Panel II: The basics of global data standards and data sharing for traceability

Addis Ababa, Ethiopia

9 May 2018
Panelists

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Master Data

Addis Ababa, Ethiopia

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GS1  9 May 2018
The Master Data problem

Every company has a database filled with master data about the products they make, sell, or buy.

But when one company changes any bit of information in their database or adds a new item, another database becomes outdated!
What happened to master data over the years

- Systems have evolved in silos over the last 40+ years
- The link between “process” and data was broken, and remains so in many cases
- Master data is found throughout the enterprise, structured & unstructured
- Lack of understanding of the intended purpose of the data (i.e. procurement, logistics, pharmacy, regulation)
- Data quality starts at the source and needs to be maintained throughout the information supply chain!
The Challenge – for manufacturers

Where do we start???

How do we define success???

What are customers looking for???

What data do I have and what do I need to start collecting???

Are we in compliance???
The challenge – for hospitals

How hospitals get data:
• Printed catalog
• Price quote
• PDF data
• Excel tables
• Text data
• Link to website
The challenge – for regulators

- U.S. Department of Defence* discovered that:
  - product catalogues had problems matching the correct manufacturer name for 30% of the medical devices and 20-25% lack the product brand name
  - the part number ‘8630’ in the product catalogue of a leading GPO was linked to 9 different numbers from different distributors

- “Different manufacturers use different standards in different ways if they use anything at all. Distributors apply their own. Hospitals apply their own. And we just sort of cascade into this series of events which means that we can’t find devices.”


- In the US from 2005 through 2009, firms initiated 3,510 medical device recalls, an average of just over 700 per year.

Regulators need to ensure highest levels of market surveillance, to efficiently manage adverse event reports and to quickly recall products, not only in their country but also across borders

* Source: US DoD Study
Managing master data: Preferred state

**Supplier = data source**

- Needs single point-of-entry
  - One database to load new item data and update data on existing items
- Needs security
  - Authorisation access by supply chain partners
- Standards-based
  - Standard identification keys
  - Predefined (set of) product attributes

**Hospital & Regulators = data recipient**

- Need single point-of-truth
  - One source for up-to-date, accurate data
  - Continuous synchronisation
- Standards-based
  - Standard identification keys
  - Consistently formatted information
  - Complete information
Data Governance

Roles and Responsibilities

Enterprise wide Data Management

Data Quality

The quality of the data is reflection on the quality of the product
Information lifecycle: Data chain of custody

1. Create, Import or Receive
   - Collect, Create, Receive & Capture

2. Enrich/Validate
   - Data Quality

3. Activate
   - Push to users

4. Audit/Evaluate
   - Routine Monitoring

5. Update/Maintain
   - Maintain, Protect & Preserve

6. Inactivate/Archive
   - Remove from active use

7. Purge
   - Delete from system
<table>
<thead>
<tr>
<th>Manufacturers</th>
<th>Distributors</th>
</tr>
</thead>
<tbody>
<tr>
<td>The quality of the data is a direct reflection on the quality of the product</td>
<td>Critical link between the manufacturer and the customer</td>
</tr>
<tr>
<td>• Take steps to improve the quality of data at the source</td>
<td>• Establish MDM &amp; Governance processes, including executive sponsorship, roles and responsibilities</td>
</tr>
<tr>
<td>• Establish MDM &amp; Governance processes, executive sponsorship, including roles and responsibilities</td>
<td>• Integrate and maintain integrity of master data provided by the data source across all internal systems</td>
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<tr>
<td>• Enterprise-wide information life-cycle process for all master data</td>
<td>• Develop an enterprise-wide information life-cycle process for all product master data</td>
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<tr>
<td>• Establish Data Quality measures and KPIs to ensure “data is fit for the intended purpose”</td>
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<table>
<thead>
<tr>
<th>Solution &amp; Service Providers</th>
<th>Data Recipients</th>
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<tbody>
<tr>
<td>Partners involved in improving data quality</td>
<td>Data sources need to understand the intended purpose of the data, hospitals and regulators</td>
</tr>
<tr>
<td>• Establish MDM &amp; Governance processes, including executive sponsorship, roles and responsibilities</td>
<td>• Hospitals need transact with GS1 Keys and integrate data into internal systems</td>
</tr>
<tr>
<td>• Maintain integrity of master data provided by the data source across all internal systems and to customer</td>
<td>• Establish MDM &amp; Governance processes</td>
</tr>
<tr>
<td>• Support the use of GS1 Keys, standards and Data Quality practices</td>
<td>• Ensure internal systems are capable of supporting GS1 standards</td>
</tr>
<tr>
<td></td>
<td>• Integrate and maintain integrity of master data provided by the data source across all internal systems</td>
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</table>
The GDSN in action

