EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health systems, medical products and innovation
Medical Devices

Brussels, 30 June 2020

Minutes

Meeting of the MDCG Subgroup UDI
Brussels, 30 June 2020

1) Opening, adoption of the agenda

COM welcomed participants and provided a brief overview of horizontal matters as related to UDI, including EUDAMED development. The agenda was adopted with requests to discuss nomenclature under AOB. COM clarified that outstanding issues on the UDI enumerations list would be resolved via written consultation of the WG. Minutes of UDI WG meeting on 17 February 2020 were sent for endorsement.

2) Draft Amendment to MDCG 2018-1 v3 clarifying specific UDI-Triggers (Maximum Number of Re-uses)

COM and the UDI WG Co-Chair presented the proposed revision to MDCD 2018-1 v3 to clarify instances where it may applicable for the manufacturers to indicate the maximum number of re-uses (Annex VI (Part B, Point 17), in the UDI database. COM proposed to revise the suggested amendment based on discussions before launching a written consultation of the UDI Working Group & stakeholders.

COM also agreed to review document presented by stakeholders comparing various available IT documents and legal requirements regarding the UDI-DI triggers and discrepancies identified.

3) Draft Guidance on linking several Basic UDI-DIs to SSCP & product certificates registered in EUDAMED

A draft guidance in response to questions raised by industry over the possibility to link several Basic UDI-DIs to the SSCP & product certificate was presented by COM. COM agreed to revise draft based on discussions with members before sending for written consultation of relevant MDCG subgroups. It was agreed stakeholders would be consulted at a later stage.

4) IMDRF N48 Annexes E-I – Discussion on potential use at EU level

COM presented and outlined an approach for potential adoption of IMDRF N48 Annexes E-I at EU level following feedback from a previous consultation. COM agreed to send draft document for further consultation if MDCG subgroups before adoption, notably on the software Annex.

5) Clarifications on UDI obligations in MDCG Guidance 2018-6

Discussion was held on a question from industry regarding possibility to distinguish economic operators could be considered "legally responsible" vs "operational responsible" for UDI obligations in the context of under MDCG Guidance 2018-6 relating to Art 16(1) MDR.

6) UDI-Triggers, Multi-device Surgical sets – Presentation

Industry gave a presentation on related challenges for UDI Traceability for non-sterile implant devices in multi-device surgical sets under the MDR and proposed solutions. Alternative methods for UDI-DI supply in these cases and a GS1 position paper on the subject were discussed.

COM agreed to consider industry's position to produce guidance on this subject and ensure sufficient time to develop and implement any solutions.

7) AOB

The possibility of conducting continued remote meetings was discussed and COM provided an update on the advancement of the nomenclature project. COM agreed to review GS1 paper relating to alternative methods of supply of UDI-DI for non-sterile implant devices in multi-device surgical sets.