European Federation of Pharmaceutical Industries and Associations

Verification of Pharmaceutical Products at the Point of Dispense

Status of the EFPIA Project

Speaker : Grant Courtney

Event: GS1 Global Forum - São Paulo

Who is EFPIA ?

- The **European Federation of Pharmaceutical Industries and Associations (EFPIA)**
  - represents the R&D based pharmaceutical industry operating in Europe
  - direct membership of 31 national associations and 44 leading pharmaceutical companies
  - EFPIA is the voice of 2,200 companies committed to researching, developing and bringing to patients new medicines that will improve health and the quality of life around the world

Who am I ?

- 15 years supply chain and product design for GlaxoSmithKline
- Member of the GS1 Healthcare Leadership Team and Co-Chair of the Public Policy Team
- Sit on various **EFPIA** groups addressing product coding

Agenda

- Objectives & European Context
- The model EFPIA supports
- The EFPIA Pilot Project: Results and conclusions
- Next Steps

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Objectives

- Improving patient safety
  - Reduce the risk of counterfeit products being dispensed
  - Detect expired products automatically
  - Perform product recalls more effectively and efficiently
  - Deliver the right product to the right patient

- These systems will also have other benefits such as supporting governments with their reimbursement processes

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Three measures to protect packs

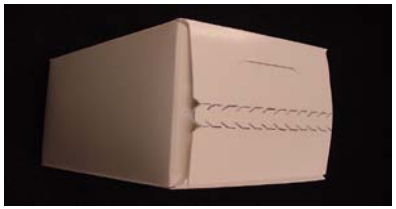
Increased Protection
(Patient/Product)

Use of harmonised coding and identification systems for secondary packs of pharmaceuticals

Use of overt and covert features to authenticate products

Guarantee the integrity of the original manufacturer's pack throughout the entire supply chain

Dispensing verification confirmation



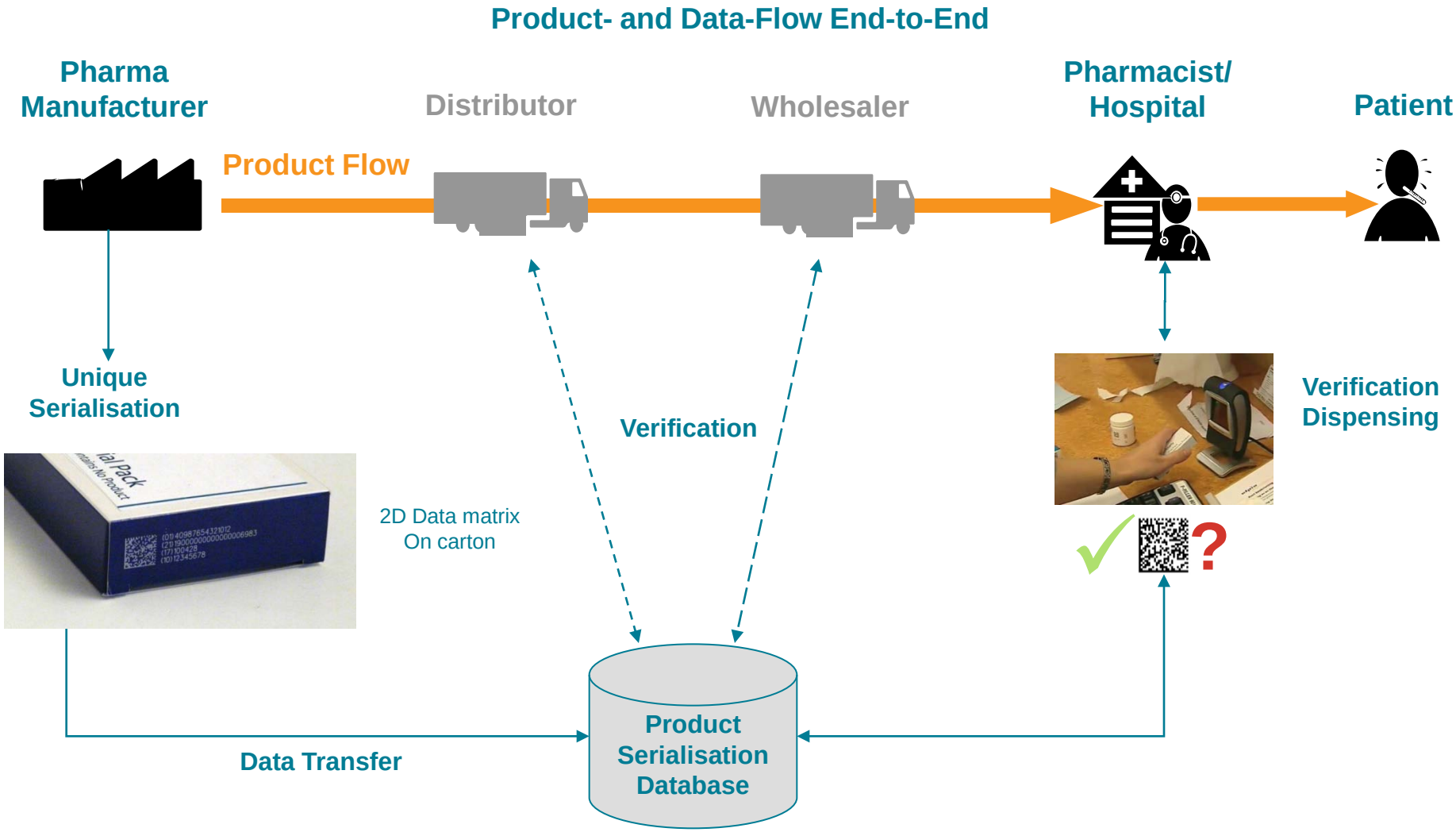
Some minimum standards are required for a pan-European product verification system

