The Global Language of Business

- GS1 Egypt Assists EIPICO Pharma in Meeting New SFDA Regulations for Export

- A GS1 Egypt Healthcare Success Story - EIPICO Pharma

- GS1 Egypt Transforming the Healthcare Supply Chain & Patient Safety (EIPICO Pharma Case Study)

Abstract:

The healthcare sector in Egypt is a major part of the economy, as there are about 10,000 types of pharmaceutical products manufactured in Egypt and exported to many countries all over the world.

The healthcare industry around the globe is facing challenges that affect the entire supply chain, from manufacturers through to distributors, healthcare providers and patients. Everyone is concerned primarily with two main issues: increasing supply chain efficiency and more importantly, ensuring patient safety.

In Egypt, we are mainly focusing on pharmaceuticals as there are many challenges when trying to ensure the right drug reaches the final point of dispense, since the counterfeit of drugs has been a serious problem.

The pharmaceutical supply chain in Egypt consists of: manufacturers, distributors, hospitals and retail pharmacies, and finally, the patient. There are more than 400 pharmaceutical factories, 500 distributors, and 60,000 pharmacies in Egypt.

The regulatory landscape continues to evolve and new regulations are being passed all the time. This has a direct impact on the pharmaceutical supply chain, requiring stakeholders to implement more accurate and advance identification technology and traceability systems to improve patient safety.

GS1 Egypt assisted EIPICO Pharma, one of the leading pharmaceutical companies in Egypt, in meeting the new SFDA (Saudi Food & Drug Authority) regulations for exporting drugs to Saudi Arabia.

Customer Background:

EIPICO is the civilized face of Egypt in the pharmaceutical industry. It was established as a private investment company in 1980 and started production in 1985.

As a continued commitment to patient safety, EIPICO operates in a highly regulated environment by applying C.G.M.P. (Current Good Manufacturing Practice) regulations throughout the operational departments, including evaluation of raw materials, calibration of equipment's, control, holding and distribution of finished products. As sterilization is of paramount importance, EIPICO plant has a U-shaped design that minimizes mix-up and/or contamination by providing a single direction of material flow and is also surrounded by a green area as a protection from surrounding environment. Each pharmaceutical process has enough space to be carried out apart to minimize mix-up and/or cross contamination. EIPICO plant is unique by its Sterile Areas (which are the largest in the Middle East and North African Region) that are environmentally controlled to obtain filtered air up to 97% - 99.7% particulate-free. The water purification system in the plant was designed to supply the production zones with dematerialized and distilled water.

EIPICO has been one of the pioneer innovators within the pharmaceutical field in Egypt. The company was the first to produce dosage forms like the spansule capsules (long-acting). In addition, it produces non-traditional dosage forms such as the soft gelatin capsules, lyophilized products, gels, sprayers and effervescent tablets.

Challenge:

A new regulation has been released in the 21st of March 2015, by the Saudi Food & Drug Authority (SFDA) that requires all pharmaceutical products exported to Saudi Arabia to have standardized identification and automated tracking of products using a **GS1 Data Matrix** that includes the following data: (**GTIN** *(Global Trade Item Number),* **Expiry Date**, **Batch Number).** Additionally, staring from the 21st of March 2016, each pharmaceutical product produced or exported to Saudi Arabia must be encoded with a **GS1 Data Matrix** that includes: (**GTIN, Expiry Date, Batch Number, Serial Number).** Since EIPICO Pharma is one of the main

exporters of pharmaceutical product to the Saudi Market, complying with these regulations will require EIPICO to implement changes to upgrade and expand their identification and serialization programs as outlined in the new SFDA regulations. This means that all production line printers must be replaced with new printers that can print GS1 Data Matrix; in addition to this, an ERP (Enterprise Resource Planning) system must be established to register all the products with the required data in high resolution (HD) images, and to encode the random serialization required for the next phase of the regulation that will be effective in 2016.

Solution:

GS1 Egypt has been at the forefront of industry education in Healthcare about how standards can improve patient safety and efficiency, and it has always been committed to serving and helping its customers. Thus, in preparation for the new SFDA regulations, GS1 Egypt has lead the charge by submitting a comprehensive solution to EIPICO Pharma to help it meet the requirements and timelines of both phases of the SFDA regulations. The solution consisted of multiple consultation sessions with EIPICO production managers to help them adopt and implement GS1 Data Matrix to meet the SFDA requirements and timeline in the most efficient way possible.

Two consultation sessions focused on the implementation of GS1 Data Matrix Standards were given to the production line team. In the first session, the GS1 Egypt consultant gave a seminar to EIPICO production team about GS1 Standards in Health Care, explaining to them how GS1 Data Matrix worked in various areas of production and accordingly, helped them in choosing the production line printers that best fit their needs. In the second session, GS1 offered a verification service to ensure the accuracy of the GS1 Data Matrix printed on the packs using the new printers at the EIPICO plant. In that session, a full report with any print errors was submitted to EIPICO, and all the necessary adjustments to correct those errors have been made and tested for accuracy.

Finally, GS1 submitted a certification stating that EIPICO Pharma could print GS1 Data Matrix according to GS1 Standards that meet the requirements (**GTIN, Expiry Date, Batch Number)** of first phase of the SFDA regulations.

Figure 1: GS1-128 and DataMatrix

Benefits:

The implementation of **GS1 Data Matrix** placed on the medicines' packaging holding the **GTIN**, **Batch Number**, **Expiry Date** and **Serial Number** proved to be fundamental to:

- Increase the protection of patients from falsified, expired or recalled medicines
- Improve customer confidence: physician, pharmacist, and patient
- Help law enforcement combat drug counterfeiting

- Prepare company to meet regulatory compliance requirements
- Enable medicine traceability
- Increase the visibility of medicines across the supply chain
- Improve the efficiency of the medicine recall process
- Helps company gain greater insight into demand patterns and inventory management.

Conclusion:

The Egyptian pharmaceutical sector is in need of implementing essential standard based solutions and supportive track and trace technologies. This is especially true today as counterfeit drugs are spreading on both a local basis and across borders, and many regions in the world continue to pass and enforce laws and regulations for product identification and traceability.

GS1 standards offer a unique opportunity for practical application of data standards that make the pharmaceutical supply chain safer and more efficient. It provides standard portfolios of data carriers that enable standardized identification and automated tracking of product, in the form of barcodes that capture the information – linearly as well as in 2D (2-Dimensional) – and a way to share the data among each stakeholder of the supply chain. GS1 Egypt continuously invests efforts in engaging manufacturers whose products have not yet been equipped with barcodes, in view of the fact that barcodes will be mandatory on primary as well as secondary packaging in the future.