The Global Language of Business

Unique Device Identification

The State of Play in Europe

Andrew Rutter, Regulatory Affairs Manager, Ortho-Clinical Diagnostics

22 October 2015

Ortho-Clinical Diagnostics

- **Headquartered in Raritan, NJ, USA**
- **Manufacturing Sites in Raritan, NJ; Rochester, NY; Pompano Beach, FL and Pencoed, Wales**
- **Key product lines: Transfusion Medicine, Clinical Chemistry and Immunodiagnostics**

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My Day Job

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UDI & Me

- **GHTF Conference – Washington, 2007**

- **EDMA UDI TF**

  Position Paper – February 2008

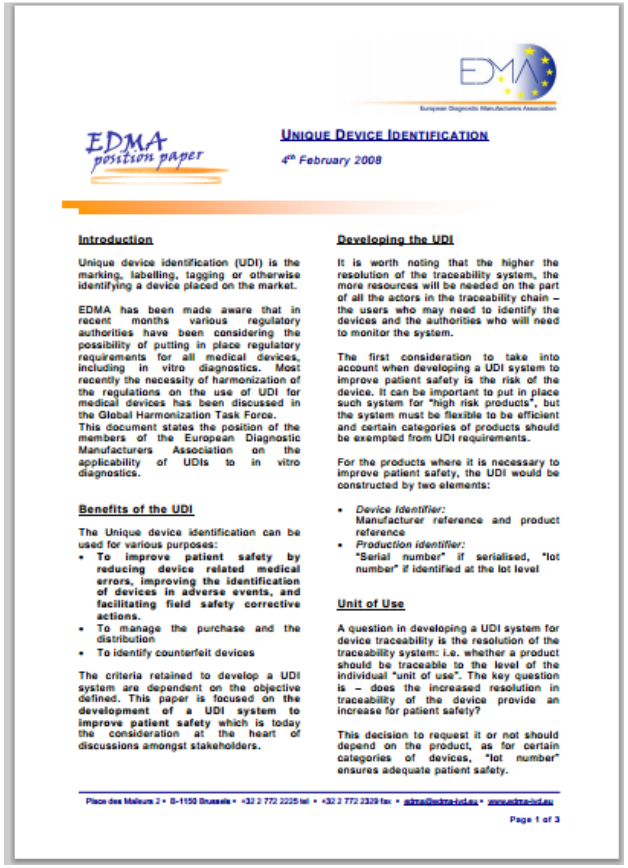
  Presented at GS1 conference (Granada)

- **Ortho-Clinical Diagnostics**

  96 US Class III products ✓

  300 Class II products

  300 Class I



EDMA position paper

UNIQUE DEVICE IDENTIFICATION

4th February 2008

Introduction

Unique device identification (UDI) is the marking, labelling, tagging or otherwise identifying a device placed on the market.

EDMA has been made aware that in recent months various regulatory authorities have been considering the possibility of putting in place regulatory requirements for all medical devices, including in vitro diagnostics. Most recently the necessity of harmonization of the regulations on the use of UDI for medical devices has been discussed in the Global Harmonization Task Force.
This document states the position of the members of the European Diagnostic Manufacturers Association on the applicability of UDIs to in vitro diagnostics.

Benefits of the UDI

The Unique device identification can be used for various purposes:

- To improve patient safety by reducing device related medical errors, improving the identification of devices in adverse events, and facilitating field safety corrective actions.
- To manage the purchase and the distribution
- To identify counterfeit devices

The criteria retained to develop a UDI system are dependent on the objective defined. This paper is focused on the development of a UDI system to improve patient safety which is today the consideration at the heart of discussions amongst stakeholders.

Developing the UDI

It is worth noting that the higher the resolution of the traceability system, the more resources will be needed on the part of all the actors in the traceability chain – the users who may need to identify the devices and the authorities who will need to monitor the system.

The first consideration to take into account when developing a UDI system to improve patient safety is the risk of the device. It can be important to put in place such system for "high risk products", but the system must be flexible to be efficient and certain categories of products should be exempted from UDI requirements.

