MDCG UDI WORKING GROUP Meeting
01 March 2022
Minutes

1. Opening & adoption of the agenda

COM welcomed participants to the first UDI WG meeting of 2022, which consisted of a competent authorities only session, followed by a plenary session including stakeholders.

COM outlined the CA discussion would focus on UDI assignment for contact lenses. The agenda of the meeting was adopted.

COM also informed participants that the MDCG UDI WG Annual work program (AWP) was endorsed by the UDI WG in writing on Friday 25th February, and that it would soon be sent to MDCG for endorsement ahead of the 21, 22 March 2022 meeting.

Two follow-up sessions were organised in order to tackle open topics which weren't resolved on 1 March 2022. Those sessions took place on 18 March and 5 July 2022. These minutes also include the resolutions arising from those meetings.

2. UDI assignment solution for Contact Lenses

COM presented a status report on the development of the 'Master UDI solution' for grouping of contact lenses. COM outlined that as a follow up of the last UDI WG meeting in 2021, it co-drafted and sent to the EU UDI issuing entities a work request, to initiate the development of the technical solution for the Master UDI.

The technical work began in Q3 2021: some issuing entities worked independently, whilst another requested an active participation of the COM. In parallel, COM started the work on the delegated act amending Part C, Annex VI MDR, supporting the introduction of the 'Master UDI'. During the meeting, COM tabled a discussion on open regulatory/policy questions related to the on-going technical work and draft delegated act, including on labelling requirements for the Master UDI-DI and the required format, and the potential additional PIs for contact lenses.

Some member states expressed the importance of having a 'Master UDI solution' that is flexible enough in case in the future the need arises to expand its applicability to other eyewear products.

The issue of the level of granularity of the assignment of the Master UDI-DI was also discussed and the topic of triggers raised.

The conclusion from the participant's interventions was that the Master UDI-DI should appear on the label of contact lenses, and on all higher levels of packaging, in both AIDC and HRI representation, except in case of space constraints as prescribed by Section 4.7 of Part C, Annex VI MDR. Some additional considerations may be needed on this exception, when drafting the delegated act.

An open policy question concerned the necessity of having additional PIs for contact lenses. The conclusion of the discussion from the majority of the member states was that additional PIs (i.e.

additional clinical sizes) are necessary in case of vigilance issues, to better identify the product affected. Having the clinical sizes not included in the PI (but exclusively on the packaging in readable format as non-HRI) is not sufficient to allow a global identification, which is a fundamental concept of the UDI system for regulatory purposes. Moreover, this addition would ensure adaptability of the solution to technical progress in the device distribution chain.

On the AIDC and/or HRI representation of the PIs, further discussion, supported by visuals, is needed in light of there being possible space constraints due to contact lenses' small packages.

COM thanked the participants for the fruitful discussion and invited them to join the second session of the WG.

3. Discussion on UDI FAQ

COM informed that the topic of the UDI Q&A, including open questions for discussion, would be addressed in another dedicated meeting due to time constraints.

The current draft of the Q&A was discussed in a follow up session with regulators, and some clarifications were made. It was decided that elaboration of some questions was to be postponed until further revisions of the document. The Q&A was endorsed by the UDI WG in writing and subsequently endorsed by the MDCG. It was published as MDCG 2022-7 on 1 May 2022.

4. Report from focus group on UDI traceability solutions for non-sterile implantable devices

The plenary session focused on the issue of full UDI capture on non-sterile implants, for which a report from MedTech Europe (MTE) was expected, in relation to the workshop held in October 2021, and the subsequent focus group meetings. COM also informed stakeholders that the MDCG UDI WG AWP was endorsed in written on 25th February 2022.

As a follow-up from the 04 May 2021 UDI WG meeting, regulators requested industry to research and propose viable solutions for full UDI capture of these implants to COM & Regulators by 26 May 2021, given the lack of progress.

Since then, COM facilitated a workshop on 26 October 2021, to which the UDI WG (CAs & Stakeholders), and stakeholders beyond the UDI WG were invited, where it was agreed MTE would lead a focus group composed of industry, hospital stakeholders (from both EU and national level) and regulators to work on solutions.

MTE reported about the activity of the focus group, and remarked work is ongoing. Whilst one of the solutions proposed is sterile packaging, COM and regulators stressed and reiterated this is a non-solution. Some member states expressed their interest in engaging healthcare associations at national level and will get in contact with MTE in order to do so.

5. AOB

No AOB was discussed.