



Serialization & Product Tracking

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

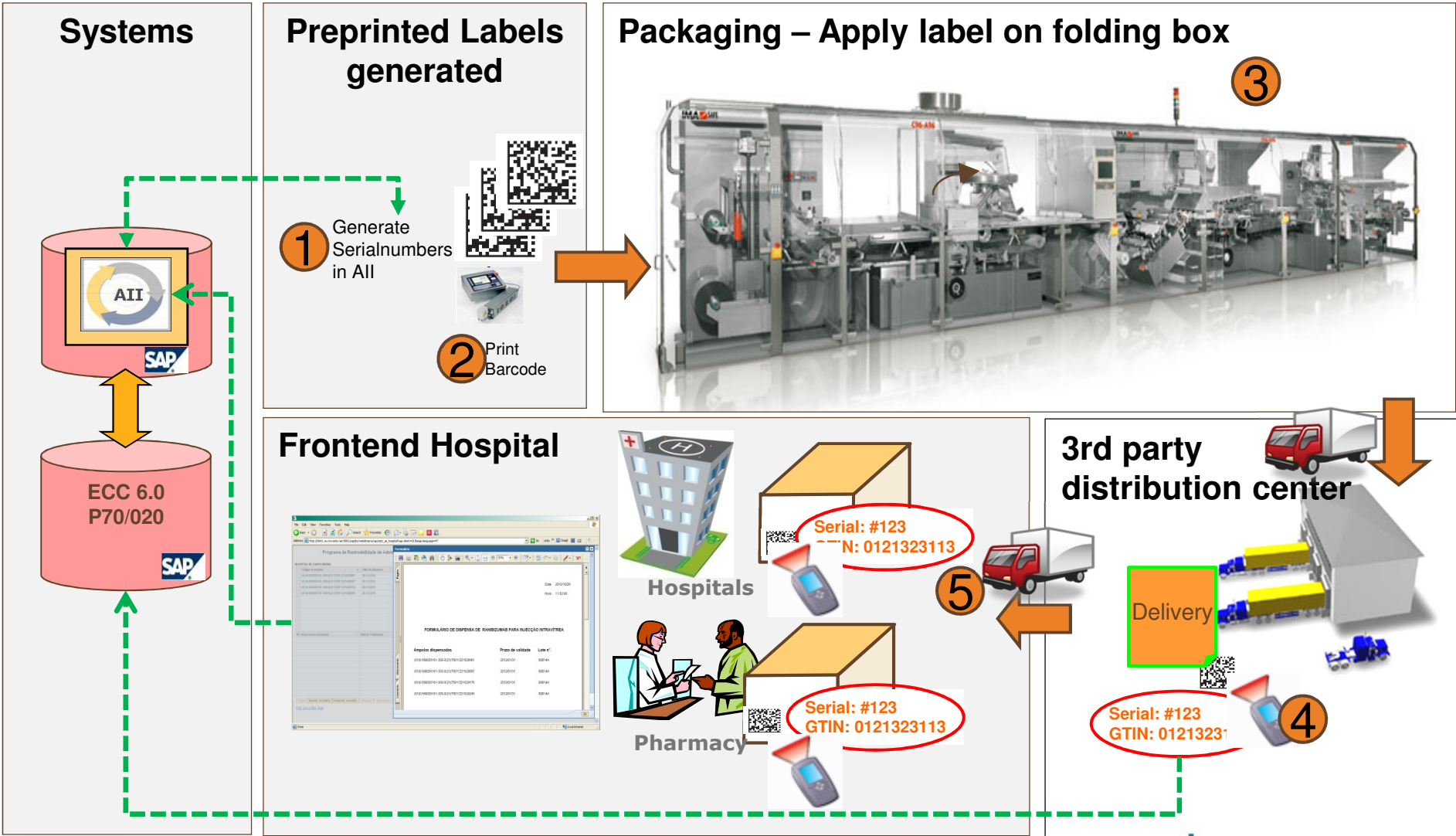
Implementing GS1 Standards in Novartis

Objectives

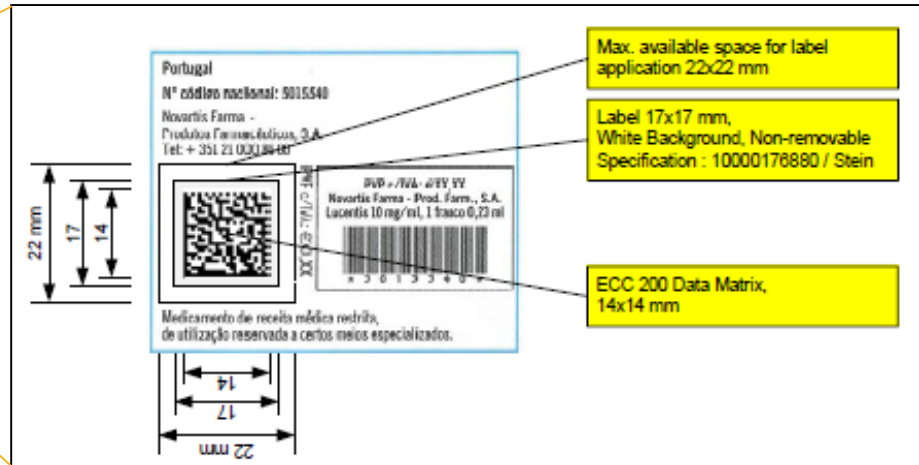
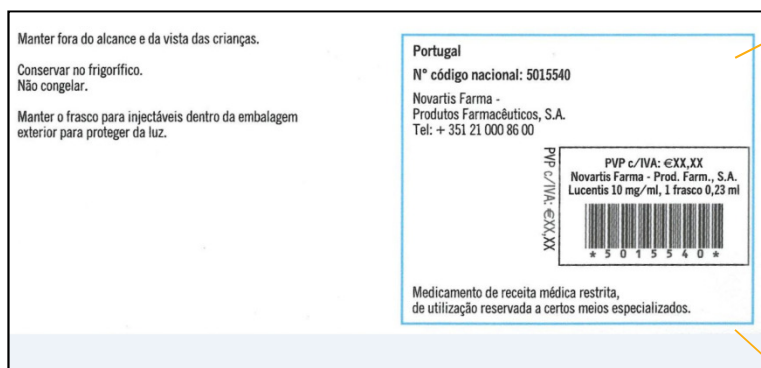
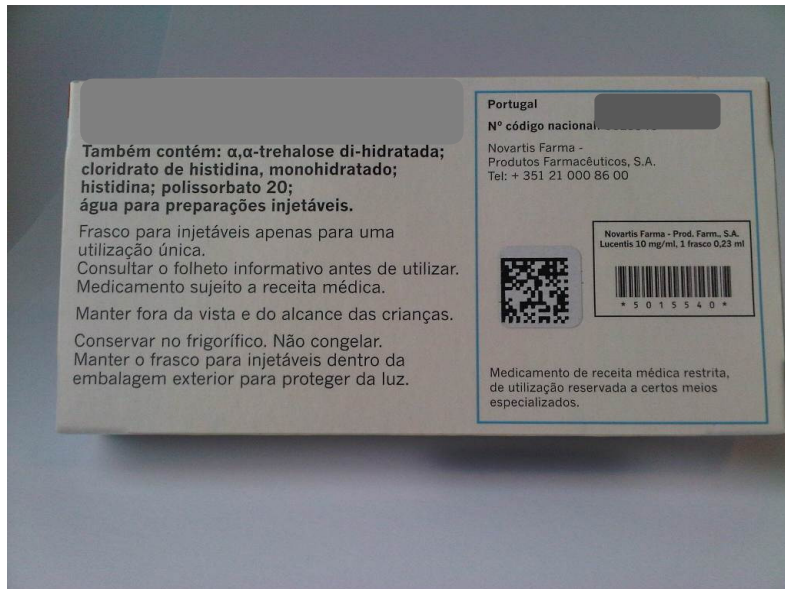
- Register the course of the medicine (not only at the level of the lot, but the unit itself) from production to administration at the hospital (patient, date and time)
- Ensure that the unique identifier on the product is registered in a database
- Enable online status check in case of an adverse event 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