For the products where it is necessary to improve patient safety, the UDI would be constructed by two elements:

- *Device identifier:* Manufacturer reference and product reference
- *Production identifier:* "Serial number" if serialised, "lot number" if identified at the lot level

Unit of Use

A question in developing a UDI system for device traceability is the resolution of the traceability system: i.e. whether a product should be traceable to the level of the individual "unit of use". The key question is – does the increased resolution in traceability of the device provide an increase for patient safety?

This decision to request it or not should depend on the product, as for certain categories of devices, "lot number" ensures adequate patient safety.

Place des Malteurs 2 • B-1150 Brussels • +32 2 772 2225 tel • +32 2 772 2339 fax • edma@edma-ivd.eu • www.edma-ivd.eu

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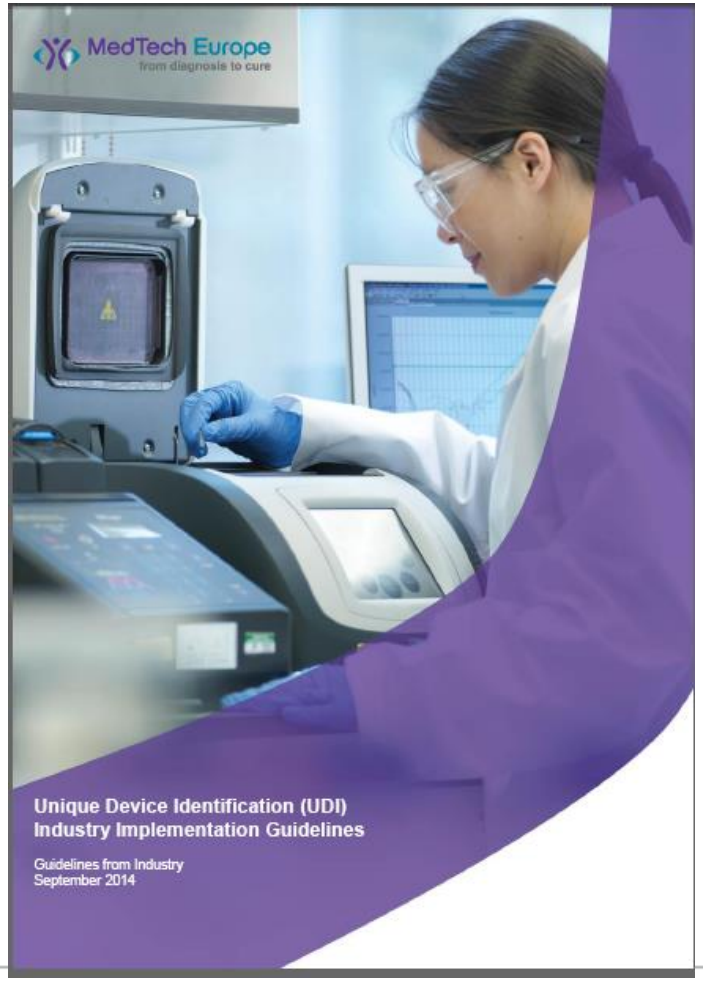
MedTech Europe & UDI



