Implementing GS1 Standards in Novartis

Minimizing risk and reinforcing patient safety

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Agenda

- Objectives
- Big picture
- Implementing GS1 Standards in Novartis
- Regulatory requirements (EU and US)
- Front end hospital
- Current Status and conclusions

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Implementing GS1 Standards in Novartis
Objectives

- Register the course of the medicine (not only at the level of the lot, but the unit itself) from production to administration at the hospital (patient, date and time)
- Ensure that the unique identifier on the product is registered in a database
- Enable online status check in case of an adverse event or any investigations by quality
- Support the process of dispensing and tracking in the Hospital (from pharmacy till the surgery room)
- Online verification of batch and shelf life
- Reduce risk of exchanging drugs

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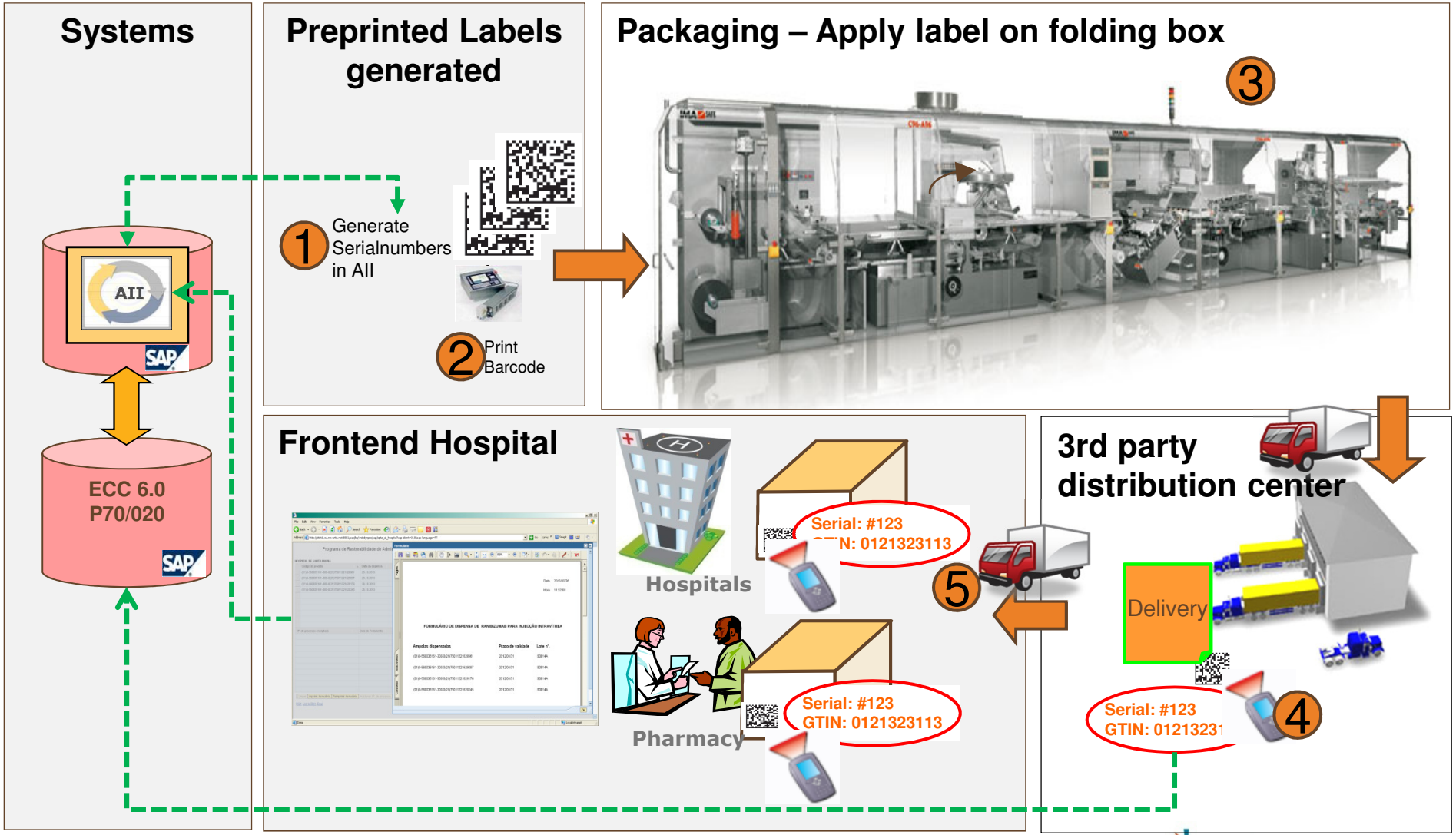
Portugal Project

