Egypt

# Safemed Keeps Counterfeit Drugs out of the Supply Chain in Egypt


## ABSTRACT

The desire to introduce or regulate standards-based traceability[1] in healthcare systems around the world has increased significantly in recent years. One important driver of these regulations is the issue of counterfeit pharmaceuticals. Regulators are introducing various safety measures to prevent counterfeit pharmaceuticals, or "falsified medicinal products", from entering the supply chain and reaching patients. These include traceability systems, but also other tools such as tamper-evident seals or holograms.



By **Dr Alaa Mohamed Afify** and **Dr Mohamed Mabrouk**


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The European Union (EU) defines 'falsified medicinal product' as "any medicinal product with a false representation of:

(a) Its identity, including its packaging and labelling, its name or its composition as regards any of the ingredients including excipients and the strength of those ingredients;
(b) Its source, including its manufacturer, its country of manufacturing, its country of origin or its marketing authorisation holder; or
(c) Its history, including the records and documents relating to the distribution channels used.

This definition does not include unintentional quality defects and is without prejudice to infringements of intellectual property rights."[2]

All supply chain stakeholders (manufacturers, distributors, hospitals and retail pharmacies) in Egypt are facing major challenges when trying to ensure the right drug reaches the final point of dispense. These include low security systems, supply chain penetrations and developed counterfeit techniques.

***Did you know? It is estimated that the value of counterfeit drugs in Egypt has reached $200 million.*** *(Egyptian Drug Authority – 2010)*

"Safemed" is a standard-based pharmaceutical traceability solution, introduced by GS1 Egypt, that enables pharmaceutical stakeholders to capture and share defined product information between trading partners, increasing the security of the extended supply chain.

Completed in March 2013, the Safemed pilot was the first standard-based pharmaceutical traceability project undertaken in Egypt.

## Pilot participants

Pilot participants included actors of the healthcare supply chain, as **Utopia Pharmaceuticals** (S.A.E) supplying the pilot with *Blokatens*, a mid-high level cardiovascular product recommended for hypertensive treatment and **Dr. Alaa Pharmacy** testing the system at the Point-of-Sale, verifying the authenticity of the product by connecting to the Safemed system before supplying it to the patient.

## Objective

The principal objective of the Safemed pilot was to implement a comprehensive, standards-based traceability solution across the pharmaceutical supply chain, from manufacturer to pharmacy, that strengthened known weak points in the legitimate supply chain making it more difficult for counterfeits to enter.

1 *"Traceability is the ability to track forward the movement through specified stage(s) of the extended supply chain and trace backward the history, application or location of that which is under consideration" GS1 Global Traceability Standard For Healthcare www.gs1.org/docs/gsmp/traceability/Global_Traceability_Standard_Healthcare.pdf*

