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National Competent Authority Access to Data in the Repository Systems

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- Relevant legislation
- Work undertaken by European Commission Expert Group on safety features
- Data requirements for each of:
  - Reimbursement
  - Pharmacovigilance
  - Pharmacoepidemiology
- Discussions with EMVO and NMVO regarding access
- Next steps

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Relevant Legislation (i)

- Article 39 of DR (EU) 2016/161
  - A legal entity …. … shall grant access … … to competent authorities … for ..
    - Supervision of repository system and investigation
    - Reimbursement
    - Pharmacovigilance or pharmacoepidemiology

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Relevant Legislation (ii)

- Article 32(4) – the repository systems shall include
  - API
  - GUI
- Article 33(1)(e) – API will enable transfer of data with NCAs
- Article 35(1)(i) – GUI will provide direct access to NCAs

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EC Expert Working Group on Safety Features

- DR published in 2016
- Four working groups established
  - WG1 Supervision (lead [IE])
  - WG2 NCA access to repository systems (lead ES) [ES] [IT]
  - WG3 Data traceability (lead IT) [BE]
  - WG4 Best practices (lead BE)
- 20 MS participating + EC and EMA

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Use of the FMD system of repositories for the purpose of reimbursement[1]

Legal Basis

Art. 39 of the Commission Delegated Regulation (EU) 2016/161 of 2 October 2015 sets out an obligation for legal entities establishing and managing a repository used to verify the authenticity of or decommission the unique identifiers of medicinal products placed on the market in a Member State to grant the competent authorities of that Member State access to the information contained in the repository for a.o. the reimbursement of medicines.

General aspects of reimbursement in Member States

Reimbursement based on number of packages delivered (BE e.g.)

Whenever a patient buys a reimbursed product in Belgium and the patient is correctly insured a mechanism called "third payer" can be used. In practice this means that a product that is reimbursed for 80% and costs €100 will be sold by the pharmacist to the patient for €20. This means that the pharmacist is missing €80. To obtain a reimbursement for these €80, the pharmacist will send an electronic data file and the paper prescription for the product to the reimbursement office. This office will do an administrative check and will then transfer this to the reimbursement institute, which will pay the pharmacist €80.

Possible fraud with this system

If the patient presents himself with a prescription containing two products, both reimbursed, it may be so that the patient only wishes to buy one of the two products. In that case it would be possible

USE OF DATA CONTAINED IN THE REPOSITORIES SYSTEM FOR THE PURPOSE OF SUPERVISION BY MMSS OF THE COMPLIANCE OF STAKEHOLDERS WITH THE PROVISIONS OF THE DELEGATED REGULATION (EU) 2016/161

Legal basis

Article 36 (j) of Commission Delegated Regulation (EU) 2016/161 (DR) establishes as one of the operations that the repositories system shall provide the creation of reports that allow competent authorities to verify compliance of individual marketing authorisation holders, manufacturers, wholesalers and persons authorised or entitled to supply medicinal products to the public with the requirements of this Regulation or to investigate potential incidents of falsification.

Information considered essential for supervision of stakeholders in Member States

Competent authorities in order to perform their supervision obligations included in Article 36 (j) must verify the compliance of stakeholders with any provision included in the DR.

That is why it should be possible for the competent authorities to obtain information for any stakeholder about the operations they have performed to comply the obligations referred in the DR. This information will also be checked during onsite inspections.

The information given by the repository system will be essential to inspect stakeholders, on site, regarding this specific matter. It will be checked if the information available on the repository system matches the one obtained during the inspection.

For manufacturers /marketing authorization holders (MAHs), it will be supervised how they are performing the upload of the information safety features and the upload of the unique identifiers (UI) to the system as well as the obligations related to the distribution of the medicinal products if they also perform such activities and how they are informing the NCA potential falsification incidents, when detected (related to the other report for investigation of potential incident of falsification).

