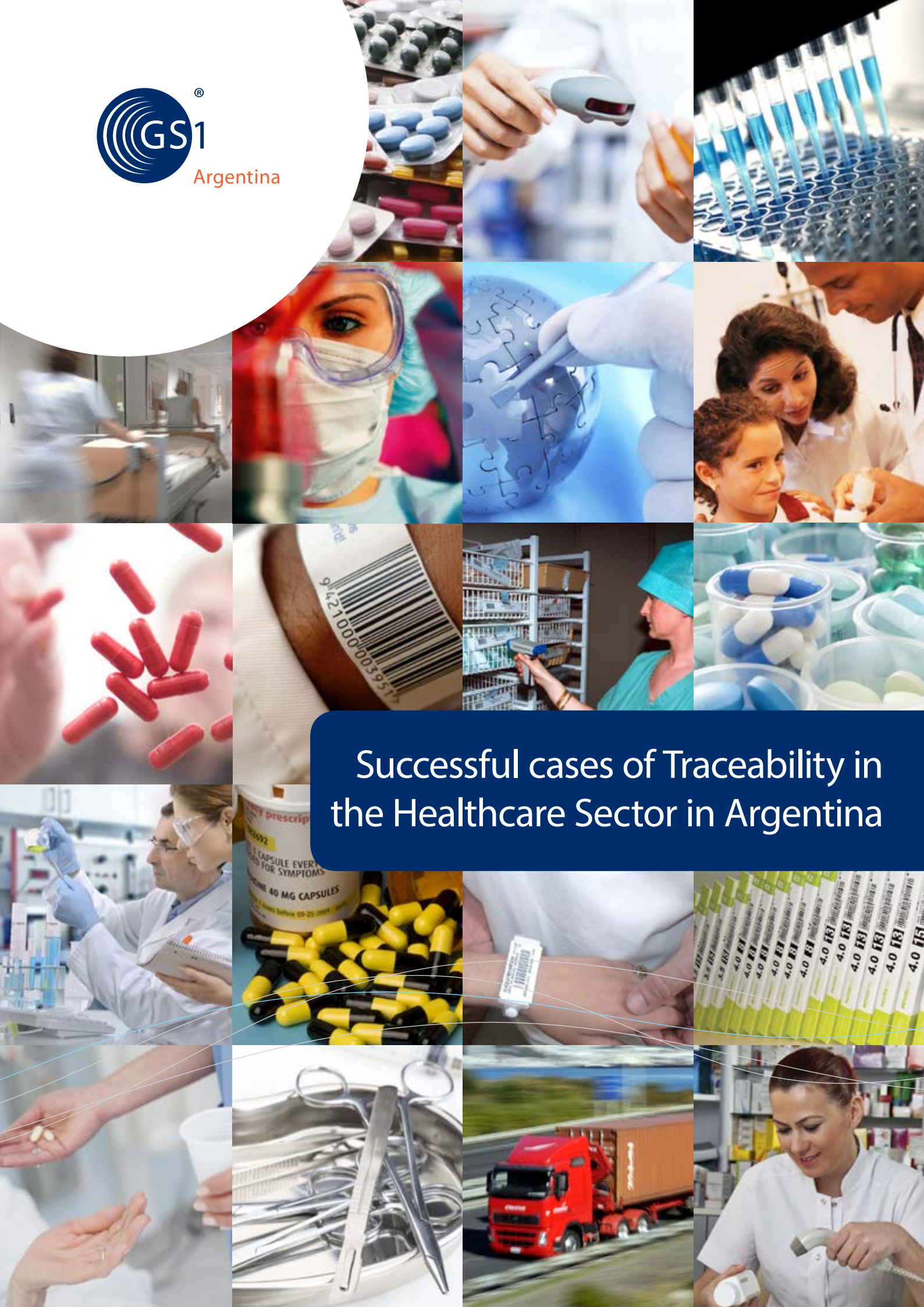
GS1 Argentina



Successful cases of Traceability in the Healthcare Sector in Argentina

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Introduction

By Rubén Calónico, GS1 Argentina

At GS1 Argentina we are extremely proud to be part of this program which has positioned our country at the lead of the group of states which have decided to implement clear actions aimed at guaranteeing the authenticity of the drugs that reach patients, and to counteract the marketing of illegal drugs. It is also an honor, that our standard for the serial identification of drugs had been chosen by ANMAT's National Drug Traceability System.

The criteria unification for the identification of products means an important step that will help healthcare stakeholders with the regulation of drugs denomination in the world of traceable products. We hope that the process initiated with the labeling of secondary packages shall give way to the opening of new ways that may lead the sector to improve the identification of single doses, groups, commercial units y logistic units, and then, to other expected solutions such as the electronic exchange of commercial documents.

The solutions needed are available and from GS1 Argentina we encourage all members of the industry, Distribution, Commerce and Healthcare Centers to remain active, analyzing and debating ideas to reach new agreements and to provide the health sector with all the efficiency that new challenges represent and, above all, to continue providing all the safety deserved by the most important recipients of the value chain: the patients.

Finally, we would like to congratulate the people who are part of this program, for whom we design this document with some of the successful cases of the great universe of institutions that jointly have exceeded the 200 millions of transactions of the National Traceability System.

Rubén Calónico
General Manager of GS1 Argentina

Prologue

By Carlos Chiale MD, of ANMAT

The implementation of a traceability system it is based in a definite and conscious decision, built on the conviction that it is essential to care for the health of the population.

The products incorporated to a traceable system provide a different kind of security, where the quality of the product is controlled and handled among terms established by the regulations in force in each particular case. Thus, it is guaranteed that the product distribution chain develops the necessary steps to achieve the final objective, which is to reach the community with a controlled product during all its process, from the manufacture to its purchase by the patient. Therefore, there is an automatic quality control of the products, their manufacture, distribution and sale, at the same time, important obstacles are raised against the emergence of illegitimate products.

The Argentine experience is a clear indicator of the benefits that offers the implementation of this type of systems. The concern about the quality of drugs is as old as the drugs themselves. The dangers of adulterated products were registered in writings that date back. On the First Century, the Greek doctor Dioscórides identified the existence of adulterations of products and recommended working in its detection. In 1997, Argentina began the implementation of a surveillance model oriented exclusively to the detection and verification of illegitimate drugs in the market. Therefore, the work strategy developed was based in the surveillance of the different steps of the drugs' distribution chain.

The development of new technologies and the possibilities they offer in addition to the progress of science, have allowed achievements that years ago were unthinkable. Therefore, since the implementation of the National Drug Traceability System at the end of 2011, the traceability of drugs in Argentina has been the subject of a wide and productive development. Its implementation defined an important paradigm change for the market and especially, for the surveillance of the distribution of drugs at a federal level.

The interaction with the system increases exponentially and speaks of the commitment of the different actors in all the national territory in compliance with the sanitary regulation and the adherence to public policies in the subject of drugs.

The results the system provides confirms that we are on a good track, it must be continued and even projected and expanded to other products.

Carlos Chiale MD
National Administration of Drugs, Food and Medical Technology

Opinions

At the Association of Private Clinics, Sanatoriums and Hospitals of the Argentine Republic – ADECRA – we are convinced that the Project regarding the National Drug Traceability System prioritizes our task. Moreover, it shall be for the benefit of all the actors of the chain and especially of the citizens, guaranteeing the quality in the care and in patients' treatments.

According to the commitment undertaken by our Association from its beginning we are involved since more than a year with the compliance of this System. In this sense, we need to be mention the effort and time needed by each healthcare center to comply with the Traceability not only due to the incorporation of new technology but also, and above all, because of the training of personnel who have the responsibility to develop and implement this new system.

To know of the origin and destination of the drugs is a guarantee of safety, reliable and excellence that enforces the commitment undertaken by ADECRA associates to build day by day, together, a healthcare system.

ADECRA
Association of Private Clinics, Sanatoriums and Hospitals of the Argentine Republic

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.

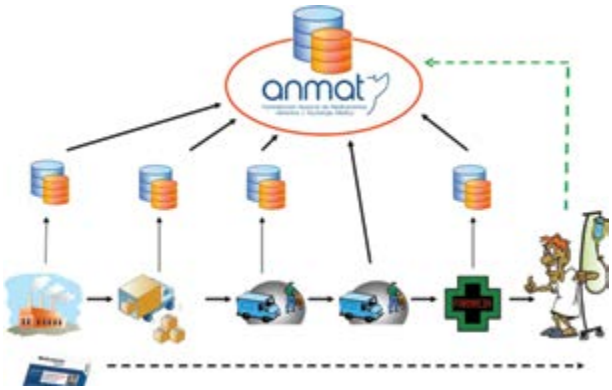
This aspect has singled Argentina out among the initiatives of implementation in other countries and its object is to prevent any disadvantages that the imposition of a specific technology may create. Nevertheless, the rule highlights that it shall be guaranteed that the data carrier "cannot be removed 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.*

Traceability: its implementation and development in a wholesale distributor

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.

By Pablo Ariel Viner

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.

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.

	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.

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.

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 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.

