

Brazil

Aché Laboratories successfully implements GS1 standards to ensure traceability

Challenge

With a growing global demand for drug traceability, Laboratories (Aché) needed to implement a traceability system that would help it track and trace its pharmaceuticals throughout the supply chain—from production to healthcare providers.

Approach

Even though Brazilian regulation helped to define “what and how” traceability should be implemented, Aché found that to be compliant, it would need to start the project from “scratch.” Patient safety was Aché’s top priority as the company implemented a traceability system, enabled by GS1 standards and aligned with the needs of consumers and the requirements of government.

100%

of secondary and tertiary packages have GS1 barcodes



aligned with national and most international traceability regulations



Applying global identification and barcode standards

180 million

drug packages are labelled with GS1 DataMatrix barcodes

aché
mais vida para você

Every company that is part of the healthcare supply chain prioritises offering its patients and consumers the best products and services, always focusing on patient and consumer safety. In today’s healthcare industry, it is essential for companies to remain competitive. With this in mind, Aché Laboratories considers innovation to be an important part of its growth strategy—one that is consistently executed.

Aché’s decision to implement the drug traceability project at its laboratory in 2018 was based on Brazilian regulatory requirements and the growing global demand from consumer markets. And considering the opportunity to innovate, Aché accepted this challenge.

Why was implementing traceability a challenge?

First, there had not been a similar drug traceability regulation in Brazil before, so benchmarking results were not available to help the company better understand the magnitude of the implementation. Rather, Aché had to start from “zero”—creating internal processes, developing production-line coding equipment, working to involve and integrate several departments of the company, training the team and much more.

About Aché

Aché Laboratories is a 100% Brazilian-owned corporation that has been in operation for 53 years. It has one of the largest marketing and sales organisations in the Brazilian market, which gives it extensive reach for publicising its products, disseminating scientific knowledge to health professionals, and providing consumers with access to a complete portfolio of quality products.

With nearly 4,900 employees, Aché is focused on diversity and its benefits for the business. More than 2,500 employees are dedicated to maintaining relationships with healthcare professionals and points of sale. The company has a broad and diversified portfolio with 327 brands. There are 145 therapeutic classes for 18 medical specialities available via multiple channels—trade, institutional, public and private.

Márcio Reis Freitas

In 2018, Aché pharmaceutical products were sold at 72,027 points of sale and 2,067 private institutions. Its products are also distributed throughout 26 countries covered by licensing agreements, such as Mexico, Nicaragua, El Salvador, Guatemala, Honduras, Venezuela, Panama, Chile, Algeria, Ukrain, Saudi Arabia, Kuwait, Arabic Emirates, Japan and many more.



Taking on a challenging project

When Aché decided to implement its traceability system, the company knew it would be a challenge. The company would need to make structural changes in the factory where any mistake—large or small—would have a major impact on production. Secondly, at that time, the Brazilian traceability regulation was in its “draft” stage and subject to change, making the company’s “return on investment” uncertain and risky.



Implementing standards on production lines

Beginning in 2018, Aché started implementing GS1 standards for use in the company’s factory located in Guarulhos, São Paulo.

Based on requirements published by ANVISA (the Brazilian health regulatory agency), a Global Trade Item Number® (GTIN®), the ANVISA registry number, serial number, expiry date and lot number are all encoded in the GS1 DataMatrix barcode, printed on labels and applied on pharmaceutical secondary packages—deployed on 23 production lines in the factory.

Later in 2018, the company expanded the project to its newly opened factory located in Cabo de Santo Agostinho-Pernambuco in Northeastern Brazil, with seven additional production lines applying GS1 standards-enabled

labels. At the same time, logistics units were each uniquely identified with the GS1 Serial Shipping Container Code (SSCC) encoded in GS1 barcodes. This level of identification met the ANVISA’s drug traceability regulation requirements to ensure traceability up to the tertiary packaging level.

Today, Aché Laboratories has 32 lines producing approximately 180 million packages, labelled with GS1 identifiers and attributes encoded in GS1 DataMatrix barcodes. The company’s initial investment was approximately €4 million.

The next phase planned is to implement GS1 standards in the logistics department to enable the integration of production with shipments to customers.

