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, 10 November 2020

Minutes

Meeting of the Medical Devices Coordination Group[1] (MDCG)
20/10/2020 and 21/10/2020

1) Opening, adoption of the agenda

COM welcomed participants to another audio meeting due to the ongoing development of COVID-19. The agenda which largely focused on implementation of IVDR was adopted with an addition by one MS under AOB on MDCG 2020-12 guidance on transitional provisions for consultations of competent authorities for devices incorporating medicinal products as ancillary substances.

The minutes of the extraordinary MDCG of 14 September were adopted, and will be made publicly available at the relevant registry for European Commission's expert groups.

2) IVDR Implementation – exchange of views

2.1 Report of activities of IVD MDCG Working Group

COM updated participants on the activities undertaken within the MDCG IVD Working Group this year. COM reported that there are big differences in engagement among CAs, and that there is a direct shortage of leads for some work streams: 3 work items were led by a Member State and 7 work streams were led by COM. Some work items are blocked despite interest from authorities as none of them is prepared to take the lead. COM invited MDCG members to liaise with colleagues at national level and ensure engagement among the CAs.

2.2 Discussion on key implementation priorities available resources and impact of COVID-19
COM emphasised the challenges related to the implementation of IVDR and the need to prioritise and engage fully in this work, in particular as the COVID-19 has illustrated the need for the stricter legislation in this area. A document was presented listing a number of priority actions for the year to come, including deliverables and timelines to meet. The proposed document was well received and it was agreed to be used as a basis for next year's work. MDCG would be consulted after this meeting with an opportunity to share their opinions and their comments will be included in an updated version of the same document. Participants were also requested to indicate their readiness to take the lead/participate in the work of the listed work items. COM and MDCG both noted the need to focus on identifying solutions to known problems posing risks of potential shortages and availability of medical devices. It was agreed to organize a follow up discussion in MDCG soon.

2.3 Monitoring the readiness of the sector

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

COM and MDCG agreed that there is a need for gathering of concrete data in order to support future steps. The work to find solutions to problems should not be conditional on collection of data on market readiness where problems are known, although it should be informed by such data.

2.4 Conformity assessment of COVID-19 IVDs

Following requests of some competent authorities (CAs), the IVD MDCG WG has looked into possible tightening of conformity assessment for COVID-19 tests. The various courses of action and their consequences have been laid out in the corresponding reflection paper. The need to designate notified bodies poses a particular hurdle, especially given that only 1.5 years remain until the IVDR enters into application. CAs were encouraged to examine the final paper to inform their decision as to whether to launch such an initiative. Any changes proposed would have to be adopted through comitology.

3) Implementation MDR/IVDR

Implementation work is ongoing with heavy workload and multiple meetings. Schedule of MDCG and all MDCG working groups updated and published on COM's website. COM reiterated that implementation is a joint effort and more active engagement in various work strands is needed from all MDCG members. In order to facilitate MDCG engaging at national level with their responsible colleagues, COM shared a list of work strands / Task Forces currently operating or planned in all MDCG working groups. COM asked for comments, including suggested de-prioritisation, and volunteers from MDCG on this document with the intention to ensure better prioritisation of work and allocation of resources.

In addition COM informed that MDCG members' names and affiliations would be made publicly available on their website for medical devices in accordance with MDR.

3.1 MDCG Working groups' update

As usual there was a general overview of main activities of MDCG working groups and it was emphasized that part of this work was relying to expertise of national competent authorities from the sector; MDCG was invited to signal missing priorities and provide comments in writing. An updated version of the overview document "Ongoing guidance development" will be published after this meeting.

3.2 NBO (Notified Bodies Oversight) Work Programme

COM updated on the advancement of the MDCG NBO work programme, which was agreed on 7th of October 2020. There are several work items to work on, divided in three clusters: designation and re-assessment process for joint assessments, notified bodies' activities, and designating authorities surveillance activities. COM highlighted that 10 taskforces were established to this end, and two more will be set up soon. COM encouraged competent authorities to engage with these taskforces, since COM is leading the vast majority of them.

3.3 Implementing acts

COM updated participants on the advancements of various implementing acts, namely on the reprocessing of single-use devices adopted on 19 August 2020, the Annex XVI devices and the MDR/IVDR standardization request. The act on "Electronic instructions for use" was also discussed and some input provided by MDCG members. COM will provided an updated version. The MDCG participants agreed that there is currently no need to adopt implementing acts on implant cards under MDR Article 18(3).