The three technologies use GS1 standards

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 technology, 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

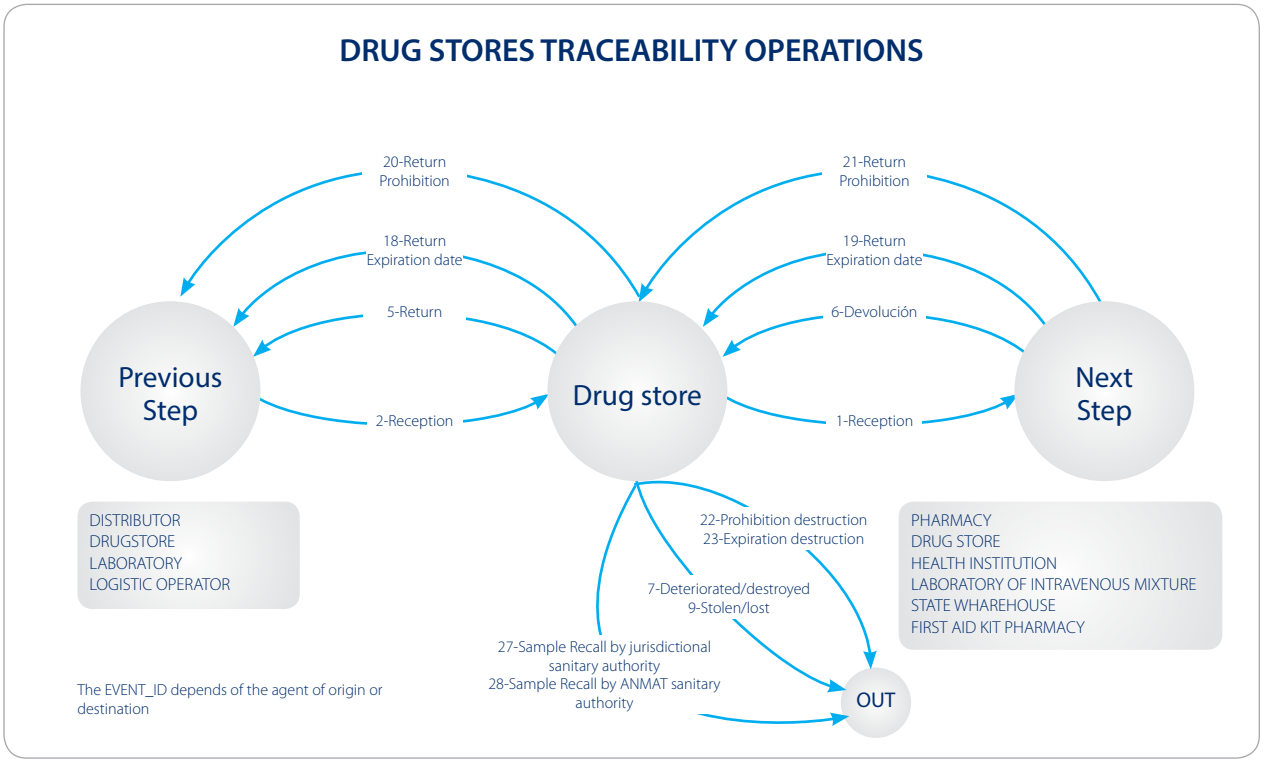


Figure 2

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.*

Providing healthcare services of high quality, safe and reliable

ABSTRACT

Sanatorio Güemes is a private institution which has 450 beds and one of its quality policies includes the accreditation by ISO Regulation 9001:2008. The National Traceability System allowed to envision the possibility of its implementation as an opportunity to improve patient care safety. Five essential stages in the healthcare process were defined: reception, re-packaging, distribution, administration and returns, in which traceability data related to the drugs is captured. To achieve this type of developments interdisciplinary work is essential, and also the training of all human resources involved.

By Estela Izquierdo MD

Sanatorio Güemes

Due to counterfeiting problems and other irregularities that took place in our country and which caused an important warning in our health system, the sanitary authorities of Argentina decided to implement the National Traceability System. This solution enables the identification, validation, communication and registration of all drug movements along the marketing chain.

The Argentine pharmaceutical market characterizes for being extremely complex because numerous actors participate in it, as well as an extensive amount health insurance companies, pre-paid or private insurance, laboratories, distributors, logistic operators, drug stores, officinal and assistance pharmacies.

Sanatorio Güemes is a private institution that has 450 beds and one of its quality policies includes the accreditation by ISO Regulation 9001:2008.
One of our principles is "to provide healthcare services of extensive quality, safe and reliable".

Since the Sanatorium is aligned with a quality management system, it envisioned the possibility of the implementation of a traceability system as an opportunity to improve the quality and the safety of the patients, as a way to offer excellence in the care.

Before the requirements established by Resolution 435/2011 by the Ministry of Health, which stated that all actors belonging to the marketing, distribution, and dispensation chains must implement a traceability system until it reaches the patient, the institution was already generating its own traceability system framed within the projects of the electronic medical history and other internal developments.

In that sense it was decided to automate the stock management linked to drugs, both ours and those of third parties, which are received normally from different health insurance companies and pre-paid insurances.

Together with the automation of the stock management we began working in internal supply traceability. For this reason, a tool was developed wherein to record all the documentation and information corresponding to each one of the drugs received, taking the data from the patients from the general ledger, performing an automatic control of the expiration and other data linked to the origin and the commercial documentation of the supplies of high cost and low incidence.

This implementation and its change in our stock management was what it helped us to be better prepared for the implementation of the compulsory traceability and it was decided to start our own development through

our systems department to move forward with this new challenge. *Figure 1*

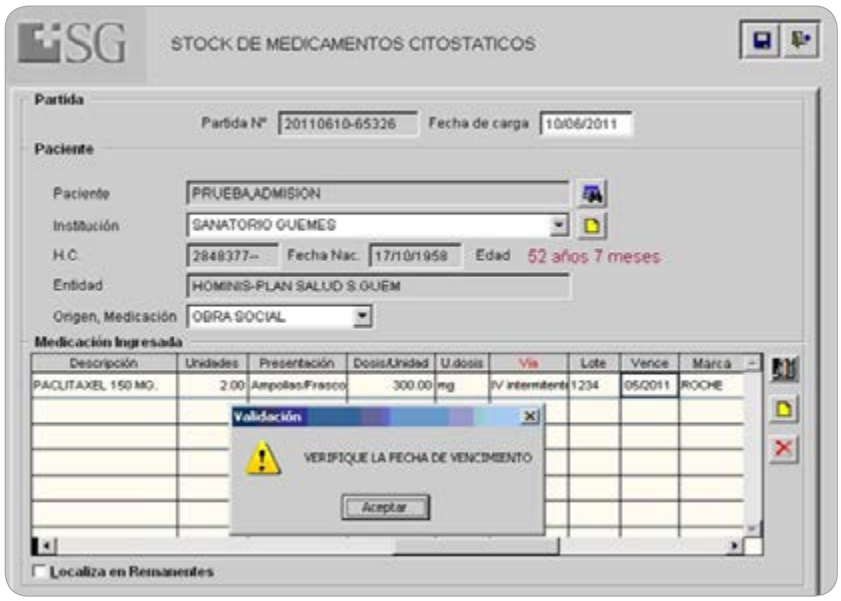


Figure 1: Stock Management

At the time of the development of the internal traceability of all our processes 5 essential stages were defined involved with our healthcare process:

- Reception
- Re-Packaging
- Distribution
- Administration
- Returns

In each one of these stages traceability data is captured associated to each of the drugs; this way the internal traceability becomes created. The communication to the National Administration of Drugs, Food and Medical Technology of Argentina (ANMAT) it is performed in two stages: a) reception and b) administration, what we consider the dispensation at patient's bed-side.

It is important to mention that in our legislation it was determined that the identification of each drug must be conducted in the secondary package no matter what type of data carrier is used: it can be a lineal code, DataMatrix or Radiofrequency, but in any case GS1 standards were designated; therefore, in the healthcare area where the daily doses are prepared to be delivered to different sectors for each one of the patients (like in our case), it is necessary to re-pack pills and ampoules to dispense them and identify to which product commercial code (Global Trade Item Number – GTIN) and serial each one belongs.

Reception:

In a first stage all the documentation that accompanies the drug is verified: dispatch order, invoice, etc., and it is loaded manually to the system. It is important to mention that from the implementation of the national system of traceability, each individual package of the drug is considered a specific supply (with GTIN and SERIAL) that must be controlled against the documentation; it is no longer enough to count the total units. In a sanatorium with 450 beds the supply volumes that are handled are immense, therefore we consider important and necessary to move forward to reach an electronic standardization of commercial documents (EDI) of the different actors that operate in our country to be able to handle electronically a massive load of data.

The second step in the reception is the reading of the identification code of the package with the scanners that in our case enable bar code and DataMatrix. Once the data is incorporated to the sanatorium system (beginning of internal traceability), the connection is established via Web Service with ANMAT's server and the confirmation of reception of each one of the units (external traceability) is transmitted. *Figure 2*..

Re-packaging:

A pill re-packaging and fractioning machine was purchased which has the characteristic of preserving the primary package intact; this way the good manufacturing practices are preserved and the quality with which they were manufactured at the place of origin, and its expiration dates. At the time of the fractioning and re-packaging, the product is identified with the data of the active ingredient, strength, pharmaceutical type, lot, original expiration date, GTIN and Serial.

Actions have been taken to achieve through the sanitary authorities that the pills should come individually identified at the point of origin (laboratory manufacturer) with all the necessary data for its traceability, but the answer was not satisfactory, therefore to be able to move forward with this challenge it is necessary to fraction,

Figure 2: Drugs reception in the system

re-pack and re-label at the hospital, which forces the creation of a production line. This is a critical step because it is not only required a substantial amount of human resources and larger costs, but also exists the risk of error in the identification of the re-packed product. *Figure 3*.

Distribution:

Our institution provides to different internal areas by the daily dose method or by stock reposition; among these areas we can find the Intensive Care Unit (UTI), on duty emergency room, emergencies, satellite pharmacy for the surgery room, coronary unit (UCO), UTI children, oncologic outpatient hospital, medical clinic, outpatient services, etc. The sanatorium decided to perform internal traceability, that is, to have internal knowledge of at what physical place can be found each of the traceable drugs that entered our institution. For this reason, we have a medium-term project of having reading devices for codes and an automated system that enables the capture of the drug data in each of the areas mentioned above. This is the necessary step before the registration of the patient's administration.

Administration:

The institution decided that the administration of the drug to the patient shall be reported to ANMAT when the institution is ready to comply with the five rights: right patient, right drug, right dose, right way and right time. For this reason we are implementing as a pilot test the following processes in the oncologic outpatient hospital, these processes shall be repeated in the rest of the areas:

First, we organized a multi-task work with different sectors: patient admission, appointments, medical specialists involved in the area, nurses' station, pharmaceutics, outpatient area, with the approval of the administrative and medical directors to perform improvements in the processes aiming at patient safety.

Oncology protocols and all the infusions administered regularly at the oncologic outpatient hospital (HDO) were standardized, conducting administration protocols for each of these infusions, in which only the doctor administers the drug dose; this stage at present is documented but it will be included soon in the electronic medical history.

On the other hand, we have an area of preparation of oncologic mixtures where we have a stock management system in which the internal traceability of all this type of drugs is registered. We have also developed a knowledge database for the preparation handling and manufacturing of these drugs; where different controls and warnings are performed before their manufacturing and we obtain what we call a virtual preparation in which all drugs that we have in stock for a specific patient are analyzed with its corresponding traceability we perform the theoretical preparation of each protocol and we

Figure 3: Repacking machine

obtain the detail of how to do it after we have performed all the verifications: expiration date, dose, interactions, stability, etc. Once we have this preparation, our system assigns a DataMatrix code that enables the reconstruction of all the drug history used.

