FALSIFIED MEDICINES DIRECTIVE – SERIALIZATION WITHIN LOGISTICS

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FMD – The theory

WHAT IS A FALSIFIED MEDICINE?

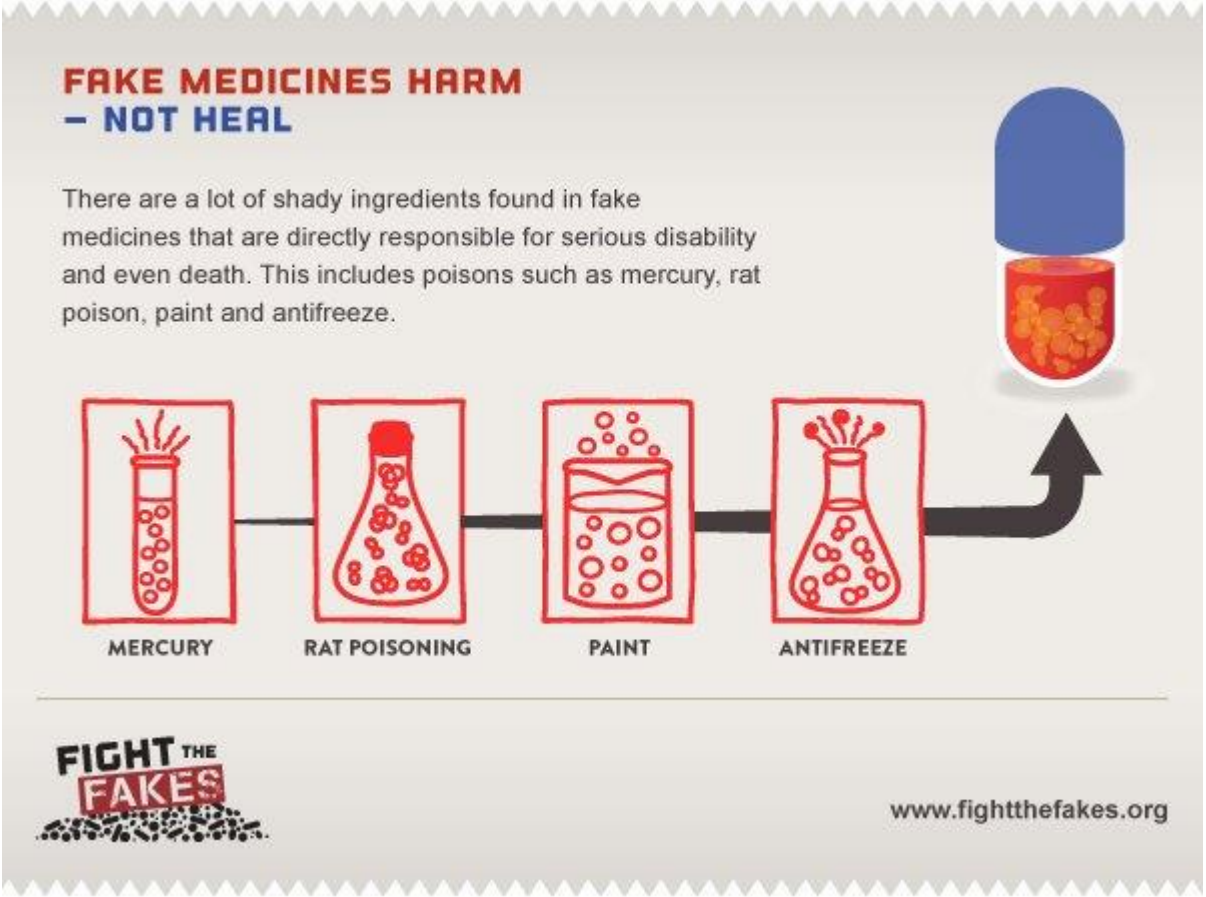
- **Falsified vs. counterfeit medicines**
- Counterfeit medicines are medicines that do not comply with **intellectual-property rights or that infringe trademark law**.
- Falsified medicines are fake medicines that are **designed to mimic real medicines**.
- According to EU legislation it is a medicine with a false representation of:
  a. **Identity e.g. name or composition**
  b. **Source e.g. country of origin, marketing authorization holder**
  c. **History e.g. distribution records**
  d. **Does not include unintentional quality defects**

At best: (not) effective

At worst: harmful or even fatal!

ACTUAL CONSEQUENCES OF FALSIFIED MEDICINES

- 2,500 child deaths during a meningitis outbreak due to the lack of protection given by fake vaccines in Niger (1995).
- Over 100 deaths (mostly children) after a falsified syrup containing diethylene glycol was used in Panama (2006).
- Two deaths and nine hospitalized when an antidiabetic contained six times the normal dose of glibenclamide (2009).
- Pubmed analysis showed 48 incidents
    a. **27 (56.3%) occurred in developing countries and 21 (43.7%) in developed countries.**
    b. **These incidents involved a total of approximately 7200 casualties including 3604 deaths.**



GLOBAL OVERVIEW

- All markets are affected by counterfeit medicines!!
- EU, USA, Australia, Canada, Japan, New Zealand
  a. **Effective regulatory systems and market control in place**
  b. **Low proportion of counterfeit medicines (i.e. < 1% of market value)**
- Many developing countries of Africa, parts of Asia, and parts of Latin America:
  a. **Overall, a reasonable estimate is between 10 and 30%;**
  b. **Many of the former Soviet republics have a proportion of counterfeit medicines above 20% of market value, falling into the developing country range;**

CHECK FOR IRREGULARITIES? WHAT TO LOOK FOR?

