

Bosch PharmaTrace

A FMD compliant solution for the pharmaceutical supply chain powered by IoT and blockchain



Agenda

1. The business case: current situation and challenges
2. Customer needs
3. Applications of PharmaTrace in the drug supply chain
4. Our Assets
5. Our value proposition
6. Harnessing Azures services

The huge size, high impact on lives and steep rise of the counterfeit drugs market are major drivers for various drug security regulations

\$200 bn

size of the global counterfeit drugs market

SIZE

~1 mn

lives lost annually due to consumption of counterfeit drugs

IMPACT

Antibiotics

Most counterfeited drugs segment and often prescribed

100X

Growth in counterfeiting in the past two decades

RISE

FMD implementation & Business challenges for value chain players



FALSIFIED MEDICAL DIRECTIVES



- ▶ **Product identification-** Serialization of medicine packages/shipments with unique identification
- ▶ **Product tracing:** An interoperable system to trace drugs distributed within Europe, securely exchange product information across the supply chain
- ▶ **Product Returns:** A system to verify requests for drug authenticity in case of product returns / recalls and notify counterfeit instances to trading partners.

CHALLENGES



- ▶ **Re-imagining** of the current business processes subsequent to the implementation of the Act
- ▶ **Implementation** of new business rules and integration into existing IT systems with minimum change management
- ▶ Need for an **interoperable solution** to establish traceability across the supply chain
- ▶ Cost effective and efficient **supply chain management and reporting**

EU's **Falsified Medicines Directive (FMD)** : For verification of the authenticity and identification of individual packs and provide evidence of tampering.

Impact of Falsified medical directives on the value chain stakeholders



1 Patient

- ▶ Safeguarding patient lives, health and well being

2 Pharma company

- ▶ Brand protection against counterfeits, market recalls
- ▶ Serialization implementation
- ▶ Supply chain control and traceability
- ▶ Condition monitoring of vaccines and specific drugs
- ▶ Compliance reporting

3 Distributor

- ▶ Product serialization
- ▶ Seamless payment contract management
- ▶ Condition monitoring of vaccines and specific drugs
- ▶ Compliance reporting

4 Dispenser

- ▶ Product traceability – origin and ownership
- ▶ Availability of medicines- avoiding stock outs
- ▶ Track of all change of hands of all serializable units
- ▶ Condition monitoring of vaccines and specific drugs
- ▶ Compliance reporting

5 Regulators

- ▶ Ensure population health and public safety
- ▶ Proper data availability on traceability of each serializable unit in the drug supply chain
- ▶ Compliance trail

6 3P Logistics

- ▶ Condition monitoring
- ▶ Certification management and compliance reporting
- ▶ Regulation compliance (FMD) – traceability of all drugs in forward logistics and saleable returns



Track and trace of prescription medicines

Provides end-to-end supply chain visibility through standardized serialization of blister packs, SKUs, pallets, shipment and associated carriers from manufacturing through distribution to end-customers



Implementation of serialization from the smallest blister pack to the shipment and the carrier using **GS1 standard barcode** for unique identity. (Global Location Number, Global Trade Item Number, Lot number, batch number, Serial Shipping Container Code)

Implementation of an interoperable and secure blockchain system to keep track of the product flow throughout the supply chain

Real time tracking by raising flags in case of counterfeit suspect enforced by incentivization of value chain stakeholders

Real time verification and validation of registered assets with the regulator's database thereby ensuring robust leakage detection and control mechanism



Saleable Returns

Fast, robust and secure verification and management of the saleable returns of pharmaceutical drugs in compliance with the Falsified medical directives.



Saleable returns are created by dispensers/retailers due to:

1. Discontinuation of the product, thereby returning old for stocking new product lines,
2. In the case of over stocking by the pharmacy, where extra inventory needs to be returned.

FMD mandates that all saleable returns should be verifiable. Hence, PharmaTrace provides real time, secure verification of the product returned by the pharmacy to the distributor/wholesaler.

