



the vital link in healthcare

Pharma security and the new European legislation to prevent counterfeiting: GIRP perspective

Global GS1 Healthcare Conference
5 October 2011



The European Association of Pharmaceutical Full-line Wholesalers

The **vital link** in healthcare

What is GIRP?

- Founded in 1960, GIRP is the umbrella organisation of pharmaceutical full-line wholesalers in Europe
- The members of GIRP
 - Employ about **140,000** staff
 - Hold products on stock from over **3,500** manufacturers
 - Supply above **100,000** medicines across the continent to more than **160,000** pharmacies

GIRP's members, the European pharmaceutical full-line wholesalers, guarantee the safe and efficient supply of all medicines to all patients through their public service function - **providing the vital link in healthcare.**



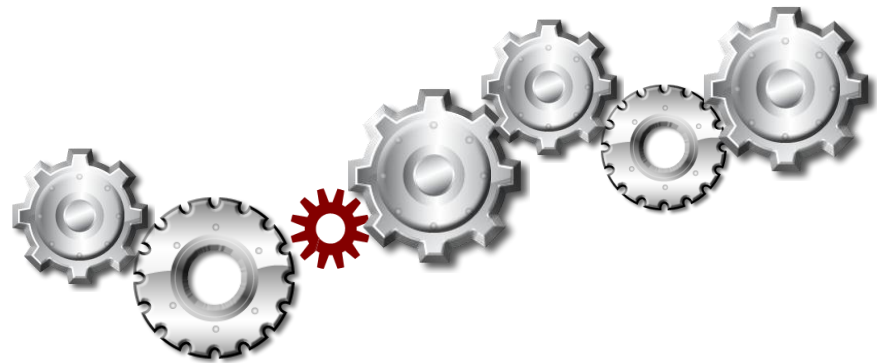
Agenda

Wholesalers and the Falsified Medicines Directive

Pharma security is more than safety features

Collaboration with other stakeholders

- Stakeholder driven approach
- Common Working Group EFPIA/GIRP/PGEU – open for other stakeholders to join
- 10 core principles
- Harmonised coding & serialisation system
- EU hub system architecture



Wholesalers and the Falsified Medicines Directive

- Wholesalers must:
 - Verify that the products received are not falsified by checking the safety features
 - Randomised serial number & tamper evidence seal (re-packagers required to apply equivalent)
 - Obligatory for prescription products (unless no risk)
 - For non-prescription products in case of risk
 - Keep records for any transaction in medicinal products (batch number at least for products containing the safety feature)
 - Verify that supplying wholesaler complies with GDP & is authorised
 - Through checking of licenses in central EU database
- Next step: European Commission to set out details in a delegated act

How it works in practice

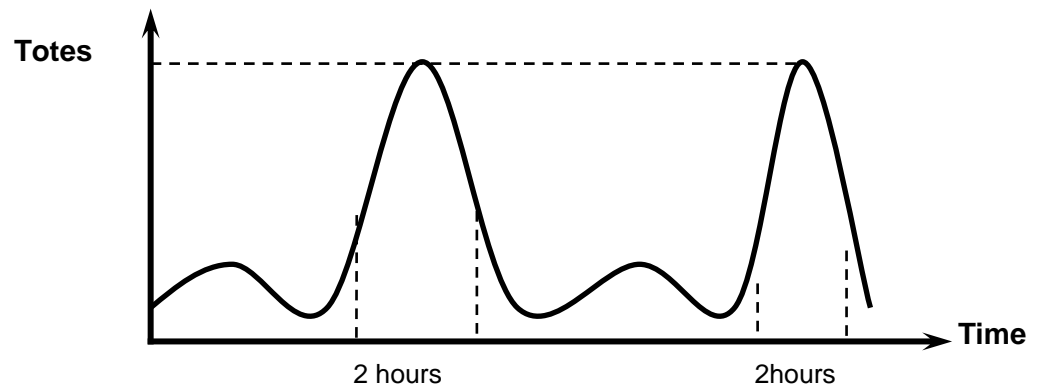
Average warehouse:

- 24 hours a day
- 365 days a year
- ∅ delivery time 2-4 hours

∅ Example: 115.000 pieces per day
8 pieces per second*
5.000 totes per day

46.000 pieces
2.000 totes

46.000 pieces
2.000 totes



* Calculated with a working day of 8hrs



Our concern: safety & speed



Automated vs manual picking



Goods-in vs dispatch



Why do we need harmonisation?



