

Pumping Up the Economy / Life on Mars

Newsweek

25.09.2015

PHONY MEDICINE

PHARMACEUTICAL FRAUD IS EXPLODING, READY AND ABLE TO STOP

FMD Implementation in



Martin J. Hug

Pharmacy

Freiburg University Medical Center

Newsweek: 25.09.2015



**UNIVERSITÄTS
KLINIKUM** FREIBURG

German Hospitals



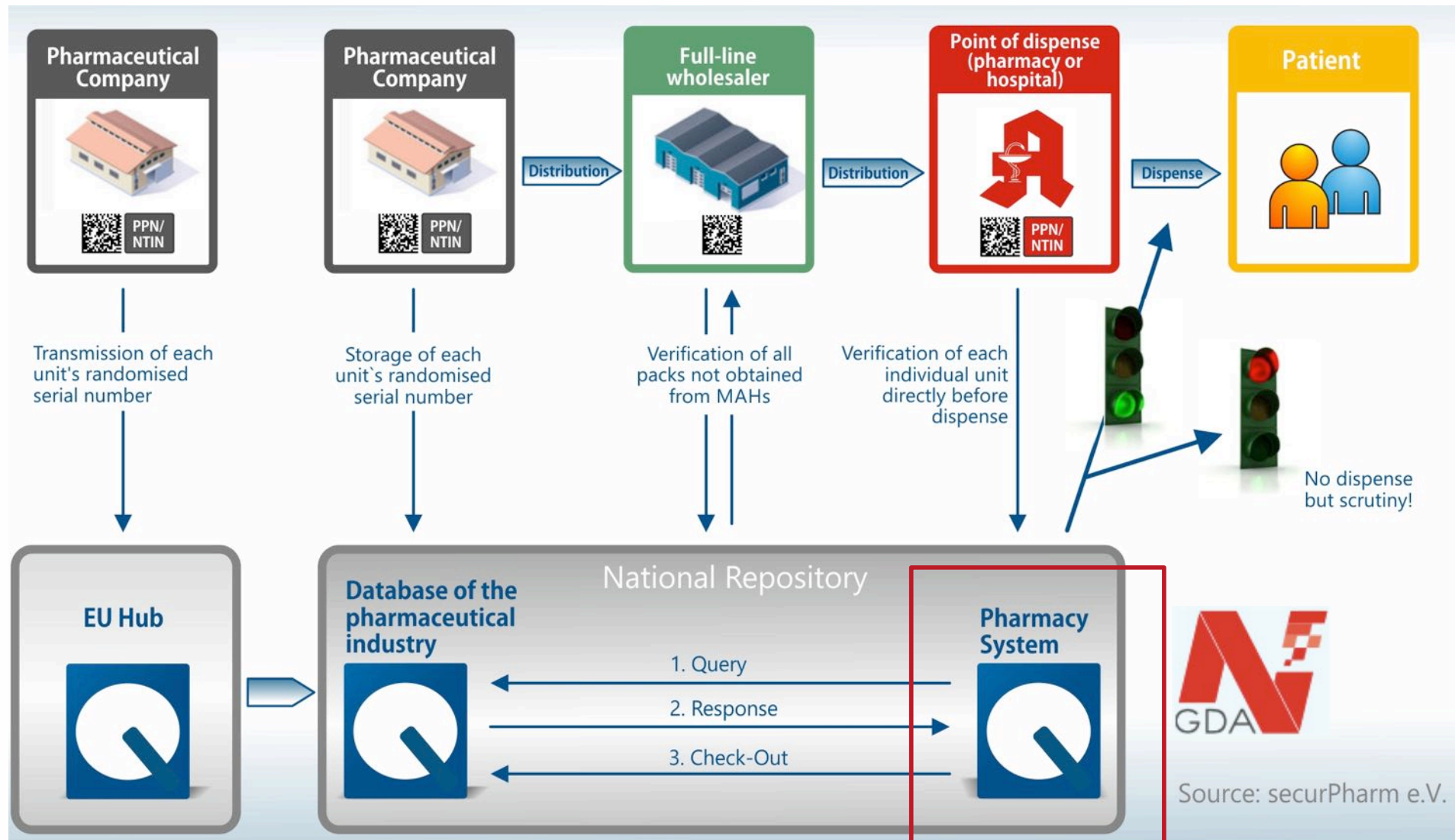
Prince

Todesursache:
Gefälschte
Medikamente?

