EU FUTURE REGULATION on UDI for TRACEABILITY

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28th Global GS1 Healthcare Conference
20-22 October 2015 Budapest, Hungary

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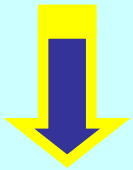
TRACEABILITY IS A GLOBAL CHALLENGE

EU Internal Market



EU 'Regulation'

International Trade

Global 'Regulation'

Two sides of the same medal

NEED FOR INTERNATIONAL HARMONIZATION…

Aspiration to convergence





IMDRF

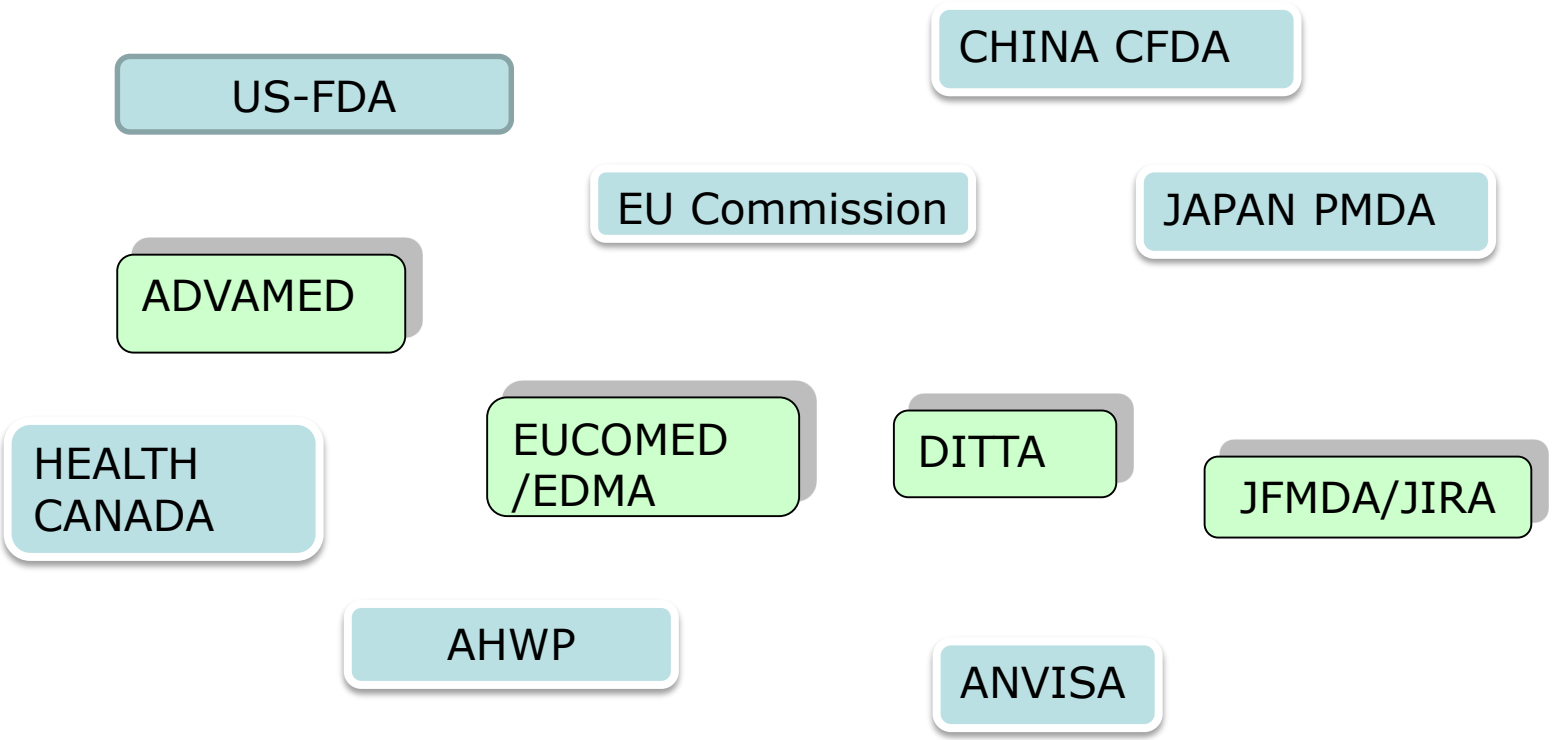
OBS.

