



EUROPEAN COMMISSION

DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health systems, medical products and innovation

Medical Devices

Brussels 16 March 2021

SANTE.DDG1.B.6/

Minutes of the expert groups

Meeting of the MDCG Subgroup Annex XVI, Regulators

Brussels, 8 March 2021

1. WELCOME & ADOPTION OF AGENDA

The Commission (COM) welcomed participants and reminded housekeeping rules.

This meeting was a closed session with Competent Authorities only.

The agenda was adopted with the addition of a new point (i) under item 2. Such point was added for endorsement of the Work Programme for the 2021.

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

Before starting the meeting, COM recalled that during 2020, after intense discussions on previous drafts of common specifications, both within the Commission services and the Annex XVI subgroup, a Task Force within this subgroup has been established to address the needs related to the risk management and the classification requirements. Thanks to weekly meetings of the Task Force, advanced drafts for the common specifications and the reclassification acts are now available. Discussions within the Task Force were complex and extensive and took more time than expected.

COM thanked the Task Force for the work done and explained its wish to find an agreement on the advanced drafts to allow the Task Force go on with the work and finalise the drafts as soon as possible.

2. WORK PROGRAMME 2021

(i) endorsement of the document

COM explained the need to formally endorse the Work Programme for 2021 at the level of the subgroup before moving for the endorsement at the Medical Device Coordination Group (MDCG) level.

COM presented the draft Work Programme, previously circulated via circabc. With reference to the foreseen date of application of the common specifications, a Member State (MS) expressed its concern on Art 1(2) of Regulation (EU) 2017/745 (MDR), not sufficient to provide legal certainty during the transition period, asking for the amendment of the MDR timeframes before the adoption of the common specifications.

COM noted that for an amendment of the MDR, the Council and the Parliament have to be involved and the co-legislative procedure would be quite long and, consequently, the Work Programme was adopted by the subgroup with one reservation.

(ii) update of the status of work items

COM provided a brief update for the work items status confirming that the work on the implementing acts is ongoing and confirming that, reflecting the activities currently ongoing within the Task Force, the deadline for the adoption of the common specifications has been updated to Q3/2021.

With reference to the analysis of needs for possible guidelines, COM said that the activities on this work item will be started during the meeting at the next agenda point.

(iii) analysis of needs of possible guidelines

COM explained that the aim of the work item is identifying the needs of possible guidelines to ensure the right planning of the work items for the 2022, involving other subgroups where needed. Referring to discussions within the Task Force, COM noted that needs related to classification or to clinical evaluation for devices without an intended medical purpose have been already identified and could be a starting point for further reflection.

The importance to clarify how the benefit-risk ratio has to be considered for Annex XVI products with reference to the clinical evaluation and the clinical investigations was confirmed.

The group agreed to develop the analysis within the Task Force to better identify possible scope and content for the classification and clinical evaluation needs, considering also the work currently ongoing within other subgroups, such as the Borderline & Classification and the Clinical Investigation and Evaluation.

3. COMMON SPECIFICATIONS

COM thanked a lot the members of the subgroup participating in the Task Force for their contribution and support for advancing the work on the draft implementing acts.

(i) state of play

COM informed that a proposal for transitional provisions has been added to the main body of the common specifications together with conditions to benefit from these provisions.

Requirements for the risk management implementation have been added to the common specifications' annexes. The main reference is the MDR, but the ISO 14971 has been also taken in consideration. Annexes related to the various groups of products have been lightly updated to ensure alignment with the changes related to the risk management.

Clinical evaluation requirements have been updated to clarify how the equivalence criteria has to be implemented and when a clinical investigation has to be considered. COM informed the subgroup that the Task Force is still working on the annexes of the common specifications.

No comments or questions on the update.

(ii) comments on the updated draft

COM shared the draft and opened the floor for comments.

The draft proposal for the transitional provisions was welcomed and, in principle, supported.

A MS asked to evaluate the possibility to include requirements for the enforcement and control of the transitional provisions, to better analyse the need for the reference to the Directive 90/385/EEC (AIMDD) and to clarify the meaning of some terms, with reference to the MDR.

The discussions on the equivalence highlighted the possibility to clarify the text and the discussions on the clinical evaluation highlighted the possibility to better explain the interconnections with the risk management process and on how consider the clinical data from analogous devices.

COM confirmed that the group agreed on the approach followed by the Task Force for the introduction of the additional requirements for the risk management and on the level of detail of such requirements. COM confirmed also the possibility to improve the text to clarify the equivalence requirements and the interrelations between the risk management and the clinical evaluation processes. The Task Force will be involved and any suggestions or contributions from the members of the subgroup will be welcomed.

4. RECLASSIFICATION IMPLEMENTING REGULATION

(i) state of play

COM informed that the draft for the reclassification of active devices without an intended medical purpose is an advanced draft and the majority of the Task Force members agreed on the proposed new classifications.

No comments or questions on the update.

(ii) comments on the updated draft

COM shared the draft and opened the floor for comments.

One member asked to consider a clarification for the software, especially if the software can enhance the performance of the device or change its intended purpose.

COM confirmed that the need will be discussed within the Task Force and invited the member to provide a proposal or, if possible, to attend the meetings of the Task Force to directly participate in the discussions.

5. AOB

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6. CONCLUSIONS

COM confirmed endorsement of the group on the Work Programme, with reservation from one MS. For the common specifications, transitional provisions have been discussed and requirements for the control of their application will be considered. For the risk management requirements, the group agreed on the approach and on the level of detail reflected by the drafts. The group agreed also on the need to clarify some requirements for the clinical evaluation and, in general, on the possibility to improve the description of how the clinical evaluation is interlinked with the risk management.

For the reclassification, the group agreed on the proposed draft and on the need to include a statement for the software, at least in a dedicated recital.

COM confirmed that the Task Force will continue the weekly meetings and that the agreed final text will be forwarded to the group. COM invited MSs to participate in the meetings of the Task Force or contribute to them, if they wish.

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

LIST OF PARTICIPANTS

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

Observers: CH, TR

Commission: SANTE B6