



Deployment of a traceability system by a pharmaceutical wholesaler leveraging GS1 Standards

ABSTRACT

The Colombian government will require that all healthcare supply chain stakeholders can track and trace pharmaceutical products throughout the supply chain. Dromayor, a Colombian pharmaceutical wholesaler, and Pfizer, a global pharmaceutical manufacturer, have successfully concluded a pilot project demonstrating how GS1 Standards can enable a traceability system to meet the government's requirements.



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Background

Currently, the process to track pharmaceutical products in Colombia is completely manual. Items are shipped with a Global Trade Item Number (GTIN)-13, a GS1 Standard, encoded in a barcode. Additional information on the manufacturing date, batch and serial numbers are printed on the package, often in small font size. Once the product is shipped to other nodes in the supply chain, it is the only information available to validate its authenticity and retrieve the additional information. There is no database to validate the information. This makes inspection and traceability very difficult, or even impossible.

A few years ago, Colombia passed a law to requiring drug traceability throughout the supply chain. Article 34 of Law 1122 of 2007 mandated INVIMA, the National Institute of Food and Drug Monitoring, to regulate such a traceability system:

"It is the duty of INVIMA to [...] to guarantee the correct identification of pharmaceutical products at any stage of the supply chain, from production to final consumption, in order to avoid counterfeiting, adulteration and smuggling. Local authorities need to require that both manufacturers and distributors comply with such requirements for all drugs marketed in their jurisdiction".

Since this law, supply chain stakeholders, including suppliers, wholesalers, drug stores and healthcare providers, have succeeded in reaching consensus on how to implement this traceability system – from which technology to use, to a coding system and information tools.

Advancing solutions to meet government requirements

Several stakeholders, in conjunction with the Health and Social Security Working Group from GS1 Colombia, have been working on initiatives to meet government requirements regarding the identification of products, processes, automatic data capture, and the use of electronic commerce to generate traceability processes based on these parameters:

A traceability system through a standard identification and communication system involves:

- unique identification for any medication throughout the different companies and entities involved in their production, distribution, marketing, supply, administration and consumption;
- a means to represent this identification that ensures security and data integrity, authenticity of products, and the possibility to have agile processes through automatic data capture;
- an online information system to register every time an event occurs regarding products and supplies: what was sent, received or sold, dispensed or administered, in what quantities, where the event occurred, what was the player responsible for, and the related transport information;
- the appropriate technology to capture the event information automatically making it available online and with the required quality when it goes to bulk operations; and
- the development of applications that enable consumers to access legal information about the product they are getting, and other applications (e.g., accessing allergenic information through mobile phones).

"Guarantee the correct identification of pharmaceutical products at any stage of the supply chain, from production to final consumption."

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The Dromayor-Pfizer pilot project



In October 2011, Pfizer and Dromayor, a Colombian pharmaceutical wholesaler, started to work together to set up a pilot project to validate the impact of a traceability system based on GS1 Standards, including: the Global Trade Item Number (GTIN), GS1 DataMatrix, and GS1 Global Data Synchronisation Network (GDSN).

An internal traceability framework needed to be set up for Dromayor and its main suppliers and customers, as well as its own pharmacies. Dromayor uses CABASnet, GS1 Colombia's GDSN-certified data pool, to synchronise product data, and integrated its enterprise resource planning (ERP) system with GS1 Colombia's traceability system, Traceability System Online, to manage serial numbers.

The pilot involved Pfizer's distribution center for consumer products, Dromayor's distribution center, and a Dromayor pharmacy in Bogotá. It focused on nine over-the-counter pharmaceutical products with high rotation.

During the pilot, those nine products were marked with a GS1 DataMatrix including the GTIN, lot number, expiration date and serial number at Dromayor's distribution center (see Image 1).

Product information was synchronised between supply chain partners through CABASnet.

