Roche Argentina: Fighting counterfeit medicines using a traceability system based on GS1 Standards

ABSTRACT

In order to fight the proliferation of counterfeit medicines, Roche Argentina implemented a traceability system in March 2010. The system, based on GS1 Standards, allows the identification of the destination of each unit, and does likewise for the whole distribution chain. Moreover, the patient can validate the legitimacy of the medicine before consuming it (i.e. that the medicine has been released to the market by the corresponding manufacturer and does not have any reported adverse event).

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The problem: Counterfeit medicines

Counterfeit medicines are those deliberately and fraudulently processed so that they do not reflect their real content or real source (WHO). Counterfeit medicines comprehend:

- Absence of Active Ingredient
- Different Active Ingredient from the declared one
- Different quantity of Active Ingredient declared
- Counterfeiting of packaging
- Adulteration of packaging
- Inappropriate storage conditions for the product (e.g. in the case of stolen or smuggled medicines)

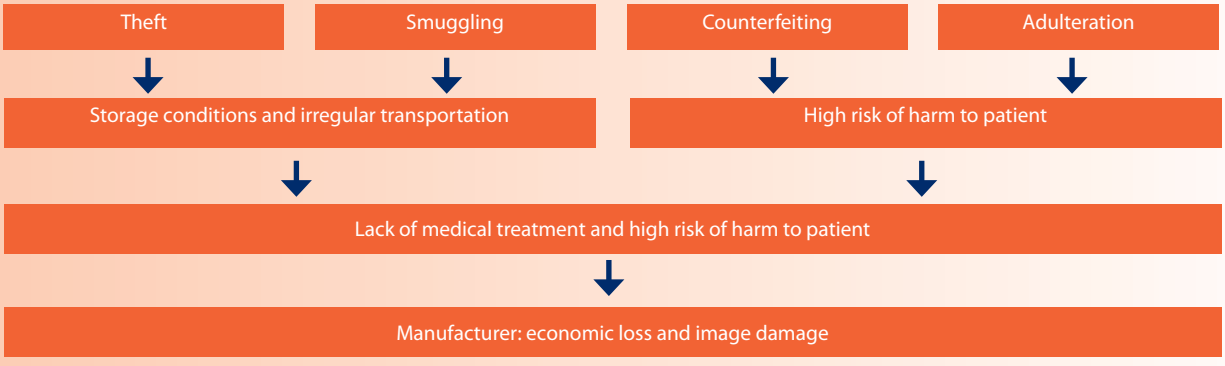
Figure 1 reflects the consequences caused by counterfeit medicines.

Currently, there is a local trend for counterfeiters to focus on high cost medicines due to:

- Management of reduced volumes which imply high profits
- Low investment is required
- Easiness to hide

The consequences from consumption of counterfeit medicines vary from a lack of therapeutic action to more considerable damage, which may include the risk of death. Most of these medicines are for Oncology treatment, and in many cases provide the only chance of life expectancy to these patients with this serious pathology.

Figure 1: **Counterfeit Medicines**



Project objectives

This situation led to the design of a process, which allows the verification of the source of the product before its consumption, avoiding the proliferation of counterfeit medicines, and in case a counterfeit one is found, it contributes to its clear identification.

For such reason, the traceability system has been implemented. It means that each product unit is uniquely identified, in order to track it in the value chain.

Application environment

At the beginning of the project, the first step was to investigate the local and global records on medicine traceability, and these were the findings:

Previous experiences

The existing traceability cases showed:

- In Argentina: important wholesalers who commercialise products for special treatments (Oncology, Aids, Arthritis, etc.) have implemented traceability, but with proprietary coding and identification, not compatible with each other.
- Latin America: implementation of proprietary coding and identification systems at manufacturers was noticed in some countries.
- Experiences in the world: only pilot experiences existed with different identification technologies (RFID and GS1 DataMatrix).

Market standard

- In Argentina: absence of national legislation and existence of traceability systems implemented by wholesalers without a coding, identification or communications standard.
- In the World: in some countries, regulations are very ambiguous, and did not detail neither coding nor technology for code carrier.

Distribution chain

Figure 2 shows a basic diagram of commercialisation of these types of product in Argentina. There are transactions among wholesalers (Step 2).

The absence of legislation that demands the distribution chain to trace units is the obstacle to implementation of steps 2 and 3.

