



Colombia

Implementing a National Traceability System in Colombia

ABSTRACT

The illegal trade of products of any nature is one of the many issues faced by Colombia. When it involves food or medications the risk for people is magnified. The ingestion of an altered, counterfeit, expired or contraband food or drug can lead to a person's death. In 2007, to address the problem in the healthcare sector, the Congress of the Republic enacted Law 1122, bringing some changes to the Social Security System in Health. It was stated that "INVIMA (the government entity that exercises duties in Inspection, Oversight and Control over food, medications, and medical devices in Colombia) has the duty to ensure the identification of medications in any part of the distribution chain, from production up to the final patient, by means of labelling technology for the purpose of avoiding counterfeiting, altering, expiry, and contraband."



by **Blanca Elvira Acosta Cajigas**

Pilot project: GS1 Colombia & INVIMA

To research the appropriate model and technology for a National Traceability System for Pharmaceutical Products, leading to the enforcement of the law, INVIMA established an agreement with the "Universidad Nacional de Colombia" (National University of Colombia).

Prior to the end of the first semester of 2012, the university recommended the use of technologies supported by GS1 Standards. From there, INVIMA, with the support of GS1 Colombia, led a pilot project to test GS1's technology in the field to ensure compliance with all legal regulations.

Eleven pharmaceutical companies (multinational and local) were voluntary participants in the large-scale pilot project and determined the players with whom they would participate: IPS (Healthcare Provider Institutions), and their wholesale distributors with their respective drugstores.

The goal was to develop a pilot for a Traceability System for Pharmaceutical Products with players from the commercialisation chain in the health and social security sectors, backed by international standards (GS1). This would allow INVIMA and all other players in the healthcare sector's supply

chain to learn the requirements that would serve as the basis to generate a proposal for regulations on medication traceability that would be further submitted to the Ministry of Health and Social Protection.

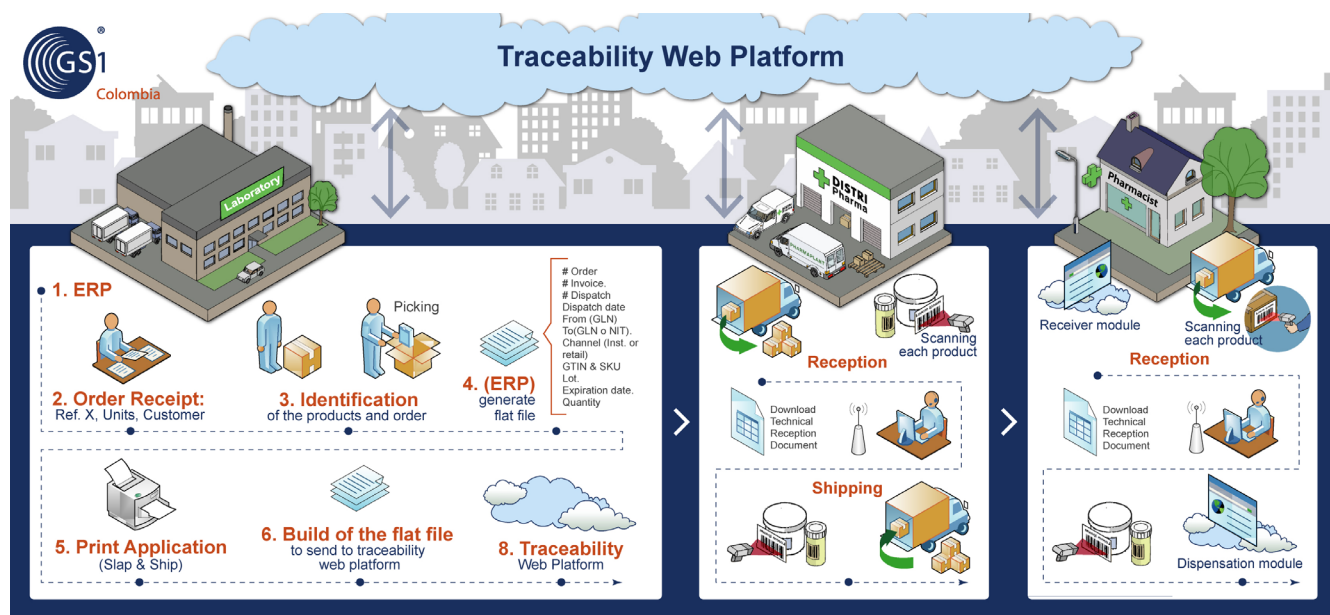
The most important consensus between the parties was to base the National Traceability System for Pharmaceutical Products on GS1 Standards, which guarantee to all players in the healthcare sector and to their patients that any medication leaving a pharmaceutical manufacturer and running through the various points in the value chain until reaching the final patient is legal and of good quality.