Deployment fora




European Commission

UDI Work Group



…With some invited observers.

UDI SYSTEM

European Commission

Bar-coding
for every Medical Device

DI
Device Information
- Company
- Product ID

PI
Production Information
-Life
-Serial or Lot Information

UDID
Database
For DI part Only

DI
-Company Name
Address
-Product Name
.
-GMDN
-code
-term
.
. etc

IMDRF UDI Guidance

ADOPTION of the IMDRF UDI Guidance by the Management Committee on 15 November 2013
Final document (IMDRF/WG/N7:2013)

IMDRF International Medical Device Regulators Forum

Final Document

Title: UDI Guidance
Unique Device Identification (UDI) of Medical Devices

Authoring Group: IMDRF UDI Working Group

Date: 9 December 2013

Despina Spanou, IMDRF Chair

IMDRF Guidance for a UDI System

Three parts of the UDI System :

1. the development of the UDI using globally accepted standards,

2. the application of that UDI on the label, and

3. the submission of appropriate information to a UDID ***(aiming at facilitating traceability)***

IMDRF Guidance for a UDI System

For a globally harmonized approach to UDI, it is imperative that:

Globally accepted ISO/IEC coding standards implemented by global organizations, such as GS1, HIBCC and ICCBBA, meet the criteria of the UDI and manufacturers shall be permitted to choose which system to use.

These organizations have responsibility for maintaining the global uniqueness of their coding systems.

These coding systems be adopted and implemented, without national deviations or changes to these global coding systems.

Proliferation of coding systems must be discouraged.

IMDRF UDI Summary table
UDI - AIDC Marking / Placing Rules

European Commission

Category	Unpacked UoU → direct marking	Base Package	Bulk Package (higher pack. config)	Remarks
Single-use MDs				
• IMDRF class A (low-risk)	-	-	DI + PI*	• *PI not required by the US FDA
• IMDRF class B (medium-r.)	-	-	DI + PI	
• IMDRF classes C+D (high-r.)	-	DI + PI	DI + PI	
Re-usable MDs				Require reprocessing between uses
• all risk-classes	DI + PI	DI + PI	DI + PI	• not all package levels necessarily exist • surgical instruments, IV pumps, etc
Implantable MDs				PI = serial number for active implants
• sterile	-	DI + PI	DI + PI	• usually single packed (1 piece)
• non-sterile	must be identifiable	DI + PI	DI + PI	• often multiple packed (‚n' pieces) • not necessarily DPM, other tech. options allowed to identify the unpacked MD
Others				
• Kits (IVD / non-IVD)	-	DI + PI	DI + PI	• concerns the kit package itself
• Standalone Software	DI + PI	DI + PI	-	• must not necessarly be packed
• config. MD Systems	DI + PI	-		• AIDC carrier to be placed on a ‚main part' (primary mode of action)
• OTC exclusively	-	-	DI (linear bar code)	• Point-of-Sale scanners can't work with PI
• OTC + other channels	-	-	DI + PI (non-concatenated)	• PI should be presented in a separate AIDC carrier due to Point-of-Sale scanners

DIVERGENCES
BETWEEN THE FDA UDI RULE AND THE IMDRF UDI GUIDANCE…?

NOTHING SIGNIFICANT… ***(Examples)***
(Minor deviations)

