Traceability: its implementation and development in a wholesale distributor

By Pablo Ariel Viner

ABSTRACT

The implantation of this innovative system developed by the National Administration of Drugs, Foods and Medical Technology (ANMAT) in the Argentine Republic has as objective to eradicate the distribution of illegitimate drugs within our territory, protecting the population from the illegal traffic and adulteration.

The novelty of this experience at a global level is that is the first time that among a massive quantity of products, "ALL THE STEPS OF THE MARKETING CHAIN" must comply with the traceability process reporting to the Sanitary Authority in real time.

As a distributing company we have embraced the commitment preparing the whole organization for this challenge.

Argentina becomes a pioneer country in the control and registration of the history of a drug from its origin to the patient. From the beginning of the implementation of traceability up to date, the increase of services has followed a gradual and sustained growth.

The inclusion of the products to the system was organized through the publication of resolutions with annexes containing detailed active pharmaceutical ingredients (API). To the date of publication of this article, three listings exist with 325 APIs which correspond to approximately 2819 SKU *(Figure 1)*.

Brief description of the pharmaceutical market in Argentina

The pharmaceutical market of Argentina in which our company participates, consists of 4 types of agents clearly defined where each one has a limited function within the health sector.

a- **Laboratories:** drug manufacturers

b- **Distributors:** created from the association of logistic and commercial efforts from different laboratories in order to use economies of scale to perform the deliveries to the next step.

c- **Drug stores:** wholesale distribution agents.

d- **Pharmacies:** Retailer distribution agents and health contact points between patients and pharmaceutical professionals.

Introduction

With the objective of guaranteeing the patient the quality and legitimacy of pharmaceutical products it is implemented during 2011 in the Argentine Republic the National Drug Traceability System.

	Period Studied: August 2013						
	Total SKU			Monthly sales of Pharmaceutical Products			
Resolutions	Total	Traced	% Traced	Total Resolution	% of total sale	Traced	% of total sale
3683/2011	295	289	97.97%	2,170	1.90%	2,170	0.019%
1831/2012	2,129	831	39.03%	784,884	6.87%	203,085	1.778%
247/2013	395	18	4.56%	483,848	4.24%	7,643	0.067%
Total	2,819	1,138	40.27%	1,270,902	11.13%	212,898	1.864%

Figure 1

e- Hospitals and Sanatoriums: healthcare points which are also reached by the National Traceability System.

regulations were identified. It was evaluated the quantity of presentations and its monthly movements to understand the impact of the logistic process.

3) Selection of complementary technology: due to the multiple data carriers it was performed an extensive analysis of the hardware which best tolerated the operations. Basically scanners of double technology are used: Optical with capacity 1D and 2D and RFID. It would be convenient to regulate towards one technology leaving the others as redundant options: this will allow to reduce implementation costs. At present only 2% of the products uses technology RFID and the other 98%, optical.

Start up difficulties
The extensive quantity of manufacturing laboratories added to the freedom of choice in relation to the data carrier to be used (lineal optical code "1D", Datamatrix "2D", Radiofrequency "RFID"), the lack of readability in the labels and the size of the some data carriers, caused at the implementation start up some difficulties which expanded the complexity of the challenge. With time and the cooperation of all the actors in the project, some of these problems were corrected.

Today we can say that the system advances favorably and follows standardization parameters established, adding the control agency (ANMAT), enhanced technological tools to improve the performance of the tasks.

The three technologies use GS1 standards

Implementation of the system
Implementation of the system required advance planning from which we describe what we consider the most important tasks:

1) Participants of the multi-task work group: a work group was created in a first stage dedicated to the analysis and the definition of internal processes and its implementation. When the system became compulsory by requirement of the Sanitary Authority, this trained group was who coordinated the process with the regulation in force and trained all human resources who participated in the processes involved.

2) Products identification: in our database all products and the presentations which contain the APIs (Active Pharmaceutical Ingredients) involved in the different

4) Software: Modifications of the software were designed which allowed the integration of WMS (Warehouse Management System) with the methodologies to apply and with the requirements established by the application authority.

5) Personnel training: to train the personnel is essential to achieve with success the implementation of a new work method. The importance of a unique code that

identifies each unit was highlighted, to have the personnel become acquainted with the different types of technologies, the right use of the scanners for data capture and the methodologies and modifications made to the computer system to be able to perform each step of the operation.

Description of main operations:

To identify the products with trace
Even though the resolution specifies which are the active ingredients reached, the manufacturers adapt their production lines progressively. Therefore, the most effective way of identifying them, at least at the beginning, it was the control at the reception area. At that stage of the process the product is tagged as traceable.

Coexistence of stock with and without serialized trace of a same article
Due to the gradual implementation of the legal regulation carried out by the laboratories, periodically, in the case in which for one SKU both traceable and untraceable lots must be manipulated. In these cases the system allows to set the traceability as "optional" or "non- compulsory". This permits the operator to use what we called "trace skip" for the products which do not have yet the traceability label.

Once there is no more stock of the SKU untraced, this option is deleted and the system forces the operator to record the trace, not allowing the use of the "trace skip".

