European Federation of Pharmaceutical Industries and Associations

EU IDMP Taskforce

Falsified Medicines Directive and European Medicines Verification System Update

19th February 2016

EMA

London

Falsified Medicines

- February 9th 2016 – Delegated Regulation (EU) 2016/161 (which supplements Directive 2001/83/EC) was published in the O.J.
  - It has the date of 2nd October 2015 probably indicating that nothing of substance has changed since the October adopted version.
  - http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2016.032.01.0001.01.ENG&toc=OJ:L:2016:032:TOC
- A Q&A document to support the DR can be found here: http://ec.europa.eu/health/files/falsified_medicines/qa_safetyfeature.pdf
- In simple terms, for those involved with medicines verification, the clock starting 'ticking' on Feb 9th 2016.
- All EU markets (Italy, Belgium and Greece excepted) have three years to implement a point of dispense verification system for prescription medicines. (9th February 2019).
- Please be mindful of misunderstandings caused by differences between the translations!

Falsified Medicines Directive – 101

Pack Marking(1)

- Each pack shall bear a ‘unique identifier’.
  - Shall be represented in an ECC200 DataMatrix code.
  - Shall comprise:
    - Product code.
    - Serial number (which is random and with a minimum distribution).
    - Batch number.
    - Expiry Date.
    - National reimbursement number if required by the member state.
- Each pack shall:
  - Display the product code and serial number in human readable form adjacent to the code where dimensions allow.
  - Display the national reimbursement number in human readable form if required by the member state.
- Each pack shall have an anti-tampering device.

(1) – there are a few exceptions defined in the annex to the DR however, In general, all prescription medicines are in, all OTC are out.

Falsified Medicines – Responsibilities(2)

- Industry.
  - Provide on each product (that is in-scope) the following safety features:
    - A unique identifier, UID.
    - An anti-tamper device.
  - Provide accurate data to feed the system.
    - Master Data and,
    - Variable Data.
  - Inform the 'authorities' in the event of suspected tampering or falsification.
  - Maintain records of interaction with the unique identifier.
  - Perform verification before removing or replacing the 'safety features'.
  - Replace the UID or TA by an equivalent UID or TA.
  - Pay for the repositories (the bulk of the system).

(2) – these and subsequent slides, are highlights only, refer to the DR for the full detail and accurate requirements

Falsified Medicines - Responsibilities

- Persons authorised/entitled to supply medicinal product to the public.
  - Shall verify and decommission the pack safety features ‘at the time of supply to the public’.
  - Exception to the above when working within a healthcare institution where the pack stays within the healthcare institution and is not ‘sold’ prior to supply to the public. In this case the verify/decommission may be undertaken at any point prior to supply to the public.
  - Must connect to the national verification repository.
  - Must verify and decommission when:
    - Packs cannot be supplied or returned to the wholesaler.
    - Packs are requested by the NCA as samples.
    - Packs which are supplied for subsequent authorised. investigational products or authorised auxiliary medicines.
  - A few exemptions are permitted – reference Article 26.

Falsified Medicines - Responsibilities

- Wholesale
  - Undertake a verification activity on product returns.
  - Undertake a verification activity when the supply is from another wholesaler who is neither the manufacturer not the MAH, nor the MAH contractually designated wholesaler.
  - Inform the ‘authorities’ in the event of suspected tampering or falsification.
  - Decommission packs in the event that:
    - Packs are permanently exported from the EU.
    - Returns that cannot be placed back on sale.
    - Packs intended for destruction.
    - Packs requested by NCA’s as samples.
    - Packs are provided to specific persons or institutions (see Art 23 for the detail!).

Falsified Medicines - Responsibilities

- NCA's
  - Must make certain information available to MAH's, manufacturers, wholesalers and 'persons authorised to supply', upon request (Article 43).
  - Responsibility for system (repository) supervision – limited to their own territory and may be delegated.
  - Right to observe inspections where the physical repository in not located within the member state.
  - Shall report to EMA any supervision activities (reports can be shared by EMA).
  - May contribute to the management of the system in their member state.
  - May access the member state system for the purposes of supervision, investigation of falsification, reimbursement, pharmacovigilance and pharmacoepidemiology. (note, the system contains no patient information).
  - Detail of the exact information available has yet to be agreed.

EMVS – National Systems

- The EMVS design includes the specification for a National System not simply the European Hub.
- EMVO have adopted the name “National Blueprint System”.
- It is a standard system design.
- It is available from three vendors with whom initial contract negotiations have been made and framework contracts agreed.
- The National Blueprint concept does not prevent member states undertaking a ‘self-build’, but:
  - The Blueprint will be faster to implement.
  - Will be guaranteed compliant.
  - Is fully expected to be more cost effective – which is critical for Industry.
  - Is a tested, validated solution.

Status of the EMVS

- European Hub Status
  - The European Hub is currently validated and operating. Operations started in May 2015.
  - Currently only has one national system connected – Germany.
  - Manufacturer/MAH on-boarding is a slow process but expected to pick up now the DR has been published.
- European Hub Enhancements – DR Related.
  - Modifications are planned, in phases, over the next 18 months and prioritised according to impact.
  - Modifications include aspects such as:
    - New master data model, cross-border queries, introduction of a GUI for end users and NCA's (note suspect pack alerting is already available), revised pack status values and support tooling.

