in the process. COM encouraged Member States to engage with their notified bodies that have not yet applied, in particular those who plan on applying for the IVDR (it was noted that approximately 65% of bodies designated to the IVDD have applied under the IVDR). In addition, the COM highlighted that the joint assessment process is triggered by receipt of the preliminary assessment report (PAR) from designating authorities (DAs), and informed that it is awaiting 9 preliminary assessment reports (PARs) for the MDR and 3 PARs for the IVDR, some of these PARs relate to applications received in January and February 2018. COM encouraged submission of the PARs or receipt of information if the applications will not be progressing. There have been 47 on-site assessments completed (with further assessments scheduled). In addition, due to the travel and quarantine restrictions imposed by the COVD-19 pandemic, and, therefore the inability to perform on-site assessments, there have been 2 preliminary remote assessments completed (both under the IVDR) in order to prevent delays to the joint assessment process and to allow CABs to progress with their applications. These preliminary assessments will be followed-up by on-site assessments in accordance with the process established by the Regulations and prior to designation of the bodies. COM stressed that the final stages of the joint assessment process (CAPA plan reviews – JAT final opinion) are progressing well and these activities have not been affected by the COVID-19 pandemic. However, Member States were reminded to continue their efforts in the review of CAPA plans (as DAs and National Experts) in as timely a manner as possible. Some average timelines within the process were presented and MSs were informed that the average timelines are reducing, in particular relating to assessments under the IVDR where the CAB has already been designated under the MDR. A total of 23 notified bodies are now designated and published in NANDO under the Regulations (19 MDR & 4 IVDR).

5.3 Update on Joint assessments for designation of notified bodies during COVID-19 circumstances

COM presented an update on joint assessments in the context of the situation created by the COVID-19 pandemic. There was a brief recap on remote assessments, which have allowed to avoid delaying the overall assessment process. The planning mechanism was showed, in order to illustrate that the designating authorities may request a remote audit if they consider it justified. COM also indicated the indicative timeline for making such a request (ideally, 6 weeks prior to the tentative date of the on-site assessment, provided that there is a need for interpretation).JAT may delay the on-site assessment if the epidemiological situation does not allow it to take place (around 2 weeks prior to the tentative date). Some Member States asked for earlier information.

COM reported about the national experts' substantial reluctance to go on-site, and suggested that the MDCG considered, in the future, the possibility of having experts participating remotely in assessments (even if the Commission goes on-site).

Lastly, COM informed that the availability of national experts is at a critical low, and that there is a risk that they become a limiting factor for joint assessments. Therefore, MDCG members were asked to encourage the participation of experts in joint assessment teams.

5.4 Commission Notice 2021/C 8/01 - Update on conformity assessment performed by notified bodies in COVID-19 circumstances

Following previous and intense discussions with MDCG about the inability for notified bodies to carry out on-site audits and the consequent risk for possible delay in certifications and shortages of devices, Commission Notice 2021/C 8/01 was adopted early January. The notice provides Member States with the necessary flexibility to allow remote audits under certain conditions, i.e. in those cases when the availability of devices could otherwise be put at risk (force majeure). It also reminds the role of Member States in monitoring and enforcing application of the Regulations, also in the exceptional and unforeseen circumstances caused by the COVID-19 crisis.

This issue was discussed in an extraordinary NBO meeting held on 5 February. Some MDCG members asked for further exchanges on the matter. Such a request will be follow up in the next NBO meeting scheduled on 16 March.

5.5 Request for data on medical devices certifications

Taking into consideration the approaching date of application of the MDR and the COVID-19 impact on the sector, COM initiated a monitoring exercise addressed to notified bodies and industry, covering both medical devices and IVDs. This was deemed necessary in order to identify and mitigate any risks of shortage of vital medical devices. COM informed that they are currently performing an analysis of the received data and they will keep MDCG informed of proposed next steps.

5.6 Update on NBO Task Force on Article 117 MDR

COM informed MDCG of the ongoing work in this TF with the participation of medical devices authorities, the European Medicines Agency and some pharmaceuticals authorities in particular those who have led the work on development of a Q&A on implementation of MDR/IVDR. The Q&A is already published on EMA (European Medicines Agency) website and COM informed on the complexity of the issue mainly stemming from different interpretation of the legal basis that often lead to questions / complains by industry and other stakeholders. COM

invited MDCG members to discuss more at national level with the pharmaceuticals counterparts in view of the next meeting of the Task Force.

6) Expert Panels

COM announced that the panels for medical devices under MDR are expected to be opened for submissions from notified bodies on 1 April. A lot of work has been invested in order to ensure that, such as the completion of expert's registration and their contracts, establishment of experts' pools, experts' trainings, development of appropriate IT tools, elections of Chairs and vice-Chairs and development of Rules of Procedures for the panels. Data management will be an important aspect of the work of the panels as their work needs to be facilitated but also to ensure secured methods for sharing confidential information.