Portugal Project

Big picture



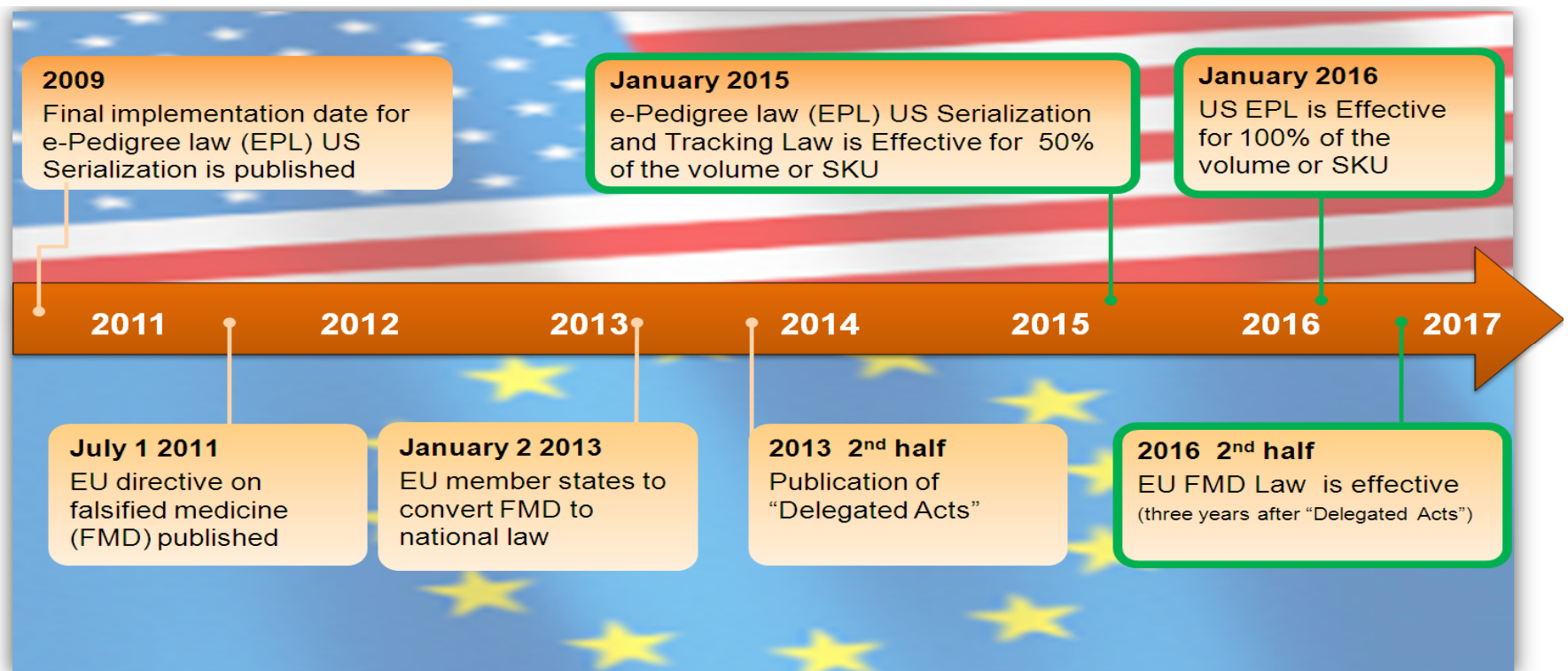
Product box – label applied on the bottom of the box