Big picture



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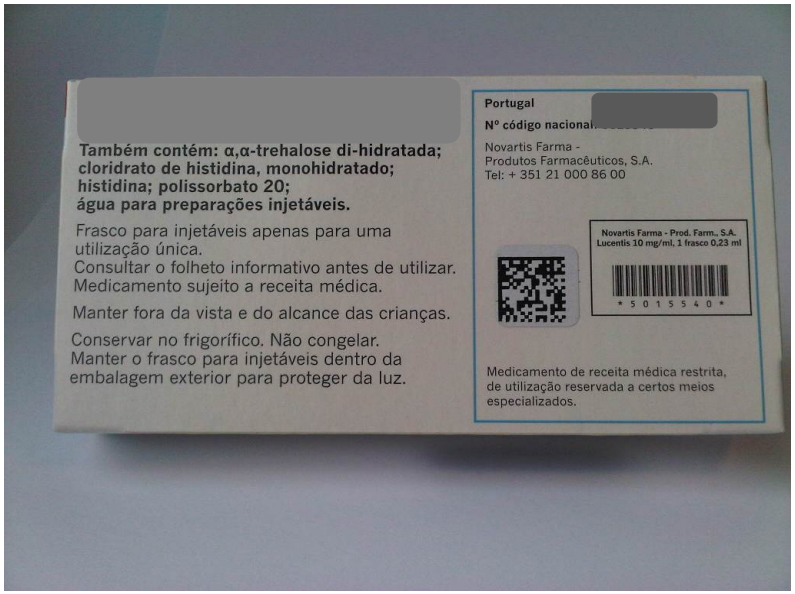
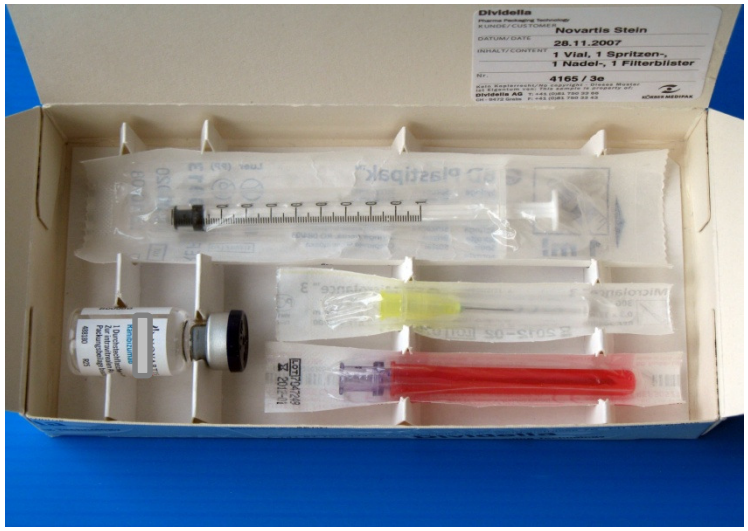
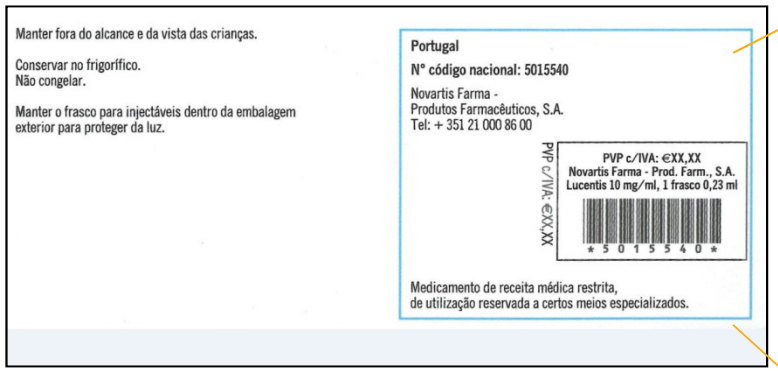
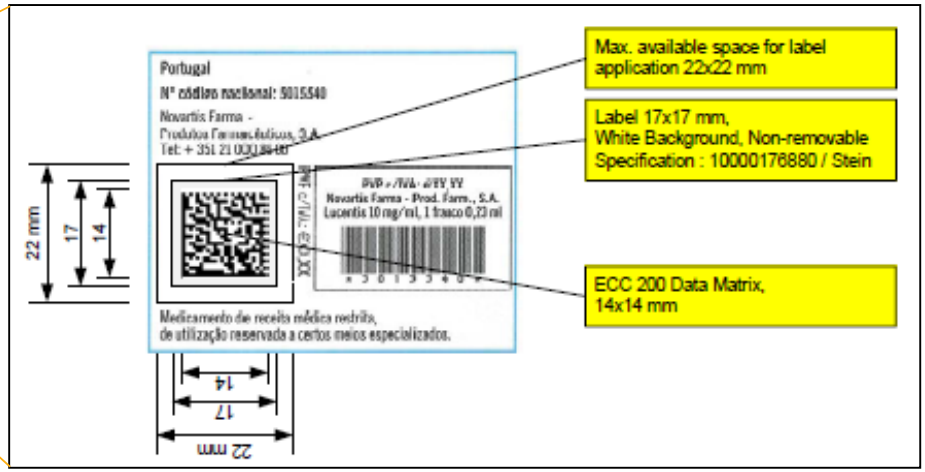
Product box – label applied on the bottom of the box









