Healthcare Supply Chain
Importance of collaboration based on global standards

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Agenda

- Why do we need global standards ?
- Where do we need global standards ?
- Who benefits from global standards ?
- Best practices
- Country-specific requirements
- Conclusions

Why do we need global standards ?

- Healthcare is a **global business** where supply chain partners **exchange** goods and information

- Manufacturers often apply 'center of excellence' concepts

- World-wide / cross border deliveries

- Country-specific Auto-ID regulations have major impact on product assortment and on supply chain management
  - Smaller production lots, additional costs for warehousing, additional administration efforts, etc.

- 'Late-fit concepts' often not possible
  - 3-level packaging hierarchy, product protection, no access to inner packaging levels outside the production environment, etc.

Why do we need global standards ?

> Global standards are
> key success factors for
> process improvements

Where do we need global standards ?

1. **Machine-readable identification**
   - Encoded data
   - Bar code carriers
   - Application standards

2. **Electronic data exchange**
   - Data pools + formats
   - Identification keys
   - Data attributes

3. **Traceability**
   - Clear responsibilities
   - Process transparency
   - Realistic level of granularity (i.e. lot no based or serialization)

Who benefits from global standards ?

The whole healthcare community !

- **Manufacturers**
  - Investment security
  - Lean processes
- **Purchase organizations**
  - Access to harmonized/qualified data
- **Healthcare providers**
  - Critical mass for i.e. bar code usage easier to achieve
- **Patients**
  - Enhanced patient safety (i.e. right patient – right product)
- **Regulators**
  - Enables effective traceability, market surveillance / vigilance, other

But any deviation complicates the supply chain …

Best practice 1: UDI Initiative

- Supply chain stakeholders are involved in the development of a global harmonized approach for UDI through the GHTF

- Risk-based approach
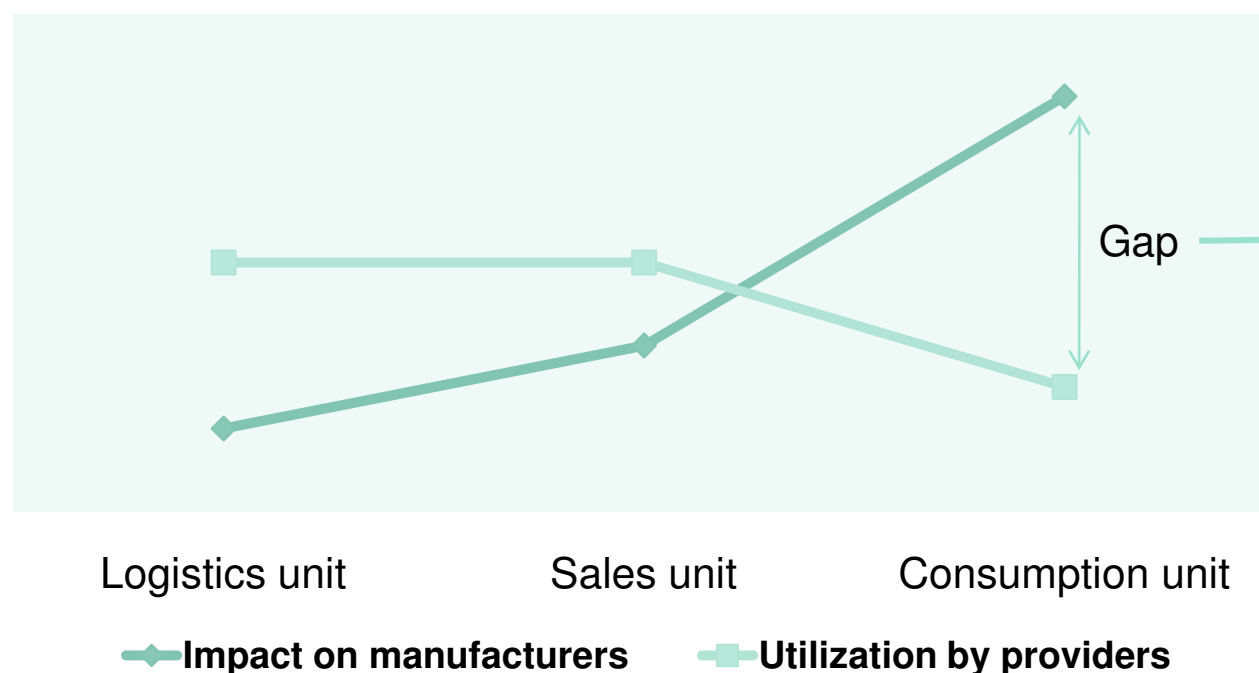
- Avoid over-interpretation

