EUROPEAN COMMISSION

DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health systems, medical products and innovation

Medical Devices

Brussels 29 November 2021

SANTE.DDG1.B.6/

Minutes of the expert groups

Meeting of the MDCG Subgroup Annex XVI, Stakeholders session

Brussels, 17 September 2021

1. WELCOME & ADOPTION OF AGENDA

COM welcomed participants and reminded housekeeping rules.

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

The agenda was adopted.

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

2. INTRODUCTION FROM THE COMMISSION CHAIR

COM informed that during the first semester of 2021, continuing the work started in 2020, the Task Force intensively worked on the common specifications for Annex XVI products and a draft has been finalised and circulated in May 2021 for consultation. COM thanked the stakeholders for their contribution.

COM informed that the internal discussions on the reclassification implementing act are still ongoing, especially with reference to the legal basis, and that a more detailed update about this act will be provided later on during the meeting.

3. COMMON SPECIFICATIONS - STATE OF PLAY

In May 2021, a draft of the Annex XVI common specification was circulated for consultation. COM thanked again the stakeholders for their contribution, confirmed that all comments have been reviewed and that, where appropriate, the draft has been updated consequently. For the rejected comments, a justification has been provided to the relevant stakeholder.

COM thanked also the members of the Task Force for their continuous work on the common specifications, also during the summer period.

With reference to the updated draft of the common specifications, COM described the main technical changes. In particular:

- the addition of specific transitional provisions for devices incorporating an ancillary medicinal substance;
- the rewording of requirements for biocompatibility and pirogenicity;
- the wavelength range established in Annex VI for products of group 5, high intense electromagnetic radiation emitting equipment.

COM opened the floor for discussions on possible major issues, both on the draft or on the reply to comments.

Starting from a comment by ECOO (European Council of Optometry and Optics) on a specific requirement for products in group 1, contact lenses, it was agreed to include a reference to national laws to properly identify the qualified healthcare professionals authorised to deal with certain symptoms.

NB-MED proposed to consider anaplastic large cell lymphoma (BIA-ALCL), among specific risks for products totally or partially introduced into the human body, included in group 2, not only associated to breast implants, but associated also to implants in other anatomical regions.

Various stakeholders commented the conditions for the home use of products in group 5, high intense electromagnetic radiation emitting equipment, asking to consider that products already marketed might be not permitted for the home use due to the proposed conditions.

Various stakeholders stressed also the labelling requirements, in particular the difficulties to include on the labelling long warning sentences for which the available space on the label itself or on the outer packaging could not allow to host also the translations into other languages. Stakeholders proposed to either remove the requirement for the label, limiting the presence of long warning sentences on the instructions for use, or to use a symbol.

After a discussion on the topics mentioned above, COM took note of proposals and suggestions to be further discussed with the Member States in the closed session of the meeting. To allow stakeholders to further contribute on these topics and also on other possible issues identified, COM accepted additional comments in writing by 21 September, 2021.

With reference to the main body of the common specifications, replying to a specific request from MTE (MedTech Europe), COM explained the rationale behind the proposed transitional period for devices incorporating an ancillary medicinal substance. COM clarified also the reference to the manufacturer and its responsibilities to benefit from the transitional provisions, replying to a comment from Euromcontact and COCIR.

Euromcontact and COCIR noted that the deadline to place on the market, make available and put into service a product benefiting from the transitional provisions will be on the same date. Such condition will result in the impossibility to further make available, for example by a distributor, or even put into service, a product lawfully placed on the market close to the deadline. COM took note of the concern, confirming to reevaluate it internally.

Except for the open points mentioned above, the draft of the common specification was agreed by the stakeholders.

Replying to a specific request from APPLiA, COM described the next steps of the adoption procedure for the common specifications and the timeline.

4. RECLASSIFICATION OF CERTAIN ACTIVE DEVICES – STATE OF PLAY

COM reminded that during the meeting held on November 2020 an update on the work on reclassification of active devices without an intended medical purpose was provided. COM informed that information based on new scientific evidence or from vigilance and market surveillance activities are necessary to support the implementing act according to the legal basis established in Article 51(3)(b) of MDR. For that reason, in May 2021 the Member States national competent authorities have been asked to provide the information and data on the active products included in the scope of the draft reclassification implementing act. COM said that the received information was under review and confirmed the intention to keep the stakeholders informed about the evolution of the activity.

Various stakeholders asked COM to share the draft reclassification implementing act. COM took note and confirmed to provide a feedback in writing.

4. AOB

No item was covered under this Agenda point.

5. CONCLUSIONS

COM closed the meeting thanking participants for the useful discussions.

LIST OF PARTICIPANTS

MDCG members: AT, BE, BG, CZ, DE, EE, ES, FI, HU, IE, IT, LU, NL, PL, PT, RO, SE.

Observers: TR

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

Commission: SANTE B6