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Project and the EU Directive on Falsified Medicines

This is the first project in Novartis Pharma that supports the process of dispensing and tracking in the Hospital.

- Regulatory timelines: California ePedigree law and EU directive on falsified medicines (FMD)

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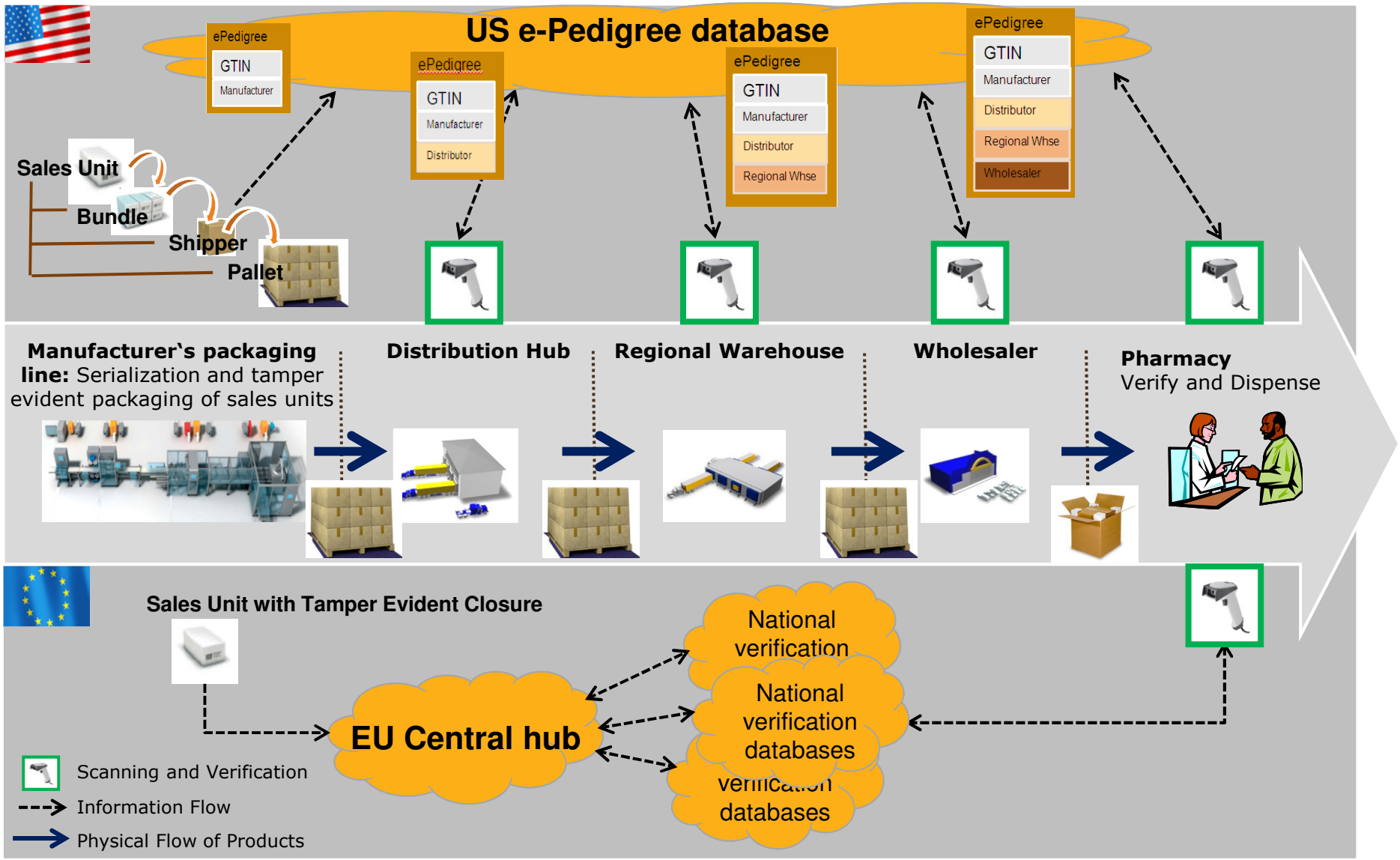
Verification Concept US & EU