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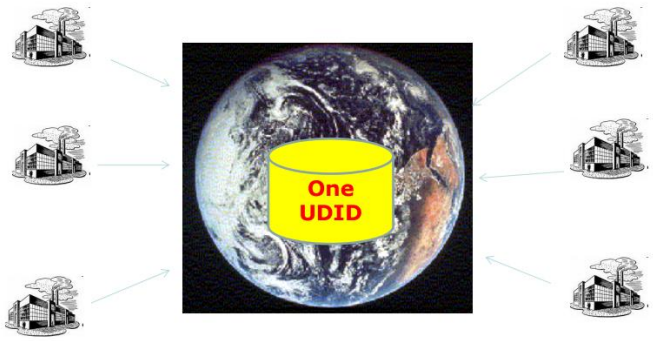
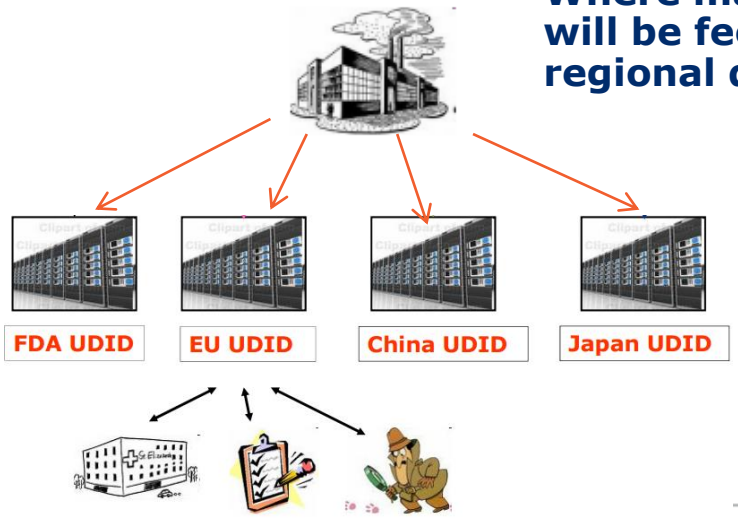
Global Harmonisation?

When GHTF/IMDRF work on UDI started – the original idea was to develop a global UDI system



As the discussions continued the deployment of a small number of regional UDI databases (UDID) may be more be more practical

Where manufacturer's UDID will be feeding into the regional databases



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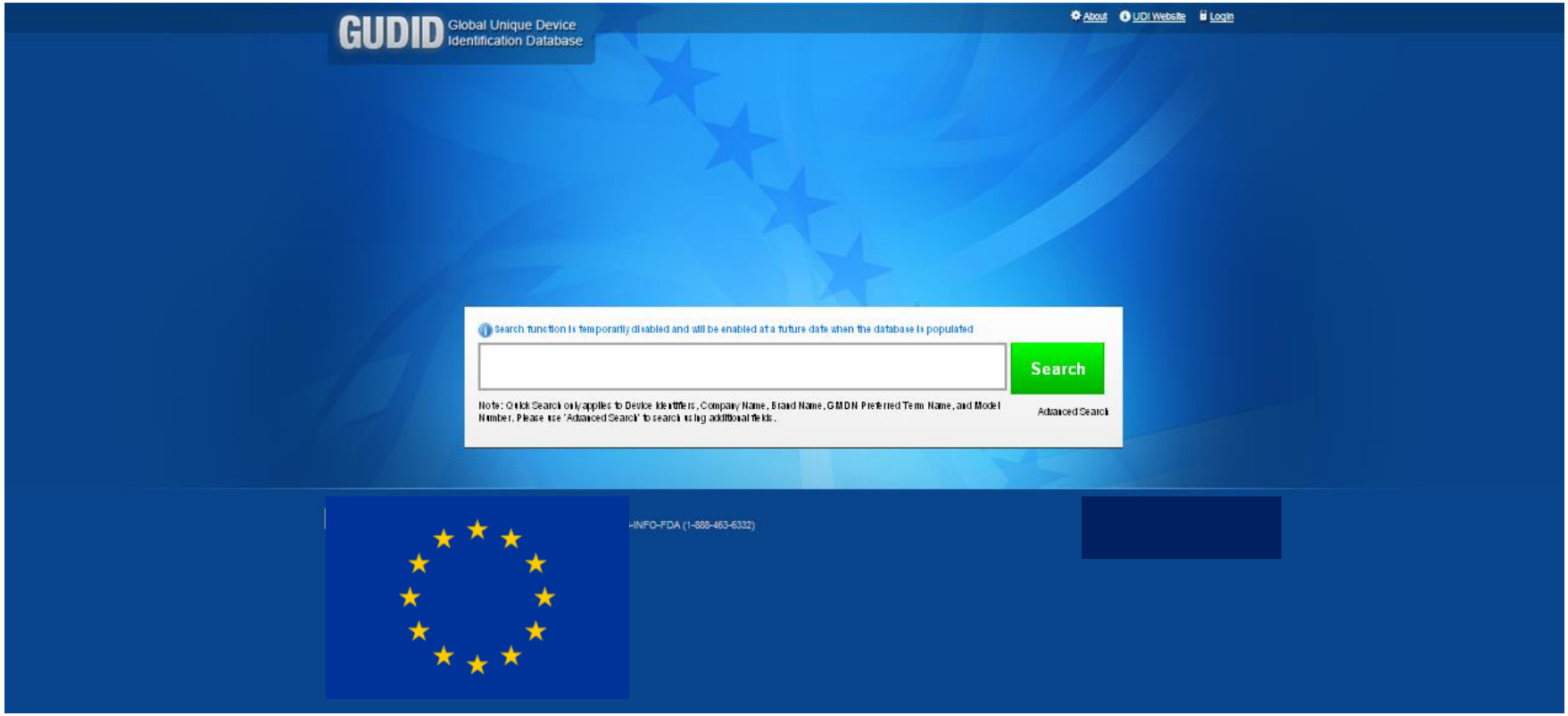
Will it look like this in Europe?