EU MEASUREMENTS UP UNTIL 9TH OF FEBRUARY 2019

- Third party Qualifications
- Check of Customer and Manufacturer Authorization
    a. **EudraGMDP database**
- Check of incoming goods and documentations (Inbound)
- Secured storage
- Destruction of obsolete goods (prevent re-entering inventory)
- Check of outgoing goods and documentations (Outbound)
- Check for irregularities
- Dedicated SOP to prevent Counterfeit

FALSIFIED MEDICINES DIRECTIVE

L 174/74 EN Official Journal of the European Union 1.7.2011

DIRECTIVE 2011/62/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

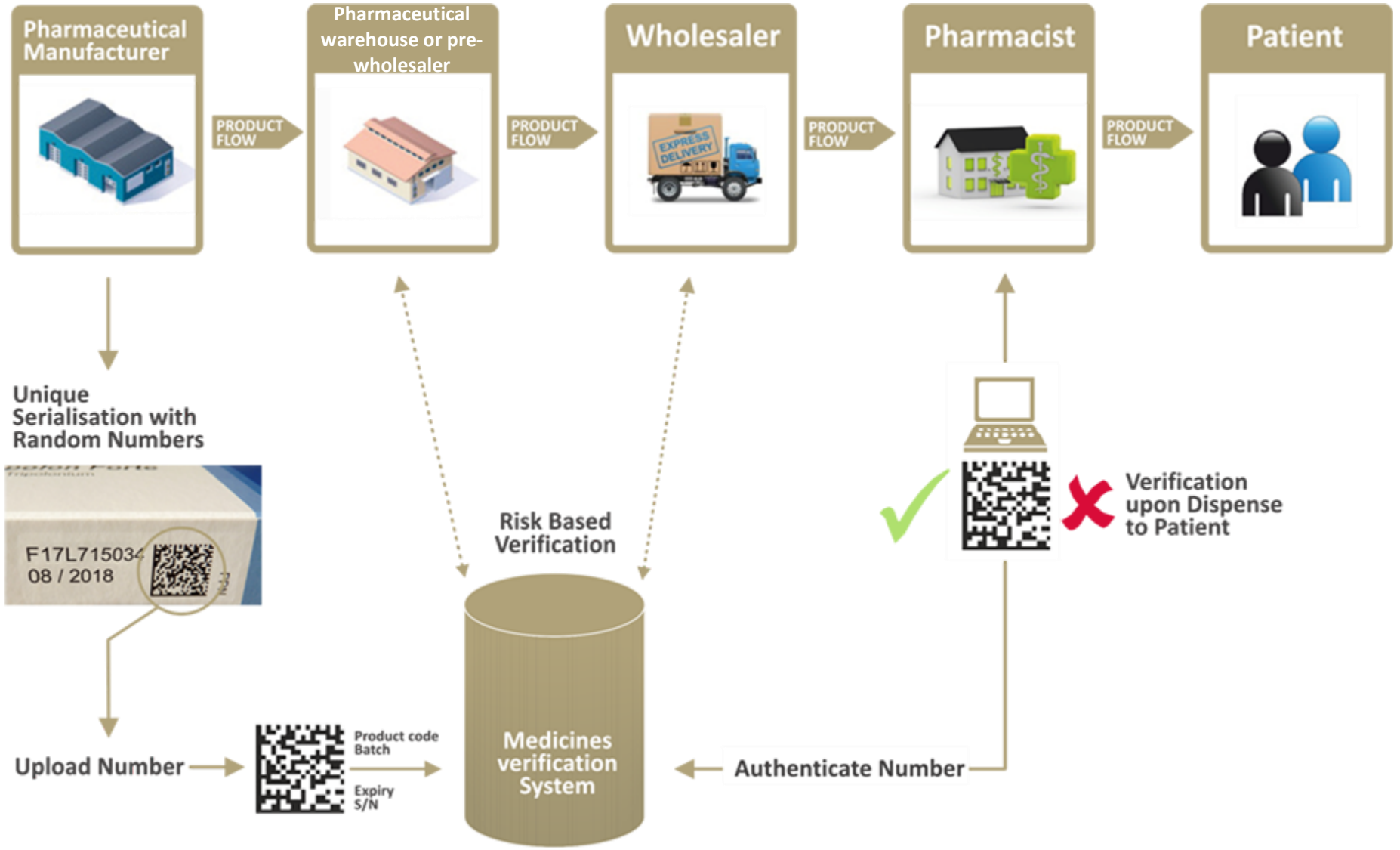
of 8 June 2011

amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products

(Text with EEA relevance)

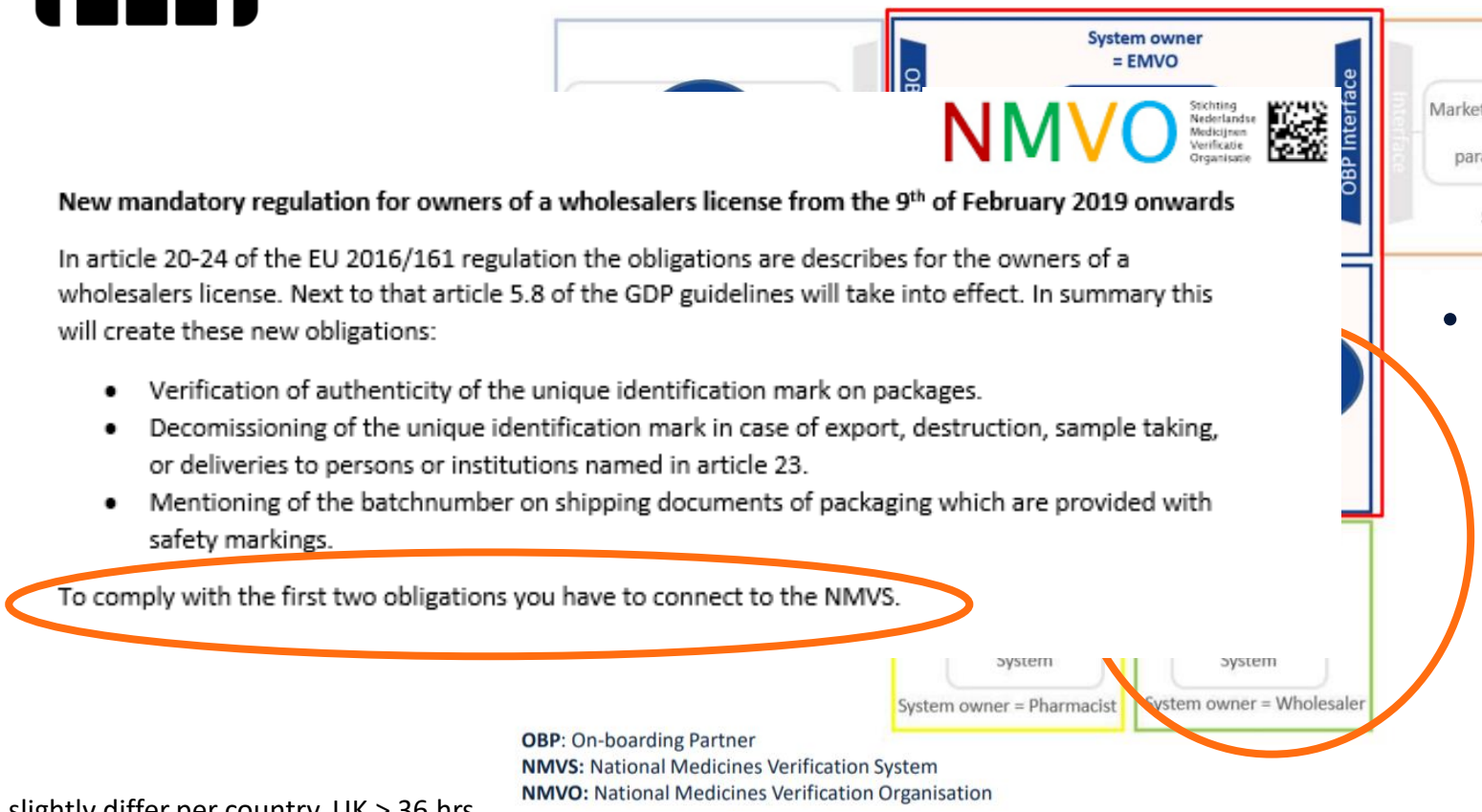
- Falsified Medicines Directive (Directive 2011/62/EU) was published on 1 July 2011, and applies since 2 January 2013
- Commission Delegated Regulation (EU) 2016/161) details the characteristics of the safety features, how medicine authenticity should be verified and by whom.

