EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health systems, medical products and innovation
Medical Devices

Brussels
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Minutes
Meeting of the MDCG Subgroup Market Surveillance
Brussels, 28 April 2021

1. Opening, adoption of the agenda

The Commission (COM) welcomed participants, including a new member state co-chair and presented the meeting agenda. A horizontal update was provided covering MDR/IVDR standardisation, the revision of the "Blue Guide" with publication planned for autumn 2022, and latest developments in the EU Product Compliance Network (EUPCN) established under Regulation 2019/1020. Publication of the adopted minutes of the MSWG on 26 November 2020 was confirmed. The agenda was adopted with a few additions my members under AOB.

2. Q&A on Importers & Distributers

COM presented the draft Q&A document on importer & distributors (Article 13/14 MDR) ahead of a planned written consultation with regulators. Key elements requiring clarification were identified and discussed, including the role of retailers or pharmacies in medical device distribution and the application of Article 13 & 14 to legacy devices.

3. Update of the Compliance & Enforcement Communication SOP & Form

The MSWG co-chair presented the revised version of compliance & enforcement communication procedures used to enhance harmonisation of surveillance activities, following consultations. The SOP and form were endorsed by the MSWG.

4. Monthly Market Surveillance Teleconferences

An overview of the recently established monthly teleconferences to discuss market surveillance cases provided by COM. A summary of case discussions was provided.

5. Updates from Task Force Meetings

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.

- Joint TF on Art.16 activities

The advanced status of the guidance document for notified bodies on certification activities according to Article 16(4) of Regulation (EU) 2017/745 and Regulation (EU), was outlined. Next steps of further consultation to finalise the guidance ahead of submission for WG endorsement were reported. COM reminded CAs to inform relevant economic operators and stakeholders that the absence of this document should not prevent Notified Bodies from conducting certificate activities outlined in Article 16. COM informed the TF is also preparing a Q&A document on the obligation of importers and distributor as outlined in Article 16, to be sent for regulators consultations soon.

- EUDAMED Reporting TF:

Both Task Forces on the EUDAMED market surveillance module, provided their proposals which were discussed and endorsed by the MSWG. In the absence of EUDAMED, the MDCG 2021-1 'Guidance on harmonised administrative practices and alternative technical solutions until EUDAMED is fully functional' will be applicable. COM informed it would follow-up to coordinate on initiatives for harmonised reporting in this phase.

- Other

A progress update was given of draft guidance documents on In-house Devices and Authorised Representatives, with plans to launch written consultations of the MSWG & IVD working groups. Finally, the Joint Inspectors Group (JIGS), informed that a training for inspectors would take place on 20 May 2021.

6. European Market Surveillance Programme

COM reported on ongoing work on the development of a European Market Surveillance Programme. This included survey results of common market surveillance activities and presentation of an initial proposal for the programme, made available to member states.

COM also provided a preliminary Gap analysis between the horizontal Market Surveillance Regulation (EU) 2019/1020 and the MDR/IVDR. Member States participation and representation in the EU Product Compliance Network (EUPCN) for information exchange and liaison on market surveillance was promoted.

7. AOB

Article 22 (1) MDR on systems/procedure packs and possible translation discrepancies were discussed. It was clarified that under Article 22(1) MDR, a system or procedure pack can consist of a combination of both CE medical devices and other conforming products.