Minimum standards required[1]

	Minimum standards	Common to all
Model / System	• End-to-end verification system (not track and trace) • Mandatory verification at point of sale (using serial number) • Storage of product data and dispensing data in national databases	• Flexibility (within limits) to allow for national level solutions – Different timelines to implementation – Different national regulations e.g. on data storage and availability – Flexibility in terms of service providers
Pack	• Two mandatory elements required for the packs 1. Product verification based on standardized mass serialization (applied on **outer package**, e.g. folding box) 2. Pack integrity by tamper evident packaging (individual solutions feasible)	
Data	• Data carrier as Data Matrix code • Information content (in GS1 format): – Product number (GTIN or NTIN) – Batch number – Expiry date – Serial number (randomized) • Link between original manufacturer's code and replacement code issued by repackager	

(1) These are independent of the governance model

The verification model EFPIA's supports



EFPIA Recommendation for Coding of Pharmaceutical Products in Europe

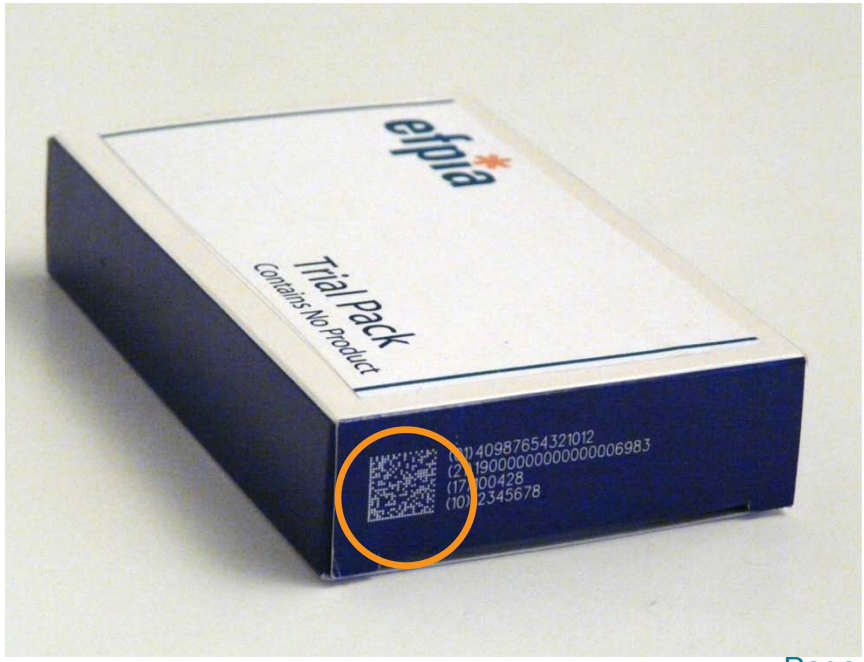
Data Matrix – Coding proposal derived from GS1 standards
(EAN 128 syntax with Application Identifiers; Data matrix ECC200)