In addition to the conclusive recommendation in regard to using GS1 Standards for the National Traceability System for Pharmaceutical Products, the university determined certain geographical parameters, as well as product types, actors and channels, for the pilot project test. Seven cities in the country were chosen, determined by three criteria: border cities (2), difficulty to reach the area (1), and densely populated area (4).

The Pilot Project began once the ground rules were established.

- **Period of execution:** from October 2012 to February 2013
- **205 shipments made** by pharmaceutical manufacturers to clients
- **31,788 units reported** to the platform (92% Commercial - 8% Institutional)
- **25 pharmaceutical presentations** for 12 active ingredients

The process & model



Relevant figures

The following indicators were measured during the period of execution of the pilot:

- **Indicator 1** - Effectiveness of Receipt process and forwarding of information to the traceability web platform - Distributor: 94%
- **Indicator 2** - Effectiveness of Receipt process and forwarding of information to the traceability web platform – IPS (Healthcare Provider Institution) : 100%
- **Indicator 3** - Effectiveness of Receipt process and forwarding of information to the traceability web platform - Drugstores: 84%
- **Indicator 4** - Medications traced by channel: 92% Commercial and 8% Institutional
- **Indicator 5** - Queries to Inspection, Oversight, and Control Process: 100%

Conclusions

Undoubtedly, everything that allows to get information on the movement of a medication through the supply chain, from its production to its sale and/or its administration to a patient, translates into safer and more efficient processes, which will benefit the legal pharmaceutical supply chain and national public health every time a medication is needed or prescribed.

For the previous reasons, the participating companies concluded:

- The identification and the marking of medications with GS1 DataMatrix, including the GTIN (Global Trade Item Number), Batch or Lot Number, Expiration Date, and Serial Number, ensure the traceability and tracking of medications throughout the commercialisation chain
- Serial Numbers on medications become an additional tool for identifying and combatting problems with counterfeiting, contraband, and alteration. For this reason, there is value in implementing the system immediately with high-cost medications that are sensible to these issues
- The implementation of the suggested traceability system facilitates and optimises processes in regard to inspection, oversight, and control through the use of information and communications technologies
- Although the framework of this pilot project did not consider obtaining traceability information up to identification of the patient to whom the medication is delivered or administered, it is important to consider this process in subsequent phases

Moving forward

From the results, conclusions, and final document regarding the Medication Traceability Pilot Project, INVIMA will report the information to the Ministry of Health, which will in turn seek for the initiative's approval with the Office of the President of the Republic. Expectations are high that the National Government will vet the implementation of the National Medication Traceability System over the short term given that the benefits are fully demonstrated.

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There will eventually be collaborative work groups with participation of all players in the health sector (both public and private) whose purpose shall be to continue developing more and better practices for the sustainability of the traceability system and efficiency in the commercialisation chain.

The implementation of a National Medication Traceability System in Colombia, using international GS1 Standards, will facilitate the harmonisation with models implemented in other countries in the region. In this manner, it will achieve the possibility of extending coverage to control imports and exports (legal and illegal) of medications.

The execution of this system is expected to generate an environment of greater safety and peace of mind for Colombians who are users of the healthcare system. Consequently, it is to hope that criminal activities derived from the trade of illegal medications will dramatically drop in the future.

About the author

Blanca Elvira Acosta Cajigas is an industrial engineer with studies in Financial Management, Quality Systems Implementation and Social Protection Management.

"The leadership of health surveillance is exercised by INVIMA with commitment to quality and public service, supported in new technologies".

Blanca Elvira Acosta Cajigas,
General Director, National Institute of Food and Drug Monitoring, INVIMA

During her career she has served as Advisor to the Health System, Quality General Director of Social Protection Ministry and Deputy Minister of Health and Welfare. She also served as Chair and member of several boards of state enterprises and President of the National Health and Social Security Advisory.

About the co-author

Leonel Pava is Communities Development Manager at GS1 Colombia. He joined the organisation in 2002 and previously served as Project Consultant. In recent years, Leonel has worked in the Healthcare industry promoting the implementation of GS1 standards and traceability systems. He has led projects with private sector actors, and more lately the "National Traceability System Pilot for Pharmaceutical Product", along with INVIMA.

