The Deadline for FMD Was February 2019 – Where Are We Now?

April 2019

Introductions

Feel free to contact me directly via email

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Be4ward

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- **More than 14 years experience of serialisation**
- **Developed GSK's serialisation strategy, established and led the global team**
- **Work with many pharma and medical devices companies helping them:**
  - **Develop strategy**
  - **Design solutions & select suppliers**
  - **Implement capabilities**
- **Career**
  - **Designing and implementation of production facilities for MARS**
  - **Business Process Design for MARS global SAP implementation**
- **Chartered Engineer**
  - **Honours Degree in Electrical and Electronic Engineering**

We have a team of experienced serialisation professionals at Be4ward.

Topics

- Some terms associated with serialisation
- EU FMD & serialisation legislation
- What has happened since 9th February 2019
- Questions

I am going to assume that everyone at this session has a rudimentary understanding of serialisation.

Some terms associated with serialisation

Some definitions for the purposes of this discussion

Product Coding

- Putting **machine readable product related information on product** and/or packaging
- Reading this information in the supply chain to improve activities

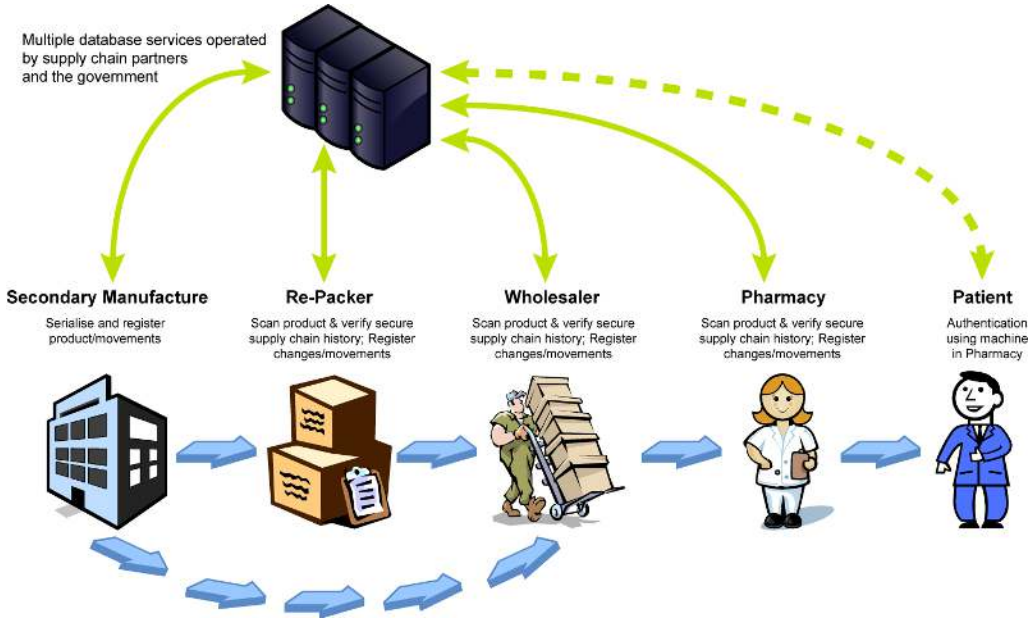
Serialisation

- **Uniquely identifying one or more levels of product and/or packaging** with a unique identifier or serial number
- Using Product Coding to put this information on the product and/or packaging
- **Transmitting serialisation, product and potentially supply chain transaction information to others**
- Reading this information in the supply chain to improve activities
- **Authenticating**:
  - Reading the serialisation information from the product/packaging
  - Retrieving the previously provided information about the product
  - Comparing the product and the information to help verify the product is authentic

Many companies deal with Product Coding & Serialisation together.

It can be useful to think about three models, of which everything else can be considered as a variation

Illustrative full serialization model:



Full aggregation is required to achieve this:

Serialized Doses ⟺ Serialized Units ⟺ Serialized Bundles ⟺ Serialized Cases ⟺ Serialized Pallets