A the time of the patient's admission in the institution, we place an identifying wristband which has, besides all the identification data, the identification of the therapeutic schedule or protocol that he will receive at the oncologic outpatient hospital. This information is in DataMatrix format.

Furthermore, each of the oncologic preparations is identified with a POF number (Oncologic Pharmaceutical Preparation), automatically originated at the time of the virtual preparation. Each POF is linked to the drug traceability data which makes up the mixture. Simultaneously, the POFs assigned to the patient are registered in the electronic medical history.

At the time of the administration to the patient we scan the code in the patient's wristband, the drug label and the personal identification of the assisting nurse. Once the system verifies the matching of the POF to the medical history to the drug to be administered and to the right patient, the infusion can be administered. At the end of the administration we register the time and automatically we communicate the administration of the associated preparations to ANMAT. Figure 4.

Training of the pharmacy team involved in the traceability system

With the objective of normalizing the personnel task which consists of tracing the supplies which required it before the ANMAT's WS, the pharmacy department worked on a training program that includes theoretically and practically, all that the personnel needs to know in order to efficiently achieve the reception and dispensation objectives of all traceable drugs.

Conclusions:

The implementation of the traceability system is an opportunity to improve internal processes, for the safety of the patients and for all who are involved in the marketing, distribution and dispensation-administration chains.

It is important to mention the importance of the training that all health team personnel must have in these cases, especially Pharmacy Service personnel and Nurses, who play an important part for the correct implementation in each of the stages.

It is imperative the multi-task work to achieve these

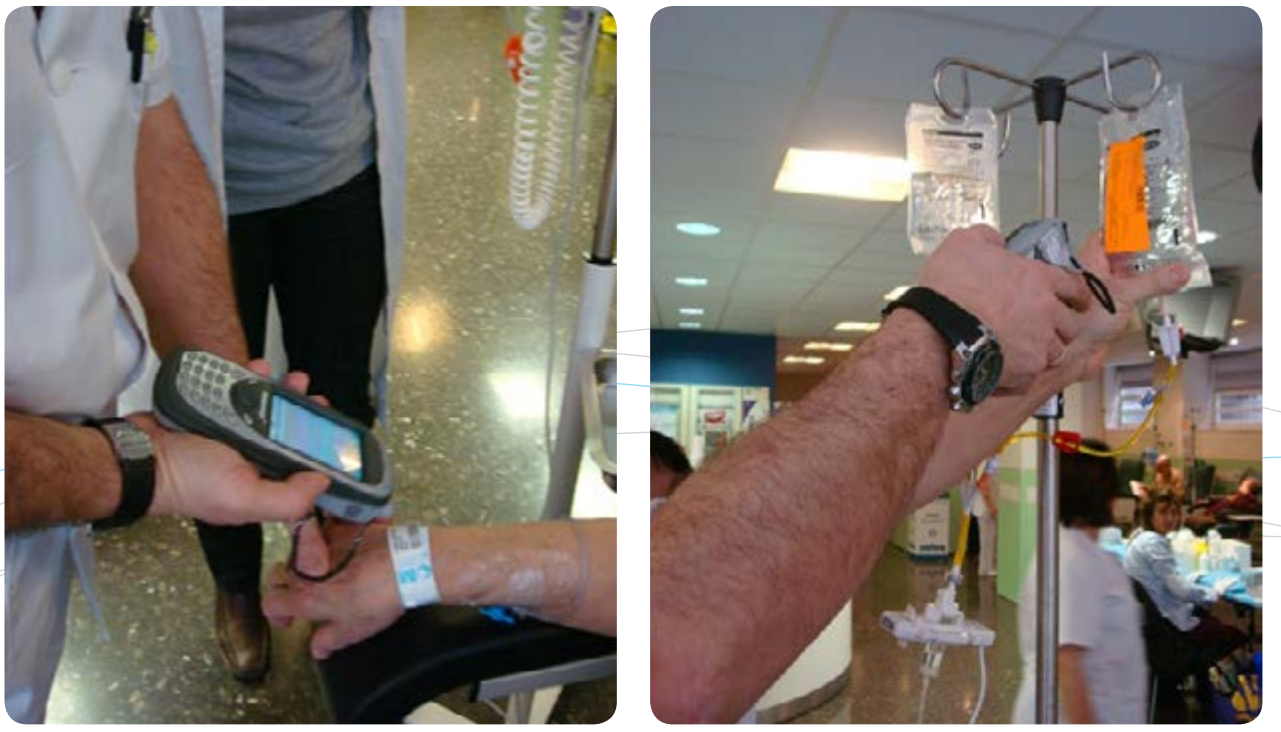


Figure 4: Administration at patient's bedside

types of developments; the disposition and the involvement of the systems and pharmacy departments play an important role. Moreover, it is essential to have the support and the complete commitment of the institution's directors, without them, it would be impossible to implement the project.

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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.

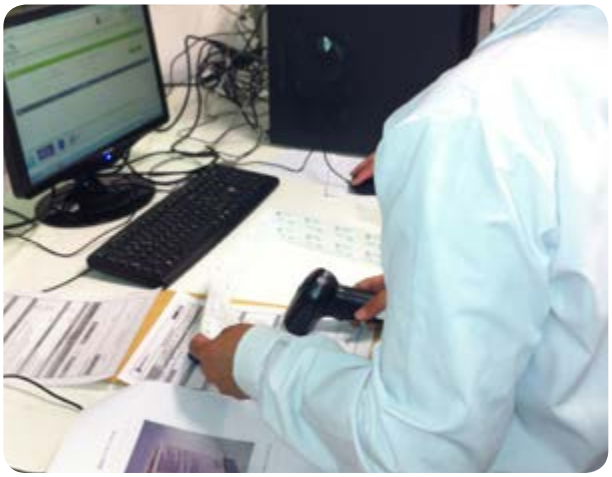
To evaluate the decision of developing or outsourcing, we had to consider all the use cases that we currently have involved in the movement of our products. This task brought us to two conclusions: a) evaluating the internal resources and development costs it was more efficient to outsource, and b) that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

Implementation of Drug Traceability at the Hospital Alemán

ABSTRACT

In order to reduce the serious risks presented by the proliferation of counterfit medicines, Hospital Alemán (HA) implemented a traceability system complying with the new legislation introduced by the National Administration of Drugs, Foods and Medical Devices of Argentina (ANMAT) in late 2011. The primary objective of the program is to counteract the distribution and supply of illegitimate drugs to guarantee patient safety. It is based on the unambiguous identification of products through IT systems and through the use of the global and harmonized language of GS1 Standards. All drug movements are recorded in real-time in a central database managed by ANMAT using Global Location Numbers (GLNs) to identify the various agents involved in the supply chain.

By Heidi Wimmers

Introduction

Counterfeit drugs present a major growing concern for public health. Although there is not a universally accepted definition for "counterfeit medicines", the World Health Organization defines the term counterfeit drugs as "medicines that are deliberately and fraudulently mislabeled with respect to identity and/or source[1]"

The most common factors increasing the occurrence of counterfeit drugs are considered to be:

- Lack of legislation prohibiting counterfeiting of drugs
- Weak penal sanctions
- Weak or absent national drug regulatory authorities
- Weak enforcement of drug laws
- Shortage and/or erratic supply for drugs
- Lack of control of drugs for export
- Trade involving several intermediaries and free trade areas.
- Corruption and conflict of interest[2]

What is drug traceability?

We are living in a world of global markets where there are few - if any - borders between sectors, countries and continents. The Healthcare supply chain is becoming much more complex with its increase in the variety of suppliers, products and buyers, and rise of large-scale productions in emerging economies like Brazil, Russia, India, and China, making it increasingly difficult to trace a product from the point-of-production to the point-of-use, or from pill to patient.

Although traceability has become a necessity, global supply chains need more complex business processes and information systems to achieve it. They need standards for identifying, capturing and sharing information, and this is where GS1 Standards can help.

In GS1 terms, Traceability is the ability to track forward the movement through specified stage(s) of the extended supply chain and trace backward the history, application or location of that which is under consideration.

1 WHO, Fact Sheet N° 275, May 2012: www.who.int/mediacentre/factsheets/fs275 en/

2 Guidelines for the development of measures to combat counterfeit medicines, WHO/EDM/QSM/99.1 consulted 30-MAY-2013: http:/wholibdoc.who.int/hq/1999 WHO_EDM_QSM_99.1.pdf

Traceability means patient safety

The progress of technology has allowed us to implement systems that were unthinkable years ago.

When the National Administration of Drugs, Foods and Medical Devices of Argentina (ANMAT) implemented the provisions of their National Medicines Traceability System, Hospital Alemán put in place an internal system not only to comply with the rule, but also to ensure full traceability of single unit doses of products when fractioning, reconstituting or repackaging the products, thus making the five patients' rights (right patient, right medication, right dose, right time and right route) a reality.

Although it is difficult to know the exact counterfeit drug rate, estimates range from 2-4% to 5-10% globally, with significant variations across countries. Many experts estimate the rates at 1% or less in developed countries and anywhere from 10 to 30% in developing countries.[3]

When evaluating the entire cycle of drugs' use, the Hospital focused on patient safety and set the goal to obtain the certification from the Joint Commission Accreditation on Healthcare Organizations (JCAHO).

How was traceability implemented at Hospital Alemán?

In the hospital, the traceability system involves three specific steps:

1. Hospital reception of traceable drugs
2. Single dose fractioning at the pharmacy with the commercial code and serial number of the drug in each unit dose
3. Administration to the patient

The traceability process begins when the hospital receives the drugs and starts capturing the data.GS1 Standards used include:

- Global Trade Item Number (GTIN)
- Global Location Number of the supplier
- Serial Number
- Expiration Date associated with the receiving GLN

All the suppliers were previously audited as part of a quality assurance program, which ensures that products are consistently produced and controlled according to the quality standards appropriate to their intended use and as required by the marketing authorization/product license (Good Manufacturing Practices - GMP).