RESPONSIBILITIES OF THE SUPPLY CHAIN PARTNERS



WHAT ABOUT LOGISTICS/WHOLESALER?

>72* hrs of storage → GDP license
= Warehouse and Distribution Agreement
= Wholesalers license



New mandatory regulation for owners of a wholesalers license from the 9th of February 2019 onwards

In article 20-24 of the EU 2016/161 regulation the obligations are describes for the owners of a wholesalers license. Next to that article 5.8 of the GDP guidelines will take into effect. In summary this will create these new obligations:

- Verification of authenticity of the unique identification mark on packages.
- Decomissioning of the unique identification mark in case of export, destruction, sample taking, or deliveries to persons or institutions named in article 23.
- Mentioning of the batchnumber on shipping documents of packaging which are provided with safety markings.

To comply with the first two obligations you have to connect to the NMVS.

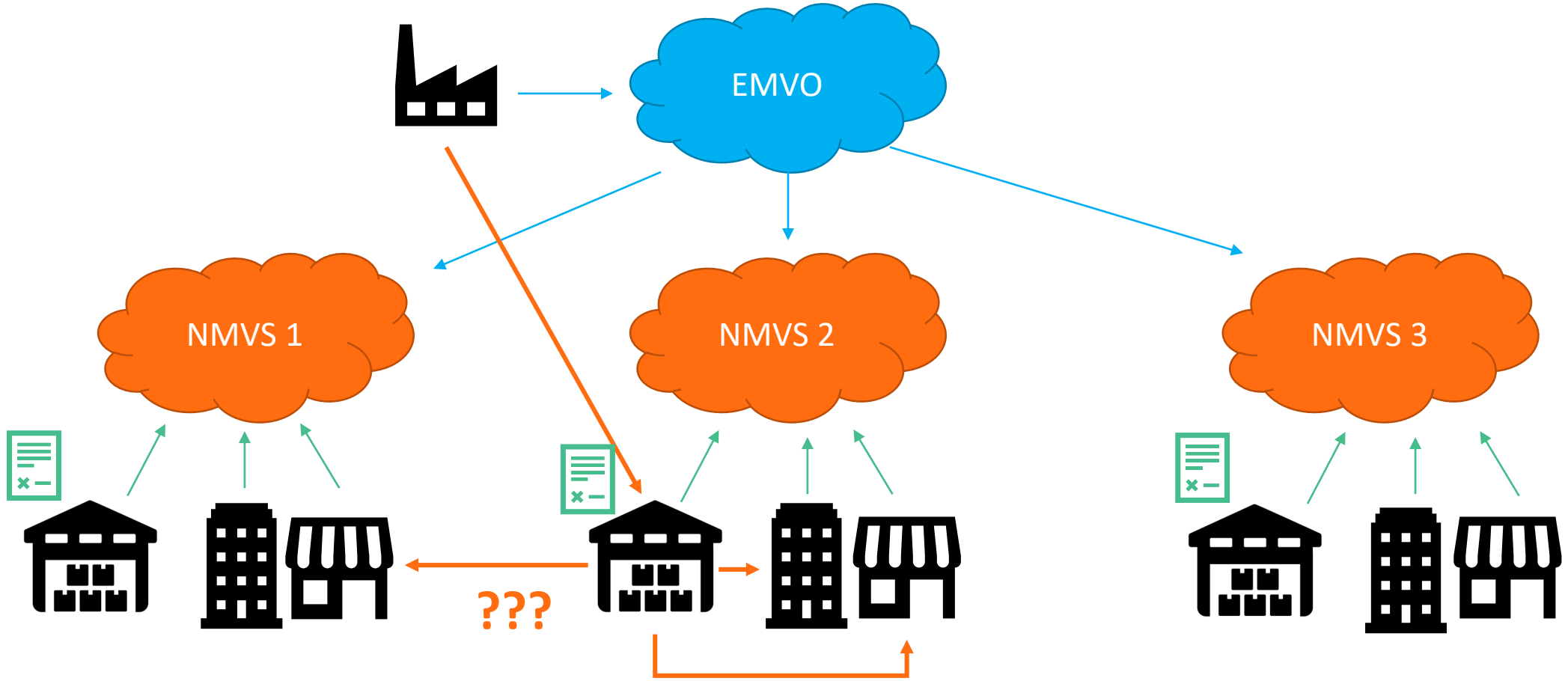
OBP: On-boarding Partner
NMVS: National Medicines Verification System
NMVO: National Medicines Verification Organisation

- Tasks:
  a. **Verification in some cases**
  b. **Decommissioning:**
     - Damaged products
     - Samples
     - Export out of EU
     - Delivery to article 23 location

*Could slightly differ per country, UK > 36 hrs

FMD – THE ACTUAL IMPLEMENTATION

MULTIMARKET WAREHOUSES



SET UP

Warehouse I – Full-line Wholesaler

- Wholesaler license holder
  or
- Use of Customer Wholesaler License
- Direct connection to relevant NMVS

Warehouse II – 3PL

- Third Party Logistics / Pre-Wholesaler
- No own Wholesale license
- Operation of products for external customers (other MAHs)

Verification & decommission

National Verification Systems

Verification & Decommission

EU-Hub

One way communication

No direct feedback in case of suspected products!

