

# *Accurate, audited and secure*

## How blockchain could strengthen the pharmaceutical supply chain

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# Introduction

*We live in a society where we question everything. When making a purchase we want to know if we are getting our money's worth. Where has the product come from? Who made it? What is it made from? These questions are also relevant in healthcare where pharmacists and others are trying to source medication.*

*The pharmaceutical supply chain has its weaknesses. Pharmacists must only sell or supply medicines that are purchased from a reputable source where appropriate distribution processes are followed and they must be sure that the medicines are fit for purpose. Sourcing products becomes an obstacle course of issues where trust has to be placed in the supplier and pharmacists have to be sure that the medicine is fit for purpose and has been securely stored and transported. With an ever increasing counterfeit medicine market as well as cases of medication not being labelled correctly, supply chain becomes an issue for everyone. And, as the focus for healthcare moves to a more community focussed setting and more responsibility is placed on patients to take control of their own health, supply chain will be a factor for patients looking for transparency and keen to ensure they are receiving the highest quality product.*

*Safety features for medicines, due to come into force in 2019, has made the industry take more notice of the issues within the supply chain particularly how the threat posed by the counterfeit market. The Falsified Medicines Directive (FMD) will change the prescription journey relieving some of the pressures of healthcare professionals in ensuring medicines are of the highest quality and from reputable sources. But key issues around cyber security and storage conditions remain.*



# Supply chain issues

## Falsified drugs

When John collects his prescription from Emma the pharmacist he assumes that the medication will be authentic, the quality of the product is of the highest standard, the product has not been tampered with and has been stored in the appropriate conditions. But falsified drugs can enter the supply chain. This is a very real threat that Emma must consider.

Falsified drugs include those:

- With little or no active ingredient;
- The wrong ingredients;
- Fake packaging;
- Tampered drugs;
- Stolen drugs.

## Product quality and authenticity

How can Emma tell if the medicine has been stored correctly throughout its journey to her pharmacy or if the tablet contains the correct quantity or strength of the drug. She must rely on the manufacturer, wholesaler and courier to have the appropriate procedures in place. At the end of the journey Emma must ensure the product the correct standard for release to the patient. But the journey of the drug is not totally transparent and Emma would need to spend significant time going through an audit trail to ensure the tablets are of the correct standard and quality.

The pharmacy supply chain involves many different parties any of which can affect the final product:

- **Manufacturers** must ensure tablets are of the correct strength, appropriate formulation and have been stored correctly and medication is fit for human use;
- **Wholesalers or suppliers and logistics companies** must ensure that the products are not destroyed by temperature or humidity as well as preventing criminals intercepting the drugs and either tampering with them or stealing them.

From John's perspective, the weaknesses in the current supply chain affect the trust between John and his medication. If he cannot trust where his medication has come from, he may stop taking it which could have detrimental effects to his health.



# How blockchain can make a difference

Currently the medicine verification system and the supply chain must meet the following criteria:

- Allow multiple parties to update data;
- Allow multiple parties to share data;
- Verification to ensure that the information can be trusted;
- Interaction with national and European medicines verification system to allow all parties to have visibility in the drug authenticity.

There are significant issues within the current system however:

A blockchain solution can make a substantive difference to the pharmaceutical supply chain. At every stage of the process, barcodes would be scanned and recorded onto a blockchain ledger system which, in turn, records and creates an audit trail of the drug journey. Sensors can also be incorporated into the supply chain, with temperature or humidity being recorded onto the ledger system. This is particularly important for drugs requiring fridge storage, such as insulin or expensive specially manufactured medicines. When the drug reaches the pharmacy, Emma can tell through the blockchain audit trail, if the drug has been compromised at any point of the journey. Even as Emma dispenses the prescription, biometric measures can be used to record the dispenser and pharmacist checking the prescription. This can all be recorded onto the ledger, allowing drugs to be tracked from the moment of creation to the moment the patient takes the drug home.

Using a blockchain solution many advantages could be realised:

- Reduced complexity and costs:
  - Supply chain becomes traceable and drugs are easier to track
  - Information systems will hold expiry date details which improves stock control and rotation
- Reduces errors:
  - Drugs can be verified and authenticity can be ensured
  - Patient harm is reduced as drug checks are improved
- Enhances security:
  - Counterfeit drugs are minimised
  - Patient harm is reduced
  - Data is kept safe
- Proven resilience:
  - The system's data will remain protected

- Intermediaries add complexity – the more parties involved in handling the medication, the higher the risk of interception or damage;
- Interactions are time sensitive – drugs must be delivered within a good timeframe as pharmacists need to be able to provide a quick service to patients;
- Manufacturers, logistic companies, wholesale and pharmacies may not be able to offer complete visibility on the authenticity of the drug whilst ensuring quality has remained intact.

- Shared, trusted transactions:
  - All parties are able to access the drug information when needed to ensure the quality of the drug being dispensed
  - Parties must be able to trust the data as it determines if a drug can be dispensed
- Creates an audit trail:
  - Drugs are easily traced making recalls easier
  - Parties can see if the process has become compromised at any point
- Enhances transparency between authorised parties:
  - All parties can see every stage of the drug journey to ensure the drug authenticity
  - Regulators, such as pharmacy inspectors, can monitor the rate of counterfeit drugs entering the supply chain, with more accuracy

Through the use of blockchain, the drug journey can become more secure and streamlined. Every delivery can be tracked, with the delivery driver traced through biometric measures. Every checkpoint involving the drug is recorded and traced via biometric measures, 2d barcode scans or sensor technology. As the drug is tracked from creation to patient, the whole of the drug journey becomes seamless, accurate, audited and secure. Emma can ensure that the drug she is providing to John is of the highest quality and has not been damaged or destroyed. John can take comfort in the knowledge that the supply chain has been recorded at every stage and the drug is authentic. As the supply chain is visible, John can see where his drug has come from, who made it and what it is made from, giving John more responsibility and control over his own health and treatment. This could aid in John complying with his medication and treatment regimen, hence living a longer life.



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