US e-Pedigree law requires significantly higher technical and transactional granularity



EFPIA proposes usage of data matrix for pack verification

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

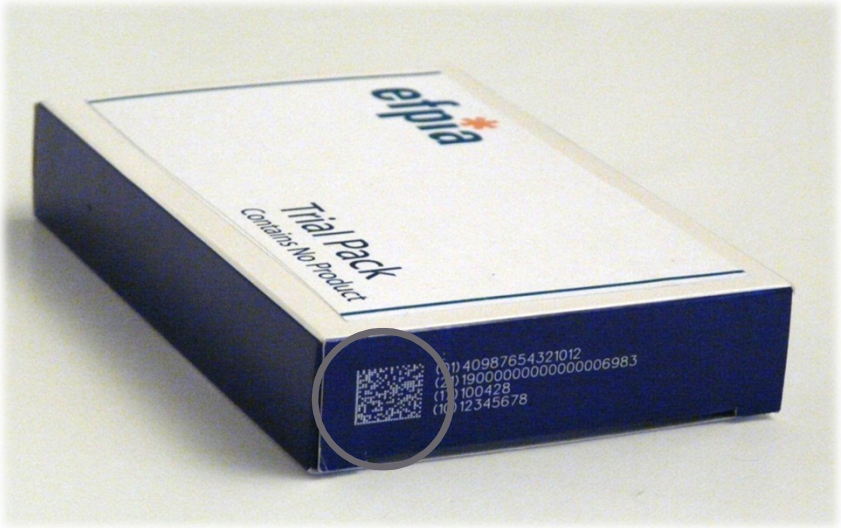
Manufacturer Product Code (GTIN or NTIN)	14 digits
Unique Serial Number (randomized)	up to 20 alpha-numeric characters
Expiry Date	6 digits (YYMMDD)
Batch Number	up to 20 alpha-numeric characters

