EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health systems, medical products and innovation
Medical Devices

Brussels, 18 June 2020

Draft Minutes

Meeting of the MDCG Subgroup Market Surveillance
Brussels, 18 June 2020

1) Opening, adoption of the agenda

COM welcomed participants to the meeting, postponed from April 2020 to June 2020 due to COVID-19 activities. The participants were thanked for their cooperation during the COVID-19 pandemic, especially for their input to the numerous guidance documents published by COM. The minutes from the last meeting in November 2019 were presented with a two-week period of adoption.

2) Market Surveillance task force: EUDAMED WP2

COM provided a general update on EUDAMED development and objectives for the market surveillance module. A brief report of a meeting between regulators to discuss specifications of the market surveillance module focusing on Articles 95 to 98 of the MDR was delivered.

3) Article 16(4) certificates: re-labelling and re-packaging

The activation of a new taskforce to draft guidance on Article 16 and in particular on Art 16(4) certificates to be jointly set up with the MDCG NBO working group was announced. COM to organise first meeting and follow-up on initial consultation with task force members.

4) Implementation of the MSWG Work Programme

COM presented the current MSWG Work Programme setting out planning of work items for MDR and IVDR implementation. These align with the terms of reference of the subgroup including obligations of economic operators and chapter II of the MDR and IVDR, enhanced cooperation and coordination on market surveillance. The Work Programme was endorsed following by the members following discussion on content.

In addition, the need for manufacturers to be provided with information on transitional periods for Class I custom-made devices was discussed. COM proposed to investigate the need for guidance, and compile information relevant to the topic to share with MS as applicable.

5) Compliance & Enforcement Communication SOP

The CO-Chair presented a proposal to update the current standard operating procedure for compliance and enforcement communication between member state competent authorities in view of MDR implementation. The scope, purpose and review process of the document were discussed. It was agreed follow-up via written consultation would take place.

6) Guidance Authorised Representatives

A short presentation was provided by industry on a best practice guidance being developed by an Authorised Representatives association and the importance of clarity from regulators regarding new obligations under the MDR was highlighted. Clarity regarding the mandate and role of authorised representatives and issues relating to liability were advocated. COM confirmed a Task force was established to produce an MDCG Guidance on this matter.

7) AOB

The status of importers was discussed based on questions raised by members, namely on the possibility to have multiple importers per device group or the feasibility of maintaining traceability in this context. COM will share preliminary written feedback from some members with participants.

The possibility of publishing a checklist on Instructions for use (IFUs) for reusable & re-sterilisable medical devices (based on EN 17466) established by the old COEN WG on COM's website, to promote its wider use across MS, was proposed. MS agreed on the usefulness of this and COM agreed to follow-up.