4) EUDAMED

COM presented the EUDAMED state of play focusing on the different development steps planned to be finished by the end of 2021 as the remaining time is necessary to perform the audit and present the audit results to the MDCG. The Playground for Actor registration is currently open. COM encouraged MS to use the actor module and avoid double registration to the extent possible in line with the statement from MDCG endorsed in August 2020. There are some data exchange (DTX) issues to be solved in the coming days. COM reminded that in order to respect the very tight and ambitions deadlines it is crucial to stick to the minimum viable product (MVP) approach and the gradual roll out of the modules as agreed in the High Level MDCG meeting of 11 March 2020.

MDCG members took the opportunity to share their views on the functioning of the EUDAMED WG; some MDCG members asked for more coordination and direct involvement and showed their willingness to collaborate with the COM. COM asked for specific examples and reminded that they are waiting for the information about the CAs and their Local Actor Administrators that need to have access in EUDAMED in order to have the Actor registration module ready by December.

5) Notified bodies under MDR/IVDR

5.1 MDCG recommendation under Article 39(9) MDR/ Article 35(9) IVDR

Following the description of the outcome of the relevant joint assessment processes, MDCG issued positive recommendations on the draft designation of two notified bodies, one under Article 35(9) of Regulation (EU) 2017/746 and one under Article 39(9) of Regulation (EU) 2017/745, according to which the applicant notified bodies should be designated within the scope proposed by their designating authorities.

5.2 Joint Assessments Progress Report

COM shared an overview of notified bodies' activities at each stage of the designation process. It highlighted that the most timely stage of the process is between the stages of the on-site assessments and the receipt of the CAPA plan by the COM, however COM reported that the average timelines are decreasing. There are currently 48 applications for the MDR and 15 for the IVDR.. In the context of restrictions posed by the COVID-19 situation (travel restrictions and quarantine orders), one MS informed participants that a joint assessment was in the process of being initiated remotely this week but will be kept open until an on-site assessment has been undertaken. This on site assessment will be conducted in accordance with the process established by the Regulation and prior to the designation of the applicant body. MDCG was informed that an on-site joint assessment for another applicant notified body was also taking place the same week.

5.3 Joint Assessments of notified bodies during COVID-19

COM presented the main conclusions of the latest MDCG extraordinary meeting on the topic, which was held on the 14th of September. Specific cases were discussed. It was concluded that, possible individual problems that may arise concerning future joint assessments planned by the end of the year will be tacked on a case-by-case basis and in view not to delay the designation process.

5.4 Discussion on conformity assessment performed by notified bodies in Covid-19 circumstances

COM presented its main concerns relating to the possible inability for notified bodies to carry out conformity assessment activities in the context of Covid-19 circumstances and consequent travel restrictions. COM and MDCG discussed the potential need to take action for increased flexibility in this respect in order to avoid delay of certifications under the Regulations and potential shortage of devices. It was agreed to take out of the draft Q&A on MDCG 2020-4 questions relating to the applicability of alternative measures to the Regulations and to follow up separately in line with the conclusions form the meeting.

6) Expert panels

COM presented the ongoing work concerning the expert panels. Declarations of interests of experts nominated for panel membership were re-evaluated, experts have been formally appointed and their contracts are currently being finalised. Webinar trainings for the appointed experts have been organised. Next steps concern the elections of Chairs/Vice-Chairs of the panels, the first Coordination Committee meeting and, subsequently, subject to adoption of the proposed sub-group structure of panels, elections of chairs/vice chairs of sub-groups. COM is moreover finishing a series of guidance documents, templates and operational procedures for panels. COM also presented the ongoing development work towards a tailor-made SHAREPOINT database which will be used in the absence of EUDAMED to monitor dossier progression, record expert remuneration entitlements, timelines and for managing expert assignment aiming at an even distribution of workload.

7) AOB

7.1 Presentation by the CAMD

DK presented the work programme of the CAMD, which included a crosslinking between the HMA and CAMD with respect to advanced therapies, medical devices and health technologies, innovative medicines, analytics and AI. MDCG members were invited to send comments on the programme in writing.

7.2 Issue on devices incorporating medicinal products as ancillary substances

One MS raised this point relating to MDCG guidance 2020-12 on transitional provisions for consultations of authorities on devices incorporating a substance which may be considered a medicinal product and which has action ancillary to that of the device. The notified bodies seem to have difficulty to find a competent authority for medicinal products to accept the responsibility for the assessment of the file. Contacts with notified bodies on this topic have been taken at national level. COM noted that the same issue has been also raised at the MDCG & Stakeholders meeting. COM invited comments in writing and noted that according to the MDR there must be an EU medicinal products authority that accepts responsibility for the consultation. Furthermore, the guidance already allows for flexibility as to the depth of the assessment by the medicinal products authority, at its discretion.

Next meeting

The next MDCG meeting is scheduled for 7 and 8 December 2020. 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