1. Load GTIN Data
2. Register Data
3. Subscription Request
4. Publish Data

Manufacturer

Distributor, wholesaler, GPO

Healthcare Provider Retailer

Source Data Pool

GS1 Global Registry™

Recipient Data Pool

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Sharing master data

Global Data Synchronisation Network:

A one to many connection
Event-Based Visibility with EPCIS

Addis Ababa, Ethiopia

Craig Alan Repec
Senior Manager, Supply Chain Visibility, EPCIS & RFID

GS1 9 May 2018
EPCIS, a GS1 and ISO open standard

- GS1 Keys identify the “what” & “where” of visibility events
- Works ideally with GS1 DataMatrix
- Helps **share visibility data** across & **between enterprises**
- Enabler for traceability solutions & services

**Serialisation & event-based visibility** will fundamentally change supply chain precision... EPCIS will support this!
EPCIS enables supply chain visibility

- **Tracking**
  Where are the products we shipped?

- **Tracing**
  Where did this batch of products come from?

- **Chain of Custody (CoC) / Chain of Ownership (CoO)**
  Which parties had custody or ownership of these products?

- **Inventory Management**
  How many units are in stock? When does my available inventory expire?

- **Recall**
  Find all Product Y shipped from facility X on 9 May 2018...
The 4 data dimensions of an EPCIS event

- **What** objects are the subject of event?
  
  *Individual objects (SGTIN) or groupings (GTIN + Lot/batch)*

- **When** did this event take place?
  
  *Date, time, time zone*

- **Where** did this occur and where are the objects thereafter?
  
  *GLN of physical location*

- **Why** did this event take place?
  
  *Business step, Disposition, Source/Destination info*
  
  *e.g. Commissioning, Packing, Shipping, Receiving, Dispensing . . .*
Designing a visibility system using EPCIS Implementation Guideline  

1. Collect visibility goals and requirements
2. Document business process flows
3. Break each process flow into series of discrete steps
Process Flow Example
Designing a Visibility System using EPCIS

- **Factory**
  - Vehicle
  - Container
  - Pallet
  - Case
  - Item

- **Warehouse**
  - Load pallet into container
  - Transport container
  - Unload pallet from container
  - Receive pallet

1. **V1** Commission item SGTIN
2. **V2** Pack items into cases
3. **V3** Commission case SGTIN
4. **V4** Pack cases onto pallet
5. **V5** Commission pallet SSCC
6. **V6** Load pallet into container
7. **V7** Receive pallet

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Designing a visibility system using EPCIS

1. Collect visibility goals and requirements
2. Document business process flows
3. Break each process flow into series of discrete steps
4. **Decide which business steps require visibility events**
5. Model completion of each step as a visibility event
6. **Decide which data to include in the visibility event**
7. Determine vocabularies to populate each data field
8. Document visibility events in a **visibility data matrix**

What info does the business application need?
Visibility Data Matrix
Designing a Visibility System using EPCIS

<table>
<thead>
<tr>
<th>Event V1</th>
<th>Event V3</th>
<th>Event V5</th>
<th>Event V6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Commission items</td>
<td>Pack items into case</td>
<td>Pack cases onto pallet</td>
<td>Ship pallet</td>
</tr>
</tbody>
</table>

**What**
- **GS1 Identifiers**
  - GTIN & Serial (SGTIN) of item
  - SGTINs of items & case
  - SSCC of Pallet, SGTINs of cases
  - SSCC of pallet

**When**
- **Timestamp**
  - 9 May 2018, 12:35 EAT
  - 9 May 2018, 13:04 EAT
  - 10 May 2018, 10:24 EAT
  - 10 May 2018, 11:37 EAT

**Where**
- **Location**
  - Packaging line 47
  - A-frame 21
  - Plant 1 palletiser
  - DC 1 dock door

**Why**
- **Business Step**
  - Commissioning
  - Packing
  - Packing
  - Shipping
EPCIS Aggregation Event
Parent-Child logistical hierarchy

