China

Tracking drugs and medical devices on a single platform

Challenge

The supervision of medical cosmetic products is quite difficult in China, and there are problems with unlicensed and smuggled products in the market. Current traceability system standards are not unified, various coding standards coexist and each traceability system is incompatible with the others. As a leading dermatology product enterprise, Galderma has three major groups of downstream distributors using various data exchange methods. Some small distributors have no IT system at all.

Solution

Based on the research on the similarities and differences between drugs and medical devices supply chain traceability, a bespoke product traceability system (PTS) based on GS1 standards has been implemented. The main functional modules include: the master data management module of enterprises and products; encoder module, label template and barcode printing module supporting GS1 coding standard; serial number management, traceability and inquiry functions; traceability report and audit function.

incompatible coding standards and traceability systems

Galderma, a leading dermatology product enterprise, has three major groups with about 40 downstream distributors

One single traceability system for drugs and medical devices based on GS1 standards

Nine medical device products and six cosmetic and drug products tracked

Introduction

In August 2019, China's National Medical Products Administration (NMPA) officially issued The Rules for the Unique Identification System of Medical Devices, marking the official start of the legislation to implement unique device identifiers (UDIs) in China. GS1 China fully meets all requirements of the UDI issuing entity mentioned in the rule. In the subsequent two years, two announcements on effective implementation of unique identification for medical devices were issued, which clearly define the scope, schedule and work requirements for stakeholders.

Also in 2019, the NMPA tightened drug administration by introducing a "full traceability" mechanism and a drug recall system. In the new version of the Drug Administration Law, the establishment of a drug traceability system was proposed for the first time.

With a series of regulations and standards on UDI and a drug traceability information system being issued or updated, it's now possible for manufacturers to implement GS1 standards for both drugs and medical devices in China.

Driving forces of simultaneous tracking of drugs and medical devices

In the healthcare industry, manufacturers, distributors and healthcare providers all have their own needs and motivations to meet the requirements of laws and regulations and improve internal efficiency. In view of the implementation trend of global supply chain standards in China, and considering drugs and medical devices are ultimately managed together at the point

of care, the demand for the construction of a traceability system based on unified standards is gradually emerging. More and more stakeholders choose to implement GS1 standards for product identification and traceability for the following reasons.

Firstly, to comply with various regulations and policies, drug and medical device suppliers, especially multinational enterprises, should not only respond to the minimum obligations required by relevant regulations, but also provide convenience for downstream distributors to enhance supply chain traceability. Secondly, in terms of information exchange, due to the coexistence of various coding standards in the past, the traceability systems are incompatible with each other, which makes it difficult to share information. Most of the data is currently fragmented and isolated, which brings obstacles to the interaction of the traceability system along the supply chain. Thirdly, from the perspective of improving efficiency, GS1 barcodes can be read and interpreted without relying on any third-party platform to obtain the product identification and additional information. This makes the management process more convenient and cost-effective, and the whole medical supply chain will benefit.

In conclusion, GS1 standards not only meet China's requirements for drug traceability and UDI, but also provide an open, harmonised business language for all stakeholders to use globally. For downstream distributors and healthcare providers, the product traceability system (PTS) based on GS1 standards enables enterprises to respond to the relevant requirements for identification and tracking of drugs and devices at the same time under the complex supply chain structure.

The characteristics of Galderma's supply chain

Galderma fully considered the different business flows of each trading partner within its supply chain, and also took the fixed product types into account. Under the guidance of GS1 China, Galderma conducted detailed data research and distributed a questionnaire to its supply chain partners to identify the complexity and possible risk points of implementing a traceability system.

As a multinational company, Galderma (China) integrates the roles of supplier and importer, in the middle of the whole supply chain. Galderma branded products come from three types of original supplying site. The first type only produces medical devices, the second type of site produces prescription drugs, and there will be a third type of manufacturer site that supplies drugs and medical devices at the initial stage of this project (as shown in Figure 1).

