



# HUG/HLS Serialisation Work Team

Berlin 30<sup>th</sup> January 2007  
Stephen Hess, Merck

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**Serialisation** – a combined effort of  
GS1 HUG™ and HLS BAG

## Serialisation

**Initial discussion:** How to address some current and potential U.S. regulations at the state and federal level about controlled substances and electronic pedigree.

Evolved to defining a way to **serialise pharmaceuticals** at **pallet, case and packaging and item level**.

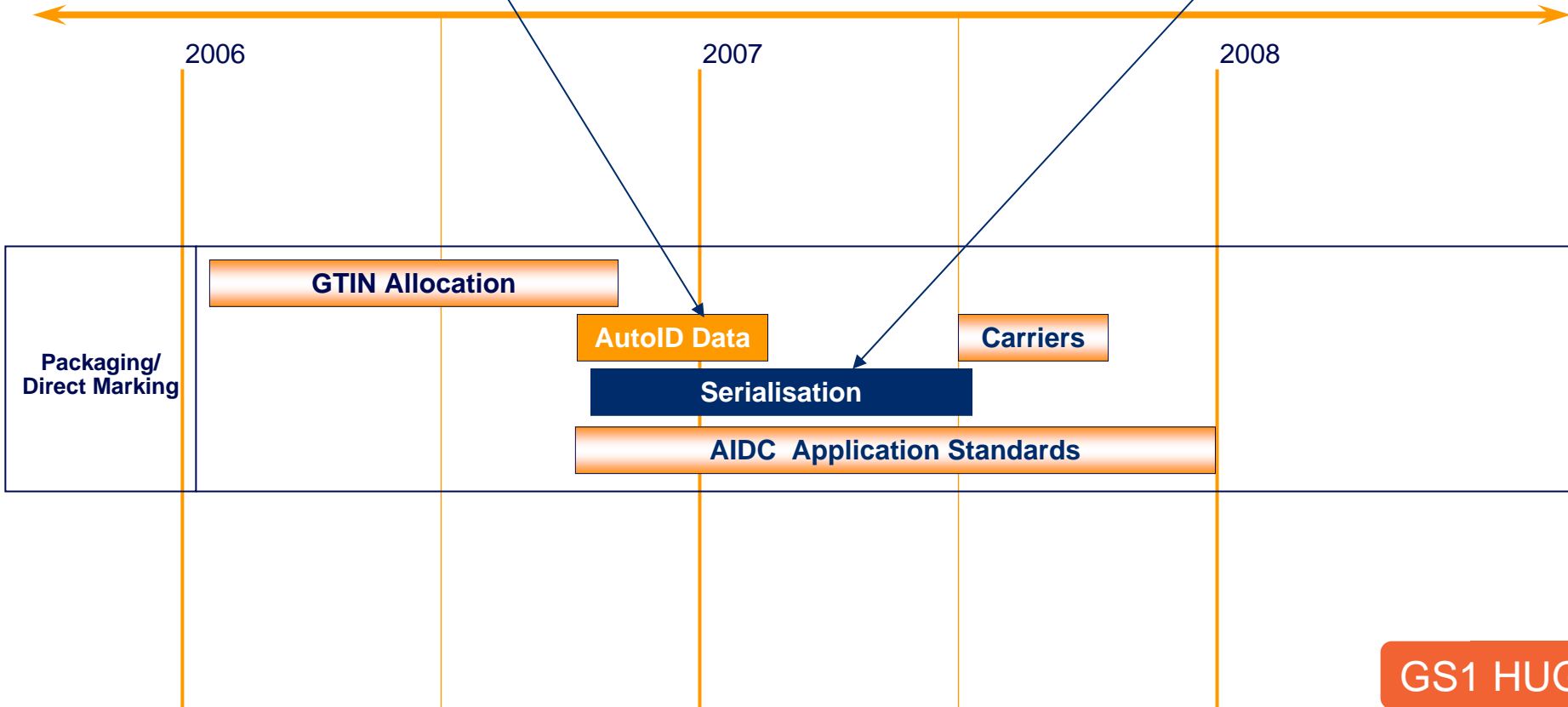
Focus then moved to **global work, covering all healthcare themes**.



# Introduction – Work Teams versus Roadmap

## “AIDC Application Standards”

AutoID Data Work Team  
Serialisation Work Team





## Serialisation Work Team Work Team Leaders



**Stephen Hess**

**Executive Director of  
Packaging Technology**

**Merck**



**Pierre Stoquart**

**Director Packaging &  
Logistics, Technical Services**

**Glaxo Smith Kline**



## Serialisation Work Team Members

- Abbott
- AdvaMed
- Aesculap
- Amgen
- Astra Zeneca
- Baxter
- Boston Scientific
- B.Braun
- Cardinal Health
- Cook
- FDA
- GSK
- HDMA
- Johnson & Johnson
- McKesson
- Medtronic
- Merck Germany
- Novartis
- Pfizer
- Purdue
- Roche
- Sanofi-Aventis
- St. Jude
- Tyco Healthcare
- Wyeth



## Serialisation Work Team Members

### - And GS1 Organizations from:

- Australia
- Austria
- Canada
- China
- France
- Hungary
- Italy
- India
- Ireland
- Japan
- New Zealand
- Spain
- Switzerland
- UK
- USA



# Serialisation

2006

2007

Nov

Dec

Jan

Feb

Mar

Apr

May

June

Review Mission & Vision

Establish Team

Approve Objective & Scope

Approve Business Requirements

Approve Data Requirements

Submit Change Request

## key

--- physical meetings

task scheduled

task complete

Berlin

tbd



## Objective

### Auto-ID Application Standards Team's Objective

Construct packaging/direct marking AIDC application standard(s) specific to appropriate product group or sub-industry requirements, with patient safety as the highest priority and minimise the number of different healthcare application standards and associated required AIDC technologies while maintaining practicality and appropriate differentiation.

**...and create a healthcare application standard to meet our business requirements ...**







## Objective Serialization Work Team - Definition



Mass Serialization is the process of generating and applying codes to identify uniquely each individual instance of a given product entity. (For example each individual pack of a pharmaceutical product defined at SKU level). The codes may be sequential or randomized. The codes may be represented in a number of ways e.g. in human readable form (alpha-numeric) or machine readable e.g. barcode or RFID.

A serial number is a code, numeric or alphanumeric, assigned to an individual instance of an entity for its lifetime. Example: Microscope model AC-2 with serial number 1234568 and microscope model AC-2 with serial number 1234569. A unique individual item may be identified with the combined Global Trade Item Number (GTIN) and serial number.



# Serialisation



## What's the interest in serialisation?

To determine the global healthcare industry's size and structural requirements for specific data elements (*e.g., lot numbers, serial numbers*) to support patient safety and product authentication for healthcare products as defined by GS1 HUG below:

- Vaccines
- Biologics
- Therapeutic nutritional products
- Pharmaceutical
- Medical Devices (*e.g., Instruments, Implants*)



## Scope

### Serialisation Work Team's Scope



The Serialisation WT will review and document business and regulatory requirements for serialisation by:

- Size (capacity needed)
  - All Healthcare
  - By product (GS1 HUG)
  - By product (GTIN)
  - By lot
  - By serial number
- Meaningful numbers versus randomization & affect on capacity
- Decentralization/centralization of allocation & affect on capacity
- Structure
  - Numeric length
  - Alpha-numeric length



# Scope Supply Chain Boundaries



Manufacture

Distribution

Care Facility



From: Finished Goods

To: End of Treatment

**These are the boundaries**



## Contact details

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# AIDC Data & Serialisation Work Teams Deliverables

