ESM

European Stakeholder Model

A European Medicines Verification System

Fighting counterfeit medicines to ensure patient safety in Europe

Speakers:

Grant Courtney

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Date:

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Who am I

- Grant Courtney
  - Part of EFPIA team working on the ESM
  - Member of the GS1 Healthcare Leadership Team
  - 18 years in product security for GlaxoSmithKline

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1. Introduction

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Context & Background

- The threat of falsified medicines penetrating the European supply chain is substantial and growing

- The adoption on July 1, 2011, of the EU Falsified Medicines Directive (FMD) is an important step in protecting patients from counterfeit medicines

- European Pharmaceutical Supply Chain actors are developing a system that will meet the requirements of the FMD, provide a high level of security for patients, be cost-effective and integrate effectively into existing supply chain practises; the ESM

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What is the ESM?

- The ESM is
  - A pan-European end-to-end system enabling medicines to be **verified at point of dispensing**
  - **Developed by the stakeholders** who will use it on a day-to-day basis and **govern it in partnership**

- The ESM is a tried-and-tested, interoperable pan-European system
  - Ensures **safe access** to medicines
  - Is **a cost-efficient interoperable** solution
    - Run on a non-profit basis. Has additional benefits
  - Is **transparent and partnership-based**

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2. Fighting falsified medicines

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What is the EU doing?

- 2011 EU Falsified Medicines Directive has measures to increase security of the medicinal supply chain
  - Manufacturers to apply safety features to allow verification of authenticity and identification of individual packs
  - Repository systems must be established to house information on safety features
- Costs to be borne by Manufacturing Authorisation Holders
- **ESM partners want to deliver an effective system** on time – mandatory compliance expected in 2017

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EMVO – Membership

Members Are Allocated to a Constituency

PGEU

Pharmacy

GIRP

Wholesalers

Innovators

EFPIA

HOPE

Hospital Pharmacy

Repackagers

EAEPC

Generics

OTC

EGA

AESGP

Plus affiliate members

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What are ESM partners doing?

- EAEPC, EFPIA, GIRP, and PGEU
  - Have agreed **a joint position paper** "Ten Core Principles to Protect Patients from Falsified Medicines"
  - Have elaborated and formally endorsed a **Memorandum of Understanding** providing the foundation for the pan-European system

TEN CORE PRINCIPLES TO PROTECT PATIENTS FROM FALSIFIED MEDICINES

EFPIA/PGEU/GIRP Joint Position Paper

March 2011

The Directive on falsified medicines introduces mandatory, harmonised pan-European safety features for medicines at risk of falsification. With counterfeit medicines a clear and growing threat, EFPIA, PGEU and GIRP fully support this move. New technologies can offer significant protection against breaches in the legitimate supply chain. However, this also demands greatest clarity on how best to use these features to provide robust protection.

EFPIA, PGEU and GIRP believe any framework for implementing the Directive, in particular the delegated acts and all preparatory work, should reflect the following key principles.

1. *Combining tamper-evident packaging with a unique serial number:*

- EFPIA, PGEU and GIRP support the requirement in the falsified medicines directive that the safety features should consist of a unique serial number placed on each pack, together with packaging that would reveal if a pack has been opened or tampered with
- Checking a unique, randomised, serial number placed on each pack against a central database at the point of dispensing is currently one of the most secure ways to verify product authenticity. However, a product verification system can only secure the content of the pack if it remains sealed at all times. Using tamper evident packaging makes it clear whether the pack has been opened or tampered with and is therefore an essential complement to a product verification system
- EFPIA and PGEU consider that safety features should be applied to all prescription medicines to ensure the same level of security. Therefore if a risk-based approach for prescription medicines is pursued, exemptions should be based on therapeutic categories, narrowly defined (e.g. ATC 4 level), rather than individual products to minimise the risk to patient safety.

