



National Traceability Pilot for Pharmaceutical Products

COLOMBIA





Agenda



- Background & Objectives
- Scope & Schedule
- The process and model
- Key conclusions & Next steps





Background & Objectives

LAW 1122, 2007

ARTICLE 34 Literal d)

INVIMA is responsible of ensuring the identification of medicines at any stage of the supply chain, from production to the final consumer, through a marking technology, in order to prevent counterfeiting, adulteration, maturity and smuggling.





Background & Objectives

INVIMA is developing the pilot with the support of GS1 Colombia, in order to establish if the technology that we used, is the appropriate one for the national conditions.

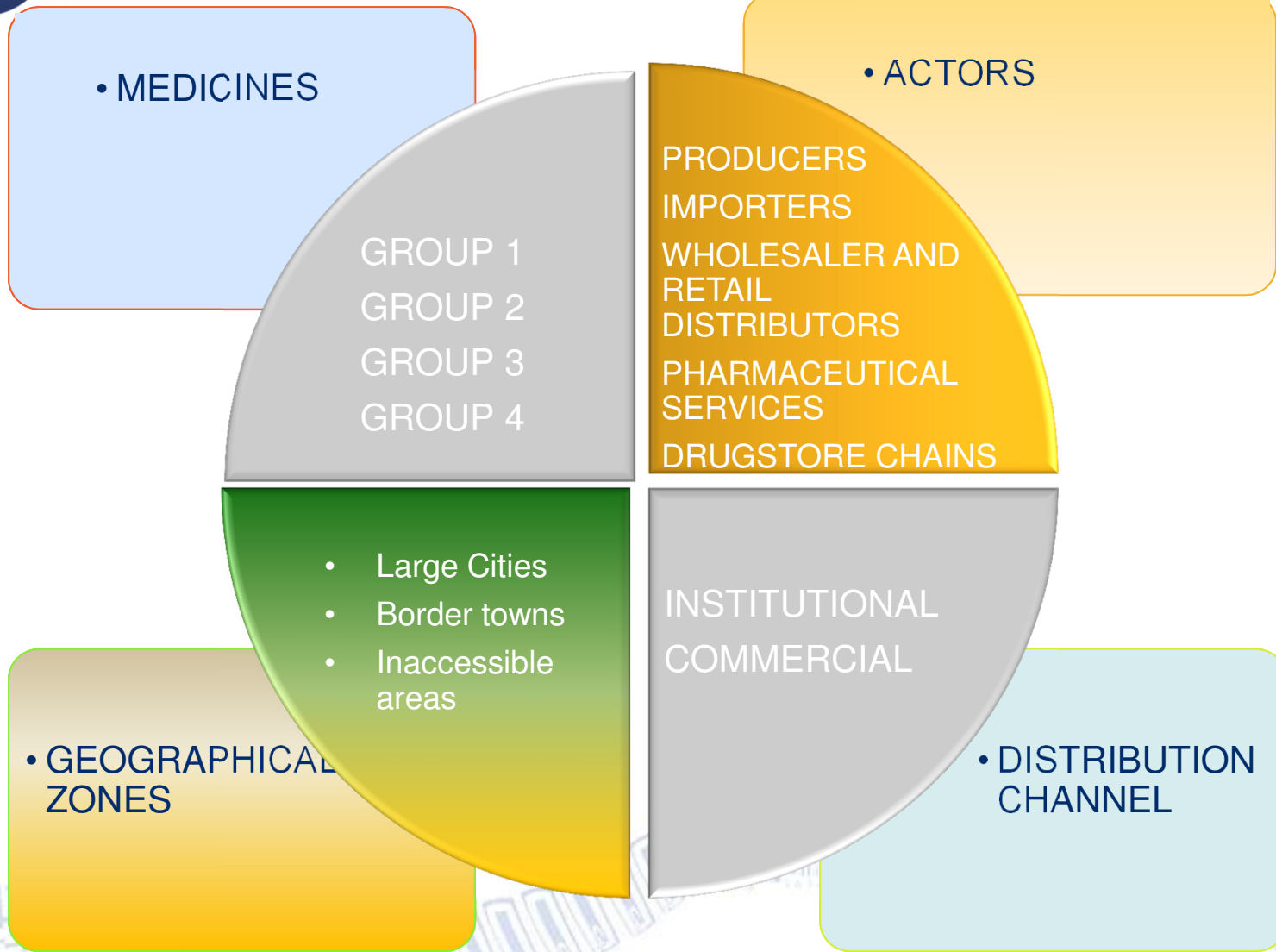
The pilot is based on the application of international standards in accordance with the recommendations given by “Universidad Nacional”,



To consider:



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To develop with healthcare supply chain actors a traceability pilot for pharmaceutical products using international standards, that allows to know the requirements to deploy a national traceability system.





