GS1 Sweden

The global language of business

Our vision

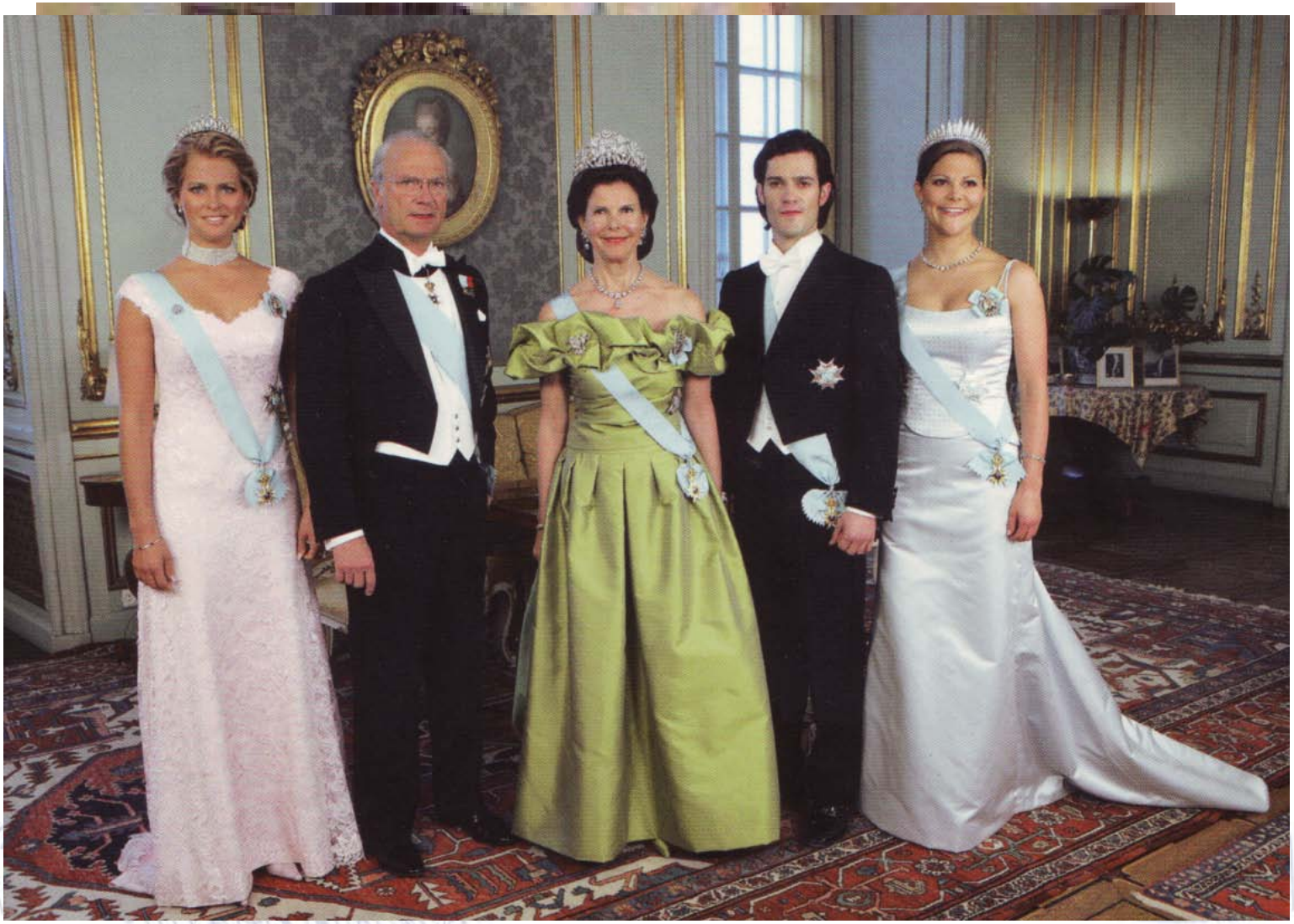
“GS1 Sweden simplifies companies’ local and global trade”

A small country with world class standard!