EMVS Technical Activities

- Currently we are:
  - Mapping out which data elements (DR Article 33 (2)) should be held by the Hub and which should be held by the national verification repositories and how the data gets to each component.
  - Adjusting the system URS and URS Lite to comply with the aspects of the DR that are slightly changed from our original scope.
  - Creating the specifications for the completely new aspects contained within the DR.
  - Aiming to complete the specification work by the end of Q1 2016 for approval by the EMVO stakeholders.
  - Reviewing how best to take advantage of IDMP…

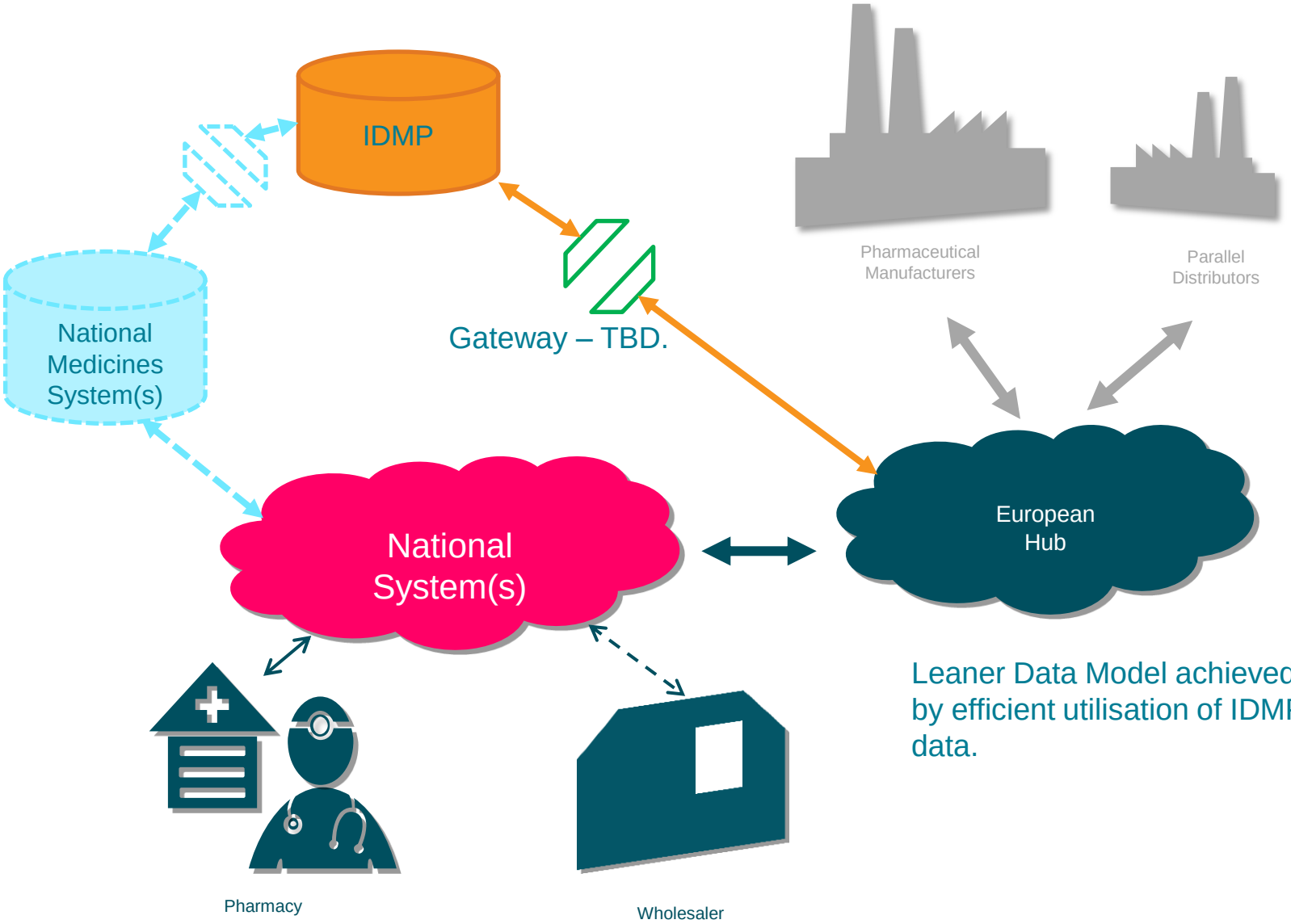
IDMP integration with the EMVS

- One of the modifications/enhancements is to integrate with IDMP.
- Our interest is primarily master data and organisational data.
  - Master Data.
    - Ideally get to the position where the connection party simply provides the product code to the Hub and the Hub then extracts all required master data from the IDMP source.
    - Need to confirm data mapping from DR Art 33(2) and IDMP.
  - Organisational Data.
    - Verify that the connecting parties are genuine manufacturer's/MAH's
    - Have an identity in IDMP (another authenticity check)
    - Determine and verify the SPOC's associated with the accounts for technical and daily interaction.
    - Potentially share the organisational data created.
      - Each account needs to be verified as genuine for EMVS.

IDMP integration with the EMVS

- The benefits.
  - The verification system is the natural repository for batch data and pack data (the latter used in the event of suspicious packs)
  - Using master data from IDMP means that there is no ‘double entry’ of data which is:
    - More efficient and
    - Makes the verification system data model much smaller.
  - Using a common product code opens the door.
  - The verification system, like IDMP, needs a means to validate & confirm connecting parties – there’s an obvious synergy here.
- The challenges.
  - Agreement to the use of the product code (e.g. GTIN) as the key field to link IDMP and EMVS data.
  - Availability and time for industry and EMA to work on the specifications.
  - Timing, 2019 for FMD isn’t far away, this needs to be operational earlier.

IDMP Data Integration Concept



Thank You

- Any Questions?