Our recommendations :

- Do not ignore economical impact of regulations, both on the side of the manufacturer and on the side of the provider

- Low-hanging fruits first

Best practice 1: UDI initiative

- Technical and financial impact of implementing bar codes and UDI varies per packaging level
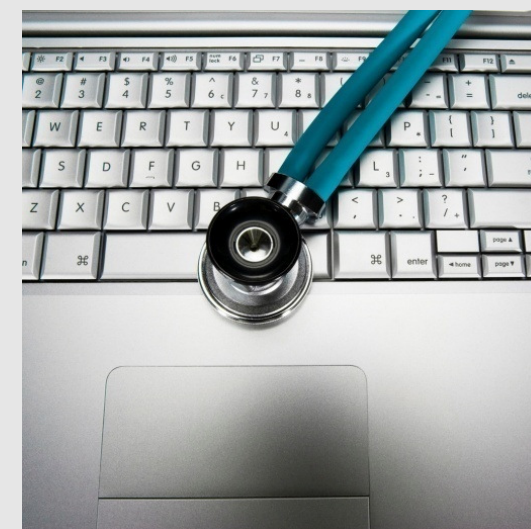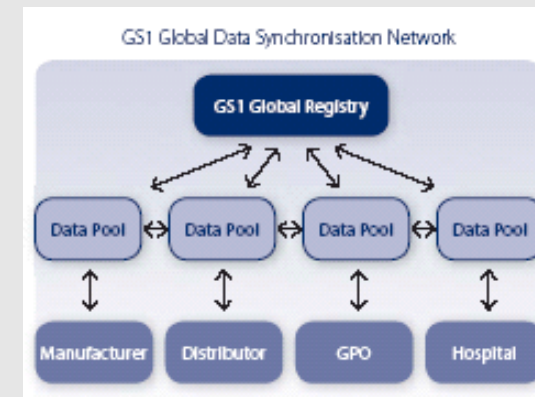
- Utilization by providers too…

Bar codes in healthcare

Gap → •Do we need bar codes for everything ?
•Nobody intends to scan everything at consumption unit level

Logistics unit   Sales unit   Consumption unit

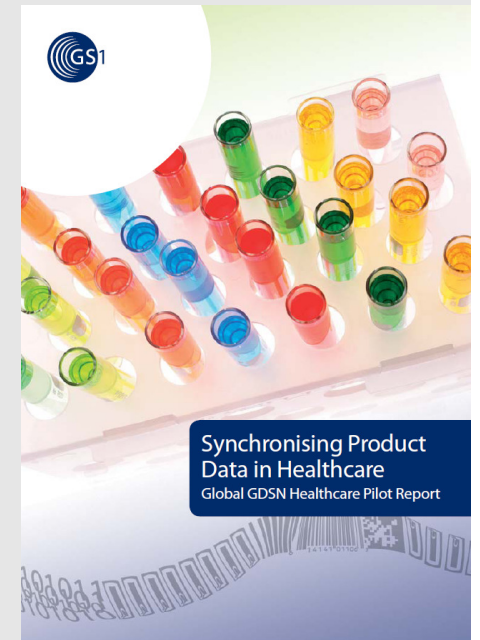◆ **Impact on manufacturers**   ■ **Utilization by providers**

Best practice 2: GDSN

- GDSN will help all supply chain stakeholders to **minimize efforts** regarding data administration and country-per-country data upload procedures

- Usage of GLN and GTIN as the single key for partner and product identification will **avoid misunderstandings**