Figure 2: **Distribution Chain**

ABOUT ROCHE

Headquartered in Basel, Switzerland, Roche is a leader in research-focused Healthcare with combined strengths in pharmaceuticals and diagnostics. Roche is the world's largest biotech company with truly differentiated medicines in oncology, virology, inflammation, metabolism and CNS.

Roche is also the world leader in in-vitro diagnostics, tissue-based cancer diagnostics and a pioneer in diabetes management. Roche's personalised Healthcare strategy aims at providing medicines and diagnostic tools that enable tangible improvements in patients health and quality of life. Roche has over 80,000 employees worldwide and holds several R&D cooperation agreements and alliances.

Logistics

Many of the medicines, which have suffered illicit events, are imported as finished products. Roche's production plants for these types of product are few, specialised and are high volume and highly automated lines. The implementation of identification and traceability at source only for Argentina (GS1 DataMatrix or RFID printing devices) is complex.

Roche, as well as more than 70% of the local pharmaceutical industry, have an internal logistics diagram, which includes three actors, as shown in Figure 3, where the main actors are:

- **Manufacturer:** product owner and responsible to authorities.
- **Distributor:** responsible for manufacturer inventory safekeeping. Manages orders, invoices on behalf of the manufacturer, and in some cases, collects payments. Most distributors delegate the warehouse management, picking, packing and transport to a logistics operator.
- **Logistics Operator:** manages warehouses, picking, packing and transport.

Developed solution

The solution was developed and implemented with the following characteristics:

Market scope

Due to the absence of national legislation, and taking into account the impossibility to have an influence on the whole distribution chain, the implementation was done in steps.

- **Step 1:** Recording sales transactions from the manufacturer to the first connecting link of the distribution chain (Step 1, in Figure 2). Additionally the patient can verify if the product contains a valid serial number from the manufacturer, or identify any events that could harm its quality (Step 4, Figure 2).
- **Step 2:** a data processing solution is implemented for the distribution chain that allows them to obtain traceability, with integration to the system of the laboratories.

Coding and data carriers

Considering the pilot tests already taking place in the world, the use of GS1 Standards was defined for coding and data carriers. This will probably facilitate the adoption of this solution or similar ones using standards, both for the market and for national regulators.

The data carrier is the means that will contain the traceability data. Considering the available technologies (GS1 DataBar, GS1-128, GS1 DataMatrix and RFID) we adopted GS1-128 for the following reasons:

- It is a technology used by all Wholesalers and Pharmacies, which means fewer barriers for the implementation of traceability in the Distribution Chain.
- Traceability solutions currently implemented by local Wholesalers are based on this technology.
- As most products, vulnerable to counterfeiting in the Argentine market, are imported as finished products, and considering that the production plants do not have the infrastructure to handle GS1 DataMatrix and/or RFID, this technology allows us to add a high security tag on finished products, with very low complexity.

Taking into account that this is the oldest technology, from the ones mentioned, and it is believed not to be the most efficient in operative terms for large volumes, a second step will be the migration of the carrier to one of the other technologies available.

