MEETING OF THE MDCG (Medical Devices Coordination) subgroup on UDI
Minutes

Date & time: **17 February 2020 (10:00-17:30)**

Venue: **Centre Conference Albert Borschette (CCAB), Rue Froissart 36, 1040 Brussels (Etterbeek)**

1. Opening, adoption of the agenda

COM welcomed member states and stakeholders to the first UDI WG meeting of 2020. The Agenda was adopted with minor editorial changes and a request under AOB was introduced.

2. Update from the European Commission

COM provided a horizontal update to participants. The upcoming UDI Helpdesk, including the scope of questions it will address was discussed.

3. Organisational matters & Co-Chairmanship

Co-Chairmanship of the UDI WG was discussed, and a new member state representative was appointed co-chair following endorsement of the members.

4. Proposed list of UDI EUDAMED Enumerations (Clinical size and Critical warnings/contraindications) – Presentation from Commission

The latest version of the enumerations list for data to be provided in EUDAMED UDI module was presented by COM. Following discussion it was concluded that further analysis to refine the list would be required with input from regulators and stakeholders.

5. UDI labelling of convenience kits of surgical procedure – Presentation

A presentation was provided by the co-chair, complemented by industry, following concerns raised over UDI labelling requirements for replenishable multi-device surgical sets. It was agreed that clarifications would be provided via a revision to MDCG 2018-3.

6. Spectacles/Frames: Rules for UDI assignment – Discussion on solution

Industry provided a short presentation on a possible solution for UDI assignment for spectacles/frames, including the reduction of UDI-DI entries in EUDAMED. Though the solution for ready readers and spectacle lenses was accepted by members, it was concluded further analysis regarding spectacles frames was needed.

7. Contact Lenses: Rules for UDI Assignment – Discussion on solution

A variety of possible options for UDI assignment rules for contact lenses and the reduction of UDI-DI entries in EUDAMED were explored. It was concluded that further analysis & discussion in the form of a workshop was required before reaching a solution.

8. Implant card guidance MDCG 2019-8

Minor revisions to MDCG 2019-8 related to language and terminology clarifications were presented & endorsed. An overview of the use of nomenclature in the Implant Card was provided by COM. Additionally, industry raised a translation issue in an MDR factsheet indicating a possible exemption of dental implants from the implant card requirement. A discussion ensued and COM clarified that it was a translation error that would be rectified.

9. Comparison between EU-US UDI systems - Presentation from MedTech and discussion

A presentation was provided by industry to address specific data elements triggering allocation of a new UDI-DI, and the differences between EU & US on this matter.

10. Draft Amendment to MDCG 2018-1 v2 clarifying specific UDI-Triggers – Possible Endorsement

The proposed draft revisions to MDCG 2018-1 v2 were presented by COM and endorsed by members of the UDI WG. Next steps were to send to MDCG for endorsement.

11. IMDRF UDI application guidance – Discussion on potential use at EU level

A discussion was had on the possibility of endorsing Annexes E-I of the IMDRF N48 at EU-level. It was concluded that further analysis to identify any potential divergences in terminology or referencing was needed via a consultation to be launched by COM.

12. Wrap-Up & Discussion on next steps for the group

COM identified organising a workshop on contact lenses, the launch of consultations & the sending of revised guidance documents to MDCG for endorsement as next steps.

13. AOB

Industry raised a question for discussion regarding the necessity to include a Basic-UDI DI of the device in the manufacturers QMS certificate.