ALIGNMENT ***(Fair…)***

The UDI Challenge

Manufacturers DBs

FDA UDID

EU UDID

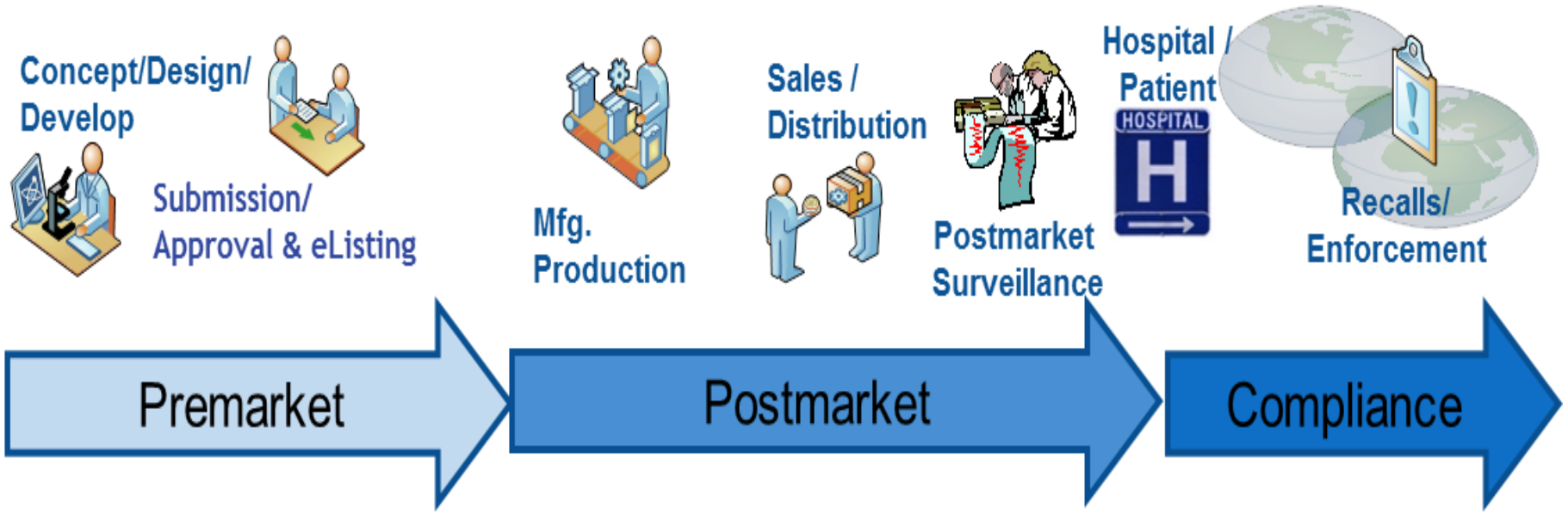
China UDID

Japan UDID

UTOPIA … One Global UDID

Deployment of a small number of regional UDIDs

Considering all Regulatory Life Cycle Phases



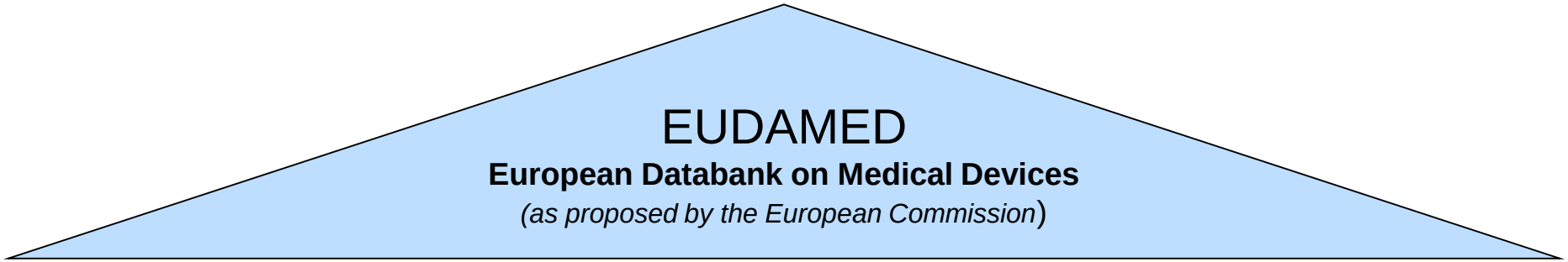
In the EU

UDI System's EU Proposals for MD/IVDs Regulations

Provisions on the future EU UDI System define:

- **The general framework of the System,**
- **The objectives of the System,**
- **The powers delegated to the Commission,**
- **UDI Electronic System Data Elements,**
- **Accreditation system (UDI issuing agencies)**

EUDAMED and UDI



Electronic system on Registration	***UDID***	***Electronic system on Certificates***	***Electronic system on Vigilance***	***Electronic system on Market surveillance***	***Electronic system on Clinical investigations***
Medical devices / IVDs economic operators, incl. Summary of Safety and Clinical Performance (high risk devices)	**Device Identifier data elements**	Certificates issued by notified bodies & Information on certificates refused suspended reinstated restricted withdrawn	Serious incidents & Field safety corrective actions & Field safety notices	Measures taken by Member States re. devices presenting a risk to health & safety preventive health protection measures	Sponsors (& manufacturers) description of: investigational device, comparator, purpose of CI, status of CI