Specific objectives



- ✓ Identify improvement opportunities in the processes related to traceability.
- ✓ Design and validate a traceability model according to local requirements.
- ✓ Develop a prototype system that can be tested in a real operation.
- ✓ Collect learnings and recommendations
- ✓ Establish the technical and functional requirements to build the web platform to be used.
- ✓ Recommend a road map for implementation.





Scope & schedule





Scope



Traceability from shipping in the Lab to reception at the pharmacy



Together with the inspection process performed by INVIMA

Participants



Wholesalers: Dromayor, Axa, Detal, Copidrogas, Copservir, Eticos Serrano Gomez, Colsubsidio, Cafam, y el Fondo Rotatorio Norte de Santander.



Hospitals: Asisfarma (2 Pharmaceutical Services), Clinica Hemato Oncologos, Clinica Vida, Clinica Stella Maris y Clinica Offimedicas Norte



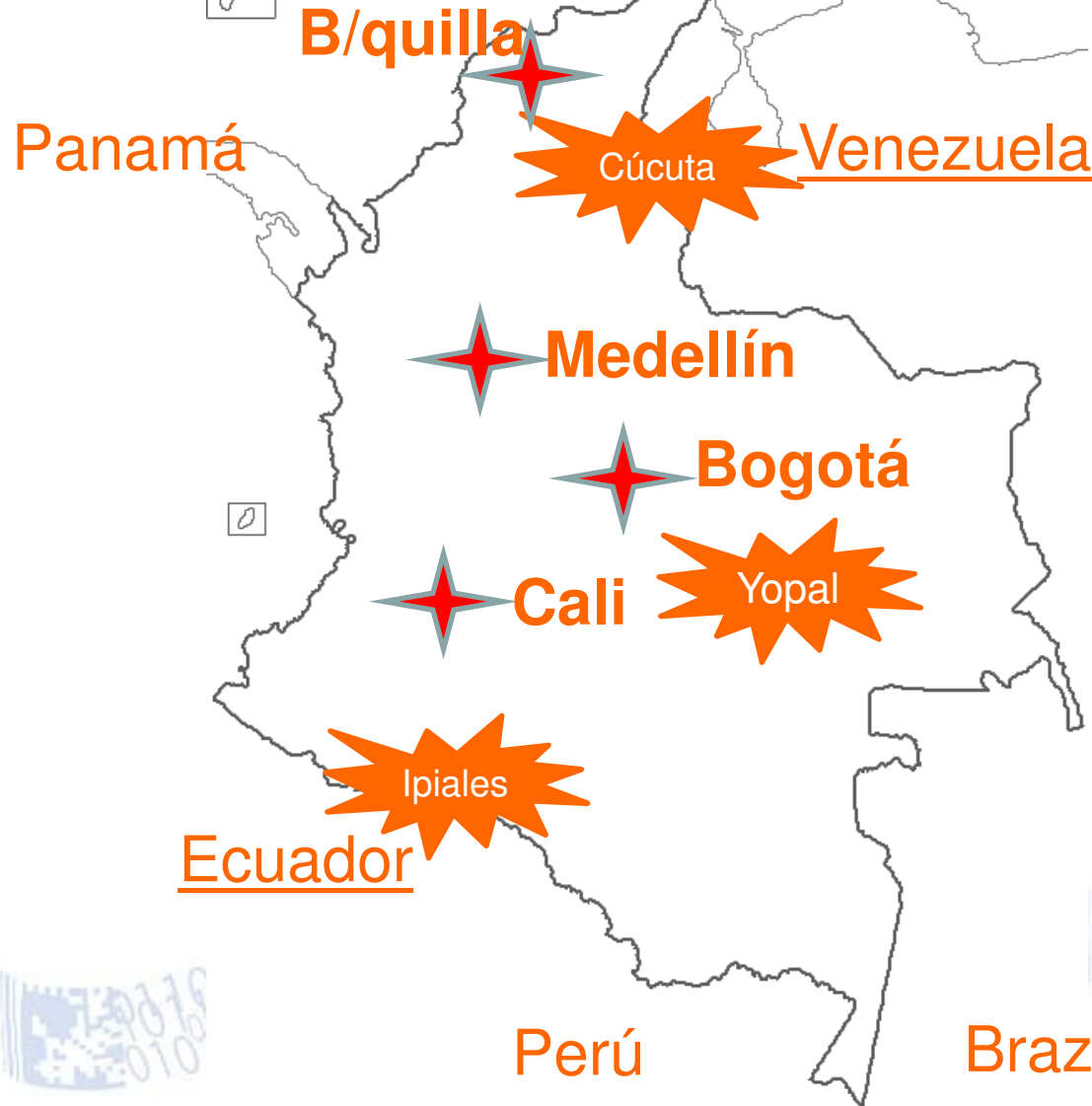
Pharmacies: 20 Pharmacies and 13 Independent Drugstores