Verification & Decommission

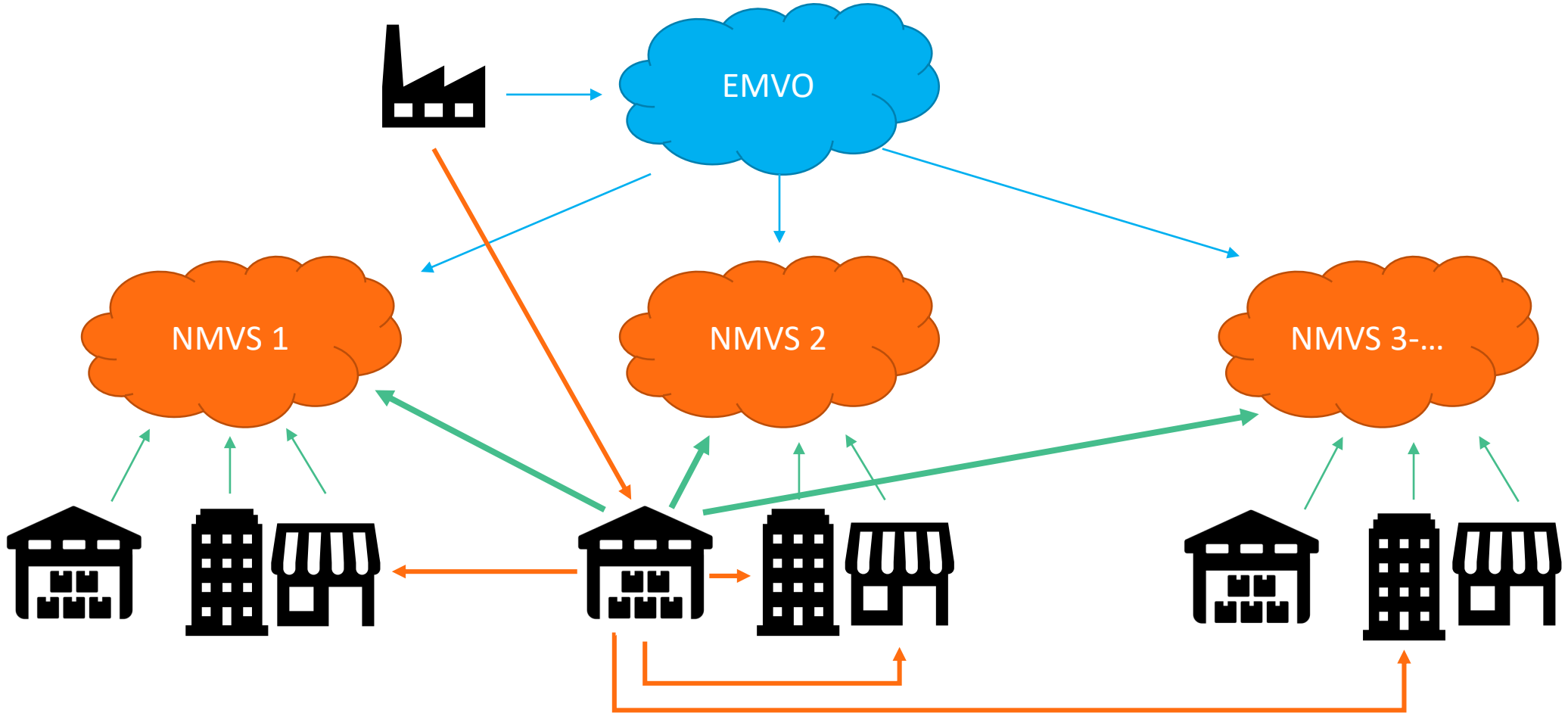
Report Verification & Decommission events

MAH/Customer

Legend

- MAH/Customer OBP account
- (Customer) Wholesale License

CONNECTION TO EVERY NMVS?

