EUROPEAN COMMISSION

DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health systems, medical products and innovation

Medical Devices

Brussels 2 February 2022

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Minutes of the expert groups

Meeting of the MDCG Annex XVI subgroup, Regulators session

Brussels, 11 January 2022

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. REFLECTIONS FROM THE STAKEHOLDERS SESSION

COM noted that during the Stakeholders session the draft Annual Work Programme for 2022 was endorsed and opened the floor for comments. No interventions from Member States were made.

3. WORK PROGRAMME

With reference to the work items under the Priority 2 package of the Annual Work Programme for 2022, on the guideline documents on clinical evaluation and classification, COM proposed to start the activities within the Task Force already established under the Annex XVI subgroup. The Member States agreed and the Annual Work Program was updated accordingly.

COM confirmed that additional Member States willing to participate in the Task Force will be welcomed.

A Member State noted that it could be relevant have the possibility to share and discuss questions received from the market at national level on Annex XVI products. Such possibility could be beneficial for the coordination at the European level and ensure the harmonisation of the information provided.

Member States supported the proposal and agreed on the proposal from COM to organise an initial specific meeting by the end of March 2022.

4. 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.

Article 51 of Regulation (EU) 2017/745 (MDR) allows the Commission to adopt an implementing act to reclassify devices, by way of derogation from the application of Annex VIII of MDR, for reasons of public health based on new scientific evidence, or based on any information that becomes available in the course of the vigilance and market surveillance activities. To explore if suitable information to justify the reclassification are available at national level, COM consulted the Medical Device Coordination Group (MDCG). A report that summarises the results of this consultation was presented.

COM opened the floor for comments.

A Member State confirmed that the information they provided should be considered sufficient and, upon a proposal from COM, confirmed their intention to submit a formal request for the reclassification, together with the supporting evidence and justifications.

Another Member State noted that the MDR aims to ensure a high level of protection of health for patients and users, and, consequently, the reclassification should be considered as a proactive measure for reasons of public health.

Finally, another Member State noted that, in the interest of time, the reclassification implementing act would be faster than an amendment of the classification rules of the MDR. In addition, the Member State noted that a reply to the consultation from the Member States that have not replied yet, would be useful to increase the availability of information.

COM took note of the comments.

5. AOB

No item was covered under this Agenda point.

6. CONCLUSIONS

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

LIST OF PARTICIPANTS

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

Observers: /

Commission: SANTE B6