MEETING OF THE MARKET SURVEILLANCE WORKING GROUP
Minutes

Date & time:	**29 November 2019 (10:00-17:30)**
Venue:	**BREYDEL building, Avenue d'Auderghem, 45, 1040 Brussels (Etterbeek), M. AYRAL (12th floor)**

1. Opening, adoption of the agenda

COM welcomed member states to the second meeting of the plenary MSWG, and provided general horizontal update to participants. The new chair of the MSWG was presented, and the agenda was adopted with minor editorial changes.

2. Adoption of minutes of the meeting held on 4 April 2019

Participants received the draft minutes of previous meeting via CIRCABC for approval within a two-week deadline.

3. 'The new Market Surveillance Regulation and the EU Product Compliance Network' (Presentation & Q&A)

Presentation provided by DG GROW on the new horizontal new Market Surveillance Regulation (EU) 2019/1020. A Q&A followed, on potential effects of the regulation on the medical devices sector. Additional information on call for proposals for funding of joint market surveillance actions in 2020 was provided.

4. Other MDCG Working Groups and CAMD (update)

An update was provided on relevant on-going work of other MDCG subgroups. In particular, the importance of reinforced collaboration with IVD WG was highlighted.

5. Organisational matters & Nomination of new Co-chair

The matter of appointing a new member state co-chair to the MSWG was discussed. Additionally, solutions for improved organisation of the COEF information exchange between authorities was covered.

6. Updated List of Task Forces (discussion)

A discussion was launched on organisation & participation of future work items linked to MDR/IVDR implementation.

7. JAMS and future initiatives (update & Q&A)

A presentation by a participant in the Joint Action on Market Surveillance of Medical Devices was provided. A discussion on the future coordination of joint inspection activities between member states was explored.

8. Custom Made Devices TF – Draft of Q&A (update)

An update of on-going work to produce a Questions & Answers document clarifying obligations regarding custom-made devices was delivered.

9. Guidance on Class I manufactures

A presentation was provided by the Task Force lead on the development of the 'Guidance on Class I manufacturers' sent for endorsement to the MDCG.

10. TF on Guidance for Authorised Representatives (update)

A presentation on the establishment of a task force to work on guidance clarifying Article 11 MDR/IVDR obligations for authorised representatives was given.

11. Updating MDCG 2019-7 re liability of the PRRC per Article 15 (discussion)

A possible revision to this endorsed guidance concerning the liability of the Person Responsible for Regulatory Compliance (PRRC) per Article 15 of MDR/IVDR was discussed.

12. Article 16(4) Certificates - Relabelling & Re-Packaging (update)

The need to draft a guidance on the new requirement for Article 16 (4) MDR/IVDR certificates in collaboration with the NBO WG was discussed.

13. Wrap-up

Conclusions in addition to a summary of the main follow-ups from the meeting was provided.