ANMAT leading the Way
A new contribution to the safety of drugs in Argentina

By Maximiliano Derecho and Marí a José Sánchez

ABSTRACT

In 2011, Argentina introduced a catalogue of drugs covered but its national drug traceability scheme, listing more than 3,000 drugs that require the placing of unique serial numbers and tamper-evident features on the secondary packaging. The drugs listed are recorded in real time in a central database managed by the National Administration of Drugs, Foods, Medical Devices of Argentina (ANMAT), which uses Global Location Numbers (GLNs) to identify the various actors in the supply chain. Last February the government of Argentina added another eleven substances to the catalogue. The purpose of this program is to actively limit the use of illegal drugs. Today ANMAT has shown that the implementation of the system has delivered more than favorable results.

When reality exceeds fiction

In the legendary tale by the Grimm brothers, knowing that their parents will try to abandon them in the forest, Hansel and Gretel try to "trace" a way back home, first with pebbles and later with breadcrumbs which will unfortunately be eaten by birds. Could we ever have imagined that the authors of these children's stories were in fact the intellectual precursors of the initiatives of traceability that have been implemented in different industries around the world? Surely not, but Hansel's idea was not so different from the ideas of those who today try to apply traceability to different production and logistic processes. Of course, the scientific and technological evolution provides many and better prospects, optimizing the means to fulfill the objective.

The progress of science and the possibilities offered by different technologies have allowed achievements that years ago were unthinkable or conceived as science-fiction stories, and that now are appreciated like a daily reality.

Likewise, drugs traceability in Argentina has been the subject of wide and productive development, resulting in the National Medicines Traceability System at the end of 2011 and representing a change in the paradigm for the national market of drugs.

Traceability as a tool to ensure drugs quality

One of the principal obligations of the Health Authorities, indicated by the World Health Organization and its regional offices, consists in guaranteeing the population access to quality, safe and efficient drugs. For this, firstly, it must be ensured that the drugs are legitimate, registered and produced by an authorized drug manufacturer. Secondly, Good Manufacturing Practices (GMP) must be applied to all products manufactured at a national level and, lastly, it must be guaranteed that such conditions are maintained throughout the complete supply chain, for which it is necessary the strict compliance of the Good Distribution Practices (BPD) in effect in the country.

Then, it is necessary to apply a post-marketing surveillance to control products in the field and provide reports on any lack of efficiency or adverse events that could happen after their use or clinical application.

Since its creation in 1992 by ANMAT's Decree 1490/92, has adopted an innovative model supported by strong surveillance controls, which has been prioritizing and deepening with the development of its actions in the framework of a politic of strengthening of the quality which has positioned it as one of the leading authorities in the region.

In 1997, ANMAT has moved forward with the implementation of the National Program to Search Illegitimate Drugs (today the National Program for the Control of Drugs and Medical Devices Market), which main objective is the surveillance and control of drug distribution processes in order to identify illegal drugs and prevent risk of usage. The operation of the Program, supported by field controls undertaken by highly qualified inspectors, presented an innovative model at the time of its creation and significantly reduced the presence of illegal drugs in the medications distribution chain. Therefore it has become at present an international reference model, especially in Latin American countries, since there are very few countries with a similar model.

Continuing with the development of the institutional policy of quality implemented by ANMAT, we add that in 2003, the National Institute of Medicines was given the National Award in Quality. In turn, from January 2008 and following a strict external audit, ANMAT joined the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (known together as "PIC/S"), two international instruments, implemented between the countries and the pharmaceutical inspection authorities, who favor an active and constructive cooperation in the field of the GMP, among authorities of high sanitary surveillance.

Moreover, in December 2009, ANMAT was named the First Authority of Reference in America following an extensive audit by the Pan American Health Organization (OPS).

In this context, the implementation of the National Drug Traceability System places ANMAT as one of the world's leading authorities actively working on this subject and, as Carlos Chiale MD, Director of the ANMAT, stated: "It represents one more step in strengthening the institutional policy of quality of ANMAT, by which we improve patients' safety concerning the legitimacy, quality and efficacy of the drugs they consume".

This development is part of a new model of "Regulatory Science" which postulates the utilization, in each decisive action, of the best scientific evidence available as a result of the convergence of professionals, scholars, regulators and society.

The National Traceability System

Drug Traceability consists of a new way of identification, individual and unambiguous, of each of the pharmaceutical products to be marketed, to allow its traceability all along the distribution chain, from the laboratory of the manufacturer/imported till it is dispensed to the patient.

Through the System the inviolability of the drug is guaranteed, and each physical movement must be confirmed in real-time through a central database managed by ANMAT, in order to guarantee that the drug has never abandoned the legal trail of production and distribution. As each package has an inviolable and incorruptible code, the patient can check that the product that he consumes has followed the right track, which gives the patient the assurance of receiving a drug of quality.

