Serialisation in 2020 – Delivery and Challenges

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Introductions

Feel free to contact me directly via email

Andy Cumming - Be4ward
Andy.Cumming@be4ward.com

- **More than 15 years experience of serialisation**
- **Developed GSK's serialisation strategy, established and led the global team**
- **Worked 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

Part of a team of experienced serialisation professionals at Be4ward.

Topics

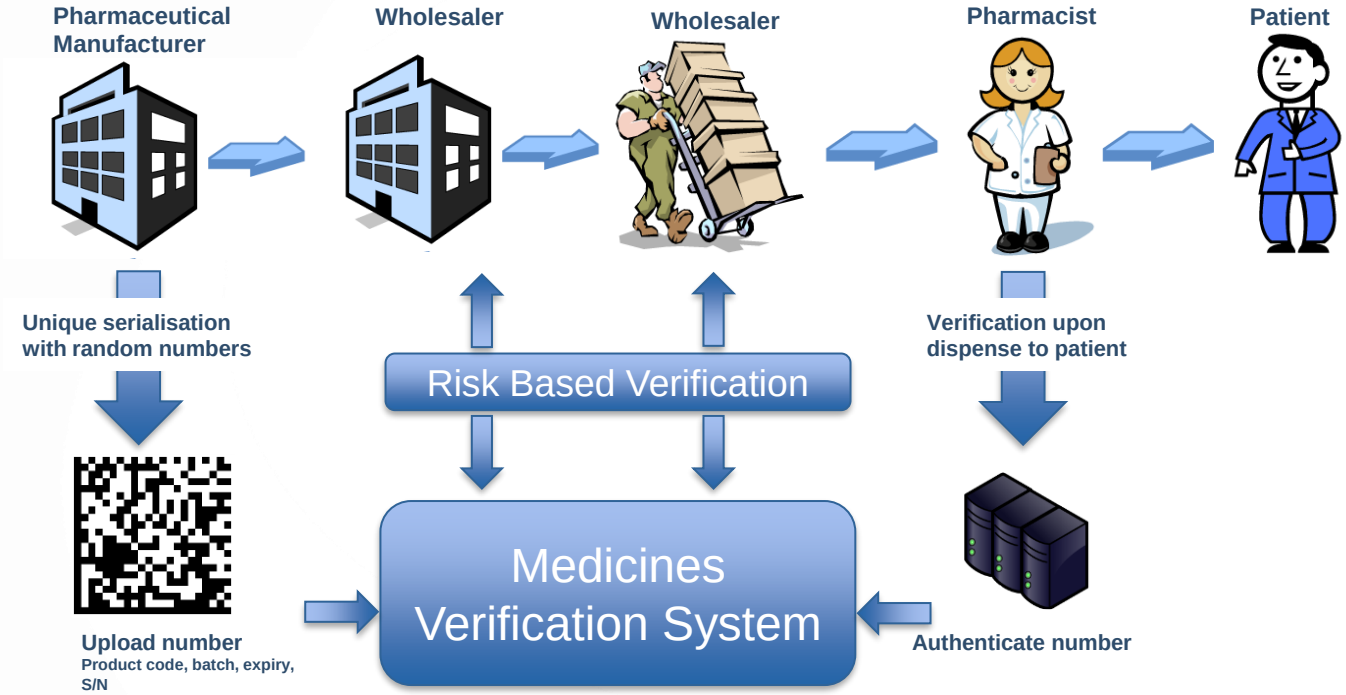
- EU FMD & Serialisation Legislation
- Some learning
  - Managing Master Data
  - Maintaining Systems Validation / Function
  - Acquisitions and Divestments
  - Market Alerts and Issue Management
  - Brexit
  - Aggregation
- Questions