Project and the EU Directive on Falsified Medicines

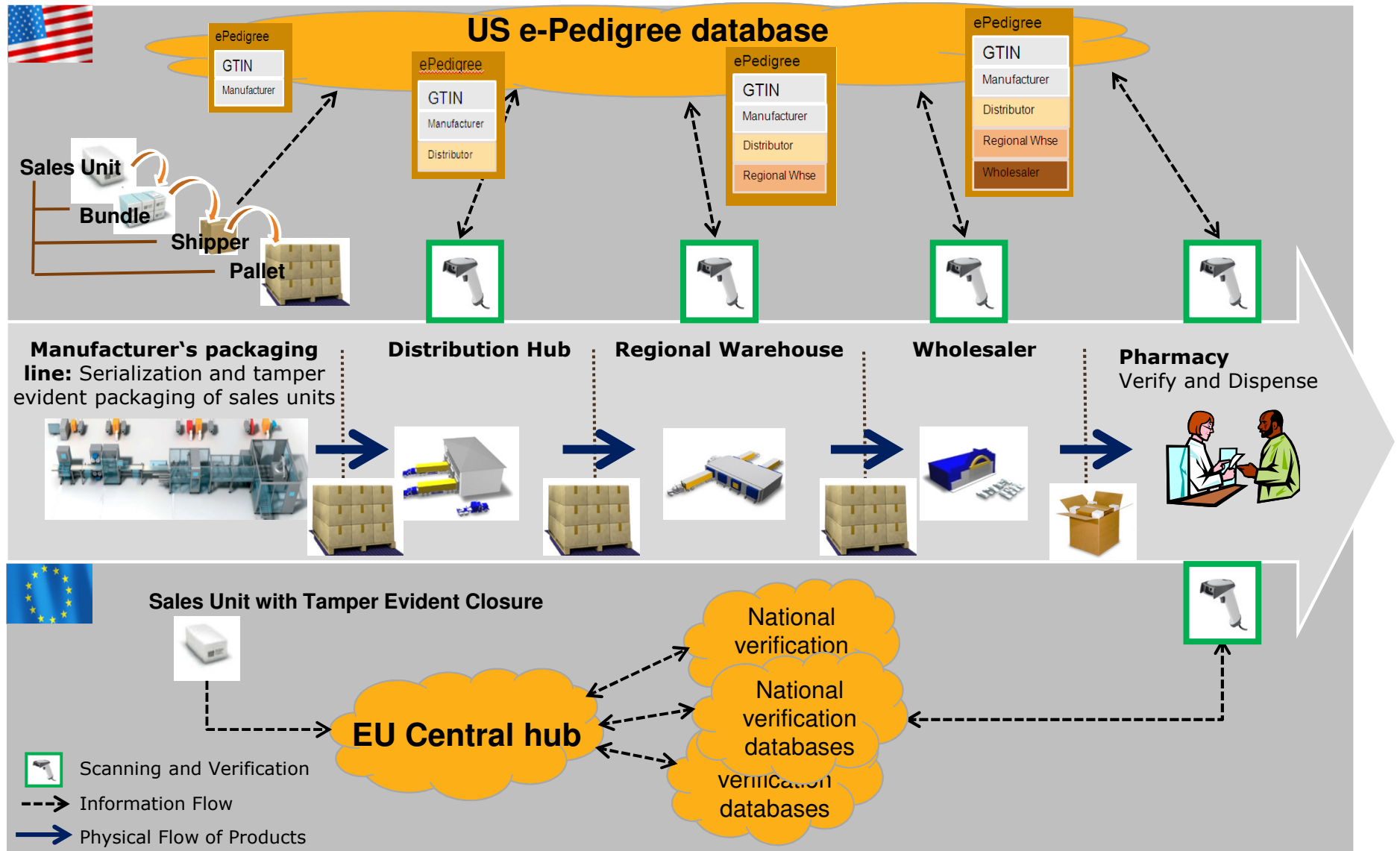
This is the first project in Novartis Pharma that supports the process of dispensing and tracking in the Hospital.

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



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"



Implementing GS1 Standards in Novartis

Frontend hospital application access

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



The screenshot shows a web form titled "Logon". It contains three input fields: "Usuário *" with the value "ALVESMA1", "Senha *" with masked characters, and "Idioma" with a dropdown menu set to "Português". Below the fields is a yellow "Logon" button and a blue link "Modificar senha".

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

Implementing GS1 Standards in Novartis

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.

