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) with stakeholders 20/10/2020

1) Opening, adoption of the agenda

COM welcomed participants to this MDCG meeting with stakeholders, which is still virtual due to the evolution of the COVID-19 virus. COM highlighted the need to work together in light of the MDR and IVDR implementation. The agenda was adopted following a request from MedTech Europe to add a point under AOB, regarding medical devices incorporating an ancillary substance which, if used separately, can be considered a medicinal product.

2) IVDR Implementation

2.1 Report of activities of IVD MDCG Working Group

COM updated participants on the activities undertaken within the IVG Working Group this year. Key strands of work related to the implementation of the IVDR were classification, performance evaluation, common specifications and EU reference laboratories. In parallel, COVID-19 activities include competent authority exchanges on market surveillance, a reflection process on a possible different conformity assessment path and development of a guidance document on the state of the art of antibody tests.

2.2 Discussion on key implementation priorities

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. COM presented a document to stakeholders and CAs listing the current priority actions for IVDR implementation, including deliverables and timelines to meet. Stakeholders raised questions on the availability of EURLs, on the scope of various guidance documents and on the achievability of this programme. They highlighted a further need for guidance on the summary of safety and performance.

2.3 Monitoring the readiness of the sector

COM highlighted the need for the MDCG to have concrete and quantifiable information on the readiness of the market, including elements such as the proportion of manufacturers who have applied for an IVDR conformity assessment with a notified body, on the number of applications in progress, on potential stumbling blocks to designation of notified bodies and on certification

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

of devices. Stakeholders were invited to be as active as possible in this monitoring exercise, notably by responding to surveys launched by COM.

3) Implementation MDR/IVDR

3.1 MDCG Subgroups update

COM updated participants on the activities of the NBO working group, on work items related to the Annex XVI devices, standards, vigilance and nomenclature. Stakeholders' questions focused on the guidance on classification, which should be finalized at the beginning of 2020.

3.2 EUDAMED

COM presented the EUDAMED state of play by showing the different development steps which are planned to be finished by end 2021, as in 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 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.
Stakeholders shared their concerns regarding potential dual registrations and enquired about the possibility to make the use of EUDAMED mandatory. COM took notes of their concerns and noted that the use of EUDAMED cannot be made obligatory until it is fully functional.

3.3 Notified Bodies

COM shared an overview of notified bodies' activities at each stage of the designation process. It highlighted that 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. Stakeholders warned COM against future backlogs for certification if remote audits cannot be conducted under the Regulations.

3.4 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.

3.5 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 of the MDR/IVDR standardization request, and on the potential modification of the "electronic instructions for use" act.

3.6 International matters

COM updated participants on the multiple international files relating to the field of medical devices, including on the latest decisions taken by the IMDRF, and the progress made in the files for Switzerland, Turkey and Taiwan. A reference was also made to UK which has applied to become a member of the IMRDF and whose application will be reviewed in January 2021.

4) AOB

- Participants were updated on the latest work on the ongoing communication campaign which primarily aims at informing regulators and stakeholders on implementation aspects of the new legislative framework. Recent work includes extensive stakeholder mappings, media mappings, website transfer from DG GROW to DG SANTE, information packs with numerous factsheets, the creation of visual and other supporting materials, as well as the organization of targeted webinars for the training of experts appointed at the expert panels.

- MedTech Europe noted that there seem to be some problems regarding medical devices incorporating an ancillary substance which, if used separately, can be considered a medicinal product as regards the lack of responsiveness of medicines authorities when there needs to be a reassessment of the file. COM will follow up.

Next meeting

The next MDCG meeting with stakeholders will be communicated to MDCG members as soon as possible but under the circumstances it will probably be another virtual meeting.

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, NO, TR

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

Stakeholders' Organisations / associations participating in MDCG sub groups.