It has been anticipated the implementation of a scheme taking into account the level of criticality, and the different categories of drugs, considering the means and technological systems available, and considering that the measures do not impair their access by the population. Moreover, today the National Traceability System has already been applied to a wide list of costly critical drugs used to treat conditions such as cancer, VIH, hemophilia, rheumatoid arthritis and cystic fibrosis. It has also been applied to drugs treating illnesses such as asthma, acromegaly, wet macular degeneration and anemia associated to the chronic renal disease. In addition, it is applied to various sedative drugs, antihypertensive and cough medicines, and analgesics for central action, psychoactive drugs and other substances which can cause addiction, but it is also extended to all new drugs registered and unique in the market. It is worth mentioning that it applies both to national and imported products.

Drugs reached by the NTS must be serialized through the application of an unambiguous code according to the recommendations of the GS1 Standards and should contain the Commercial Product Code, the Global Trade Item Number (GTIN) and a unique Serial Number . This information can be incorporated into any type of data carrier, provided that it complies with the standards mentioned above, allowing each owner to choose the most appropriate data carrier for their products (whether it is a linear bar code, GS1 DataMatrix, RFID or any other). Notwithstanding the data carrier of choice, the information must always be placed in human readable format so the patient may read it.

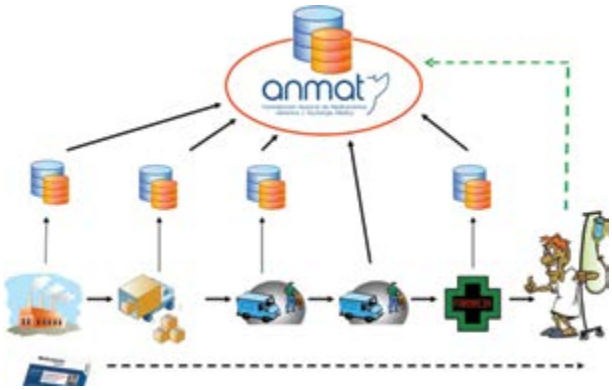
This aspect has singled Argentina out among the initiatives of implementation in other countries and its object is to prevent any disadvantages that the imposition of a specific technology may create. Nevertheless, the rule highlights that it shall be guaranteed that the data carrier "cannot be removed without leaving an evident mark on the packaging, that allows the realization that the package has been violated, or without the latter, shall prevent its reading by an electronic scanner. The drug under the mentioned conditions shall be considered adulterated …"

System objectives

With the implementation of the National Traceability System, the following objectives should be achieved:

Regularize the distribution of drugs at a federal level.

- Limit/Prevent the diversion of products and the distribution of falsified drugs.
- Detect products duplication.
- Improve efficiency and reduce the costs of health systems.
- Provide patients with quality, safety and efficiency of the drugs they consume.
- Minimize wrong supply of products.
- Discourage theft and adulteration of products.
- Facilitate effective product recalls from the market.
- Evaluate in real time the consumption of each type of drug.
- Encourage the rational use of drugs.



GTINs registered in the National Traceability System
2,974 products

Agents of the System	
Laboratories:	221
Distributors:	11
Logistic Operators:	10
Drug stores:	577
Pharmacies:	8,685
Healthcare Institutions:	405
Public Institutions:	172
Lab. of Intravenous Mixtures:	1
TOTAL:	**10,082**

Results and future developments

When we talk about the implementation of a National Drug Traceability System we speak of a real challenge in order to encourage access for the population to drugs of the highest quality, and therefore, access to a higher level of healthcare. The implementation of the new National Traceability System established in Argentina represents an important paradigm change in the surveillance of drug distribution on a federal level. As such, this represents considerable challenges and the different stakeholders involved must demonstrate that they are capable of dealing with the circumstances. Such efforts are accepted due to the important advantages that the System brings and that have already been mentioned.

The implemented efforts enable us to communicate with pride that the implementation of the Traceability System has begun successfully, with a large number of agents already incorporated into the System and interacting within it, having been reported from December 2011 until today more than 65 million of logistic events, which correspond to more than 16 million of individual units of medicine (GTIN + Serial Number). All these figures that increase exponentially, which shows that the commitment of the different agents in all the national territory in compliance with the sanitary resolution, adhering to public policies in the subject of drugs.

These results confirm that the Traceability System is on the right track and ready to broaden the scope of traceability to new drugs and other products regulated by ANMAT, such as medical devices and pharmaceutical raw materials.

As Minister Ramón Carrillo once stated, "The scientific breakthroughs in healthcare are useful only if they are accessible to all people". Time and history will tell us if the implemented initiative is based on stable foundations which will allow us to reach our objectives or if we are only tracing the trail with breadcrumbs that birds will eat in a fairytale. In the meantime, we will continue leading the way…

ABOUT THE AUTHORS

Maximiliano Derecho *is a Lawyer who graduated from the University of Buenos Aires with an honorary degree. In 2002 he joined ANMAT as a Legal Advisor for the National Program fighting against counterfeit drugs, and in January 2008, he was appointed Alternate Coordinator for the program. He is also the legal advisor of the National Program for the Control of Drugs and Medical Devices Market since its implementation in April 2011.*

María José Sánchez *is a Pharmacist graduated from the University of Buenos Aires. In 2001 she joined the ANMAT as an inspector in charge of controlling the different steps of the drugs distribution channel. Since January 2008 she is the Coordinator of the National Program in Search of Illegitimate Drugs and since April 2011 she has become the General Coordinator of the National Program for the Control of Drugs and Medical Devices Market.*