Whitepaper
On

Securing the Pharmaceutical Supply Chain

Team Phoenix

Team Category: Student

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Abstract

As the economy grows rapidly, one of the toughest challenges Bangladesh is facing is a lack of a solid and secure supply chain system in the pharmaceutical system. Among many reasons, we could identify two main reasons among all of them: lack of accountability in the solid supply chains and of course, lack of knowledge in technologies of the general people, which is entirely creating a new sector for corruption, enhancing counterfeit and inefficiencies. At this moment, counterfeit pharmaceuticals constitute a big hazard since it is impossible for individuals to know the exact worth of acquired medicines due to the current system's substantial lack of transparency. To address this problem, we have come up with a solution, **using blockchains to protect supply chain information and AI to detect frauds in supply chain mainstreams.** Furthermore, interference inside the supply chain is difficult to examine when there is suspicion of unlawful or unethical behavior. The system focuses to minimize the most amount of interference in this sector. Since blockchain stocks all the information to generate a single supply stock, even a single error will not be tolerated hence corruption will be detected on spot. AI systems will work on vendor to client transactions and information exchange to detect frauds and inefficiencies. We have designed our system keeping four goals at hand. Firstly, securing the pharmaceutical supply chain, secondly, keeping track of tax on pharmaceuticals, thirdly, on spot corruption and fraud detection, fourthly, less paperwork, finally, keeping track of the supplies. Mainly four parties are getting the most advantage, Government, buyers, suppliers and manufacturers.

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Current Scenario

Every day Hosne Ara goes to his son's grave near her house and still she can not believe his son is no more in this world. As her son was sick she went to the nearest hospital. The doctor put a needle in his hand to give him an injection but the baby started to cry. Hosne Ara saw her son gradually fainted. She started to cry and the doctor told her to leave the room. On the same day many other children died because of that sort of injection.

According to a survey by Bangabandhu Sheik Mujib Medical University, as many as 2,700 children died due to renal failure after taking toxic syrup from 1982 to 1992. Most of the 2700 kids had minor colds and seasonal fever and were thus prescribed the medicine that would take their lives. Even till now the remedy is not stopping in this 3rd world country. Many specialists have predicted that this kind of drug can cause kidney failure to the babies and also be a reason for heart attack which can lead them to death

Midford is the wholesale market of medicine in Bangladesh from where medicines are supplied all over the country which is also the hub of contaminated medicines which worth more than half a million dollars.In 2013, law enforcement officers seized around $640,000 worth of fake and unauthorized medicines from the Mitford, and nearly 30 shops were closed down following the crackdown. But, the shops later reopened after the vendors protested.

According to Ayub Hossain, director and spokesperson for the Directorate General of Medication Administration, the country has around 500 registered Unani, ayurveda, and herbal drug production enterprises. According to Ayub, the DGDA has received reports that some of these companies are involved in counterfeiting medications. According to DB officer Saifur, there were large rings that included Mitford-based medication merchants, phony businesses, members of the packaging sector, and courier services. He said that unscrupulous manufacturers made fake medicines and used different courier services to distribute the medicines across the country.Monas of Acme Pharmaceuticals, Losectil of SK+F, Seclo capsule of Square Pharmaceuticals, Naproxen-Plus of Jenith Pharmaceuticals and Pantonix of Incepta Pharmaceuticals are among the widely-faked drugs, said officials.

Problem Identification

There are many reasons behind the failure of proper supply chain in the pharmaceutical .They can be summarized as following:

- **Shipment invisibility :** Shipment is one of the more valuable supply chain management terms because it offers companies and their customers more time and actionable information about their supply chain orders. In the current scenario, we can see that shipment visibility is not being shown properly.
- **Expiration :** We can not keep track of the number of expiration dates of the pharmaceutical products that may lead to a company's massive loss.
- **Slow Process and Error prone paperwork :** The current process is very slow and errors occur as it's done manually and can be modified easily.
- **Mutable and Invalid source :** There are lots of frauds local companies are replicating pharmaceutical products without any proper process which can't be traced in the current system.
- **Lack of coordination :** In the last few years, many new companies have entered the market densely concentrated in the city areas, but the capacity of the sector and the size of the skilled workforce hasn't increased. This has led some of the new companies to have high NPL ratios. This problem could have been solved if the companies could come together in building a system where they could share data efficiently. But as of today, no such system exists in Bangladesh.
- **Tax Fraud:** In this case, mostly we find problems with updated licenses as most of the organizations are not willing to keep their documents updated. Consequently, they can not satisfy the Govt. and native rules. As to the issue, personal duty authorities let New Age know that they were setting up a data set of social event data through field visits and from various sources to figure out the real wages of the experts concerned.