- The **tender process for the first phase** of the European Medicines Verification System (EMVS) is ongoing – to be operational Q2 2013

- Talks ongoing with AESGP, EAHP, EGA and HOPE

AESGP	Association of the European Self-Medication Industry
EAHP	European Association of Hospital Pharmacists
EGA	European Generic Medicines Association
GIRP	European Association of Pharmaceutical Full-line Wholesalers
HOPE	European Hospital and Healthcare Federation
PGEU	European Association Representing Community Pharmacists

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ESM view on implementation of the FMD

Safety Features	• Combine tamper-evident packaging and a unique randomised serial number • Verify product authenticity by checking each pack against a central database at the point of dispensing
System Design	• Harmonised standard coding system across the EU that allows national codes to be incorporated as necessary • Sufficient flexibility to implement national or multi-country solutions within an overall EU technical framework
Data	• Manufacturers do not seek, and will not have access to, individual patient / prescribing profile information • Transactional data belongs to stakeholder that created it e.g. pharmacists for dispensing data
Governance	• Systems should be established and managed by the stakeholders that will use them day-to-day • Systems governed by independent non-profit organisations jointly managed by relevant stakeholders

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3. The ESM in practice

Timelines

2005

EFPIA agrees to work towards point-of-dispensing verification and 2D barcodes

2006

GIRP adopts zero tolerance position against counterfeit medicines entering the legitimate supply chain

2007

PGEU issues a statement on counterfeiting and possible EU level action to combat the threat of counterfeiting

2008

EAEPC launches an anti-counterfeiting warning platform for protection against suspicious trading offers

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EU proposes FMD legislation

2009

Roll-out of mandatory GDP audit programme for EAEPC members and their suppliers

2009-10

EFPIA, GIRP and PGEU test verification system in a pilot project in Sweden. Results exceed expectations

2010

EFPIA, GIRP and PGEU issue a joint position on serialisation and start work on developing a Pan-European verification system

2011

EU legislators adopt FMD

2012

EAEPC, EFPIA, GIRP and PGEU complete partnership and launch the ESM

The stakeholders submit a joint response to the Commission consultation on safety features

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ESM partners scale up engagement with end users including patients and public authorities

2013

ESM partners continue work on national interface with 'SecurPharm' project in Germany

2014

EU to give precise details of serialisation feature

2017

FMD serialisation requirements due to be implemented

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2D barcodes

- The ESM uses a 2D barcode, developed to internationally recognised standards

- Four key data elements:
  - 14 digit Manufacturer Product Code
  - Randomised Unique Serial Number
  - Expiry Date
  - Batch Number (up to 20 alpha-numeric characters)

- Example:

Product #: (01)09876543210982
Batch: (10)A1C2E3G4I5
Expiry: (17)140531
S/N: (21)12345AZRQF1234567890