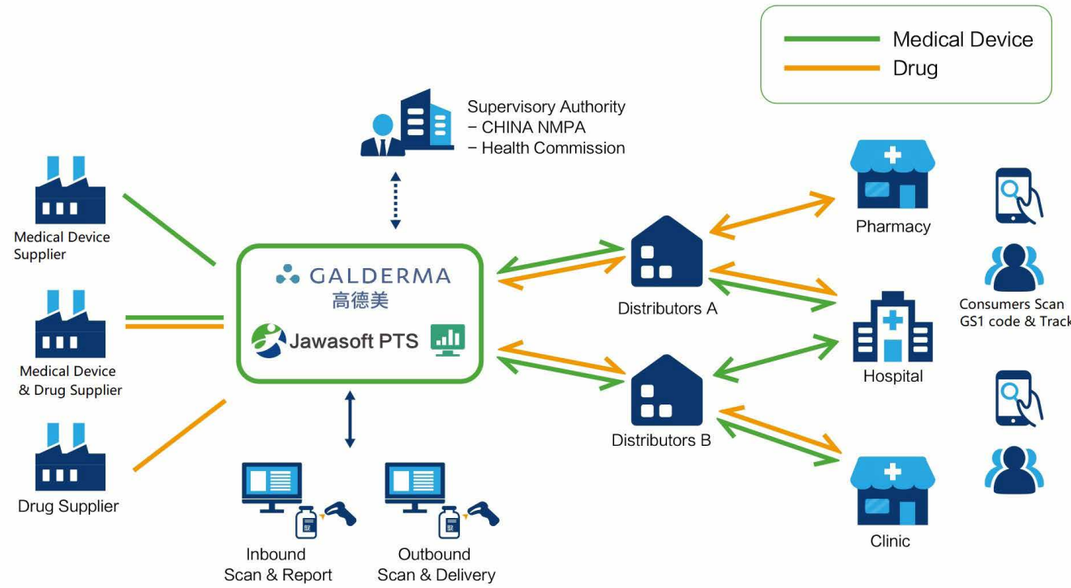

Figure 1: Galderma's drugs and medical devices supply chain

The products sold by Galderma in China include up to nine medical device products with GS1 barcodes containing GTIN, batch number and/or serial number, and six imported cosmetic and prescription drug products with GS1 DataMatrix. In downstream distribution, some distributors mainly sell medical devices, while others sell prescription drugs at the same time. As there was no unified coding system, distributors have traditionally used multiple systems to manage purchase, inventory and data of sales.

The product traceability system (PTS) based on GS1 standards will help Galderma and distributors use the same platform and unified coding system to complete the data collection and traceability of various products.

Implementing a single platform with multifunctions

Galderma reached out to one of the leading traceability solution providers in China, Jawasoft Technology. After the completion of comprehensive research on products and distribution processes, a Galderma dedicated product traceability system (PTS) based on GS1 standards was designed and implemented. The main functional modules include: the master data management module of trading partners and products, a GS1 encoding and label template module, serial number management, traceability and inquiry functions, a report and audit function.

The original manufacturing sites for Galderma have adopted GS1 standards as the unified coding scheme. Although various sites provide different types of products, both drugs and medical devices use the GTIN as the product identification. The Application Identifier (AI) elements can be configured in the PTS's GS1 encoding and label template module.

The traceability of products is based on serial numbers and/or batch numbers. For products that are only managed to batches, the PTS will provide a batch query report to help users check the products movement. The distributors scan the GS1 barcodes upon receiving the product at the inbound warehouse and this informs the PTS that the goods have been received. Similarly, when the distributor sends product to clinics, the delivery order can be automatically created by scanning the GS1 barcode using the PTS app. Galderma's supply chain managers can query the traceability information through PTS.

