European Federation of Pharmaceutical Industries and Associations

European Medicines Verification System:

long way travelled, still a long way to go…

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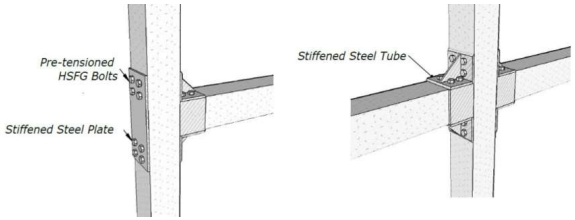
Our vision

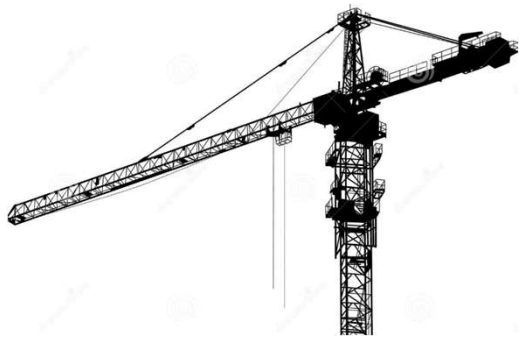

EFPIA’s vision is for a healthier future for Europe. A future based on prevention, innovation, access to new treatments and better outcomes for patients.
We represent the innovative pharmaceutical industry.

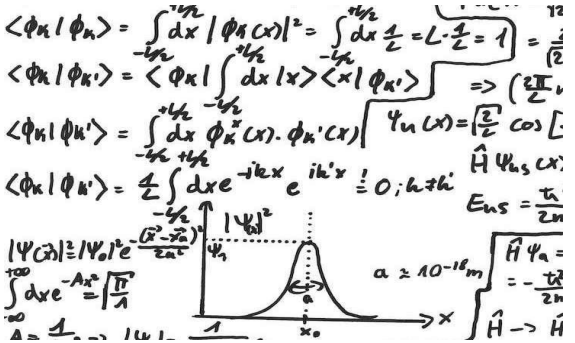
Our mission

In collaboration with health and research players, EFPIA's mission is to create an environment that enables our members to innovate, discover, develop and deliver new therapies and vaccines for people across Europe, as well as contribute to the European economy.

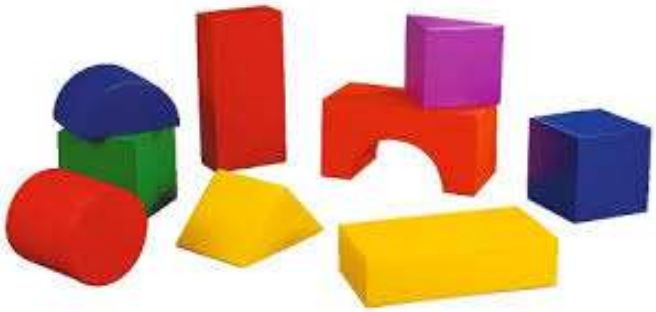
What do you think of when you hear EMVS/FMD?