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EU Industry Perspective

- **Traceability:** in the proposed Medical Device and In Vitro Diagnostic Regulations will depend on all stakeholders collecting and securing data on devices.
- **Compatibility:** it is imperative that any system introduced in the European Union is compatible with global systems and at the very least with with the FDA system already in place
- **UDI Electronic Database System:** The format of any electronic system introduced MUST be compatible with any other global systems in place in order to enable exchange of regulatory information in a meaningful way….
- **Impact:** Any system introduced will require huge investments from economic operators (manufacturers, importers, distributors and authorised representatives) but also from National Healthcare Systems.
- **Timing:** In order to limit fragmentation it is critical that the development of an EU wide system is prioritised with clear timelines and expectations communicated to Member State authorities, economic operators and national healthcare systems etc.

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Around the EU Today

Turkey – database in place for reimbursable devices (TITUBB)

Serbia – request GMDN codes

Macedonia – require GTIN

Portugal – National Product Database

Italy – Medical Device database now includes Annex II IVD

UK – NHS e-procurement strategy

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There is a will!

"There are currently no legal rules about traceability in the field of medical devices so we cannot impose any in this field at European level," Ms Lecrenier said. "We need to have a legal basis to impose common rules and create a common database," she continued. Without this, Ms Lecrenier stressed, there can be no EU-wide UDI system.

(MedTech Forum, 15-17 October, 2014)

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Yes – There is a will!!

- **EU Commission & EUDAMED - GROW Eudamed Team**
  - **Steering Committee**
    - **Working Groups**
      - Clinical Investigations
      - Registration
      - Vigilance
      - Market Surveillance
      - Unique Device Identification
      - Exchange of Data
      - Notified Bodies