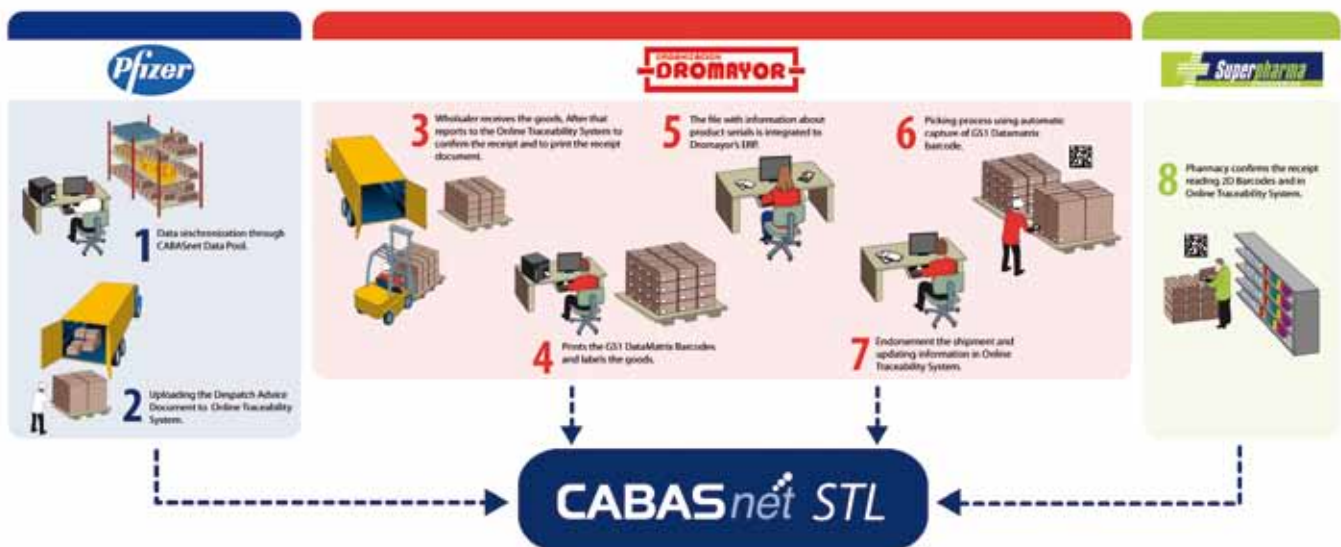


When shipping the products to Dromayor, Pfizer uploaded the Dispatch Advice Document to the CABASnet Online Traceability System.

When Dromayor received the shipments, the labels with the DataMatrix barcodes and the right information were printed and put on the package. Manual labeling took nine seconds on average per item and cost US\$0.05 per label. Dromayor reported back to the CABASnet Online Traceability System to confirm receipt and to print the receipt document. The serial number for each package is linked to the GTIN, lot number and other product data in its ERP system and the CABASnet Online Traceability System. During the picking process, the GS1 Datamatrix barcode was automatically read and the CABASnet Online Traceability System updated.

“GS1 Standards enable online traceability systems that can be used to manage and verify serial numbers.”

Figure 1: Pilot process



Finally, the drug store also scanned the GS1 DataMatrix barcode and confirmed receipt to the CABASnet Online Traceability System.

This report shows information about order numbers, invoice and shipment dates, including products shipped, their lot numbers and expiration dates (see Figure 3).

The CABASnet Online Traceability System provides visibility throughout the whole process. This is of particular importance for the technical receipt document, which is a regulatory requirement (see Figure 2).

