

Supporting the implementation of a traceability system for the healthcare sector in Colombia

ABSTRACT

In view of new government regulations requiring the different stakeholders of the supply chain in the healthcare sector to develop traceability systems for medications, Colombian organisations have been left with the need to find the least disruptive solution possible to adapt current processes. This solution needs to be functional and adaptable by the different types of organisations. GS1 Colombia designed CABASnet STL (Online Traceability System), a tool based on the GS1 System of Standards that enables organisations to find product flow and information online and in real time. Cafam and Wyeth Consumer Healthcare (now Pfizer Consumer Healthcare), two of the main organisation's in the Colombian healthcare sector, have lead the implementation of this solution by undertaking a pilot. In mid-2010, it is anticipated that all other suppliers will be invited to begin using the solution.



By **Luis Gonzalo Giraldo Marin**, CEO Cafam

Background

For the last two years, various stakeholders from the healthcare sector in Colombia have identified the development of a traceability system for medications and medical supplies as a top priority. The system should improve the wellbeing of patients and ensure the complete traceability of products throughout a more efficient supply chain.

New regulations issued in 2007 by the National Government increased the need for a traceability system. Therefore, Colombian healthcare sector organisations were invited to explore solutions that could provide them with full traceability of medications and medical supplies.

The solution selected contains a large number of local requirements (in terms of processes and operations). The consensus of the community was critical as traceability is a process that calls for a joint, synchronised effort throughout the entire supply chain as it involves considerable time, resources and technological development and needs to follow a structured implementation plan.

Cafam, one of the key stakeholders in the Colombian healthcare sector supply chain, has an extensive network of pharmacies nationwide, provides healthcare services and is currently one of the shareholders of the country's largest Healthcare Management Organisations, Nueva EPS (previously the Social Security Institute). Cafam's executives recognised that the regulation set a significant milestone for the healthcare sector and led them to pay special attention to the solutions available that could optimise healthcare services and improve patient wellbeing.

To comply with government regulations and improve their services, Cafam participated in numerous meetings with key associations and organisations from the healthcare sector. In these meetings, one of the issues with achieving traceability was that capture, storage and access to data on medications in real time was poor or non-existent. In many cases, while manufacturers have powerful internal solutions, wholesalers do not have an information system robust enough to store and manage such data.

Therefore, Cafam decided to approach GS1 Colombia. "Our previous experience with GS1 Colombia as regards product coding and synchronisation, as well as developing solutions on a standard system for both chains and suppliers, made us think that it would be less complex to develop and implement a traceability solution created by GS1 Colombia", a Cafam spokesman said.

Due to the interests they shared with GS1 Colombia, in regards to the development of a simple solution to solve the traceability challenge efficiently, Cafam decided to play an active role in the traceability pilot proposed by GS1 Colombia. For the pilot, GS1 Colombia's eCom team developed CABASnet STL (Online Traceability System), a tool that could be used by the different stakeholders to trace medications and medical supplies across the supply chain.

CABASnet STL allows the various supply chain stakeholders to check the information on a product at anytime, anywhere using mobile devices or the internet. It is supported by the use of other GS1 Colombia applications, such as CABASnet synchronisation, and is available for use by GS1 Colombia members without the need for any major technological investments.

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CABASnet STL supports GTIN, GS1 DataBar, GS1 DataMatrix, and EPC/RFID and, in addition to logistics data and updated images (lot, shipment date, addressee, etc.) from the CABASnet data pool, it is capable of holding and providing product information related to physical characteristics.

Main challenges

Once the national government had issued the resolution, the organisations in the healthcare sector began to face a series of challenges that put their capacity to work collaboratively with other business partners to the test:

1. Information systems were not ready to handle traceability information: even though manufacturers identify products with barcodes to enable traceability, data was not being captured or used.
2. The awareness of manufacturers and other stakeholders in the healthcare sector supply chain of the importance of participating in an initiative that could provide visibility of medication all the way through to the end user. As many of the manufacturers already had robust internal traceability systems, the idea of having to adjust to a new system operating based on the GS1 System of Standards was not an easy sell. It would be important that lot number and expiration date already marked on product packaging by the manufacturer, be captured automatically by using GS1 standard symbols, such as GS1 DataBar, GS1 DataMatrix or GS1-128,
3. Another interesting challenge faced local subsidiaries of multinational manufacturers, where the parent company determines organisational processes – how to build on what was already in place. Therefore, working with a solution based on international standards became increasingly interesting.



4. It was important also to develop a standard ship notice that would satisfy the needs of the supply chain and the supplier. The ship notices being used contained just one expiration date and lot/batch per product, when in reality, a shipment of just one product may have several lot/batch numbers and different expiration dates.