Best practice 2: GDSN (cont'd)

- **Functionality of GDSN is proven**

  - Global pilot (Australia – US / 2008) successfully completed

  - Demonstrated how the GDSN supports healthcare supply chain and product data needs

  - Demonstrated how the GDSN works across international boundaries

Best practice 3: Global Traceability Standard

Published in March 09, the Global Traceability Standard for Healthcare (GTSH) is the first time ever to have a **process description** for tracking & tracing healthcare products

- includes physical flow and information flow
- contains definition of minimum requirements
- to comply with regulatory guidance on recalls
- to reduce business risks above and beyond legal compliance
- to support effective logistics and quality management
- etc.

GS1 Standards Document
Business Process and System Requirements for Supply Chain Traceability
Global Traceability Standard for Healthcare
Issue 1.0.0, Feb-2009

Best practice 3: Global Traceability Standard (cont'd)

Published in April 09, the GTSH Implementation Guide **assists any and all stakeholders** to implement a traceability system in line with the GTSH

- Common language
- How and what to track & trace
- Which data to exchange
- Which technologies to use
- Etc.

GS1 Global Traceability
Standard for Healthcare (GTSH)
Implementation Guide
Issue 1, April-2009

Country-specific requirements

- **Avoid** country-specific requirements / regulations

- **Existing country-specific regulations** should be

  - identified

  - analyzed

  - discussed

  - **migrated** to global standards

  - within a suitable time-frame

- **Pre-requisite**

  - proven **global standards that meet country-specific needs** must be available
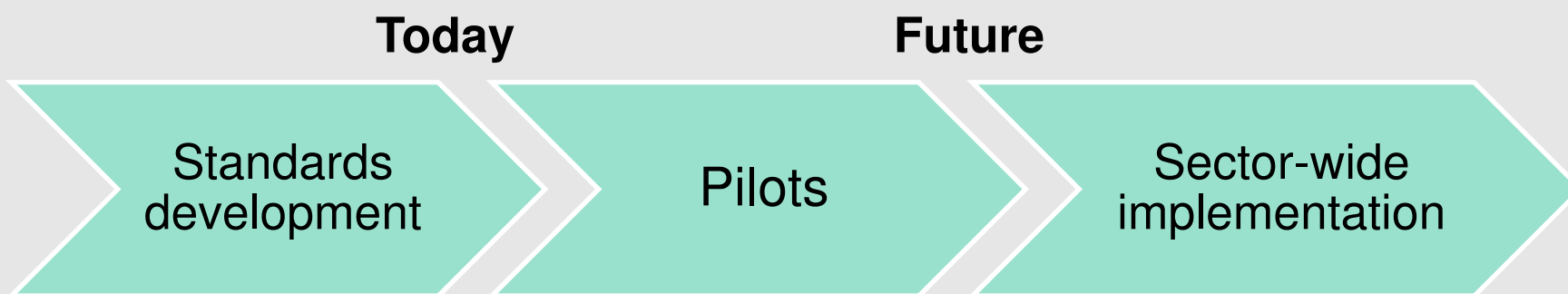
Conclusion 1: Believe

Eucomed and B. Braun

- **Believe in global standards**
- Have been contributing to its development since the beginning
- Endorse GS1 Standards and recommend its step-by-step implementation

BUT the best standards won't be beneficial if not used across the entire supply chain - 'gear box effect'

- Manufacturers deliver the pre-requisites
- Healthcare providers have to be ready to use those global standards
   Planning resources, investments, process adjustments, etc.

Conclusion 2: Move forward

Today

Future

Standards development

Pilots

Sector-wide implementation

Let's not stop half way

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Conclusion 3: Keep it simple

The most important key success factors are:

- Ability of all supply chain stakeholders and regulators to **contribute** to the standards development process

- Willingness to **adopt** the global standards or to promote its usage

- Keep the **balance** between theoretical models, technical feasibility and cost effectiveness of any solution

  "It's better to start at a lower level in an appropriate timeline than to wait for the perfect solution for ever !"

  "Simple solutions break down barriers !"

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Thank you very much for your attention !

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