We highlight that the tag of "traceable product" is an attribute of the article, and it is applicable to the 12 warehouses of the drug store. On the other hand, the tag "optional" is an attribute related to the article and the warehouse, as soon as each warehouse exhausts its untraceable stock, only for that warehouse the use of the "skip" remains blocked. It is essential to have control and post blockage which shall not allow to continue the logistic process if the serials of the order were not registered.

Reception
Pharmaceutical products in Argentina are delivered by the distributors to the drug stores weekly. The volumes and the control of the quantities received of each distributor are in themselves a process of significant magnitude.

To this process, it must be added the registration of the serials, which in 98% of the products use optical technol-

ogy, forcing a unit by unit reading.

Downloading the data of the national traceability system, it is possible previous to the reception of the order to know which are the serials to be received. This data originates in the information that the previous step sends to the traceability system.

Adopted solutions
a) Only with the reading of the serials the product is identified; it is not necessary to scan the product's GTIN separately. The software must be prepared to receive a GTIN and/or a serial encapsulated in the chain of reading of the scanner, either optical or RFID.
b) Allow that the registry of the received serials can be optionally performed in a different sector of the area of reception, keeping the operations in one direction. The objective is to free space in this sector.
c) Use the information previously obtained of the serials to be received to perform a control by sample. If the total of the sampled units is performed without mistakes, all the serials are taken as valid without the need of proceeding to the individual reading of the complete lot.
d) Maintain in computer and physical quarantine the units freeing them only when the registry of the traces is completed.

Preparation of orders
The process of preparation of orders uses many techniques:
1) **Manual preparation:** the indicated product is selected in the preparation sheet named "picklist". In these cases the registry of the serials is performed in a control table.
2) **Manually assisted preparation:** the operator uses a mobile equipment on its arm with a scanner which guides him in the preparation: it allows him to control the selected product and register the associated serial.
3) **Manual preparation in automated system stations:** through a mobile device or a fixed terminal the operator can control the products and register the associated serials.
4) **Automatic preparation using the technology A-Frame or devices of automatic ejection:** Suizo Argentina handles in different plants the technology that exists at a global level of the two Austrian manufacturers of these types of robots. Neither of them has developed at present a mechanism that allows the optical reading during the orders preparation process. The solution found in this
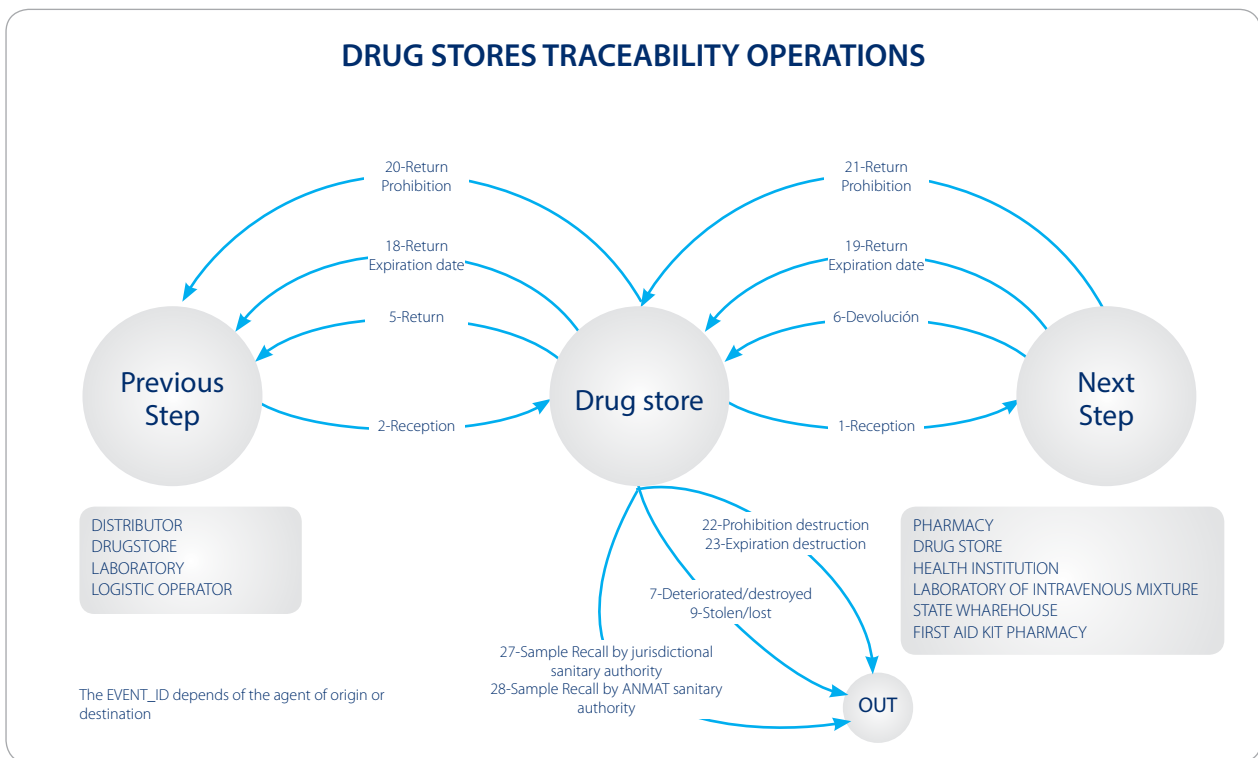
DRUG STORES TRACEABILITY OPERATIONS

Figure 2

case was to separate from each order the orders with traceability in one or more buckets. These are sent near the end of the line, to a control station where the traces of the products which require it are registered.

