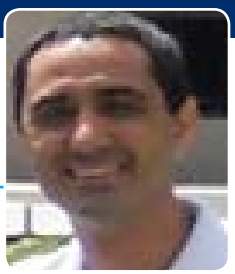
Drug traceability, more quality and safety for patients

ABSTRACT

The so called "traceability" is the most efficient tool to control in real time drug transactions, to verify its origin and register the history of their location and movements along the complete distribution chain. Moreover, we speak of the ideal mechanism to detect discrepancies in a circuit of defined legal provisions. Hereafter we describe the system steps which Phoenix is already implementing.



By Mariano Hernández , Engineer

The National Administration of Drugs, Foods and Medical Technology of Argentina (ANMAT) has among its functions to guarantee the control of all drugs produced and consumed in the country, this contributes, among other things, to eradicate the circulation of illegitimate drugs. Because of this, it established through a specific resolution the "Traceability System", which must be implemented for all the people and companies which are part of the marketing, distribution and dispensation chain of pharmaceutical products.

What does the system consist of?

Basically of the individual and unambiguous identification of each unit of pharmaceutical products to be marketed, with the objective of tracing them along the whole distribution chain from laboratories and distributors through logistic operators, drug stores, pharmacies healthcare institutions and patients.

An adequate traceability system should enable, for example, to locate immediately drugs which for any sanitary reasons had to be recalled from the healthcare or commercial circuit. In this case, the actors of the distribution chain must be capable of reporting the location of each package of a specific drug at all times, from its production until it reached the patient.

The regulation established that the Traceability System was to be implemented gradually, always considering the level of criticality of the different drug categories.

In this sense, resolution 1831/12 of 2012 established the IFAs (active ingredients) which had to be traced, forbidding the marketing of products containing these IFAs it they were not traceable. But until now not all IFAs must be traced but only the ones reached by the regulation, which are defined according to the risk and cost of the API; these are psychotropics, oncologic and high complexity drugs. We are talking about a dynamic regulation, since new APIs can be added regularly.

At a global level, the system has been implemented for two years, even though it has not been enforced everywhere. Only in some countries – like Brazil, France, Spain and now Argentina – have regulated it.

How is the trace performed?

There are three methods to "trace" products:

a. Through a label stuck to the packages. This is the method used by distributors who offer traceability services, for example Disprofarma.

b. Through an imprint on the package at the packaging level: the package is sealed on both sides with an inviolable tape and the traceability data is printed on

the package. This is the method we used at Phoenix.

c. Via RFID: it is a chip which it is incorporated to the package and it is used in high cost and complexity drugs.

The application of each one will depend on the quantity of units to be traced, the cost and the complexity of the production process.

This extensive trace effort has as an objective which is to benefit patients who can with this implementation be certain that the drug which reaches them is completely safe and it is not adulterated. In fact, the patient can trace the movements of the package with the imprinted traceability numbers, all through an ANMAT's website.

How is the traceability process at Phoenix?

GSK, the multinational company of which Phoenix is a part of, is developing a traceability project globally which name is "Fingerprint" and which implementation is foreseen by 2016/2017.

In Argentina, the process was accelerated due to the mentioned regulation which was enforced in 2012, from which, following a technical-economic study and an intensive analysis that demanded four months, the approval was reached for the capital investment to proceed with the reference project's execution at Phoenix's Plant – Villa de Mayo.

The technical-economic study revealed that due to the quantity of units which had to be traced, it was less costly to perform it at the Plant than the label stamped method offered by the Distributor.

The initial investment at Phoenix to implement this process was of 320,000 pounds. This is how Phoenix – Villa de Mayo became the first GSK plant in the world to perform the traceability of the products at the facility.

How was this process implemented?

As we have mentioned, it was foreseen that the enforcement of the regulation would be flexible at the beginning. Because of this, once we acknowledged the reach of the law regarding Phoenix products, in January 2013 we presented the Adjustment Plan to the regulation which establishes the stages for the incorporation of traceable products. This Plan, approved by ANMAT, implies an established date for each product which contains the regulated IFA. From this date on, then, it would not be possible to market these products without being traced. In May the plan was reviewed since two new products were added due to the dynamism of the regulation.

In January began the installation of the necessary equipment, once the Adjustment Plan was approved by ANMAT. It was installed and prepared one of the two production lines, the network, hardware and software. The first line of production ended the qualification process on November 13th. For the launching we still had to comply with all the documentation and the administra-

tive requirements. The start-up of the second production line is planned for the end of March 2014.

Besides the production lines, a complex software was installed, which consists of two servers, two switches, two industrial computers, fiber optic interconnection and its own and independent traceability network from Phoenix - GSK's computer network. It was also implemented a traceability software which reports to ANMAT, with different profiles for the different users.

What does this project imply to GSK?

In the first place implies complying with the regulation in force, keeping our production volume. It is worth mentioning that in Phoenix – Villa de Mayo the regulation reached twelve family of products, which means 1,300,00 units to trace per year. An important volume, considering that the plant produces 12 millions of Phoenix product units per year.

Second, it is about added value that positions Phoenix as an innovative and reliable company.

Third, the project generates a commercial differentiation, since it will enable us to offer a new service to our industrial customers, which is the trace of the products. In this sense, traceability will be implemented in many steps:

Step 1: Phoenix products manufactured at Phoenix – Villa de Mayo.
Step 2: Phoenix export products.
Step 3: Novartis products, laboratory for which drugs are produced at Phoenix's plant.
Step 4: Products of other Industrial Customers.
Step 5: GSK imported products which at present outsource their traceability.

It is worth mentioning that the fact of having our own and independent traceability network adds the necessary flexibility to include the service to third parties.

Moreover, to perform it at the Plant implies a significant cost reduction that as we have mentioned, resulted from the technical-economic study which compared it to outsourcing the process.
Finally, it is important to mention that the implementation of all the process implied a fundamental adjustment in the Plant's daily operations, including actions like packaging adjustments, production operative and personnel training. It is an extremely complex project in which the whole company was involved.

ABOUT THE AUTHOR

Mariano Hernández
Operational Excellence Champion, Pharma Division at Phoenix Laboratories (a company of the GSK Group).
Mariano Hernández has extensive experience in project's implementation and as work team leader. He has more than 18 years' experience in Production, Quality, local and regional Projects, Logistics, Productivity and Operational Excellence Process Implementation, Quality Management System and EHSS.
Experienced in management changes and integrate them in a competitive environment aligned with the Customer and business' needs.
Mariano graduated as a Chemical Engineer from the National Technological University (UTN) – FRBA) he performed post-graduate studies in Occupational Health and Security at the University of Buenos Aires and has a Master's degree oriented to Business and Sustainability at the UTN.