*FBI hat Untersuchungen eingeleitet



The German stakeholder model: securPharm e.V.

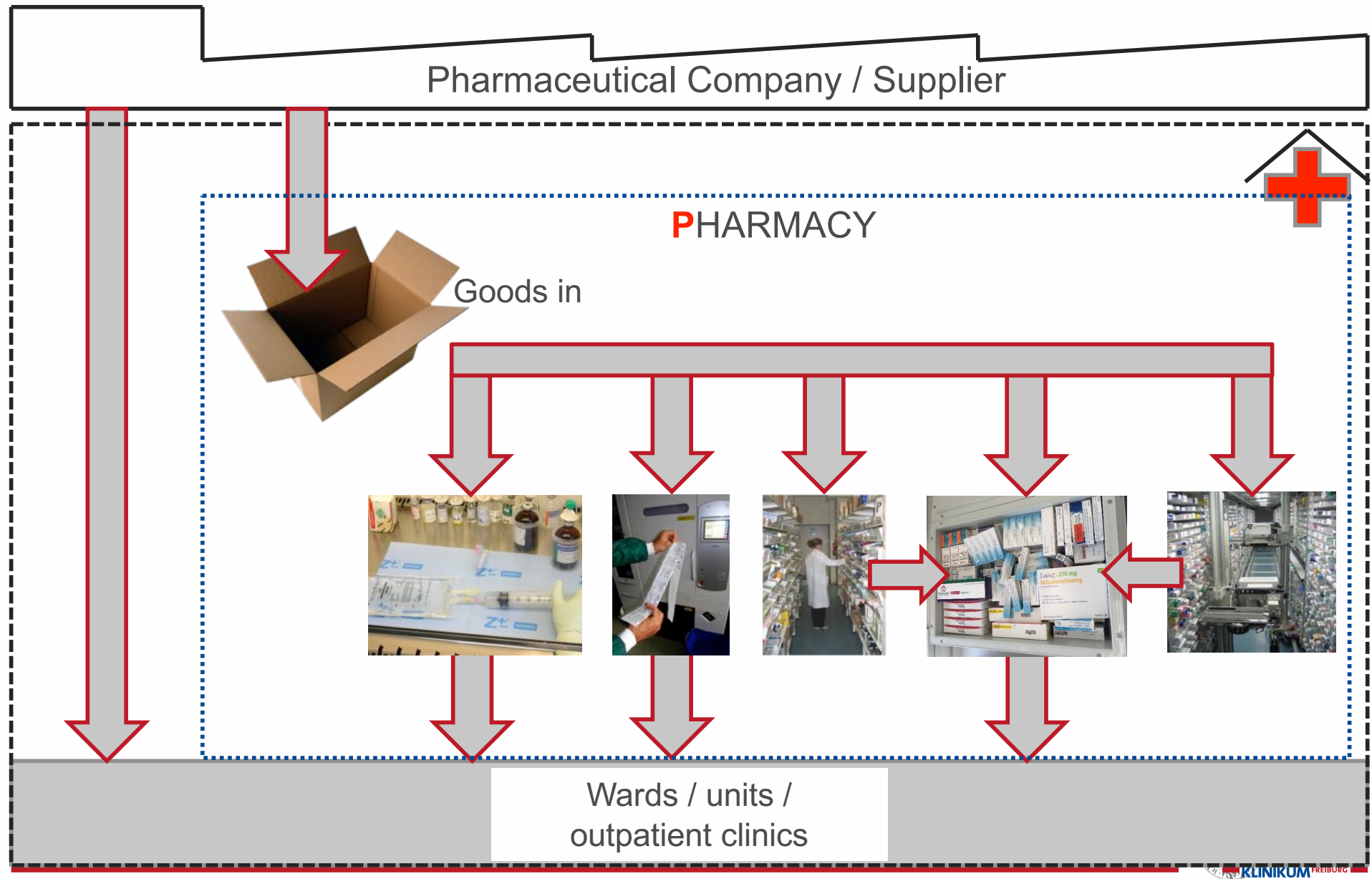


Commission Delegated Regulation, Article 25

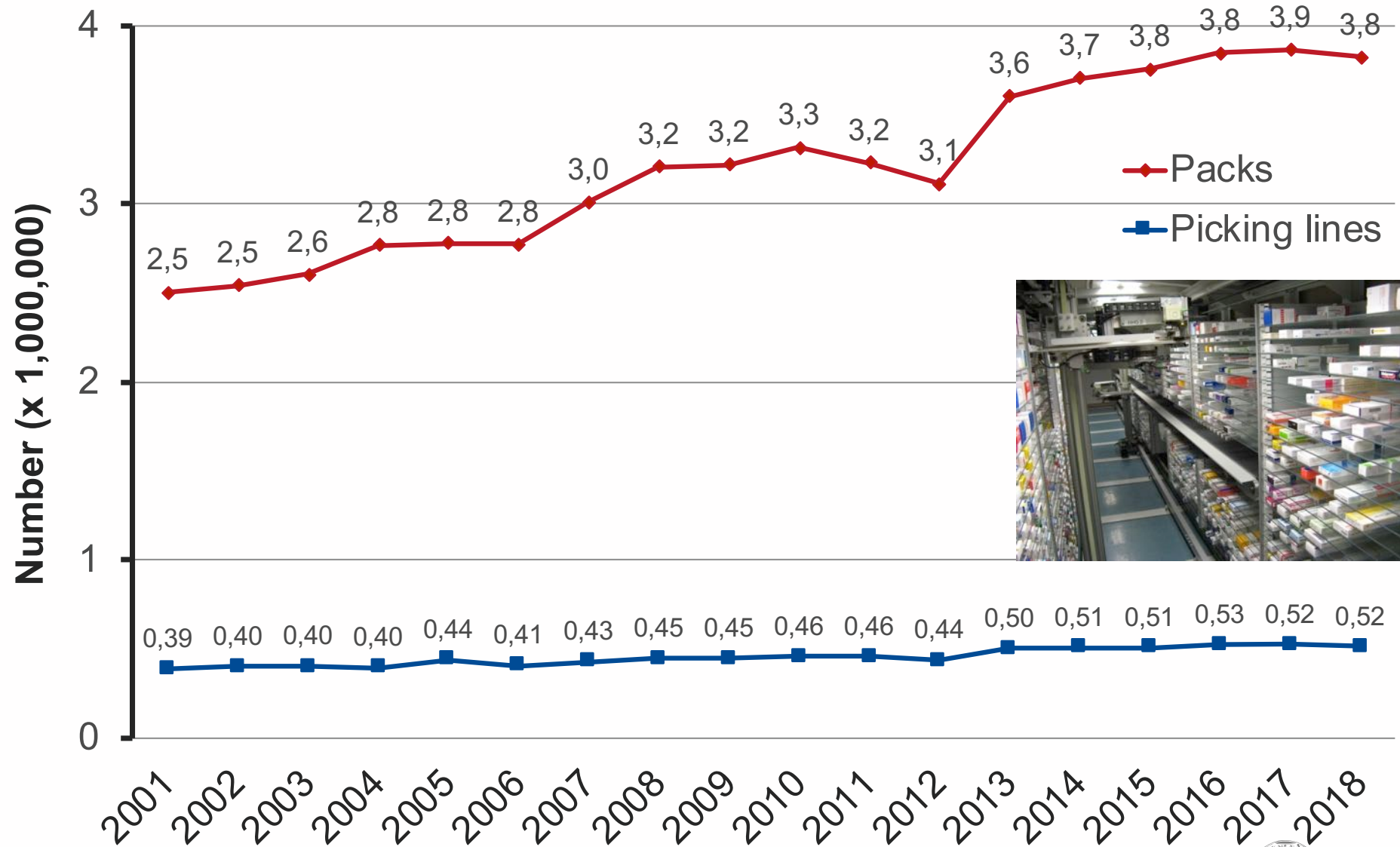
Obligations of persons authorised or entitled to supply medicinal products to the public

1. Persons authorised or entitled to supply medicinal products to the public shall verify the safety features and decommission the unique identifier of any medicinal product bearing the safety features they supply to the public **at the time of supplying it to the public.**
2. ... persons ... operating within a healthcare institution may carry out that verification and decommissioning at **any time** the medicinal product **is in the physical possession of the healthcare institution...**