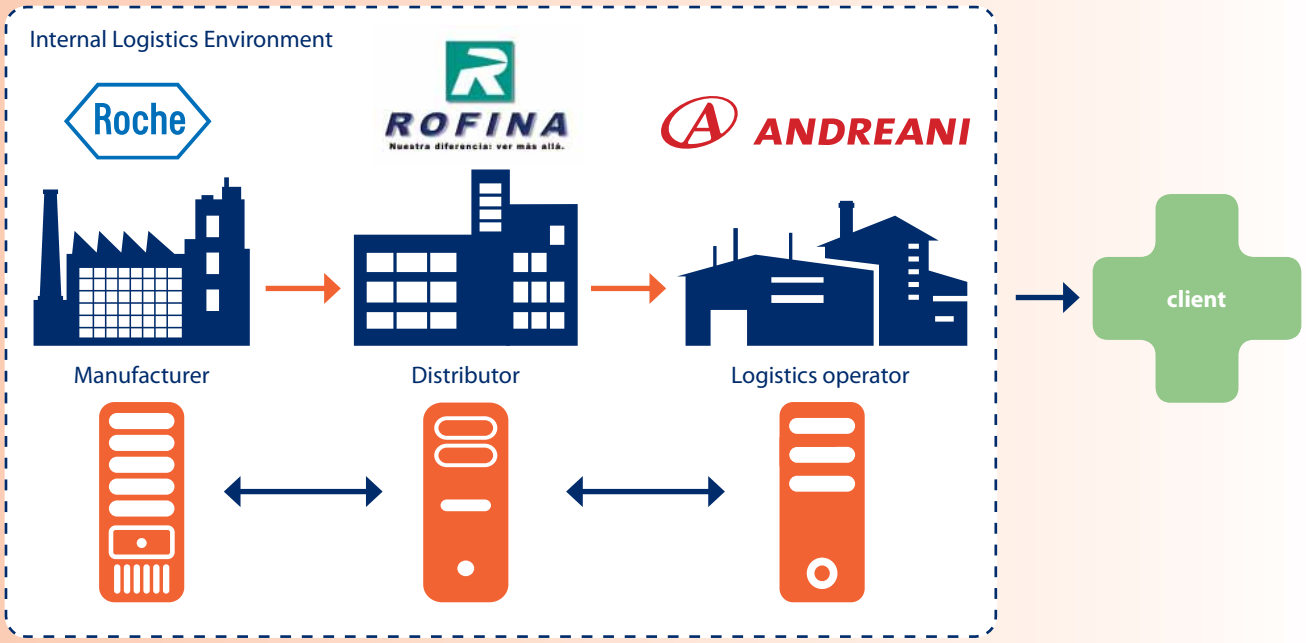
Figure 6 shows the tag, which contains the following information:

- GTIN
- Serial number (8)
- Hidden code for validation (scratch-off). This is an additional safety measure to the GS1 Standard, and it is not found in the GS1-128 code, only in Arabic numerals.

The tag contains the following safety measures:

- Logical Measures of Safety
  - Random 8 digit serial number (100 million combinations for each GTIN)
  - Random 6 digit alphanumeric 'scratch-off' code (more than 2 billion combinations for each GTIN)

Figure 3: **Logistics**



The three actors have independent data processing platforms, which are linked by interfaces that synchronise the information (Inventories, Sales, Accounts Receivable, etc.). Nobody was, at the time of implementation, prepared to handle traceability by unit.

- Physical Measures of Safety in the tag:
  – Destroyable tag when taken off, leaving proof on the container
  – Visible safety measures for the user (micro texts, special inks containing cholesterine, scratch-off, etc.)
  – Safety measures to be verified only by the Manufacturer (UV inks, hidden codes, etc.)

Characteristics of the system

Functions of the system:

Its functions are (Figure 5):

- **Identification:** allows the identification of each unit with a unique serial number. The system generates random unrepeated serial numbers. The products are identified and a relation between serial number and batch is made. It also allows the addition of serial numbers (group of serial numbers in one tag, for example for managing pallets).
- **Traceability:** this module is responsible of managing the serial numbers in the inventory, permitting:
  – Entry of serial numbers, transfers among actors (manufacturer, distributor and logistics operator)
  – Control and adjustments of serial numbers in warehouse
  – Registration of sales transactions (sales and returns)
- **Validation:** informs both the distribution chain and the patient of the status to commercialise or consume a serial numbered item. Consults and validations may be done on the web or by telephone to a toll free number. In the future, the validation will be able to be done by text messaging through mobile phones.

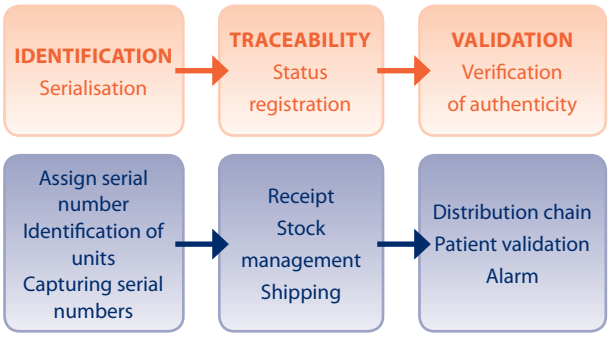
It also generates different types of alert, for example if more than one patient validates a serial number.

Serial number: Status diagram

The serial numbers may have various functions in the system. Each status limits the type of transaction that may be done with it.