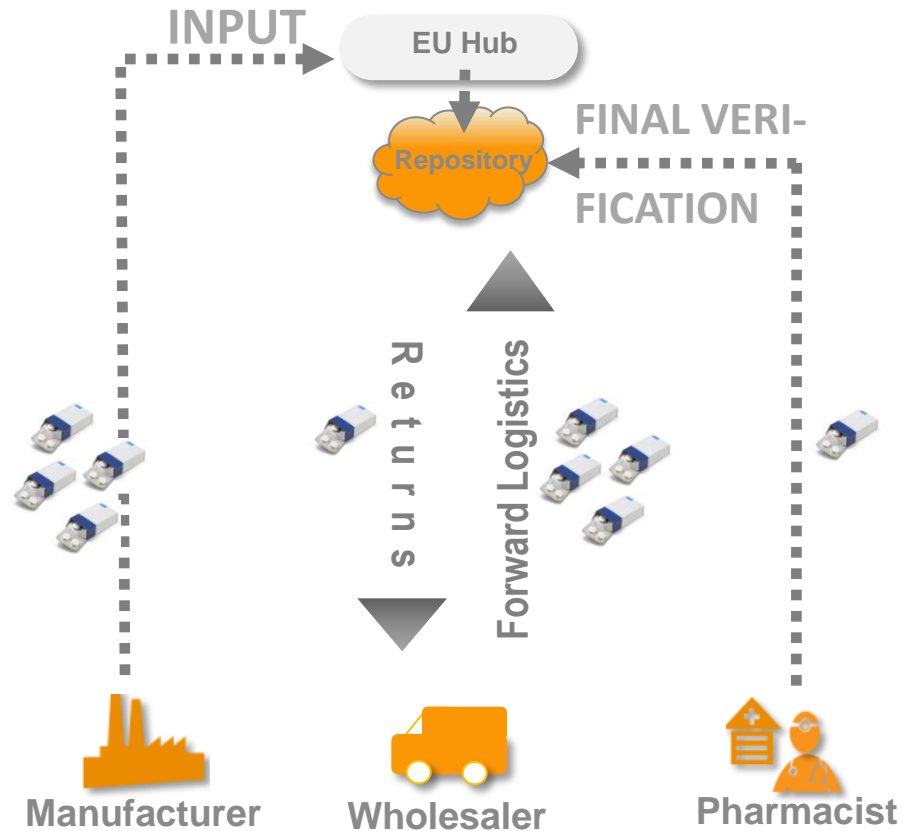
Our favoured solution: 2D Data Matrix code & End-to-end verification

- For products carrying safety features, a Data Matrix code on secondary packaging should be implemented



including:

- Randomised serial number
- National identification number
- Batch number
- Expiry date



Our suggestion: selective product verification – according to a risk assessment



- The delivery units containing medicinal products, which carry safety features on the outer packaging, must be checked by the wholesale distributor.
- For medicinal products carrying safety features obtained from the marketing authorization holder or a person who is authorized by the marketing authorization holder to supply these products, the wholesale distributor is, however, deemed to have satisfied this condition and thereby Article 80(a)(ca) of the Directive.
- If medicinal products are returned from those persons authorized or entitled to supply to the public, the wholesale distributor must verify that they are not falsified or tampered with by checking the safety features on the outer packaging.

