



Argentina

ANMAT Marking the Way

A new contribution to the security of drugs in Argentina

ABSTRACT

In 2011, Argentina introduced a catalogue of drugs covered by its national drug traceability scheme, listing more than 3.000 medicines 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 and 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 11 substances to the catalogue. The purpose of this programme is to actively limit the use of illegal drugs. Today, ANMAT has shown that the implementation of the system has delivered more than favourable results.



by **Maximiliano Derecho** and **María José Sánchez**

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, optimising the means to fulfil the objective.

The progress of science and the possibilities offered by different technologies have allowed us to achieve things that were unthinkable years before. Likewise, the traceability of medicines has been the object of a broad and fruitful evolution, resulting in the National Medicines Traceability System at the end of 2011 and representing a change in the paradigm for the national market of medicines.

Traceability as a tool to assure the quality of drugs

One of the principal obligations of the Health Authorities, indicated by the World Health Organisation and its regional offices, consists of assuring that people have access to quality, secure and efficient drugs:

- First, it must be assured that the drugs are legitimate, registered and manufactured by the authorised drug makers
- Second, Good Manufacturing Practices (GMP) must be applied to all products manufactured at a national level
- Third, it must be assured that these conditions are maintained along the entire supply chain, and comply with the Good Distribution Practices (GDP) in the country
- Lastly, it is necessary to apply a post-marketing surveillance to control products in the field and provide reports on any lack of efficacy or adverse events that could happen after their use or clinical application

Since its creation in 1992 by the Government Resolution N° 1490/92, ANMAT has adapted and improved its role, 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 Programme to Search Illegitimate Drugs (today the National Programme for the Control of Drugs and Medical Devices Market).

The main objective of this Programme is the surveillance and control of drug distribution processes in order to identify illegal drugs and prevent risk of usage. The Programme, supported by field controls undertaken by highly qualified inspectors, presented an innovative model which significantly reduced the presence of illegal drugs in the medicine distribution chain. The Programme reached such a success that it has become an international reference model, and inspired many Latin American countries who had not implemented any model yet.

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In 2003, the National Institute of Medicines was given the National Award in Quality. In addition, following a strict external audit, ANMAT joined the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (known together as "PIC/S") in 2008. These two international instruments, implemented between the countries and the pharmaceutical inspection authorities, favour an active and constructive cooperation in the field of the GMP.

Moreover, in December 2009, ANMAT was named the First Authority of Reference in America following an extensive

audit by the Pan American Health Organisation (PAHO).

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. As Dr. Carlos Chiale, Director of the ANMAT, states: "It represents one more step in strengthening the institutional policy of quality of ANMAT, by which we improve the security of patients concerning the legitimacy, quality and efficacy of the drugs they consume".



The National Traceability System

The system requires the individual and unambiguous identification of each pharmaceutical product to allow its traceability all along the distribution chain (pharmaceutical companies, logistic operators, drug wholesalers, pharmacies, healthcare institutions and patients). At each step of the process, the product data is confirmed in real-time through a central database managed by ANMAT. As each container has an inviolable and incorruptible code, the security and authenticity of the drug is therefore ensured and guarantees that the product has never abandoned the legal trail of production and distribution.

In order to allow a scaled implementation scheme, the system takes into account the different categories of drug products and the means and technological systems available, whilst reducing any obstacles that the patient may face. Today the National Traceability System has already been applied to a wide list of costly critical drugs used to treat conditions such as cancer, AIDS, haemophilia, rheumatoid arthritis and cystic fibrosis. It has also been applied to drugs treating illnesses such as asthma, acromegaly, wet macular degeneration and anaemia 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. The scheme will then be extended to all new drugs registered and launched in the market. It is worth mentioning that it applies both to local-produced and imported products.

The National Traceability System imposes that all drugs be serialised through the application of an unambiguous code,

according to the recommendations of the GS1 Standards. Each drug should contain the Commercial Product Code, the Global Trade Item Number (GTIN) and a unique Serial Number placed on the secondary packaging. This information can be integrated 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, EPC/RFID tag 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.

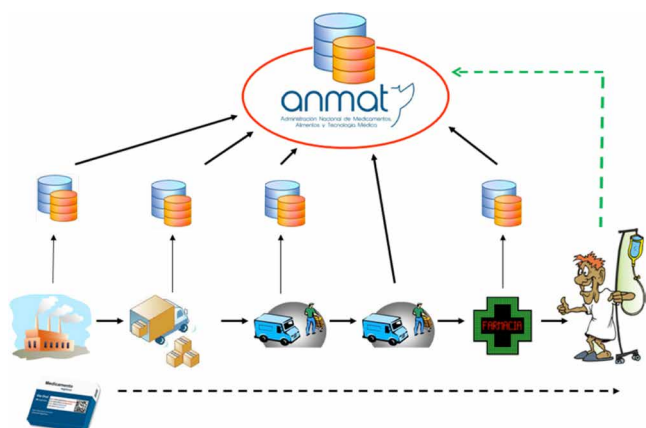
Argentina does not impose the data carrier and the choice is left to the manufacturer. Nevertheless, the rule highlights that: "The data carrier cannot be removed without leaving an evident mark on the packaging. A drug that shows signs of label tampering or that cannot be read by an electronic reader shall be considered adulterated ..."



Objectives of the system

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

- Regularise the distribution of drugs at a federal level
- Prevent the diversion of products and the distribution of falsified drugs
- Detect product code duplication
- Improve efficiency and reduce the costs of the healthcare systems
- Provide patients with quality, security and efficacy of the drugs they consume
- Minimise 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



Results and future developments

When we talk about the implementation of a National Drug Traceability System this includes access to medicines of the highest quality, and therefore access to a higher level of healthcare for everyone. The implementation of the new National Traceability System established in Argentina represents an important change in the surveillance of drug distribution on a federal level. This represents considerable challenges for the different stakeholders involved, which are accepted due to the important advantages that the System brings.

The implementation of the Traceability System has begun successfully, with a large number of agents already incorporated into the System and interacting within it. **From December 2011 until today this includes more than 111 million logistic events, which correspond to more than 25 million individual units of medicine (GTIN + Serial Number).** This reflects the commitment of the different agents

in Argentina to comply with the Traceability rules issued by the Health Authorities.

GTINs registered in the National Traceability System

2,974 products

Agents in the System

Laboratories:	221
Distributors:	11
Logistic Operators:	10
Wholesalers:	577
Pharmacies:	8,685
Healthcare Institutions:	405
Public Establishments:	172
Lab. of Intravenous Mixtures:	1
TOTAL:	10,082

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 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 will allow us to reach our objectives or if we are only tracing the trail with breadcrumbs that birds will eat. In the meantime, the programme will continue marking 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 Programme fighting against counterfeit drugs, and in January 2008, he was appointed Alternate Coordinator for the programme. 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 distribution channel of medicines. Since January 2008 she is the Coordinator of the National Programme 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.