INVIMA

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- ✓ 4 Major Cities
- ✓ 2 Border towns
- ✓ 1 Difficult access City



Medicines Involved

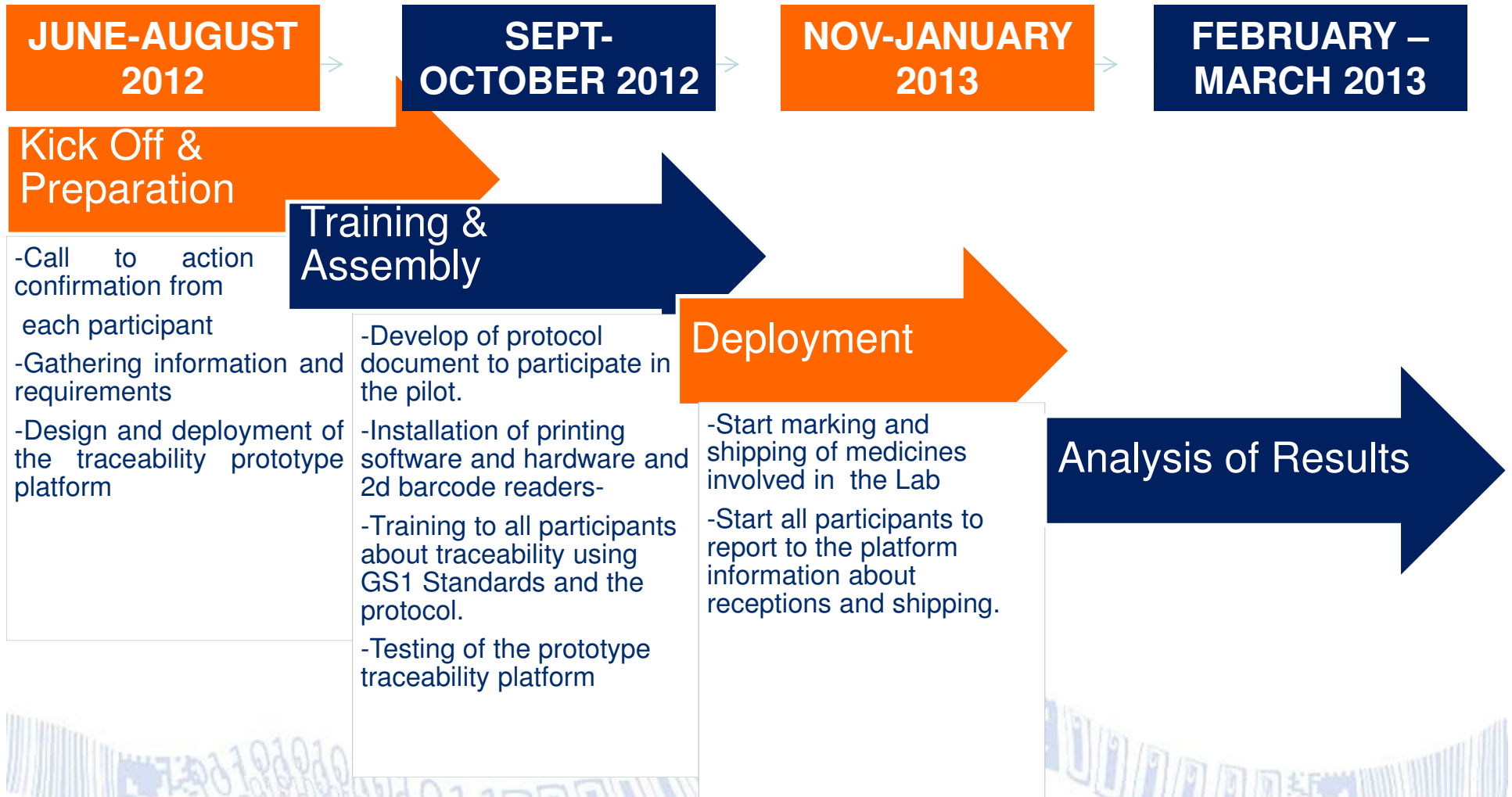


- TRASTUZUMAB
- RITUXIMAB
- BORTEZOMIB
- DASATINIB
- INFLIXIMAB
- IXABEPILONE
- LEVOFLOXACIN
- METOPROLOL
- OXYCODONE
- METHADONE
- DICLOFENAC
- SILDENAFIL





Schedule





The process & model





1. ERP

2. Order Receipt:
Ref. X, Units, Customer

3. Identification
of the products and order

4. (ERP) generate flat file

- # Order
- # Invoice.
- # Dispatch
- Dispatch date
- From (GLN)
- To (GLN o NIT).
- Channel (Inst. or retail)
- GTIN & SKU
- Lot.
- Expiration date.
- Quantity