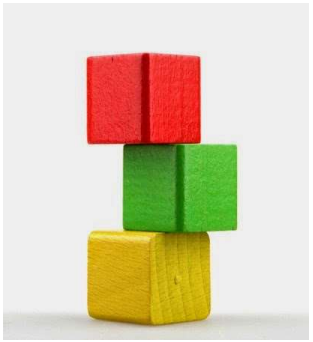




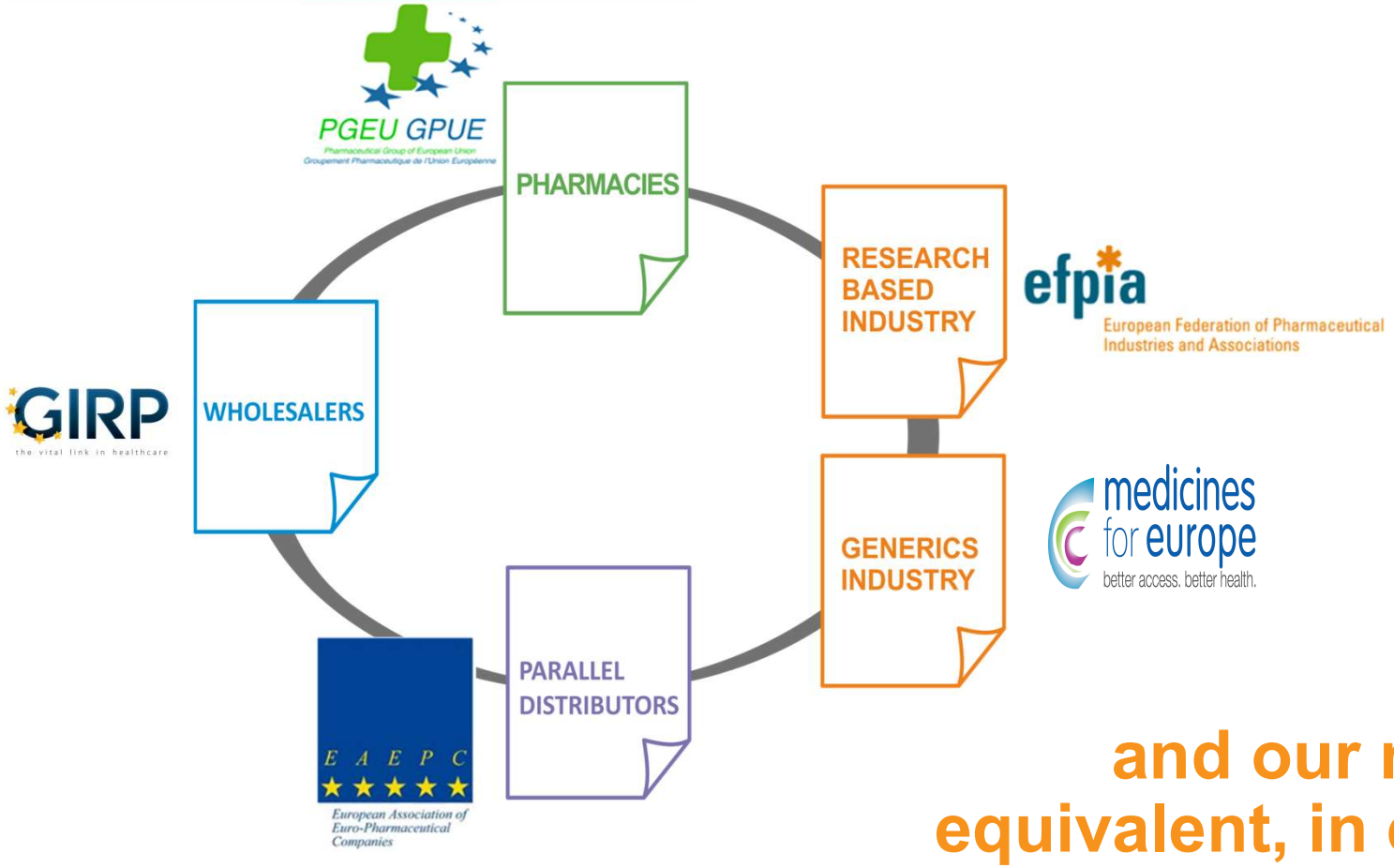


But today we will talk about this





First stakeholder implemented system in EU legislation



and our national level equivalent, in each country

What we have achieved together

- We have put aside our differences, for the greater goal: protecting patients from falsified medicines
- We have blended a unique mix of expertise to deliver a hugely complex system, on time and within budget
- We have put in place a system which has the potential to change the paradigm of the pharmaceutical supply chain of the future
- We have built trust amongst each other, in a supply chain where trust used to be under constant shortage

There still a long way to go…EFPIA priorities

- 1st priority: reduce number of alerts before the end of stabilisation period(s)
- 2nd priority: ensure provision of reports to National Competent Authorities for purposes of investigation, supervision, pharmacovigilance/ pharmaco-epidemiology and reimbursement
- 3nd priority: address end users (un)readiness
- 4rth priority: ensure appropriate allocation of resources for maintaining efficient and fit for purpose system

Why I have enjoyed working on FMD?

