Brief report on
the International Workshop on global use and application of UDI
European Commission – Medtech Europe/COCIR,
Febr. 12, 2018, Brussels, Belgium

Following the UDI project of the FDA Europe published the Medical Device and In-vitro-Diagnostica Regulation (MDR & IvDR) May 5, 2017. What about UDI worldwide? UDI worldwide had been addressed by the International Medical Device Regulatory Forum (IMDRF), the forum for harmonizing health care projects like UDI for worldwide application. The UDI workshop has been initiated by the European Commission and Medtech Europe/COCIR in order to promote the UDI project for global traceability, patient safety and efficiency. Regulators and Healthcare institutions have been invited as well as manufacturers to share experiences and to discuss the developments. More than 200 participants joined the call for the workshop. The not exhausted list includes territories like

*Australia	Austria	Belgium	*Brazil	*EU	*Finland	France	*Germany	Italy	*Japan
*S. Korea	Norway	Sweden	*Saudi Arabia	*Singapore	*Switzerland	*Taiwan	*Turkey	*USA	

and institutions like

AHWP	Assobiomedica (IT)	COCIR	DITTA	GMTA	GMDN	**GS1	**HIBC	HOPE
**ICCBBA	FM Health (F)	MedTech Europe	PMDA (JP)	WHO	ZVEI (DE)			

* *Representatives of the Regulators have been present* ***Issuing Agency for UDI*

The 22 speakers provided comprehensive information and the delegates used the occasion for detailed discussions.

Fig. 1) Harald Oehlmann presenting HIBC (source Nianzhuang Liu)

Workshop summary

UDI is moving toward a global project for achieving worldwide traceability for Medical Devices and In-vitro-Diagnostica. Some countries are ahead, like Turkey and USA and Europe is in the middle of the implementation process. Many countries are in the planning phase. IMDRF is coordinating the efforts and supplies the guidance. The UDI concept receives overwhelming support for global implementation. Where the suppliers side of the healthcare community are recognizing both, the load and the benefit, the users side with the hospitals still has to learn about the benefit they can earn in addition to the responsibilities they have got, e.g.

freely available master data. In essence, the UDI ball is rolling, nobody can avoid it but everybody can benefit from it as well in balance between stress, individual benefit of involved parties and common welfare. Nevertheless UDI is just a module for overall traceability for all products and processes. It was reported that Turkey already started an advanced project on this overall level and the German Normalization Institute (DIN) published a guideline on tracking and tracing throughout the supply chain from production to the point of use not only for health care but for global application. The workshop impressively demonstrated how UDI has already brought the health world closer together as a continuing process.

Workshop discussion points

Erik Hansson, Deputy Head of Unit, European Commission, DG Health and Consumers, welcomed the delegates and provided the introduction.

Salvatore Scalzo, European Commission, Health Technology and Cosmetics Unit, Brussels, Chair of the IMDRF UDI task force presented an update of the work item UDI on the IMDRF level. Just to remember, IMDRF developed the globally harmonized approach to the UDI system publishing the IMDRF UDI Guidance Document "IMDRF/WG UDI/N7Final:2013". US FDA and EC regulations included the key elements of the document. Salvatore Scalzo reported, that the actual IMDRF work item based on this document (FDA and MDR are referring to) is on Harmonized UDI Application Guides, focusing to

- 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

Dr. Matthias Neumann, Federal Ministry of Health, Germany, highlighted on the key features of the 2013 IMDRF document for achieving worldwide traceability which is mirrored in the running UDI projects , like UDI System Infrastructure, Core Data Set for the UDI data bases and how to feed a global system.

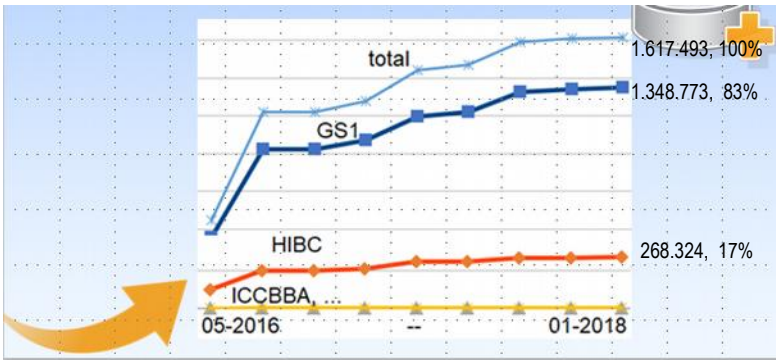
Jackie Rae Elkin - Global Medical Technology Alliance (GMTA) and James Turner - Global Diagnostic Imaging, Healthcare IT, and Radiation Therapy Trade Association (DITTA) shared the opinions about the UDI Opportunities for Industry and supplied helpful information by "Lessons learned" with advises for UDI implementation from the perspective of the manufacturers.