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

EU FMD & Serialisation Legislation

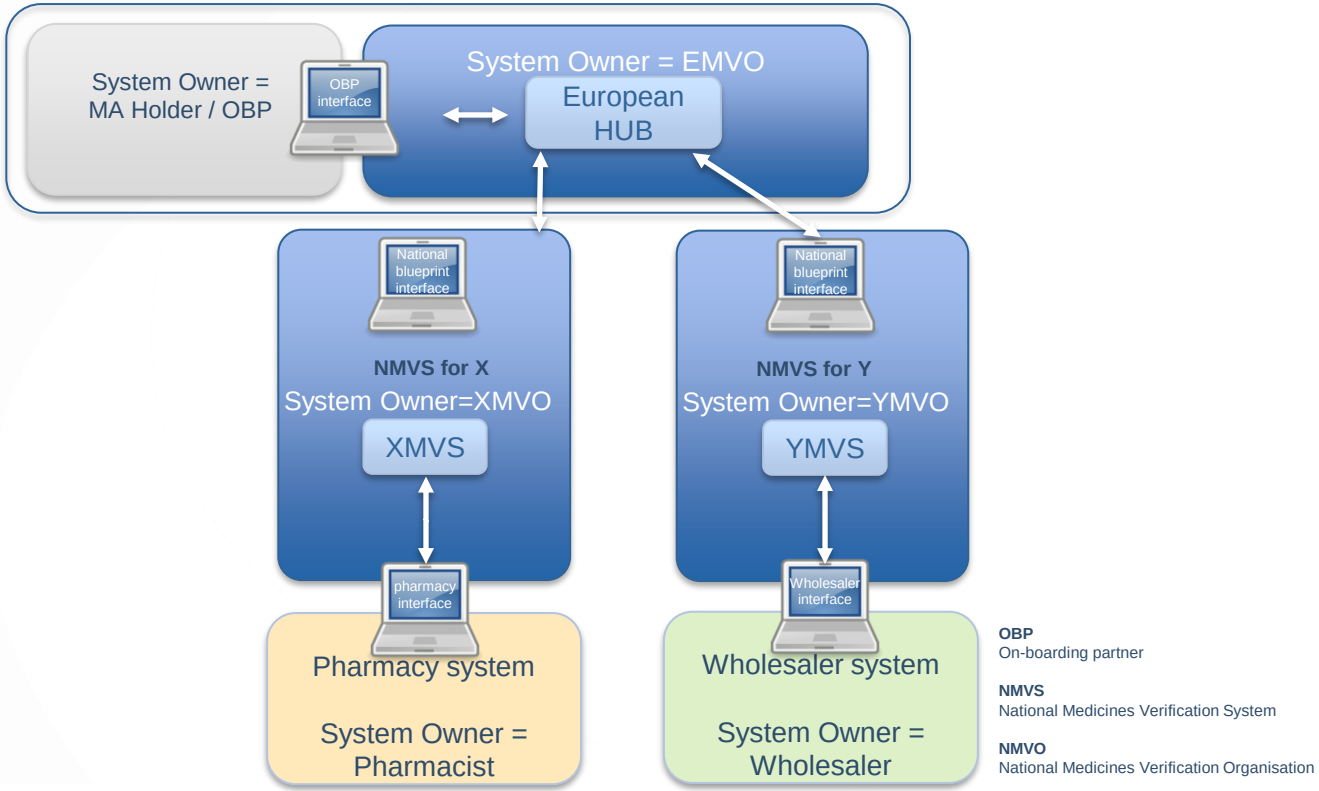
EMVO Authentication Model

Product Flow



EMVO / NMVS Architecture

System Landscape



OBP
On-boarding partner

NMVS
National Medicines Verification System

NMVO
National Medicines Verification Organisation

Where are we now?

