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DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health systems, medical products and innovation
Medical Devices

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Minutes
Meeting of the MDCG Subgroup Market Surveillance
Brussels, 12 November 2021

1. Opening, adoption of the agenda

The Commission (COM) welcomed participants and provided relevant updates, including a summary of the market surveillance discussions held at the MDCG meeting of 19 October 2021. Members where informed of the publication of the adopted minutes of the MSWG on 28 April. The agenda of the meeting was adopted with a few additions by members under AOB, including points on national derogations under Article 59 MDR and certificates under Article 16 MDR.

2. European Market Surveillance Programme

The COM presented a proposal on the framework for a European market surveillance programme (EMSP Framework) outlined in Article 105(f) of the Regulation (EU) 2017/745 (MDR), as agreed by the MDCG during 19 October 2021 meeting. Preliminary discussions were held on the proposed structure, format and content of the EMSP Framework, including on key areas for coordination amongst competent authorities. The COM informed that it will revise the EMSP Framework on the basis of discussions and circulate the first draft for consultation of the MSWG.

2.1. Article 93(2),(4),(8) Reporting Templates

COM shared the feedback it has received from Member States on the harmonised templates developed for use until EUDAMED is fully functional (Article 93 (4) and (8) MDR) and the template for national market surveillance activity plans (Article 93(2)MDR) to align reporting and facilitate cooperation amongst the Member States. Based on further discussions and revisions by Member States, the draft templates will be circulated for a written consultation of the MSWG.

3. Joint Inspectors Group (JIGS) Task Force

A task force (TF) member delivered a presentation on the background and ongoing work of the JIGS TF, including the inspectors training courses of 20 May and 14 October 2021, and a recent

submission of an application for funding inspection activities via a Joint Action under the EU4Health Programme 2022.

4. Harmonised Evaluation Procedures 'First Principles'

A presentation was delivered on a proposed Task Force to develop harmonised evaluation procedures for market surveillance activities, including device risk assessments under Article 94 MDR. This was welcomed by participants and would be raised to MDCG at December meeting.

5. Use of CEF Summaries

A presentation was provided by the MSWG co-chairs on the use and categorisation of compliance exchange form summaries in order to improve the harmonisation of market surveillance actions across member states. As a follow-up, various possible solutions would be analysed.

6. Task Force Updates

The leads of Task Forces within the MSWG provided updates of the on-going work, with opportunity for members to further discuss, ask questions and comment. It was noted that two guidelines from joint task force on Article 16 were published. The task force on authorised representative reported on progress with the draft ahead of a planned stakeholder consultation. An update was also provided on the draft guidance for in-house devices, following the close of a recent stakeholder consultation. The draft questions & answers document on Article 13 & 14 MDR/IVDR submitted for endorsement was discussed, and it was concluded that the MSWG endorsement period would be extended for final review of adapted text by member states.

7. Follow-up of Gap Analysis MDR/IVDR & Regulation 2019/1020 – follow-up & discussion

The Commission presented an updated version of the Gap Analysis provided at the 28 April 2021 working group meeting, including initial reflections on applicability of specific articles of Regulation 2019/1020 on market surveillance (e.g. Article13 on national strategies & Articles 28 and 34, relating to customs) to the medical devices sector.

8. AOB

Additional points raised by member states included questions regarding derogations requests under Article 59 MDR, and the issuance by notified bodies of quality management system (QMS) certificate issuance under Article 16 MDR. Finally, COM provided an information point on the update of the MSWG Work Programme for 2022.