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, Regulators

Brussels, 17 September 2021

1. WELCOME & ADOPTION OF AGENDA

COM welcomed participants and reminded housekeeping rules.

This meeting was a closed session with Competent Authorities only.

The agenda was adopted.

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

2. WORK PROGRAMME 2021

(i) update of the status of work items

COM presented the Work Programme and described the status of each item.

With reference to work item 1/1 (common specifications - CS), COM summarised the latest activities performed (e.g.: consultation of the subgroup, review of comments, update of the draft CS) and informed about next steps in view of adoption.

COM explained that processing the comments received during the consultation took longer than expected, given both the nature and the amount of comments received. Considering the next steps of the adoption procedure, adoption of the act is foreseen for Q1 2022.

With reference to work item 1/2 (reclassification implementing act), considering the ongoing work and the link with the CS, COM proposed to keep timelines of the two work items aligned. A more detailed update on the state of play of the act will be provided during the meeting under agenda point number 5.

COM opened the floor for comments.

A Member Sate noted that for coherence, also the timeline for work item 2/1 (analysis for the identification of possible needs of guidelines) could be aligned to the new deadline proposed for work items under Priority 1. The work programme was updated accordingly and endorsed by the group.

(ii) analysis of needs of possible guidelines

With reference to work item 2/1 (analysis for the identification of possible needs of guidelines), COM noted that the current text of the CS includes requirements for risk management and information for safety and that clinical evaluation requirements removed from the former draft of the CS could be included in a possible guidance document.

COM opened the floor for comments.

A Member State stressed the importance of having the clinical evaluation requirements covered by the CS to support manufacturers also for the application of those requirements. After a brief explanation of the rationale behind that decision by COM, the Member State proposed to include a more detailed explanation, at least on clinical investigations, in the recitals of the draft and volunteered to provide some text. COM thanked and confirmed they will evaluate the proposal.

A Member State proposed to consider also a possible guideline on classification, specifically dedicated to products listed in the Annex XVI of Regulation (EU) 2017/745.

COM took note of the two possible guidelines on clinical evaluation and classification.

3. REFLECTIONS AND COMMENTS FROM THE STAKEHOLDERS SESSION

COM summarised the main points raised by the stakeholder during the open session and opened the floor for comments.

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

NBCG-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. On this point the group identified the need for more detailed

information on this risk. COM will ask NBCG-MED for more specific information. For the time being, the group agreed to keep the reference limited to the breast implants.

Various stakeholders commented the conditions established for the home use of products in group 5 (high intense electromagnetic radiation emitting equipment) asking to give due consideration to the fact that products already marketed might not comply with such conditions. The group confirmed the need to carefully consider the risk profile of the product for home use to ensure its safety in such environment.

Various stakeholders commented also the labelling requirements, in particular the difficulties to include on the labelling long warning sentences for which the available space on the labels or the outer packaging could not be sufficient to host translations into other languages. Stakeholders proposed either to remove the requirement for the label, limiting the presence of long warning sentences on the instructions for use only, or to use a symbol. The group confirmed the feasibility of this requirement considering that, in general, the packaging of these types of products is big enough to allow manufacturers to accommodate also the additional warning messages.

4. COMMON SPECIFICATIONS

(i) results of the last subgroup consultation

COM reminded that on May 2021, a draft of the Annex XVI CS was circulated for consultation. COM thanked the members for their contribution and confirmed that all the received comments have been evaluated. Some changes to the draft have been made to accommodate some of those comments while for all the rejected comments, a justification has been provided.

Before the meeting, an updated draft was circulated.

(ii) comments on the updated final draft

COM opened the floor for comments on other sections of the draft CS not discussed yet.

Taking into account how different wavelengths are absorbed by the skin and other tissues, a Member State stressed the need to reconsider the new proposed upper limit for the wavelength range for high intense electromagnetic radiation emitting equipment in group 5.

Except for the two open points on the wavelength range and on the recital on clinical investigation mentioned in point 2(ii), the draft CS was agreed by the Member States.

COM invited Member States to provide comments on the open points and also on possible additional issues and fixed the deadline on 21 September, 2021. Comments will be assessed and discussed within the Task Force.

5. RECLASSIFICATION OF CERTAIN ACTIVE DEVICES

(i) results of MDCG consultation

COM reminded that internal discussions on the implementing regulation on reclassification of active devices without an intended medical purpose highlighted the need of detailed information based on new scientific evidence and/or on vigilance and market surveillance data. Such information will serve as a justification to support the adoption of the implementing act according to the legal basis established in Article 51(3)(b) of MDR.

In May 2021, COM asked the Member States national competent authorities to provide the available information and data on products in the scope of the draft reclassification implementing act. COM informed that some Member States replied and gave an overview of the information received.

To try to collect more data and information, COM proposed to send out a reminder to Member States national competent authorities and committed to share a summary of the information received.

(ii) comments and next steps

Some Member States underlined the importance of this draft implementing act and the need to have it available together with the CS. For that reason, they stressed the importance to proceed quickly.

6. AOB

No item was covered under this Agenda point.

7. CONCLUSIONS

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

LIST OF PARTICIPANTS

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

Observers: TR

Commission: SANTE B6