5. Print Application
(Slap & Ship)

6. Build of the flat file
to send to traceability web platform

8. Traceability Web Platform

Reception

Scanning each product

Download Technical Reception Document

Shipping

Receiver module

Reception

Scanning each product

Download Technical Reception Document

Dispensation module

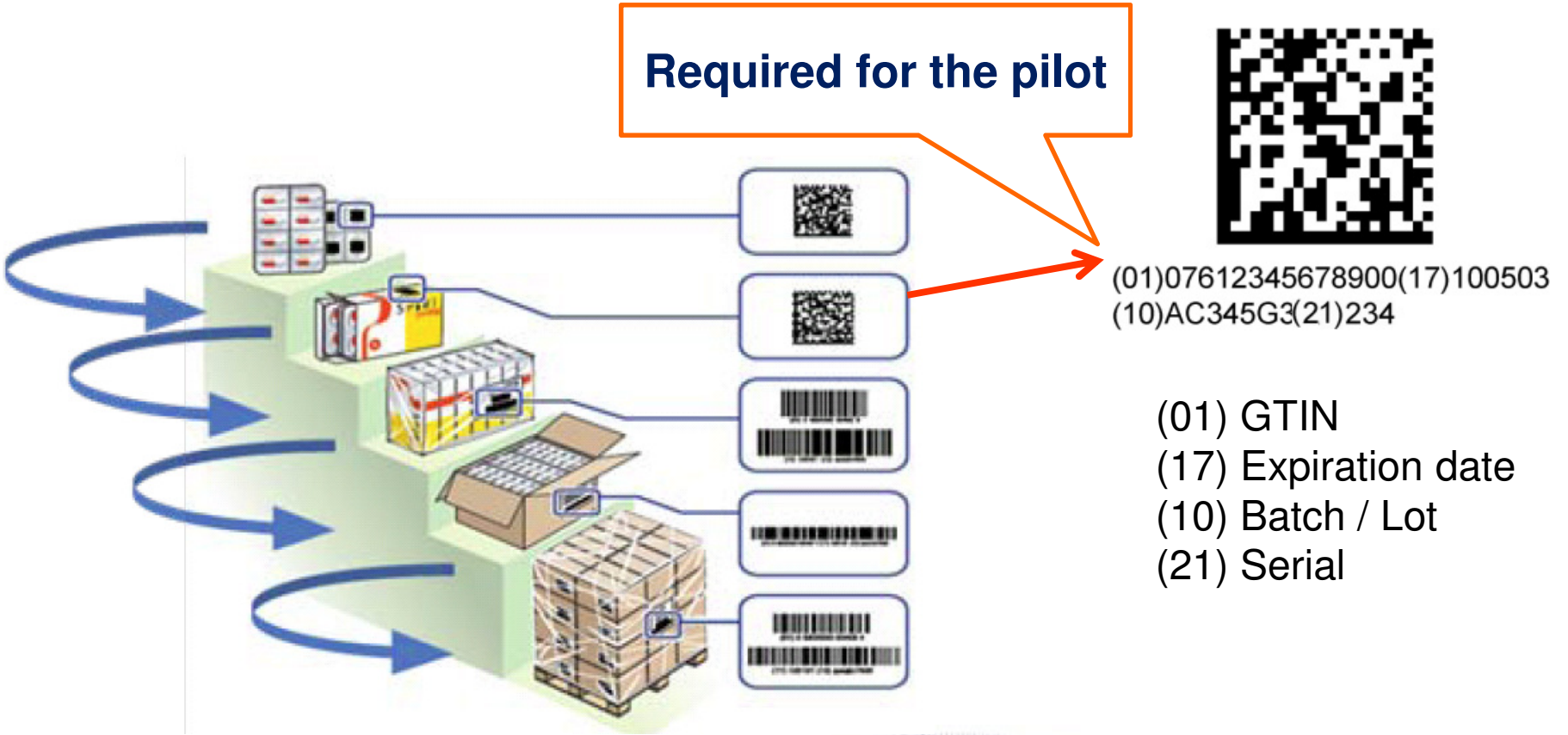




Starting Point



Required for the pilot



SERIALIZATION

Label TTL 1.25 x 0.5" (1cm x 3.15cm)



GS1 DataMatrix
An introduction and technical overview of the most advanced