449,964 km^2

fourth largest in Europe

The Swedish Royal Family



Who am I …

- Tomas Wennebo, MSc Industrial Engineering and Management
- Like to sing in a choir

- Employed at GS1 Sweden since 2006
- In GS1 Sweden responsible for healthcare activities in Sweden

Goal: Increase Patient Safety

The right product to the right patient

No counterfeit products
No expired products
Perform product recalls

But also
Help Governments with reimbursement process

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"

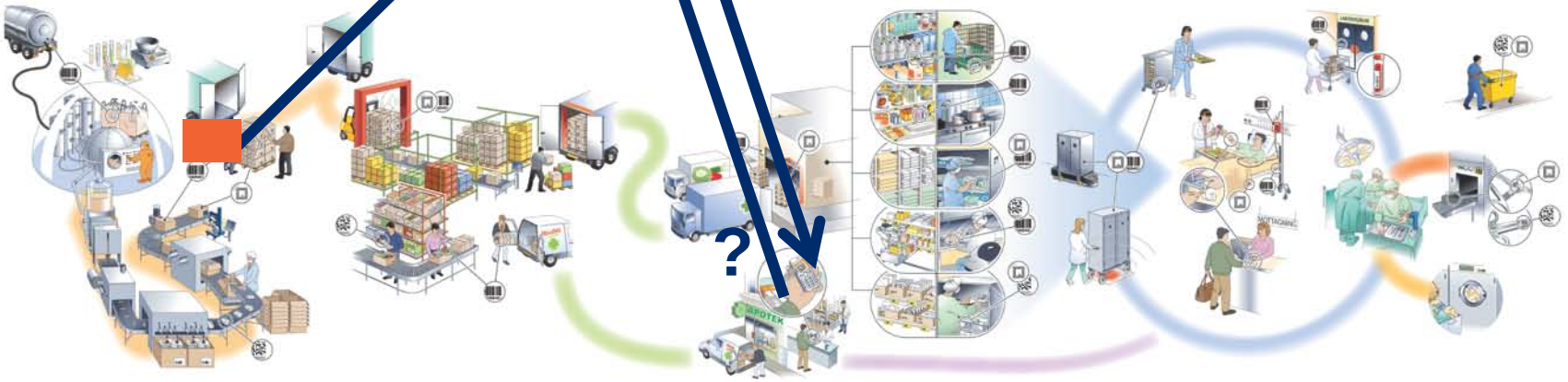
Don’t let counterfeiters put profit above patient safety

efpia db !

Manufacturing

Distribution

Healthcare



?

From: Healthcare products

To: Treatment finished

GTIN: 07311631524128
Serial Number: 1234567890 1234567890
Expiry: 110731
Batch: A1C2E3G4I5 A1C2E3G4I5

Track&Trace

Expected answers from the database

- ✓ Yes, We have a product record. It has not been dispensed
- χ Yes, We have product record but it has already been dispensed
- χ No, We do not have a record of this product.
- χ Yes we have a product record. This product has been recalled

Product verification

Duplicate instance of product code can be detected

Copying/Counterfeiting of the 2D DataMatrix code will be identified by the system