The suppliers must also provide properly identified packages in accordance to the national traceability regulation. It is imperative that full identification using one of the three GS1 compliant Data Carriers are placed on secondary packaging:

- Linear bar code
- DataMatrix
- RFID

Once the drug is received, ANMAT is reported and an ID is obtained. The traceability of the drug is confirmed on ANMAT`s website using the transaction ID, from the GLN of origin to the GLN of destination (Hospital Alemán as informant agent).

The traceable drug is fractioned in unit doses at the pharmacy in the inpatient ward.
These medicines are re-labeled in all types of presentations and dosage forms using a printed GS1 DataMatrix linking to all the original information from the marked secondary packaging.

Figura 1: Ejemplos de portadores de datos utilizados.

The unit dose re-packaging is done through an aseptic process where the original blister packs are cut and each unit doses individually overwrapped. A program of preventive maintenance is implemented in order to control the machine, the printers and the labels.

3 McKinsey & Company "Strength in Unity: The promise of global standards in healthcare, october 2012"

The role of the nurse in the traceability process

Nurses are an essential link in the supply chain. Not only do the standards help increase patient safety, but they also allow to save time. A survey conducted by the Nursing Times in the UK showed that "more than a third of nurses waste up to two hours a shift searching for missing medical items[4]".

The work of nurses is essential in the Hospital Alemán program. Prior to administering the medication to a patient, which is one of the critical stages of treatment, nurses read the bar code of the medicine dispensed by the pharmacy, confirming usage of the drug in the electronic system.

The work of the technician is under the close surveillance of a pharmacist[3].

3 Cina, J Et al. Drug errors in the packaging center based in pharmacy bar codes. Am. J Health-Syst Pharm 2006; 63(2):165-168

4 http://news.bbc.co.uk/2/hi/health/7881807

Figure 2: Machine for unit dose repackaging in the HA-Pharmacy

Findings

Quality and safety are more important than ever. The medicine traceability process is very important for the safety of our patients, especially in the treatment of older patients who are polymedicated.

To continue improving the traceability process in the hospital, Hospital Alemán developed a comprehensive quality management system in compliance with the ISO 9001[5] norm .One of the key findings of the implementation of a full traceability system is that it is essential to constantly train the staff, while involving internal members aligned in cross-functional teams.

Hospital Alemán targets continuous improvement and allows medicine-confidence for the patients, the medical professionals and the management, ensuring that the drugs administered fulfill the specified quality requirements.

About Hospital Alemán

Hospital Alemán is a school hospital located in Buenos Aires, with more than 700 professional medics that give assistance in all specialties. The Hospital has 240 beds in individual rooms, 11 Surgery Rooms, one Coronary Unit and Intensive Care Units for children and adults, Burn Care Units an d Transplant Units.

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5 Regulation UNE-EN_ISO 9001/2008

http://www.quality-works.com/download/the-perfect-manual.pdf

Traceability in the Pharmacy area of the Children's Hospital "Prof. Dr. Juan P. Garrahan"

ABSTRACT

The pharmacy area of the Children's Hospital "J.P. Garrahan", has complied with the traceability implementation at the product Reception stage reached by the National Traceability System (NTS). In regard to the Dispensation to patients, we are working in the first stage of distribution to patients from the pharmacy.

To achieve these objectives implied the modification of reception and dispensation circuits and the updating of the integral computer system that the institution uses.

It is a long way to achieve the institutional objective of bringing drug traceability to the patient's bedside, improving the quality of care by increasing safety and preventing management errors.

By Patricia Costanzo MD

Hospital de Pediatría S.A.M.I.C. "Prof. Dr. Juan P. Garrahan"

The Hospital

The Children's Hospital "Prof. Dr. Juan P. Garrahan" is a public pediatric center of high complexity that started operating in 1987. It has 510 inpatient beds, of which 120 correspond to the Intensive Care Units. In this institution we receive annually 450,000 external consultations; we perform 10,000 surgeries and 21,000 sessions of chemotherapy treatments, among other practices of medium and high complexity.

The Pharmacy area

The pharmacy area offers a central service integrated to the hospital structure whose mission is to guarantee the quality, support and the maximum benefit of the pharmaco-therapeutic process, which has the patient as center of all its activity form the concept of Clinical Pharmacy and Pharmaceutical care, both understood with the commitment and the responsibility that the pharmacist develops in the treatment and care of the patient.

This area provides management, supplying and distribution services and biomedical materials simples and of high technology. It is organized in different sectors: Warehouses, Reception, Technical Pharmacy, Dispensation to inpatient and outpatient, Pharmaco-therapeutic follow up, Pharmacokinetics; and Unit of Sterile Intravenous Mixtures, which includes the preparation of single doses of cytostatics and antibiotics and the manufacturing of parenteral nutrition.

Introduction

The hospital Pharmacy Area works with a distribution system of single doses for the in-patients; this system is essentially based in the intervention of the pharmacist in the dynamics of the drugs prescription and of the control of the therapeutic of each one of the patients, through Pharmaco-therapeutic Follow up Chart. The system, which was initiated with a manual operation, moved to an automated system for the follow up and control of the patients' therapeutic, linked to the stock management and drug distribution, and also to the work of the Reconstitution Centrals of Cytostatics and Antibiotics. The information of the Pharmaco-therapeutic Chart also allows the daily creation of the printed medical order sheets, which contributes to the avoidance of reading errors.

This system of intensive control of the prescription by the pharmacist has proved to be the most efficient method to reduce prescription errors.

The C-Page system, acquired by our Hospital, is the one we use for the pharmaco-therapeutic follow up of the patients, which also, handles stock management and the distribution, has a control format of the movements of each of the drug units from the time they enter pharmacy warehouses to its dispensation to the patient through the assignment of internal lots. This System started operating 18 years ago.

New Traceability Resolution

In 2010, facing the migration to another database of the computer System, the need to provide improved safety to the patient was considered, and due to the fact that the original product traceability by lot was a pending issue for the Service certification, it was decided to work in a modification of the internal lot trace method of the product that would now be established by brand, original lot and expiration date of the drugs.

Amid the development of this modification, arises the need to comply with the new traceability regulations that require drugs trace by GTIN and product Serial. Facing this fact we had to reconsider the development of the new System which required the modification of some processes.

In making the first decisions we had GS1's support in reference to what type of codes to internally use, selecting the DataMatrix bi-dimensional code. Moreover, by the type of requirements of our Area which possess an important production sector, we applied for our Global Location Number (GLN), which enables us in the future to have GTINs for the products we manufacture.

The final objective that our Hospital considers institutionally in relation to the traceability system, is the assignment of the GTIN and the drug Serial used at the time of the administration to the patient – what we would call traceability at bedside; this not only would comply with the regulation but also would provide our patients a better level of safety in drug use. It would mean to take maximum advantage of the development for an improved patient's safety.

Reception from a previous step

According to the new regulation, from June 2012 all healthcare centers had to start reporting the NTS (National Traceability System) all GTINs and Serials received from a previous step.

We worked previously modifying the management of products' reception. The first thing we did was to tag in the system's matrix that defines each one of the generics(*) and their presentations with internal drug codes-, those active pharmaceutical ingredients (IFAs) reached by ANMAT's resolutions. A level 3 of traceability was established for those products that required it, by GTIN and Serial, with reporting to the NTS. The coded IFAs in our system and included in the listings of the resolutions 3683/2011 and 1831/2012 were some 160(**) IFAs with their respective presentations.

Different reception operations were adjusted, which include purchase orders, purchases by drug store, national programs and oncologic drugs.

The reception is the first step of the product within the pharmacy that was modified so that in the cases of products tagged of traceability Level 3, the System requires the time of the data input of:

- Provider and its GLN.
- Dispatch order Identification.
- Amount of the product entered.
- GTIN.
- Original Lot.
- Expiration date.
- Loading of the Serials corresponding to this reception, controlling that the amount of Serials entered shall be the corresponding ones according to the presentation specified by the GTIN.

The GTINs and Serials loaded are performed with

(*) In Argentina is in force a law requiring a prescription for generic drugs rather than brand name.

(**) 160 IFAs handled by the hospital a total of 314 IFAs.

scanners, since its manual loading would be impossible. Moreover, the System enables the printing of a small double-sided stick tag with the data of the internal code, description, GTIN, Serials, original Lot and product Expiration date in a Datamatrix code.

The Hospital Systems' Management received assistance from ANMAT to obtain GTINs' product listings and GLNs from suppliers and was made compatible to our System to accelerate reception steps. During the first six months while the Web server was being prepared for the transfer of data to the NTS' Web services, we prepared the reception reports from a previous step through the NTS Web page via internet, individually.
With the preparation of the Web service, our System selects from the reception daily movements for the traced drugs, all the data required by ANMAT, and are placed in an Inbox for its transfer through the Web server.

The reception problem of traceable drugs from a previous step was solved and the functions associated such as devolutions –for different reasons- to the providers. The inbox transfer is also prepared to send the dispensation information to patients within the same connection with the server.

In March 2013, ANMAT implemented a modification in the information reception format; the GTIN's and Serials of the products received from a previous step do not need to be reported, only to confirm the reception from the own data which NTS allows to select. This is an advantage since the receiving institution has previous information of what will be received from the suppliers, in the NTS' Website.

Before these facts we decided to keep the reception circuit and the schedule of the computer system. The only modification will be, as a first step, to confirm the GTINs and the Serials received with ANMATs' information online. At the time of the physical reception and using the code readers, we will confirm that the GTINs, the Serials, the dispatch order data and the suppliers are the ones that correspond to the transfer sent to the NTS. Once all the data is confirmed, we enter the products received to our System through the reception in its current format and we confirm the reception to NTS, through the Web server. The input stage of Serial products is in this way completed.

Patient's dispensation

The System is planned in a way that according to indication of the pharmaco-therapeutic follow up sheet with

data, requested drug, dose, frequency and way of administration, our system calculates the unit numbers of each product that must be delivered to each patient.

