

Traceability on medicines: their implementation in the wholesale distribution

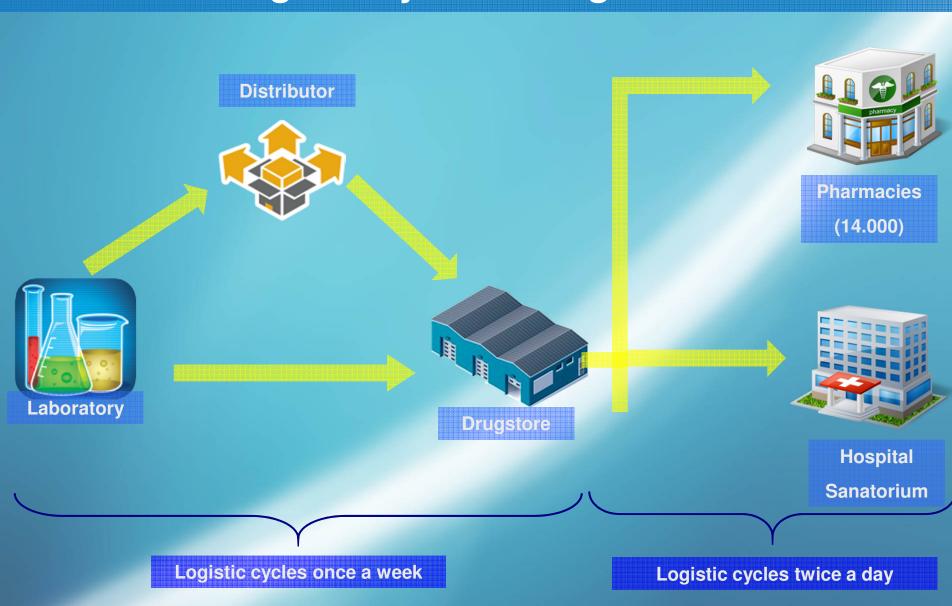
Branches- Suizo Argentina S.A.



- •More than 90 years experience in the distribution of medicines, medical products, cosmetics and foods.
- •12 distribution sites, 900 employees (professionals in different fields, technicians and qualified operators)
- Monthly distribution: 12 million units.



Logistic cycles in Argentina.



Information of logistic cycles in the market

• 25 Drugstores affiliated to ADEM (Association of medicine distributors).



• 60,000 daily orders from pharmacy to drugstore.

• 140,000 square meters of drugstore facilities.

• 50 million units per month.

Automation process

Semi automatized process



Automatizaded process





In order to complete in due time and form the logistic cycle fully described above we work with latest generation technology.

Related regulations

- Drug legislation 16463/64 and decrees 9763/64 and 150/92
- •Decrees1299/97. Regulate medicines in the different stages of the supply chain.
- •Disp. 5037/09 "Good practices in storage, distribution and transportation of medicines".
- •Traceability 435/11. Objective: avoid the illegal circulation of medical products.
- Disp.3683/11. Set up 88 IFA'S (Active ingredients) and establishes an implementation schedule in the supply chain: Laboratory drugstore pharmacy.
- •Disp. 1831/12. Set up 226 IFA'S and establishes the use of an univocal code.
- Disp. 247/13. Set up 11 IFA'S psychotropic substances.

Traceability figures

IMPLEMENTATION DATE	REGULATION NUMBER	POSSIBLY TRACEABLE		ALREADY TRACED		CALCULATION ACCORDING TO A MONTHLY SALE BASE			
								%	
		UNITS	SKU	UNITS	SKU	UNITS	TOTAL SKU	TRACEABLE	% TRACED
Dicember/2011	3683	3.129	176	3.129	176	10.213.000	12.590	0,03%	0,03%
April/2012	1831	730.733	1.772	118.962	462	10.213.000	12.590	7,15%	1,16%
June/2013	247	445.785	375			10.213.000	12.590	4,36%	0,00%
	Total	1.179.647	2.323	122.091	638	10.213.000	12.590	11,55%	1,20%

Sale base Suizo Argentina S.A. January 2013

Problems caused by:

Lack of standarization.