Project commissioning

In the end, the development of a two-phase pilot was suggested:

The first phase, "Traceability with bar code without serialisation – sales unit level using CABASnet STL – Online Traceability System", consisted of a pilot test carried out with Wyeth Consumer Healthcare in an effort to provide a short-term solution that would allow the Cafam Distribution Centre, as well as its pharmacy and point of sale staff, to access information online about a GTIN, lots/batches and expiration dates of the products shipped by the supplier.

The objective of the first phase was to connect product flow and information flow (a fundamental enabler for traceability), making use of the GTINs used by the supplier to identify its products.

One additional operational control introduced for the pilot was that the products being received for the pilot was stored in a different location.

Figure 1. PHASE I Work Methodology



Figure 2 illustrates how the traceability information was centralised on CABASnet STL during the first phase, with a simple scheme connecting product flow to information flow through the Ship Notice message, based on the active use of the Data Synchronisation process also through CABASnet.

This methodology also required the identification of critical points of sales and the selection of a group of products with similar characteristics; these were treated in a special manner throughout Phase I. On behalf of Cafam and Wyeth Consumer Healthcare, GS1 Colombia played a very important role in training the personnel that were going to participate in this phase of the project.

Product and information flow can be diagrammed as follows:

1. Product Shipment from Supplier DC to Client DC
2. Information Report (SHIP NOTICE) to CABASnet STL
3. Product Shipment from Client DC to Points of Sale / Dispensing
4. Information Report (SHIP NOTICE) to CABASnet STL
5. Information Inquiry by Users (Wyeth Consumer and Cafam) using the Internet and/or a mobile device, upon request or with the permission of a regulating authority.

For this first phase, it was crucial that the solution operated without affecting the existing processes of the supplier or the supply chain.

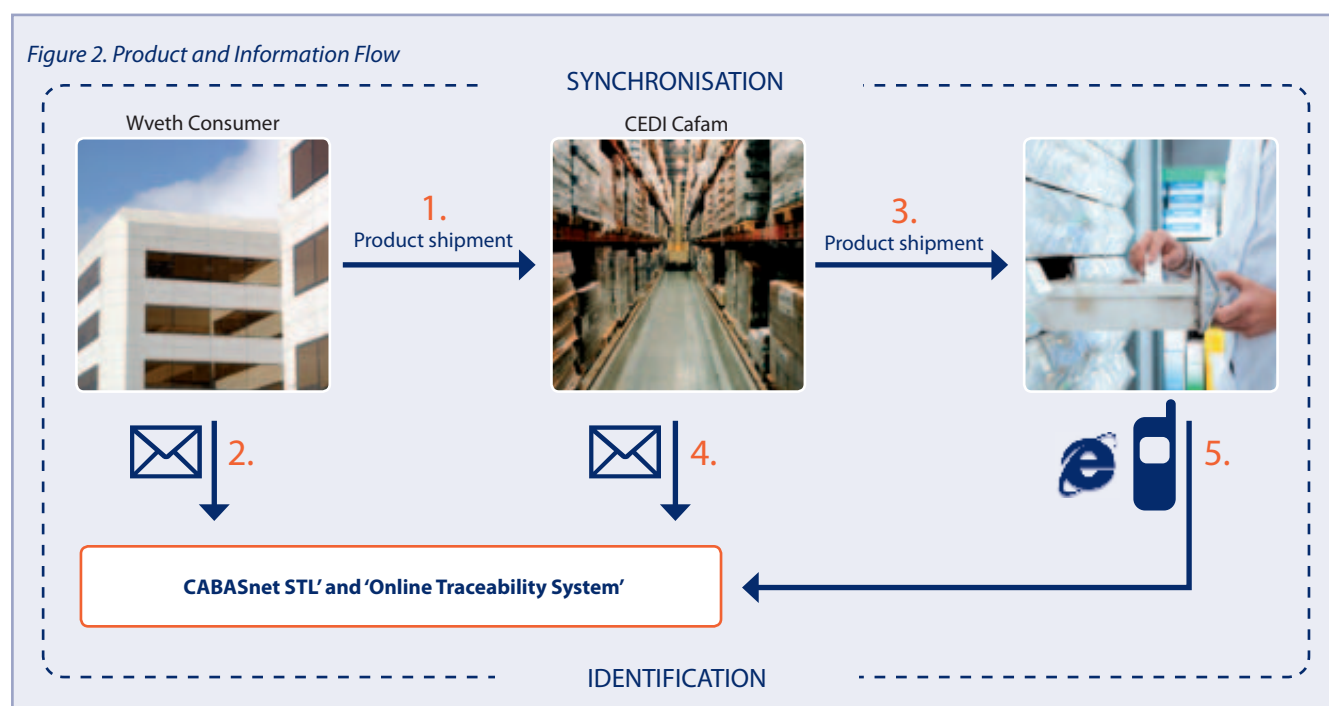
The pilot was carried out between April and May 2009 and, in the words of Luis Tapias, Administrative Sales Manager of Wyeth Consumer Healthcare "The objective of this pilot will enable us

to establish, based on the different technologies evaluated, in the context of the infrastructure available in Colombia and the horizon of the worldwide pharmaceutical industry development, the implementation of traceability among business partners; it provides a response for the regulatory requirements, generates added value with secondary results and has less impact on product costs for the main benefit of guaranteeing the specific medication for the end user".