Aggregation of items into a case

Aggregation of cases onto a pallet

Disaggregation of items from a case

Disaggregation of cases from a pallet
Pharma Traceability Experiences & Learnings

• **Serialisation**…
  • is highly complex, much more than adding line equipment
  • impacts many internal and external stakeholders
  • requires extensive planning and testing

• **Collaboration** with regulators and trading partners is critical

• **Standards**-based solutions and clean master data are essential for **interoperability**

• Shared learnings allow for continuous improvement
The Basics of Global Standards and Data Sharing for Traceability
GETTING PEOPLE BACK TO DOING THINGS THEY LOVE

Nutrition
Diagnostics
Medical devices
Medicines
TACKLING CHALLENGING HEALTH NEEDS AROUND THE WORLD

Demand for healthcare rising in growing economies

People living longer

Innovation in personalized medicine

Prevalence of chronic conditions

People taking a more active role in healthcare decisions to live their fullest lives

65% OF SALES OUTSIDE THE U.S.

58% OF SALES IN DEVELOPED MARKETS

42% OF SALES IN EMERGING MARKETS
Emerging Markets

Abbott is the only global company whose pharma business is 100% focused on emerging markets.
What does Serialization & Traceability implementation mean to us?
New regulations are changing the information, symbols and data sharing requirements at the saleable unit.

**Dynamic Coding**
- Human readable lot and expiry
- GS1 DataMatrix with GTIN, lot, expiry

**Serialization**
- GS1 DataMatrix with GTIN, lot, expiry, SN
- China – Code 128 with Chinese Product & Serial Number

**Track and Trace**
(includes Serialization)
- Government
- Packaging Sites
- Distribution
- Distributor
- Dispenser

Proprietary and confidential — do not distribute
Serialization & Traceability is equal to Complexity and Big Data

- The implementation of Serialization and Traceability will transform the supply of medicines
- The complexity will increase and therefore it is wise to invest in the design of the regulation
  - What are the objectives?
  - What kind of stakeholders are effected by the implementation?
  - What are the benefits of using global standards?
  - What are realistic timelines to implement Identification, Data Capture and Sharing Data?

Proprietary and confidential — do not distribute
Example: Turkey

**Model:** Full Track and Trace  
extended to the drugs reimbursement to the patient –  
In- and out-bounds are reported

**Implementation:** Phased - by requirements  
Prescription drugs  
- Serialization in 2009  
- Aggregation and Reporting in 2012

**Success:** Efficient serialization model  
Designed for stopping fraud to reimbursement. The savings granted ROI shortly. The Turkish government is using this system for other purposes, recalls and tax verification-controls

**Challenges:** Gap in Master Data between national repository and industry's data:  
Returns in the first weeks and missing specifications about quality of the barcode led to errors at dispense
Example: China

**Model:** Full Track and Trace  
System controlled by the Authorities  
In- and out-bounds are reported

**Implementation:** Phased - by requirements  
- National production in 2011  
- EDL imports in 2012  
- Remaining products in 2014

**Challenges:**  
Coding is not based on GS1 standards  
Underestimation of complexity and impact on operations  
Linear barcode with Serial numbers generated by a central system  
Central system is not owned and governed by the Regulators  
Additional cost occurring for the manufacturers and distributors

**Outlook:** Launching a GS1 pilot in 2018
Example: Pakistan

**Model:** Full Track and Trace

**Implementation:** Phased - by requirements
- Dynamic Coding in 2017
- Serialization, Aggregation and Reporting in 2019

**Challenges:**
- Coding is not compliant with GS1 standards
- Master data and prices are to be included in the 2D or in the human readable text
- Short implementation timelines
- Serialization of primary packaging is new to the industry on large scale basis
- New, cost efficient solutions are to be developed for this
Challenges for the implementation of different coding systems

- **Equipment is not able to print all codes**
  
  Longer lead times and efforts (verification and testing) driving up the cost

- **Additional information are difficult to print**
  
  Size limitation to read a 2D code are existing as well as the number per lines printable by one print head

- **Upstream complications for external manufacturers**
  
  Same efforts for internal manufacturing needs to be implemented where sourcing is externalized

- **Centralized distribution of serial numbers**
  
  The more we have non-standardized codes and centrally maintained serial numbers the higher the risk is for failures or data breaches
Serialization beyond Compliance – We see also opportunities!