- Very complex project – lots of moving and inter-dependent parts
- It is a game changer with respect to the pharmaceutical supply chain
- It can (and it will) provide the foundation for a number of other interesting projects in the future
- Touches upon a lot of areas – packaging, IT, mathematics, supply chain, regulatory, legal, market access, data protection etc.
- Stakeholder led model – 1st of its kind in European legislation implementation
- One gets to really hone ones negotiation skills

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THANK YOU!

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Back up

4 pillars of the EU Falsified Medicines Directive

Product Safety Features

- Unique identifier + anti-tampering
- Authenticity
- Pack Identity
- Tamper evidence

Feb 9, 2019

Good Distribution Practice

- Requirements to qualify their suppliers & customers + transaction tracking
- Wholesalers & Brokers
- GDP

2014-Q1

Active Substances

- GMPs for Excipients

Jan 2, 2013

- Registration API activities

July 2, 2013

Internet Sales

Recognised Community logo

2015

European Medicines Verification System is only one part of the Falsified Medicines Directive

Safety Features

UNIQUE IDENTIFIER

Product #:	09876543210982
Batch:	A1C2E3G4I5
Expiry:	140531
S/N:	12345AZRQF1234567890

ANTI – TAMPERING DEVICE

What are the steps?

FMD nomenclature

1. Manufacturers place the safety features on each medicine

2. Manufacturers upload the corresponding data into the repository system, prior to release for sale

(3). (Medicinal packs circulate through the normal supply chain)

4. Wholesalers verify the authenticity of some medicinal products (risk based approach)

5. Pharmacists systematically verify and decommission each pack before dispensing to patient

What does it mean in practice?

Each medicine (secondary packaging) will have a unique identifier and anti-tampering devices

Each serial number (corresponding to each individual pack) is transmitted to the EU Hub, which then re-routes it to the relevant national system
(i.e. packs intended for France will have their corresponding data stored in the French system)

(Simple supply chain example: manufacturer -> 3PL -> wholesaler 1 -> wholesaler 2 -> pharmacist -> patient)

Wholesalers have to scan the medicinal pack in some cases (returns or deliveries from other wholesalers), against the data previously uploaded by the manufacturer in the system

