The Global Language of Business

EU Falsified Medicines Directive (FMD) and Beyond

Implementation Challenges for a Manufacturer

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Bayer AG

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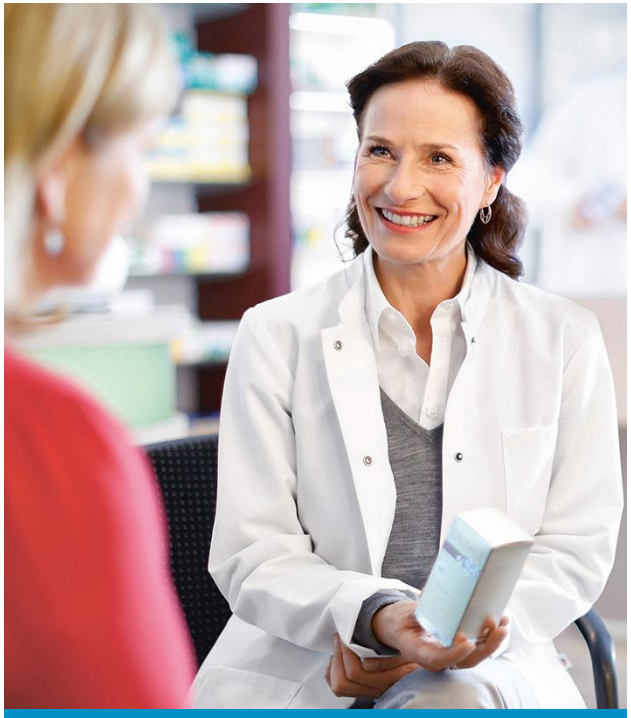
Our Mission
Bayer: Science For A Better Life

Our Business Areas

Pharmaceuticals

- Prescription drugs



Consumer Health

- Over-the-counter medicines, dietary supplements, dermatology products, foot care and sunscreen

Crop Science

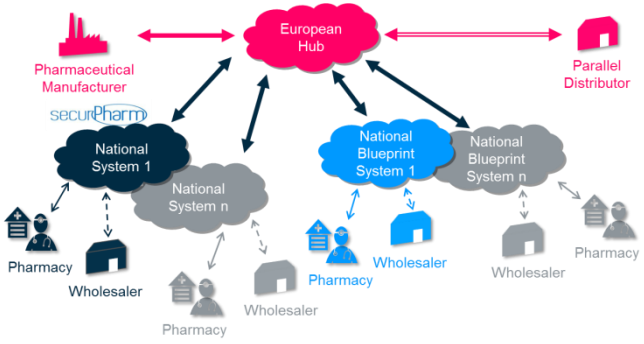
- Innovative crop protection and seeds
- Animal Health

EU-FMD @ Bayer: Implementation Challenges

- Ensure **technical readiness** of **100+ parties**
  - ## Bayer-owned manufacturing sites, ## packaging lines
  - ## Contract Manufacturers (CMOs)
  - ## Bayer-operated warehouses
  - ## Distribution Partners (3 PLs)
  - ## Customers where Bayer acts as Contract Manufacturer (CMO)
- Establish **serialization data exchange** with all **CMOs** and **Customers**
- Establish **exchange** of **regulatory** and **serialization data** with **European Hub**
- **Establish** new / **revise** existing **business processes** for e.g. pack decommissioning, complaint handling, batch recall
- Execute **change process** incl. **regulatory submission** for approx. **4.000 products** (Stock Keeping Units (SKUs))
- Be ready by February 2019

EU-FMD Readiness – Collaborative Challenge for Pharmaceutical Supply Chain Partners

- **Stakeholders** in EU member states to establish Nat'l Governance Organizations
- **Nat'l Governance Organizations** to select repository system providers
- **Stakeholders** and **Nat'l Authorities** to collaborate and determine coding scheme(s)
- **Manufacturers** to equip packaging lines with serialization and tamper-evidence capabilities
- **Wholesalers** and **3PLs** to adapt IT systems and establish business processes for decommissioning and risk-based verification



- **IT suppliers** to integrate verification in pharmacy Point-of-Sales software
- **Retail pharmacists** and **hospitals** to integrate verification in workflows

Joint Goal: Make Medicines Verification Happen in EU by Feb. 2019 **to Ensure Patients' Access to Safe Medicines**

