UDI Application Guide Working Group update

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European Commission
Health Technology and Cosmetics Unit

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The Working Group

It is chaired by the EU and includes representatives from:

- All IMDRF MC countries (European Union – Chair -, Australia, Brazil, Canada, China, 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 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 work
  - 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

- Three draft documents
  - Main UDI Application Guide
  - Information document mapping the use/specifications of UDI data elements in different jurisdictions (based on voluntary contributions submitted by jurisdictions that have started to implement a UDI system)
  - Information document related to system requirements related to use of UDI in healthcare including selected use cases
- Public consultation July-October 2018: about 550 comments in total.
- WG focus sessions on issuing entity responsibilities (at the presence of the issuing entities), role of UDI in registries, nomenclature.
- Now for final endorsement.

The UDI Application guide

- Objective: details and specifications o ensure consistency for enabling a harmonized approach in the application of the requirements in the IMDRF UDI Guidance Document (IMDRF/UDI WG/N7Final:2013)
- Intended users of the document
  - Primarily medical device regulatory authorities and manufacturers that plan to develop and implement UDI systems but…
  - also all relevant stakeholders within the healthcare supply chain and clinical care systems to gain a better understanding of their role and impact on the UDI system
- Core contents:
  - Technical considerations on UDI (including considerations on UDI structure, UDI carrier specifications and bar code readers)
  - Consideration on UDID design (for regulatory authorities)
  - UDI-related responsibilities across the distribution chain
  - Considerations on transition to UDI systems
  - UDI rules for specific products
  - Very detailed appendices (which include many pics and practical examples) intended to facilitate practical understanding of the subjects

The information documents

- Information document on use of UDI data elements across IMDRF jurisdictions
  - Provides stakeholders with a practical tool to comply with UDI requirements in different IMDRF jurisdictions
  - Provides a UDI data elements dictionary containing descriptions of the data elements as collected in National UDI databases (UDID) across IMDRF jurisdictions
  - Data elements mapped against the core data elements listed in the IMDRF UDI Guidance of 2013
  - Relies on information provided by IMDRF jurisdictions, at a stage when they have defined the data fields in their respective UDID systems
  - Regular update is considered by the UDI WG to be of high value to operators worldwide (a maintenance project will be discussed and proposed to the IMDRF MC)
- Information document on System requirements related to use of UDI in healthcare including selected use cases:
  - Rationale: Benefits of UDI are more likely be achieved when the UDI is recorded in real world electronic health systems (e.g. electronic health records (EHRs), device registries, material management systems, and reimbursement data) and used as part of real world evidence to improve clinical and regulatory decision making
  - Aims to provide a common set of best practices that can be generalized for use by all data sources wishing to scan the UDI and use data extracted from the UDIDs as a source for auto-populating information into forms/electronic information

Next steps

- Additional UDI-related application issues were identified by the Work Group for possible future consideration at IMDRF level. These include:
  - Considerations on UDI assignment and recording in UDI databases for specific device types (notably contact lenses and SaMD)
  - Harmonisation of UDI-DI triggers and assignment of other multiple UDI-DI use cases
  - Utilization of UDI along the supply chain
  - Tools and device categorization nomenclature for grouping similar devices
  - Harmonised structure for information related to data attributes in UDIDs
  - Issues related to data quality management in UDIDs and data validation criteria
  - Low unit of measures
- A NWIP has been submitted by the WG to the MC including some of these aspects which are deemed to be more urgent (notably review of harmonized list of UDI-DI triggers and considerations on UDI assignment and recording in UDI databases for specific device types)

Thank you for your attention !

Salvatore Scalzo

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