

# How Blockchains Could Save Patients' Lives

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**For pharmaceutical companies, blockchain could soon enough become vital. The public perception of this technology has undergone an exciting development over the recent years - from a complex playground for software developers to a solution for all kinds of challenges up to a money-burning gambling machine. Now that the hype seems to have levelled off, inspiring and feasible use cases are developing fast and are expected to be a real game changer for business between untrusted parties. But how can blockchain technology contribute to preventing the rise of counterfeit drugs? And why has even the FDA selected it as one of the most promising technologies to achieve this goal?**

## **Fake drugs - a global challenge for patients and drug manufacturer**

Fake drugs, also called counterfeit drugs, are an increasing challenge for the global society. At best, these “pills” are only ineffective. However, ineffective vital drugs for chronic diseases can cause severe damage, and many fake drugs even contain potentially harmful and sometimes even life-threatening substances. This is not only a local, but a global problem as indicated by numbers from the WHO: According to a [report](#) published in 2010, more than 1 million people die from counterfeit drugs every year.

Although Africa and Asia are affected most severely with up to 30 % of all drugs sold being fake, counterfeit drugs have become an increasing challenge for the western world as well. Latest numbers estimate the annual market volume lost through [counterfeit drugs at more than € 73 billion](#). Especially when buying drugs over the internet patients should be cautious. According to the WHO, more than 50 % of supplies distributed by internet pharmacies without appropriate certifications are counterfeit. These include not only over-the-counter drugs or substances for erectile dysfunctions. There is also a tremendous market for fake lifesaving prescription, or Rx, drugs.

The booming e-commerce business for pharmaceutical products, for example by Amazon's growing healthcare platform ([see our previous blog article](#)), will further boost the spread of fake drugs in the western world. Counterfeit drugs not only cause immense harm to patients, they also severely affect drug manufacturers. Besides missing out on revenue from unsold original products they also suffer from the negative reputation provoked by faked drugs and their adverse effects on patients.

This ever-growing challenge raises the question of how to safeguard the authenticity of drugs

along the pharma supply chain – all the way from the manufacturer to the patient. For years, producers have been improving packaging through increasingly sophisticated approaches such as holograms and imprint codes. Their success, however, has been limited. Current counterfeit blisters and packaging are often hard to distinguish from the original product, even for trained personnel (see Fig. 1).



Which one is the counterfeit product? Source:

[Bayer.com](http://Bayer.com)

## The Drug Supply Chain Security Act (DSCSA) - FDA's approach to fight counterfeit drugs

In order to address this global challenge with a top-down approach, the FDA launched a 10-years program as early as in 2013, the Drug Supply Chain Security Act (DSCSA). It defines a set of guidelines for all stakeholders of the drug supply chain to enable a safe end-to-end delivery of authentic Rx drugs. Importantly, these guidelines not only affect US-based drug makers. All manufacturers serving the US market have to be compliant with the guidelines, independent of the company's provenance. Consequently, the DSCSA has gained a lot of attention from pharmaceutical companies across the globe. The different milestones are described in Fig. 2.

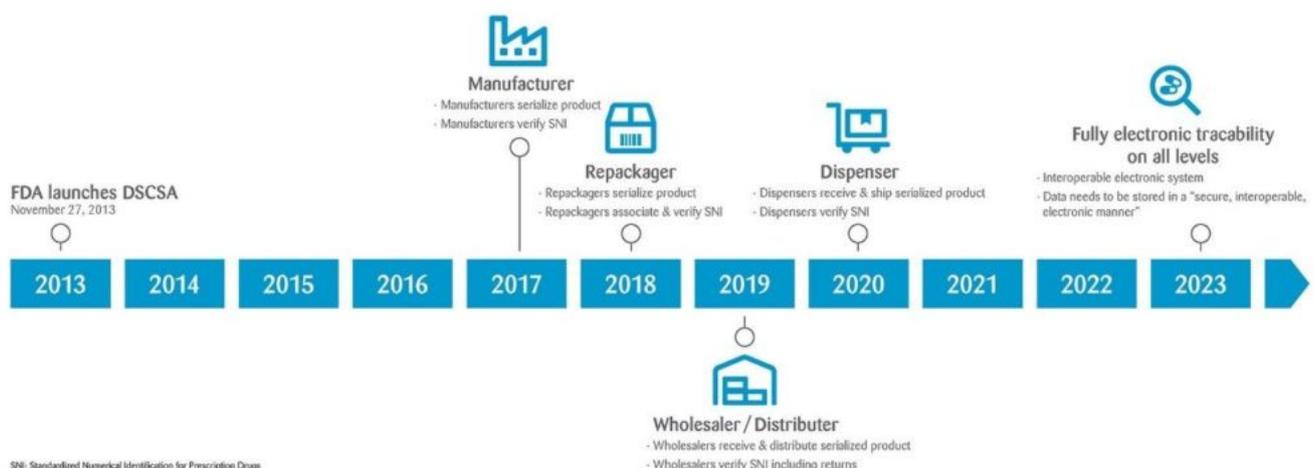


Figure 2: FDA's DSCSA Timeline for to fight anti-counterfeit drugs. In 2023, all stakeholders of the drug supply chain need to participate in an interoperable electronic system, likely based on the blockchain technology.