Programa de Rastreabilidade de Administração intra-vítrea de Ranibizumab

HOSPITAL DE SAÍTA MARIA

Código do produto	Data da dispensa	Hora da dispensa	Data do Tratamento	Status
(01)0-560035161-300-0(21)75011221628961	26.10.2010	11:50:17		
(01)0-560035161-300-0(21)75011221629097	26.10.2010	11:50:58		
(01)0-560035161-300-0(21)75011221629176	26.10.2010	11:51:30		

Adicionar código de produto

Código do produto: * (01)0-560035161-300-0(21)75011221629245

Utilizador: * ALVESMA1

Gravar Cancelar

Nº. de processo encriptado | Data do Tratamento | Olho direito/olho esquerdo

Limpar | Imprimir formulário | Reimprimir formulário | Adicionar Nº. de processo | Remover código do produto | Devolver produto | Relatório | Finalizar | Log Off

RCM [Link to EMA](#) [Email](#)

Local intranet

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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.

Programa de Rastreabilidade de Adm

HOSPITAL DE SANTA MARIA

Código do produto	Data da dispensa
(01)0-560035161-300-0(21)75011221628961	26.10.2010
(01)0-560035161-300-0(21)75011221629097	26.10.2010
(01)0-560035161-300-0(21)75011221629176	26.10.2010
(01)0-560035161-300-0(21)75011221629245	26.10.2010

Nº. de processo encriptado Data do Tratamento

Data 2010/10/26
Hora 11:52:08

FORMULÁRIO DE DISPENSA DE RANIBIZUMAB PARA INJEÇÃO INTRAVÍTEA

Ampolas dispensadas	Prazo de validade	Lote n.º
(01)0-560035161-300-0(21)75011221628961	2012/01/31	S0014A
(01)0-560035161-300-0(21)75011221629097	2012/01/31	S0014A
(01)0-560035161-300-0(21)75011221629176	2012/01/31	S0014A
(01)0-560035161-300-0(21)75011221629245	2012/01/31	S0014A

Limpar Imprimir formulário Reimprimir formulário Adicionar Nº. de processo

[RCM](#) [Link to EMA](#) [Email](#)

Done Local intranet

Implementing GS1 Standards in Novartis

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.

Programa de Rastreabilidade de Administração intra-vitrea de - Microsoft Internet Explorer provided by Novartis

File Edit View Favorites Tools Help

Address http://ttint1.eu.novartis.net:8001/sap/bc/webdynpro/sap/zptz_ah_hospital?sap-client=0108&sap-language=PT

Programa de Rastreabilidade de Administração intra-vitrea de Ranibizumab

HOSPITAL DE SANTA MARIA

Código do produto	Data da dispensa	Hora da dispensa	Data do Tratamento	Status
(01)0-560035161-300-0(21)75011221628961	26.10.2010	11:56:02	26.10.2010	ADMINISTRADA
(01)0-560035161-300-0(21)75011221629176	26.10.2010	11:52:08		
(01)0-560035161-300-0(21)75011221629245	26.10.2010	11:52:08		

Adicionar Nº. de processo

Código do produto: (01)0-560035161-300-0(21)75011221628961

Nº. de processo: * 22222222

Utilizador: * ALVESMA1

Data do Tratamento: 26.10.2010

Olho direito/olho esquerdo: Esquerdo Direto

Gravar Cancelar

Nº. de processo encriptado	Data do Tratamento	Olho direito/olho esquerdo
FFAA689EEBAD9F42792F02201E4AB09438F65F03	26.10.2010	ESQUERDO