The points of view on the "The role and tasks of UDI issuing entities" have been presented by the 3 representatives of the accredited Issuing Agencies for supplying Unique IDs and UDI data syntax Geraldine Lissalde Bonnet (GS1), Harald Oehlmann (HIBC) and Paul Ashford (ICCBBA). All three representatives provided supporting statements to the functionality of the harmonized UDI. Harald Oehlmann added information on further developments, e.g. DMRE for UDI Codes fitting to smallest devices (Fig. 2) and motivated to use UDI in conjunction with general traceability concepts by extensive Barcode strategies, e.g. for whole clinical processes. He reported that HIBC is providing unique alphanumeric codes for fulfilling the responsibilities of documentation and for increasing patient safety and efficiency in one hit (reference document: AIDC supported clinical processes).

Fig. 2) DataMatrix Rectangular Extension (DMRE) with UDI on a small and rounded medical instrument

Terrie L. Reed, MSc, Industrial Engineering, Senior Advisor for UDI Adoption, US FDA Center for Devices and Radiological Health, supplied a comprehensive overview of the US UDI project and its expected outcome with more rapid and accurate device data capture at the point of care, reduction of medical errors in conjunction with more efficiency. It was great to have her in the workshop learning about implementation of the UDI system. Terrie reported on the content of the GUDID in terms of no. of entries and code types expected another growth if the class 1 products are due as of Sept. 24, 2020.

Harald showed similar observations regarding the distribution of the codes GS1, HIBC and ISBT/ICCBBA and added a trend diagram for the period between May 2016 and Jan. 26, 2018. The growing rates shown are from 15% to 17% for HIBC and from 85% to 83% for GS1 (see Fig. 3).



DATE	GS1	HIBC	ICCBBA	NDC	total	HIBC %	GS1%
2018-01-26	1348773	268324	56	340	1617493	17	83
2016-12-16	1070117	208074	53	278	1278522	16	84
2016-05-24	553317	95304	38	0	648659	15	85

Fig. 3) Chart: Trend GUDID records from 2016 to 2018-01-26 (source Harald Oehlmann)

Alfred Kwek, Singapore, Asian Harmonization Working Party (AHWP) Technical Committee, Co-Chair (Industry) reported on the work in the Asian region with special efforts of the members China, Kingdom of Saudi Arabia, Korea, Taiwan and more in order to connect on the harmonized UDI concept for “End to End” traceability.

Hélio Bomfim de Macêdo Filho, Anvisa, Brazilian Health Regulatory Agency, supplied Updates related to developments in the UDI field, where a draft of regulations regarding UDI adoption has been produced already prior to implementation. Anvisa is on the way to raise awareness of the UDI importance in Brazil.

Hiroshi Ishikawa, Technical expert, Division of Standards for Medical Devices, Office of Standards and Guidelines, PMDA, reported on the current Situation in Japan regarding UDI based on a long history with Code JAN 13 since 1999. He stated openly “Even we start to use Bar Coding system from the last decade, we are still struggling about what for the Barcode should be used, who the real stakeholder is, what else this tool can be used for patient safety purpose, how effectively we can use this tool.

Eng. Meshal Alamri, MBA, Executive Director, Premarket Approval & Scientific Evaluation Directorate Medical Devices Sector - Saudi Food & Drug Authority (SFDA) reported about the goal of enforcement of UDI according to Classes of MDs as step 4 due Q1, 2020. The presentation about the programs of SFDA not only for UDI has been impressive and how to align with the IMDRF UDI Guidance and the US FDA and EU MDR/IVDR UDI regulations connecting to the global UDI system.

Kim Byung-gwan, Ministry of Food and Drug Safety, Korea presented the current status of the UDI system for Korea planning for enforcement dates Jan. 1, 2019 for highest risk Classes (4), Jan. 1, 2020 for Class 3, Jan. 1 2021 for Class 2 and for all MDs Jan.1.2022.

Burak İbrahim Sevindi, Turkish Medicines and Medical Devices Agency (TMMDA) was able to report about the success of the running Turkish UDI system “TITUBB” established 2007. He declared that Turkey is planning to connect to EUDAMED as soon as EUDAMED will be ready. TMMDA recognized that UDI is fine, but what really is needed is to track products from the source to the point of use, a true tracking and tracing system. For realization the Product Tracking System “ÜTS” has been launched June 2017. “ÜTS” aims at developing the infrastructure to track medical devices manufactured in (or imported to) Turkey from the production band to the place where they are sold and used. The presentation showed impressively what could be done above UDI.

Mao-Ting Sheen, Food and Drug Administration of Taiwan showed the schedule for mandatory labeling of UDI: MDs Class 3 June 1, 2921, IvDs and Class 3 and Class 2 MDs June 1, 2023 joining the global UDI concept as well.
Pascal Garel, Hospital Europe (HOPE) addressed the difficulties of practicing traceability in hospitals and referred to the very different practices in each country. This showed that the hospitals must be integrated more strongly than before.

Adriana Velazquez, Senior adviser on medical devices, World Health Organization (WHO) contributed about "Using UDI from innovator to hospital" concluding that WHO supports IMDRF's initiative on UDI, working with global standards for global outcomes.

Fruitful discussions completed the workshop and everybody was able to take home valuable information and the confidence that global use of UDI will be a success.

Noted by
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- HIBC presentation access: www.hibc.de
- DataMatrix Rectangular Extension (DMRE) access: www.dmre.info