During the first stage we worked manually. Each of the traceable drug units, at the time of the reception, is tagged with the double-sided stick label where states:

- Description data
- Expiration date
- Original lot
- GTIN and Serial as DataMatrix Code

Our distribution procedure is performed by single dose and by patient. At the time of the delivery of the product a proof of delivery is created, then on the copy of the patient's ticket- which remains at the pharmacy- we put the double-sided stick label of the product with its DataMatrix code, with the GTIN and Serial information. Therefore we know what Serial we deliver to each patient and we can manually report the dispensation to the NTS. Each patient's medication is placed in an envelope identified with the patient's personal information, its location and a detail of the drug sent inside the envelope. The nurse takes the drug from the envelope, we consider the drug and the serial that we registered in the system, is the one that the patient receives. In a second stage, Systems Management gave us an additional application that enables us to use the data of the delivery tickets by patient, is attached to the products tagged as traced, the Serials and GTINs corresponding to the dispensation. These data are stored by inpatient medical chart and by patient, remaining available in the system to be reported to NTS through the Webservice.

The reading of the ticket data and of the product, is done through barcode readings at the time of the dispensation and only generates a modification in the distribution circuit, but adds to the same a third drug control of the dispensed drugs detecting errors, since the system performs crossings such as GTINs vs. generic drug, and generic drug vs. medical prescription, and rejects the cases which do not match. The system performs a control of the serials dispensed and it blocks them so they prevent Serials from being reused. In the case of pills that since there are many in each package they share the same Serial number, are packed individually and through new a software our packaging machine enables the addition of a DataMatrix code with GTIN and Serial to the label, for these pills, the system controls the Serials in a way that when the contents of the original package are used up, the Serial is terminated.

We should consider that ANMATs' regulation allows the dispensation of a same Serial for different patients until the content of the package is used up.

Clearly, it is possible through consultation functions to know which Serial each patient received, the number of units left in a Serial and in cases of returns for lack of usage, to identify the patient who did not receive his dose and investigate the causes.

This entry process of the Serial in the last stage of the dispensation, will enable us - when the conditions are appropriate – to carry the serial assignments to the administration time, that means to the patient's bedside, which will increase significantly his safety. An error in the last step, at the time of the administration, is a risk that exists and in many cases, the damage is irreversible.

Pending

a)Transfers within warehouses

Currently the system is not developed to move the Serials among internal warehouses. We work as if all the serials entered can be used from all the sectors, from a unique general warehouse.

b) Reconstruction Centrals for Antibiotics and Cytostatics

When preparing a unitary dose it can be requested one or more medicine bottles to complete the total of milligrams required by the dose; in this case the dose prepared will be linked to one or more Serials that later shall be reported as used in the patient that received such dose. It is possible that for a single dose of a specific drug for a patient many Serials of such drug are reported to ANMAT without creating conflict.

At the reconstitution centrals, in cases of small doses, it is possible that they share the contents of one bottle (unique serial) in the preparation of doses destined to different patients. This means that the same Serial Number will be linked to many doses and many patients. The regulation takes into consideration these types of cases and enables us to report one serial for many patients as long as it does not exceed the content in milliliters of the bottle.

This last case is similar to the one of the pills included in one package. The serial is the same for all of the pills in the package, but in an institution with distribution by single doses, the pills are assigned to different patients. When we report to ANMAT the dispensation we find that many patients use the same serial of pills and this is correct, as long as we respect the contents of the package. For example, if we had 10 pills in the package and each patient used 1 pill we can use the serial for those 10 patients.

The challenge – for centrals as ours that prepare doses for children -, is to identify GTIN and Serial at the time of the preparation and link it to the patient that will receive the dose, while the content of the package is controlled.

We should consider that each single dose that is manufactured is identified with data that include name, medical history, patient location, drug and dose. Then, to each label of dose generated by the system, it shall be added the medical chart number of the patient and the drug's internal code; during the preparation the codified data of the label will be read online – to identify patient and prescription – and it be will linked through the reading of the GTIN data and Serial of the bottle's label. The system will verify that the GTIN and Serial correspond to products received in the institution, and that match the patient's prescription, thus increasing the control and improving the safety of the preparation.

Conclusion

To solve these issues requires great effort by the whole institution and its professionals, nevertheless it is worth it when we can have the conviction that the patient received the right legitimate drug, with the right dose, at the right time, since this is the primary objective of our work as hospital pharmacists.

ABOUT THE AUTHOR

Patricia Damiana Costanzo MD
Pharmacist, graduated from the Pharmacy and Biochemistry Faculty of the University of Buenos Aires (UBA). In 1987 joined in as assistant Pharmacist at the Children Hospital "Prof. Juan P. Garrahan". She has worked as a pharmacist in the Inpatient, Training and Pharmacy Management areas of the hospital.
Since 1987 she is the Leader of the Automation Project of the Pharmacy Area.
Since 2006 she works at the Children Hospital "Prof. Dr. Juan P. Garrahan", as Chief of the Pharmacy Area.

Implementation of National Drug Traceability System at the Hospital Italiano

By Nora Cáceres Domínguez MD

ABSTRACT

During 2012 the National Drug Traceability Regulation was enforced, which requires that healthcare institutions, together with the rest of the actors in the marketing chain to implement a system that enables traceability from beginning to end of a list of drugs. At first, the list consisted of high cost and low turnover, but shortly drugs of massive consumption were added that complicated an already difficult process. The Hospital Italiano of Buenos Aires with the objective of complying with these regulations began a series of changes in its processes and computer systems, which continue to develop and require the conclusion of other related projects before completing the traceability cycle of the patient.

The Hospital Italiano of Buenos Aires is an institution of 750 beds, it consists of two high complexity hospitals and 23 peripheral healthcare centers of outpatient care. The insurance plan of the Hospital services more than 150,000 members. It also has a health computer department which develops its own computer programs; a Pharmacy Service and a Committee of Patient's Safety. All this implies that for the implementation of the Traceability Regulation the Hospital had already taken actions and performed some investments, which without being directly related to Traceability, but related to patients' safety, contributed in some aspects to diminish the implementation impact.

Computer System

The Hospital Italiano has been working in the automation of its healthcare processes for many years. It works with an electronic medical history, electronic prescription, electronic nurse sheet and works on a project to develop the electronic registry of the administration at patient's bedside.

In a complex process such as the follow up of the drug traceability through all the steps in the institution until they reach the patient, and with the volumes handled, it is inconceivable any other way than through hospital systems. Therefore, we have modified the SAF or Pharmacy Management System to add the serial number (until now it only showed lot and expiration date), and we have tagged the generics of those traceable drugs. Transactions that involve entering drugs and the ones that contemplate the use of these drugs tagged as traceable shall be the ones that will automatically and through the Net report the movements to ANMAT.

Since drug traceability is directly related to logistics, we will evaluate each step once they entered the institution.

The steps are: reception, storage, re-packing and/or fractioning; distribution and/or dispensation and administration.

Reception

The first observation to highlight throughout the complete process is that in institutions where the drug volumes are high (the hospital moves around 500,000 ampoules units, pills, bottles, etc. per month) it is impossible to carry a traceability from the reception to the patient with the use of scanners.

Secondly, and since in the laboratories the way of transporting the data required by the regulation is not

unified, it is necessary that the institutions obtain scanners that enable the reading of barcodes, DataMatrix and radiofrequency. This becomes the procedure because the availability of requested drugs to guarantee healthcare treatments at the institutions forces us to have more than one supplier.

Thirdly, since each package is by definition unambiguous, it is required that the reception be performed unit by unit to register each serial. Even with the use of scanners this activity is extremely difficult to achieve when the reception volumes are large. For example, if the hospital receives 500 units of albumin, the reception must be performed reading package by package, which delays the complete following process and the availability of the drug for its use.

For this reason, the hospital it is only reporting to the controlling authority ANMAT, the reception of drugs in Annex I, of high cost and low turnover.

To move forward it is essential, to have the information in labels that handle groups. A single reading that contains the total information of a pack will streamline the process, but this availability does not depend of the hospital but of the previous steps of the marketing chain.

Storage

This stage is closely related to a posterior process that is the re-packaging in single doses of commercial presentations with more than one unit. The transformation of the package which contains more than one pill in multiple units considerably increases the necessary volume to store the same quantity of pills, reducing our storage capacity. This situation does not arise in all institutions and it shall depend on how they have solved data registration of the serial number of each unit, for example labeling them instead of placing them in an envelope. In any case, to register the serial of each unit forces us to add processes and to destine more human resources and more physical space within the warehouses.

Re-packing or fractioning

Patient safety has always been our priority at the hospital, and drug related errors an important subject to consider. As a consequence, 15 years ago it was decided to invest in machinery that enabled the transformation of multi-doses packages in single doses, for solid pharmaceutical forms such as pills and capsules, with large labels, easy to read, that facilitated a rational dispensation and also the reduction of drug errors due to misinterpretation of the label.

This activity until the implementation of the Regulation it was performed in bulk since the data to group was the lot (1,000 pills with the same lot could be performed in one single step); today the process is delayed since we have to constantly change the label because to each package corresponds a different serial, even if they share the same lot (10 packages of 100 pills with the same lot implies 10 different serials and 10 different labels to re-package 1,000 pills).

A disadvantage that needs to be mentioned is that to interrupt the re-packaging process every time that it is required to change the serial, implies a slowing down that increases the possibility of errors in the creation of new labels. On the other hand, and for those drugs that do not follow this process such as pre-filled syringes, aerosols, bottles, etc. it is necessary to label them to be able to carry the serial to each unit, which increases the need of human resources.

We can provide an example of this: in a work shift and with a resource destined to this activity a year ago the Pharmacy re-packed 6,000 units per day. Today, under the same conditions but taking into consideration the serial, it only re-packs 4,000 units.

This process which has the objective the right identification of single doses depends of the hospitals because the pharmaceutical industry does not provide this service and forces the institutions to have re-packing lines.

It is worth mentioning that the investment in these equipments was made a long time ago, the implementation of the traceability system did not have an economic impact in the hospital.

Distribution/Dispensation

Independently of the method chosen by each institution for the delivery of drugs, Pharmacy Services have in common that we do not deliver the product directly to the inpatients. The Hospital Italiano dispenses the drugs by patient and for 24 hours of the treatments to the nurses' stations that administer them following doctor's prescriptions.

Due to the fact that the only ones that can guarantee drug administration are those who perform it, the hospital decided the registry of the administered drugs were the source of information for ANMAT notifying the patient's consumption and with this, the end of the cycle.

The electronic registry of the administration from the

nurses and other healthcare professionals at bedside, is part of a hospital's project to guarantee the five rights: right patient, right drug, right way of administration and right time, related to patient's safety.