Figure 2

ACTA DE RECEPCION TÉCNICA DE MEDICAMENTOS Y DISPOSITIVOS MÉDICOS												
NUMERO DE LA FACTURA REMISORIA:		402433										
NUMERO DEL DESPACHO REMISORIA:												
NUMERO DEL PEDIDO REMISORIA:		110053										
FECHA DE RECEPCION:		19/10/2011										
FECHA DE DESPACHO:		19/10/2011										
NOMBRE DEL PROVEEDOR - DIRECCIÓN		WYETH CONSUMER HEALTHCARE LTD.								CR 7 71 21 TO B P 14		
NOMBRE DEL CLIENTE - DIRECCIÓN		CEDI DROMAYOR BOGOTA										
ITEM	CODIGO	NOMBRE	F.FARMACEUTICA	CONCENTRACION	PRESENTACION	UNIDADES	LOTE	REG. INVIMA	F. VENCIMIENTO	LABORATORIO	OBSERV	
1	7702132003784	ROBITUSSIN JARABE X118mL	ROBITUSSIN		6 Numero de articulos	72	E76152	INVIMA2009M-012891R1		Wyeth Consumer Healthcare LTD.		
2	7702132004439	ADVIL CHILDREN SUSP ORAL 60 ML	ADVIL CHIL		6 Numero de articulos	36	E76129	INVIMA2008M-011320R1		Wyeth Consumer Healthcare LTD.		
3	7702132004484	MAREOL x72 TABLETAS	MAREOL		1 Numero de articulos	48	1D508A	INVIMA 2001M-0000142		Wyeth Consumer Healthcare LTD.		
4	7704403005640	Mucosina suspension				48	1B544A					
5	7702132006433	Z-bec granulado fresa x 300 g			300 Gramos	72	T1091B	INVIMA2001M-0000661		Boehringer Ingelheim s.a. bogota		
6	7702132008048	ADVIL MAX DISPLAY X60 CAPSULAS	ADVIL MAX		1 Numero de articulos	144	1036709	INVIMA 2004M-0003510		Wyeth Consumer Healthcare LTD.		

Figure 3

Fecha de recibo	Empresa Origen	Empresa Destino	Nro. Orden	Nro. Factura	Referencia de producto (GTIN)	Descripción de producto	Lote
18/11/2011 11:22:17 AM	7702132000811 WYETH CONSUMER HEALTHCARE LTD.	770999910294 DROMAYOR BOGOTA S.A.	110053	402433	7702132003784	ROBITUSSIN JARABE X118mL	676152
					7702132004439	ADVIL CHILDREN SUSP ORAL 60 ML	676129
					7702132004484	MAREOL 72 TABLETAS	10368A
					7702132006433	Z BEC GRANULADO FRESA 300 G	71091B
					7702132007817	CENTRUM ADULTOS 100 TABLETAS	617477
					7702132008048	ADVIL MAX DISPLAY X60 CAPSULAS	1036709
					7702132008028	ARTICULO CREADO X CABASNET	103705
					7702132008852	CRISTIAN TRIPLE ACCION 450 MF	341
					7704403005640	MUCOSINA SUSPENSION 450 ML	1B544A
18/11/2011 10:44:33 AM	7702132000811 WYETH CONSUMER HEALTHCARE LTD.	770999910294 DROMAYOR BOGOTA S.A.	1300083	402433	7702132003784	ROBITUSSIN JARABE X118mL	676152
					7702132007817	CENTRUM ADULTOS 100 TABLETAS	103705

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Conclusion

Serialisation helps to verify authenticity of pharmaceutical products. GS1 Standards enable online traceability systems that can be used to manage and verify serial numbers, so that implementing serialisation does not require major developments for a wholesaler's ERP. This online system allows to effectively manage technical receipt documents required in Colombia and provides easy access to historical records through a cloud computing system. Basic infrastructure is required to achieve traceability, including Internet access and 2D barcode scanners.

Ideally, serial numbers are encoded in the barcode by the pharmaceutical supplier at the point of production using global, industry-wide standards. This reduces the risk of errors later in the supply chain and allows for efficient receiving and shipping processes. If the wholesaler has to label the package afterwards with the serial numbers, this adds cost and risk. Furthermore, the wholesaler needs to have an area in the warehouse where they can label the packages.

ABOUT THE AUTHOR

Jorge Enrique Gonzalez is National Director of IT and Logistics at Dromayor, one of the largest Colombian pharmaceutical wholesalers. Mr. Gonzalez is cofounder and official speaker of the Foundation "I believe in Colombia" for more than 11 years with more than 500 conferences in several cities of Colombia, Venezuela and United States. He is a systems engineer, specialising in artificial intelligence and logistics. He was trained in strategic management and management skills at University Politecnico Gran Colombiano and at the University of Pennsylvania in the US.