USE OF DATA CONTAINED IN THE REPOSITORIES SYSTEM FOR THE PURPOSE OF INVESTIGATION OF POTENTIAL INCIDENTS OF FALSIFICATION

Legal basis

Article 39 (a) of Commission Delegated Regulation (EU) 2016/161 [DR] establishes that the legal entity establishing and managing a repository used to verify the authenticity of or decommission the unique identifiers of medicinal products placed on the market in a Member State shall grant access to that repository and to the information contained therein, to competent authorities of that Member State for the purpose of supervising the functioning of the repositories and *investigating potential incidents of falsification*.

The minimum data held within the repositories system is set out in Article 33(2) of the DR and the data elements of the unique identifier (UI) are set out in Article 4(b).

Also Article 35(1)(g) between the characteristics of the system states the need to '*maintain a complete record ('audit trail') of all operations concerning a unique identifier, of the users performing those operations and the nature of the operations; the audit trail shall be created when the unique identifier is uploaded to the repository and be maintained until at least one year after the expiry date of the medicinal product bearing the unique identifier or five years after the product has been released for sale or distribution in accordance with Article 51(3) of Directive 2001/83/EC, whichever is the longer period*';

Information considered essential for investigation of potential incidents of falsification in Member States

Once a notification of a potential falsification incident is received, different cases may occur when investigating a potential falsification incident.

Sometimes the suspected pack will be physically available whilst others not, and even the facts investigated may have happened sometime ago so it should be possible to obtain this information without scanning the pack.

It should be always possible for Member States (MMSS) to obtain immediately a full audit trail for the individual/s pack/s investigated. This audit trail must include all the operations, its type, the time and the stakeholder that performed it, as well as the country where the operations occurred.

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FMD – USE OF DATA HELD WITHIN THE REPOSITORIES FOR THE PURPOSES OF PHARMACOVIGILANCE AND PHARMACOEPIDEMIOLOGY

Legal Basis

Article 54a(5)(second indent) of Directive 2001/83/EC permits member states to use the information retained within the repository systems for the purposes of pharmacovigilance and pharmacoepidemiology amongst other things. This is also foreseen within Article 39 of Commission Delegated Regulation (EU) 2016/161 [DR]

The data held within the repositories system is set out in Article 33(2) of the DR which states:

For a medicinal product bearing a unique identifier, at least the following information shall be uploaded to the repositories system:
(a) the data elements of the unique identifier in accordance with Article 4(b);
(b) the coding scheme of the product code;
(c) the name and the common name of the medicinal product, the strength, the pack type and the pack size of the pharmaceutical form, the Member State or Member States where the medicinal product is intended to be placed on the market;
(d) the Member State or Member States where the entry corresponding to the medicinal product bearing the unique identifier in the database referred to in Article 57(1)(l) of Regulation (EC) No 726/2004 of the European Parliament and the Council (2);
(e) where applicable, the code identifying the safety features;
(f) the name and address of the manufacturer placing the safety features;
(g) the name and address of the marketing authorisation holder;
(h) a list of wholesalers who are designated by the marketing authorisation holder, by means of a written contract, to store and distribute the products covered by his marketing authorisation on his behalf, and address of the manufacturer placing the safety features;

The data elements of the unique identifier are set out in article 4(b) of the DR which states:

The unique identifier shall consist of the following data elements:

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Discussions with EMVO & NMVOs

- Formal discussions held alongside EC meetings
- Detailed discussions with WG2
- Need for NCAs to discuss with NMVOs data relevant on a national basis and how these will be accessed

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Work still to be completed

- Few reports required by NCAs are foreseen in the blueprint
- Some reports remain not clear for EMVO/Other reports will be developed but expensive
- Flexibility for the future is needed
- API has not yet been developed
- Good progress but much still to do
- Involvement of NMVO is essential

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Thank you!

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GIRP the vital link in healthcare

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

medicines for europe better access. better health.

efpia European Federation of Pharmaceutical Industries and Associations

E A E P C European Association of Euro-Pharmaceutical Companies

Association of Pharmaceutical Manufacturers in Estonia

emvo European Medicines Verification Organisation

Republic of Estonia Agency of Medicines

Republic of Estonia Ministry of Social Affairs