EUROPEAN COMMISSION
Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

Directorate D – Consumer, Environmental and Health Technologies
Unit D4. – Health Technology and Cosmetics

Brussels, 17 June 2019

Minutes

Meeting of the MDCG sub-group: Post Market Surveillance and Vigilance (PMSV) Brussels, 5 March 2019

1) Opening, adoption of the agenda

The first meeting of the Post Market Surveillance and Vigilance Working Group as a MDCG sub-group took place on 5 March 2019 with the representatives of the Member State Authorities and of stakeholders' organisations. Tour de table followed to introduce new members and for the time being the group will be chaired by COM.

2) Draft minutes of November 2018 meeting

Minutes were adopted.

3) MIR (manufacturers incident report) - coordinated by UK and JRC

The new MIR form for the reporting of serious incidents by manufacturers will become applicable from 1st January 2020. Discussions focused on which operators will be entitled to report the serious incidents in Eudamed: either the manufacturers, or their authorised representatives, or a sub-contractor on behalf of the manufacturer but no other operators (distributors, importers). Only one operator for each device to notify incident reports in Eudamed to avoid redundancy.

4) MPSR (Manufacturer Periodic Summary Report) - coordinated by NL and COM

The Task Force finalized the MPSR form. It will become applicable only under the MDR. To be endorsed by the MDCG, to develop a guidance on MPSR and to publish them (MPSR and guidance) on Europa website. Light MIR form still under development in the context of Eudamed: to be periodically transmitted to the competent authorities which have agreed with participating to the MPSR.

5) PSUR (Periodic Safety Update Report) - coordinated by FI

Development is focused on the data to be registered in Eudamed: the Task Force in charge of the development of the PSUR template and the guidance is on hold pending the appointment of the Chair. The PSUR would apply only for MD with MDR certificates. In addition to the PSUR template, it is also necessary to develop the document for the notified body validation of the final PSUR.

6) Field Safety Corrective Action (FSCA) - coordinated by DE and TF

The Task Force concluded that it is not feasible to have a form but direct integration in Eudamed is possible. Aim to continue making progress as it is a priority for Eudamed.

7) IMDRF Adverse Event nomenclatures (International Medical Device Regulators Forum) – coordinated by COM/JRC

The nomenclatures on health effect have been endorsed by the IMDRF Management Committee. Transitional period of 12 months for industry after the future publication of the nomenclatures by the IMDRF. Need to develop a Web browser tool to facilitate the choice of appropriate terms and codes.

8) Addendum to Vigilance Meddev guidelines - coordinated by IE and COM

This addendum relates to the MDD only. It was also agreed to launch the development of a new guidance on PMS and Vigilance for the implementation of the MDR / IVDR. Comments from the stakeholders on the addendum have been received. The Addendum to be finalised and adopted through written procedure.

9) Public access to vigilance data and transparency - coordinated by IE and COM

The objective is to provide large access to Eudamed data for the public and for health professionals without reducing the level of information provided by manufacturers in their incident reports which is required for a detailed investigation by the competent authorities. A Task Force, co-chaired by IE and COM, has been launched to submit proposals to the MDCG. All stakeholder organisations of the PMSV WG to be consulted prior to defining these proposals.

10) AOB

Next PMSV Working Group to take place on 17-18 September 2019.