Manufacturer Product Code (GTIN or NTIN)	14 digits
Unique Serial Number (randomized)	up to 20 alpha-numeric characters
Expiry Date	6 digits (YYMMDD)
Batch Number	up to 20 alpha-numeric characters

+ minimum requirements on quality of randomisation

Example:

GTIN: (01) 07046261398572
Batch: (10) TEST5632
Expiry: (17) 130331
S/N: (21) 19067811811



Specifications provided in EFPIA's:
"European Pack Coding Guidelines"

How does the EFPIA product verification solution work?

Product verification: the action of comparing data held within the product code with a secure product record on a database and confirming that:

a) Product record exists and matches data held on package

b) Product record has not been previously marked as 'dispensed'

c) Product record does not contain any warnings or advisory notices (such as recalled, expired, etc)

Product verification

- Any duplicate instance of product code can be detected prior to widespread proliferation of a potential problem
  - Any copying/counterfeiting of the 2D Matrix code will be identified by the system

Does not guarantee the genuine nature of the product contained within the coded product pack

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EFPIA pilot project

- EFPIA conducted a pilot project in cooperation with pharmacists
- Objective was to demonstrate the EFPIA proposal as:
  - an aligned approach with the EC's pharmaceutical package
  - a practical and effective solution for relevant stakeholders (manufacturers, pharmacists, wholesalers)
    - That can be fully integrated into their existing operations
  - a model that works based on common standards & mature technology
    - High performance and a secure system
  - A credible alternative to proprietary national systems, aligned with government requirements

Pilot project overview

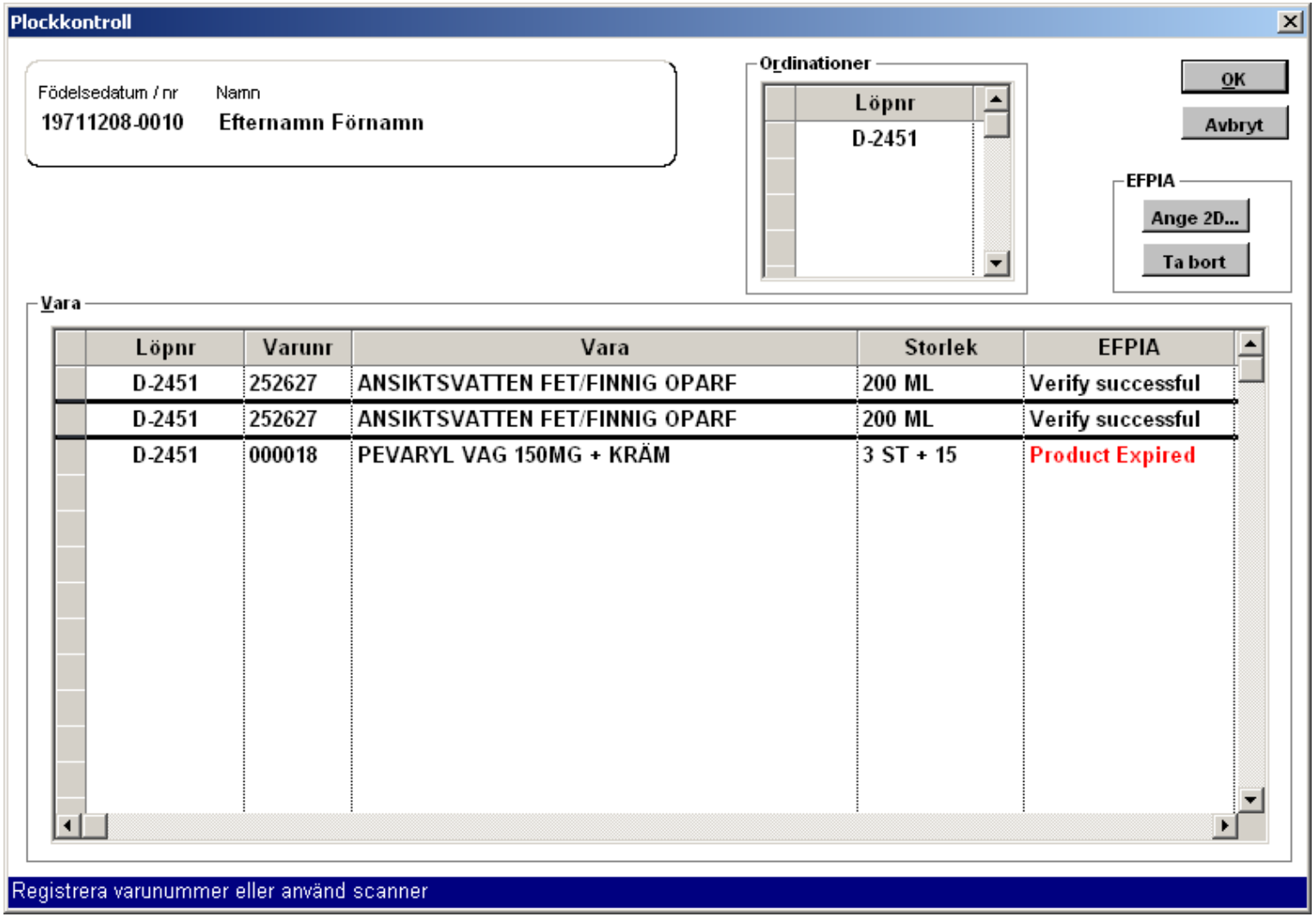
- Key figures
  - 25 pharmacies in the greater Stockholm area (owned by Apoteket AB) with a total of 180 dispensing points
  - 25 products (SKUs) with total of 110.000 packs
  - 14 manufacturers
  - 4 months duration of operational phase