Receipts' creation

The system was modified to associate to the receipts (invoice and dispatch order) the numbers of the serials of each product. This is possible since they are generated at the end of our logistic process.

Returns

To comply with the regulation in force that requires to have knowledge of the origin of the drugs, return shall only be accepted when referred to an order or purchase invoice previously shipped by our drug store. In the case of traceable products this information it is completed with the registration of the serials and the verification that it has been reported to that client; otherwise the return is rejected.

Additional tools

- Order enquiry: it was included in the consultation of orders the possibility of viewing the serials associated to each product.
- Serials Consultation: it is possible to view the history of any serial.

- Stock and serials controls: allows to perform a control of the physical serials with the registered ones.

As a result it shows:

1) Registered serials not physically present.

2) Physical serials not registered.

3) Physical registered serials but already tagged as shipped.

4) Inconsistencies between stock and the addition of the serials (it is frequent when products with and without trace co-exit)

- Control of upcoming expiration dates by serial
- Serials reader: allows to check if the system and the readings of the different scanners are interpreted correctly by the system.

Information exchange with the National Traceability System (NTS)

The NTS consists of a web interface and a series of functions accessible through web services. We have developed our own communication modules with such services. Exists the possibility to purchase these modules and to incorporate them to the system or to use the services of a third party that is in charge of performing this task.

In the cases of the drug stores, the events reported can be grouped in basic groups.

1) Reception

a- From a previous step (purchases)

b- From a return

c- From a return by expiration/prohibition

2) Distribution to next step (sales)

3) Shipment from return / expiration / prohibition

4) Deregistration damages / theft / lost

The main volume of information corresponds to reception and distribution.

A communication tool of own development, reports all the events to the NST (National Service of Traceability) and registers the code of transaction resulting from each event, or it stores the rejected response for further analysis. That information is available for consultation and for an internal control of errors enabling the performance of the corrective action and returns to report the event in case it is necessary. *Figure 2.*

Conclusions

In a world where technology advances day by day, we need to take advantage of the development that such technology brings to adapt the benefits in favor of our quality of life. In regards to health, we believe that every achievement in the logistic processes related to drugs shall be analyzed and implemented as long as enhances patient safety.

The implementation of traceability meant for us a major investment in equipment and the development of new processes. The challenge consisted of being extremely efficient to be able to maintain the work pace and improve the quality of the dispensed product.

We highlight some key factors which have positively influenced in our implementation such as: formation of multi-task teams, important development of identification technology, highly developed pharmaceutical industry, highly specialized logistics processes and control agencies engaged with the project.

We are convinced that "DRUG TRACEABILITY" is part of the present. It is possible that in a few years we will be in advanced stages, but to reach such stages we must take the first steps. We have accomplished these first steps. We trust that we will move forward in the project and lead this change to keep ADDING VALUE to the health of the population.

References

- *Resolution 435/11. Objective: to eradicate the circulation of illegitimate drugs.*
- *Resolution 3683/11. Establishes 88IFA's (Active Pharmaceutical Ingredients) and sets a schedule of implementation for the Laboratory – Drug store – Pharmacy distribution chain.*
- *Resolution 1831/12 Incorporation of 226IFA'S and it states the implementation of a data carrier to store an unambiguous code.*
- *Resolution 247/13. Incorporation of 11IFA'S psychotropics.*

About Suizo Argentina

- More than 90 years of experience in wholesale distribution of pharmaceutical products, medical products, cosmetics and foods in the Argentine Republic.
- It has 12 plants of distribution, 900 employees (professionals in different areas, technicians and qualified operators). All the distribution centers have systems of automatic order preparation. These systems, in some cases automated and in others with a high interaction of computer tools of the latest technology, work with great precision and effectiveness.
- Distributes monthly: 12 millions of units.
- It has 20,000 SKU (Items) among pharmaceutical products and cosmetic products.
- 60,000 daily pharmacy, sanatoriums and healthcare centers' orders are prepared.

ABOUT THE AUTHOR

Pablo Ariel Viner *is a Public Accountant, graduated from Universidad de Belgrano. He is Director of Suizo Argentina S.A. where he deems services from more than 20 years. He is in charge of leading the operational management within the company. Together with the mentioned expertise, has developed computer systems that unite sanitary requirements from the controlling Authorities with the logistic requirements of a distribution market highly specialized. Previous to this publication, he has obtained acknowledgements from different projects presented to the Argentine Technology Fund (FONTAR) that depends from the Agency for Science, Technology and Innovation. He is part of the work table of GS1 Argentina in the task group of the Healthcare sector.*