MDCG-PMSV (Post-Market Surveillance and Vigilance) Working Group

MINUTES

Date & time:	**26-27/10/ 2022**
Venue:	**Hybrid meetings (Conference Center Albert Borschette, 36 rue Froissart, 1040 Brussels, and Videoconference WebEx)**

1. Opening, minutes from last meeting and adoption of the agenda

The Commission welcomed the participants to the third Post-Market Surveillance and Vigilance (PMSV) Working Group meeting of 2022. The agenda was adopted with no changes.

2. Q&A document on key Vigilance terms and concepts

Following the contributions received from other relevant PMSV Task Forces and the consultation of the PMSV Competent Authorities (CAs) WG, a revised version of the document was sent by the Commission to the PMSV CAs for a possible agreement.

Main points discussed were the following:

- Question 8 on 'side-effects' and the reporting requirements for 'expected side-effects'. Extensive discussions took place on the scope of the terms "side effects" and on the reporting of serious incidents listed in the technical documentation under "expected side effects". A drafting proposal on the reporting requirements was issued and agreed by the PMSV CAs WG during the meeting.

- Question 17 on the role of the 'evaluating competent authority'. Member States noted the importance of establishing a common understanding of that role for assessing and commenting Field Safety Corrective Actions (FSCAs) and Field Safety Notices (FSNs). The draft text was revised to clearly indicate that it is the responsibility of the individual Member State to assess the FSCA affecting its territory including commenting on the draft FSN. This topic could be further developed in the future MDR vigilance guidance document.

Following the organisation of a new consultation of the PMSV Stakeholders WG, a revised Q&A document will be sent to PMSV CAs WG for agreement and then to the Medical Device Coordination Group (MDCG) for final endorsement.

3. Manufacturer Incident Report (MIR) Form and associated PDF file

Following the adoption of the revised MIR form (version 7.3.0) at the MDCG meeting of 20th May 2022, several follow-up actions were launched: (i) the IT development of the MIR PDF file and of associated files, (ii) their preliminary testing and (iii) the revision of the MIR Helptext. All these files need to be finalized before their publication together with the MIR from 7.3.0 on the Commission website.

Main points discussed were the following:

- On the **revised MIR form 7.3.0.**, comments were received from the industry and some Member States on the display of the fields 2.2. a and b and 2.3.a (proposal for splitting a box in 2 boxes and moving up the box on medical device terms). Due to the impact of these changes in terms of extra IT work required, significant delay and limited added value, it was agreed to keep these fields unchanged.

  A clarification related to the field 3.2.a was made to broaden the scope of cases where either no adverse event IMDRF code are available or not specific enough to properly describe the type of incident.

- On the **MIR PDF file**, Commission informed that a preliminary IT development followed by a testing phase by EU industry organisations and some Member States were performed.

  It was agreed to organize dedicated meeting(s) to examine all comments received in view of finalizing the MIR PDF file. A further testing of the updated PDF file before publication should also take place.

- On the **MIR Helptext**, it was agreed to set up a dedicated TF with the participation of Member States and EU industry organisations to revise the current MIR Helptext and align it on the new MIR form.

4. Device Specific Vigilance Guidance (DSVG)

- On DSVG 04 on breast implants, the TF Chair confirmed that the revised DSVG on breast implants covers both the medical devices and the devices for aesthetic purposes (Annex XVI products). This DSVG was already agreed by the PMSV CAs WG of July 2022 meeting. After circulation to the Stakeholders WG, it will be submitted to the MDCG for final endorsement.

- On DSVG 05 on insulin infusion pumps, the TF Chair reported on progress made and the TF proposal to report incidents for pumps without alarms through a MIR or a Periodic Summary Report (PSR) and those for pumps with alarms through a Trend report. Discussions took place on this aspect without reaching an agreement: suggestions were made to further distinguish between the various rationales for alarms (e.g. those intended on purpose for triggering urgent actions from the user or health professional and those linked to a malfunctioning of the device).

- On DSVG 01 on cardiac ablation, DSVG 02 on coronary stents and DSVG 04 on breast implants, the TF Chair reminded that they are almost ready for publication as all the IMDRF adverse events codes have been identified except for DSVG 01.

- On DSVG 03 on cardiac implantable electronic devices and DSVG 05 on insulin infusion pumps further work is required at TF level, including on the choice of the relevant IMDRF codes.

5. Trend report revision

- The TF Chair reported on the progress made for the various documents under development: (1) Q&A document for which the comments have processed and the document updated. An additional question based on the outcome of the discussion on the reporting of the expected side effects to be added; (2) Template – most of the comments have been processed and the text partly updated, (3) Manufacturer Trend Report (MTR) form is still under development as well as (4) MTR Helptext document.
- Commission invited more CAs to participate to this TF. No further discussion took place.

6. Post-Market Surveillance guidance

- The TF Chair presented the state of play: a first draft guidance was sent out and many of received comments can be accepted. Several parts of the draft guidance are under review and should be discussed during the next TF meetings. A first consultation of the PMSV; Market Surveillance and NBO Working Groups is planned to take place.

- Commission invited more CAs to participate to this TF. No further discussion took place.

7. MDR Vigilance guidance and designation of a PMSV WG Co-Chair

- Following the Commission call for applications to the function of PMSV WG Co-Chair, an application from one Member State competent authorities was received. This application was welcomed by the PMSV CAs WG.

- Discussions took place with the applicant on how he could facilitate the work of the PMSV WG and his future contribution to the EU coordination on Vigilance and safety issues.

- It was also decided to relaunch an application call for setting up a new group of CAs to become members of the MDR Vigilance guidance Task Force.

8. Testing of the EUDAMED Vigilance module

- The need for feedback from the COM Eudamed team on the comments and shortcomings identified during the testing of the Playground was stressed by several Competent Authorities and professional organizations.

- An exchange of findings from the Eudamed Vigilance module testing, including the “high level” of the Functional Specifications took place. Several competent authorities consider that this modulet may allow for an Eudamed minimum viable product (MVP) that passes the audit but would not have sufficient functionality and usability to already comply with all the MDR / IVDR requirements related to Eudamed.

- In addition, technical issues as well as the need for further interpretations and guidance works related to some Vigilance provisions were identified.

- The need and willingness to participate in a coordinated and structured testing of the Eudamed Vigilance module was supported by several CA's. The need for setting up a strategy, structure and coordination at EU level for that testing was acknowledged. A Member State informed about its willingness to coordinate this work.

9. AOB

No additional points were raised.

List of participants

CA Members: AT, BE, CY, CZ, DE, DK EE, ES, FI, FR, GR, HU, HR, IE, IT, LV, MT, NL, PL, PT, RO, SE, SI, SK.

CA Observers: NO, TR, LI, IS.

Stakeholder Members: MedTech Europe, COCIR, AESGP, BIOMED Europe, EAAR, EPF, ESC, EFPIA EUROM VI, EUROMCONTACT, IAMERS, MedPharmPlast, NBCG-Med, Team-NB

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