We have mapped out three main aspects that the DSCSA standard requires to have been implemented by 2023:

- **Serialization:** The smallest sellable unit of a product has to be labelled with a national drug code (NDC) and a unique 2D-data-matrix-code, comprising four data elements – a product identifier, a serial number, a batch number, and an expiry date.
- **Verification:** Serial numbers must be verified if a returned product is sold back into the commercial supply chain or as a consequence of the examination of suspicious or inadmissible products.

- **Electronic exchange of information between trade partners:**

The transaction data has to be shared with all trade partners electronically as part of the transfer of ownership between stakeholders. Key data include information about the transaction history and the transaction statement.

Since the FDA requires an interoperable, electronically traceable pharmaceutical supply chain, it is important for European pharma companies to get familiar with potential digital solutions now to achieve DSCSA compliance by 2023. However, the question remains which of the technologies is the most promising.

### **Blockchain - a promising technology for a safe digital pharma supply chain**

In February 2019, the FDA [announced](#) a pilot project to explore and evaluate innovative digital technologies for its electronic tracing system. One of the potential candidates for such a solution is blockchain. This technology offers data transparency and mediates collaboration between different untrusted parties including manufacturers, re-packagers, wholesalers, hospitals and pharmacies through its trustless and digital nature.

In our opinion, there are three main benefits to blockchain adoption for pharmaceutical companies:

- **Blockchain enables trustless trust:** The role of trust amongst all stakeholders changes. Whereas it used to be vital for all business partners to have immense levels of trust in one another, it is now more important to trust in the system, more specifically in the decentralized platform.
- **Blockchain creates an immutable transaction registry:** Blockchain allows for an immutable registry of data and transactions that is transparent to all participants along the supply chain as well as for governmental authorities. Thus, blockchain ensures auditability and, hence, regulatory compliance and verifiability of the authenticity of drugs.
- **Exploring further use cases:** Familiarizing oneself with blockchain facilitates further

exploration of potential use cases and application areas beyond DSCSA compliance through a deeper understanding of the technology.

Meanwhile, we also see challenges that need to be overcome in order to facilitate blockchain adoption. The most relevant are:

- **The physical-digital world intersection:** At the intersection of physical products like medicine and the digital world, there is always a certain degree of susceptibility to failure. Sensors may be tampered and scanning devices used in the authentication process could potentially be hacked. While this is an issue that needs to be considered whenever there is an intersection of the physical and digital world, this vulnerability is not exclusive to blockchain application.
- **The lack of a gold standard:** Blockchain is still relatively immature. Consequently, a “gold standard” yet remains to be established. This may lead to certain levels of uncertainty on the one hand, but also allows early adopters to shape such standards – for example with regards to governance – for the future.
- **A matter of mindset:** One of the main benefits of blockchain arises out of its network character. Contrary to the prevailing business mindset, blockchain adoption requires sharing information with different stakeholders: suppliers, clients and customers, competitors, and service providers. Thereby, who gets access to what extent of which data depends on the specific use case.

### **Which Blockchain should I choose?**

There is a variety of blockchain providers out there – and the number appears to be growing by the day. It may seem quite overwhelming having to choose between the different platforms. In the case of supply chains, experts often rate Ethereum and Hyperledger as the most beneficial and mature candidates. While Ethereum is a public, decentralized, and mature platform that is not controlled by a governing entity, Hyperledger also allows for permissioned solutions in which only selected entities can participate.

This difference notwithstanding, both networks allow for smart contracts – computer protocols that enable automated, self-executing contractual clauses. Therefore, which of the two to choose depends largely on one’s specific demands: is it, for example, a mere business-to-business application or should patients be included? In the latter case, we see Ethereum as one of the best contenders, as it allows patients to participate on the platform and check whether their drugs are legit without having to “manually” extend the network to consumers. If you are interested in further details about the different blockchain technologies, feel free to contact us at any times.

### **Competitive advantage by getting familiar now with digital supply chain solutions**

Pharmaceutical companies across the globe are currently adapting their processes to the

progressing DSCSA standards. For a fully digital traceability of drugs, potential digital technologies including blockchain have to be evaluated. It remains to be seen which technology will win the race to become the new standard for the drug supply chain. However, one thing is clear: by 2023, the FDA demands a digital solution. Hence, it is crucial to get familiar now with potential solutions in order to facilitate a fast implementation and integration.