Logistic pathways within the hospital



Development of drug logistics at UMCF



Pro's and Con's of FMD

Viewpoint of German Hospital Pharmacists

Protection against counterfied medicines



Possibility to *Track & Trace* on pack level



Easier control of lot numbers and exp. date



Connection to a central data hub



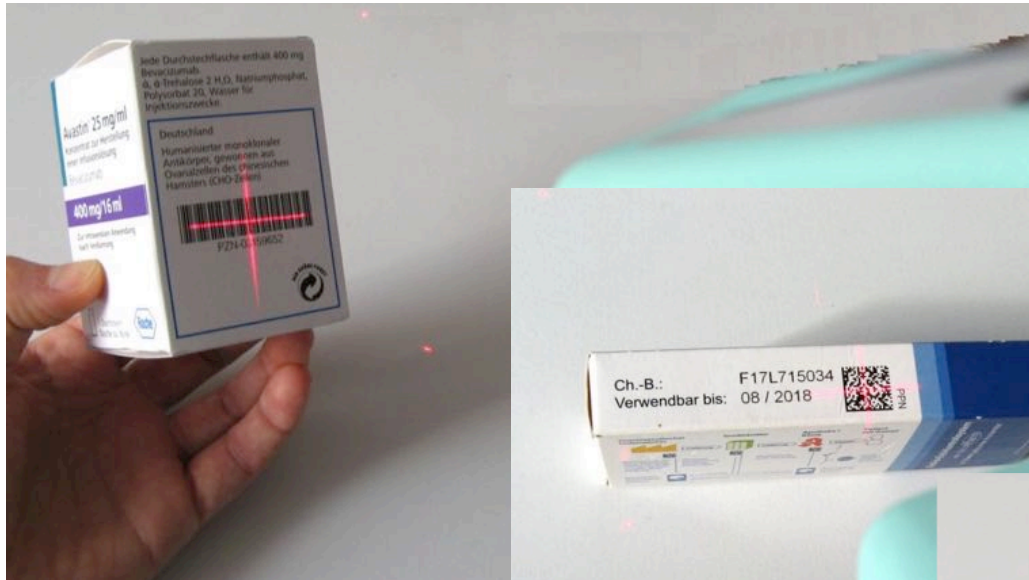
Hard- and software acquisition necessary