Worth the investment

Aché advises that GS1 standards has provided the company, its healthcare providers and consumers with a wealth of benefits and a solid return on the initial investment. The company's traceability system now includes 100% of secondary and tertiary packages produced in São Paulo and Recife factories.

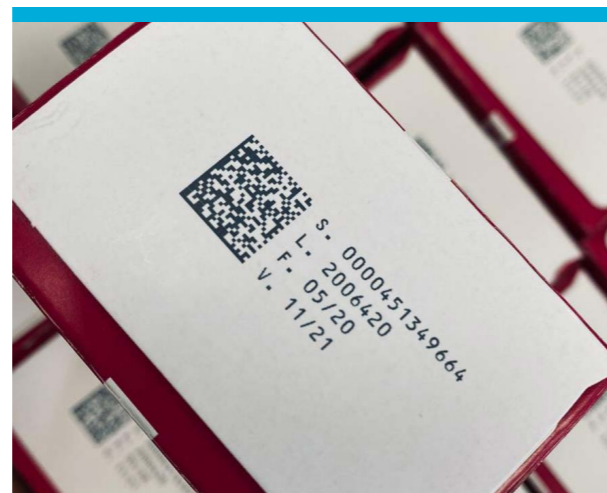
Aché has developed an app for consumers so that they can access valuable information about

their Aché medicines. By using global GS1 standards, the pharmaceutical manufacturer is aligned with national regulations and the vast majority of global traceability regulations. The foundation of standards has given Aché the ability to serve multiple markets that require drug traceability, thus, allowing it to expand into new markets.

Lessons learned

The implementation of the traceability project was a strategic decision for Aché Laboratories. The company seized the challenge of implementing GS1 standards, giving itself enough time to implement standards on its production lines, and to correct any mistakes. It was also the opportunity to create a "lessons learned" database that can provide best practices and a benchmark, for Aché itself and for other companies.

Aché Laboratories is currently prepared to export to international markets requiring drug traceability and can now ensure high-quality service to customers and consumers.



Colombia

Traceability: The key for driving efficiencies in the supply chain

<p>Challenge</p> <p>Alexion needed to create a traceability system that would address Colombia's pilot specifications.. Working with multiple stakeholders across the company's supply chain, Alexion led the way to implement GS1 standards, align processes, integrate systems and manage the necessary change for full traceability.</p> <p>Approach</p> <p>Alexion chose GS1 standards to uniquely identify, barcode and label packages and individual units of Soliris, a medicine selected for the traceability pilot. As the packages of Soliris traveled throughout the supply chain, employees and caregivers scanned the GS1 DataMatrix barcodes to capture and share information with all stakeholders.</p>	<p>100%</p> <p>end-to-end traceability—from factory to patient bedside</p>	<p>Visibility of medicines across the supply chain</p>
	<p>Traceability information successfully captured and accessed by all stakeholders</p>	<p>Collaboration between all stakeholders for fully integrated system in compliance with the Colombian pilot requirements regulation</p>

