GS1 Ireland Healthcare User Group (HUG) Information Day

FMD Implementation challenges for the manufacturers

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FMD Implementation Challenges – Industry Perspective

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Industry Perspective

Introduction Pfizer History

Serialization Implementation – The Basics

Key Challenges

Serialization Best Practices & Lessons Learned

Key Takeaways
Pfizer Serialization History

- **Compliance** – China, India, Korea, US (Argentina, Saudi Arabia)
- **Active** – China, Korea, Saudi Arabia, US, **EU**, Brazil
- **Monitoring** – 20+ mandates …. and counting
- 40+ live sites/CMOs (100+ lines), 15 logistics facilities and 50+ active ongoing implementations
- **Collaboration** – Trade Associations, GS1, Rx-360, Regulators, etc.
Serialization Implementation

Configuration of Pfizer and Contract Manufacturers packaging lines based on unique mandate requirements.

All data management occurs within the PFE Serialization Control Tower (SCT) system.

Packaging Sites (Pfizer sites, Contract Manufacturers, etc)

Packaging Line

100+

349+

349+

~10,000 SKUs

Encoding of key data elements into a GS1 2D Data Matrix barcode.

• GTIN
• Serial Number
• Expiry Date
• Lot Number

Pfizer / CMO Plant Warehouse

Capture of key events from Operations for each Serial Number as it moves through the Supply Chain.

Wholesale Distributor

Hospital / Pharmacy

Communicating event data to governments and/or trading partners in support of compliance.

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In a Nutshell

The DR’s official title states that it is “laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use.”

The DR therefore provides the legal basis for the key elements of the FMD ( Directive 2011/62/EU), notably:

- Serialization by manufacturer
- Verification at point of dispense
- Safety Features:
  - Unique Identifier (PC, Lot, Exp, SN)
  - Anti-Tamper Device (ATD)
- System set up and governed by stakeholders under supervision of competent authorities

PC: 09876543210982
Lot: A1C2E3G4I5
Exp: 140531
SN: 12345AZRQF1234567890
FMD Implementation Strategy

- Transition member states from nonserialized to serialized operations based on market readiness
- Align regulatory and artwork impacts with line enablement for SKU commercialization in line with the provisions of the Delegated Regulations
- Assess impact on logistics activities performed in the member state
- Enable member states via deployment plan, taking into consideration key drivers detailed below

**Regulatory Impact**
- Product notification – e.g., central, MRP / DCP, national
- Product launches & transfers

**Artwork Impact**
- Shared packs
- Batching of changes to artwork and notifications to competent authorities

**Source Location Enablement**
- Transition to line enablement – equipment installation, SKU configuration
- Individual member state requirements for coding

**Market Readiness**
- National System Readiness
- Data upload to systems
- Store in SCT & retrospective upload
- Logistics readiness
Leverage a regional and local concept – includes national level interactions and enablement of key functions, led by a Project Manager, Logistics/Planning (GSCPM), Regulatory and Artwork. Members from the Global Serialization PMO – led by Market Coordinator Support Team – will join regularly occurring meetings as needed.

Note: Team structure is flexible to meet individual country needs i.e. Ad-hoc representation from Finance, Commercial, Government Affairs, Legal etc. as needed.
KEY CHALLENGES
Implementing Serialization is highly complex, and much more than adding packaging line equipment.

- Standardization of a global technology solution for Serialization data configuration and reporting
- Create interoperability with multiple types of site/line solutions
- Rationalize master data
- Leverage centralized project management capability to ensure compliance to global standards
Stakeholders

Serialization impacts a large number of internal and external stakeholders throughout the supply chain.

- Campaign for broad organizational awareness of impacts of Serialization
- Leverage a strong governance structure to gain support of senior leaders cf. signing of contracts etc.
- Collaboration with trading partners and regulators is key to a successful deployment
Serialization comes at a large cost (financial and operational) to the organization that must be minimized. Deviations from global standards further increases cost and complexity and reduces efficiency.

- Align with business and investment plans (network optimization, sourcing strategies, etc.)
- Create harmonized standards, modular builds and consistent timing
- Leverage global solution architecture to improve speed and flexibility
- Focus on sharing learnings and working for continuous improvement

• Operational Efficiency impacts can be significant in beginning phases, and eventually return to normal
• Implementation costs can be high, especially if utilizing a non-standard solution
Achieving initial compliance is the first of many steps towards sustainably embedding serialization in BAU operations.

**Journey to Business As Usual**

**TAKEAWAYS**

- Drive for broad awareness from the onset
- Leverage existing business processes, systems, and stakeholders wherever possible
- Develop solutions with a mindset for future operationalization in the business
- Embed and Optimize

**Business As Usual**

- Sustainable execution of operations by the appropriate end state owner with serialization processes and tools incorporated as required
- Owners of BAU processes vary by function

"Operationalization is the journey, BAU is the destination"
Serialization Best Practices & Lessons Learned

Serialization Implementation Timeline & Project Schedule

Understand and mitigate Project Risk

Adopt and advocate for Global Standards

Serialization Master Data

Key Takeaways
**Typical Enablement Project Timeline**

The average timeline for enabling a packaging line for Serialization is 18 months start to finish, and requires integrating with numerous other site priorities.
Timeline – deadline quickly approaching

At EMVO level:
- Connect approx 2500 manufacturers to the EU Hub
- Establish National Systems for 32 countries
- Connect many thousand Pharmacies and Wholesalers
- Serialise all pharmaceutical packages in scope (10.5 bn)

- **February 09, 2019** - 22 months **Not Started ???** - Alternative Serialization Strategies
  - Serialization Hubs (Internal/External)
  - Pre-serialized Components
  - Standalone Serialization Modules/Stations
The Devil’s in the detail!