Figure 6 shows the status generated by each transaction in a normal sales flow. At the lower part, it also shows the permitted transaction for each status.

Figure 5: **Traceability systems, Main fonctions**



How information is shared

Due to the fact that none of the actors of the internal logistics environment (manufacturer, distributor and logistics operator) have a traceability system implemented, the implementation of a unique and external system was defined, which everyone can access and operate (Figure 7). The advantages are:

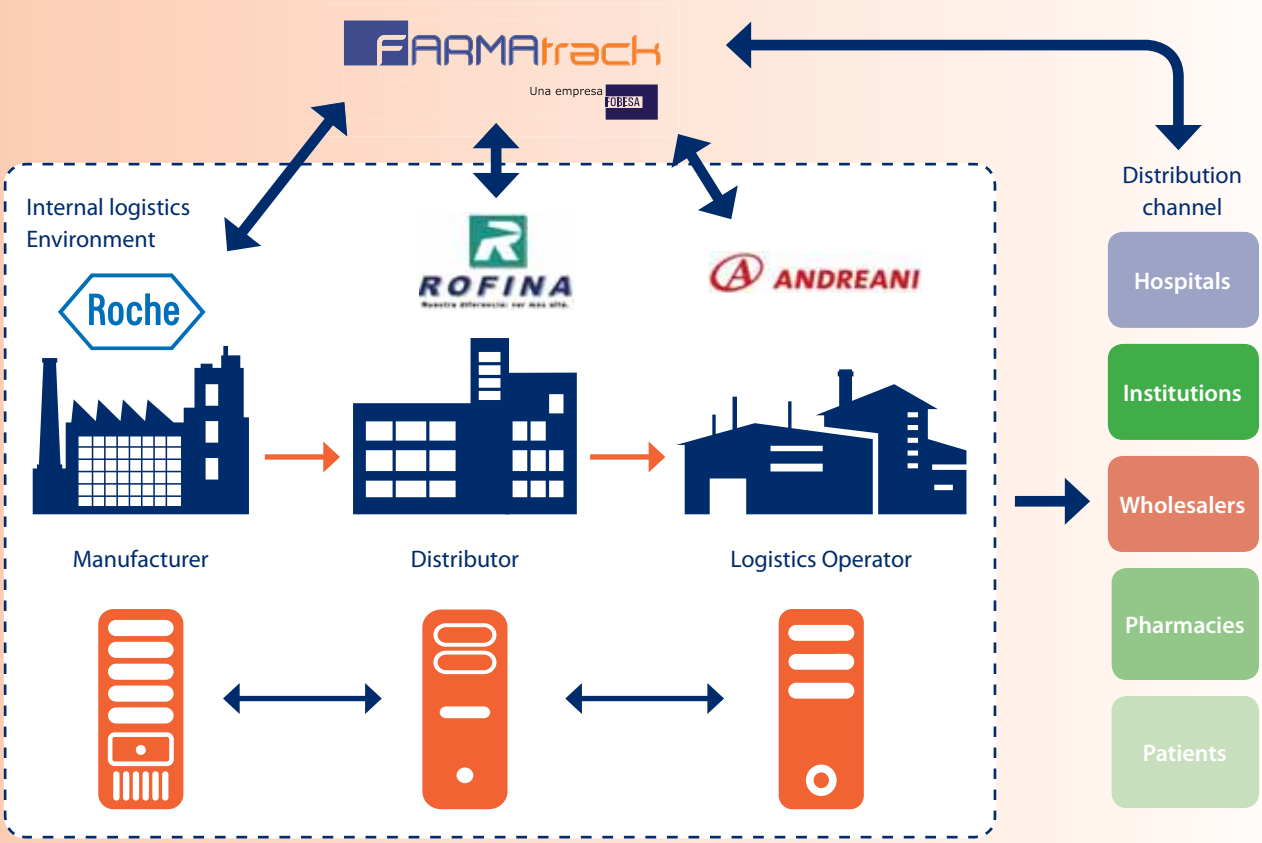
- Less interfaces between the systems of the actors, decreasing complexity.
- On-line updating of the serial number status due to the fact that there are no interfaces between systems.

