Brussels, 25/10/2021

Minutes

Meeting of the Post-Market Surveillance and Vigilance Working-Group
01-02 March 2021, Brussels

1. Approval of the agenda and of the minutes of previous meeting

The agenda of the meeting was approved and there was no comment on the minutes of the Post-Market Surveillance and Vigilance (PMSV) Working Group of 28-29th September 2020.

2. Nature of the meeting

The Post Market Surveillance and Vigilance Working Group[1] is composed of all national competent authorities and stakeholders' organisations representing the industry from the medical devices and pharmaceutical sectors, the notified bodies, authorized representatives, health professionals and patients which have been selected by the Commission after an open call for participation.

This sub working group of the Medical Device Coordination Group (MDCG) is dedicated to the implementation of Regulation (EU) 2017/745 on medical devices (MDR) as regards Vigilance and Post-Market Surveillance issues.

3. List of points discussed

- **Manufacturer Incident Report (MIR) form and associated documents- coordinated by Commission (COM)**

The current MIR form requires some adaptations to make it fully compliant with the MDR / IVDR as well as the future Eudamed database.

Several professional organisations stressed the need to revise the MIR based on an exhaustive list of points to reflect both the changes introduced by the MDR / IVDR and the Brexit.

It was agreed to resume the work of the MIR Task Force to develop a revised MIR form (version 7.3) before circulating it to the Competent Authorities for comments.

- **Reporting of incidents for systems and procedure packs**

Several competent Authorities and industry organisations pointed out a possible liability issue for the reporting of serious incidents and the issuing of a Field Safety Corrective Action (FSCA) when the System and Procedure Pack (SPP) producer does not act as a manufacturer.

[1] Published in the Register of Commission Expert Groups and Other Similar Entities, code number X03565

The Commission (COM) suggested that the SPP producers should forward the received incident reports to the legal manufacturer which, after examination and where relevant, would notify a serious incident report to the responsible competent Authorities. However no agreement was found on that proposal which needs further examination in the context of the future MDR Vigilance guidance.

- **Draft Periodic Summary Update Report (PSUR) guidance**

COM presented the draft consolidated PSUR guidance developed by the PSUR Task Force (TF). First reactions were positive but due to late circulation of the document, Competent Authorities and stakeholders need further examination of the document before confirmation.

- The TF proposal for the implementation of Art 83(4) and the scope of Corrective Actions and Protective Actions (CAPAs) to be reported through the PSUR was agreed.
- The TF proposal for the notify body evaluation of PSUR reports for Well Established Technologies raised concerns from several CAs and was not agreed.

- **Draft MDR Vigilance guidance**

The focus of the Task Force is on the identification of key definitions and concepts of the MDR which require an interpretation and on certain provisions of Articles 86 to 90 related to Vigilance requirements.
It was agreed to set up a sub Task Force to address specifically the definitions and concepts issue.

- **PMSV 2021 Work programme (WP)**

The PMSV WP was presented by COM before its adoption by MDCG on 5th March. It foresees in particular the setting up of 2 new Task Forces on:

- The revision of the Trend report including the Trend report form for Eudamed. It was agreed that it will be chaired by FI
- The development of a Post-Market Surveillance (PMS) guidance to be co-chaired by industry and NL.

- **Transparency**

COM informed that the MIR Transparency document was agreed by the PMSV CAs WG. However it should be aligned on the updated MIR form before being submitted to the MDCG for final endorsement and publication on COM Website.

4. Next meeting

The next meeting of the PMSV WG was planned on 8th – 9th July 2021.

5. List of participants

- Commission: DG SANTE / B6 representatives
- Member States: Representatives of the 27 national competent Authorities for Post-Market Surveillance and Vigilance.
- Stakeholders: Representatives of the organisations which are members of the MDCG.