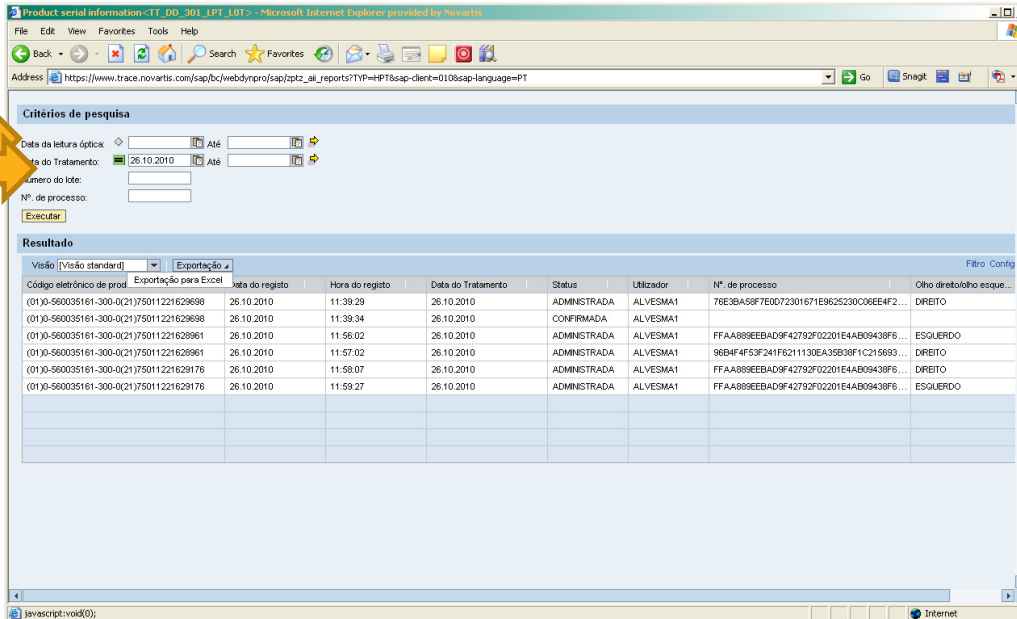
Limpar Imprimir formulário Reimprimir formulário Adicionar Nº. de processo Remover código do produto Devolver produto Relatório Finalizar Log Off

RCM Link to EMA Email

Done Local intranet

Implementing GS1 Standards in Novartis Reports

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



The screenshot shows a web browser window displaying a Novartis application. The address bar shows the URL: https://www.trace.novartis.com/sap/bc/webdynpro/sap/zptz_all_reports?YP=PT&sap-client=010&sap-language=PT. The page is titled "Product serial information <TT_DD_301_LPT_LOT>".

The "Critérios de pesquisa" (Search Criteria) section includes the following fields:

- Data de leitura óptica: At6
- Data do Tratamento: 26.10.2010 At6
- Número do lote:
- Nº. de processo:

An "Executar" button is located below the search criteria.

The "Resultado" (Results) section shows a table with the following columns: Código eletrônico de prod., Exportação para Excel, data do registro, Hora do registro, Data do Tratamento, Status, Utilizador, Nº. de processo, and Outro direto/olho esqu... The table contains six rows of data.

Código eletrônico de prod.	Exportação para Excel	data do registro	Hora do registro	Data do Tratamento	Status	Utilizador	Nº. de processo	Outro direto/olho esqu...
(01)0-560035161-300-0(21)75011221629698		26.10.2010	11:39:29	26.10.2010	ADMINISTRADA	ALYESMA1	78E38A58F7E0D72301671E9625230C06EE4F2...	DREITO
(01)0-560035161-300-0(21)75011221629698		26.10.2010	11:39:34	26.10.2010	CONFIRMADA	ALYESMA1		
(01)0-560035161-300-0(21)75011221629691		26.10.2010	11:56:02	26.10.2010	ADMINISTRADA	ALYESMA1	FFAA889EEBAD9F42792F02201E4AB09438F6...	ESQUERDO
(01)0-560035161-300-0(21)75011221629691		26.10.2010	11:57:02	26.10.2010	ADMINISTRADA	ALYESMA1	96B4F4F53F241F521130EA35B38F1C215893...	DREITO
(01)0-560035161-300-0(21)75011221629176		26.10.2010	11:58:07	26.10.2010	ADMINISTRADA	ALYESMA1	FFAA889EEBAD9F42792F02201E4AB09438F6...	DREITO
(01)0-560035161-300-0(21)75011221629176		26.10.2010	11:59:27	26.10.2010	ADMINISTRADA	ALYESMA1	FFAA889EEBAD9F42792F02201E4AB09438F6...	ESQUERDO

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

Implementing GS1 Standards in Novartis

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.

Questions & answers



Thank You!



Serialization & Product Tracking Program

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