- Operational phase
  - Started with 3 pharmacies on 17 September
  - Remaining 22 pharmacies joined on 24 Sept

- Wholesalers labelled and distribute packs(*)
  - Kronans Droghandel
  - Tamro

(*) Serial number management system provided by Melior Solutions

Example screen: Integrated client



Final results – quantitative

- Number of packs sold:
  - Ca. 95.000 packs which is ca. 84 % of packs coded
- Excellent system response times
  - ~ 94,5 % of transactions completed in < 0.5 sec
  - ~ 99,7 % of transactions completed in < 1.0 sec
  - ~ 99,9 % of transactions completed in < 2.0 sec
- System >99,9 % online
- Exception alerts
  - 180 verification / dispense transactions for packs with incorrect serial number
  - 373 packs verified after having been marked as dispensed (cf backup slides for explanation)
  - 283 packs sold although already marked as dispensed

Why were there exception alerts

Simplified example

1. Pack 1 is scanned and verified
2. Pack 2, of the same product, is scanned and verified
3. Patient decides not to collect both packs
4. Pack 1 is checked back into the system

5. **Pack 2** is returned to the shelf

. . . Some time later

1. Pack 2 is scanned and fails to verify – already shown as dispensed

Understanding all the processes undertaken within the pharmacy is critical to ensure the system operates correctly

Response from pharmacists

- A survey was undertaken to obtain feedback from the pharmacists
  - 10 questions with option to provide comments
  - 123 pharmacists submitted a response, from 230 who participated

Results

- Q. Did you find the product verification system easy to use?
  - 94% of pharmacists found it easy or very easy to use
- Q. Was the response time of the verification system acceptable?
  - 85% found the system fast
- Q. Do you feel that this project required additional effort in dispensing products to patients?
  - 96% of pharmacists found the level of effort acceptable or better

- Positive feedback included
  - Ease of use of the system
  - Little additional effort to verify
  - Good experience with the scanning equipment

Feedback was very positive

Response from pharmacists

- Issues identified
  - Additional effort when scanning – scanners read linear bar code instead of the 2D
  - One defect that led to a number of cases where a pack was marked as “dispensed” although it was still in stock (cause has been identified)

- Feedback specific to the pilot
  - Special ordering process (this would not be required beyond a pilot)
  - Sufficient supply of coded packs

A single barcode on the pack prevents confusion when scanning the pack

Response from pharmacists

- In addition to the questionnaire a Focus group meeting with 5 pharmacy managers was held to obtain more detailed feedback to clarify open questions

