Brussels, 7/12/2021

Minutes

Meeting of the Post-Market Surveillance and Vigilance Working-Group
01-02 July 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 01-02 March 2021.

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 Commission (COM) presented the state of play of the revision of the MIR form (version 7.3.0). Several proposed changes were examined including the introduction of the "manufacturer awareness date" and of the "manufacturer awareness date of reportibility". The draft revised MIR form will be circulated to the competent Authorities and the stakeholder organisations for comments until mid August.

It was agreed to provide a 6 month period from the date of publication of the revised MIR form on the Commission website where either the revised MIR form or its previous version could be used by operators.

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

COM presented the revised draft guidance document reflecting the progress made at the PSUR Task Force level as well as the questions which remain open.

Industry organisations were in favour of providing full flexibility for either re-synchronisation of the data collection period at the first MDR certification date or

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

keeping the same cadence than for the corresponding legacy device. Notify body organisations were in favour of re-synchronisation on the MDR certification date.

On Well Established Technologies (WET) no agreement was reached on the proposed approach for the evaluation of PSURs by the notified bodies - through their surveillance and audit activities instead of an individual evaluation report for each PSUR (class III and implantable devices).

On the issue of legacy devices, COM informed about the setting up of an ad hoc MDCG Task Force on "transitional provisions" (legacy devices and old devices) covering in particular the provisions for PSUR for legacy devices.

COM invited both the competent Authorities and the stakeholder organisations to send their comments on the draft revised PSUR guidance by the end of August.

- **Questions and Answers (Q&A) document on Vigilance concepts and terms**

An extensive revision of the draft Q&A document was presented by the COM. The discussion took place on the proposed changes (e.g. meaning of a "device malfunction or deterioration", use errors not linked to ergonomic features, meaning of "abnormal use", meaning of "side effects"; meaning of "unanticipated deterioration of state of health"; determination of "manufacturer awareness date"; how to calculate the number of reporting days, the removal of the draft definition of "non serious incident").

COM invited the competent Authorities to send their comments on the revised document by the end of August.

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

The industry organisation MedTech underlines the need to start adapting the various PMSV guidance to In Vitro Diagnostic Medical Devices, including the PSUR guidance.

Two new Tasks Forces were set up:

- The Post Market Surveillance (PMS) TF co-chaired by the Dutch Authorities and the industry organisation (MedTech). Applications to participate to this Task Force from the French Authorities and the notified body organisation Team-NB and the industry organisations MedTech, COCIR and AESGP.
- The Trend report TF chaired by the Finnish Authorities. Initial works to take place with the competent authorities at a first step before consultation of the stakeholder organisations on a draft proposal.

4. Next meeting

The next meeting of the PMSV WG was planned on 30th November- 1st December 2021.

5. List of participants

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