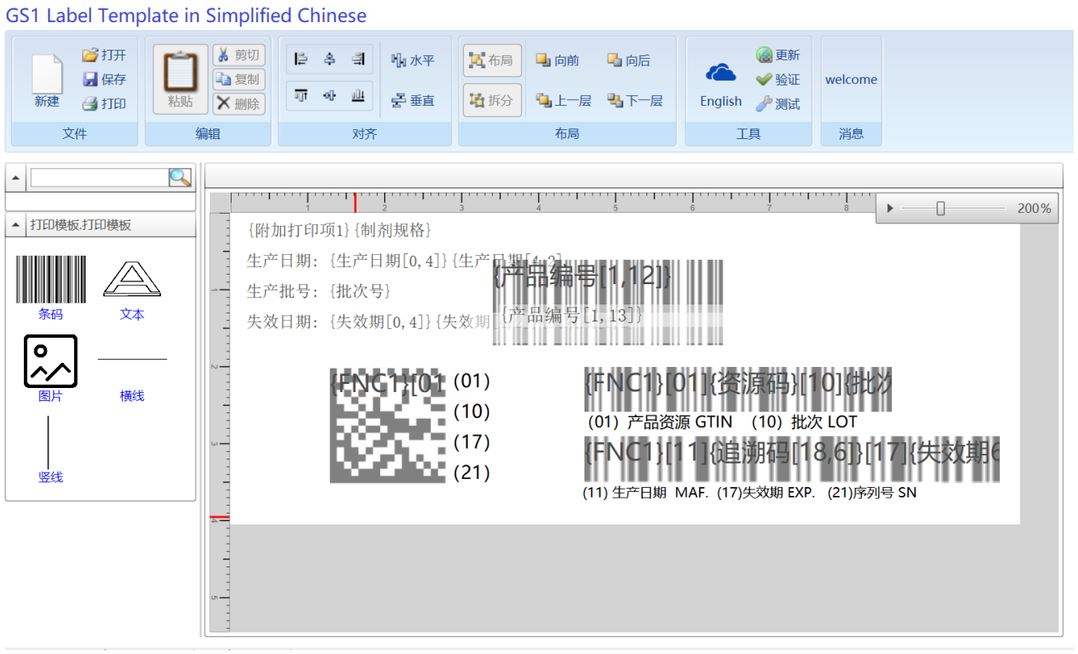

Figure 2: GS1 encoding and label template

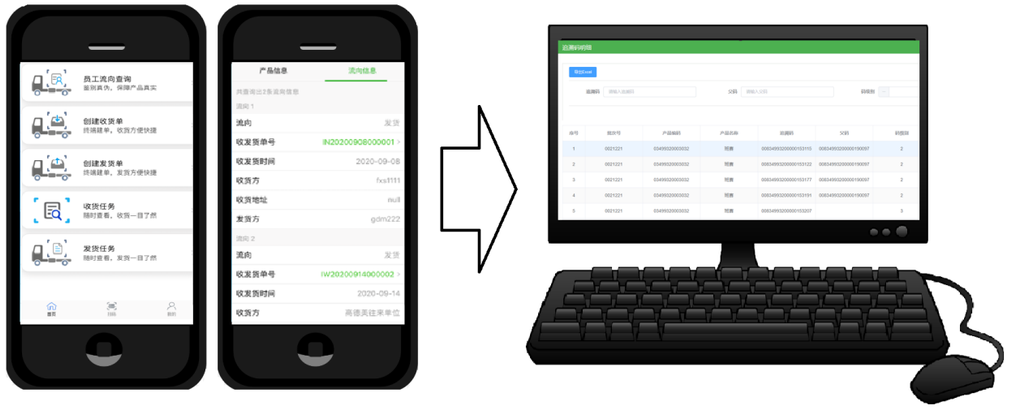

Figure 3: Distributors use mobile PTS app to stock and report

When the product reaches the clinic or consumers, users can directly scan the GS1 DataMatrix barcode using a WeChat mini-app, regardless of whether the product is a prescription drug or a medical device. A WeChat mini-app will query whether the product is genuine, and display the product name, batch, expiration date, etc. If illegal products are found, the system will alert consumers immediately.

In addition, PTS guarantees data security by authorisation management. Once a distributor is onboarded, access levels will be granted based on the supply chain structure. The main principle is that Galderma can see the data reported by its downstream distributor, but the parallel distributors' data cannot be viewed by each other. The authorisation setting is completed by the management personnel of Galderma, and the audit trail function is supported.

Figure 4: Customer scanning the UDI marking using WeChat app

Successfully on-boarding downstream distributors

According to the survey data collected from the Galderma distributors before the implementation of the system, the main factors distributors were concerned about included potential extra costs, impact on current business processes and data security issues.

Thanks to the openness of GS1 barcodes and the integrated design of PTS, downstream distributors have settled into the system as stakeholders without participating in the system construction.