Lack of implementation of technology which allows massive readings.

1.Multiple technologies AIDC (AUTOMATIC IDENTIFICATION DATA CAPTURE)

The coexistence of 3 different types of technology causes delays in the knowledge of information, forcing the next link of the chain to make a higher investments to interpret them.





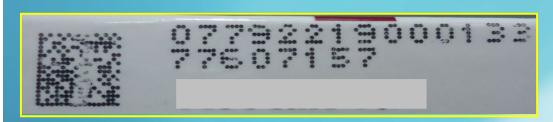




Solution: to define only one kind of technology that allows a massive capture of series, or a combination that may be useful to the rest of the chain (Ideal: Datamatrix and RFID in the same packaging).

2. Difficulty in reading

- Lack of legibility.
- Size of some supports.
- Use of the tracebility support as a safety strip.
- Existence of another support next to the tracebility one.













It prevents the normal automatic capture of the information causing mistakes in the series records and delays in the operative processes, so we must make the entry in manual way.





Solution: to standardize the kind of material, printing quality, size and location of the supports in the packaging, and to establish the obligation of making them valid according to GS1.

3. Possibility of including any kind of information in the supports

Though the standards of traceability specify that out of 4 items of information, 2 are obligatory (GTIN and serie) and 2 optional (batch and expiration date) there are laboratories which include other pieces of information in the support (eg. production date), which makes the other actors of the chain have to modify their systems whenever a new code appears so as to be able to read it.



(01) 07790375002046

LOT: ABWP

ELAB: 29/11/2012 VEN: 28/11/2014



Solution: to allow the agents who started the trace to include only the 4 items specified in the standards and that all of them be obligatory, since the batch and expiration date are demanded by ANMAT in business transactions.

4. Series with alphabetical characters

The incorporation of alphabetical characters both in capital or in small letters causes another problem in the configuration of different technologies for the automatic capture.

> Risperidona 2mg Comp rec x20 Venc:31/10/2014Lote: 102053

(01)7795332021122 (17) 141031 (10) 102053

(21) ww9dvr8m2y





Solution: to standardize either one or the other parameter (capital or small letter).

5. Later reception not serialized

The reception of articles without serializing, after having received an already traced batch generates complication in the storage, since we must separate and identify them to avoid mistakes in the register series.



Solution: once a SKU has been traced, the following deliveries must also be traced.

6. Lack of electronic information

The diversity of active ingredients which were incorporated by the last two provisons include articles of high rotation with large volumes of sales, which makes that the reading of the units individually can cause considerable losses of time during the reception process.



Solution: to have the electronic information of the series to be received incorporating them massively. For this it is obligatory that the previous link transmits the data. (implementation of GS1 health work shop).

7. Lack of standardization packaging

The lack of standardization packaging causes delays in the reception and storage processes, because it is necessary to open the packaging to read the series.







Solution: to standardize the place of the series so that everything all could be seen.

8. Correction of series badly informed

In certain occasions, the series informed in the supplier's invoice does not coincide with the one we received in the secondary package.



Solution: to establish correction mechanisms for a mistake in the delivery checked after the reception, in such a way that the supplier can change the series informed automatically without changing the articles.

Conclusions:

- High level of commitment of government technical staff responsible for the implementation of the project (A.N.M.A.T.).
- High level of commitment of all industry participants (laboratories, distributors, drugstores, pharmacies).
- Financially and logistically very difficult to fulfill as regards to all prescription drugs.
- World-wide unique experience for which there is a lack of massive technology.
- The time-limit for a successful implementation seems to be longer than it appears.

Proposals:

- To continue with pilot experiences in certain high-cost and low turnover IFAs.
- To acquire the necessary experience between public and private participants.
- To expect technical means to continue evolving.
- To accompany these developments with experiencies acquired.

Questions and/or suggestions

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Thank you.

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