Time and staff consumptive



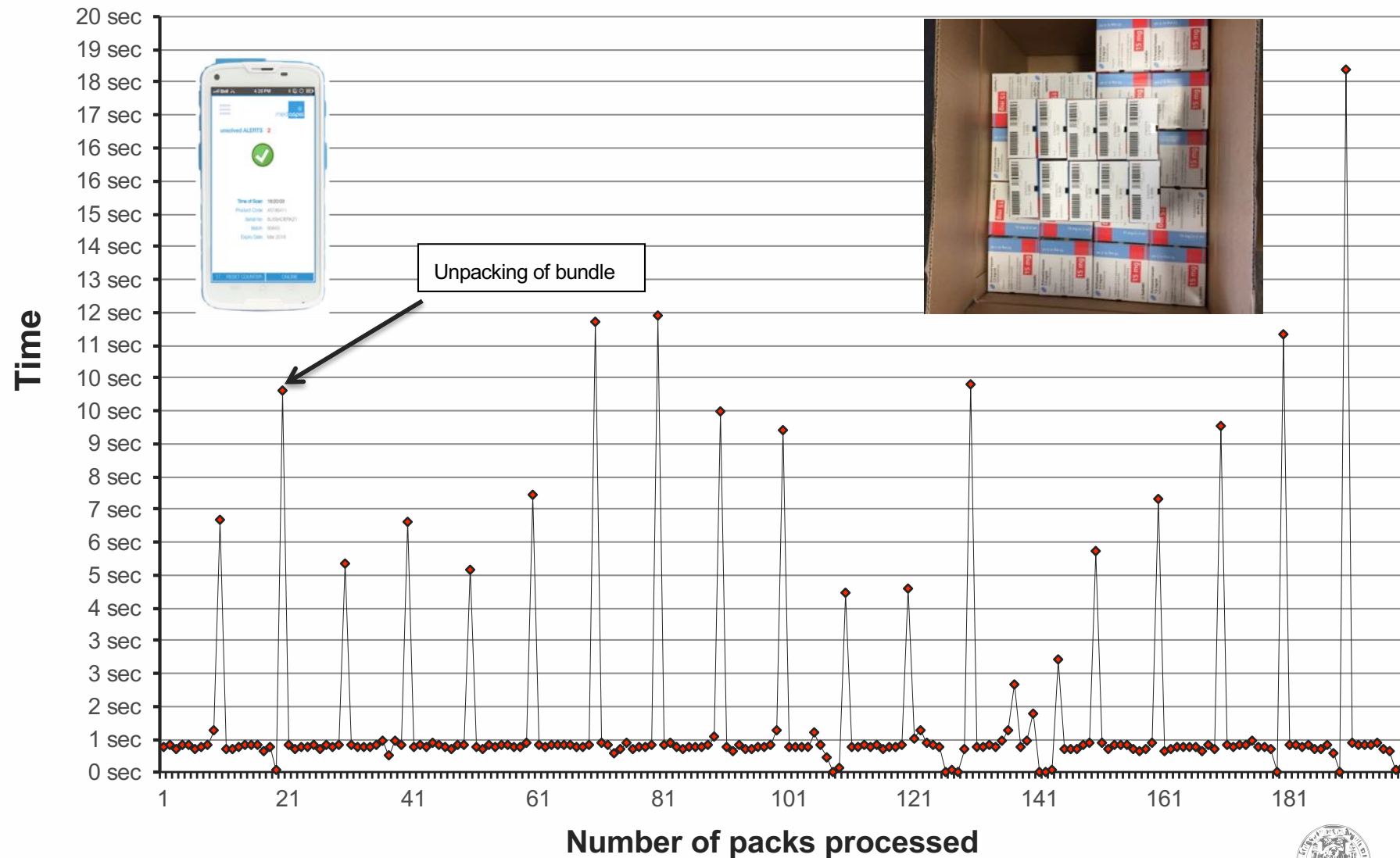
Simulation of the verification process at UMCF



