European Medicines Verification Organisation

EMVO FMD Workshop

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Supervision by National Competent Authorities and Access to Data

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European Association of Euro-Pharmaceutical Companies

medicines for europe
better access. better health.

efpia
European Federation of Pharmaceutical Industries and Associations

GIRP
the vital link in healthcare

PGEU GPUE
Pharmaceutical Group of European Union
Groupement Pharmaceutique de l'Union Européenne

FMD & DR objectives (1)

- FMD - purpose of the SF
  - Art. 54 – SF placed on outer packaging enable [1] wholesale distributors and [2] persons authorised or entitled to supply medicinal products to the public to [a] verify the authenticity of the medicinal product, and [b] identify individual packs.
- FMD - data protection instruction to EC for DR
  - Art. 54 – when adopting the DR, EC required to take due account of [1] the protection of personal data; [2] the legitimate interests to protect information of a commercially confidential nature; [3] the ownership and confidentiality of the data generated by the use of the SF.
- The system complies with all data protection regulations appropriate to the European Union.

FMD & DR objectives (2)

- FMD –instruction to EC to provide for NCA access rights to information on SF
  - Art. 54 – NCA access right - EC should set out in DR provisions on the accessibility of the repositories system in which information on the SF, enabling the verification of the authenticity and identification of medicinal products, is contained.
- FMD – MS / NCA information use right
  - Art. 54 – MS's may, for the purposes of [1] reimbursement, [2] pharmacovigilance or [3] pharmacoepidemiology, USE the information contained in the repositories system.

DR Compliance

- NCA access to repository system and its information – 5 NCA needs/options
  - Art. 39: NMVOs shall grant access to the repository and to the information contained therein, to NCA for the following purposes: [1] supervising the functioning of the repositories and [2] investigating potential incidents of falsification; [3] reimbursement; [4] pharmacovigilance or [5] pharmacoepidemiology.
- NCA 'physical' access right to repositories system
  - Art. 32 – structure of the repositories – API to allow NCAs access the repositories system by means of software for Art. 39 purposes.
  - Art. 35 - characteristics of the repositories system – each repository shall have an [1] API able to transfer and exchange data with the software used by NCAs and [2] shall include GUIs providing direct access to NCAs for Art. 39 purposes.

Operation of the repositories system

- NCA 'information on UI' request right
  - Art. 36: the repositories system shall provide for [1] the immediate provision of information concerning a given UI to the NCA and the EMA, upon request.
- NCA 'user compliance report' request right
  - Art. 36: the repositories system shall provide for [2] the creation of reports that allow NCAs to verify compliance of individual users with the requirements of the DR
- NCA 'investigation report' request right
  - Art. 36: the repositories system shall provide for [3] the creation of reports that allow NCAs to investigate potential incidents of falsification.
- NMVO obligation as a 'facilitator' / 'gate-keeper'
  - Art. 37 NMVOs shall: [1] following an immediate investigation alert the NCA, EMA and EC of confirmed falsifications. [2]. carry out regular (each year for first 5 and every 3yrs thereafter) audits of the repository to verify compliance with the DR and supply reports of audits to NCA, upon request. [3] make the audit trail immediately available to NCA upon request; [4] make the individual users compliance reports referred available to NCA upon request.