- Optimized Inventory
  - In-transit inventory
  - Reduce & stabilize lead time
  - Updated planning process with actual lead times
  - Multi-stage inventory (safety stock)

- Improved Recall Management
  - Theft stock recalls
  - Faster and partial batch recalls

- Shipping visibility and alerting
  - Error free pick & pack
  - TPL performance management

- Competitive Advantages
  - Value added services by T&T for customers
  - Increase customer loyalty through loyalty programs
  - Inform patients better through e-leaflets and target info
  - Direct distribution to patients possible
  - Customer consumption alerts/monitoring & compliance

- Better Waste Management
  - Waste Statistics (Intelligence)
  - Avoid waste to revert to Supply Chain

- Improve Operations
  - Gain warehouse performance KPIs
  - Process harmonization and standardization
  - Gain production performance

- Avoid Brand Damage
  - Minimize anti-counterfeits
  - Avoid consumption on recalled batches
  - Avoid consumptions of expired batches

- Visibility in parallel trading
  - Price adjustments
  - Better negotiations with distributors / wholesalers

Proprietary and confidential — do not distribute
Global Standards are a Key Success Factor for Serialization and Traceability
Global Standards and Data Sharing
Implementing traceability using a global company perspective

Dirk Van den Wouwer
EMEA Serialization & Traceability Leader
Johnson & Johnson Supply Chain

Regional GS1 Healthcare Conference, Addis Ababa, Ethiopia
May 2018
Johnson & Johnson

- Global science & technology company focused solely on healthcare
- More than 275 operating companies in 60 Countries
- Selling products in more than 175 Countries
- Approximately 130,000 employees worldwide
Our Credo

We believe our first responsibility is to the doctors, nurses and patients, to mothers and fathers and all others who use our products and services. In meeting their needs everything we do must be of high quality. We must constantly strive to reduce our costs in order to maintain reasonable prices. Customers’ orders must be served promptly and courteously. Our suppliers and distributors must have an opportunity to make a fair profit.

We are responsible to our employees, the men and women who work with us throughout the world. Everyone must be considered as an individual. We must respect their dignity and recognize their need. They must have a sense of security in their jobs. Compensation must be fair and adequate, and working conditions clean, orderly and safe. We must be mindful of ways to help our employees fulfill their family responsibilities. Employees must feel free to make suggestions and complaints. There must be equal opportunity for advancement, development and advancement for those qualified. We must provide competent management, and their actions must be just and ethical.

We are responsible to the communities in which we live and work and to the world community as well. We must be good citizens — support good works and charities and bear our fair share of taxes. We must encourage civic improvements and better health and education. We must maintain in good order the property we are privileged to use, protecting the environment and natural resources.

Our final responsibility is to our stockholders. Business must make a sound profit. We must experiment with new ideas. Research must be carried on, innovative programs developed and mistakes paid for. New equipment must be purchased, new facilities provided and new products launched. Reserve must be created to provide for adverse times. When we operate according to these principles, the stockholders should realize a fair return.
Johnson & Johnson Portfolio

Consumer

Baby Care • Body Care • Facial Skin Care • Sun Care • Feminine Personal Care • Allergy Care • Compromised Skin Care • Cough and Cold Care • Digestive Health • Oral Care • Pain Care

Medical Devices

Wound Closure & Surgical Devices • Minimally Invasive Surgery • Joint Replacement • Sterilization • Eye Health • Diabetes Care

Pharmaceuticals

Oncology • Infectious Diseases & Vaccines • Immunology • Cardiovascular & Metabolism • Neuroscience & Pain • Pulmonary Hypertension
Traceability Entails an Integrated Systems & Processes Approach
Enabled by GS1 Global Standards (GTIN, GLN, SSCC, EPCIS, ...)

Enterprise Serialization & Traceability (EPCIS based)

Regulatory Reporting

ERP/WM

Pack Line / Device

3PLs, CMOs, Wholesalers, ...

Enterprise Data Management

Harvesting GTINs
Validating GTINs
Enumerating
Populating GTINs

Artwork – Labelling & Enterprise Standard
Using GS1 Standards to Uniquely Identify and Trace Products

Each product in the supply chain is assigned a globally unique identification number.

