MDCG UDI WORKING GROUP Meeting
04 MAY 2021
Minutes

1. Opening & adoption of the agenda

COM welcomed participants and provided an overview of horizontal matters related to UDI, including the MDCG endorsement of the UDI WG Work Programme. A presentation on the publication of the European Medical Device Nomenclature (EMDN) was also given. The agenda was adopted with requests to discuss few topics under AOB.

2. UDI EUDAMED Enumerations (Clinical Size)

Following finalisation of the enumeration lists for 'storage/handling conditions' & 'critical warnings' for the UDI/Device module of Eudamed, COM presented the last two enumeration lists on ‘clinical sizes types’ and ‘clinical sizes measure units’ subject to consultations in 2020 and 2021, for agreement. Based on discussions, some modifications were made, and the lists agreed by regulators.

3. Contact Lenses/Spectacle Frames: Rules for UDI assignment

COM together with UDI co-chair and industry gave presentations respectively outlining views on a workable solution for UDI Assignment to contact lenses and potentially other products with a high level of individualisation, based on the creation of specific application identifiers.

COM communicated it would draft MDCG Position Paper clarifying obligations for concerned operators on UDI assignment, labelling and registration for contact lenses/spectacle frames/other relevant eyewear products, from 26 May 2021, whilst a specific UDI assignment solution is being developed. In parallel, work will continue to agree the solution to resume between regulators & stakeholders and the EU Issuing Entities.

4. Discussion on UDI FAQ

A draft Questions & Answers document on UDI, produced as a follow-up from previous meetings with input from regulators and stakeholders, was presented and further discussed with regulators. COM agreed to complement the draft based on participants contributions ahead of a first consultation with regulators and a following consultation including stakeholders.

5. Guidance on Integration of UDI into QMS of Manufacturer

COM provided an overview of the draft Guidance and background to consultations during 2020. COM explained revisions to the document taking into account extensive feedback which was well received. COM will launch a final consultation of the document, for both Regulators and stakeholders, with view to subsequently launching a written endorsement procedure of the UDI WG.

6. IMDRF N48 Annexes E-I - potential use at EU level

Following progress of consultations in 2020, a draft MDCG document on 'The status of Appendixes E-I of IMDRF N48 under the EU regulatory framework for medical devices' was presented. COM outlined the intention to send this to MDCG for their consideration & proposed endorsement at 27/28 May meeting, following a last review of the UDI WG.

7. UDI traceability solutions for non-sterile implantable devices

Industry re-presented challenges for UDI traceability for non-sterile implant devices in multi-device surgical sets under the MDR and an analysis of possible solutions. However, COM & regulators stressed no exemptions to capture of full UDI (UDI-DI & UDI-PI) for the non-sterile implants concerned is possible under EU MDR.

Industry were requested to research and propose viable solutions for full UDI capture of these implants to COM & Regulators by 26 May 2021.

8. Update on UDI Helpdesk

COM provided a status update and announced the launch of the UDI Helpdesk, in the upcoming weeks. COM highlighted the importance of the Helpdesk in supporting economic operators during the implementation of the new UDI obligations introduced by the MDR and IVDR.

9. AOB

Definition of IVDR / MDR Basic UDI-DI & UDI-DI attributes in the UDID data dictionary to be registered in the EUDAMED database was raised by industry. Industry also reiterated their request for a publication of a comprehensive list of UDI triggers ahead of the launch of the EUDAMED UDI/Devices Module.