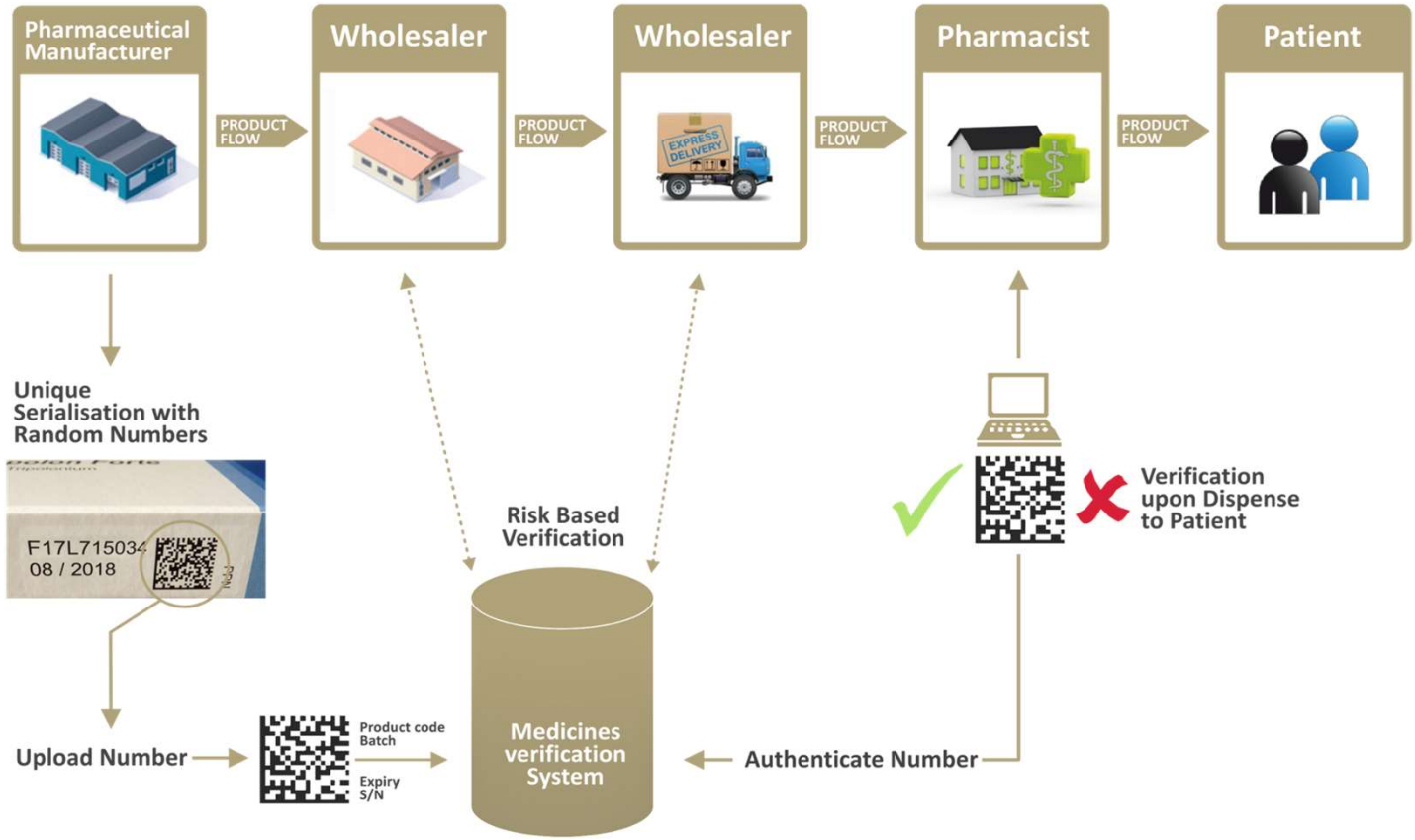
If the national system contains the respective serial number then all OK, wholesalers can sell the pack to the pharmacist

Pharmacists scan each pack, against the data previously uploaded by the manufacturer in the system