SECURPHARM – THE GERMAN SHIELD AGAINST FALSIFIED MEDICINES

For video please search for 'securPharm version A' on YouTube

What are the Future Coding Requirements in EU Member States + EEA Countries

Coding of single-country packs in Europe – Some examples

- EAN-13 coding already established in most EU countries
  - Migration path to GTIN-14 pretty straight forward
- Nordics to allow for continued use of NTINs for existing products; as of 2019, new products need ‘real’ GTIN
- Belgium to transition from national CNK code to GTIN

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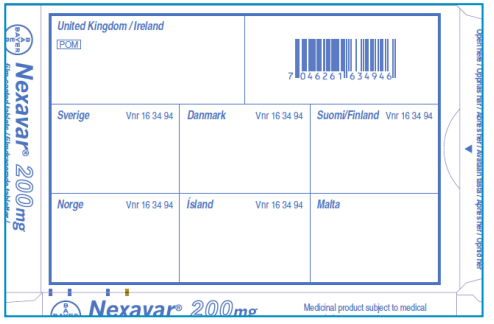
EXP 02/2019



The ‘real’ challenge: Coding of multi-market packs

- Easy where packs bear only one EAN code already today
- Germany to allow for GTIN + NHRN (5th data element) e.g. for DE-AT packs
- Open topic for packs shared between Spain and Portugal
- …

Members of GS1 Healthcare are always up-to-date through access to EU-FMD Coding Tracker

How Can We Avoid Varying Pack Coding Requirements Around the Globe ?

De-facto Standard

- GS1 DataMatrix encoding four data elements (GTIN, S/N, Batch, Expiry date)
- Some countries continue to require inclusion of nat'l number (e.g. Germany, France, Brazil) via NTIN (Nat'l Trade Item Number) or NHRN (Nat'l Health Reimbursement Number) using AI (7xx)

However

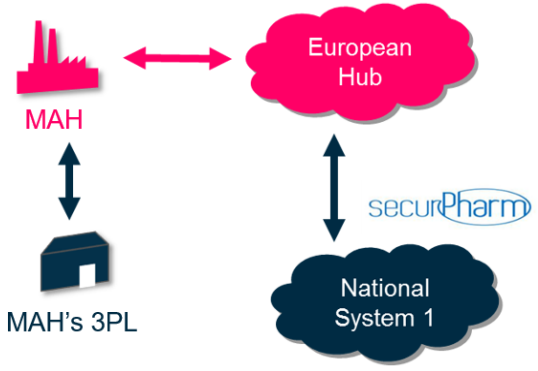
- China has introduced proprietary non-GS1 coding
- Countries consider/request to add information to code (e.g. pack size, tax code, manufacturer name, …)
- Challenge for manufacturers who need to upgrade and re-qualify equipment; space restrictions on packs do not allow for extensive extension of encoded information

Consider to join GS1 Healthcare to benefit from advocacy of GS1 Healthcare and GS1 member organizations for de-facto standard

How Should MAH's Distributors (3PLs) Connect to Verification Landscape?

Problem Statement

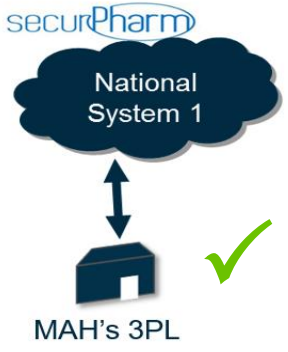
- 3rd Party Logistics Providers (3PLs) need to perform verification and decommissioning activities on behalf of Marketing Authorization Holders (MAHs)



Question

How should 3PLs connect to nat'l verification system (NMVS)?

Remote Access via MAH system and European Hub	• 3PL transactions recorded under MAHs identity • 3 PL to build interface for each MAH he is working with
Direct Access to NMVS via 3PL wholesaler account	• Less systems involved i.e. quicker response times • 3 PL only needs one access channel to nat'l system



Answer

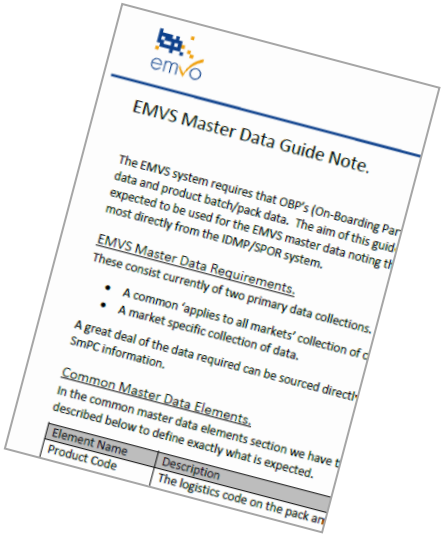
Direct access is preferred model envisaged by EMVO URS

GS1 Healthcare Public Policy workgroup provides access to network of company experts for experience exchange

How are Master Data Reqs. set forth in Delegated Regulation to be Understood?