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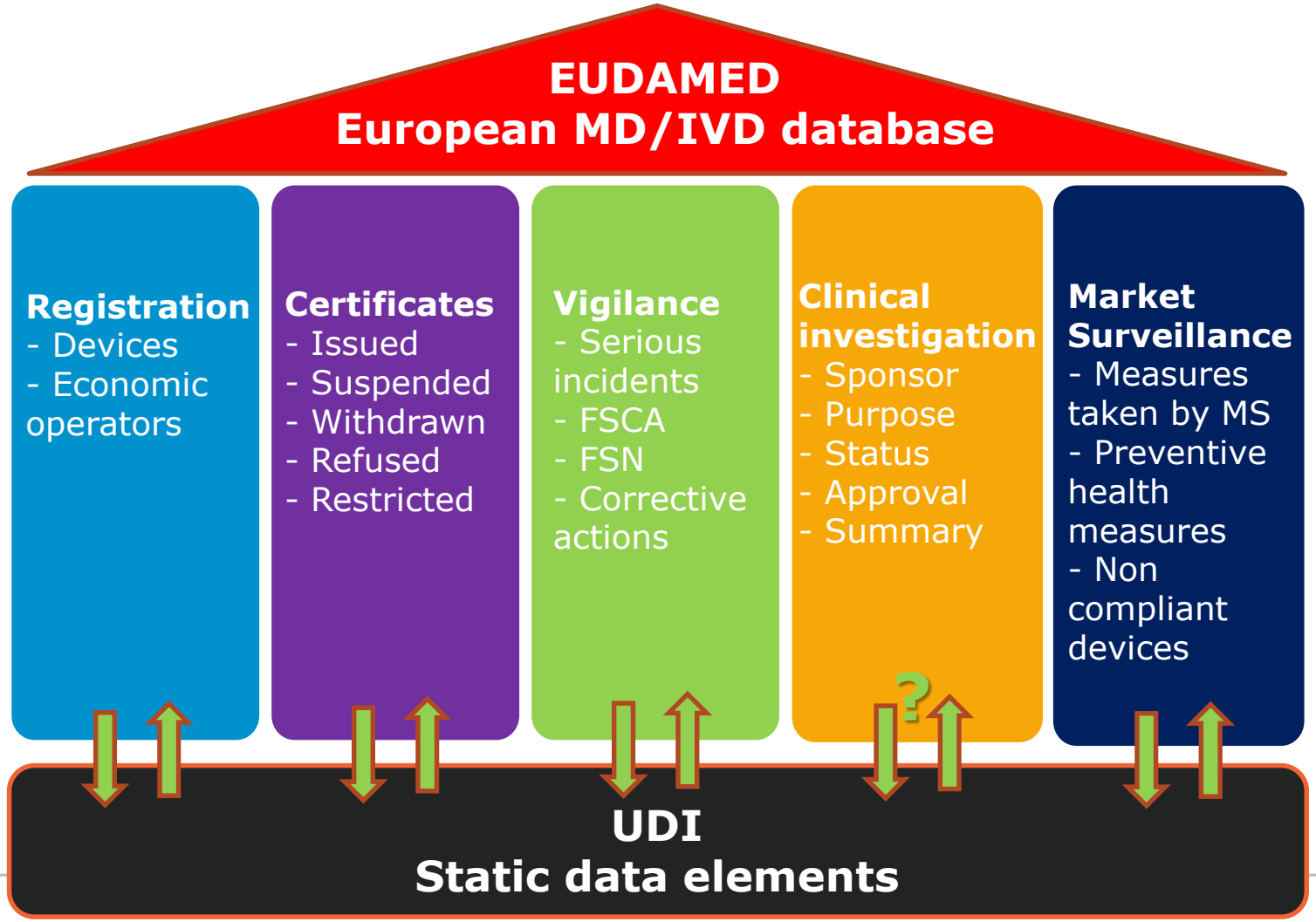

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Commission Roadmap

Business Modeling

Architecture design

Global functionality

Analysis & development of the 1st set of Modules (Actor & Device registration, UDI, Certificates)

Roll-out

Analysis & dev. of the 2nd set of Modules (CI, Vigilance, Market Surveillance)

Roll-out

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Recent Developments

- **EDMA/Eucomed Meeting with EU Commission (8th October 2015)**
  - Head of Unit, Salvatore Dacunto
  - UDI/Eudamed parts of the Medical Device and IVD Regulations

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Points for Discussion

- **Inconsistency with the FDA/IMDRF** – Risk of divergent systems
- **Eudamed and National Databases** – risk of fragmentation and loss of traceability
- **Lack of the process -** for applying for UDI exemptions, alternatives and time extensions
- **Vague obligations - for** the economic operators, healthcare institutions, and other actors