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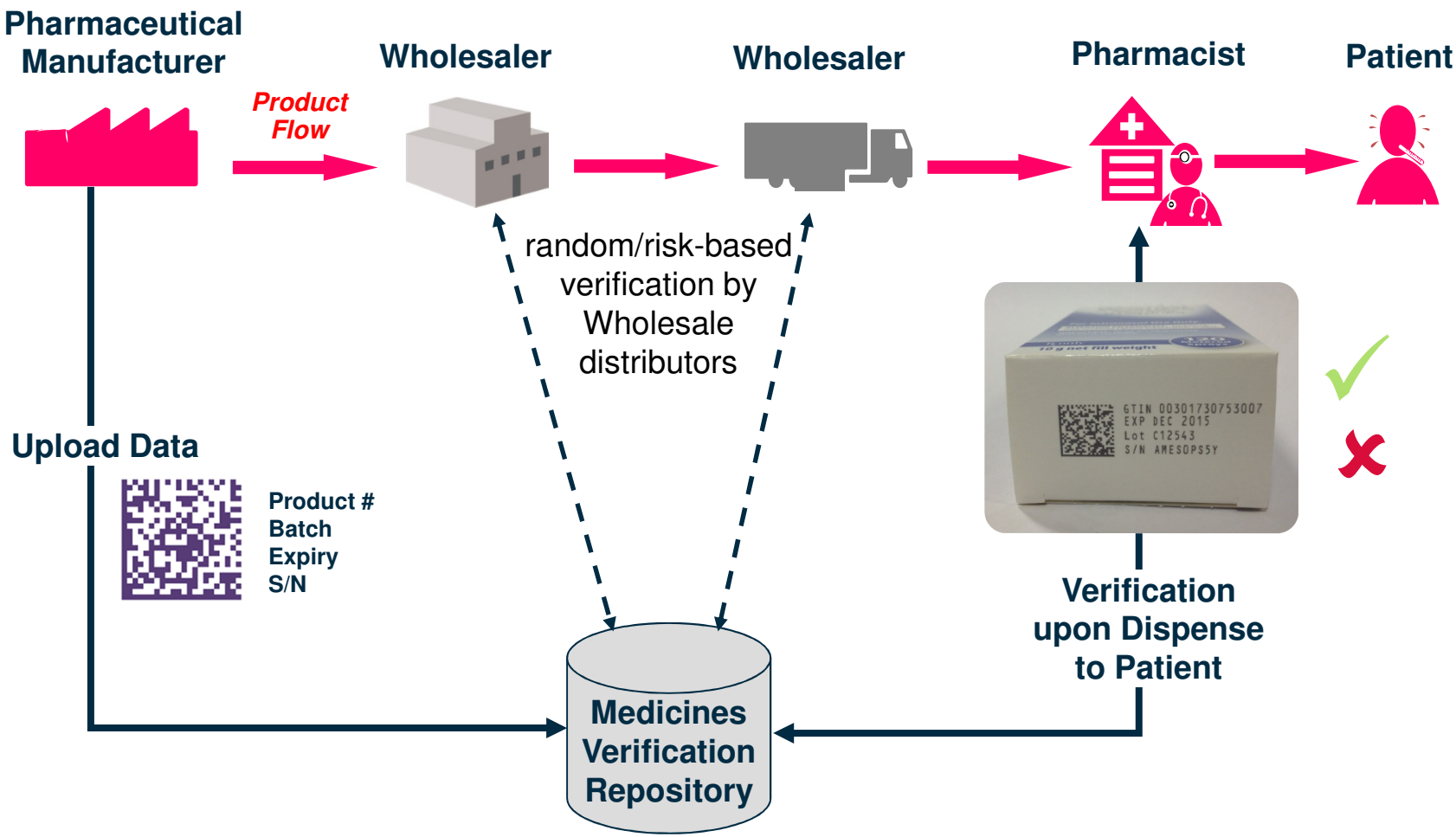
Process



The key stakeholders all support the Point-of-Dispensing verification concept

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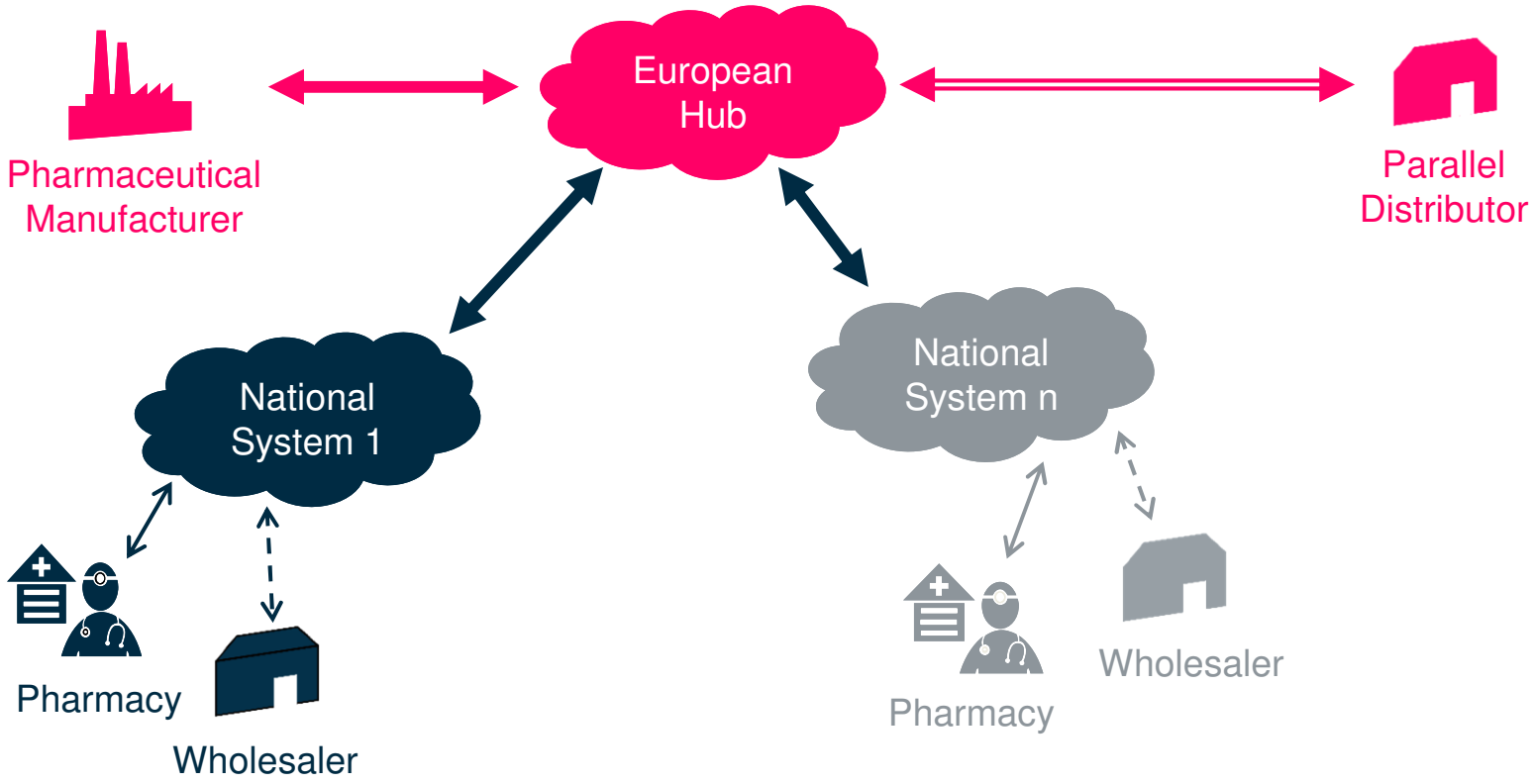
Process - European Hub