This project is under way and once implemented the patient's consumption will be reported to ANMAT.

Conclusions

The National Traceability System has been designed as a measure to guarantee that the drugs that will reach the patients are original and safe. The objective is clear and viable, but when the indications that regulate this resolution are analyzed, we can see that originally the regulation was not planned for its implementation in healthcare institutions, where many of the drug commercial presentations once they have entered the institution follow different steps and transformations, which makes considerably difficult to achieve a successful practice. From the Associations and working jointly with other Institutions and with ANMAT, these provisions have been changing, and even though we are not completely prepared to guarantee traceability the way it is required, we are in the process to achieve it.

In our case the implementation has implied:

1. A computer system modification
2. A process modification
3. More Human Resources
4. Investment in scanners for the Hospital Italiano
5. Training of Pharmacy personnel and professionals involved in drug administration

In order to move forward we need:

1. development of labels that identified groups.
2. development of tools such as the invoice or electronic dispatch order that enables to streamline the management of information.
3. presentation of single doses correctly identified and serialized for the pharmaceutical industry.
4. development and implementation of the hospital's registration project at bedside that enables the closure of the traceability cycle in the patient.
5. Lastly, the implementation by steps that enables to demonstrate at public institutions and at private ones that it is possible to efficiently implement the measurement.

As long as all the steps in the marketing chain and the controlling authorities understand that drug related processes at the healthcare institutions and as a consequence our needs, there will be a higher probability of achieving this process which benefits everyone.

ABOUT THE AUTHOR

Nora Cáceres Domínguez, Pharmacist.

Pharmacist graduated from the Pharmacy and Biochemical Faculty of the University of Buenos Aires (UBA) in 1991.

Graduated from the specialization course in Galenic Development and Pharmaceutical Production in 1998. She has worked in the hospital sector for more than 20 years. Joined the staff as a pharmacist at the Hospital Italiano in 1994 to perform clinical activities. Responsible for the Administration in the certification process of the Pharmacy Service by ISO 9000- 2001 regulation from 2002 to 2006.

Chief of Pharmacy Service from 2005 and 2012.

From 2013 Head of the Pharmacy Department.

Working with Medical/Pharmaceutical ethics and responsibility

By Yanina Sarnagiotto and Ma. Cecilia Fragata

ABSTRACT

Helios Salud is an Infectious Disease Medical Center founded and lead by Daniel Stamboulian MD specialized in the integral care of patients with VIH and chronic hepatitis, among other pathologies with services in the whole country.
Jointly with Helios Salud emerges Helios Pharma, Pharmacy and Drug Store, to guarantee the patient the safety and quality of Pharmacy dispensed drugs, and the distribution in the whole country to the Pharmacy network, through the Drug Store.

Why do we choose GS1?

Due to ANMAT's new drug traceability regulation, Helios Pharma developed its own system. This tool speeds up traceability daily work, automatizes traceability processes, guarantees drug administration to the patient reporting the dispensation in real time, and also the reception processes from the Laboratories. At the same time diminishes margin error and reduces costs. To be able to optimize all these processes we appealed to GS1's health team and we adopted the use of global standards, with the purpose of achieving a continuous improvement not only in the services but also in patient safety.

What sectors were involved for the certification?

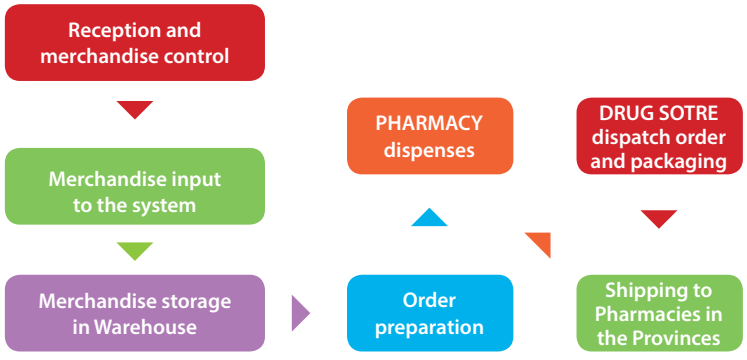
In Helios Salud the Patient Admissions sector was involved due to the importance that has, since it is the place where the patient is received as soon as he enters the Institution, to request healthcare services and for its derivation to pick up his medication. The required documentation for the health insurance is also verified.

In Helios Pharma were audited the areas of reception of traceable units sent by suppliers, storage, order preparation, distribution and dispensation.

Implementation challenges

In Helios Salud we developed the procedure manuals with good practices processes. In order to document the

MAP OF HELIOS´TRACEABILITY PROCESSES

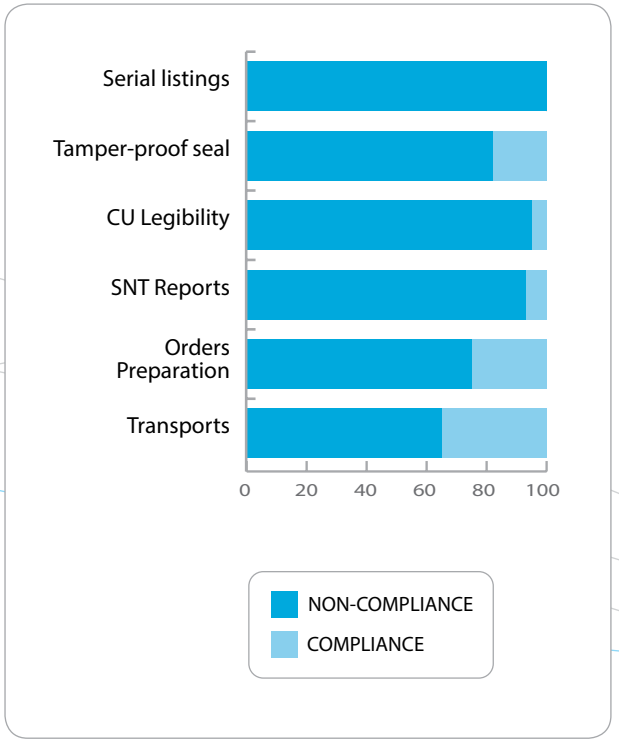


admission of patients the information is digitalized to record it in the Electronic Medical History. At the same time the medical prescription is validated according to requirements of the Health Superintendence (S.U.R) to manage the delivery of the medication. At Helios Pharma the good practices manuals for drug traceability were implemented developing the following items:
En Helios Pharma se implementaron los manuales de buenas prácticas en trazabilidad de medicamentos desarrollando los siguientes ítems:

- Master Data listings
- Unambiguous identifications
- Continuous monitoring
- Internal Audits
- Requests and replies of traceability reports among trade partners
- Implementation of risk crisis
- Logistics recall and market recall
- Personnel training
- Internal electronic dispatch order

At the same time we notified some "non compliances" that involved some trade partners to achieve the certification, obtaining a change and good results benefiting both parties. In the graphic of *figure 1* some of the results are detailed:

Figure 1



Commitment, working with GS1

At Helios Pharma's Pharmacy all processes previously developed by our system were validated, at the same time the identification of logistic units (SSCC) was implemented for each treatment, allowing the compliance with the patient's five right steps (patient, drug, doses, route and right time)

At Helios Pharma Drug Store besides validating the procedures that were being implemented in the good practices manuals, it was also developed:

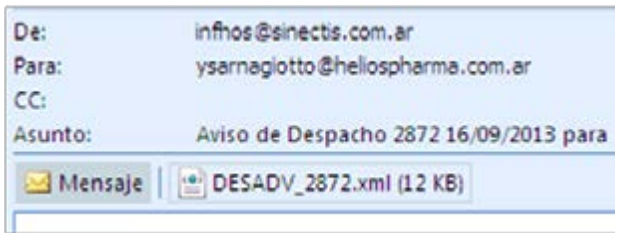
- **Unambiguous identification of logistic units (SSCC)**
- **Dispatch notice (filed in XML)**

Both tools can be used by our customers as an Electronic Dispatch Order since they contain the shipping data, optimizing the entry of merchandise.

SSCC: structured according to GS1 regulations

Unambiguous identification of the shipping, and can be used to enter into our web form, and it will automatically enter all drugs contained in that package; this way the input is more efficient and safe.

Dispatch notice:



The dispatch notice is an XML file sent to the client (Pharmacy) via mail, which has all shipping data. This file is structured according to GS1 regulations and can be processed as an Electronic Dispatch Order, streamlining drug reception.

Insight of the future, TODAY:

GS1 Certification helped standardize processes in a global way, earning the trust of our trade partners, positioning the company in a level of excellence, guaranteeing quality thorough traceability implementation.

This way we become the First Institution, Drug Store and Pharmacy in certifying standards with GS1 Argentina.

About Helios Salud: *it is an Infectious Disease Medical Center specialized in VIH, chronic hepatitis, among others, with services in the whole country. It has a team of highly qualified medical professionals trained by Daniel Stamboulian MD, who work in an interdisciplinary way to provide excellent, immediate and personalized care, supported by modern technology in all its areas. The service, training and investigation are essential pillars of our organization, because we think that it is the best way to reach our patients with task efficiency and care in the established human relations. We have a broad network of providers with doctors who are referents in the whole country, with an extensive experience in our specialty. At the same time, we maintain constant relationships with centers and specialists abroad.*

About Helios Pharma: *We are a Drug Store and Pharmacy that complies with the regulations and provisions in force in all the steps of the marketing chain. We guarantee drug reliability through our system, transmitting online all data to ANMAT, providing the patient the delivery of a safe drug and providing distribution in the whole country.*

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Experience in traceability of essential drugs in the public sector

ABSTRACT

The Remediar Program *begins in Argentina in 2002 in the framework of a crisis which our country experienced, as a national sanitary policy which intended to guarantee drug access to the most vulnerable population. The results obtained regarding drug access, supported by a new logistic system for the public sector for quality and reach, since 2009 it was possible for Remediar to become a logistics' operator of Programs and Directives of the National Ministry of Health which provide drugs and medical supplies.*
ANMAT's provision related to the drug Traceability System is a great challenge for the public sector as a whole. In this article we intend to detail the work from Remediar and the adaptation of its processes to comply with the regulation in force and to extend drug traceability until it reaches the patient in the public system sector.