PharmaTrace provides interoperability so that wholesalers and distributors can easily verify barcodes with the manufacturer's database and flags as well as logs transactions that are suspicious.



Condition monitoring

Communicates with the IoT condition monitoring device to keep track of the cold storage parameters and reports adverse events to regulators and relevant stakeholders.



The PharmaTrace blockchain platform is capable of interacting with the condition monitoring IoT device placed in the cold storage containers—large cold storages, refrigerators, vehicles, etc.

This use case is relevant for drugs that need to be stored under prescribed temperature, pressure, humidity, etc. E.g. Vaccines, photosensitive drugs

In case of any breaches, PharmaTrace's autonomous agents raise flags, log into the system and reports it to the relevant stakeholders.

The in-built track and trace mechanism then allows removal of spoiled medicines from the supply chain system



Certificate Management

Digitizes paper based documents and allows it to be shared across the network for faster information flow, an efficient supply chain and fraud prevention



Digitization of compliance certificates and supply chain documents like invoices, e-bill of lading, title of ownership, customs clearances, bank letters of credit etc.

Selective sharing of digital assets with relevant stakeholders like pharma company, distributors wholesalers and dispensers for compliance and completeness of the process

Seamless process optimization and faster payment cycles solves the problem of inefficiencies, forgery and large account receivables.

Tracks every detail of the document and keeps tab of all changes made to it in order to avoid malpractices.

Bosch Assets



Digital Identity Agents

- Reads information of the drug package on scanning
- Verifies the meta-data properties of the drug from EPCIS database via Verification Router Service (VRS)
- Triggers smart contract execution on the DLT through smart contract agents
- Available at all scanning end points of all the supply chain stakeholders



Smart Contract Agents

- Communicates with Digital Identity agents and IoT agents to execute smart contracts on the ledger
- Takes necessary actions in case of condition anomalies
- Records the defined information into the ledger as per the smart contracts.
- Stores change of ownership from manufacturing to point of sale and into the ledger



IoT Agents

- Works with any IoT device - Bosch TDL and non-Bosch devices
- Used for condition monitoring
- Monitors up to 9 different parameters - temperature, humidity, pressure, acceleration, etc.
- Energy efficient connectivity
- Supports different connectivity protocols such as BLE, LTE, MQTT etc.



Digital feedback & AI

- Indicates progress, re-inforce actions
- Monitors condition of IoT devices
- Ensures predictive maintenance of IoT devices
- Drug Stock Optimization
- Drug Replenishment Optimization
- Descriptive Analytics



DLT network

- Maintains forward and return as well as condition traceability and makes it available across the value chain
- Effective returns verification and immutable traceability across the supply chain
- Manages digital certificates in immutable and interoperable way
- Autonomously governs the decentralized, distributed network

Bosch's value proposition



BLOCKCHAIN ENABLED HARDWARE

Automation of shared business processes with the convergence of IoT and Blockchain where our Blockchain enabled Hardware automates the smart contracts.



INTELLIGENCE

The autonomous agents on our blockchain platform deliver autonomy to our edge devices by qualifying them to perform machine to machine settlements.



INTEGRATION

Tight integration of digital and physical identity – leading to higher accuracy and immediate consensus. Easy integration with the existing IT infrastructure.



FMD COMPLIANCE

Our solution equips value chain players to implement the various upcoming drug security regulations like the FMD in the Europe.



TRACEABILITY & SAFETY

Securing the global supply chain through serialization, traceability and data interoperability to track the safe movement of pharmaceutical drugs.

Harnessing Azure services



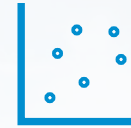
Integration to
speed data into
cloud



Storage to
scale without
latency



Visualizations
to surface
insights



Analytics to
predict and
plan



Security to
protect data



Ready to experience the power of blockchain and transform your business in compliance with the FMD?

- We will connect you with the Bosch PharmaTrace sales team: bhuvan.Shetty@de.bosch.com
- Learn more: bosch-india-software.com