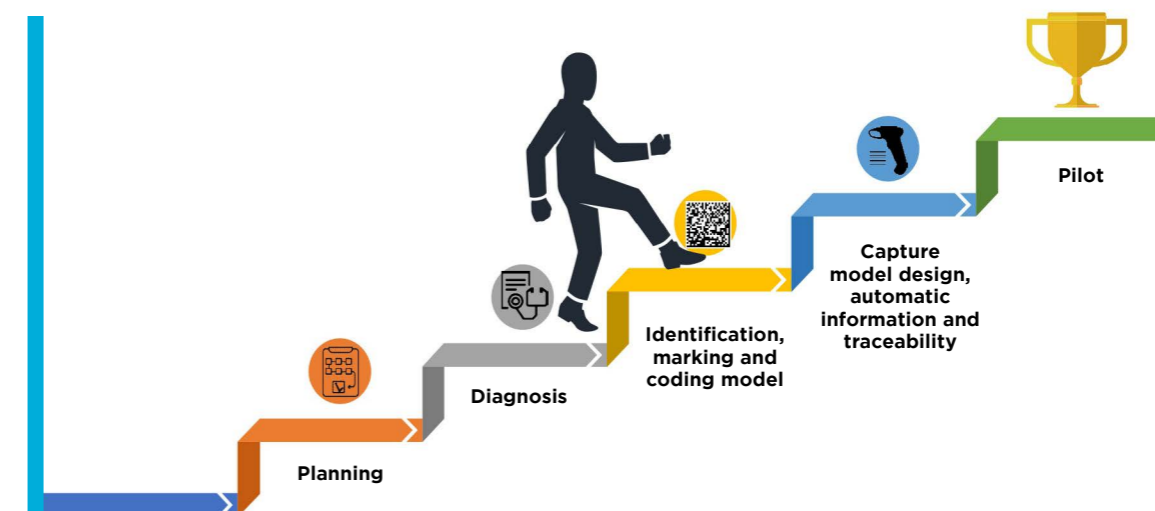


Sponsored by Alexion, the medicine traceability project established a model to capture information using GS1 standards and guidelines. The purpose of the project was to increase the visibility of the medicine, Soliris, throughout the supply chain.

By ensuring pharmaceutical traceability with GS1 identification and barcodes, Alexion aimed to minimise, and even eliminate, the falsification of medicines in its supply chain.

Alexion, in collaboration with its partner, Audifarma, sponsored a project to establish a traceability system that would capture information and enable the visibility and traceability of pharmaceuticals throughout the supply chain. The project initially focused on the medicine, Soliris. Five phases were executed: planning, diagnosis, implementation of GS1 standards for medicine identification, and development of the scanning methodology to capture information about the medicine as it traveled from the factory to patients.

Giovanny Cruz



About the author

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Industrial Director
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Márcio Reis Freitas is Industrial Director of Aché Laboratories with 29 years of experience in pharmaceutical industrial environments. With a degree in Industrial Chemistry, Mr. Freitas specialises in Six Sigma "Black Belt" methodology with a masters degree in Business Management from Fundação Getulio Vargas (FGV). He has extensive knowledge in the areas of Production, Industrial Engineering, Industrial Excellence, Industrial Projects and Quality Assurance. Mr. Freitas has been at Aché Laboratories since 2005, where he is responsible for five sites in the areas of Production, Industrial Engineering, Projects and Operational Excellence.

About the organisation

Aché Laboratórios Farmacêuticos S.A. is a Brazilian-owned corporation. For more than 50 years, the company has been in operation and is, today, one of the largest pharmaceutical companies in Brazil.

www.ache.com.br

Every part of the supply chain

The scope of the project's trial encompassed every part of the supply chain. At its headquarters in Bogotá, Alexion assigned a Global Trade Item Number® (GTIN®) to uniquely identify the Soliris product. The GTIN and other information—lot number, serial number and expiration date—were encoded in a GS1 DataMatrix barcode,

printed on a label and applied to the medicine's individual unit of dosage as well as packages. These packages were then shipped to the company's distribution centre. Two major wholesalers in Bogotá and Barranquilla ordered packages of Soliris and distributed them to two healthcare providers for dispensing and administration to patients.

