Traceability, the prescription for safe drugs

ABSTRACT

The drug traceability resolution affected directly the processes of the distribution chain. To adapt to this new modality presented a challenge; with a little time, a lot of effort and support we could comply with the established terms.
We know that the current solution must keep evolving but we also know that we make good decisions and we are on the right track.

By Ricardo Barriopedro

We have spoken considerably about drug traceability in regard to objectives, definitions, advantages and benefits; for this reason I believe that in this occasion it is important to speak about the experiences achieved in the implementation of the system that enables us to comply with the Resolution.

Within the pharmacy industry there are many actors along the distribution chain, and that made us think about the process along the complete chain and not only about our step. As there are many variables, our idea from the beginning was to facilitate to the maximum possible the flow of the information as we move forward on each step.

Each operation has its particularity and complexity; in our case for being the drug distributor with the majority of the imported products, we have our own.

The first thing we had to understand was that the objective of the NTS (National Drug Traceability System), consists of a "search" system where we provide information about each step of the product while it is in our hands and about the place where it is being shipped; but on the other hand, we will not have information about where our product stands within the chain, because the information entered into the system will be reserved so that ANMAT can do the necessary audits, and eventually request more data if they find an inconsistency.

From the latter, it can be inferred that all our new processes will provide information but they will not receive it, at least from ANMAT. With these first guidelines, if we need information to speed the process, we also will have to think about how we will provide the information to the other actors.

The following issue we debated was how to begin product traceability. Resolution 435/11 states that the products must be traced from its origin. For many of our customers this means that they must do it at the country of origin, and as it is easy to imagine, we knew we could not ask the corporate headquarters of the multi-national laboratories to implement a traceability code that complies with Argentine regulations in six months.

We reached the point in which we found ourselves with more questions than answers and then we realized that if the objective is clear and simple, at least in our case, the implementation was sufficiently complex and we could not only be a concentrator of each of the projects of each laboratory, individually. It was then that we made one of the most important decisions of the project, the initiative of leading a unique solution as standardized as possible for all our customers, to develop it from the systems area, and to involve the Technical Management, Logistics and Marketing areas of each laboratory and the distributor.

Once the decision was made, we defined the reach of the project in the following points:

- Operate in real time and generate availability of access for all the actors online. Comply with the resolutions of the local sanitary authorities, GS1 standards, and quality and safety regulations of the principals.
- Neither generates modifications in the logistic management nor in the transactional systems of the principals.
- Guarantee that the information is protected in encrypted databases and with restricted access.
- Possibility of verification of product's origin for the patient in its final delivery stage, from access to a Website.
- Design a solution sufficiently open, to support the different standards that may emerge in the origin of the production of each one of the laboratories.

With these premises we outlined the project, we made in July 2011 a presentation to all the laboratories and we agreed to implement it leading it from Globalfarm as an only solution.

At the middle of the same month, we already had the main definitions drawn and many questions about how we had to handle the processes to achieve the solution. Then, the following important definition it was to decide if the solution was to be developed by us or by a third party. The important fact to make this decision was to know the impact on our current systems and operation.

We must highlight that in the drug market the traceability is performed at production lot level, but from the new regulation it had to be implemented for each package individually. We had to identify and report ANMAT each movement of each "pack" from each lot.

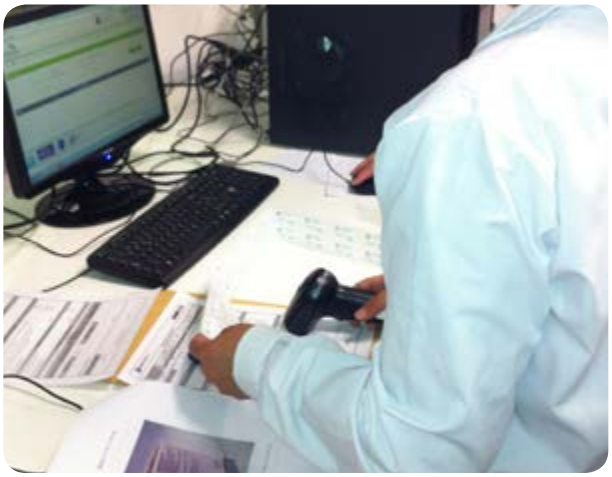
To evaluate the decision of developing or outsourcing, we had to consider all the use cases that we currently have involved in the movement of our products. This task brought us to two conclusions: a) evaluating the internal resources and development costs it was more efficient to outsource, and b) that we had more use cases or operations than the defined by ANMAT as events to report.

What do events to report mean?

