

Afinitor® Track & Trace Case Study

- Authentik Assists Novartis Pharma Pakistan Limited in meeting Drug Regulatory Authority of Pakistan (DRAP) SRO 470(i)/2017 with upgraded labeling rules
- Authentik – Afinitor® is a Track & Trace success story in Pakistan
- Authentik is Transforming the Healthcare Supply Chain & Patient Safety in Pakistan

Abstract:

The healthcare sector in Pakistan is a major part of the economy, as there are about 66,000 pharmaceutical products registered and manufactured in Pakistan 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 Pakistan, 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 Pakistan consists of: manufacturers, distributors, hospitals and retail pharmacies, and finally, the patient. There are more than 700 pharmaceutical companies in Pakistan.

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.

Authentik's solution assisted Novartis Pharmaceutical Pakistan Limited, one of the leading pharmaceutical companies in Pakistan, in meeting the new DRAP SRO 470(i)/2017 regulations for labeling and drugs in Pakistan to sure curb grey and counterfeit market.

Customer Background:

Novartis Pharma Pakistan Limited (NPPL) is a world leader in the research and development of products to protect and improve health and well-being. Being one of the largest Pharmaceutical products manufacturer in Pakistan,

As a continued commitment to patient safety, NPPL operates in a highly regulated environment by applying CGMP (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.

NPPL has been one of the pioneer innovators within the pharmaceutical field in Pakistan. The company was the first to develop and produce Psychotropic Medicinal group as well as Broad Spectrum Anti Biotic and Inflammatory products.

One of the Major portfolio NPPL in Pakistan holds is the Oncology Products.

Challenge:

The DRAP regulation required that requires all pharmaceutical products produced in Pakistan to have standardized identification and automated tracking of products using a GS1 Data Matrix that includes encoded with a GS1 Data Matrix that includes: (GTIN, Expiry Date, Batch Number, Serial Number). Since NPPL Pharma is one of the main producers of pharmaceutical product in the Pakistani market, complying with these regulations will require NPPL to implement changes to upgrade and expand their identification and serialization programs as outlined in the new DRAP SRO 470(i)/2017 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 and to encode the random serialization required for the next phase of the regulation.

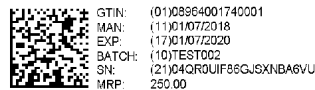
Afinitor®, being one of the key drugs used in Oncology treatment, is imported from Basel, Germany for sale in Pakistan. Due to the implementation of the DRAP SRO 470(i)/2017, NPPL needed to implement Serialization Labeling on the SKU without damaging or defacing the labels.

Counterfeit and Grey Market was a major threat to the NPPL supply chain in Pakistan. Not only it negatively impacted the sales, it created a major Patient Safety risk in the local market.

Solution:

Authentik 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. This in preparation for the new DRAP SRO 470(i)/2017, Authentik had proposed a comprehensive solution to NPPL to help meet the requirement and timelines of the new labeling regulation. The solution consisted of multiple consultation session with NPPL production managers to them adopt and implement GS1 Data Matrix to meeting the DRAP regulation in the most efficient way possible.

The Authentik application, which is available on iOS and Android Playstore, is integrated as per GS1 Global Standards with the serialization solution deployed at NPPL, allows Patient or Care Givers to ensure that the medicine procured is from NPPL and are not exposed to any Grey Market or Counterfeit products.



NPPL was able to identify Grey products and had the taken off the shelves due to Authentik's Track & Trace and Ant-Counterfeit Solution. This resulted in better market penetration and improved patient safety.

Benefits:

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

- Increase the protection of patients from falsified, expired or recalled medicine
- Improve customer confidence: physician, pharmacist and patient
- Help Law enforcement combat drug counterfeiting
- Prepare NPPL to meeting regulatory compliance requirements
- Enable medicine traceability
- Increase the visibility of medicine across supply chain
- Improve the efficiency of the medicine recall process
- Helps company gain greater insight in the demand pattern and inventory management.

Conclusion:

The Pakistan pharmaceutical sector is in the need of implementing essential starts based solution and supporting track and trace technologies. This is especially true today as counterfeit drugs are spreading on both the local bases and across borders and many regions around the world continue to pass and enforce laws and regulation for product identification and traceability.

Authentik's Track & Trace and Anti-Counterfeit solution offer a unique opportunity for practical application of data standards that make the pharmaceutical supply chain safe and more efficient. It provides standard portfolio of data carriers that enable standardized identification and automated tracking of products, in the form of barcodes that capture the information and a way to share the data among each stakeholder of the supply chain.

Authentik continuously invests in efforts to engaging manufacturers in collaboration with GS1 Pakistan whose products have not been yet equipped with barcodes, in view that barcodes are becoming mandatory on primary, secondary and tertiary packaging in the future.

About Authentik:

Authentik specializes in Track & Trace Solutions with core focus on Anti-Counterfeiting strategies and Supply Chain visibility. Authentik's Research & Development team constantly efforts to adapt and enhance its solution for Track & Trace and Anti-Counterfeit Solutions.

Our solutions equip companies with the right tools and market expertise to enhance their anti-counterfeiting strategies and optimize supply chain logistics.

Our solutions enable efficient monitoring and documentation of the distribution channels, to hamper and prevent counterfeiting, as well as to protect and secure various

transactions. We help make customer king with ability to know what they are buying.

Authentik develops innovative and practice-proven systems, including hardware and software components. Our product

portfolio ranges from complete systems for the production through technologies for the serialization, late stage customization of packaging, and track & trace for the Pharma, Food, FMCG and Petroleum Sector.

Authentik's Client Base:



Authentik's Hardware Partners:



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