In-Market Team Awareness and Kickoff meetings

- EU On-boarding Participation Contract
- CP Products strategy LDT
- Comms Strategy
- Pilot Strategy & Process
- Redressing serialized products LDT
- SKU Compliance for “Low Hanging Fruit”
- Assessment for LSP reporting to SCT or to National System only
**EFPIA/M4EU Priority**

- Need to progress setting up of NMVOs and selection of the IT provider (several countries are significantly lagging behind);

- Importance to manage Member States' expectations with respect to data access (to be in line with Article 39 of the Delegated Regulation) in order to monitor costs and complexity;

- Need to get clarity about the data elements to be included in the datamatrix code (coding requirements) at country level in order to enable companies to start the serialisation process;

- Importance for manufacturers to get the option to apply safety features to those products which do not have the obligation to bear safety features (non harmonisation of POMs/OTCs status at EU level);

- Need to address issues related to the mandatory notification of changes to the packaging due to the placing of the safety features (submission of variations to marketing authorisations in some cases with associated fees);

- Need to increase companies' awareness about importance of early on-boarding to European hub;

- Need to progress the implementation of the flat fee cost allocation model (importance of NMVOs to provide up-to-date data on systems costs);

- Importance to enable bulk decommissioning of products (e.g. vaccines) under well-defined specific circumstances (EMVO to elaborate proposals […] at 5 April 2017 FMD implementation workshop).

*Based on EFPIA EMC FMD backgrounder, 23/02/17*
What are Global Data Standards?

**IDENTIFY: GS1 Standards for Identification**

- **GLN** Global Location Number
- **GTIN** Global Trade Item Number
- **SSCC** Serial Shipping Container Code
- **EPC** Serialized Global Trade Item Number

**CAPTURE: GS1 Standards for Automatic Identification & Data Capture**

- **GS1 BARCODES**
  - EAN/UPC
  - GS1-128
  - ITF-14
  - GS1 DataBar
  - GS1 DataMatrix
- **GS1 EPC/RFID**
  - EPC HF Passive
  - EPC UHF Passive

**SHARE: GS1 Standards for Automated Data Exchange**

- **MASTER DATA** GLN Registry for Healthcare®, Global Data Synchronization Network™ (GDSN)
- **TRANSACTIONAL DATA** eCom (EDI)
- **EVENT DATA** EPC Information Services (EPCIS)

**TRACEABILITY**

- Track
- Trace
- Authentication
- Chain of Custody / Ownership
- Returns
- Recalls
Why Global Data Standards?

- Global Data Standards apply irrespective of the geography, economy or regulatory issue being addressed
- Enable operational efficiency
- Replicable across multiple sites
- Simple and cost effective
- Ensure Interoperable product identification, capture and sharing of data
- All supporting improved Patient Safety and helping the fight against falsified medicines
What is Serialization Master Data

Master Data is the “DNA” for the Serialization Program
- It is the “Identity” of the Product and Company Data with necessary elements
- It is the “Bond” that ties all internal and external supply chain solutions together

Serialization Program Key Components
- Business processes are the work flows to be executed
- Master Data is the definition / identity of what the business processes are to be acted on and how

Business Process Integration
- Many internal and external business systems need to be able to work interactively
- The master data serves as the bond that enables the different solutions to talk in a common language
Landscape of Serialization Master Data

Focused on Tactical Support of Packaging Line Implementations

Internal Network
Packaging & Warehouses

External Network
External Warehouses & Distribution

HC Providers & Patients

Patient Protection Is the Ultimate Goal

Source: GS1 US
 Serialization Data Verification

➢ Background
  – Some incidences of missing or incomplete serial number (SN) data in the Serialization Control Tower (SCT).
  – This has led to batches reworked, delays in product shipments, and supply risks in some cases.
  – There are many service tickets logged with SCT serial number data related issues.

➢ Approach
  – Develop a uniform process and standardize documentation across Internal and External sites to confirm accurate serialization data in place at time of:
    (a) batch release, (b) goods dispatched and (c) sale
  – Develop an automated report to confirm and validate serial number data uploaded into the SCT is accurate and complete and matches both physical goods and inventory records in SAP
  – Incorporate Serialization Verification Form (SVF) at different time points as serialized product moves through the supply chain (referred to as clean data hand offs) depending on different business processes
  – The SVF is available to be incorporated into appropriate Batch Documentation or Logistics Records either by inclusion or reference
  – The Serialization Data Verification Process will be incorporated into applicable SOPs and related batch and logistical documentation
  – Investigate deviations and reconcile serial number data in SCT prior to batch release
  – Impacts to contract language in commercial and quality agreements will need to be considered
Key Takeaways

• Start yesterday! Regulatory - Artwork – Line Enablement
• Do not underestimate complexity... especially coding schema and multi-market packs
• Build technical and operational knowledge – promote Blueprint
  – Develop tools and toolkits to enhance competencies through your organization
• Keep your antennae up – don’t ignore changing signals from Markets, minimize proliferation of national requirements
• Communicate and Collaborate
  – Proactive engagement with colleagues & stakeholders
• Consider all impacts to your organization
• Work to a Core Solution and Global Data Standards wherever possible