Phase II of the project is currently underway. Its objective is to extend the scope to other stakeholders. The pilot was undertaken with Wyeth Consumer Healthcare, but now has the participation of other suppliers including Novartis and Tecnofarma. A work plan has been designed with these manufacturers with the support of GS1 Colombia, identifying the parties responsible at each stage of the process.

In addition, important decisions have been made, such as using GS1 DataMatrix, taking advantage of the fact that products are already identified with this symbol, thus facilitating the receiving, storage and shipping process from Cafam's Distribution Centre to its pharmacies and points of sales. GS1 DataMatrix was chosen as it can hold more product information than a linear barcode. In addition, several medications are already identified with GS1 DataMatrix by the head office and other countries worldwide use the same technology for similar purposes. The decision was taken together with the supplier in recognition of the mutual benefits obtainable.

In this regard, it is important to point out that the receiving process at the Cafam Distribution Centre included a visual inspection of the expiration date of each lot/batch of products received, pursuant to certain corporate parameters (products



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with expiry date less than one year could not be received). It was a completely manual process.

In addition, the use of Electronic Product Code (EPC/Rfid) on the product insert sent out by manufacturers (box identification) was established. To this end, reading portals were installed at the receiving docks of Cafam's Distribution Centre.

At the same time, work began on a pilot for identification of high-cost medicinal products (sales unit) using EPC/Rfid, to understand how the technology would work in this context. In order to manage these products, GS1 Colombia provided cabinets equipped with RFID readers, which were installed at Cafam's Distribution Centre and at selected points of sale.

The second phase is expected to be fully implemented by mid-January 2010 and, by mid-year, a larger number of suppliers is expected to be involved and identifying the range of products selected for full traceability.

In the case of Wyeth Consumer Healthcare, the products identified with GS1 DataMatrix from the head office were selected, but product margin and turnover will also be taken into consideration.

Benefits

At Cafam, the broadcasting process is expected to begin in mid-2010 once the ship notice with the modifications necessary is approved by GS1 Colombia's e-commerce committee. Thus, Cafam is asking its suppliers implement and achieve total traceability using CABASnet STL. GS1 Colombia fully supports the process of reaching an agreement with all the stakeholders of the healthcare sector.

Although the benefits obtained up to now are more qualitative than quantitative, it is important to point out the impact of using a traceability solution in key processes such as:

1. Specific control by product and lot/batch
2. Visibility of inventory expiration dates
3. Support for decision making and return management
4. Efficient monitoring of products
5. Visualisation of specific points of filtration
6. Increased product safety for the benefit of the end user
7. Better relationships between supplier and supply chain
8. Less product aging
9. Increased level of satisfaction in patients
10. Supply chain efficiency
11. Patient safety (right patient, right medication, right administration, right product, right time)
12. Increased visibility in regard to counterfeits
13. Information regarding the final destination of the product
14. Compliance with government traceability regulations
15. Elimination of manual operating processes to reduce errors
16. Client claims elimination and control.



Special thanks

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- The Logistics Management Committee of the GS1 Colombia pharmaceutical industry, the roundtable where the different alternatives to establish the best practices of the category are analysed, debated and suggested.
- Wyeth Consumer Healthcare Colombia, for its role and assistance at all the stages of the project.

ABOUT THE AUTHOR

Luis Gonzalo Giraldo Marin is the CEO of the Caja de Compensación Familiar Cafam [Cafam Family Compensation Bureau]. He has held the post since 2005. From the beginning, he has managed to consolidate Cafam as one of the most solid family compensation bureaus in the country, strengthening services in the areas of housing, education, healthcare, recreation, promotion and marketing. Over the last few years, he has promoted new culture and sports-related products and services, in addition to the construction of the Bogotá Fine Arts Theater at Cafam Floresta. Moreover, under his administration, Cafam has developed a large number of solutions focused on optimising services, particularly for the healthcare sector, which is one of top priorities of this compensation bureau.

One of his most important achievements has been the creation of the member and user defence unit, which plays a role in guaranteeing the timely, qualified care of its users, in addition to being a spokesman and making his best efforts to protect members' rights.