ESM

European Stakeholder Model

ensuring patients have access to safe medicines

A genuine threat to public health

Over 30 million counterfeit medicines have been seized by customs at EU borders over the last five years[1].

Counterfeiters do not discriminate between branded or generic medicines.

Counterfeit medicines market is lucrative only for counterfeiters and has a huge cost to European patients and society[2].

62% of medicines purchased online are fake or substandard[3].

95.6% of online pharmacies researched are operating illegally[4].

Ensuring the delivery of safe medicines is a responsibility for all in the pharmaceutical supply chain.

1. *European Commission Directorate-General for Taxation and Customs Union*
2. *€10 billion / year. Nunwood survey data November 2009. Online consumer survey, participants 14,000. Countries included the UK, Belgium, Switzerland, Spain, Norway, Denmark, Sweden, Austria, Germany, France, Italy, Netherlands, Finland and Ireland.*
3. *European Alliance for Access to Safe Medicines (EAASM)*
4. *European Alliance for Access to Safe Medicines (EAASM)*

Guaranteeing the safety and security of the pharmaceutical supply chain has become a growing concern for all. The risk of counterfeit medicines entering the legitimate supply chain is now greater than ever before and has begun to raise concerns over the capabilities of the present supply chain system to deal with more sophisticated and structured criminal activities.

"Falsified medicines are a serious public health risk in the EU. They have not been subject to an authorisation procedure where aspects of quality, safety, and efficacy of the medicine are verified. The Falsified Medicines Directive introduces harmonised, Pan-European safety measures that provide the highest possible level of assurance that only high-quality medicines are sold within the legal supply chain in the EU."

European Commissioner for Health and Consumer Policy, John Dalli

The EU Falsified Medicines Directive

paving the way for safe supply of medicines

On July 1 2011, Directive 2011/62/EU, the Falsified Medicines Directive, was published in the Official Journal of the European Union.

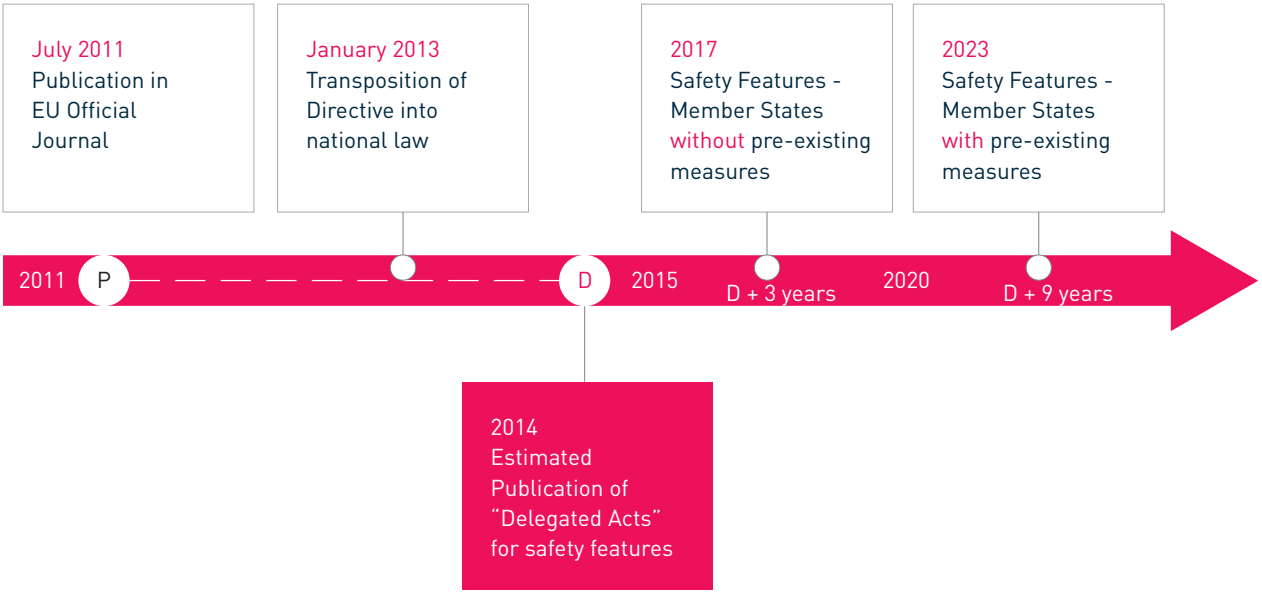
The Directive aims at safeguarding the medicine supply chain and protecting patients via the use of safety measures for prescription-only medicines and some high-risk over-the-counter medicines.

The Directive introduces the following safety features

- Serial numbers and tamper evidence
- Measures to tackle the internet trade in fake medicines
- Tougher criminal sanctions
- More stringent rules on importing Active Pharmaceutical Ingredients (APIs)
- Development of a consistent, harmonised approach to Good Manufacturing Practice (GMP) inspections
- Tighter scrutiny of supply chain middlemen such as brokers and traders

The Directive aims to stop falsified medicines reaching patients by introducing harmonised, Pan-European safety and control measures.

