



A BLOCKCHAIN BASED FRAMEWORK TO MONITOR THE USE AND HANDLING OF THE CONTROLLED SUBSTANCES

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ABSTRACT A controlled substance is a drug which is not legitimate, and which has damaging effect on mankind. National and state administration and governments take utmost care to regulate these controlled substances. But production or usage of these substances are not always illegal. Since these drugs are sometimes prescribed by medical practitioners for various genuine treatment purposes and are also available through pharmacies. All entities who manufacture, procure, distribute and sell the controlled substances have to send detailed reports to the Drug Enforcement Agencies (DEA) at regular intervals. Instead of different parties in the supply chain sending individual reports to the DEA, these movement of the controlled substances should be tracked in a Blockchain environment so that without the manual reporting from different sources a complete tamper proof history can be maintained. DEA would be able to get the full traceability of the controlled substances from the point of manufacturing to the point of consumption. This product lifecycle would be transparent to all the stakeholders in the supply chain to get better visibility about the source and end consumer of the product.

KEYWORDS : Controlled Substances, Blockchain, DEA, Medicine Supply Chain, Narcotics

INTRODUCTION

A controlled substance is usually a drug or chemical which has strict protocols for production, ownership, or usage and is strictly controlled by a government. These can be classified as unlawfully used drugs or prescription medicines. These controlled substances have many negative bearings in the society. One of them is drug overdose. Drug overdose is the primary reason of death due to injury or damage in many countries like United States (Paulozi et al., 2015). The other important problem related to usage of controlled substances are their side-effects on human body. More and more prescriptions of controlled substances are being written for healing different types of long-lasting ailments with critical settings. The controlled substances help in acute pain and hence they are commonly used in such situations (Benyamin et al., 2008). But usage of these substances in medication lead to problems like tolerance which are of two types innate and acquired. The acquired tolerance happens due to change drug metabolism after recurrent drug administration (Collett, 1998). The repetitive use of controlled substances damages the immunity system and these people can be more susceptible to chronic diseases. Studies have shown that heroine addicts are more prone to HIV virus (Benyamin et al., 2008). Another problem of using these controlled substances is sleep disturbances. Use of controlled substances increase the number of sleep-waking state swings (Koren et al., 2006) and reduce total sleep time and sleep efficiency (Kurz & Sessler, 2003). The substances also have side-effects on bowel and bladder dysfunction (O'Riordan et al., 2000). Substances like Morphine have adverse effects in cardiac side and hypotension (Brunton et al., 2006). Hence it is critical to understand the production and consumption of such type of substances.

As per United Nations (UN) controlled substance policy, US and other countries have their own Drug Enforcement Agencies (DEA) to regulate and monitor the use and handling of the controlled substances. Two UN conventions held in 1961 and 1971 on narcotic substances and psychotropic drugs respectively planned to confirm satisfactory accessibility of controlled substances for legitimate purposes like medical treatment and scientific research, but at the same time ensuring the stoppage or leakage of legal production bypassing to the illegitimate market. But these conventions were only partially successful. They could not challenge the universal growth of these drugs and chemicals in manufacturing, selling and consuming illegally. Hence in 1990 UN called for a United Nations General Assembly Special Session (UNGASS) on drug abuse 19. This session asked for a declaration by the administrative heads of different countries to shield and rescue the society from the illegal possession, distribution and consumption of controlled substances (Jelsma, 2016). As a result of these conventions many new and important laws came into force. The regulators must monitor the use and handling of these substances. Illegal possession of controlled substance would lead to monetary penalty and imprisonment under various section of law enforcement and all entities who manufacture, procure, distribute and

sell the controlled substances have to send detailed reports to the DEA at regular intervals. The idea is to have a complete visibility of the controlled drug right from the manufacturing point to the point of consumption by the patients. In that way the DEA would be having a full visibility of the life cycle of the controlled drug - who manufactured it, who procured it, who distributed it, who prescribed it to whom and who is consuming it. To report the controlled drugs transaction done in different ERP solutions, all pharma companies must develop a custom solution which involves huge cost and effort. The DEA solution in one of the pharma companies took around six months to develop and test. Instead of different parties in the supply chain sending individual reports to the DEA, these movement of the Controlled Substances could be tracked in a Blockchain environment so that these type of manual reporting from different sources could be replaced with a more immutable solution. DEA would be able to get the full traceability of the controlled substances from the point of manufacturing to the point of consumption. This product lifecycle would be transparent to all the stakeholders in the supply chain to get better visibility about the source and end consumer of the product.