Parallel Distributor: mandatory verification + data upload

Manufacturer: data upload + voluntary verification

Periodic cross-region update

Pharmacy: mandatory verification

Wholesaler: voluntary verification

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Testing and evolution

- Swedish pilot project (Sep 09 - Feb 10)
- 25 pharmacies in greater Stockholm.180 dispensing points
  - 25 products. 110,000 packs. 14 manufacturers
- Key findings
  - Allows pharmacists to **work at normal pace**
  - Is customised to **existing workflows**
  - Is **integrated** into existing pharmacy software
  - Pharmacists and wholesalers are keen to get expiry date and batch number in machine-readable form

ESM partners continue work on national interface with 2013 'SecurPharm' project in Germany

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4. Next steps

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Next steps

- ESM is an effective, interoperable, cost-efficient and partnership-based system to combat counterfeit medicines and ensure patient safety across Europe
  - ESM ensures **safe access** to medicines
  - ESM is a **cost-efficient interoperable** system
  - ESM is **transparent and partnership-based**

- Focus now on:
  - Dialogue with end users inc. patients and public authorities
  - Continue to work with the remaining constituencies/ associations
  - **Pilot project in Germany with SecurPharm**
  - Establishing the European Medicines Verification Organisation (EMVO)
  - Continue phased implementation of the ESM

Thank you

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

GIRP the vital link in healthcare

efpia
European Federation of Pharmaceutical Industries and Associations

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

Joining forces to provide
the best solution for patients

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ensuring patients have
access to safe medicines