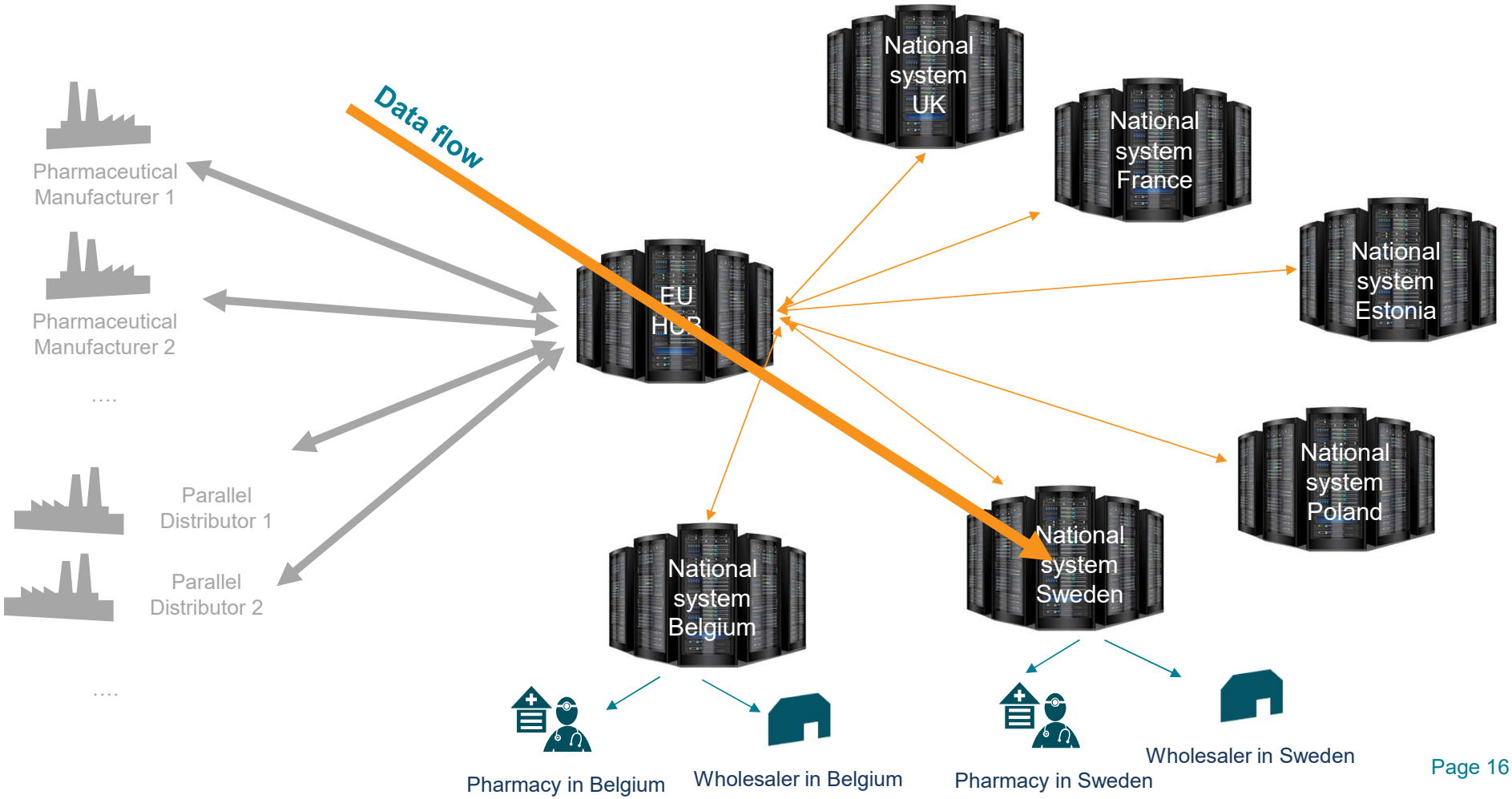
If the national system contains the respective serial numbers then all OK, pack can be dispensed to patient

When pack is dispensed to patient, the system records the respective serial number as “dispensed” – if a falsified medicinal product would copy the exact same serial number, it could not be dispensed

How does it work along the supply chain?



How does it work in Europe?



Key Elements

1) Unique Identifier	Fully harmonised across the EU: **2D barcode on each package containing 4 mandatory elements** – 1) product code, 2) serialisation number, 3) batch number and 4) expiry date and – optionally – as a 5th element the national reimbursement number (if requested by Member States)
2) Tamper-Evidence	Medicinal Products must be tamper-evidenced (EN standard EN 16679:2014 recommended)
3) Repackagers	Parallel distributors to **replace safety features with equivalent features** = UI de/re-commission
4) Scope	**All prescription** medicines (unless white-listed), **no OTC** medicines (unless blacklisted)
5) Process	**Systematical end-to-end verification** (*"before being dispensed to patients e.g. at pharmacy level")* supplemented by **risk-based verifications by wholesale distributors:** *"Medicines at higher risk of falsification (returns or medicines not being distributed directly by manufacturers or marketing authorisation holders or wholesalers distributing on their behalf)"*
6) Timing	Compliance across all 28 MS (+ 3 EEA) on 9 February 2019 (+ 6 years for IT, GR)
7) Establishment and Operation of the Repository Systems	The repository containing the unique identifiers should be set up and managed by stakeholders (**stakeholder model**) with access and a supervisory role granted to National competent authorities
8) Funding	**Manufacturers bear the cost** of the repository systems