These procedures will allow for easier identification of falsified medicines, and enhance verifications and controls within the EU and at its borders.



The European Stakeholder Model (ESM)

a point-of-dispensing verification system

In order to meet the implementation needs of the Falsified Medicines Directive EFPIA[5] , EAEPC[6] , GIRP[7] , and PGEU[8] have embarked on developing a technical solution called the European Stakeholder Model (ESM).

The ESM solution is a point-of-dispensing verification system that allows pharmacists to check a unique identification code on each individual pack when it is dispensed to the patient.

Objectives of the ESM model are

- A harmonised serialisation system across Europe for greater patient safety
- A stakeholder governed point-of-dispensing system for cost-effectiveness
- A 2D data matrix based on international standards for interoperability across the EU

The codes are generated and applied by manufacturers using a 2D data matrix barcode that contains a unique serial number. By simply scanning the barcode, any unregistered code will immediately alert the pharmacist to the possibility of a counterfeit product. The data matrix also has the capacity to contain other information such as national codes.

The Data Matrix code contains four key elements

1. Product number
2. Batch number
3. Expiry date
4. Random serial number

Continuity of **protection** throughout the **supply** chain via a single **identification system**

5. *European Federation of Pharmaceutical Industries and Associations*
6. *European Association of Euro-Pharmaceutical Companies*
7. *European Association of Pharmaceutical Full-line Wholesalers*
8. *The Pharmaceutical Group of the European Union*

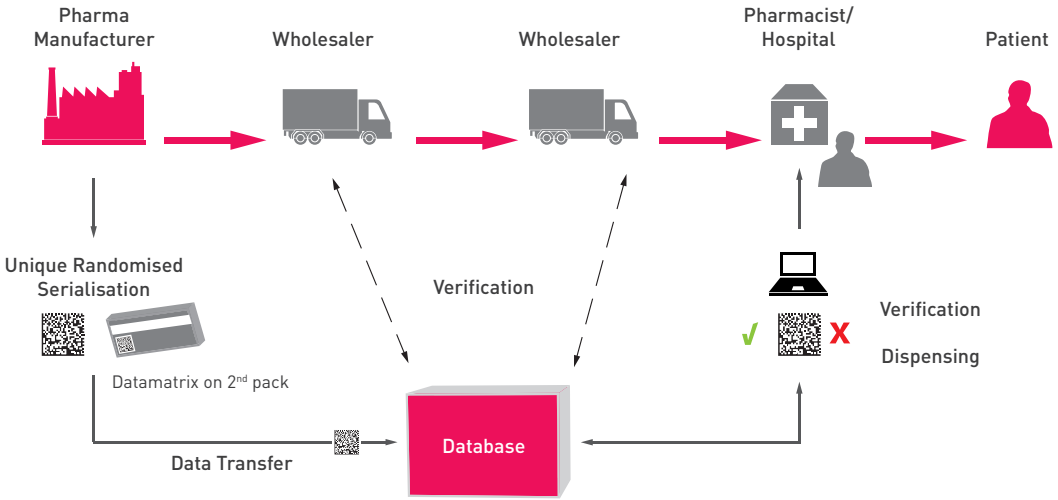
ESM: ensuring patient safety

throughout the entire supply chain

The founding principle of the ESM approach is that each pharmaceutical pack is checked individually before it is dispensed to the patient, ensuring that the patient receives a 100% genuine product.

Two main components ensure that we achieve this goal

1. The manufacturer of a pharmaceutical product applies a machine readable unique code to each individual pack. The contents of the code are sent to a database before releasing the product.
2. The pharmacist verifies each pack before it is dispensed to the patient by scanning the code and checking it against the information stored in the database. Once the medicine is dispensed, its status in the database will be changed to "dispensed".



ESM milestones

stakeholders converge on a single product verification system for Europe

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

The ESM provides a safe and cost-effective system, brought to you by experts in the pharmaceutical field, to combat counterfeit medicines and above all ensure patient safety across Europe.

1. The ESM ensures that patients have access to safe medicines

Since 2005, we have developed and tested a scalable, technically advanced Pan-European point-of-dispensing verification system, using an internationally recognised 2D data matrix, to authenticate medicines at point-of-dispensing.

This system not only enhances the healthcare service that the pharmacist provides to patients, it also ensures that patients can have full confidence in the medicines they receive.

2. The ESM is a cost-effective system

The ESM will run on a non-profit basis and integrate into existing supply chain practices to be cost-effective.

The ESM is a solution that increases security but with minimal disruption to the flow of medicines and the workflow of pharmacies.

3. The ESM was developed by the experts in patient safety

The ESM was developed based on sustained collaboration between stakeholder organisations with the aim of ensuring that patients receive safe and effective medicines.

