Minutes of the expert groups

Meeting of the Medical Device Coordination Group – Subgroup on Market Surveillance[1]

30 & 31 March 2022, Brussels

Nature of the meeting

The meetings of the Medical Device Coordination Group (MDCG) and its subgroups are not public, and are intended only for MDCG members and observers (where relevant) and are chaired by the relevant Commission services (COM) in the field of medical devices[2].

This was a bi-annual meeting of the MDCG Market Surveillance subgroup, which is closed to to national competent authorities only. The meeting took place virtually via Webex.

1. Opening, adoption of the agenda

The draft agenda was adopted and minutes of the last meeting on 12 November 2021 circulated to members for approval.

The Commission announced a role of working group co-chair was open for expression of interest to all member states. A short summary of relevant market surveillance discussions held at last MDCG meeting of 21/22 March 2022, including endorsement of the MDCG MSWG 2022 Annual Work Programme and the European Market Surveillance Programme Framework under Article 105(f) MDR. The Commission also updated participants on the latest information for a joint action on market surveillance included in the EU4Health 2022 Work Programme and urged member states to be aware of relevant timelines.

2. European Market Surveillance Programme Framework (EMSP Framework)

Following the endorsement of the EMSP Framework under the MDR at the MDCG meeting of 21/22 March 2022, expanding its scope to the IVDR in view of the 26 May 2022 application date, was discussed. This covered the methodology of expansion, possible IVD related activities to be included, and the implementation of coordinated initiatives in the EMSP Framework. The Commission also requested and received feedback from member states on the usefulness of harmonised templates for Articles 93(2),(4),(8) MDR/Article 88(2),(4),(8) IVDR.

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

[2] Directorate-General for Health and Food Safety (DG SANTE), Unit B.6 - Medical Devices, Health Technology Assessment. Commission's sectorial website on medical devices: https://ec.europa.eu/health/medical-devices-sector_en; contact: SANTE-MED-DEV@ec.europa.eu.

3. **Harmonised Evaluations Task Force**

The Task Force lead by IE provided an update from the first meeting which took place on 23rd March and further elaborated on the task force objectives and deliverables related to assessments under Article 94 MDR and sharing best practice on practical implementation of Article 95, 97, 98 MDR provisions.

4. **National measures taken under Article 95, 97, 98 MDR/Article 90, 92, 93 IVDR**

The Commission presented visuals outlining the procedural implications of the various market surveillance notifications under the MDR/IVDR, to promote a common understanding of the application of such measures. These include for devices presenting unacceptable risk to health and safety, other non-compliances and preventive health protection measures.

5. **Use of Compliance Exchange Form (CEF) Summaries**

A presentation of a potential categorisation of final CEFs was provided by the MSWG co-chair. The aim of this it to facilitate efficient use of information provided in exchanges amongst the member states and identify market surveillance trends including those related to non-compliances.

6. **Medical Devices Inspectors Task Force (MDITF)**

A member representing the Medical Devices Inspectors Task Force (MDITF) formerly called 'Joint Inspectors Task Force 'JIGS TF', provided an update of on-going work. This included EU4Health funding opportunities to support the cooperation of inspectors (sharing of expertise, capacity building activities, IT infrastructure to exchange information) and enable competent authorities to perform joint inspections of economic operators.

7. **Task Force Updates – Guidance documents**

The draft 'Guidance for Authorised Representatives under Regulation 2017/745 and Regulation 2017/746' following a recent consultation of the competent authorities was presented and discussed. An agreement was reached on aspects of the guidance in preparation for launching a consultation including MDCG stakeholders in April.

The task force lead provided an update on the draft Guidance document on In-house Devices, and outlined the proposal to host a workshop including competent authorities and stakeholders to advance the guidance.

8. **Follow-up of Gap Analysis MDR/IVDR & Regulation 2019/1020**

The Commission presented an updated Gap Analysis of the MDR/IVDR and the market surveillance Regulation 2019/1020, on which it has reached some preliminary conclusions. The inclusion of medical devices in the Article 13 Regulation 2019/1020 national market surveillance strategies, with 16th July 2022 deadline was noted. COM will provide updated information to member states elaborating further on the applicability of Regulation 2019/1020 to the medical device sector.

9. **AOB**

The Commission addressed the issue of some manufacturers limiting the use of their Declaration of Conformity causing a problem for distributors outside the manufacturer's official distribution chain (parallel traders). The Commission informed that the Declaration of Conformity is a public document and that there is no legal justification for manufacturers to limit the use of the document including applying 'internal use' restrictions.

10. **Next meeting**

The second 2022 annual plenary meeting MDCG MSWG will be scheduled for the Autumn (October or November).

COM will define and confirm timing and modalities of this meetings as soon as possible.

List of participants

Members - National competent authorities:
Austria (AT), Belgium (BE), Bulgaria (BG), Croatia (HR), Cyprus (CY), Czech Republic (CZ), Denmark (DK), Estonia (EE), Finland (FI), France (FR), Germany (DE), Greece (EL), Hungary (HU), Ireland (IE), Italy (IT), Latvia (LV), Lithuania (LT), Luxembourg (LU), Malta (MT), Netherlands (NL), Poland (PL), Romania (RO), Slovakia (SK), Slovenia (SL), Spain (ES), Sweden (SE),

Observers - National competent authorities:
Turkey (TK)

European Commission:
SANTE B.6