+ minimum requirements on quality of randomization

Example:

GTIN: (01)09876543210982
Batch: (10)A1C2E3G4I5
Expiry: (17)140531
S/N: (21)12345AZRQF1234567890

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



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Frontend hospital application access

- It is a web based application therefore the access is very simple: www.trace.novartis.com

- Each hospital has access with as many users as necessary.

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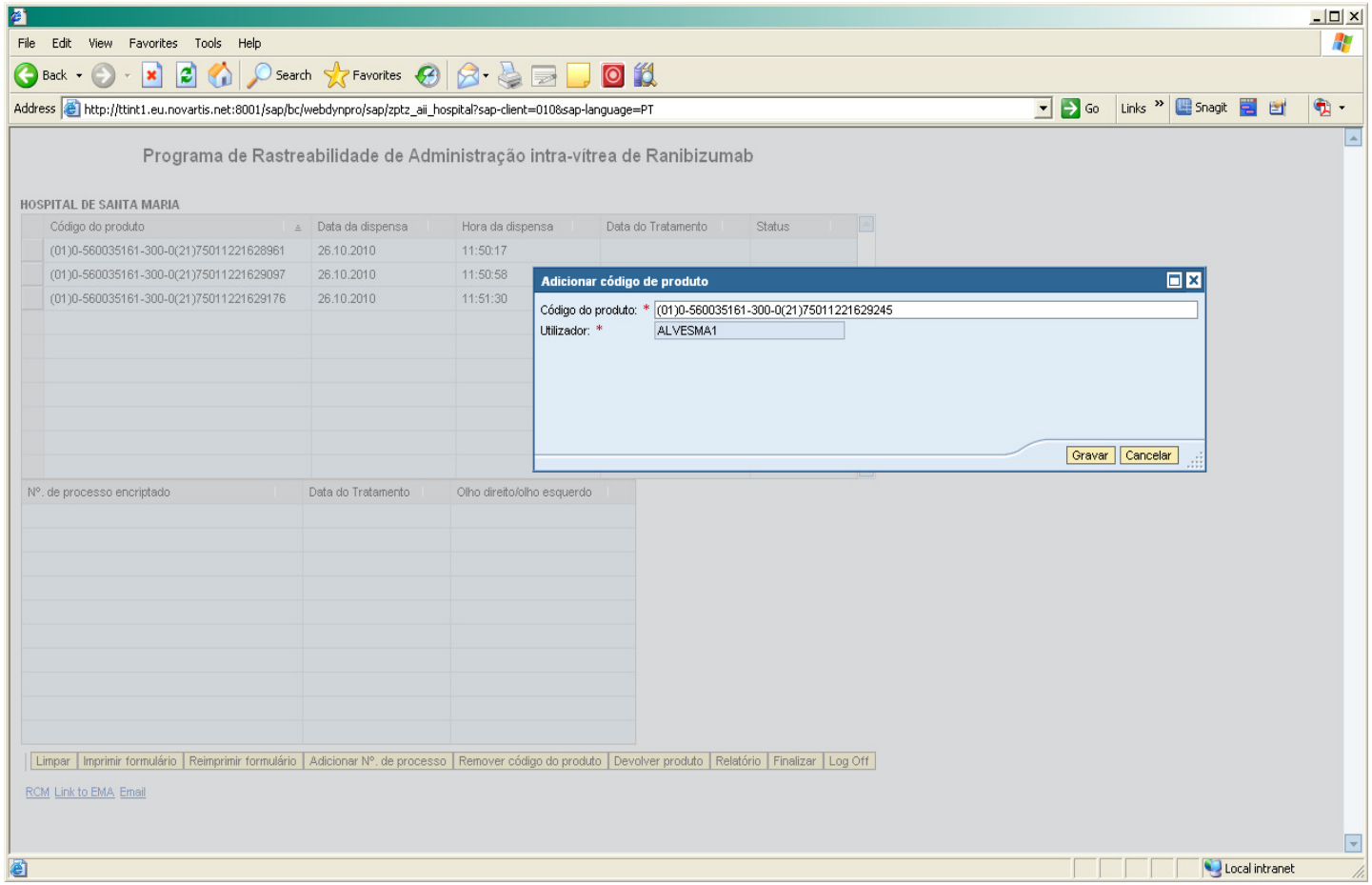
Although the technology is complex the system is simple