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Back up slides

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About EFPIA

European Federation of Pharmaceutical Industries and Associations

represents the **research-based** pharmaceutical industry operating in Europe

brings together 31 national pharmaceutical associations and 38 leading companies

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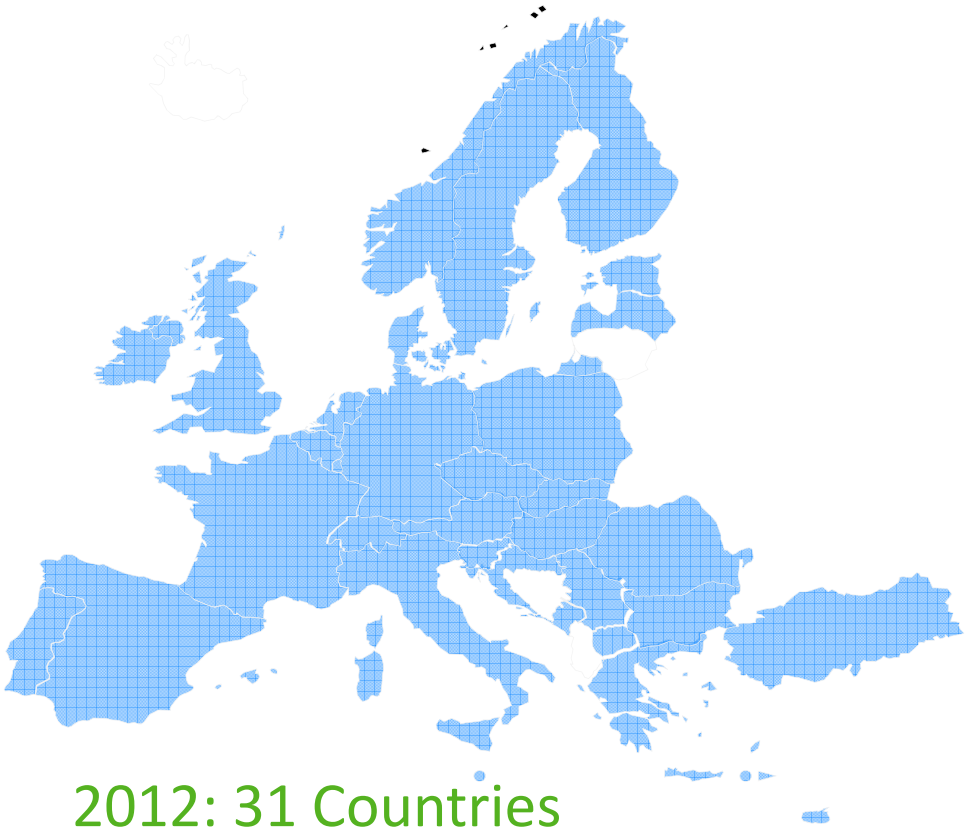
What is GIRP?

- 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 **170,000** 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.**

Pharmaceutical Group of European Union

Members: Professional Bodies & Pharmacists' Associations



2012: 31 Countries

- Austria
- Belgium
- Bulgaria
- Cyprus
- Czech Rep
- Denmark
- Estonia
- Finland
- France
- Germany
- Greece
- Hungary
- Ireland
- Italy
- Luxembourg
- Malta
- Netherlands
- Poland
- Portugal
- Romania
- Slovakia
- Slovenia
- Spain
- Sweden
- United Kingdom
- Croatia
- FYR Macedonia
- Norway
- Serbia
- Switzerland
- Turkey

PGEU GPUE

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

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What are falsified medicines?

- **Growing threat to public health** and safety in Europe
- Counterfeit medicines seized at the outer border of the EU tripled between 2006 and 2009, reaching approximately 7.5 million items
- **Over 30 million counterfeit medicines** have been seized by customs at EU borders, internal and external, over the last five years
- Fake medicines may:
  - Contain low quality ingredients or the wrong doses
  - Have their identity or source deliberately mislabelled
  - Have fake packaging or the wrong ingredients