2 *http://ec.europa.eu/health/human-use/falsified_medicines/index_en.htm*

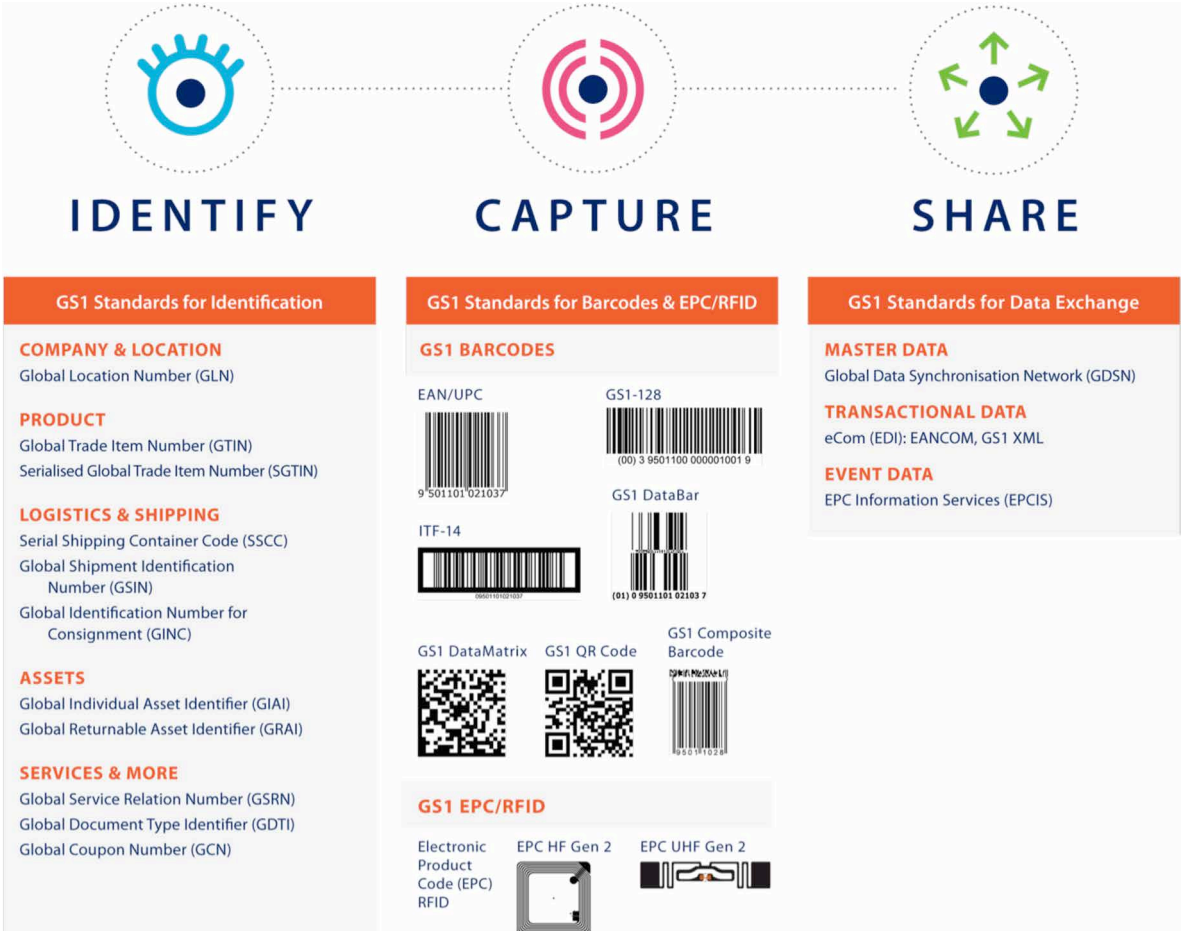



**Figure 1**: The GS1 System of Standards

## GS1 Standards in action

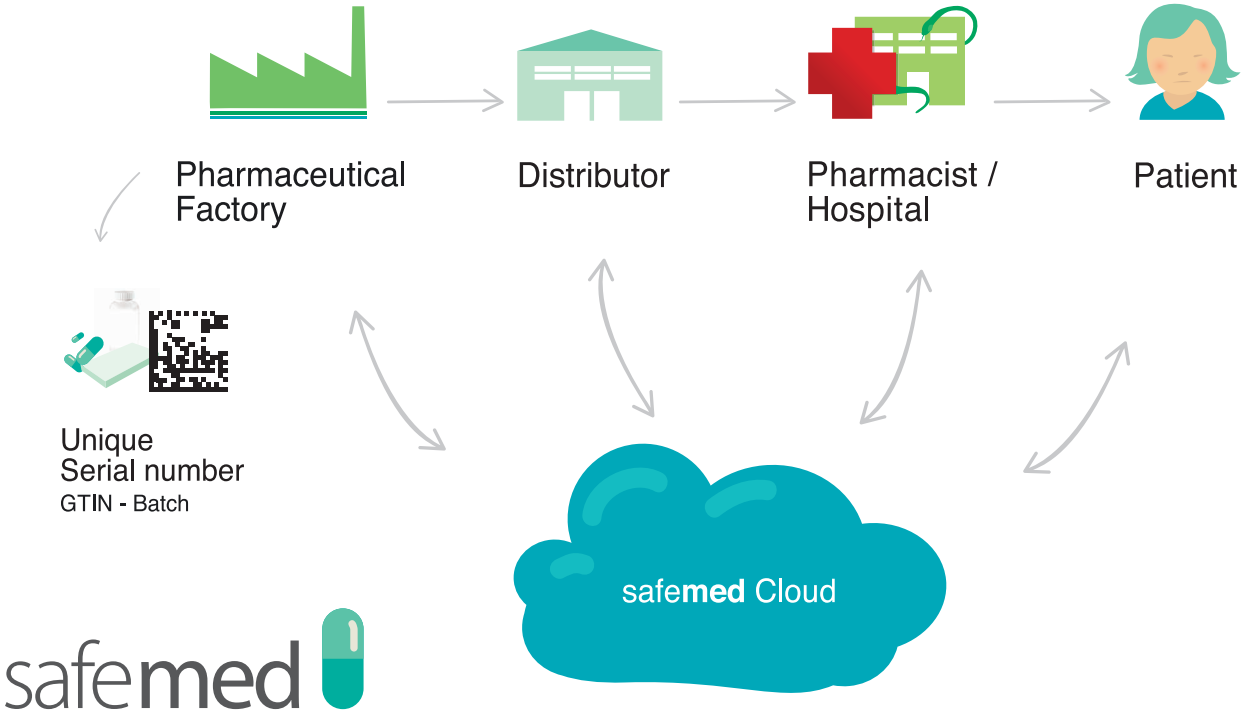
GS1 Egypt supported all participants with the implementation of GS1 Standards (Figure 1), in particular the Auto Identification and Data Capture (AIDC) and healthcare traceability standards, whilst complying with the local regulatory requirements.