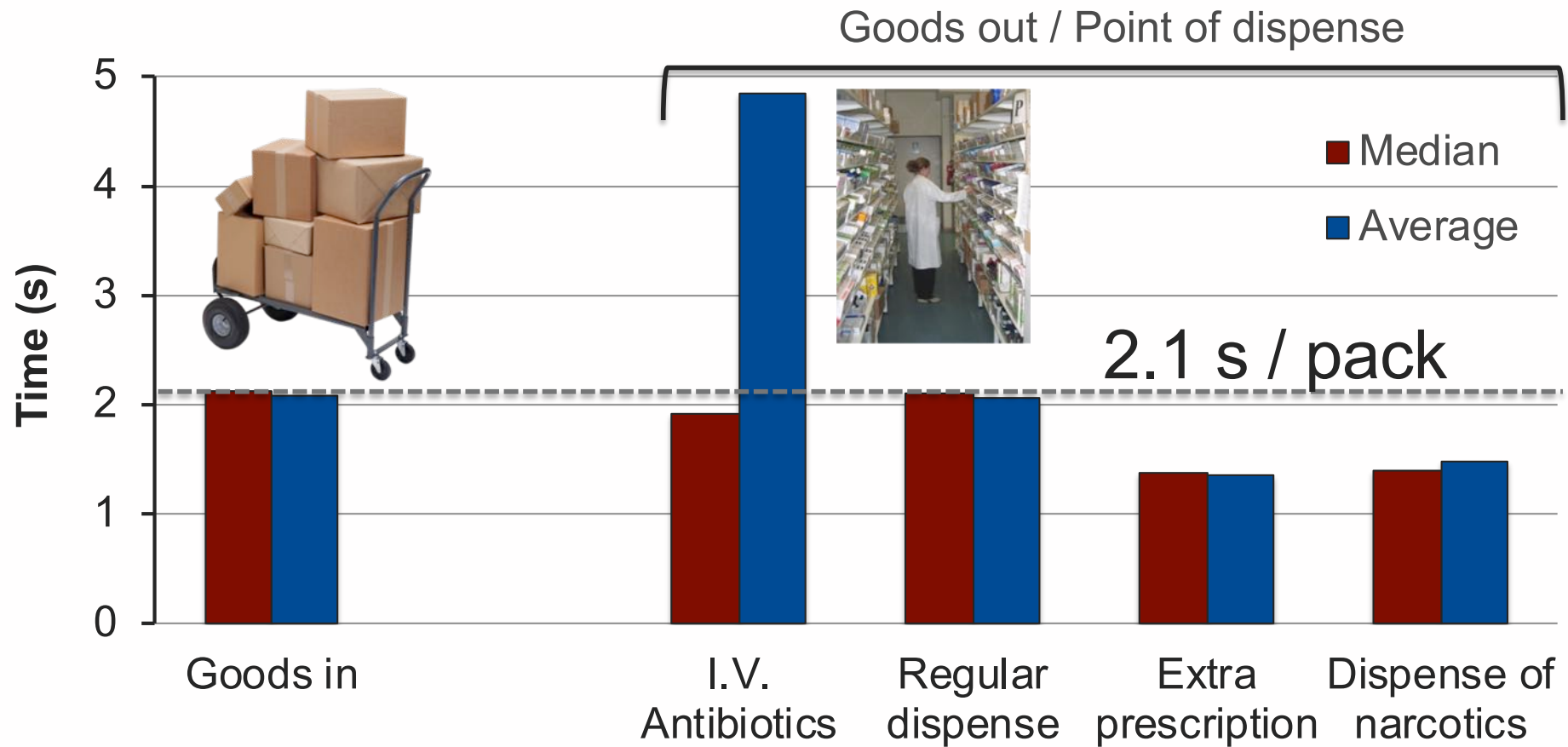
Situation at *Goods in*



Example: Piritramid (i.v. opioid)



Comparison: Process time



How much *Manpower* do we need?

Example UFMC

3.8 Mio. Packs / Year

-1,2 Mio. Packs not within the scope of the
Commission Delegated Regulation

2,6 Mio. Packs x 2.1 s = 5.46 Mio. s = 1,520 h / Year

-> 1.1 – 1.3 Full Time Equivalents

How to connect the hospitals to the NMVS?

Inventory management software



No

Infor M3



We demand from the pharmaceutical companies:

User friendly design of boxes and shipping containers



We would like to have: **Aggregated Codes**

Q&A Dokument (Version 5.0 June 2016)

3.4. Question: Is it allowed to simultaneously verify the authenticity of or decommission multiple unique identifiers by scanning an aggregated code?

Answer: **Yes**, it is possible to verify the authenticity of or decommission multiple unique identifiers by scanning an aggregated code rather than scanning each individual pack, provided that the requirements of Regulation (EU) No 2016/161 are complied with.

What is an **aggregated** Code?