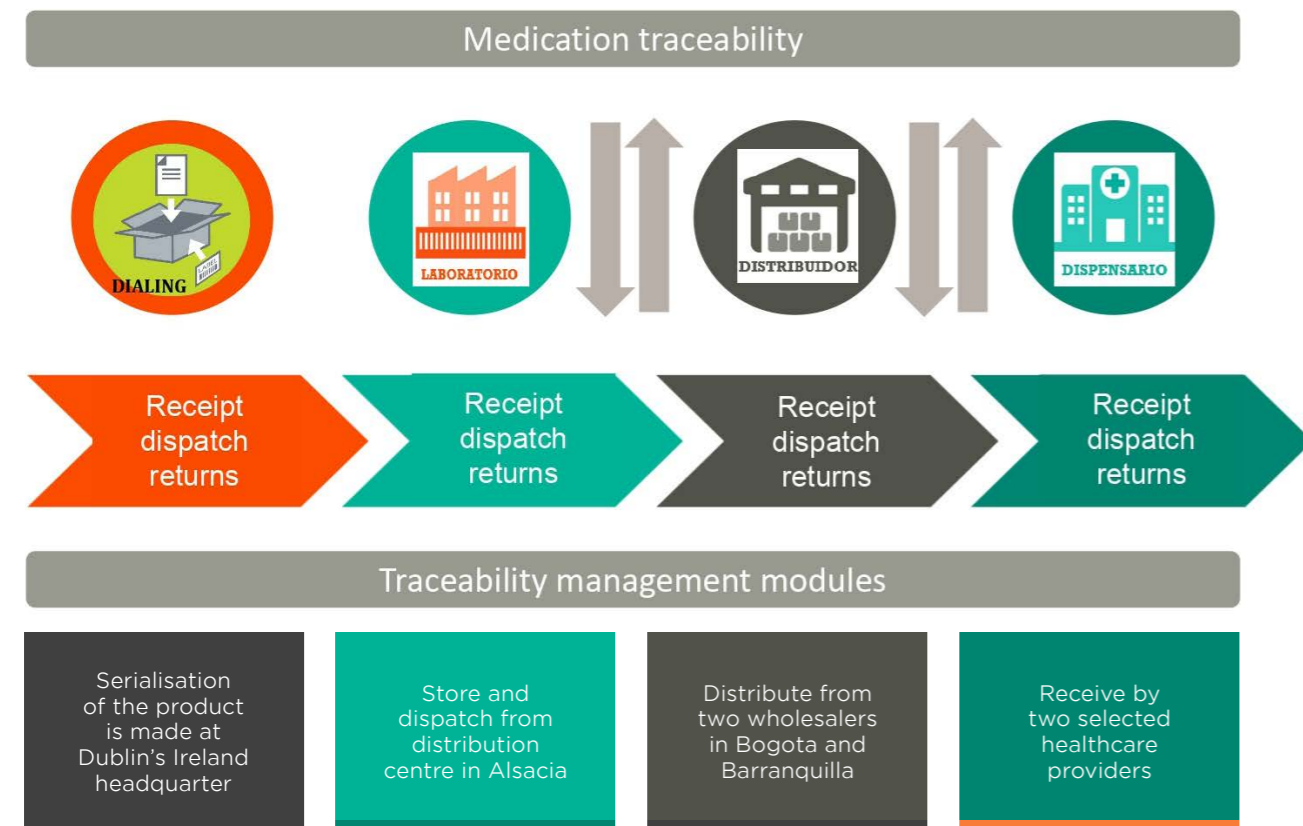
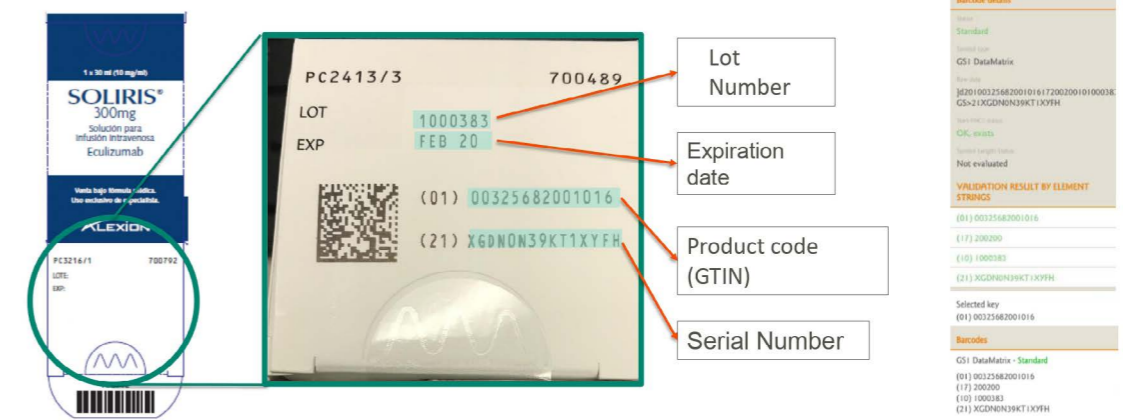


Figure 1: Traceability management modules

Each step of the way, GS1 DataMatrix barcodes on Soliris packages, and then individual dosage units, were scanned to capture information about the medicine throughout the supply chain. The GS1 system of standards was chosen since it offered a global standardised way to uniquely identify and barcode pharmaceuticals. The GS1 DataMatrix barcode was especially important since it is small enough to fit on individual dosage units, yet can hold a large amount of information that can be captured with a single scan.

The project has demonstrated how a medicine like Soliris can be tracked to the patient bedside where it is administered, and then traced back to the factory where it originated. This traceability system, enabled by GS1 standards, confirms Alexion's compliance with Colombia's pilot specifications and improves patient safety each step of the journey.

