EUROPEAN COMMISSION

DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health systems, medical products and innovation

Medical Devices

Brussels 18 December 2020

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Minutes of the expert groups

Meeting of the MDCG Subgroup Annex XVI, Regulators

Brussels, 12 November 2020

1. WELCOME & ADOPTION OF AGENDA AND MINUTES OF THE MEETING HELD ON 16 SEPTEMBER 2020

COM welcomed participants and reminded housekeeping rules.

This meeting was a closed session with Competent Authorities only.

The draft minutes of the meeting held on 16 September 2020 has been circulated via CIRCABC. No comment has been received, either in advance and during the meeting, consequently the minutes was adopted. Also the agenda was adopted.

Due to the COVID-19 crisis the meeting was organised virtually with video-audio connection.

2. REFLECTION ON SESSION WITH STAKEHOLDERS

COM summarised the main points raised by the stakeholder during the open session.

Some of the stakeholders expressed concerns about the 6 months transition period established by Article 1(2) of Regulation (EU) 2017/745. It is too short for the implementation of the common specifications, at least for devices that need a design change and a new conformity assessment.

Stakeholders generally consider standards as a good source of technical requirements for Annex XVI products and thought that common specifications should consider applicable standards for analogous devices. For products listed in group n. 5 of Annex XVI, the

different risk profile for devices for professional use and devices for home use should be considered and reflected in the common specifications requirements.

COM opened the floor for comments. A couple of Member States (MS) agreed that the 6 months transition period won't be enough to allow manufacturers placing on the market all devices. It was added that, for certain devices, the transition period should also consider the time needed for the execution of clinical investigation.

COM reminded that the legal requirement for the applicability of the common specifications is clearly established by the Regulation (EU) 2017/745 and that no "grace" period has been granted to devices without an intended medical purpose.

3. DRAFT IMPLEMENTING ACTS

i Common specifications

COM informed that the common specifications should be adopted by 26 May 2021, according Article 1(2) to MDR. Considering the time left, it is of high importance to focus the discussions within the Task Force on the risk management as all the other parts of the act have been extensively discussed and agreed in the past.

COM informed that it has carefully considered the possibility to simply make reference to the ISO 14971, instead of drafting new implementation requirements for the risk management. However, COM still believes that the agreed solution to include new risk management requirements is most appropriate and feasible solution.

COM opened the floor for comments. A couple of MS confirmed their preference for the simple reference to the ISO 14971 to solve the issue related to the risk management. COM informed that the point is still under discussions within the Task Force.

ii Reclassification

COM presented the draft reclassification act. The list of active devices without an intended medical purpose that should be reclassified to classes IIa, IIb and III was presented in detail.

COM opened the floor for comments asking also for specific views about the devices of group 6 of Annex XVI. Different proposals have been discussed, including to consider analogous devices with a medical purpose to address the reclassification as well as to consider the risk profile and the possible biological effects of those devices. COM took note of the proposals and confirmed that the point will be further discussed within the Task Force.

4. AOB

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5. CONCLUSIONS

COM closed the meeting thanking the participants for the useful discussions.

LIST OF PARTICIPANTS

MDCG members: BE, DE, DK, ES, FI, FR, HR, HU, IT, LU, MT, NL, PL, PT, SE, SI.

Observers: CH, TR

Commission: SANTE B6