FRAMEWORK

Frequently called the chain of trust, Blockchain technology is a distributed system recording and storing transaction records. More specifically Blockchain is a shared, immutable record of peer-to-peer transactions built from linked transaction blocks and stored in a digital ledger. It has the capability to support and sustain the modern-day transaction applications and capacity to streamline business processes by establishing trust, accountability and transparency. What TCP/IP has been for the exchange of information, Blockchain can be for the exchange of value. It provides a decentralized peer-to-peer architecture with nodes consisting of market participants and uses a protocol that peers validate and commit transactions in order to reach consensus. It is built on four pillars, Shared Ledger - Append-only distributed system of record shared across business network, Smart Contract - Business terms embedded in transaction DB and executed with transactions, Privacy - Ensuring appropriate visibility, transactions are secure, authenticated, and verifiable, Consensus - All parties agree to network-verified transactions.

Each event or transaction is time stamped and becomes a permanent record that cannot be tampered with later (Chen et al., 2019). Blockchain should be used to store important piece of information as it is a proof of existence of any piece of data and when stored, it is immutable (Benchoufi et al., 2017).

Blockchain Nodes

In this framework or architecture, a government narcotic department or drug approvers like FDA can work as the regulator and the main Blockchain node or master-node. Master-nodes are typically more equipped than normal nodes. Apart from validating, saving and broadcasting transactions, master-nodes often facilitate other events

on the blockchain dependent on their nature like leading voting events, giving implementation of protocol operations and applying the laws according to the blockchain (Jimi, 2018). Other nodes would be comprised of controlled substance manufacturers like pharmaceutical companies, their distributors and retail outlets which sells the controlled substances. Nodes are any kind of device such as computers or servers. Nodes create the infrastructure of a blockchain. Every node on a blockchain is connected to each other and they constantly exchange the latest blockchain transactions such that all nodes stay up to date. They store, spread and preserve the transactions, hence theoretically a blockchain exists on nodes.

Smart Contract

A smart contract is an executable program or code that runs on the blockchain to enable, accomplish and impose the terms of an agreement among untrusted parties. It can be thought of as a system that releases digital assets to all or some of the involved parties once the pre-defined rules have been met. Unlike the traditional contracts, smart contracts do not depend on a trusted third party to operate, resulting in low transaction costs. There are multiple blockchain platforms that might be utilized to develop smart contracts, like Ethereum, Hyperledger etc. (Alharby & Van Moorsel, 2017). The smart contracts would be the traceability and provenance rules for manufacturers, dealers, distributors and retailers. The smart contract rules will be designed to make the process as much full-proof as possible to make the process automated. But there would be exceptional scenarios which needs to be handled manually, but still blockchain would record that transaction. Expert opinion is such kind of an exception where a jury of legal authorities would give the final verdict if the reporting process were followed correctly or not. But future audit would get the information from the blockchain tamper-proof history.

The below figure (Figure 1) shows the Blockchain network in this case.

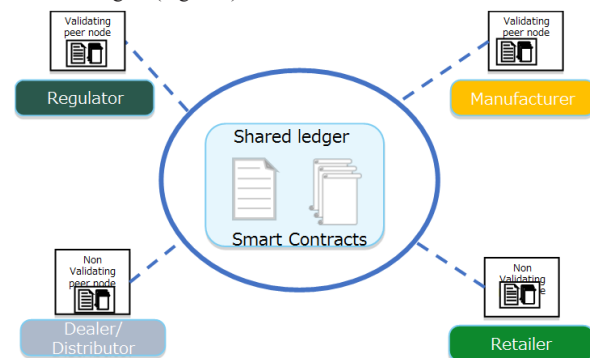


Figure 1: Blockchain network for controlled substance reporting

DISCUSSION

On implementing this idea of having Blockchain to track and monitor the controlled substance have multiple benefits.

Tamper proof

Nobody would be able to tamper the data of which company is distributing the controlled substance, the legitimacy of the distribution, whether it has proper approval, the quantity etc. The distributive ledger will allow the tamper-proof transactions.

Provenance

Provenance of all the Supply Chain points for the entire life-cycle of the product; e.g. Customer might want to know who is the actual manufacturer of the drug, distributors may tune up their forecasting model by getting a better visibility of the end consumers.

Near Real-Time Visibility

The data monitored by DEA would be more transparent and near real-time reducing the lag of reporting. Appropriate action can be taken if any illegitimacy identified anywhere in the transactions.

Cost Reduction

This would reduce the cost of developing, testing and maintaining the expensive custom solutions in SAP and other ERP systems.

CONCLUSION

From the very advent of its journey any business relies on the fundamentals of trust and identity. In simple words they depend on the

tangibility of the things being shared and the person checking and approving them. It was quite easier to do business in those days where business happened in-person and there was nothing called online business. On the other hand, in today's scenario businesses are conducted majorly through online and we need regulators like government agencies, financial institutions and central authorities to verify the identity of each business entity and create an environment of trust among them. However, involvement of these mediators leads to inefficiency in the whole process like higher cost, lower speed and even fraud. Another thing which can also become vulnerable in this context called privacy. Even the central repositories of the regulators can be hacked, and sensitive and private information can become accessible. Hence, Blockchain should be used in such a sensitive and important area of reporting the traceability of the controlled substance supply chain to make it robust and immutable.

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