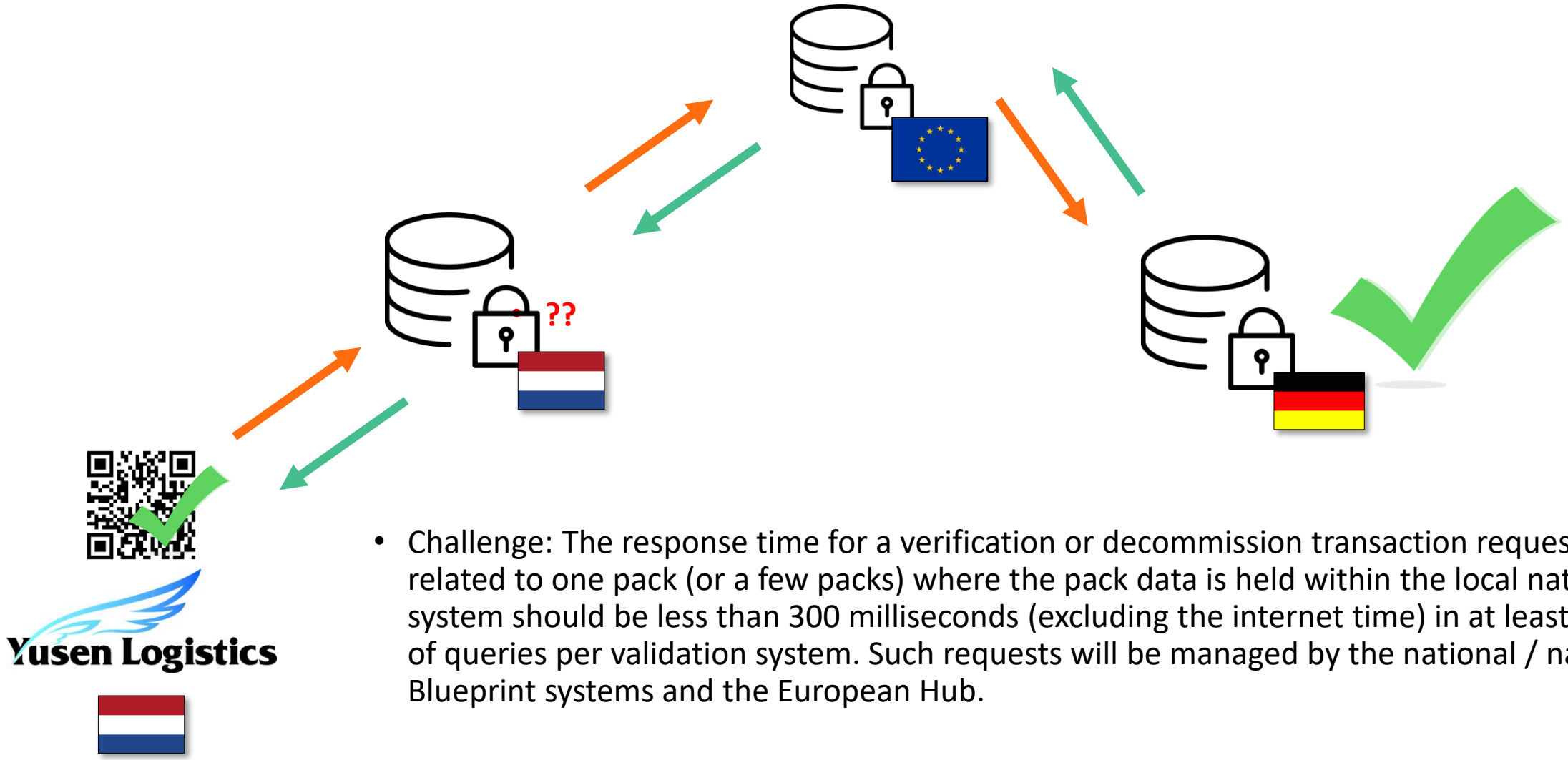


RESPONSE EMVO

- "Holders of a wholesale distribution authorisation can onboard to the national repository system, in the country which has issued the license. As required by the DR, wholesalers (and also persons authorised to dispense medicinal products to the public) can verify via their national connection the authenticity of any product and decommission the unique identifier in any Member State via their national connection. This triggers a so called IMT (Inter Market Transaction), for which however response times are longer."

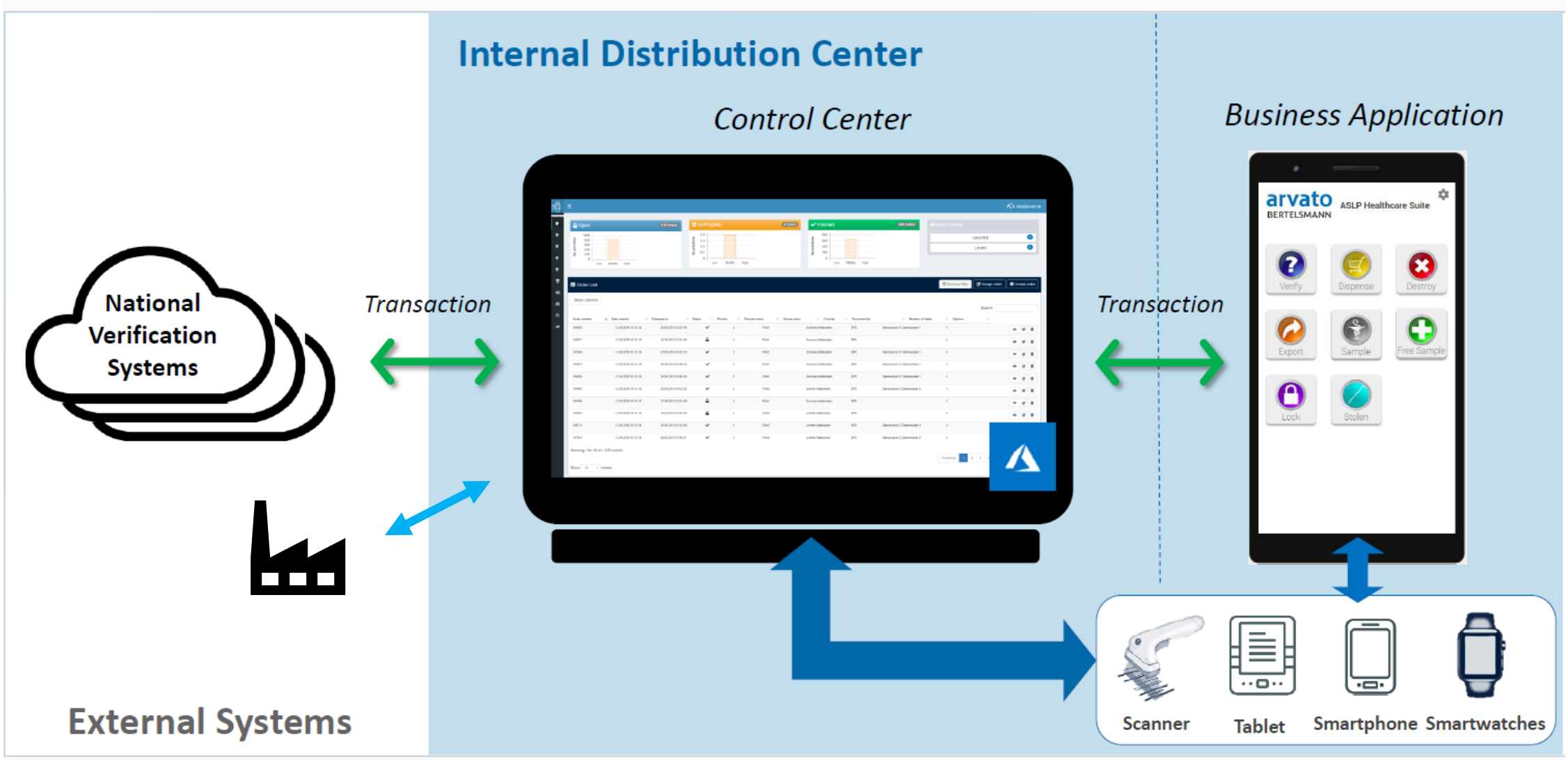
emvo European Medicines Verification Organisation