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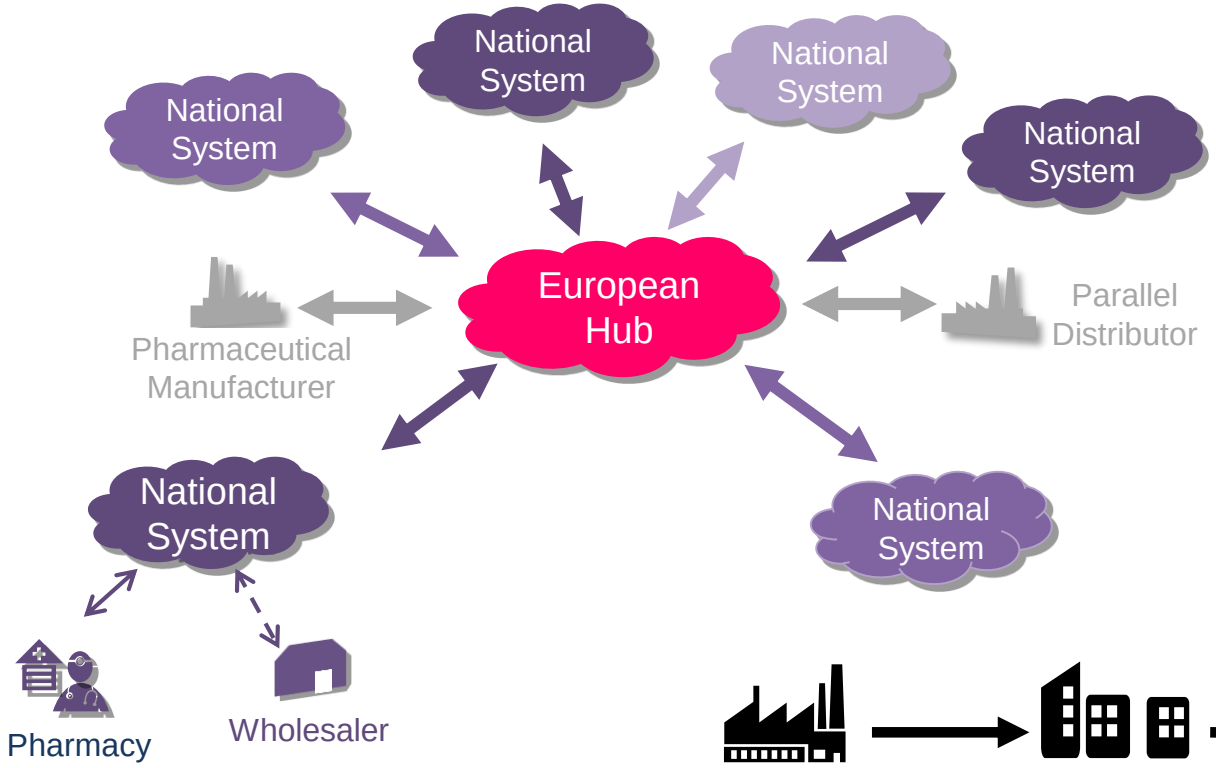
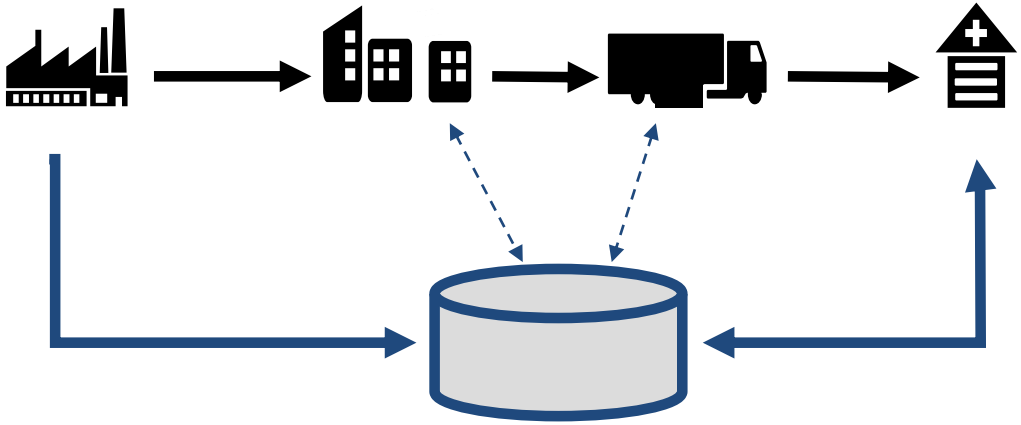
What can the system provide?

- Primary purpose:
  - The verification of medicinal packs supporting the enhancement of patient safety. The system is an end to end verification system only.
- The European Hub:
  - Routes master data and pack date across Europe.
  - Routing inter-market requests across Europe.
  - Handling shared pack synchronisation.
  - Some centralised reporting.
  - It does not store information on data at pack level.
- EMVS National Systems:
  - Connect wholesalers and pharmacist and hospitals etc.
  - NCA's via the GUI

System Overview





System and Data Security

- Security is critical and our top design goal.
- Verification of valid users before connection is an exhaustive process.
- The NCA GUI is an access point that must be secured.
  - Our intention is to implement user level access to the NCA GUI.
  - It grants access, for regulatory purposes only to legitimate users.
  - Access will only be available over a secured connection.
  - User interaction will be recorded within an audit trail.
- The system is not a freely searchable data warehouse by design.
- Access to data is carefully controlled and ownership of data is a paramount design principle.
- In principle, the owner of the data has to be informed.
- The system therefore only provides standard and agreed reporting which are in-line with the DR and with the Stakeholder Agreements for EMVO for pack verification and decommissioning.
- Data compilation beyond the scope of the system is not supported.

