Unique Device Identification

European Diagnostic Manufacturers Association

Andy Rutter – Chairman of EDMA UDI Task Force

GS1 Healthcare Conference

11th-14th February

Granada, Spain

Disclaimer

- This presentation is the position of the members of EDMA
- This is not the position of Molecular Light Technology Research Ltd or Gen-Probe Incorporated

About EDMA

- **EDMA was constituted in 1979 as the European organisation for national associations representing the *in vitro* diagnostics industry in the major countries of Europe**
- **EDMA now has 34 Corporate Association Members and 21 National Member Associations. Over 500 different companies (and 700 legal entities) dedicated to the IVD sector are active members of at least one of the National Associations affiliated to EDMA**

About EDMA (continued)

- In the 1980's EDMA initiated a process of European harmonisation for *in vitro* diagnostic products, with the intention of promoting the free movement of products and maintaining high standards of health care protection within Europe. This process was continued and was incorporated by the European Commission into a Directive on In Vitro Diagnostic Medical Devices 98/79/EC which introduces uniformity of regulation throughout the European Union.

Importance of UDI

- EDMA has established a task force specific to UDI
- EDMA has recognised that various regulatory authorities have been considering the possibility of regulatory requirements for UDI
- The necessity of harmonisation of any such regulations has been discussed in the Global Harmonization Task Force

EDMA Position

- The focus for legislation related to UDI for IVDs should be Patient Safety
- The key value of a UDI system should be to support traceability from the manufacturer to the patient
- The system must be flexible in order to be efficient
- A stepwise approach based on the level of risk should be envisaged

Benefits of UDI

- Improve patient safety
  - reducing device related medical errors
  - improving the identification of devices in adverse events
  - facilitating field service corrective actions
- Management of purchasing and distribution
- Identification of counterfeit devices

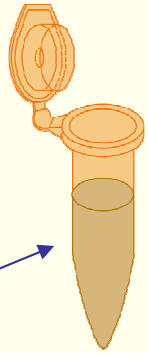
Developing the UDI

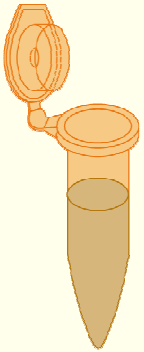
- Risk based approach
  - high risk (with respect to traceability) products first
- UDI assigned by the manufacturer
- UDI Construction
  - Device ID
    - Manufacturer, product reference
  - Production ID
    - serial number (instruments)
    - lot number (reagents)

Unit of Use - IVDs

- UDI should be implemented at the level of finished product
- UDI should not be placed on components
- IVDs
  - laboratory analyzers
  - reagents – commonly in the form of a kit
  - self-testing devices

Example of a kit…





Critical question – what information needs to be tracked where?

Patient Safety & UDI

- Vigilance – essential part of a regulatory system
- MEDDEV 2.12-1 Rev 5
- Field Safety Corrective Actions
- Essential that mechanisms exist for tracing
- System for IVDs in place today shown to be adequate
- UDI should not impose more stringent regulatory requirements

Considerations for IVDs

- Instruments
  - Unique serial number (EN 61010-2-101)
  - UDI of highest resolution
- Reagents
  - produced in homogeneous batches
  - several reagents together in form of a kit
  - identified by lot number
    - kit level
    - at level of individual reagents

UDI Technologies

- Number of specific technologies
  - linear bar codes
  - data matrix bar codes
  - high capacity colour bar codes
  - RFID
- Use of a specific technology should be standardized
  - single device ≡ single UDI
- Standardisation initiatives
  - GS1 – unique forum and opportunity

UDI Database

- Unique European Database (language independent)
- Clear identification of minimum dataset
- Confidentiality of data
- Manufacturers responsible for data entry
- Other points –
  - relationship of UDI with EUDAMED?
  - relationship with GMDN?

UDI & Counterfeiting

- UDI is NOT the solution to counterfeit devices
- UDI enables better control of the supply chain
- Thus provides another tool to control counterfeiting
- UDI one of the many steps required, also -
  - product authentication
  - enforcement

Summary

- UDI should serve to support traceability in order to ensure patient safety
- It can be important to put in place such a system for ‘high risk’ devices
- Stepwise approach based on the level of risk
- Global harmonisation of the regulations on the use of UDI is essential
- Level of traceability of IVDs shown to be adequate
- UDI should not impose more stringent regulations

UDI Working Group Members

I. Andrew Rutter, Chairman (Molecular Light Technology Research Ltd)

II. Ben Jacoby (Ortho-Clinical Diagnostics)

III. Thomas Mall (Roche Diagnostics)

IV. Bernard Fleury (BioMérieux)

Thank you!

Questions ?

Andy Rutter

+44 29 2076 8707

andy.rutter@mltresearch.com

European Diagnostic Manufacturers Association

Place des Maïeurs 2
1150 Brussels
Belgium
Tel +32 2 772 22 25
Fax +32 2 772 23 29
edma@edma-ivd.be

EDMA represents the In Vitro Diagnostics Industry in Europe
Visit our website: www.edma-ivd.be