EUROPEAN COMMISSION

DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health systems, medical products and innovation

Medical Devices

Brussels 13 October 2020

SANTE.DDG1.B.6/

Minutes of the expert groups

Meeting of the MDCG Subgroup Annex XVI

Brussels, 16 September 2020

1. WELCOME & ADOPTION OF AGENDA AND MINUTES OF THE MEETING HELD ON 8 MAY 2019

COM welcomed the participants and reminded the housekeeping rules.

This meeting included only a closed session with Competent Authorities. COM informed that the stakeholder selection process has been closed and the appointed stakeholders will be invited in a dedicated session from the next meeting as observers.

The file was transferred from DG GROW to DG SANTE with the new Commission.

The agenda was adopted.

The minutes for the meeting held on 8 May 2019 was adopted.

Due to the COVID-19 crisis the meeting is a virtual meeting with video-audio connection.

2. INTRODUCTION FROM THE COMMISSION CHAIR

COM stressed the impact of the Covid-19 on the Medical Devices sector and thanked the Member States for the significant work realised despite of the critical situation.

As a consequence to the crisis, the MDR date of application has been postponed to 26 May 2021. COM pointed out that this may have a positive impact for the manufacturers of Annex XVI devices, leaving them more time for the implementation of the new MDR requirements. In order to maximize such opportunity, the common specifications laying

down the new requirements for the devices without an intended medical purpose should be finalised as soon as possible.

COM informed that during the last months, the current draft of the common specifications has been intensively discussed among the relevant Commission services with specific reference to the classification and risk management requirements. Some changes have been performed to the text and few open issues will be discussed during the meeting. Possible solutions have been identified and these options will be presented to the group during the meeting.

3. COMMON SPECIFICATIONS

i. State of play (short presentation)

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 structure of the text, a new annex has been added to the common specifications to group together all the horizontal requirements, applicable to all groups of devices listed in Annex XVI, previously included in the main act.

With reference to the risk management requirements, COM explained the need to add further requirements to widely cover the implementation of Section 3 of Annex I to MDR.

With reference to the classification, COM explained the need to address the issue outside the common specification and suggested that this is addressed in a separate legal act with a different legal base.

ii. Risk Management requirements

COM pointed out that according to Article 1(2) of MDR, the common specifications shall address requirements for the application of risk management as set out in Annex I to MDR.

After discussion, participants agreed to include additional requirements for the risk management methodology, taking inspiration from the relevant applicable harmonised standard (EN ISO 14971:2012).

4. CLASSIFICATION REQUIREMENTS

COM explained that a legal act on common specifications cannot be used to 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. It was explained that, according to MDR, active devices without an intended medical purpose would be classified according Rule 13 of Annex VIII to MDR, as class I. It was agreed that this might not be consistent with the inherent risk of several active devices listed in Annex XVI, neither would it assure a classification of products without an intended medical purpose coherent with the classification of analogous devices with a medical purpose.

After discussion, it was agreed by most participants that a separate proposal for an implementing act based on Article 51 of MDR to reclassify active devices without an intended medical purpose would be the most appropriate way forward.

5. AOB

Nothing discussed under this point.

6. CONCLUSIONS

To proceed on the draft common specifications update and to develop the reclassification implementing act, COM proposed to create a new Task Force within the Annex XVI subgroup.

Next MDCG Annex XVI Subgroup meeting was scheduled on 28 October 2020, but after the meeting, while this document was being drafted, COM postponed the meeting to 12 November 2020.

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

LIST OF PARTICIPANTS

List of participants: MDCG members: AT, BE, CZ, DE, DK, ES, FI, FR, HR, HU, IE, IT, LU, MT, NL, PL, PT, RO, SE, SI

Observers: CH, TR

Commission: SANTE B6