Feedback

- Confirmed very positive feedback for overall system
- Expect high value from automatic detection of expired or recalled products
- Clearly prefer to have only one code on the pack
- Would like to see the same code type on all packs
- Would like to see more information provided by the system:
  - Description of tablet colour and shape (is it easy to split it to obtain half dose ?)
  - Photograph of a pack / blister / tablet
- The system may become discredited if it does not provide the right answer under all circumstances
- Scanners:
  - More sensitive than existing ones
  - Minor issue with new scanner for poor quality linear bar codes (low contrast)

Key conclusions of the Pilot

- The model EFPIA supports works in practice and allows for effective identification of fake packs
- System availability and performance allow pharmacists to work at normal pace and without significant additional effort
- System is easy to use when fully integrated into pharmacy workflow and existing IT system
- System must provide correct answer to all transaction requests to achieve sustained credibility
- System should be customised to existing pharmacy workflow, processes, local conditions and regulatory requirement. It is therefore recommended to run a pilot phase for each deployment (region) so that defects can be eliminated before roll-out
- The presence of more than one code on the pack causes confusion for the user and will jeopardise user acceptance
- Necessary data segregation and security can be technically ensured
- Pharmacists are highly interested to get expiry date and batch number in machine readable form through the 2D data matrix

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Next Steps

- Continue Engagement with national Authorities and the European Commission to establish legal frameworks to enable use of an harmonised coding system at National/EU level
  - Support harmonisation of product codes across Europe (GTIN or NTIN) - ex : evolution of PZN in Germany
  - Ensure original pack integrity throughout the entire supply chain (including original manufacturer code), which supposes tamper evidence on all original packs.
  - Promote choice of Data matrix as harmonized standard carrier across Europe as well as systematic control at the dispensing point
  - Ensure companies commitment to implementation of Data matrix and mass serialization on all packs over an agreed period of time

Conclusion

- Product verification at the point of dispense
  - Is an ambitious and long term project which will improve supply chain security and patient safety
  - Involves costs for all parties and requires definition of governance structures between key stakeholders

- EFPIA proposes an approach that is
  - Based on cooperation with key stakeholders
  - Based on open standards
  - Feasible, interoperable, efficient, and cost effective
  - Flexible for future extension

- Governments and European Commission support is critical to deliver requirements for pack integrity in the supply chain and verification at point of dispense

Thank you

Grant Courtney

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European Federation of Pharmaceutical Industries and Associations

Back up

Proposed EU Directive on counterfeit medicines - EFPIA interpretation

Visual summary of Draft EC pharma package

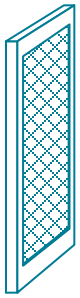
Prescription medicines will need to have:

a) Covert, overt, and forensic devices

b) Individually identified packs

c) Tamper evident closure of packs

Risk assessment



HIGH RISK

a), b), c)

LOWER RISK

c)

Repackaging rules

- Prohibits removing, replacing or covering safety features on packs by actors in the supply chain
- UNLESS the repackager reapplies **equivalent safety features as on the original pack**

What are the consequences ?

- **Mass serialization in Europe should be a reality over the next 3-5 years**
- **Need for a unique standard for adoption in Europe in order to ensure the introduction of an efficient and cost effective system (serialized Data Matrix)**

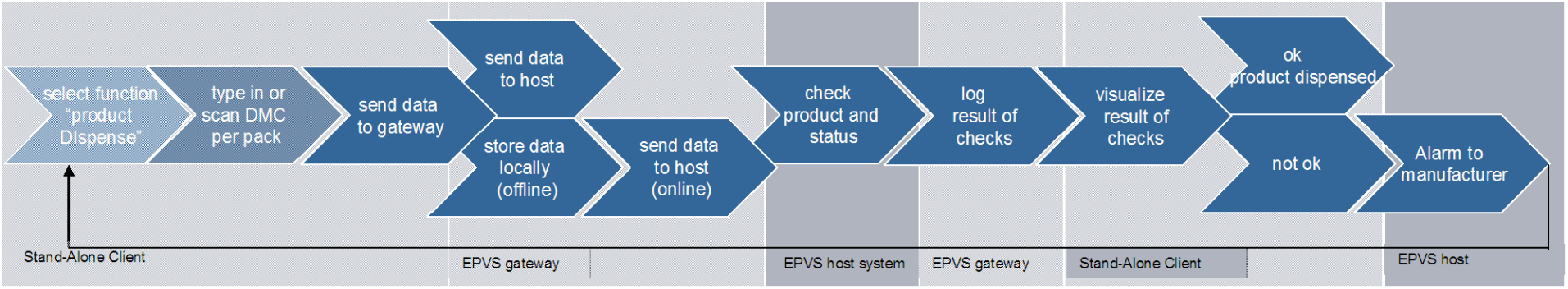
Key principles for verification in Europe