- Systems went live on 9th February 2019
  - 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 Learning

Managing Master Data

- Robust processes to record, communicate and configure master data are requried
- The accuracy of master data is critical to the success of operation
  - In one example 8 systems need to have aligned master data (CMO Line, CMO L3, CMO W/H, CMO L4, MAH Interface, MAH L4, MAH W/H, Govt System)
- Confirming that each first packaging of a code/change is accurate avoids repack
- Alignment of management of NTINs not all systems are following the GS1 Guidance
- Where the NVMS requires the NTIN to be reported can identify issues with master data (pack/NMVS)

Maintaining Systems Validation / Function

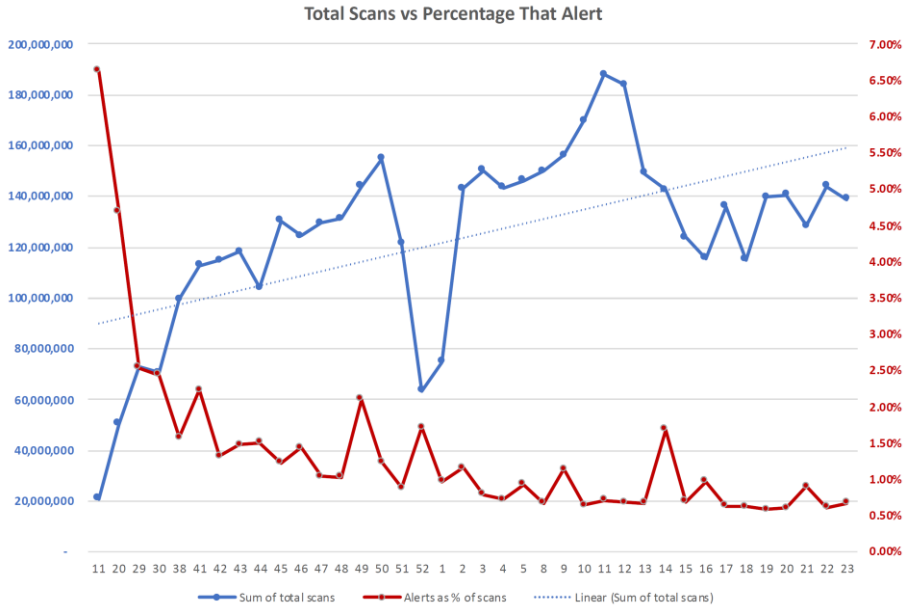
- The EMVS test environment is not fully representative of the EMVS production system. Additional testing required in Production
- Companies Level 4 systems require update and extension
  - Upgrades can have unexpected consequences
  - CMO & Customer connects need revalidation
    - The accountability for validation is with the company using the system not the software supplier. There are often differences in approach between software suppliers and users
  - System upgrades are not synchronised across supply chains
  - Testing can absorb a lot of energy
- Different suppliers have different strategies on environment. 3 environment and 2 environment systems have conflicting development approaches

Acquisitions and Divestments

- The accountability for legacy data needs to be explicit
  - Suitable data migration plans are required
- Change of product code often required
- NTINs need to be transferred between entities. This requires action from the divestor

Market Alerts and Issue Management

- Market alerts need new processes. The level of alerts is around 1% of scans. MAH accountable for responses
  - Processes need to cover the investigation of Market alerts and ensuring that all physical product has data in EMVS
  - Some markets expect responses in short time periods
  - Many issues seem to be created by “poor” scanning in the supply chain
  - Special characters in GS1 DataMatrix have caused some issues
- Risk that there will be a proliferation of reporting requirements
  - Alert management tools are available and can support the MAH processes
  - EMVS developing a tool
- L4 system issues need active management



Brexit

- UK NMVS not expected to be connected to the EMVS after the transition period
- EMVO have a team working on the impacts of Brexit
- Northern Ireland will be a complex issue

Aggregation

- EMVS is looking in to aggregation. A number of purchasers require aggregation. The industry needs a consistent approach

Questions

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UK - London +44 (0) 203 318 0936
Canada - Montreal +1 (514) 800 2106
www.be4ward.com
48 Warwick Street, London, W1B 5AW

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