INTERMARKET DECOMMISSIONING - EXAMPLE

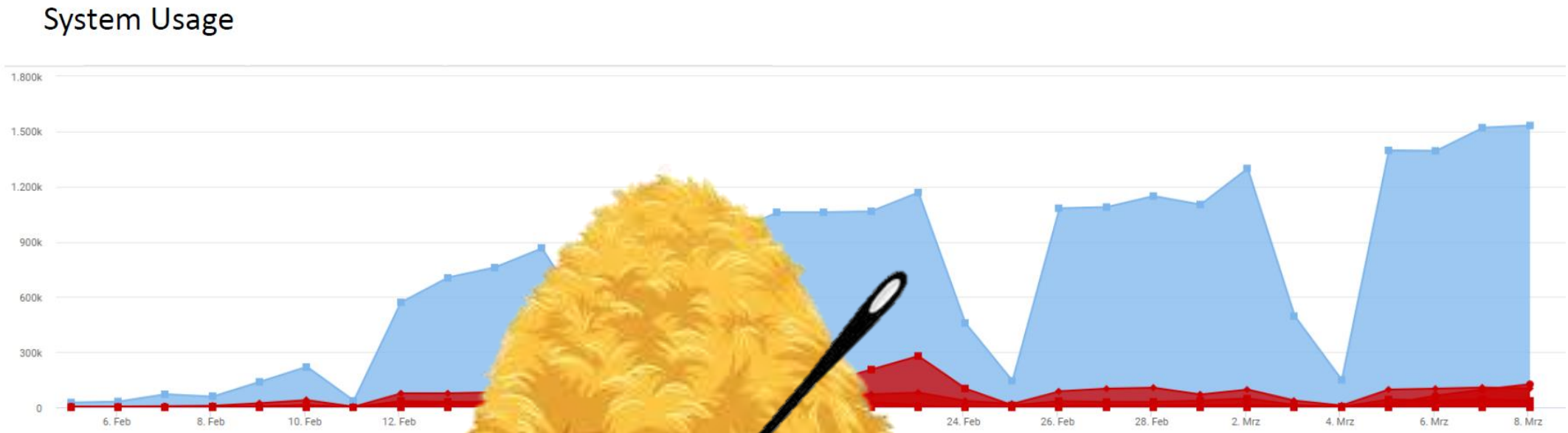


- Challenge: The response time for a verification or decommission transaction requests related to one pack (or a few packs) where the pack data is held within the local national system should be less than 300 milliseconds (excluding the internet time) in at least 95% of queries per validation system. Such requests will be managed by the national / national Blueprint systems and the European Hub.

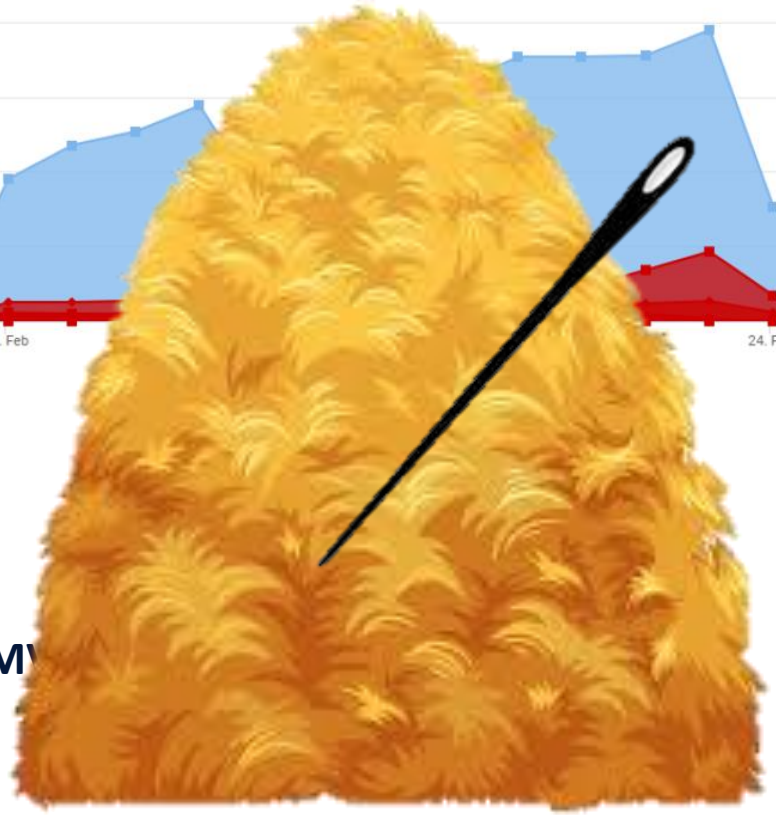
IMPLEMENTATION WITHIN YUSEN PHARMA WAREHOUSES



IMPLEMENTATION FMD UP UNTIL NOW?