Figure 6: **Serial Number Conditions**

Usual transaction in a sale flow

	SERIAL NUMBER GENERATION	TAG PRINTING	PRODUCT TAGGING	PRODUCT SALE TO CLIENT	VALIDATION BY PATIENT
Generated status	Generated	Entered	Assigned	Sold	Validated
Permitted transaction per status					
Sell from manufacturer	✗	✗	✓	✗	✗
Commercialize in the market	✗	✗	✗	✓	✗
Patient usage	✗	✗	✗	✓	✗

Figure 7: **Internal logistics and distribution channels**



- Unique and centralised information: everyone accesses the same information at the same time.
- Increased safety: considering that the serial numbers are random, and the fact that the serial numbers are found in a unique data repository, decreases the possibility of information extraction.
- In step 2, when the distribution channel is included, the communication will be permitted instantly.

The system is on the web and may be accessed through any Internet connection.

System development and operation diagram

It was decided that the system should be developed by a technology provider with experience in traceability, Farmatrack, from the Fobesa Group was chosen.

In order to have continuous improvements and updates, it was decided to choose the developer for the operation and maintenance of the system; who will provide the traceability service.

Therefore, the Farmatrack System has the following characteristics:

- Investment on development, hardware and communication is done by the provider
- Responsibility for the systems hosting
- Service based on a fee for each serial number used by manufacturer
- The service can be provided to other manufacturers, distributors, logistics operators, wholesalers and pharmacies.

The adoption of this tool, by other manufacturers and other actors of the distribution chain, is a key factor for the long-term sustainability of the project, due to the fact that the bases are established to:

- Contribute to establish a standard for the local market.
- Increase dissemination and knowledge about the tool.
- Incentive for use, so Healthcare professionals and patients become used to validating the products before providing or consuming them.

Implementation

Impact on the operation

Identification

The impact on the identification of the product is summarised in the following:

- Cost of tags
- Operation of tags

Warehouses
It must be guaranteed that all products leave the warehouse are scanned [read], without crossing units (serial numbers) among orders.

During the dispatch process, the serial number reading takes place at the moment of packing, which guarantees that the serial numbers packed are exactly the ones read. The system controls the consistency of batches and quantities of each order, making possible the dispatch of the order only if it is complete and coincides with what is required.

Traceability has an impact on the logistics operation when time is added for picking and inventory management, which is translated into costs.

Validation
The validation on the web has no cost; while through the contact centre there are communication (free call) and operation costs for the contact centre.

Product selection, sequencing and batch considerations

The products traced were chosen in relation to the risk of being counterfeited. Products that have been counterfeited the most were chosen as the highest risk, considering their sales volume and billing amounts.

Based on these variables, SKUs were taken as a priority and were included in an implementation chronogram, incorporating a new SKU every 15 days.

The criteria is tracing only complete batches (not partial ones). Once the SKU begins to be traced, all future batches will be traced.

We have already traced all the products that had suffered adulteration, plus some that were likely of suffering it, with a total of 12 SKUs, which represent more than 80% of the local pharmaceutical sales.

Communication plan

Dissemination is a key factor for success. We have designed a communication plan with the objective of communicating about the new system and motivating patients and health professionals to use it.

The plan, developed in 2010, had various actions targeted inside and outside the company.

Expected benefits

For the patient and the society:

- Product legitimacy validation prior to consumption
- Lower risk of harm from the use of counterfeit medicines
- Access to expected therapy

For the manufacturer:

- Less counterfeit units, which implies:
  - Greater demand for original units, more sales
  - Lower risk of recall
  - Image improvement, if there is more consumption of original units there is provable therapeutic action.
- Recall cost reduction; by identifying only counterfeit units for recall versus the recall of complete batches.

Next steps

Today, two other multinational manufacturers are implementing this solution in Argentina, which will be useful for consolidating the concept in the market. There are two more local companies studying its adoption.

On the other hand, there are several projects, both legislative and from the Argentine Ministry of Health, to regulate and extend the implementation of traceability. The projects are mostly compatible with what we have implemented.

ABOUT THE AUTHOR

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Pablo Grimald is responsible for Sales Administration, Distribution and Demand Planning. He has more than 20 years experience in pharmaceutical market and he has leaded several projects, providing his know-how in projects aimed at harmonizing processes and systems among Latin America Region.

Pablo has a degree as Engineer in Information Systems conferred by National Technological University (UTN), and is MBA graduated from CEMA University (UCEMA), Argentina.