GS1 Application Identifiers compliant symbology



The crucial guideline to define an application standard
according to your sector business needs

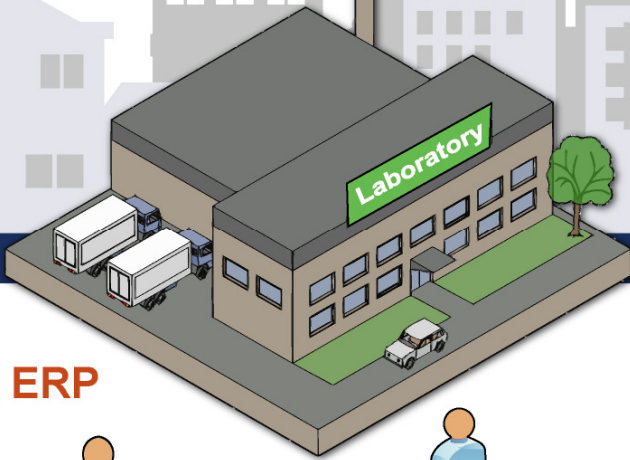


Our guide!





Traceability Web Platform



1. ERP



2. Order Receipt:
Ref. X, Units, Customer



3. Identification
of the products and order

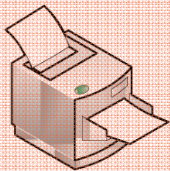


4. (ERP)
generate
flat file

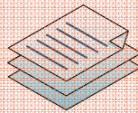


Order
Invoice.
Dispatch
Dispatch date
From (GLN)
To (GLN o NIT).
Channel (Inst. or
retail)
GTIN & SKU
Lot.
Expiration date.
Quantity