- **Effective across Europe** - Facilitates the specific requirements of the individual member states whilst ensuring patient safety across Europe
  - Allows product which is re-packed and traded across boarders to be traced back to the manufacturers original serial number and product volumes to be consolidated.
  - Allows full visibility of product serialisation information to be given to appropriate parties in the event of a recall
- **Point of Dispense Model** - Mandatory verification at the point of dispense but able to be interrogated by other supply chain parties
- **Standards driven** – GS1 standards for product identification and verification including a 2D as the data carrier
- **Secure** – must not allow unauthorised access and resistant to malicious attacks
- **Private** – data must only be available to those authorised to access it
- **Accessible** – linked via standard pharmacy system for point of dispense verification
- **Easy to use** – processes aligned with Pharmacy workflows
- **Robust** – must cope with high volume of verification transactions (5 – 20bn year) with high peak periods of activity
- **Available** – must be 100% on line 24/7 – 365 days a year
- **Fast** – verification must return a result in under 1 second on average

Integrated pharmacy client

System operation fully integrated into pharmacy work flow:

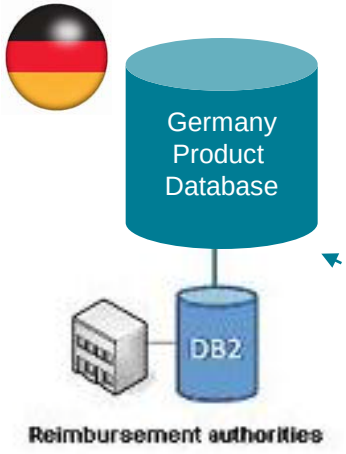
- Pack verification during “picking control”
  1. Scan Data Matrix code
  2. Check online for pack status with content of remote data base
  3. Display warning if necessary
- Pack verification while product is paid for
  - Display warning if necessary



Interoperability around common standards are essentiel for efficient controls by Authorities

Interoperability of databases is required (for systematic control of serial numbers)

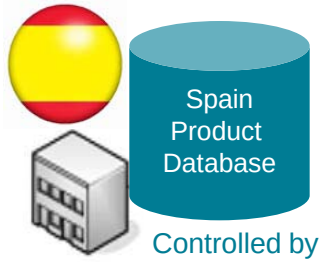
Databases and 'verification systems' work in the same fashion using common level of information – not necessarily interlinked



2D Data
Matrix on 2°pack

GTIN: (01) 07046261398572
Batch: (10) TEST5632
Expiry: (17) 130331
S/N: (21) 19067811811

Controlled by the authorities



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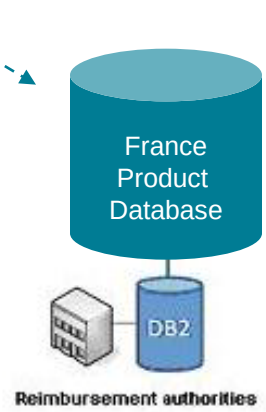

Multi-stakeholder system at national level governed by existing organisation (e.g CIP/GERS) ?

Cause for the “double dispense issue”

- Dispensing products is a two-step process in Swedish pharmacies
  - Picking control step: check if the correct packs are selected; scan pack and system accepts or rejects it – a pure verification step in the EPVS; accepted packs are put into plastic bag sealed with a barcode label
  - Sales step: bag label is scanned at the till. IT system knows which packs are inside from the picking step

Cause for the “double dispense issue”

- What can go wrong ?
  - The problem can occur in those cases where more than one pack of the same product is required by the prescription
  - The required packs are scanned and then the patient decides not to buy all of them
  - One or more packs must be returned to the shelf and the same number of packs is deleted from the “prescription”
  - As each pack has its individual identity exactly those packs have to be returned to the shelf that have been deleted from the prescription
  - If this happens to be not the case one or more packs that should be put into the bag is returned to the shelf and vice versa
  - The IT system, however, will mark all packs as dispensed that are supposed to be in the bag – if they are back in the stock they will be identified as previously dispensed the next time they get picked