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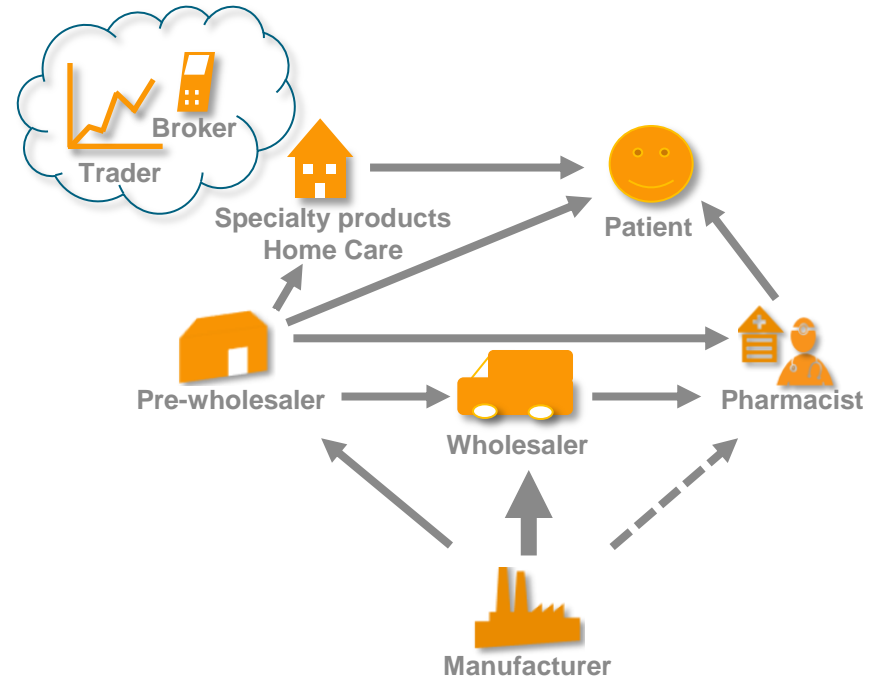
Pharma security is more than safety features



Complex supply chain

- Identification
- Licensing
- Inspection
- Transparency...

of **ALL** actors in and around the supply chain



Identification, licensing & inspection of all actors

- “Persons may only broker medicinal products if they are registered with the competent authority of the Member State of the permanent address...” (Art. 85b, 2)



Broker

Simple registration procedure



Manufacturer

GMP – Good Manufacturing Practice



Wholesaler

GDP – Good Distribution Practice

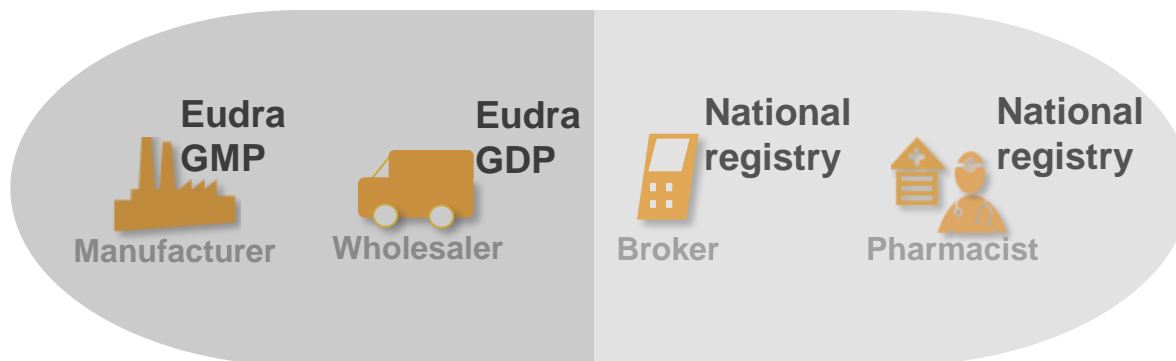


Pharmacist

National retail pharmacy licenses

Transparency of actors & licenses

- “The competent authority shall enter information concerning the person brokering medicinal products in a registry that shall be publicly accessible.” (Art. 85b (2))
- “Member States shall enter the certificates of good manufacturing practice and good distribution practice which they issue in a Community database managed by the Agency on behalf of the Community.” (Art. 111(c)(6))





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Thank you for your attention.

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