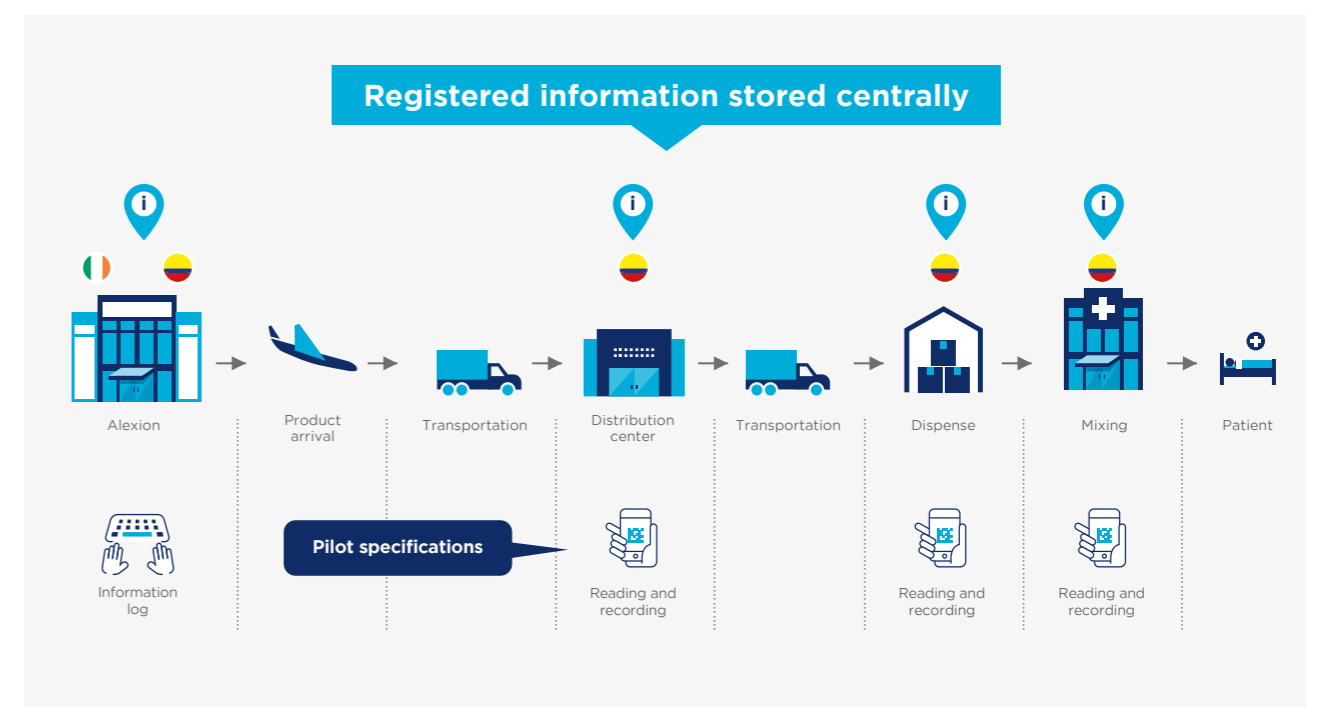


Figure 2: Traceability platform

Systems integration

To gain visibility of the medicine, it was necessary for the various stakeholders' systems to be integrated so that all could have access to the medicine's information—its status and location throughout the supply chain.

By working together in a collaborative way, the project stakeholders understood and realised the value of integration and applied strategies for the success and sustainability of the traceability system.



About the author



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Giovanni Cruz is an industrial engineer and specialist in International Logistics Management with 20 years of experience in the Pharmaceutical sector. He joined Alexion Pharmaceuticals in 2012 as leader of the company's logistics process. Currently, Mr. Cruz is the manager of the traceability project that addresses high-cost medicines for the Colombia supply chain.

About the organisation



Alexion is a worldwide pharmaceutical company that is dedicated to an understanding of rare diseases, which began with its pioneering work in complementary biology. This knowledge allows the company to innovate and evolve into new areas, where there is great unmet need and opportunity to help patients and families fully live their best lives. Alexion has delivered transformative medicines for people with PNH, aHUS, AQP4, NMOSD, gMG and HPP.

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