EUROPEAN COMMISSION

DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health systems, medical products and innovation

Medical Devices

Brussels 2 February 2022

SANTE.DDG1.B.6/

Minutes of the expert groups

Meeting of the MDCG Annex XVI subgroup, Stakeholders session

Brussels, 11 January 2022

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 the meeting was planned to mainly discuss and endorse the Annual Work Programme for 2022 while the other points included in the agenda are more informative.

3. WORK PROGRAMME

3.1. Update for 2021

COM informed that the Work Programme for 2021 was updated simply to reflect the situation of the work items at the end of year. COM presented the updated document and the group endorsed it.

3.2. Draft for 2022

COM presented the draft of the Annual Work Programme for 2022 and described its content. In detail, Priority 1 for the two implementing acts already present in the 2021 document and Priority 2 for two possible guideline documents.

For the common specifications, COM explained that a delay of two months was accumulated due to the need to address some comments received during the Commission Inter Service Consultation. Consequently, the expected publication of the act on the Official Journal is foreseen in Q2/2022, a couple of months after the previous deadline. Same date is foreseen for the draft implementing act on reclassification.

With regards to the guideline documents, COM explained that the one on the clinical evaluation could include clarifications on the application of the equivalence criteria, on the need of clinical investigations and on specific elements for the execution of the investigations.

COM added that the guideline on classification could be drafted to complement the already available MDCG 2021-24 "Guidance on classification of medical devices" providing examples for the groups of products without an intended medical purpose without repeating the general concepts included in that document that are already applicable to the Annex XVI products. Even if not strictly related to the classification of a device, the guidance could include clarifications for the products with both medical and non-medical intended purposes.

No comments were made on the draft that was therefore endorsed by the group.

4. COMMON SPECIFICATIONS - STATE OF PLAY

COM mentioned that after the consultation of the MDCG, during the meeting held on 19 October 2021, the Commission Inter Service Consultation was launched. The draft of the common specifications was updated to accommodate comments received from other Commission services.

COM ensured that the technical content of the draft has not been changed, considering that few comments were of legal nature and the majority of them were mainly editorial and devoted to improve the clarity of the requirements.

COM confirmed that soon after the closure of the Inter Service Consultation the draft common specifications will be published for the public feedback procedure. COM will inform the group of the publication.

Some stakeholders, concerned about the date of publication of the draft common specifications, asked COM for more details. COM confirmed that the draft should be published on the Have your say portal very quickly and, in any case, not after the following week (by 21/01/2022).

5. AOB

No item was covered under this Agenda point.

6. CONCLUSIONS

COM closed the meeting thanking participants for the useful discussions.

LIST OF PARTICIPANTS

MDCG members: BE, DE, DK, ES, FI, FR, HU, IE, IT, LU, NL, PL, PT, RO, SE, SK, SI.

Observers: /

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

Commission: SANTE B6