European Commission – Medtech Europe/COCIR International Workshop on global use and application of UDI

DRAFT AGENDA

Brussels, 12 February 2018

Venue: Conference Centre Albert Borschette (CCAB) room 0.D
36 rue Froissart, 1040 Brussels, Belgium

Item	Detail	Delegation	Time
09:30-10:00 Introduction			
Welcome and opening address		S. D'Acunto (European Commission), O. Bisazza (MedTech Europe), N. Denjoy (COCIR)	15
Presentation of new IMDRF work item on UDI		E. Hansson (European Commission), S. Scalzo (European Commission)	15
Session 1: 10:00-11:35 Introduction to the UDI concept			
Background: Objectives and rationale of a UDI system		T. Reed (USFDA)	20
Background: The IMDRF Guidance of 2013 and the main features of a UDI system		M. Neumann (Federal Minister of Germany)	20
Implementation of UDI in the medical device industry		Representatives from the industry	25
The role and tasks of UDI issuing entities	The point of view of GS1/HIBCC/ICCBBA	GS1/HIBCC/ICCBBA Representatives	15
Discussion/Q&A			15
Coffee break – 11:35-12:00			**25**
Session 2: 12:00 – 12:35 The value and experiences with UDI in the hospitals			
Hospitals	Representative from HOPE TBC		20
Discussion			15
Lunch break – 12:35-14:00			**85**

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Session 3: 14:00 – 16:30 UDI developments in world jurisdictions			
Implementation of UDI system in the US/EU			
Implementation of UDI system in the US	Ms Terrie Reed (USFDA)		25
Implementation of UDI system in the EU	Mr Salvatore Scalzo (EU)/Mr Pierre-Francois Ryelandt (EU)		25
Update from various jurisdictions			
Update from jurisdictions related to developments in the UDI field	1- Representatives of IMDRF members 2- Representatives of other worldwide jurisdictions		65
Update from WHO and Regional Harmonisation Initiatives			
Update from WHO	Ms Adriana Velasquez (WHO) TBC		10
Update from ASEAN	ASEAN representative TBC		10
Discussion			15
Coffee break: 16:30 – 16:45			
Session 4: 16:45 – 17:15 IMDRF new UDI Work Item – Next steps			
Presentation of next steps	S. Scalzo (European Commission)		15
Discussion			15
Closing remarks 17:15-17:30			
E. Hansson (European Commission), O. Bisazza (MedTech Europe) and N. Denjoy (COCIR)			15