



EUROPEAN COMMISSION

DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health systems, medical products and innovation

Medical Devices

Brussels 30 May 2022

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Minutes of the expert groups

Meeting of the MDCG Annex XVI subgroup, Regulators session Brussels, 18 May 2022

1. WELCOME & ADOPTION OF AGENDA

COM welcomed participants and reminded housekeeping rules.

This meeting was a closed session with Competent Authorities only.

A Member State requested COM to provide a short update also on the state of play of work items included in the Annual Work Programme of the subgroup for 2022. The point was added under AOB and the agenda was adopted.

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

2. COMMON SPECIFICATIONS – STATE OF PLAY

COM informed that the draft of the common specifications was presented to the Committee on Medical Devices during a meeting that took place on 26 April 2022. COM added that some Member States proposed amendments to the act, various Member States expressed their concerns on the reclassification issue and one Member State indicated its intention to formally request the reclassification according to Article 51(3) of Regulation (EU) 2017/745.

COM, after having specified that the update of the draft was still ongoing, presented the changes proposed to the draft, mainly for the transitional provisions, and informed that the next meeting of the Committee on Medical Devices will be convened shortly to present and discuss the updated draft.

COM confirmed that the updated draft will be shared for information also within the Annex XVI subgroup.

A Member State noted that the wording for the transitional provisions remains quite complex and difficult to be understood and enforced. COM noted that the wording reflects the need to specify which conditions have to be fulfilled in each moment in time during the transitional periods. In addition, COM explained that some requirements have been combined to simplify the structure of the text.

Other comments on transitional provisions were related to the availability of notified bodies and their workload foreseen for the initial months of 2024, due to the expiration of certificates issued under the Council Directive 93/42/EEC on medical devices.

COM took note of the comments and mentioned that also some products covered by Annex XVI hold certificates issued according to the Directive 93/42/EEC and are currently placed on the market as medical devices. It was agreed that the qualification of such products as medical devices, based on national measures, as established by the third paragraph of Article 1(2) of Regulation (EU) 2017/745, has to be considered only pursuant the Directive. COM informed that the specific case of Annex XVI products qualified as medical devices and holding a valid certificate was considered when proposing the updates for the transitional provisions. COM noted also that further postponing the adoption of the common specifications would imply a reduction of the transitional periods for the manufacturers of those products.

3. RECLASSIFICATION – STATE OF PLAY

COM reminded that the subgroup has been working on a draft implementing act to reclassify certain active products without an intended medical purpose and presented an updated draft that included the necessary provisions in case one or more Member States formally request the reclassification.

A Member State confirmed its intention to formally request the reclassification.

COM described the steps and the timeframe for the adoption of a possible Commission Implementing Regulation on reclassification. A Member State noted that the adoption of the common specifications should not be further delayed and that a suitable solution should be found in case the adoption of a reclassification act would be delayed. COM took note of the comment.

4. AOB

4.1. 2022 Annual Work Programme

COM presented the Annual Work Programme of the 2022 and, more in detail, the work package number 2, related to the guidance documents was discussed. COM confirmed that the Task Force will start that work shortly.

5. CONCLUSIONS

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

LIST OF PARTICIPANTS

MDCG members: AT, BE, BG, CZ, DE, DK, EE, ES, FI, FR, HR, IE, IT, LU, NL, PL, PT, RO, SK, SI, SE.

Observers: TR

Commission: SANTE B6