- Upon prescription the pharmacist scans the packs. Serial number, date and time of dispensing are recorded.



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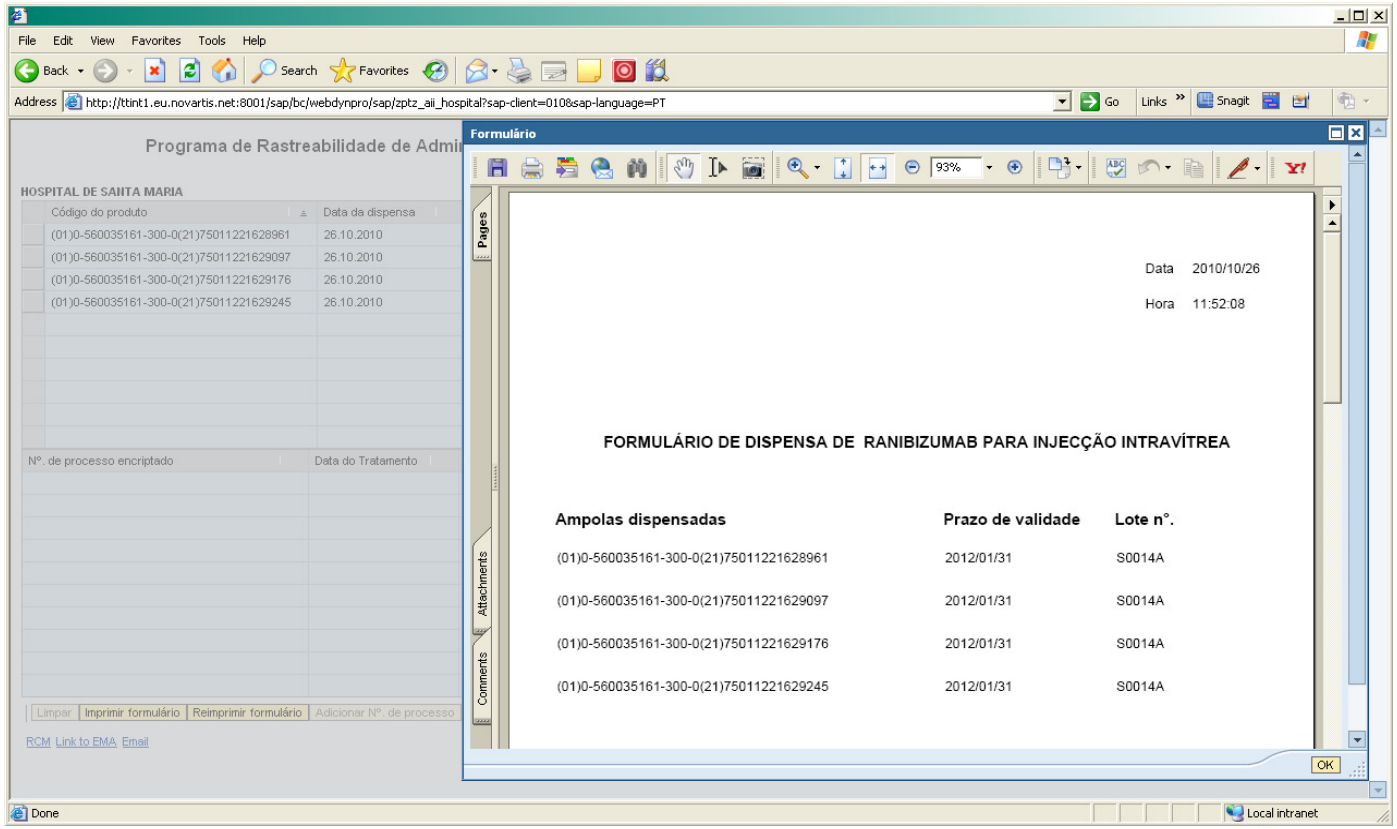
Printing shipping document