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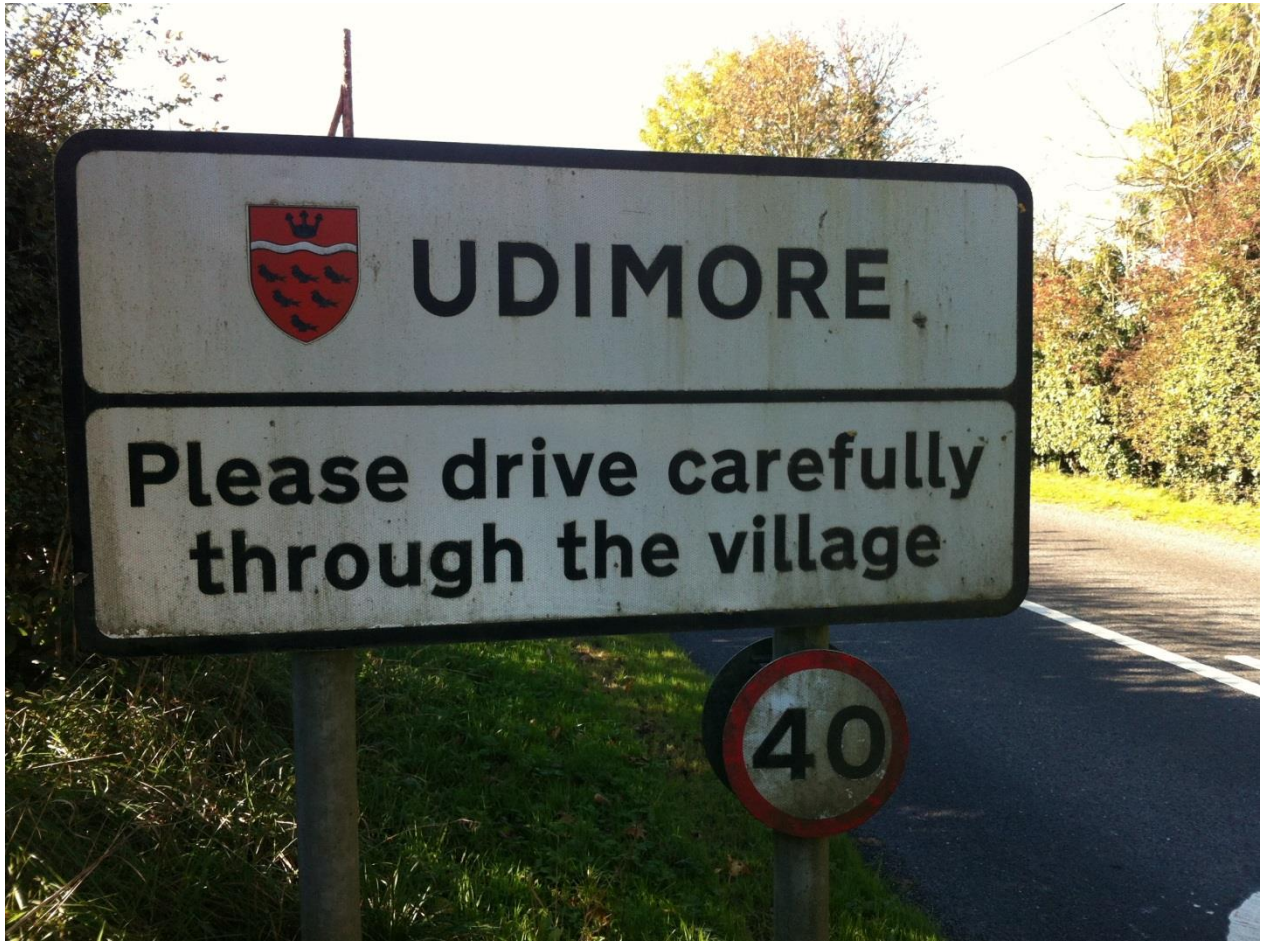

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Thank You

Andrew Rutter

Manager, Regulatory Affairs

+44 (0)1656 778038

ARutter@its.jnj.com

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