7) Eudamed

Following COM presentation at the meeting of the previous day MDCG & Stakeholders on Eudamed state of play and roadmap, COM reminded that the roadmap is an ongoing process constantly revised on basis of the advancement on gathering requirements and the progress done.

The Actor module is in production since December 2020, the Actor module Data Exchange M2M issues have been solved and M2M functionalities are currently used.

For the UDI/Devices and the NB & Certificates modules the COM will deploy two playgrounds, one in March and another in July and the deployment of production will take place in September. A number of MDCG members expressed their disappointment on the announced timeline and some argued that it has an important impact on IT, HR and budget planning at national level, communication with stakeholders and others. Overall, they asked to be regularly informed and made aware of any postponement asap.COM underlined that the Playground allows MS to prepare their systems and adapting their IT.

On the Eudamed work programme currently with the Eudamed MDCG sub-group, MDCG asked for two more guidance documents, a Q&A or guidance on actor registration and validation. COM suggested that such guidance should be discussed at a more horizontal level.

8) IVDR Implementation

8.1 EU Reference Laboratories (EURLs)

COM informed on technical work in relation to EURLs: internal consultation ongoing on implementing acts on tasks and criteria and on fees; call for applications in preparation; processing the results of the survey on EURL demand; development of a continuously updated Q&A based on questions received from Member States. Member States were invited to send any additional questions they may have.

MDCG members underlined the importance of preparing a publicly available information pack for possible candidates. This is included as a work item in the IVD MDCG sub-group work programme, to be completed when the implementing acts on tasks and criteria and on fees are adopted.

Two specific topics are being discussed in IVD MDCG sub-group: state of the art (whether the EURL should do this on a routine basis and publish the state of the art and/or whether ad-hoc requests should be allowed) and designation scopes of the EURLs (whether the designation scopes can be simplified by designating by categories only). More information will be shared in future MDCG meetings.

8.2 Discussion of specific IVDR transition issues

COM presented a draft Q&A for the application of transitional provisions for certification of class D *in vitro* diagnostic medical devices. It intends to clarify the requirements related to expert panels and EU reference laboratories during the transition period and thereby to mitigate the risks of significant delays of certification of class D devices.

Some MDCG Members underlined the importance of establishing the EURLs as soon as possible. The Commission expressed its full agreement and reiterated its commitment to complete the work on the prerequisites for EURL establishment (such as the implementing acts and the call for application) as soon as possible.

COM proposed that this Q&A could be endorsed as an MDCG document. Many MDCG members could support this approach. Two expressed reservations and asked for more time to perform their analysis. Following discussion, it was agreed to submit the document to the MDCG for endorsement by written procedure.

9) Joint Implementation Plan

COM presented the revised version of the IVDR Joint Implementation Plan following the 7-8 December 2020 meeting and including further proposals on an alternative work item for companion diagnostics and revision of some timelines. The modifications were agreed. Participation of competent authorities in the companion diagnostics work item is to be confirmed. The JIP was agreed to be used as a living document to monitor progress of the work items and to be proposed for endorsement in principle at the next MDCG meeting.

10) COVID-19 and IVDs

10.1 Guidance on state of the art COVID-19 antibody tests – *for endorsement*

MDCG endorsed a guidance on state of the art of COVID-19 rapid antibody tests which has been under development since May 2020 and aims to provide clarity on particular elements related to the current state of the art for COVID-19 rapid antibody tests, notably the modalities of performance evaluation and performance levels of the devices.

The guidance aims at facilitating the fulfilment of the legal requirement of Directive 98/79/EC on *in vitro* diagnostic medical devices which establishes that devices must be designed and manufactured in such a way that they are suitable for the intended purpose specified by the manufacturer, taking into account the generally acknowledged state of the art. The manufacturer should therefore justify why the device is suitable for the intended purpose claimed, in light of the state of the art.

11) AOB

11.1 Notification obligations under Articles 111 & 113 MDR, COM reminded that they are expecting to receive this information from competent authorities

11.2 Reprocessing of single use devices –Member states have notification obligations under Article 17 MDR. COM reminded that they are expecting to receive this information from competent authorities

11.3 Draft Q&A for clinical investigations; COM informed that the doc is being finalised in the MDCG sub-group on Clinical Investigation and will be soon sent to MDCG for written endorsement

11.4 Update on the development of the EMDN (nomenclature); COM informed on the work progress for the development of European Medical Device Nomenclature with the support of the Italian Ministry of Health

11.5 France raised the issue of a serious risk in MDR and proposed that the issue be discussed further

11.6 Ireland raised some questions for further reflection on transition from Directives to MDR and how some elements are taken into consideration at EU level, in terms of legal consistency. Further exchanges may be needed at a later stage

Next meeting

The next MDCG meeting is scheduled for 27 and 28 May 2021. More information to follow.

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: CH, IC, LI, NO, TR.

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