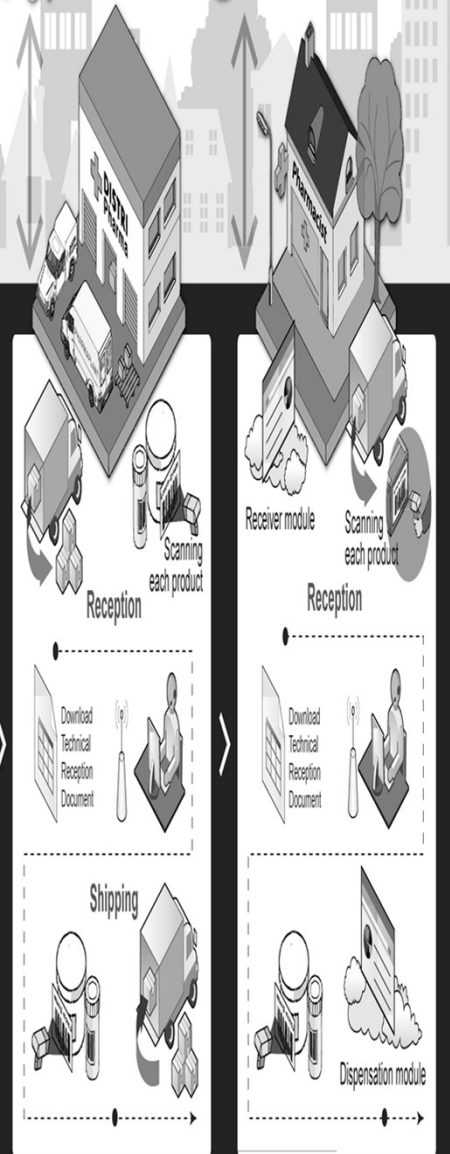
5. Print Application
(Slap & Ship)



6. Build of the flat file
to send to traceability
web platform



8. Traceability
Web Platform



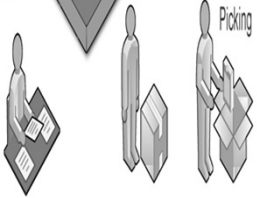


Colombia

Traceability Platform



1. ERP



2. Order Receipt: Ref. X, Units, Customer

3. Identification of the products and order

4. (ERP) generate flat file

5. Print Application (Slap & Ship)

6. Build of the flat file to send to traceability web platform

8. Traceability Web Platform

Order
Invoice
Dispatch date
From (GLN)
To (GLN o NT)
Channel (Inst. or
retail)
GTIN & SKU
Lot
Expiration date
Quantity

Reception

Scanning each product

Download
Technical
Reception
Document

Shipping

Reception

Receiver module

Scanning each product

Download
Technical
Reception
Document

Dispensation module



STL

Consulta de Trazabilidad

- ↳ Despacho
- ↳ Recepcion
- ↳ Productos
- ↳ Consultas
 - ↳ Consulta Trazabilidad

Seleccione el criterio de búsqueda e ingrese el valor indicado.

Informacion de Producto

Ingrese Lectura de DataMatrix

GTIN

Fecha Vencimiento lote

Lote

Serial



Informacion del Producto	
GTIN	07640128014195
CUM	19903070-1
LOTE	lot123pru
FECHA DE VENCIMIENTO	5/31/2014 12:00:00 AM
DESCRIPCION	HERCEPTIN® POLVO LIOFILIZADO PARA INFUSION 440 MG
MARCA	HERCEPTIN
FORMA FARMACEUTICA	POLVO LIOFILIZADO PARA RECONSTITUIR A SOLUCION INYECTABLE
CANTIDAD CONTENIDA	1
REGISTRO SANITARIO	INVIMA 2010 M-14188-R1
CONCENTRACION	A
PRESENTACION	CAJA CON 1 VIAL DE 50 ML CON 440 MG DE LIOFILIZADO + 1 VIAL CON 20 ML DE SOLVENTE
PRINCIPIO ACTIVO	TRASTUZUMAB
CANTIDAD	440
UNIDAD DE MEDIDA	MG



Información de Trazabilidad

Fecha	Factura	Despacho	Orden	Origen	Destino	Función
9/20/2012 10:35:24 PM	FACp001	DESP0001	PED90001	ROCHE	DROMAYOR	Despacho
9/20/2012 10:36:06 PM				DROMAYOR		Recibo
9/20/2012 11:25:48 PM	FACp003	DESP0003	PED90003	DROMAYOR	DROGUERÍA LIFE	Despacho

TRAZABILIDAD

Acta de Recepción

Consulta de Facturas. Puede verificar los productos asociados a una factura que le haya sido despachado previamente para realizar el proceso de recibo.

Observacion: El acta de recepcion solo se genera si ha sido recibida el 100% de todos los productos de esta en el sistema.