The DataMatrix shall contain the following information:

- **(01) GTIN**: 14 characters, numeric
- **(21) S/N**: 12 characters, numeric, randomized
- **(17) EXP**: 6 characters, numeric
- **(10) LOT**: max. 20 characters, alphanumeric

**GTIN A**

**GTIN B / SSCC**

**SSCC**

12 serialized boxes in a case

12 serialized boxes in a case

261 cases to a pallet

The DataMatrix shall contain the following information:

- **GTIN**: 00359676562016
- **S/N**: 123456789012
- **EXP**: 12-2015
- **LOT**: 123456

**SAMPLE**
Different Patterns in Regulations Create a Patchwork
Result - extra complexity, development costs, implementation time and risk
Turning EC FMD Regulation into European Industry Standard
EFPIA recommendation for coding of pharmaceutical products in Europe

DataMatrix – Coding proposal derived from GS1 standards

Manufacturer Product Code (GTIN or NTIN): 14 digits
Unique Serial Number (randomized): up to 20 alpha-numeric characters
Expiry Date: 6 digits (YYMMDD)
Batch Number: up to 20 alpha-numeric characters

+ Minimum requirements on quality of randomisation

EEA License Plate Example:

PC: 012345667891283
SN: 123456789012
EXP: 12-2018
LOT 123456

SAMPLE

(01) 012345667891283
(21) 123456789012
(17) 122018
(10) 123456
Harmonizing Unique Identifier in European Economic Area

Trending to GS1/EFPIA recommendation

- **GS1 GTIN – EFPIA recommended**
  - (UK, Ireland, Czech Republic, Slovakia, Latvia, Lithuania, Estonia, Malta, Belgium, Netherlands, Romania, Bulgaria, Croatia, Hungary)

- **GTIN allowed or will evolve to GTIN**
  - (Scandinavia, Iceland, France, Poland, Switzerland, Slovenia)

- **Include National Reimbursement Number in 2D Data Matrix**
  - (Spain, Portugal)

- **National number for Country Packs**
  - (Austria, Germany)

- **Countries implementing at later date – coding discussions ongoing**
  - (Greece, Italy)
Standards for Improved IT Systems Communication
Opportunity connecting European verification system to SPOR (IDMP)

GTIN = Unique Product Identifier
Global Data Synchronization Network (GDSN)
Improving OTC and supply chain efficiencies by sharing our product content with our customers

- Established in consumer retail ~12 years
- Significant growth in medical devices last 4 years
- Initial pharmaceutical pilot this year
- Consumer retail moving to rich product content
GDSN - A Strength in Global Content Strategy
Collaboration between J&J and customers critical for getting data aligned & improving accuracy

- Treat product data as a highly-valued digital asset as we treat our products
- Publish and maintain accurate product data for customers across the globe – via GDSN
- Leverage standardized language of GS1
- Ensure conversion of physical data to electronic data
- Grow best practices across regions and segments
- Enabler of end-to-end connected visibility
Extend Learnings to Medical Devices and Pharmaceuticals
Involvement of stakeholders is the critical success factor

Supporting Medical Devices
• Several thousand GTINs
• Now in 25 countries – Significant growth in last few years

Preparing for Pharmaceuticals
• Working with GS1 Global and new Use Cases
• Current analysis to prepare Pharmaceutical data
• Pilots initiated in US and EU

Lessons Learned
• Collaboration with each hospital necessary
• Accurate data is imperative
• Continue to improve quality
• Understand business needs
• Start small and share learnings in quick cycles
Importance of Standards
The world is a global village, let’s speak the same language

Internal Communication
- Multiple sectors
- Multiple regions
- Different ERP systems

External Communication
- Regulatory instances
- External manufacturers, distributors, 3 PLS
- Trade organisations, wholesalers, pharmacies

Avoiding Operational Complexity
- Manufacturing & distribution for different regulations
- External manufacturers producing for different Marketing Authorisation Holders

Mergers, Acquisitions & Divestitures
- Decrease transition complexity when adhering to standards

Interoperability
- One networked company IT system environment
- One IT development for each deviation
- Linking product codes reduces complexity
7 Billion Reasons to Care

GS1 Global Standards Will Benefit Patients and Consumers Everywhere
Discussion

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