By Mauricio Monsalvo

The *National Drug Policy* arises as one of the decisions that enabled to face the social and institutional crisis that took place in Argentina at the end of 2001. Its primary objective was to promote equity and to guarantee drug access to the population with exclusively public health coverage, integrating as central components the *Ley de Promoción de la Utilización de Medicamentos por nombre Genérico* [Law of Promotion of Drug Use by Generic Drug] and the free supply of essential drugs to the First Level of Care (PNA) through the Programa Remediar.

Remediar was designed with the purpose of encouraging long lasting reforms in the public health system, prioritizing the strategy of Primary Healthcare (APS). After 11 years of history, it proved to be an efficient policy that guarantees Argentineans access to drugs and contributes to ensure the population the right to health from the strengthening of the resolution capacity of the provincial public systems and the financing of a social good and of high redistributed impact like drugs.

From its beginning, Remediar has reached monthly directly and uninterruptedly more than 7,000 Primary Healthcare Centers (CAPS) distributed in the whole country, with first-aid kits with a vademecum of essential drugs responding to the 80% of the consultations of first care level, guaranteeing the coverage for more than 15 million users of the public health system. Free drug supply represented a financing modality which enabled a wider, more equitable and focalized access for the population in need. Its implementation required transparent mechanisms of negotiation between the health system and drug suppliers, Remediar became the most important program for drug purchasing and distribution of Latin America.

Remediar first-aid kits have a list of 54 essential drugs which were originally consented between the National Ministry of Health and the total of the argentine provinces. Drugs reach the pharmacy of the CAPS directly, without stopping at provincial or municipal intermediate warehouses.

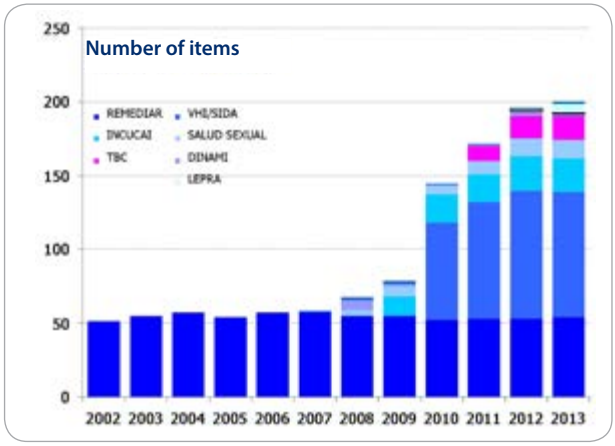
With the purpose of guaranteeing the transparency and the competence, the Program performs public tenders for the purchase of the drugs it distributes. This way, at the instance of the preparation of bidding documents a series of technical requirements are established which enable us to guarantee product quality from the

purchase selection stage to the delivery of the first-aid kits in the CAPS and to the posterior dispensation of the pharmacological treatment.
Its design contemplates the outsourcing of storage, production and distribution processes in two private logistic operators, authorized by the National Administration of Drugs, Foods and Medical Technology of Argentina (ANMAT), who become the executers of the public tender.

The drugs have their own package, requested to the suppliers in the bidding document. This way, the packages present secondary packaging colors chosen according to the anatomical groups over which they act and from the Anatomic Therapeutic Chemical Classification (ATC). Twelve different colors are used which facilitate the drug organization in the pharmacy at the CAPS. The quantity of primary units per package is defined for each product in accordance with the official therapeutic guides or schedules, in order to adjust the size of the packages to the recommended treatments, thus promoting the rational drug use and avoiding the unnecessary expenditure of financial resources. On the other hand, secondary packages have a data carrier of public domain DATAMATRIX ECC200 (data codification 2D), which indicates the GTIN, lot, expiration date, Remediar product code and, when applicable, the unambiguous serial. Moreover, the expiration date is expressed in format "MM-YY" for an easier identification.

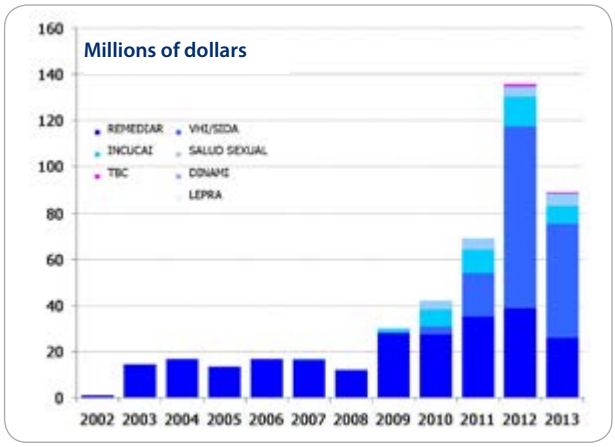
From 2009 Remediar became the Logistic Operator of the Programs and Directives of the National Ministry of Health which provides drugs and medical supplies due to the experience and good results achieved in relation to the logistic distribution. Figures 1 and 2, shown below, demonstrate the volume growth of the distribution incorporated by the Program in the last years.

Figure 1: *Progress of units distributed by Remediar according to the Program.*



Source: Created by the author

Figure 2: *Progress of Remediar transfers. In millions of dollars..*



Source: Created by the author

Traceability is a tool that enables the registration, the knowledge and the verification of the origin and the final destination of the drugs, and their movements and transfers along the whole distribution chain. Therefore, a drug traceability system enables to guarantee their control and contributes to eradicate the circulation of those which are illegitimate. From the beginning, Remediar understood the importance of having a drug traceability system which purchases and distributes, from its own information system which enables a follow up of the product at lot level from its reception until it reaches the CAPS.

ANMAT's provision 3683/2011 related to the drug Traceability System which intends to professionalize the processes involved in the drug supply chain cycle, implies an important challenge for the actors of the public health sub-sector. Facing this challenge the National Ministry of Health in general and Remediar in particular, are working to adapt their processes, to fully comply with the regulation and to extend it to the patient's delivery in the area of the public health system.

In relation to the improvement of the processes in the central level, the Program is executing a plan of technology incorporation in the drugs' warehouses and a quality certification plan (ISO 9001) for critical processes. On the other hand, it is in its implementation phase the exchange of electronic information with suppliers for the improvement of drug reception processes.

Moreover, with the purpose of consolidating a federal drug supply network in the public area, Remediar started the survey of approximately 60, provincial regional and municipal warehouses. The objective of this survey is to identify the breeches in the current state of affairs in relation to the compliance requirements of the Good Distribution Practices, Storage and Transport established by ANMAT and to finance the necessary investments in furniture and basic equipment. From data collectors to racks, including signs, refrigerators, generator units and pallet transporting equipment are included in the investments. These investments are complemented with a wide training program for administrators in subjects such as traceability, good practices, pharmaceutical services and purchase planning. From 2014, hospital pharmacies will be included also in the investment plans, due to the strategic role they occupy in the distribution chain of high cost drugs and basically of hospital use.

In order to move forward in the digitalization of the dispensation in healthcare centers to guarantee traceability until it reaches the patient, it implies the performance of a series of previous actions. Healthcare services in Argentina are decentralized (in provinces and/or municipalities according to the case), and the majority already have their own computer systems. The challenge is basically not to duplicate efforts and to guarantee the flow of information from the sanitary units to the central level.

Remediar has considered incorporating to the digital pattern of transmitting information more than 1,000 healthcare centers in the next two years. Therefore, it has been performing surveys in the field to have a proper diagnosis in relation to the main characteristics which the healthcare centers present mainly in terms of availability of physical space for the delivery of drugs, furniture, and computer equipment. The National Ministry of Health's investment in regard to furniture (mainly furniture for the drugs storage and work tables) and computer equipment (computers and data optical scanners) with information systems which store data of dispensed drugs and patients, will enable to guarantee the compliance of the traceability circuit and to have improved and more information available for decision making.

ABOUT THE AUTHOR

Mauricio Monsalvo

He graduated in Political Science at the University of Morón. He has a Master's degree in Social Research Methodology of the Universitá di Bologna/National University of Tres de Febrero (without a thesis) and a Master's degree in Epidemiology Public Health at the Oswaldo Cruz Foundation (Fiocruz/ANLIS), with approved thesis.

Currently he works in the Coordination of the Programa Remediar of the Ministry of Health, in which he participates since 2002.

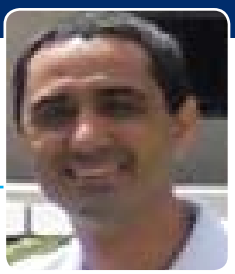
At academic level he works as a professor at the University Institute ISALUD, at the Master's course in Administration of Mental Health Services; at the University Favaloro, at the Master's course in Management and Administration of Health Systems and Services; and at the course of Political Science at the University of Morón. Additionally, he has given courses about Statistics in the Health Sector at the Latin-American University of Social Sciences (FLACSO) and in the Master's course in Health and Drugs' Economics of the University Pompeu Fabra.

He has participated as assistant in different research projects and in publications, mainly related to the health area in general and the use of drugs in particular.

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

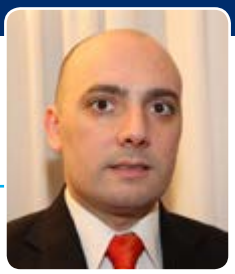
Mariano Hernández
Operational Excellence Champion, Pharma Division at Phoenix Laboratories (a company of the GSK Group).
Mariano Hernández has extensive experience in project's implementation and as work team leader. He has more than 18 years' experience in Production, Quality, local and regional Projects, 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.

Coming up

Traceability of surgical instruments in Argentina

ABSTRACT

Currently, all surgical instrument of this company are traced with the GS1 Standard Datamatrix which carries a GTIN and a Serial Number, allowing each unit to be unique. The individual identification of the instruments gives legitimacy to the products, fights counterfeiting, brings more safety to the processes in the supply chain and enables management of instruments inside sterilization areas in healthcare centers. FAICO is the first argentine company of surgical instruments that incorporates traceability in all its products with the premise of enhancing and optimizing clinical safety for the patients.



By Hernán Fernández

Instrumental Quirúrgico FAICO S.A.I.C. is a company which main activity is the manufacturing and marketing of surgical instruments. With more than 68 years in the local and international market, the company has earned a reputation based on its fair treatment, integrity and trust. Currently, the commitment for the constant added value to its products and the continuous improvement of its services, has made the company consider and develop tools for a proper management of the surgical instrumental inside healthcare centers.