Models for the purpose of this discussion

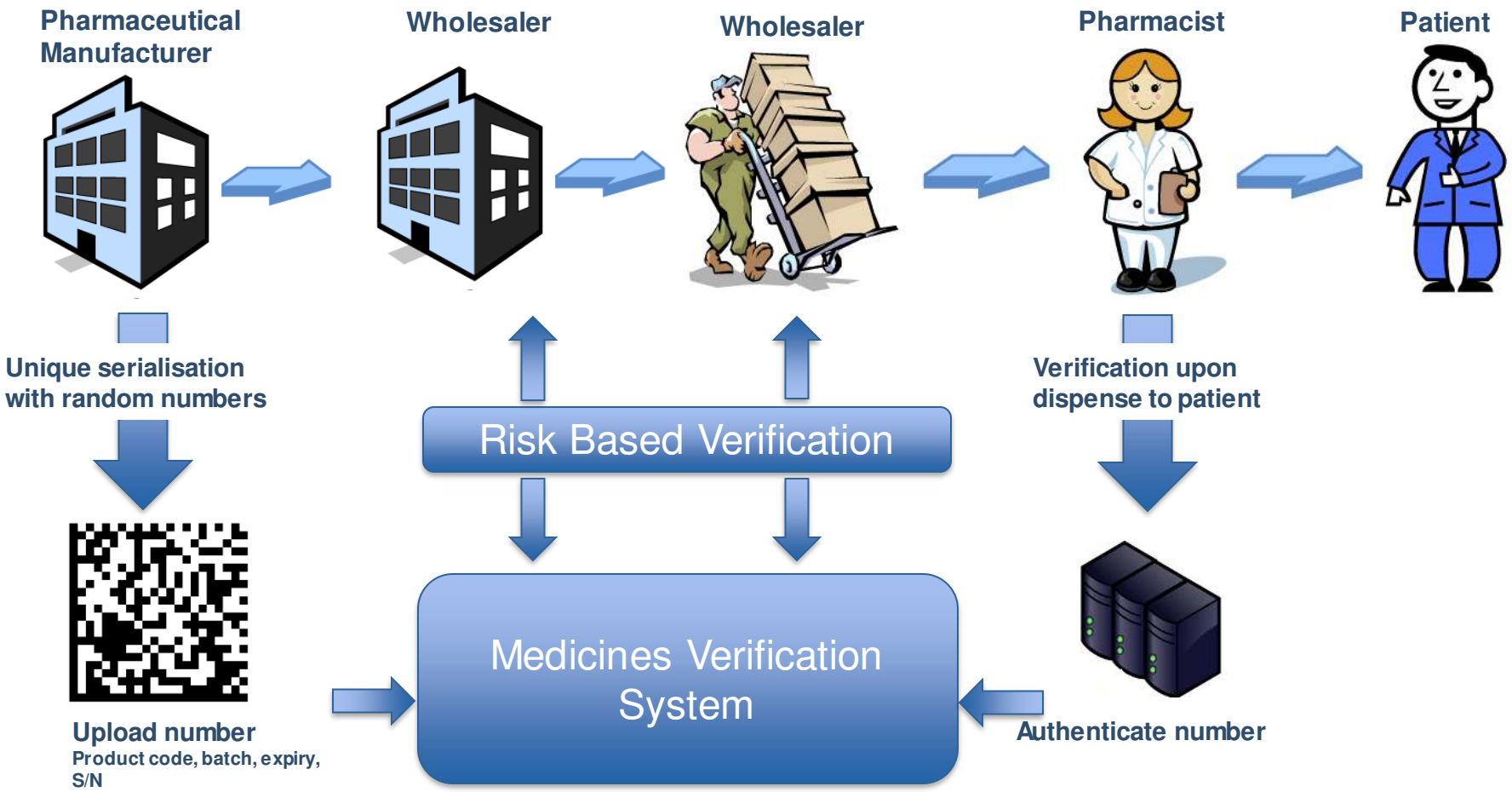
1. **Product Coding**
   - Batch variable product coding
2. **Serialise and Authenticate**
   - Unique identification & publish
   - Authenticate at point of use
3. **Track & Trace**
   - As Serialise and Authenticate, plus…
   - Serialise shippers & aggregate
   - Supply chain transactions update

Examples: France Coding = 1; EU =2; Turkey = 3.