- The product is then sent from the hospital pharmacy into the surgery room with an internal shipping document containing the serial number, batch number and shelf life.



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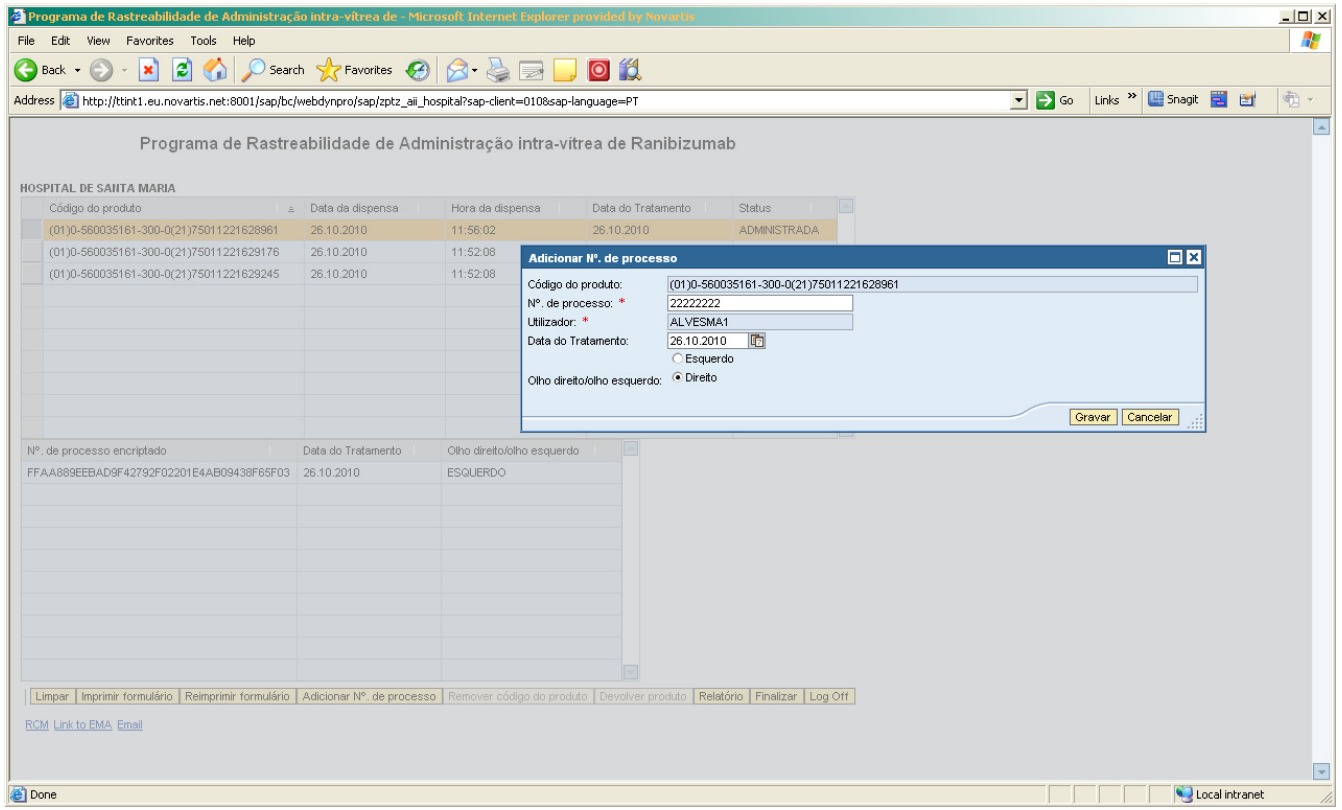
Scanning and inserting patient code