For distributors that currently use other systems or do not have any traceability system, there is no additional participation cost, and there is no need to carry out complex training for operators. The distributor can also continue to use the existing hardware equipment, such as basic barcode scanning equipment, a handheld PDA terminal, etc, which can transfer data with PTS without purchasing many new equipment.

From the business process perspective, compared with many systems previously used, the GS1 coding system adopted by Galderma is very convenient and fast. The downstream distribu-

tors of Galderma do not need any software or platform to analyse. It can immediately obtain the basic information, product identifier, batch number, expiry date and serial number of various products by using only one system. This not only makes the distribution process faster, but also saves a lot of system construction and operation costs for distributors and ensures that each shipment of goods is accurately and timely distributed to domestic destinations in China.

Benefit to healthcare provider and consumers

In medical cosmetic clinics, the previous manual management process has been replaced by scanning a GS1 barcode, which has improved the efficiency of stock and inventory management. The human error in the process of selecting medical products is greatly reduced in the clinic. In addition, the new process also shortens the time required for data verification and entry, enabling staff to spend more time caring for consumers.

Next steps

GS1 China plans to engage with more healthcare providers to implement GS1 standards for drugs and medical devices, and to explore what benefits GS1 standards can bring to all stakeholders. Galderma's experience shows how to solve the difficulty of managing different types of products in the healthcare supply chain.

Conclusion

GS1 China, along with global and some local stakeholders, has long been promoting the virtues of global harmonised product identification in the healthcare industry. The establishment of the simultaneous tracking of drugs and medical devices on one integrated platform based on GS1 standards proved that GS1 standards are not only compliant but also efficient in China. The project has involved a smooth transition from multiple traceability codes to the GS1 coding system for medical cosmetic company, showing a turnkey solution that can be promoted in the healthcare industry. This solution improves the overall supply chain efficiency of the industry without requiring significant additional cost.

"To provide better services to customers, we pay great attention to the safety and quality of drugs and medical devices. The GS1 standards-based drug and device traceability system used by Galderma products can help the pharmacies and clinics quickly obtain various information on drugs and medical devices. That information can be related to the treatment information of each customer, providing data and system support for healthcare provider's refined management needs."

Ray Zhang
Head of supply chain, Galderma China

About the authors

Ray Zhang
Head of Supply Chain, Galderma China

Mr Zhang is head of supply chain at Galderma China. He has contributed to the development of Galderma China's supply chain management strategy and continuously improved the process to ensure efficient distribution and logistics operation. He pays great attention to the safety and quality of Galderma products, aiming to solve the distribution challenges faced by the company.

Xuejing Wang (Chris Wang)
Deputy Manager, Jawasoft

Chris Wang, MBA of Nankai University, is one of the co-founders of Jawasoft Technology. She has been in the field of pharmaceutical traceability for more than 15 years, leading the Jawasoft team to obtain nearly half of the market of the pharmaceutical industry in China. She is familiar with the traceability regulations, supply chain security and system construction in China, the United States and the European Union. She is also expert in medical device UDI requirements and in implementing UDI system for enterprises.

Local coordination

Han Du
Director of the Article Coding Innovation Application Promotion Studio, GS1 China

Han Du achieved a master's degree in information management from the University of Sydney. In 2006, he joined GS1 China, responsible for the technical research and application promotion of internet of things. He has undertaken national projects such as research on electronic product code (EPC) internet of things standard system, GS1 transport and logistics pilot on EPC and EU FP6, and started research on GS1 in mobile commerce/B2C business. Since 2019, he has served as the director of the article coding innovation application promotion studio. He has a deep understanding of GS1 standards and their application, and is fully responsible for the application and promotion of GS1 standards in healthcare, transport and logistics, and industrial internet.

About the organisations

GALDERMA

With a unique legacy in dermatology as well as decades of cutting-edge innovation, **Galderma** delivers a science-based portfolio of premium flagship brands and services that spans the full spectrum of dermatology. As the pure-play dermatology category leader, it is advancing dermatology for every skin story.

www.galderma.com

嘉华汇诚 Jawa Huicheng

Jawasoft is an industry leading service provider of end-to-end traceability solutions. The Jawasoft team focuses on global regulatory consultation, traceability system construction, platform bridging, drug serialisation for import and export, medical device UDI, packaging line coding system and CSV service.

en.jawa-huicheng.com