Falsified Medicines Directive: Overview from the Irish Medicines Verification Organisation (IMVO)

LEONIE CLARKE - 28TH MARCH 2017 - HUG
EU requirements* for repositories of unique identifiers

- Every MS must be served by national or supranational repository based in EU
- Must be set up & managed by non-profit entity established by marketing authorisation (MA) holders and manufacturers of products with safety features
- Cost of repository system to be borne by manufacturers
- Wholesalers, persons authorised/entitled to supply medicines to public (pharmacists) & national competent authority must be consulted when setting up
- Wholesalers & pharmacists entitled to participate in legal entity on voluntary basis at no cost
- Repositories system does not include scanners needed to read unique identifiers

*These requirements have set the brief for IMVO

* Commission Delegated Regulation (EU) 2016/161 – Chapter VII
Unique Identifiers – how will process work?

Pharmaceutical Manufacturer

Generates Unique Identifiers

Upload to European Hub

Product Flow

Wholesaler

Verification / decommissioning as required

National Medicines Repository

Authenticate Number

Wholesaler

Pharmacist

Patient

Verification & decommissioning when dispensing to patient & an alert if any problems
Unique Identifiers - how will process work in health services?

- Requirement to verify safety features & decommission unique identifiers applies to all products supplied to patients in ‘healthcare institutions’, not just those dispensed through a hospital pharmacy.

- ‘Healthcare institution’ very broadly defined in DR as “hospital, in- or out-patient clinic or health centre”.

- Verification & decommissioning steps may take place at any time when product is in possession of the institution, e.g. at goods inwards.

- Member States may allow wholesalers to verify & decommission medicines supplied to hospices, nursing homes, doctors, dentists, paramedics and some other groups (NB – this exemption cannot be applied to ‘healthcare institutions’).

- If product is received without payment from a wholesaler belonging to same legal entity as the healthcare institution, the wholesaler in question may carry out the verification & decommissioning steps.
European Medicines Verification System

- Stakeholder collaboration to oversee implementation of unique identifier requirements across Europe
- EMVS comprises European Hub and national/regional repositories of unique identifiers
- Overseen at European level by European Medicines Verification Organisation (EMVO)
Overview of EMVS
Features of EMVS

- System based on electronic validation of data via Internet connection
- Pharmacists and wholesalers connect to repository system via standard software systems, e.g. pharmacy dispensing systems will be adapted to interface with the repository
- Direct Internet connection (GUI) also available to pharmacists and wholesalers for emergency use if their software systems fail.
- National competent authorities have access to system to generate reports
- Protocols in place to deal with exceptional events, including escalation procedures, and Internet outages
- Full audit trails available but not a track and trace system
- System designed to deal with parallel trade and multi-market packs but not aggregated codes
IMVO’s role

- To set up and manage repository of unique identifiers for Ireland
- To interface with EMVO to ensure full interconnectivity of national repository with EU Hub
- To verify credentials of system users in Ireland – IT software providers, pharmacists, wholesalers, HPRA
- To levy fees on MA holders whose data is held in the repository
- To manage alerts generated from repository system
Who’s involved in IMVO?

- Founding members:
  - **Research industry** – Irish Pharmaceutical Healthcare Association (IPHA)
  - **Generic medicines industry** – new organisation formed from merger of Irish Generic Medicines Association and Healthcare Enterprise Alliance
  - **Pharmaceutical parallel distributors** – Association of Irish Pharmaceutical Parallel Distributors (AIPPD)
  - ** Pharmacists** – Irish Pharmacy Union (IPU)
  - **Wholesalers** – Pharmaceutical Distributors Federation (PDF)
  - Hospital Pharmacists’ Association of Ireland (HPAI) & BioPharmaChem Ireland (BPCI) have also been involved

- Affiliate membership option will be available
IMVO activities to date

- Setting up a not-for-profit independent legal entity (will operate as company limited by guarantee)

- Communications programme:
  - Engagement with wider industry stakeholders (manufacturers, MA holders & wholesalers)
  - External communications with HPRA, Dept of Health, PSI etc.
  - Meetings with HSE including Chief Information Officer, Director of Acute Services, Director of Primary Care, National Immunisation Office
  - Meeting with Private Hospitals Association
  - Formal public consultation undertaken last summer

- Mapping of national users/stakeholders & work practices in medicines supply chain to identify any Irish specific requirements

- IT provider to develop national repository system has been selected
System developer due to start work on national repository shortly

IT project manager will be appointed to work with system developer & local IT software providers

Onboarding of wholesalers and pharmacies/hospitals

Pilot testing to begin in Q3 2017 (assuming serialised packs are available in Irish market) - will run for several months

New IMVO systems to support national repository including:

- Quality management system
- Procedures for validating system users and granting access credentials
- Protocols for managing alerts from repository
Funding

Two elements of cost in IMVO:

- Governance/running costs of the organisation
- Costs of repository system i.e. national repository costs & IE share of EU Hub costs

Will be funded by membership subscriptions & annual user fees charged to all MA holders who place products with safety features on Irish market.

Pharmacists and wholesalers will not pay for repository system costs (as per DR).

Manufacturer members of IMVO will cover initial set-up costs and these will then be recouped from all MA holders.

System users also have to pay their own costs:

- Manufacturers/MAHs – adding safety features to packaging, creating interface with EU Hub to upload unique identifiers, etc.
- Pharmacists/wholesalers – scanners, IT system changes, etc.
Data Access & Ownership

- Transactional data in the system belongs to stakeholder that generated it, e.g. pharmacists will own dispensing data.
- No access to data of other stakeholders except for verification purposes or with their agreement.
- Competent authorities may access data for following purposes:
  - Supervising functioning of repository and investigating incidents of falsification.
  - Reimbursement.
  - Pharmacovigilance or pharmacoepidemiology.
Will you be ready?

9th February 2019

- Manufacturers cannot release in-scope medicines to market after this date without safety features.
- In-scope medicines already on the market without safety features will not be repacked and will be in circulation for some time after Feb 2019.
- Medicines with safety features cannot be supplied to patients after 9th Feb 2019 unless safety features have been verified and unique identifiers decommissioned in national repository.
What needs to be done by Feb 2019?

- **IMVO** - national repository system up and running efficiently
- **Manufacturers / MA holders:**
  - Packs compliant with new requirements
  - Unique identifiers uploaded to national repository via EU Hub
- **Wholesalers / community pharmacists / hospital pharmacists & healthcare institutions**
  - Scanning equipment in place to read barcodes
  - Internet connection for communication with national repository
  - Software systems upgraded to interact with national repository to enable verification & decommissioning of unique identifiers
  - Necessary changes in work practices & facilities to support scanning & checking operations

**Remember this is not just an IT project!**

**Just 693 days to go (495 working days not allowing for holidays!)**
For more information...

- **Email:**
  - IMVO Project Manager: leonieclarke@ipha.ie

- **Websites:**
  - **European Medicines Verification Organisation (EMVO):** [https://www.emvo-medicines.eu/](https://www.emvo-medicines.eu/)
  - **Coming soon -** [www.imvo.ie](http://www.imvo.ie)
Questions?