- After administration the pack is again scanned and the internal patient code is introduced manually or by scanning the patient barcode if available.



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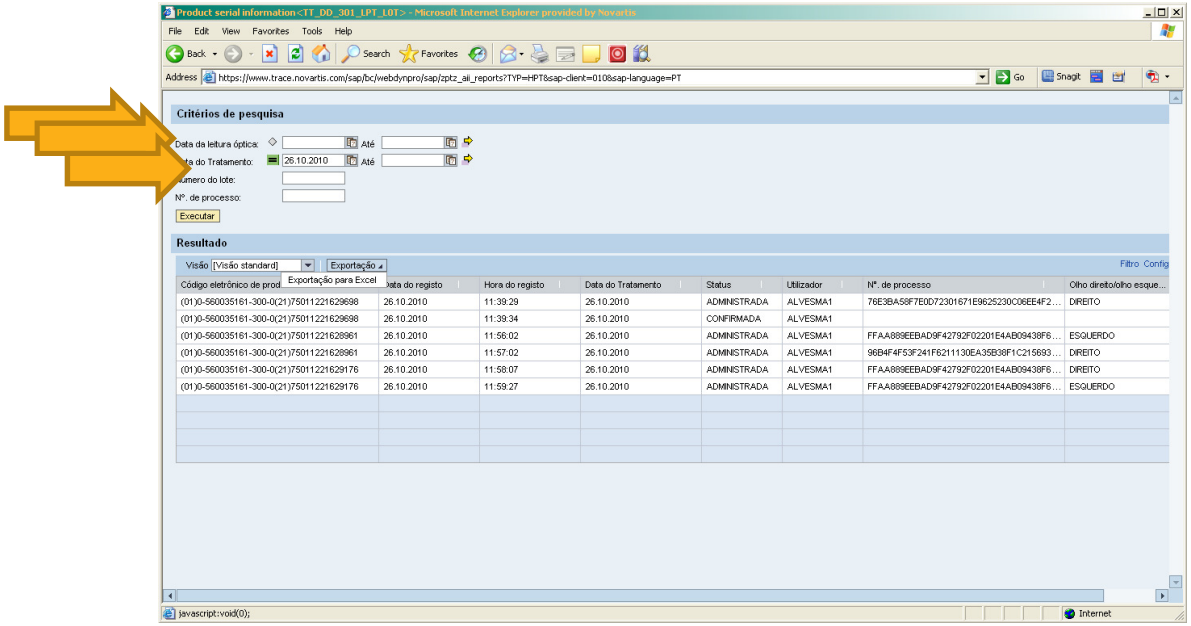
Reports

- The patient data remains confidential during the entire process through a complex encryption system.



- In the hospital reports are available by “Date of scanning”, by “Date of treatment”, by “Batch number” and by “Patient number”

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Status and conclusion

- Since September 2010 **all** units of ranibizumab available in Portugal have data matrix code with serial number.
- The pilot in hospitals started in October 2010 in Instituto Oftalmológico Dr. Gama Pinto. During 2011, 4 other public hospitals joined the pilot, 979 treatments have been tracked and traced.
- The pilot project designed and developed in Portugal is under evaluation for adoption in Spain.
- Project very well perceived, with great potential to expand to other products in areas where a more restricted control over medication is needed, such as oncology.

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Questions & answers



Thank You!

Serialization & Product Tracking Program