Seleccione Origen
Seleccione Factura u Orden

1 of 1 Page Width

NUMERO DE LA FACTURA REMISORIA: 451590
NUMERO DEL DESPACHO REMISORIA: 8007552533
NUMERO DEL PEDIDO REMISORIA: 5006883622
FECHA DE DESPACHO: 13/12/2012 03:57:30
FECHA DE RECEPCIÓN: 12/15/2012
NOMBRE DEL PROVEEDOR / DIRECCION: BRISTOL MYERS SQUIBB S.A. / Sin Direccion
NOMBRE DEL CLIENTE / DIRECCION: HEMATO ONCOLOGICO S.A. / Sin Direccion

Cantidad	GTIN	CUM	Nombre	Forma Farmaceutica	Concentracion	Presentacion	Cantidad Contenedora	Lote	Fecha de Vencimiento Lote	Registro INVIMA	Laboratorio / Proveedor
4	08027950150038	20001660-1	IXEMPRA® 15 MG POLVO SOLUCION INYECTABLE	POLVO LIOFILIZADO PARA RECONSTITUIR A SOLUCION INYECTABLE	A	KIT-ESTUCHE CON SISTEMA DE DOS VIALES DE VIDRIO TIPO I, EL PRIMERO CONTENIENDO EL POLVO CON IXABEPILONA 15 MG/VIAL Y EL SEGUNDO	1 U	2J00736	5/15/2014 12:00:00 AM	INVIMA 2008M-0009025	BRISTOL MYERS SQUIBB S.A.
4	08027950150045	20001658-1	IXEMPRA® 45 MG POLVO PARA SOLUCION INYECTABLE	POLVO LIOFILIZADO PARA RECONSTITUIR A SOLUCION INYECTABLE	A	KIT-ESTUCHE CON SISTEMA DE DOS VIALES DE VIDRIO TIPO I, EL PRIMERO CONTENIENDO EL POLVO CON IXABEPILONA 45 MG/VIAL Y EL SEGUNDO E	1 U	2J00743	3/30/2014 12:00:00 AM	INVIMA 2008M-0009026	BRISTOL MYERS SQUIBB S.A.



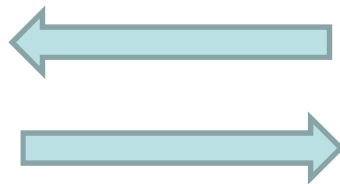
Inspection, Surveillance and Control Model



Sanitary registration system



Traceability System



<p><u>Static Information:</u></p> <p>Data sheet, sanitary registration, brand, brand owner, etc.</p>	<p><u>Dynamic Information:</u></p> <p>From, To, Lot, Expiration date, serial, etc..</p>
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Key conclusions & Next steps





Figures & Results



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- ✓ **205** deliveries
- ✓ **31.788** units
- ✓ **25** Pharmaceutical Presentations
- ✓ **12** Active ingredients
- ✓ **100%** Effectiveness of reception and dispensation at hospitals
- ✓ **94%** Effectiveness of reception at wholesalers*
- ✓ **84%** Effectiveness of reception at pharmacies*



* **Time was not enough to conclude the traceability process**



Findings



- ✓ There was total acceptance from the headquarters of the Labs involved in the project.
- ✓ The model matches with Lab brands protecting systems.
- ✓ The proposed system enables us to accomplish regulations such as the Technical Reception Document
- ✓ The platform allowed us to identify the interchange of a medicine between 2 hospitals, it should be considered by the model to be implemented.



Findings



- ✓ Using GS1 eCom messages as DESADV and RECADV, will facilitate the implementation of the model proposed.
- ✓ Not only does the system need to use GTIN to identify medicines, but also the GLN to identify the locations
- ✓ The POS system at pharmacies must be synchronised with the traceability system.





Key Conclusions



- All participants agree to use the **GS1 Datamatrix Code** to implement the traceability system
- Serialization: helps to detect issues with the origin and exact destination of the pharmaceutical products, but it will be implemented gradually starting with **high cost and specifically controlled medicines.**
- Direct marking on the product implies reviewing the speed of the production line, packaging material and **costs for all actors.**





Next Steps



- Considering the results of the pilot, INVIMA will write a regulation proposal to the Healthcare Ministry on the 4Q of 2013
- To start a stage with manufacturers and distributors to size the **capacity and costs** to deployment the traceability system





Leonel Pava

Communities Development Manager

GS1 Colombia

Avda. El Dorado 70 - 16

T + 57 1 4270999

E lpava@gs1co.org

W www.gs1co.org