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

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

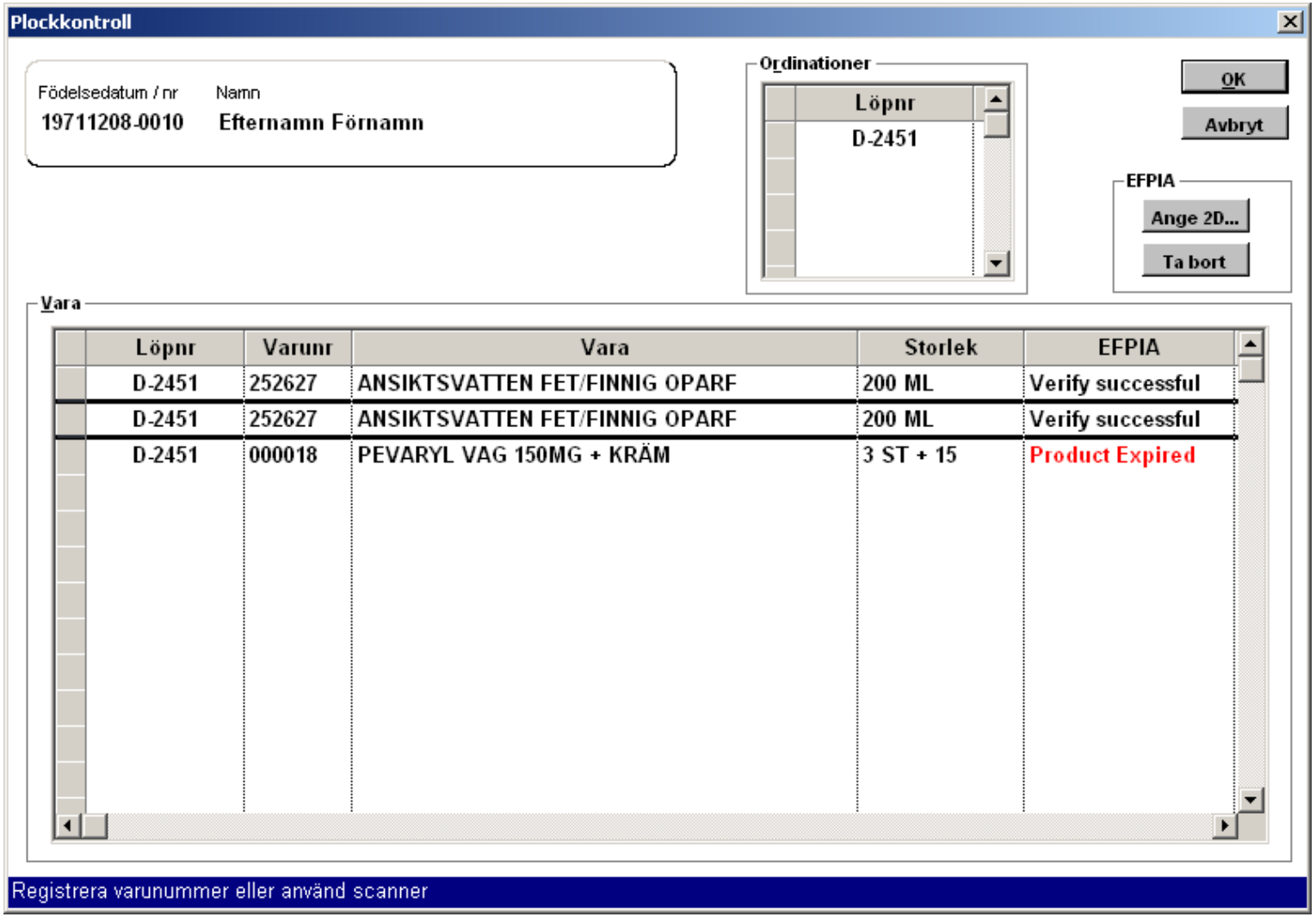
- Key figures
  - 25 pharmacies in the greater Stockholm area (owned by Apoteket AB) with a total of 180 dispensing points
  - 25 products (SKUs) with total of 110.000 packs
  - 14 manufacturers
  - 4 months duration of operational phase

- 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
- System was online 99,1% of time
- 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

Pharmasist view

Form to pharmacist's:

- Easy to use
- A fast system
- Little additional effort to verify

Additional answers from interviews:

- One single barcode on the pack prevents confusion when scanning the pack
- Expect high value from automatic detection of expired or recalled products
- Would like to see more information provided by the system:
- The system must always be right
- Scanners used in pilot was More sensitive than existing 2D scanners

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

Results from Apoteket AB

Apoteket's employees were satisfied with the pilot,

Authentication works with 2D Data Matrix.

Dispensing and administration functioned without interruption

No problem to put in an extra routine to verify the product authenticity

Apoteket also saw that inventory management could be improved.

Confirms that the patient receives product from the manufacturers responsible for product

Do not build into national solutions. Global perspective is important.

Lars Rönbäck, Apoteket AB

What has to be solved

National number, Nordic Item Number issue

- GTIN like but not according to GTIN rules
- not sufficiently unique

Traceability

- If you find a fake drug, Where does it come from?

Infrastructure

- Database and future technology solution
- Information Security

Competition perspective

- The right to take part of the accumulated information. Is the industry

Industry association

Action taken to build a European system to track every single pharmaceutical packaging,

- Rely on EFPIA work on a European-wide control system
- Increase patient safety
- Make it difficult to counterfeit drugs
- Hinder fake drugs into the regular pharmacy and into the legal supply chain.
- Reduce confidence in medicine in general.

Act now

- We do not want to see different solutions in different countries as they may create loopholes for rogue traders

Works starts in Sweden Thursday 11th of November.

Richard Bergstrom, President of LIF, the trade association for the research-based pharmaceutical companies.

Politicians view

- Swedish politicians think this is good
- Minister of Social Affairs in favour of this
- Included in the Swedish eHealth Initiative

Vision

- Follow a product along the entire supply chain and ensure the deployment will be as safe as possible.
- With unique identities based on global standards (GTIN)
- With serialization (GTIN plus serial number)
- Read from a 2D GS1 DataMatrix (AI)
- All product levels identified and readable
- Secure information structure for the handling of individual packages

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