EUROPEAN COMMISSION

DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health systems, medical products and innovation

Medical Devices

Brussels 18 December 2020

SANTE.DDG1.B.6/

Minutes of the expert groups

Meeting of the MDCG Subgroup Annex XVI, Stakeholders session

Brussels, 12 November 2020

1. WELCOME & ADOPTION OF AGENDA

COM welcomed participants and reminded housekeeping rules.

This meeting was an open session with Competent Authorities and Stakeholders.

APPLiA requested to give a presentation on "Input to MDCG Annex XVI WG for Home use IPL Devices". This was added under AOB and the agenda was adopted.

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

2. INTRODUCTION FROM THE COMMISSION CHAIR

COM thanked the Stakeholders for expressing their interest in joining the subgroup as observers and welcomed them to the first meeting open to stakeholders. COM also thanked the stakeholders who provided their contribution to the consultation on the reclassification of active devices without an intended medical purpose.

COM stressed the impact of the Covid-19 on the Medical Devices sector and mentioned the postponement of the MDR date of application, to 26 May 2021, as a consequence.

COM informed that during the last months, the draft common specifications have been discussed among the relevant Commission services, with specific reference to the classification and risk management requirements. A number of issues have been identified and a Task Force established within the Annex XVI subgroup (only regulators) is currently working to address them.

3. COMMON SPECIFICATIONS STATE OF PLAY

COM gave a presentation on the state of play for the common specifications to inform about the updated structure and the issues related to the risk management and the classification requirements.

With reference to the text sent to the stakeholders of the MDCG for an informal consultation, a new annex will be added to the common specifications to group together horizontal requirements applicable to all groups of devices listed in Annex XVI. Vast majority of such requirements were previously included in the main act.

With reference to the risk management requirements, COM explained the need, from a legal perspective, to add further requirements to properly cover implementation of Section 3 of Annex I to MDR, taking inspiration also from relevant applicable standards (e.g.: ISO 14971 "Medical devices - Application of risk management to medical devices").

With reference to the classification, COM explained that the implementing act on common specifications cannot extend application of certain classification rules (namely, those ones listed in Section 6 of Annex VIII to MDR) to devices without an intended medical purpose as there is no legal mandate to deal with this in the same act. Consequently, the issue has to be addressed outside the common specification and COM informed about its intention to address this in a separate legal act with a different legal base.

COM explained that the acts will be available to stakeholders when published for feedback. Considering that 26 May 2021, the deadline for the adoption of the common specifications, is approaching quickly, the 4 weeks period of publication is the most suitable way to collect comments in a fast, structured and comprehensive way.

APPLiA and MedTech Europe claimed the 6 months transition period established by Article 1(2) of the Regulation (EU) 2017/745 is too short, considering the need for some manufacturers to adapt the design of the devices to the new requirements established by the common specifications and, then, to complete the conformity assessment. Also Notified bodies will need a learning period before being fully operational. APPLiA proposed a period of 3 years while, for MedTech Europe, different transition periods could be defined considering the requirements complexity can vary for different groups of products. COM reminded about the legal limitations set by MDR.

TEAM-NB informed about possible difficulties related to clinical investigation applications where Ethic Committees will be asked to approve studies for products not having a clinical intended purpose. COM stressed that this is a separate issue, but clarified that for Annex XVI products, the clinical benefit should be considered as to confirm the performance of the device, according Article 61(9) of Regulation (EU) 2017/745. Moreover, COM clarified that notified bodies will be able to accept applications for conformity assessments of Annex XVI products as soon as the common specifications will entry into force.

Euromcontact highlighted that standards are a good source of technical requirements for Annex XVI products and the common specifications should take into account existing applicable standards for analogous devices. APPLiA welcomed that comment and added

that standards can be useful also considering that they include notes for the interpretation of the requirements.

4. AOB

APPLiA gave a short presentation on Intense Pulsed Light (IPL) equipment for home use. The presentation highlighted some differences between the IPL devices for professional use and for home use and the need for specific requirements for both categories to ensure safety for users and consumers. Considering the risk control measures, the presentation included a recommendation for referring to international standards for the risk mitigation requirements. Finally, the presentation explained the need for a longer transition period for the common specifications implementation. A period of 36 months was suggested.

5. CONCLUSIONS

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

LIST OF PARTICIPANTS

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

Observers: CH, TR

Stakeholders: AESGP, APPLiA, COCIR, EAAR, ECOO, EUROM 1, Euromcontact, GIRP, MedTech Europe, NB-MED, SMEunited, Team-NB.

Commission: SANTE B6