TERMS OF REFERENCE

MDCG WORKING GROUP ON EUROPEAN DATABASE ON MEDICAL DEVICES

1. Tasks and roles

The group provides advice on issues related to the establishment, management and maintenance of the European Database on Medical Devices (EUDAMED) under Regulation (EU) 2017/745 on medical devices (MDR) and Regulation (EU) 2017/746 on in-vitro diagnostic medical devices (IVDR).

In particular, the group shall advice on policy and technical matters related to EUDAMED, including on the implementation and application of the relevant provisions of the MDR and IVDR.

In the field of its activities, the group coordinates the work of the ad-hoc technical EUDAMED working groups (as operated outside of the MDCG), as well as supports the work of other MDCG working groups linked to a specific EUDAMED module[1]. Most importantly, this shall involve providing directions on future work items for the benefit of all interested parties. The group may also advise the Commission in the early preparation of implementing acts foreseen in the MDR and IVDR.

2. Membership

Members of the MDCG Subgroup on EUDAMED are experts representing the competent authorities of the Member States. Each Member State appoints one member and one alternate and it shall ensure that the appointed persons provide a high level of expertise.

Iceland, Liechtenstein, Norway, Switzerland and Turkey attend meetings of the MDCG and its working groups in the capacity of observers.

Organisations representing the interests of the medical device industry, other economic operators, healthcare institutions and/or professionals, conformity assessment bodies, patients and consumers at Union level may be appointed, following a public call for applications, as observers to the working group.

Members and observers' representatives should enable the appointing country or organization to participate in discussions on policy and technical matters. For that reason, each country may appoint more than one member/observer to the group.

The members and their alternates are appointed for a term of three years which may be renewed. They remain in office until they are replaced or their appointment is renewed. When the appointment of a member or an alternate has been terminated before the end of the three-year term, the Member State appoints a replacement for the remainder of that three-year term.

[1] In particular, the following working groups are concerned: MDCG Unique Device Identification (UDI), MDCG Post-Market Surveillance and Vigilance (PMSV), MDCG Clinical Investigation and Evaluation (CIE), and MDCG Market Surveillance.

Any changes in the appointment of members and alternates by the Member States and of observers' representatives shall be notified to the Commission immediately.

Stakeholders may participate in open sessions of the group either in the capacity of observers or following ad hoc invitations, in accordance with the Rules of Procedure of the MDCG.

3. Operation

The group operates in accordance with the terms and rules applicable to the MDCG, unless specified otherwise in these Terms of Reference.

The group shall be chaired by a representative of the Commission. The group shall report to the MDCG.

The meetings are convened by the Chair.

The group shall meet either in physical meetings or for audio- or videoconferences.

Physical meetings of the group take place at least twice a year.

Minutes of the discussion on each point on the agenda and on the positions delivered by the group shall be meaningful and complete.

The group coordinates its activities with other MDCG working groups as appropriate.

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4 May 2020