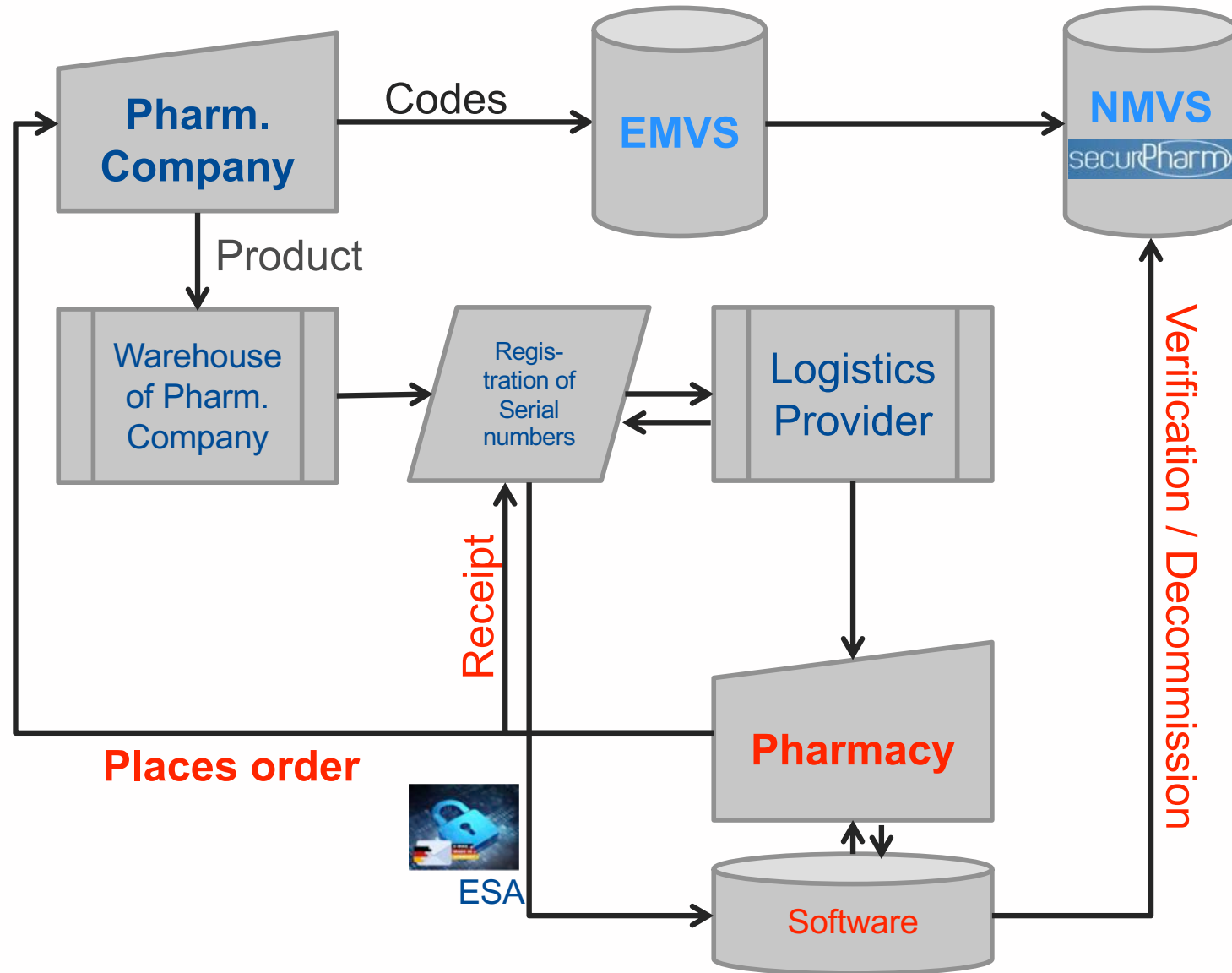
An aggregated code is a reference to all serial numbers in a shipment unit

Problem: neither the database structure of the European Medicine Verification Organisation (EMVO) nor that of the individual national systems had been designed to process aggregated codes