During the last year, FAICO began to work in traceability of surgical instruments using the identification and codification of all its products, using global standards defined by GS1. At present, the extensive quantity of units marketed lacks a standardized identification, their characteristics are only displayed on the primary package label, which is discarded when the product is used. The intensive dynamic that exists inside the different healthcare centers needs special attention, even more in those surgical instruments where the investment is important and requires an effective and safe administration.

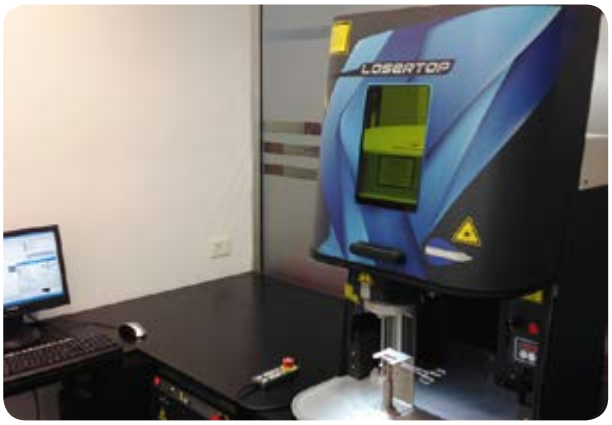
The technological advances and experiences achieved in other industries, enable us to solve the above mentioned difficulties, offering a new range of possible services and solutions.

National and international health-control agencies adapt and improve health procedures as a consequence of the global increase of surgical practices, with the objective of protecting and offering more safety to patients, in addition to detecting defective products and recalling them quickly from the market.

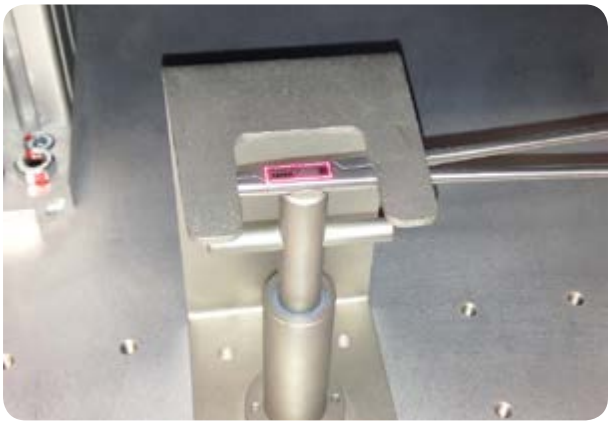
Traceability is the ability to trace forward the movement along the different steps in the extended supply chain, and to trace backwards the history, the application or the localization which is being considered.[1]

In order to implement a proper and possible traceability of any product it is important to have a global standardization which provides a unique identification to all of them. Standardized identification enables the development of a management service within healthcare centers which in Argentina, until now, was something unknown or to which we had no access to.

1) Source: Global Traceability Standard in the Healthcare Sector (GTSH)



Engraving area



Engraving Laser

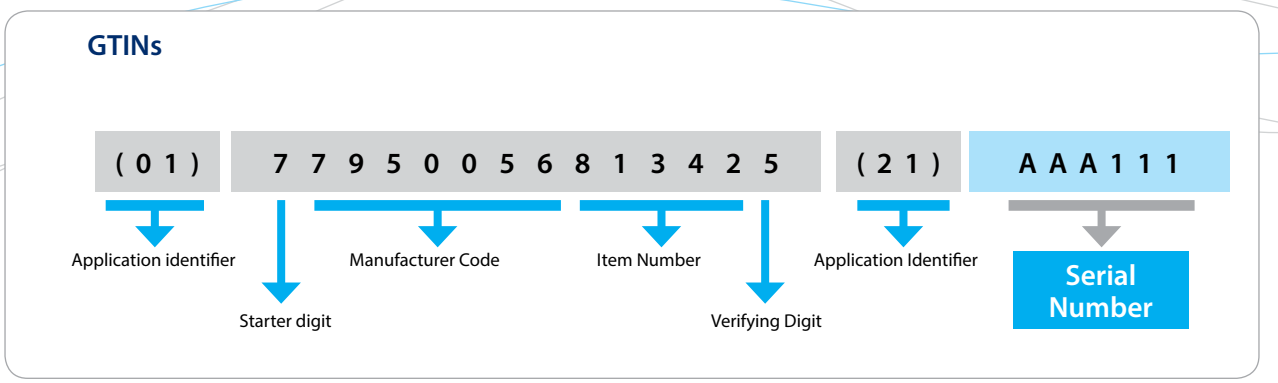
FAICO has ordered that all its products shall be identified with a bi-dimensional code GS1 Datamatrix. The necessary printing area for this code is only of 6 mm2 in each unit approximately. In this way, the engraving of virtually the whole universe of surgical instruments is possible, which are read with a bi-dimensional code scanner. Each Datamatrix identifies the surgical instrument with the following data, of which some are defined and standardized by GS1 and others by the company using specially developed software for this process:

1. **Application identifier (01):** corresponds to the Global Trade Identification Number (GTIN). GTIN or Global Trade Identification Number: it is the numeric structure that identifies the instrumental. In its structure we can find the identification code of the country where the code was defined (779 in Argentina), the identification code of the manufacturing company and the generic identification of the product. Lastly a verifying digit.
2. **Application Identifier (21):** indicates that the next data to be read correspond to a Serial Number, and indicates to the systems the extension of the code (up to 20 characters) and the data format (alphanumeric of variable extension).
3. **Serial number:** FAICO designates a unique and exclusive identification number to each product.

In order to reach an optimal engraving of the GS1 Datamatrix code, the company implemented a review and an adjustment of every productive and administrative process, and also incorporated new latest-generation technologies, developing an internal management software that manages from the different manufacturing processes up to the final deliveries to the customers, assigning to each surgical instrument an alphanumeric serial code. In order to initiate this process it was essential to purchase engraving laser machines developed with advanced techniques.

The engraving was made with the standardization GS1 Datamatrix, it is worth mentioning that the usefulness granted to the engraving and its complementation with a software that is being developed by FAICO to be installed in healthcare centers that wish to have a management system for surgical instruments.

As we can identify them individually, the management system of surgical instruments can record every one of the stages or processes in which each piece is involved.



Now let's see, which are the main advantages obtained from the management system of surgical instruments:

- ***Estimation of useful life of surgical instruments:*** early detection of useful life of surgical instruments is essential for a quick action and patient safety. In order to precise the antiquity of the instrument and make the right decision about the possibility of disposing of it, we will only need to read the GS1 Datamatrix code in which we will be able to access a database and obtain the accurate date in which it came into use. Due to its frequent use, many instruments need to be repaired or disposed of when they can no longer fulfill the purpose of their creation. The traceability of surgical instruments enables us to know the costs paid for the maintenance of an instrument during all its useful life, and even make the right decision regarding keeping it or not in stock.
- ***Loss and/or theft of surgical instruments:*** one of the problems discovered in many healthcare centers which are easy to solve with the implementation of this management system, are due to theft or loss. Other times they result from outsourcing and/or lack of control in sterilization areas. For this reason, the management of recalled or received products is tedious or cumbersome without a specific tool for that end.
- ***Sterilization Follow up processes:*** maybe one of the most important advances of the implementation of this tool is the control of the sterilization processes, which enables us to know who, what, and how is been done.
- ***Quick and accurate set up of surgical sets:*** through automatic reading of each surgical instrument: the setting up of the different specialization sets is quickly achieved, avoiding errors or problems that arise when the elements from a specific composition are missing for each set. This facilitates the quick replacement and availability for its use.
- ***Control of instruments before and after surgical operation:*** to read directly in the surgery room all the pieces placed on the instrumental table has the purpose of controlling that they are all returned once the operation is completed.
- ***To keep the stock updated:*** instruments engraved with GS1 Datamatrix together with the management software enables us to register, deregister and record any movement made.

Manufacturing companies and official control agencies are who assume the main responsibility when working together in the development of tools, procedures, and regulations to improve and optimize clinical safety of the patients, incorporating useful techniques for the traceability of products and medical devices. FAICO is not unaware of this situation nor has it been in all its company life, has even acknowledged the need to work intensely to offer to the health system the development of an innovating management system of surgical instruments.

Engraved instruments

ABOUT THE AUTHOR

Hernán D. Fernández, *Surgical Instruments' Director FAICO S.A.I.C.*
He was born in 1976. Hernán obtained his degree in International Commerce in the Facultad John F. Kennedy. He started working for FAICO in 2009 and has more than 10 years of experience in executive positions in international companies. Currently, he leads the incorporations' project of new technologies for the traceability of medical products that the company manufactures and commercializes.

Annex
Resolutions and Provisions

"2013 - Año del Bicentenario de la Asamblea General Constituyente de 1813"

Ministerio de Salud
Secretaría de Políticas,
Regulación e Institutos
A.N.M.A.T.

DISPOSICIÓN Nº 0247

BUENOS AIRES, 15 de ENE 2013 de 2013.

VISTO la Ley Nº 16.463, los Decretos Nº 150/92 y sus modificatorios y complementarios, Nº 1490/92 y Nº 1299/97, las Resoluciones (ex MSyAS) Nº 538/98 y (M.S.) Nº 435/2011, y las Disposiciones ANMAT Nº 7439/99, Nº 3475/05, Nº 3683/11 y Nº 1831/2012; y

In order to see the Resolutions/Provisions clic on their name.

2011 **Resolution 435/2011**
Ministry of Health
MEDICAL SPECIALTIES
http://www.gs1.org.ar/documentos/DisposicionANMAT/resoluciones/Resolucion_435-2011.pdf

2011 **2011Provision 3683/2011**
National Administration of Drugs, Foods and Medical Devices of Argentina
MEDICAL SPECIALITIES
http://www.gs1.org.ar/documentos/DisposicionANMAT/resoluciones/Disposicion_3683-2011.pdf

2012 **Provision 1831/2012**
Ministry of Health, Politics Department, Regulation and Institutes
ANMAT
http://www.gs1.org.ar/documentos/DisposicionANMAT/resoluciones/Disposicion_1831-2012.pdf

2013 **Provision 247/2013**
Ministry of Health, Politics Department, Regulation and Institutes
ANMAT
http://www.gs1.org.ar/documentos/DisposicionANMAT/resoluciones/Disposicion_247-2013.pdf

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