Jordan

Hikma Pharmaceuticals adopts GS1 standards for regulatory compliance and traceability

Challenge

Hikma Pharmaceuticals (Hikma) needed to put in place a track and trace system for its full line of pharmaceuticals. The company wanted a system that would easily scale across its three global regions in response to emerging regulatory requirements.

Approach

The company implemented GS1 standards to uniquely identify its medicines at the individual dosage level. These GS1 identifiers were encoded in GS1 DataMatrix barcodes for application on packages. By scanning these barcodes, Hikma can now easily capture information in its IT systems for traceability—from its plants to healthcare providers, and ultimately, to patient bedsides.

Reduced packaging line changeovers with standardised processes

Solidified brand image and reputation as a market leader

Met regulatory requirements in majority of markets

Built a strong foundation of GS1 standards and infrastructure for future regulatory requirements

These are the main Hikma markets that have adopted GS1 standards as a mandatory requirement for regulatory compliance and shipping.

1. US
2. Jordan
3. Egypt
4. Saudi Arabia
5. Oman
6. Qatar
7. Bahrain
8. Lebanon
9. Slovakia

hikma.

Founded more than 40 years ago, Hikma's purpose is to provide high-quality, affordable medicines to the people who need them. As a global pharmaceutical generics market player, Hikma has always strived to be a leader in adopting the latest technologies to enhance product quality and ensure patient safety. In 2019, the company's revenue exceeded US $2.2 billion, including Middle East and North Africa (MENA), US and Europe for injectables, generics and branded businesses.

Khalid Abughoush

Responding to regulation

With ever-increasing global regulatory demands, Hikma had to comply with new regulatory requirements demanding the implementation of track and trace systems. As of 2020, more than 80% of Hikma's global markets are requiring the use of GS1 standards for traceability, as a requirement for drug manufacturers.

Hikma started the implementation of GS1 standards to enable the track and trace system in many of its facilities across MENA, Europe and US. This meant assigning each medicine a serialised Global Trade Item Number® (GTIN®) that was encoded in a 2D GS1 DataMatrix barcode, printed on a label and applied to the medicine's package.

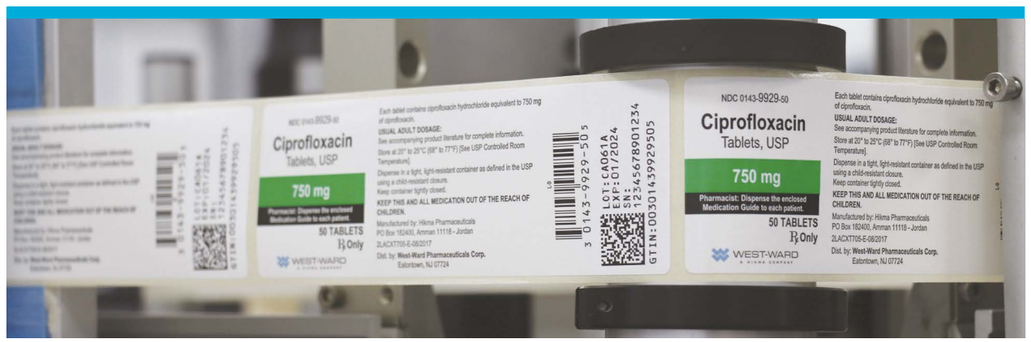
With GS1 standards in place, Hikma had the necessary foundation to enable a traceability system that would enable it to securely track products throughout its supply chain, thus protecting healthcare providers and patients against counterfeit products.

As an early adopter of GS1 standards, Hikma had already installed machines and upgraded its IT infrastructure for traceability when regulations were more flexible—actions taken in order to secure its position in the company's target markets. This provided Hikma with a head start and ease of implementation for countries that had recently required GS1 standards' implementation.

Becoming an early adopter

When implementing GS1 standards, Hikma invested millions of dollars in new packaging machinery capable of serialising bottles and cartons. The company also upgraded its IT infrastructure and internal procedures for quality assurance so that products are properly encoded with the correct GS1 standards.

By implementing GS1 standards, Hikma is paving the way for the next steps in creating its track and trace system. This foundation of standards will also help to enhance quality control systems in final packaged products. Newly installed machines along with new capabilities and standardised process parameters have streamlined setup procedures for packaging machines and provide real-time productivity reports.



Experiencing early benefits

While Hikma's track and trace system has not been completed for all manufacturing sites, the benefits of using GS1 standards are already being realised on the shop floor level with the installation of new machines and the ability to track every product.

By implementing GS1 standards, Hikma has achieved the following benefits:

1. Reduced packaging line changeovers based on standardised process parameters and enhanced technology implemented for serialisation.
2. Solidified brand image and reputation as a market leader with the highest quality and technology standards.
3. Met regulatory requirements needed in the majority of Hikma's target markets.
4. Built a strong infrastructure, knowledge of GS1 standards and serialisation best practices—all needed as prerequisites for aggregation. Aggregation will be the new requirement by all countries that currently need serialisation as a regulatory requirement.

Securing a leadership position with standards

As of April 2020, aggregation will be mandatory for all shipped pharmaceutical products to Saudi Arabia. Saudi Arabia is considered one of the main markets in the MENA region and has three manufacturing plants—General Formulation, Cephalosporin and Penicillin.

Since Hikma has used GS1 standards for many years and has the proper infrastructure for its track and trace system, the implementation for aggregation of the Saudi Arabian sites has been flawless without any major challenges. After implementing the aggregation and synchronisation of data with the Saudi Food and Drug Administration (FDA), whole chain traceability will be achievable for all batches shipped to Saudi Arabia, starting with the manufacturing site and ending with the patient.

Hikma has always strived to achieve the highest quality in drug manufacturing capabilities to ensure the safety of its patients globally. The company will always adopt the latest technologies for this purpose. By using GS1 standards, Hikma will continue to secure its global position across its main target markets and enhance its manufacturing capabilities.

About the author

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Khalid Abughoush is the Packaging Manager of Hikma Jordan's General Formulation plant. He has completed his dual degree from Queen's University, Canada in Chemical Engineering and Biochemistry, and completed his graduate degree from Harvard University, US in Strategic Management through correspondence. He is currently leading the implementation of GS1 standards for Hikma Jordan plants and has five years of experience in the healthcare industry.

About the organisation

Hikma helps put better health within reach every day for millions of people in more than 50 countries around the world. For more than 40 years, Hikma has been creating high-quality medicines and making them accessible to the people who need them. Headquartered in the UK, Hikma is a global company with a local presence across the United States (US), the Middle East and North Africa (MENA) and Europe. The company uses its unique insight and expertise to transform cutting-edge science into innovative solutions that transform people's lives. Hikma is committed to its customers, and the people they care for. By thinking creatively and acting practically, the company provides them with a broad range of branded and non-branded generic medicines. Together, Hikma's 8,400 colleagues are helping to shape a healthier world that enriches all our communities. Hikma is a leading licensing partner, and through its venture capital arm, is helping bring innovative health technologies to people around the world.

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