



IMDRF

International Medical
Device Regulators Forum

UDI Application Guide Working Group update

Working Group Chair: Salvatore Scalzo
European Commission
Health Technology and Cosmetics Unit

IMDRF MC meeting – Stakeholder Day
21 March 2018
Brussels, Belgium



The Working Group

It has been formed in November 2017. It is chaired by the EU and includes representatives from:

- 9 IMDRF countries (European Union – Chair -, Australia, Brazil, Canada, Japan, Russian Federation, Singapore, South Korea, United States)

- World Health Organisation (WHO)

- Global industry associations GMTA and DITTA





Background and scope of the project

- Work Item proposal adopted at the IMDRF-12 meeting in Ottawa (September 2017), based on a GMTA proposal
- Purpose: To promote a globally harmonized approach to the application of a UDI system in support of the IMDRF UDI Guidance Document (IMDRF/WG UDI/N7Final:2013)
- Scope of the proposal
 - Responsibilities for establishing and maintaining a UDI
 - General UDI assignment rules
 - Considerations related to placement of UDI on all packaging levels, on package labelling and on the device itself
 - Use of UDI in forms and databases
 - Considerations related to submission of UDI core data elements to UDI databases
 - General principles for good implementation of a UDI system (transition to UDI system and feasibility issues for UDI marking)
 - General principles of a good UDI-Database design
- Based on a preliminary working draft of the UDI Application Guide provided by the GMTA industry for review and edit by the IMDRF UDI Work Group



State-of-play and next steps

- F2F meeting took place in Brussels on 12-15 February 2018
- The first day of the meeting was organised in the form of an open international workshop on Global Use and Application of UDI (around 170 attendants and 25 Competent Authorities)
- A revised version of the draft was produced during the meeting and is currently under internal consultation with the group members
- Main focus of the group during the meeting was:
 - Further development of sections on UDI-related operators' responsibilities, principles of good UDI design
 - Indication of principles for UDI System Design and Operation
 - Complementing Section 10 of UDI Guidance of 2013 (specific device types)
 - Provision of examples
- The WG intends to submit a draft to be possibly endorsed for public consultation by the Management Committee at its June teleconference



Timelines of the project

| Actions | Expected deadlines |
|--------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Formation of the WG and kick-off teleconference | November 2017-early December 2017 |
| Review and, where necessary, amend preliminary working draft of UDI Application Guide provided by GMTA industry members | Dec 2017 - May 2018 |
| Publish draft for Public Consultation | Adoption of draft at IMDRF-MC teleconference of June 2018. Public Consultation to last Jul/Aug 2018 |
| Analysis of Consultation Contributions | Start in Sep 2018 |
| Draft proposal of UDI Application Guide to the IMDRF-MC | Depending on number and significance of comments received during public consultation, submission of final document for final adoption either at the Dec 2018 MC teleconference or at the MC F2F meeting in March 2019 |



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Thank you for your attention !

Salvatore Scalzo

European Commission

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