Portugal

Minimising the Risk and Reinforcing Patient Safety for Novartis Products

ABSTRACT

In 2010, Novartis Pharma in Portugal developed and implemented a traceability programme using GS1 2D DataMatrix. This programme allows to track the product, from the warehouse to the patient, including all the moves in the hospital from the pharmacy to the operating theatre. It also enables online status checks in the case of an adverse event or any investigations due to quality aspects. The programme is set up to include other products and is being adopted by other countries.

by **Margarida Alves**

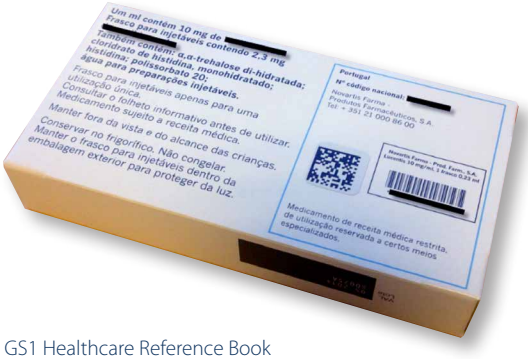
With patient safety as the focus, in 2010 Novartis Portugal developed and implemented a traceability programme for one of its medicines, which is now available in five Portuguese public hospitals. From September to December 2012, around 2000 units of the concerned medicine have been tracked.

What is the programme?

The programme consists of implementing a tracking system based on GS1 2D DataMatrix, which allows registering the course of the medicine from the Novartis warehouse to the hospital where the patient receives treatment, and ultimately to the patient to whom the product is administered. This includes the date and time of each of the various steps.

How does it work?

Pre-printed labels containing a GS1 DataMatrix, including the Global Trade Item Number (GTIN) and a Serial Number, are applied onto the secondary packaging. The inclusion of a serial number allows the individual identification of each pack of product, which can then be linked with the patient to whom the product was given.



When the product leaves Novartis' warehouse, each pack is individually scanned. This step ensures that the unique identifier on the product is registered in a database available to the hospitals.

Front-end hospital

To allow the registration of the course of the product once in the hospital, Novartis has also developed a tracking programme with an access provided to the hospitals who have adopted the tracking system. Due to the great variability of systems used by the different hospitals, easy access was very important. Therefore, a web-based application was designed (www.trace.novartis.com).

Each hospital has an account and as many users as necessary to meet internal dispensing procedures.

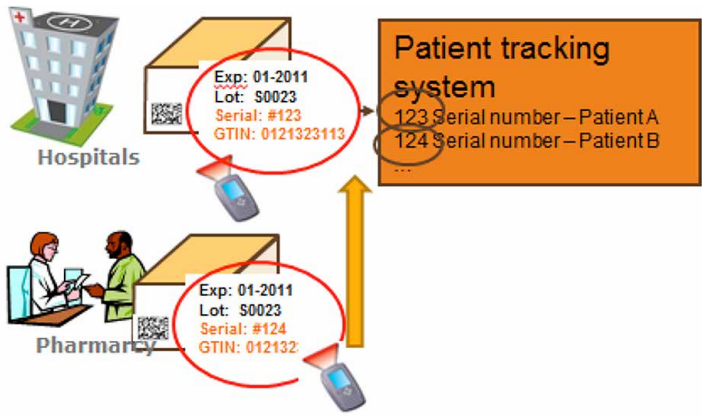
In the hospital, once doctors prescribe the product, the pharmacist scans the packs to be dispensed, and the information is again stored in the same database. Scanning allows confirmation that the product was supplied by Novartis with an online verification of batch and shelf life.

After administration of the product, the patient number is allocated into the database so that the dispensing of each unit to a single patient can be recorded.

This programme allows to perform queries by date of dispensing/scanning, date of treatment, and by patient

number, thus allowing a fast identification of the status of each individual pack if necessary.

Confidentiality



The system is based on an auto-identification solution in which the patient data remains confidential (except to the hospital pharmacist) during the entire process through an encryption system. When the patient number is introduced, it is automatically hashed with an alpha numeric key. Furthermore, patient numbers are different from hospital to hospital, which contributes to the security of the information.

Conclusion

Although the technology is complex, the system itself is very simple to use. The traceability programme is effective and has the advantage of offering a user-friendly and low-maintenance system.

Additionally, it supports the process of dispensing and tracking inside the hospital, from pharmacy to the operating theatre, reducing then the risk of exchanging drugs and supporting the management of stocks. It enables online status check in case of an adverse event or any investigations due to quality aspects, both at the hospital or at Novartis.

The project has great potential and is to be expanded to other products, including into areas where a more restricted control over medication is needed, such as oncology as well as to other countries where it is already under evaluation for adoption.

Fully designed and developed at Novartis Portugal, this programme has anticipated the changes which will be introduced in the European Union following the publication of the EU Directive on Falsified Medicines.

About the author

Margarida Alves *has worked in the pharmaceutical industry since 1990. She started in a Portuguese Animal Health company and joined in 1992 the Health Division of Ciba-Geigy which became Novartis following a merger with Sandoz. She has served as a Logistics Manager and Regulatory Affairs Manager at the company and has been involved in several projects both in Animal Health and Pharma Divisions at Novartis.*

About Novartis

Novartis *provides innovative healthcare solutions that address the evolving needs of patients and societies. Headquartered in Basel, Switzerland, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, eye care, cost-saving generic pharmaceuticals, preventive vaccines and diagnostic tools, over-the-counter and animal health products. Novartis is the only global company with leading positions in these areas. For more information, please visit http://www.novartis.com.*

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