

EUROPEAN COMMISSION DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health systems, medical products and innovation Medical devices, Health Technology Assessment

Minutes of the expert groups

Brussels, 13 July 2021

Minutes

Meeting of the Medical Devices Coordination Group $^1\,(MDCG)$ with stakeholders 28/5/2021

1) Opening, adoption of the agenda

The agenda was approved and minutes of last meeting held on 4 March 2021 were endorsed prior to this meeting through written procedure and are published in the registry for European Commission's expert groups.

2) Implementation MDR – Medical Device Regulation

Commission welcomed participants to this short special MDCG meeting with stakeholders to mark the date of application of (EU) 2017/745, Medical Device Regulation – which was on 26 May 2021. They referred to the long journey of the process which started in 2008 with a public consultation, the 2012 Commission proposals, the finalisation of the lengthy legislative negotiations in 2017 and eventually the postponement of the MDR's date of application to May 2021 due to the extraordinary situation caused by COVID-19 crisis. The Commission thanked all actors who contributed to the amazing amount of work that has been accomplished. Still, the work continues in the same collaborative spirit with close collaboration with MDCG members, competent authorities for medical devices (CAMD) and relevant European associations of organisations and economic operators.

The Chair of CAMD and representatives of AESGP, Biomed Alliance, COCIR, EAAR, EAHP, EUROMCONTACT, MedTech Europe, Team-NB shared also their perspectives on the implementation of MDR, appreciated the opportunity to intervene and highlighted from their point of view the most relevant aspects, main achievements and remaining challenges. Dedicated discussions and consultations on specific technical issues are ongoing and will continue either in the various MDCG sub-groups or in writing.

3) AOB

Next meeting

The date of the next MDCG meeting with stakeholders (most likely in virtual format) will be communicated as soon as possible.

¹ Published in the <u>Register of Commission Expert Groups and Other Similar Entities</u>, code number X03565

List of participants

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

Observers: IC, NO, TR.

Commission: SANTE B6, SANTE F5, JRC F2, SANTE A4

Stakeholders' Organisations / associations participating in MDCG Subgroups.