TERMS OF REFERENCE OF THE MDCG WORKING GROUP

WORKING GROUP ON POST-MARKET SURVEILLANCE AND VIGILANCE (PMSV)

1. Tasks and roles

PMSV provides assistance to the MDCG on issues related to post-market surveillance, incident reporting and vigilance, with the aim of effective and harmonised application and implementation of Regulation (EU) 2017/745 on medical devices (MDR) and Regulation (EU) 2017/746 on *in-vitro* diagnostic medical devices (IVDR). It prepares draft technical guidance and forms for use, for endorsement of the MDCG. It also assists the MDCG in coordinating the activities of the competent authorities of Member States in the field of vigilance.

PMSV provides a forum for sharing of information and experience, discussing actual incident cases, reviewing current reporting practices and discussion and sharing of suspected safety signals and trends detected from the relevant data sources. It provides advice on matters related to manufacturers' post-market surveillance responsibilities, including use of terminologies, post-market clinical follow-up (PMCF)/ post-market performance follow-up (PMPF), device registries, real world data and other data sources, including the existing pharmacovigilance systems.

PMSV contributes to development of measures aimed to improve post-market surveillance and the reporting behaviour of the relevant actors. Where appropriate, it contributes to international guidance and practice in this area e.g. IMDRF, WHO, etc.

2. Membership

Members/observers to PMSV are experts appointed by Member States and third countries participating in the MDCG. They represent the national authorities responsible for post-market surveillance and vigilance. Member States / third countries may appoint alternates.

Appointments are not time-limited. Any changes in the appointment shall be notified to the Commission without delay.

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

3. Operation

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

PMSV shall be chaired by a representative of the Commission. Where appropriate, it may be co-chaired by a member of the working group. PMSV shall report to the MDCG.

The meetings are convened by the Chair.

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

Physical meetings of PMSV take place at least twice a year. A teleconference takes place once a month.

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

PMSV coordinates its activities with other MDCG working groups as appropriate.

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25 September 2018