Events to report are the operations that ANMAT requests we report for each drug movement performed. For example, ANMAT requests that we report to them when the drug is created.
In the case of multi-national laboratories, its manufacturing is in the country of origin, it is shipped to Argentina, enters through Customs and then in the majority of the cases reaches Globalfarm to be completed. It can also arrive in bulk and it has to be conditioned by a third party or at the laboratory's plant, and then shipped to Globalfarm.
It was defined that the first shipping of the imported products from Customs to its destination was allowed without trace.
Something important to highlight is the good disposition of ANMAT to receive this type of concerns and quickly give us a definition to solve each of the situations which aroused.

Another important factor was to determine how to perform the identification and codification of each product.

We had to build that area and to request the approval in six months, was that possible?
Yes, it was possible thanks to our logistic operator TRF, and sanitary authorities who enabled us to perform the formal procedures in the necessary terms.
Following with the definitions of the regulation, we proceeded to solve the manner of identification of each package. For the identification it can be used 2D codification, barcode with EAN13 format, bidimensional 2D with QR formats, DataMatrix and RFID or radiofrequency identification.



If the imported product enters in its final form to be marketed, we shall have a secondary conditioning area authorized by the Ministry of Health and by ANMAT that enables us to perform the identification process.
We preferred 2D identification with GS1 DataMatrix format, because it is an approved format and we were aware that if in the future the process became normalized, the approved formats were the right ones to use.

ANMAT's requirement is to identify GTIN and Serial Number

From the beginning we incorporated in the GS1 DataMatrix the date of expiration and the lot number, because we thought that it helped the rest of the actors of the chain to obtain information easily, especially since the volume of the traced drugs was going to increase as the process progressed.

I did not mention it before but in June 2011 ANMAT published a list of 88 active ingredients that had to be traced, and in March 2011 227 more were added to the list. The traceability regulation requires that all drugs sold under prescription must be traced, for this reason at one point we will reach the entirely amount of our traceable drugs. At Globalfarm at first the list contained about 24,000 units to be traced per month, and with the second listing we reached about 350,000 units.

When we had made the decisions that gave us the frame of reference for the project, we proceeded to define details to begin to give it real and definite shape.

The identification should be achieved by the manual sticking of a label in the secondary packaging. The label had to comply with the safety features that the regulation requires and it also had to comply with the standards of the multi-national companies that we service. For this reason we had to have grouping labels to facilitate the control as the volume grows.
The interfaces which would connect our system to that of third parties, who we would hire, had to be automatic with Web services' technology. The system had to be accessible and operable from any required place (laboratory, outsourcer, logistic operator, etc.) , being able to handle products created with our operation and also products created in origin (abroad), in another outsourcer of secondary conditioning or in local production plants.
At this point, it was very important to have a traceability control point before the drug was dispatched. This point was seriously discussed, especially with the operations area, since it created a double control and of vital importance.

When we dispatched products it is necessary to report to ANMAT which serial numbers are shipped to each customer, and when the customers receives them, they must report to ANMAT which serial numbers were received and who has shipped them. These transactions are controlled by the NTS and any inconsistency generates a warning which alerts the authorities of ANMAT; it is important to ensure that what has been electronically reported to ANMAT it is the same that what is physically shipped to a specific destination.

The project advanced and in November 2011 we began the traceability of the first units; and successively we incorporated units volume and laboratories reaching on December 15th, date required by ANMAT, with the total of the products of the first stage traced.

The second stage is also underway but the increase of volume brought new challenges and questions. Will we be able to continue tracing manually the process when we have the total of the handled units to be traced, some 3,500,000? Will we continue to use the same identification technology?

Multi-national laboratories are considering shipping us the units already identified, but until now this is performed by the distributor, when will that happen? We do not have precise definitions.

With these uncertainties it shall be a challenge to design a local identification solution, because possibly it shall become useless when we receive the units identified at the point of origin.

At present we are analyzing partial automated alternatives for the labeling process

At Globalfarm we were able to comply with the established terms thanks to the dedication of many people who was part of the work team, to the laboratories who gave support and agreed to different corporate standards, to ANMAT who made decisions promptly and to GS1 who provided support to standardize the identification.

The way was not too long but it was arduous; we still have a long way to go and to learn but we know that it brings great benefits for the patients to have a system that provides enhanced certainty when consuming original products.

ABOUT THE AUTHOR

Ricardo Barriopedro *is currently Systems manager of Globalfarm S.A., which is a drug distributor where he works since its creation in 1999. From the beginning he is responsible for the development of all the processes, systems and infrastructure which at present carries out the operation of the distributor.*

Previously he worked at massive consumption industries, petroleum, petrochemical and cosmetics, always in the systems area and deeply involved to logistic and commercial processes.