- High alert rate
  a. **Expiry date format (00)**
  b. **MAHs upload issues to EMV**
  c. **10% → 3-4%**



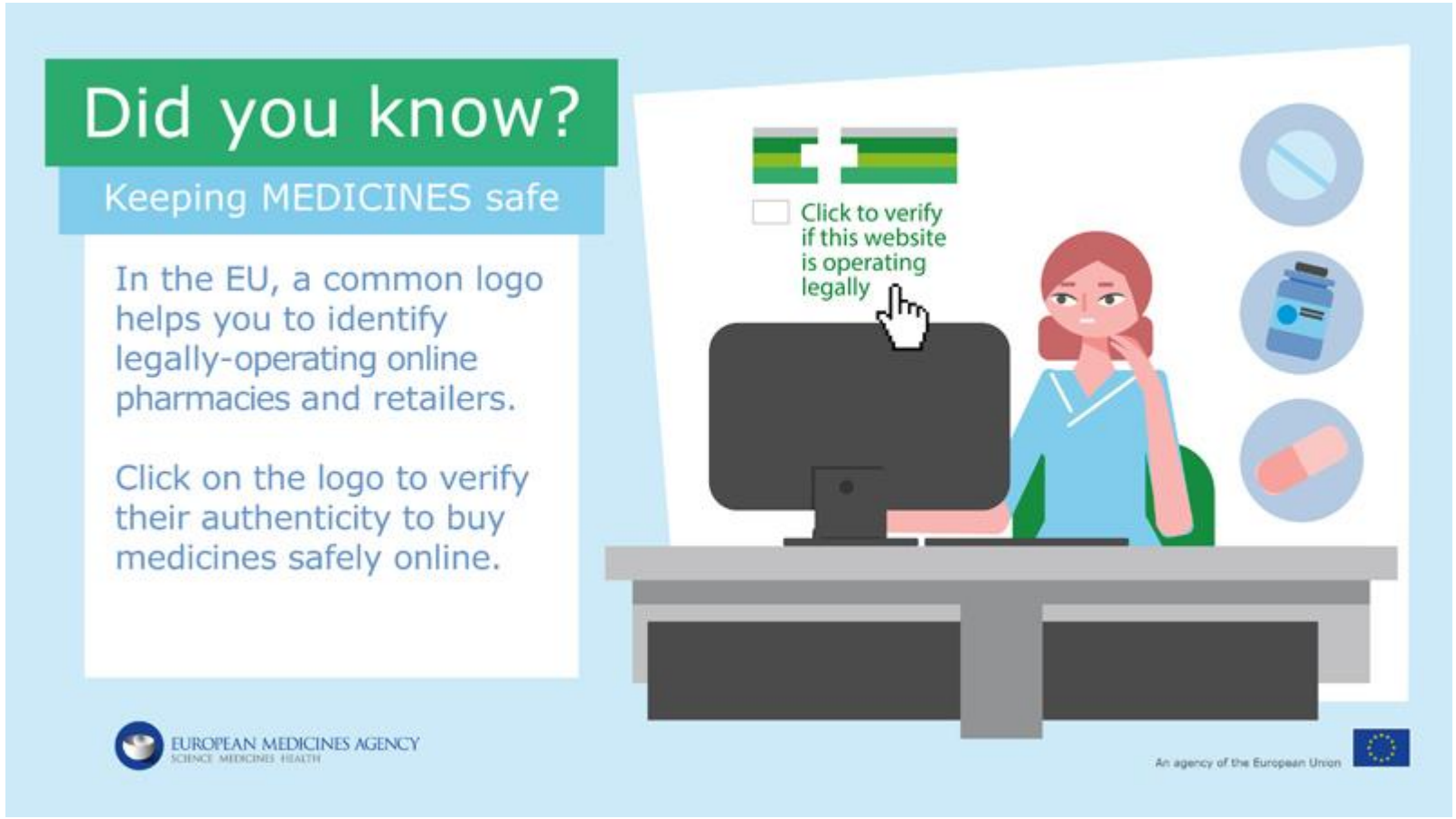
FMD – THE FUTURE?

WHAT ABOUT THE INTERNET?

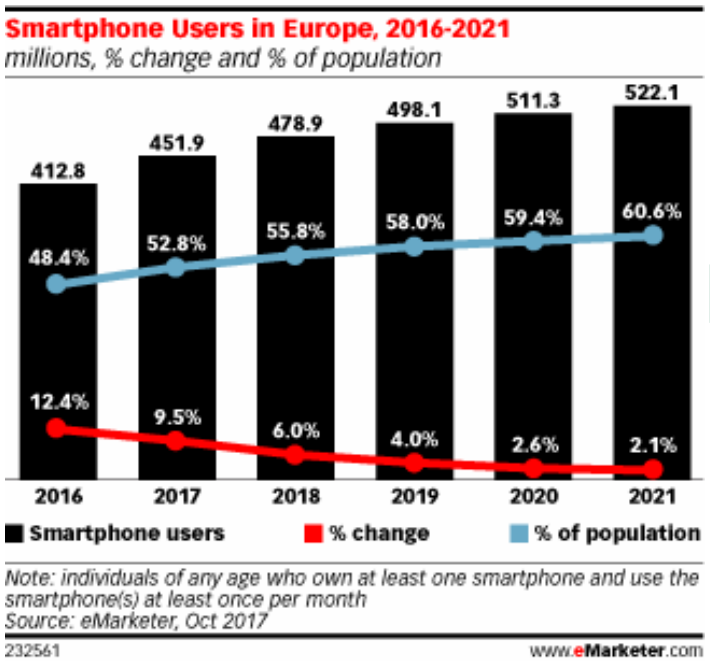
INTERPOL'S OPERATION PANGEA - 2018 FIGURES

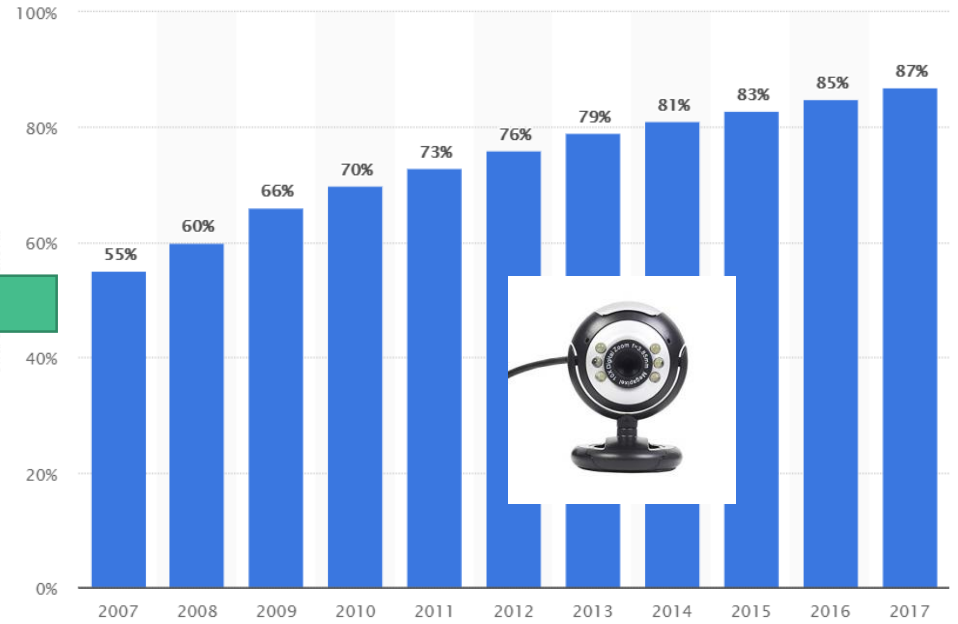
- Police, customs and health regulatory authorities from 116 countries focusing on illicit online sale of medicines and medical products
- 859 arrests worldwide, seizure of USD 14 million worth of potentially dangerous pharmaceuticals, 3,671 web links closed down
- Almost one million packages were inspected during the week of action, with 500 tonnes of illicit pharmaceuticals seized worldwide.
- Anti-inflammatory medication, painkillers, erectile dysfunction pills, hypnotic and sedative agents, anabolic steroids, slimming pills and medicines for treating HIV, Parkinson's and diabetes.