Problem Statement

- EU Delegated Regulation 2016/161sets forth requirements on master data reporting e.g.
  - Product Name, Common Name, Strength, Pharmaceutical Form, Pack Type
  - Article 57 code / PCID
  - List of ‘Designated Wholesalers’


emvo

EMVS Master Data Guide Note.

The EMVS system requires that OBP's (On-Boarding Par
data and product batch/pack data. The aim of this guid
expected to be used for the EMVS master data noting th
most directly from the IDMP/SPOR system.

EMVS Master Data Requirements.

These consist currently of two primary data collections.

- A common 'applies to all markets' collection of d
- A market specific collection of data.

A great deal of the data required can be sourced directl
SmPC information.

Common Master Data Elements.

In the common master data elements section we have t
described below to define exactly what is expected.

Element Name	Description
Product Code	The logistics code on the pack an

Question

- What does this all mean, and from which source can MAH retrieve this data?

Answer

- Most of required data can be found in regulatory submission / xEVMPD / IDMP
- Guidance will be provided in Master Data Guidance by EMVO (European Medicines Verification Organization); publication expected in June 2017

GS1 Healthcare Public Policy network of experts provides access to recent information regarding EU-FMD implementation

Can Linear Barcode be Dropped upon Introduction of 2D DataMatrix Code?

Problem Statement

- GS1 DataMatrix code and accompanying information requires additional space for printing on outer packaging
- Space is restricted in particular on small packages

Question

- Can linear barcode be dropped upon introduction of 2DMC to free up space on outer packaging?

Answer

- Clear tendency by industry to keep existing linear barcode for interim period until Feb. 2019 (and drop it afterwards as part of any forthcoming change
- Rationale: Stakeholders are only obliged as of Feb. 2019 to be capable to read 2 DMC; dropping linear barcode will pose problems to non-equipped parties

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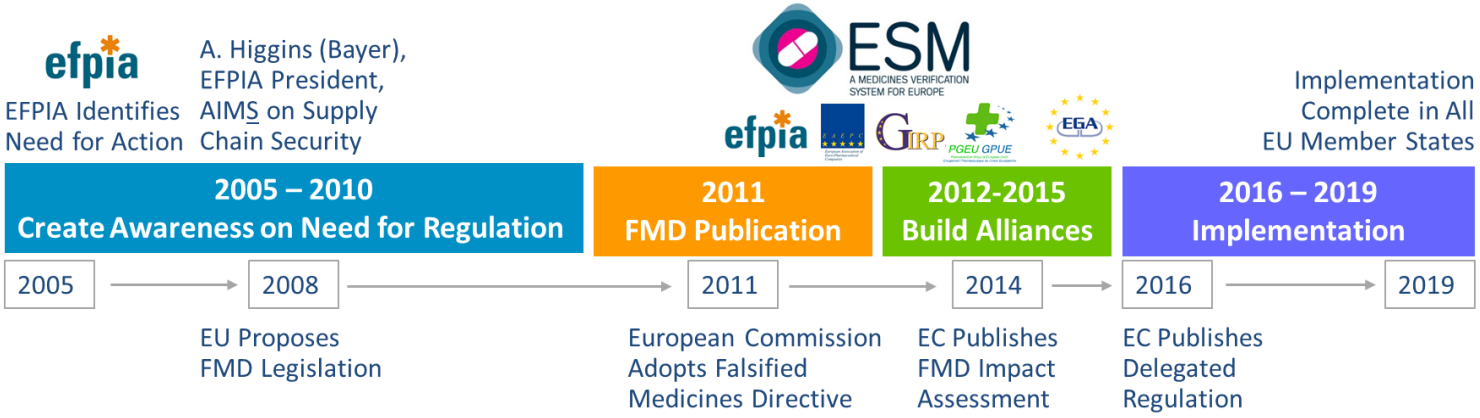
Long Way Already Passed – Challenging One Still Ahead



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It's Definitely Worth to Consider a GS1 Healthcare Membership – Feb. 2019 is Nearby But it's Never too Late !!!

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