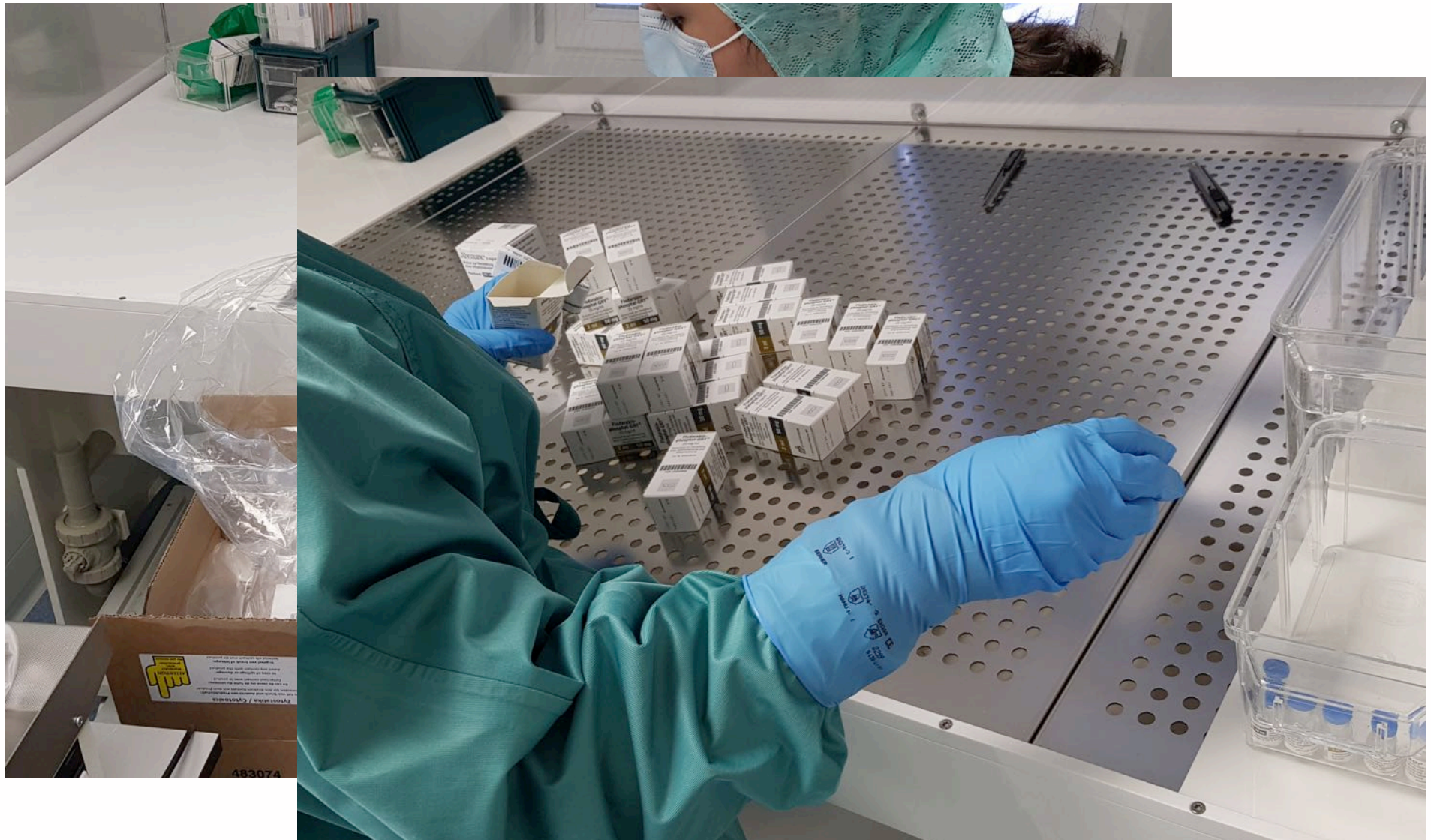
Easier verification / deactivation by institution

With assistance of the electronic shipment advise (ESA)



Why is it so important?

Unpacking of cytotoxic drugs in the cleanroom



Opinion by the EU Commission

Questions and Answers Document

6.6. Question: Is it acceptable for hospitals/hospital pharmacies to subcontract their decommissioning obligations to wholesalers?

Antwort:

*Wholesalers could acquire the information on the UIs in the hospital consignment and make this information available to the hospital, by secure means. The hospital would then use such information to perform the decommissioning (**without having to physically scan the packs**).*

Results of the Pilotproject

Organised by the German Association of Hospitals (DKG)

DKG Krankenhausapotheke-Prototyp

154 Packungen

ALLE VERIFIZIEREN

ALLE AUSBUCHEN

ALS CSV EXPORTIEREN

NEUE PACKUNGEN LADEN

NEU AUTHENTIFIZIEREN

Lieferung 412221709, 154 Packung(en)

Nr.	PPN	Charge	Verfallsdatum	Seriennummer	Kodierung	Verifiziert	Ausgebucht
1	04150055435152	183558131	210731	00027594614183063916	GS1	✓	✓
2	04150055435152	183558131	210731	0003066041885037609	GS1	✓	✓
3	04150055435152	183558131	210731	00066290149174663295	GS1	✓	✓
4	04150055435152	183558131	210731	00203972613016330957	GS1	✓	✓
5	04150055435152	183558131	210731	00219287079073525517	GS1	✓	✓
6	04150055435152	183558131	210731	00320160811470715265	GS1	✓	✓
7	04150055435152	183558131	210731	00346598383756937524	GS1	✓	✓
8	04150055435152	183558131	210731	00593233668702611948	GS1	✓	✓
9	04150055435152	183558131	210731	00626746272453709359	GS1	✓	✓

Verification: 7s

Decommissioning: 7s

Open questions:

- Will the servers of the EMVO/NMVO be capable in processing the large amount of data transmitted by the hospitals?
- How to separate serialised from unserialised packs? (Identifier?)
- What is the optimal way in connecting the hospitals?
- How to deal with products that fall under different distribution pathways (cf. Article 23)?
- Which procedures are to be followed when drugs are being supplied from one health care institution to another?