INTERNET SALES

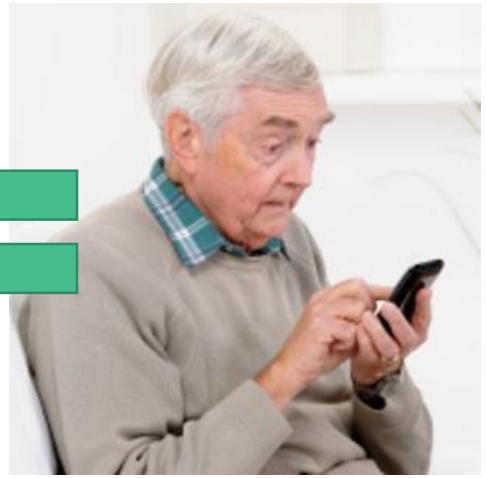


PATIENT IN CONTROL?



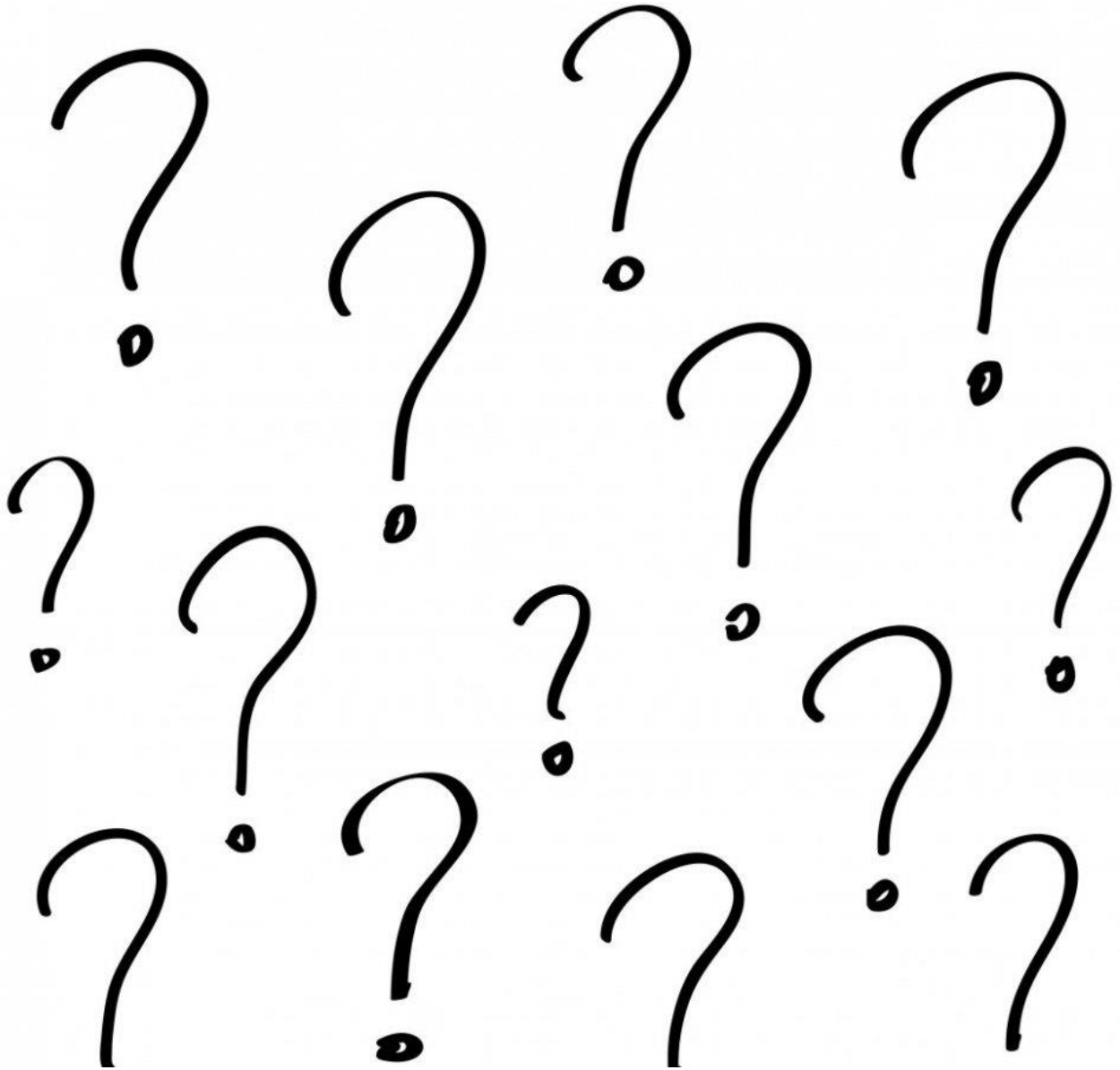


Share of households with internet access in the European Union (EU28) from 2007 to 2017



- Offer additional verification/trace functionality to the patient?
- This approach would cover internet medication as well!

QUESTIONS?



THANK YOU!