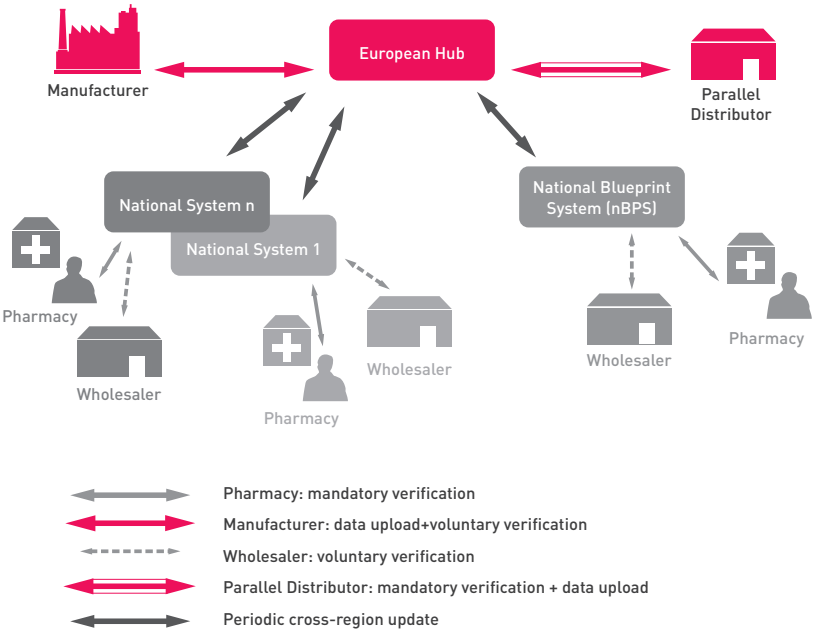
Besides developing a cost-effective, secure and practical system, the ESM project is engaging in dialogue with patient organisations and end users to ensure the system will respond effectively to the needs of patients.

Our goal is to create a harmonised verification system for the whole of Europe, with patient safety at the forefront of our efforts.

Safety features that are simple, **robust** and cost-**effective**

Verification on a macro and micro level

The ESM will be overseen by a not-for-profit stakeholder organisation, called the European Medicines Verification Organisation (EMVO). The EMVO will oversee the European hub that links national systems throughout Europe. It will also serve as the central point from which product recall actions can be initiated. The ESM system will not generate, process or store any personal or patient data.



Maximising the **benefits** of mass serialisation including not only **detection** of falsified medicines but also of expired and recalled medicines

Benefits of the ESM

- Datamatrix code is harmonised and easily identifiable
- "Point-of-dispensing verification" is effective for ensuring patient safety
- Including batch number and expiry date allows for logistics and patient safety advantages
- Based on common principles and can accommodate regional needs
- Stakeholder governance is critical to ensure a responsive, cost-effective system that works for patient safety
- European hub provides a single point of data entry for manufacturers, facilitates multi-country packs, and links parallel distributed products to facilitate recalls
- Pharmacists in any country can verify the authenticity of medicine packs prior to dispensing

Ensuring product **verification database** systems can work together **across** the **EU**

The ESM

tried and tested...

The stakeholder-governed model was tested at national level through a successful pilot project carried out in Sweden in partnership with Swedish retail pharmacy chain Apoteket AB and locally based wholesalers Tamro and Oriola KD from September 2009 to February 2010.

- 6 month period
- 25 products with a total of 110,000 packs
- 25 pharmacies in the greater Stockholm area
- 14 leading pharmaceutical companies
- A total of 180 dispensing points

… and it works

Key results of the pilot study are

- The model works
- The system allows for effective and immediate identification of fake packs as well as expired or short dated packs and recalled products
- The system provides patients with assurance that the products they receive are 100% genuine
- Availability and performance allow pharmacists to work at normal pace and without significant additional effort
- The system is easy to use and easily incorporated into the daily routine of pharmacists

"The main benefits are increased security, you can check with the database if it's an original pack. We also have the expiry date in the code which means we don't have to check them manually. The system is also very easy to use."

Petra **Öström**, Pharmacist

A multi-stakeholder approach

is key to success

Stakeholders joining forces to provide the best solution for patients.

EFPIA

The **European Federation of Pharmaceutical Industries and Associations (EFPIA)** represents the research based pharmaceutical industry operating in Europe. Through its direct membership of 32 national associations and 35 leading pharmaceutical companies, EFPIA is the voice on the EU scene of 2,000 companies.

EAEPC

The **European Association of Euro-Pharmaceutical Companies (EAEPC)** is the representative organisation of the European licensed parallel distribution industry. Through national associations and individual company membership, it encompasses over 70 firms from 21 countries in the European Economic Area (EEA).

GIRP

European Association of Pharmaceutical Full-line Wholesalers (GIRP) is the umbrella organisation of pharmaceutical full-line wholesalers in Europe. It represents the national associations of over 600 pharmaceutical full-line wholesalers serving 31 European countries, including major Pan-European pharmaceutical full-line wholesaling companies.

PGEU

The **Pharmaceutical Group of the European Union (PGEU)** is the European association representing community pharmacists. PGEU's members are the national associations and professional bodies of community pharmacists in 31 European countries including EU Member States, EU candidate countries and EEA/EFTA countries.

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in the interests of **patients**