UDI: EU Implementation

European Commission

Revision proposals

(26th September 2012)

Recommendation a common UDI System in the EU

(March 2013)

Ordinary legislative procedure by EP & Council (EU member States)

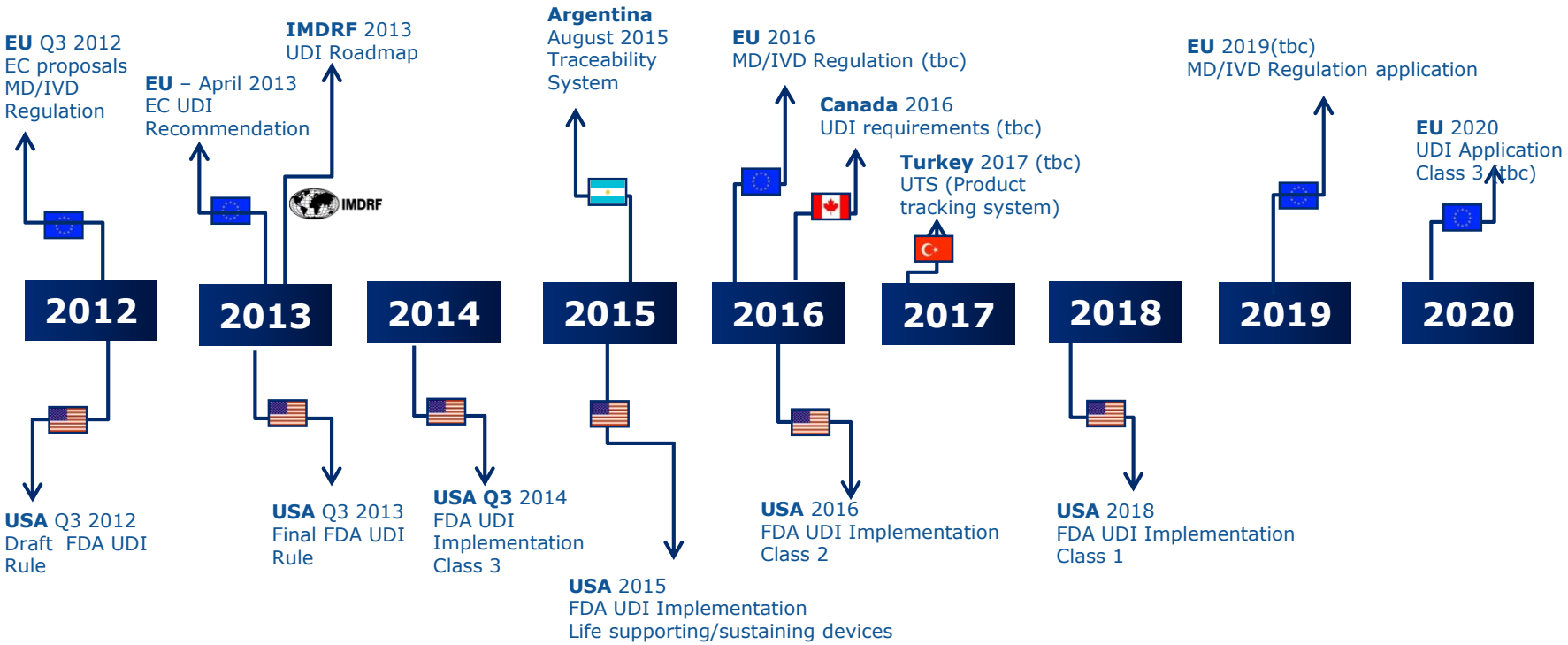
Adoption of the New REGULATION

(still in 2015?)

UDI and traceability requirements

(2016)

Medical Devices – UDI Labelling and Databases



Japan: UDI industry commitment implemented

China, S-Korea, India, Brazil, S-Africa …
UDI regulatory requirements under consideration

THANK YOU


Mō zhe shítou guòhé.
摸着石头过河。
Crossing the river by feeling each stone.