EU FMD & Serialisation Legislation

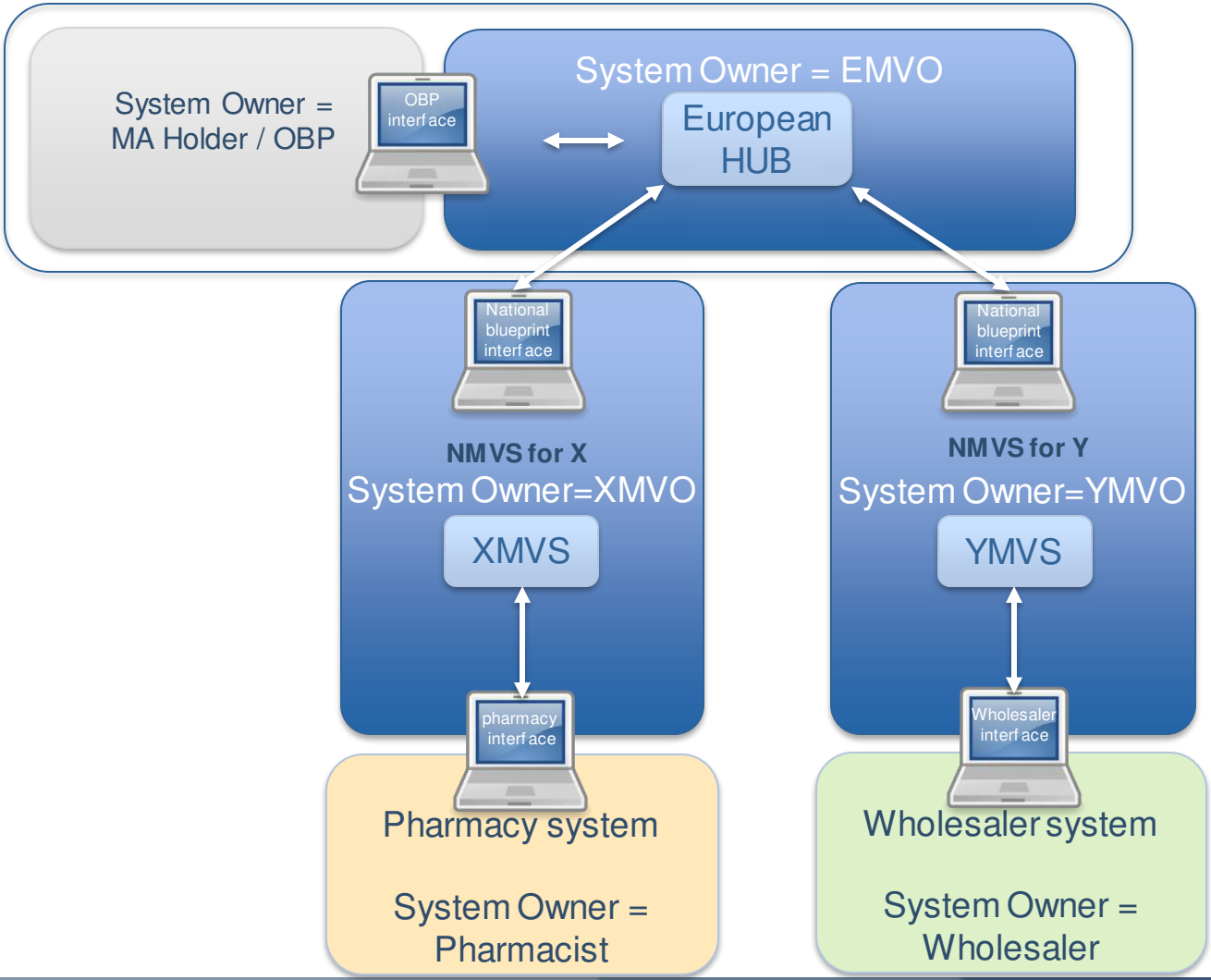
EMVO Authentication Model

Product Flow



EMVO / NMVS Architecture

System Landscape



OBP
On-boarding partner

NMVS
National Medicines Verification System

NMVO
National Medicines Verification Organisation

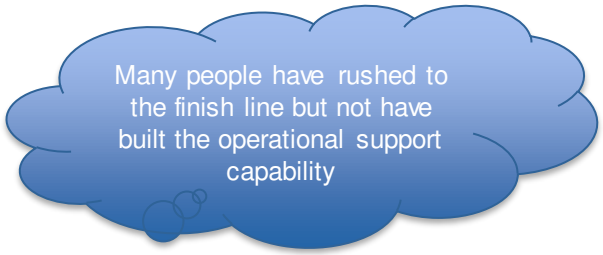
EU FMD Where are we now

Where are we now?

- Systems went live on 9th February
  - EMVS
    - OBP / MAH accountabilities (what CMOs can do)
    - Manual upload
    - Alerts
  - NMVS (multiple countries)
    - Reliability of verifications
- Manufacturers are serialising products
  - Change to certification processes
    - Discussion on certification before or after upload
- Where is decommissioning happening?
  - Supply chain (Export – it must not have a UID on not registered with the EMVS)
  - Pharmacy (MAH observation by Client 700 alerts a day)
  - Where should decommissioning be happening (Article 23 – when is a customer article 23, how does the warehouse know) – leads to need for automated decision making
- Tamper Evidence (no standard for Efficacy)
- Multi-Market packs
  - Restrictions less than they could have been

Some Glitches - if it can go wrong it will…

- Configuration of NTINs
- Usage errors of Serials
- Conflicting Dates in pack / EPCIS
  - What is the right thing to do when no day is in the expiry date human readable.
- Upload of historic data issues
- Make sure that some how you are very clear that the serials are correct complete and accurate before you lose control of the product.



Questions

Be4ward is a niche management consultancy with award winning success in delivering pack change and artwork capability

- Be4ward provides specialist consulting services to the global pharmaceutical industry
- Our team combines operational management experience, subject matter expertise and excellent consulting skills to help our clients deliver successful change
- Whilst we have in depth knowledge of the supply base in our areas of focus, we provide independent advice to our clients
- Our current areas of focus include:
  - **Packaging and artwork management**
  - **Product coding, serialisation and anti-counterfeiting**
  - Product complexity management, late customisation and postponement
  - Secondary packaging supply chain design
  - Post merger legal entity and brand integration
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Our team have won many awards for their work, including the establishment of a world class global artwork capability for a Top 3 Pharma Co.

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