Supervision (1)

- Auditing
  - The system is subject to annual security audits as part of the contractual obligations on each provider.
  - EMVO has partnered with EDQM and they subject the system to annual compliance audits.
    - April 2017 – initial audit. Annual thereafter.
  - The suppliers are also audited by EMVO and subject to ISO audits.
  - These audits do not prevent any additional audits from competent authorities.
- Compliance of the system and operation.
- Governance & potential participation in the management of the NMVO.

Supervision (2)

- The system can (for inbound product)
  - Determine the number of packs loaded into the system.
  - For single market packs, it can identify how many were batch released in specific markets.
  - For shared packs it can only provide the total across all markets and not the split between market.
- The system can for (outbound product)
  - Provide a total of all packs decommissioned (for a given product within a given time period).
  - Access to a more granular view and is subject to data access rules as the finer granularity is commercially extremely sensitive and thus is not readily available.

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Supervision (3)

- Reporting Metrics.
  - Number of connecting stakeholders.
  - Number of product pack data upload transactions.
  - Number of transactions per transaction type.
  - Number of products in the system.
  - Number of product packs in the system, listed per pack status.
  - Transaction times.
  - Service Level Agreement Transaction times. (summary of the contracted Critical Service Levels)
- Contracted Wholesaler list by market.
  - Shows the list of MAH contracted wholesalers by market and product code.

Investigation

- Investigating potential incidents of falsification.
  - Pack Disclosure Report is provided for this purpose.
    - It details every point at which the pack has been scanned and gives as much information as the system has to define where the pack was injected into the system and what specifically the issue is.
    - The availability of this report is notifiable to the relevant NCA by means of the system escalation process.
    - Suspected incidents of falsification are defined as Level 5 alerts and these have the ability to be signalled to a given NCA by means of email.
    - The report containing the data is obtained via the GUI.
  - Packs Stolen Report.
    - Shows the number and serial number of packs denoted as Stolen for a given Product Code and Batch ID.

Investigation

- Audit Trail Records (all required a specific date range)
  - Data Transmission Audit Trail.
  - System Access Audit Trail.
  - Exceptions Audit Trail.
  - Master Data Audit Trail.
  - Recall Batch Audit Trail.
  - Withdrawn Product Audit Trail.
  - “For Repack” Audit Trail.
- Product Master Data report.
  - Shows the master data records for the stipulated/connected client. Only available to the client and EMVO/NMVO.
- Records of data placed into the system should also be maintained by each ‘manufacturer’ (OBP).

Reimbursement

- The system is an end to end pack verification system and does not act as a reimbursement system.
- We have no reports available to support reimbursement and believe that the system data cannot be reliably used as a proxy for reimbursement.
- A genuine reimbursement system could however use the data scanned from the pack in parallel.

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Pharmacovigilance

- The system provides:
  - A faster means to invoke batch recalls.
  - A faster means to invoke a product withdrawal.
  - A Product Recall Report.
    - Shows the impact of the invoked recall on a given Product Code /Batch ID combination in the affected markets. This shows how many packs in the affected batch were in what state at the point of recall.
  - A Product Withdrawal Report.
    - Shows the impact of the invoked withdrawal on a given Product Code for all known batches in the affected markets. This shows how many packs in the affected batch were in what state at the point of recall.
- Eventually the European Hub will be linked with IDMP (SPOR) to streamline regulatory investigation.

Pharmacoepidemiology

- The system does not:
  - Store or use any patient data.
  - Store or use any medicinal 'indications' data.
  - Have a feedback mechanism to record outcomes of medicine use by a patient.
- The system 'simply' confirms that the pack is 'OK' to decommission and provide to the patient.
- At the NMVO level, it could be possible to request a report giving an indication of consumption by a given product/batch combination for the given territory.

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Questions?

Thank you very much!

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Back Up

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