GS1 DataMatrix was the key data carrier adopted for the pilot. It was chosen as it is emerging across the world as the preferred data carrier in healthcare, due to the fact that it can hold the same amount of data as a linear data carrier (e.g. GS1-128) but takes up less space (Figure 2) whilst providing error detection and correction capabilities. This approach is aligned with developments in other parts of the world (e.g. Turkey, Korea, Argentina, Europe).


**Figure 2**: GS1-128 and DataMatrix

For this pilot the GS1 DataMatrix was structured to carry four data element strings with related application identifiers (AIs), as follows:

- GTIN (Global Trade Item Number) AI (01) - unique identification for the manufactured drug Blokatens and Utopia Pharmaceuticals
- Expiration Date AI (17) – as determined by the manufacturer
- Batch Number AI (10) – the product control number
- Random Serial Number AI (21) – randomised, non-sequential event serialisation for every single pack




## Process description

- In the production phase, the manufacturer's production line Enterprise Resource Planning (ERP) system was programmed to print the GS1 DataMatrix bar code symbols on the product packaging and upload the 4 data elements (GTIN, Expiration Date, Batch No. and Serial No.) and related information (e.g. active ingredient and/or drug specifications) to the Safemed platform
- When product cartons and/or pallets were dispatched from the manufacturer (to a distributor for example) all related information about that consignment was shared and accessed by trading partners registered to use Safemed
- The distributor then accepted the received consignment after checking them on Safemed by scanning the GS1 DataMatrix bar code symbols on the cartons/pallets
- After that, the distributor performed various internal operations (e.g. Mixing/Separating/Dividing boxes as per order), while uploading all modified data to Safemed. Safemed generated another authenticity confirmation so that the products could be shipped. The modified data was then shared with trading partners downstream (e.g. sub-distributors and/or retail pharmacies)
- Finally, the pharmacy received cartons/packages from the distributor and checked the Serial Numbers on Safemed. The bar code was scanned once more when the medicine was sold to the patient. This dispatched Serial Number was then marked as "Sold" in Safemed to overcome the problem of returns facing the pharmacy and the distributor

## Pilot counterfeit scenario

A total of 60 packages of Blokatens supplied by Utopia Pharmaceuticals were included in the pilot.

- 50 packages were aggregated into two cartons and their data uploaded to Safemed
- The remaining 10 packages acted as "counterfeits" to test Safemed and its traceability process and their data were not uploaded to Safemed

The "counterfeit" packages were brought back to the pharmacy by a made-up "distributor". As the pharmacist could not authenticate the packages scanned into Safemed, it rejected the delivery.

## Outcomes, concerns and recommendations

The implementation of the Safemed solution, utilising GS1 DataMatrix, enabled traceability. Each participant was able to record, share data and track the movement of the drugs in a timely manner, in and out of their custody directly via Safemed.

The pilot also demonstrated that such standard-based traceability solutions could enable future recall processes, inventory management and financial reconciliation, which will generate further process efficiencies.

Some concerns were raised during the pilot, such as the complexity of coding and printing on the production line, the space required to print the GS1 DataMatrix symbol directly on the packages, and the inexperience of the staff. All these concerns were overcome enabling the Egyptian pharmaceutical stakeholders to realise the positive impact of improving patient safety whilst reducing the plague of counterfeit drugs.

The Egyptian pharmaceutical sector needs to implement essential standard based solutions and supportive track and trace technologies as soon as possible. This is especially true today as counterfeit drugs are spreading on both a local basis and across borders.

## About the authors

*Dr **Alaa Mohamed Afify** is a pharmacist and now owner of Dr. Alaa Pharmacy Chain, which counts 3 retail pharmacies in Egypt. Dr Alaa Mohamed Afify is an experienced healthcare executive and has been a medical representative since 2008.*

*Dr **Mohamed Mabrouk** has a degree in Veterinary Medicine and an MMBA from Missouri State University. Before joining Utopia Pharmaceuticals Egypt in 2007, he started his career as a medical representative at Lilly Egypt, then worked his way up to become the Business Development Manager at Utopia and since 2011, their Business Development Director.*

## About Dr. Alaa Pharmacy

*The pharmacy is one of the local retail pharmacy chains in Cairo. Dr. Alaa Afify, owner of the chain, is extremely concerned about the counterfeit problem in Egypt and is working to help overcome this challenge through enhancing transactions' efficiency and security along the chain.*

## About Utopia Pharmaceuticals (S.A.E)

*The company was established in 2008 as a specialised company in the field of pharmaceuticals manufacture and health care. Utopia Pharmaceuticals produces more than 40 pharmaceutical products, which are available on the Egyptian market and Kingdom of Saudi Arabia. Such a regional supply chain has pushed Utopia Pharmaceuticals towards searching among newly adopted pharma best practices and concepts, especially those related to counterfeit of drugs.*