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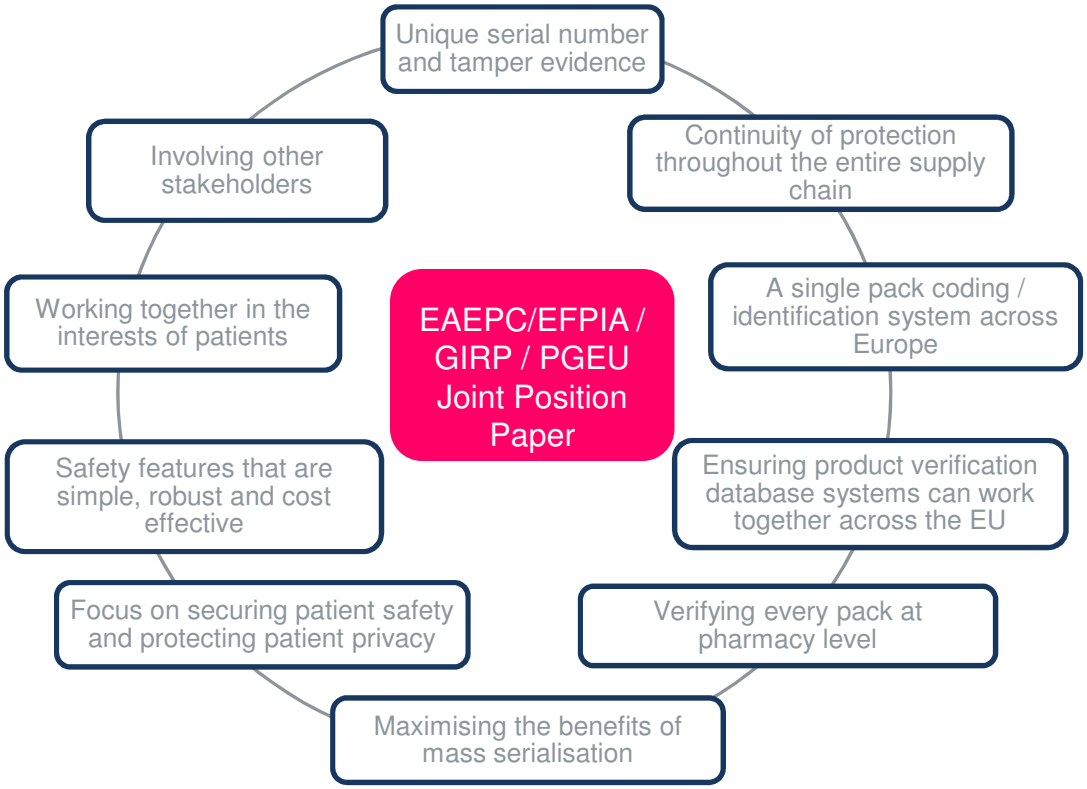
What are ESM partners doing?

- Ten Core Principles to Protect Patients from Falsified Medicines



- ESM partners are set to consult and engage patient groups

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Verification by wholesale distributors

- Systematic verification at point of dispense with additional random/risk-based verification by wholesale distributors:
  - Wholesale distributors to check packs received from other authorised sources (other than MAH and marketing authorisation holders or persons made responsible by them) and returns from pharmacies
- Full verification at the level of wholesale distributors is not useful

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5. Why it works

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efpia European Federation of Pharmaceutical Industries and Associations

EFPIA

The ESM for Patient Safety

- **Patient safety:** joining forces across the pharmaceutical supply chain means increased security for the patient
- **Interoperability:** the ESM paves the way for an interoperable system across the EU, avoiding the challenge of 27 different systems
- **Cost-effectiveness:** stakeholder governance puts those who operate the supply chain every day in the front seat when it comes to design and set-up

- **Keeping the speed** of commissioning and delivery
- **Inclusion of batch number** in harmonised, machine-readable code as pre-condition to fulfill new legal obligation from Falsified Medicines Directive (article 80 e)

- **Verification at point of dispensing with additional risk-based verification** by wholesale distributors
  - Protects against entry of falsified medicines in supply chain
- **Stakeholder-led approach** combining full market expertise to make system robust, cost-efficient and effective

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EAEPC

European Association of Euro-Pharmaceutical Companies

Key Issues Resolved

What the FMD requires parallel distributors to do:

- Replace (under GMP conditions) safety features with 'equivalent' ones
- Verification of product authenticity prior to repackaging
- Inform competent authorities and MAH (where applicable) in case of suspicion of falsification
- As MAH, bear the costs of the system

Achievements:

- **Data handling, ownership and data protection**
  - Legal principle "Who generates, owns" and restrictive access rules defined in URS → secure handling of data and NO traceability
- **Linking of codes of outgoing and incoming packages at batch level**
  - Recall function: PD is immediately informed of recalled batches and must perform own recall if required, following national procedures
- **Reboxing as mandatory form of repackaging for those products meeting the FMD safety feature requirements (i.e. tamper evidence and unique identifier)**
  - In combination with bilateral understanding on equivalence of replacement of safety features
- **Costs and cost sharing**
  - EU Hub provides for cost-effective interface for verification and upload
  - Overall system costs driven by number of regional DBs attached
  - Costs per pack a combination of volume and value

PGEU

Pharmacists wish to develop a system which:

- Puts patient safety first and nothing else
- Is consistent with current pharmacy practice
- Causes the minimum of delays, disruption and complexity for pharmacists and the supply chain as a whole
- Uses stakeholder knowledge and experience
- Is cost effective
- Can provide, where appropriate, enhancements to patient safety through for example, the detection of expired stock and improved recall processes