Solutions

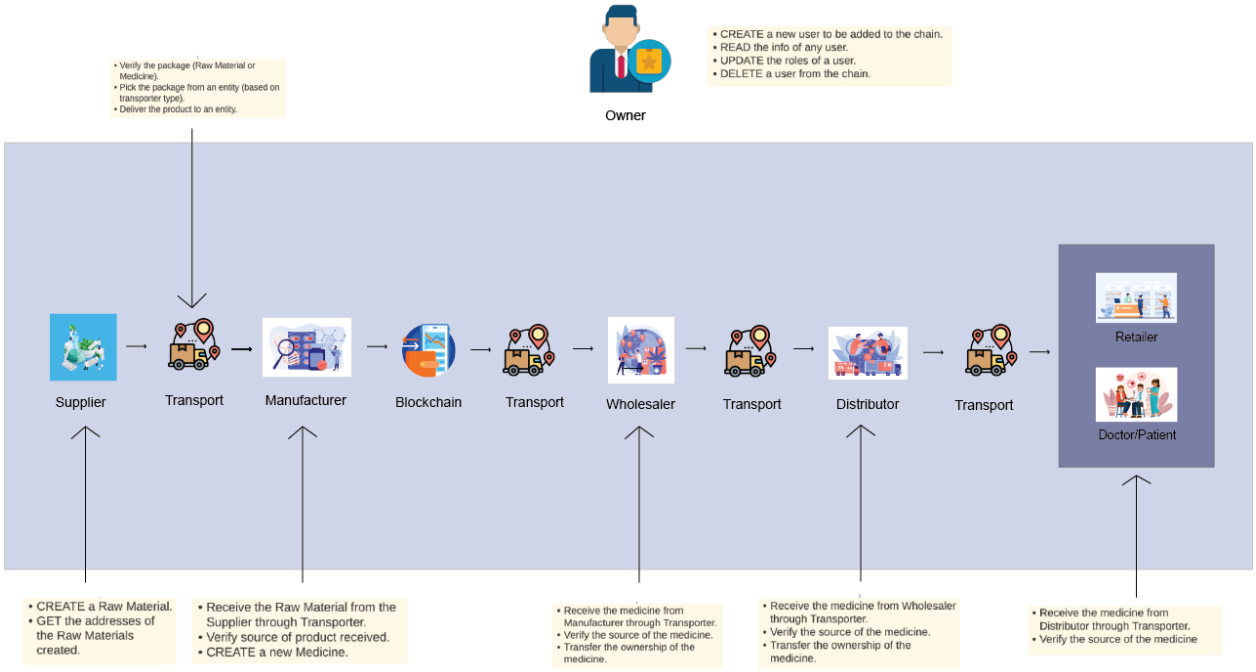
Lending Process

Whether or not a medicine is qualified by a pharmaceutical company can't be determined easily. Fraud medicine can cause irreparable damage to the patient. This also puts the pharmaceutical company at risk of financial loss. To solve all this problems we have come up with the following solutions:

- Accurate information across the entire chain at any point and at any location
- Instant access to real-time updates and alerts if issues are detected
- Visibility of all handovers in the supply chain
- Traceability back to source of all materials
- Seamless collaboration between all parties
- Reduce paperwork and Speedup process

Proposed System

Our approach combines two strong technologies: Blockchain and AI. Blockchain is an open, distributed ledger that may efficiently and permanently record transactions between two parties. Blockchains can readily solve counterfeit drugs since they are decentralized, distributed, transparent, and unchangeable. AI in pharmacology improves customer service and loyalty while also providing quick access to blockchain-based medical intelligence.



Why Does It Work?

This project offers a method that employs blockchain and artificial intelligence to ensure the safe supply of medicinal pharmaceuticals across the supply chain. Using an event request-response protocol, each product in the chain may be exchanged between authorized entities in the chain. All transactions between entities are logged on the blockchain using smart contracts, allowing a product to be tracked back to its origin. We created a Rasa chatbot that is connected into a Flutter app, allowing for ordering, medication tracking, and improving blockchain-based credit evaluation. The React Framework was then used to create a DApp. Ganache offered a local blockchain on which the smart contracts were installed.. Using Web3.js and Truffle framework, DApp is connected to the blockchain. The experimental results show that our solution is feasible and comparatively more secure than existing systems.

Why Blockchain?

We chose a blockchain-based solution over a simple cloud-based application because we want to take advantage of some fundamental properties that blockchain provides, such as data immutability to ensure that supply data is not tampered with, secure data sharing to improve collaboration between entities without compromising security, and data transparency for customers who deserve quality medicine in a system that currently lacks such transparency.

Privacy and Security Risks

In this third world, the more important thing is data privacy. As we are proposing a system which carries data on medicines and ensures the original medicine. So, data leakage may hamper our system. But in blockchain, we are storing data using hashing. These hashes can’t be decrypted easily and even if they decrypt some parts, it won’t help someone leak the information. Besides, data will be managed by the government and pharmaceutical companies. Data can be tracked when the head of the database gives permission to access. Else, people won’t see the result. They will see the hashes and the people connected to this system can add data into the database and the head of the database has to approve the access. This system has control to access specific data of the system. But they must need permission to store or delete data. When data is stored, it can’t be removed by anyone. It will be automated. If one person buys medicine, the shopowner has to scan a QR code and the buyer should feel how many medicines he has purchased and put his fingerprints in the system to verify that he has bought that medicine.

Market

Pharmaceutical companies are one of the biggest assets to a country and we have seen how they have contributed throughout the pandemic when there was a race for making the vaccine as soon as possible. The reason behind this is that when they make a vaccine, the company will put out a patent at first and after that, they will make the medicine or in this case the vaccine for the Covid19. There is a huge business target for this and this has an overall effect on the whole world’s population. This is the market of this solution and to secure this kind of information with

heavy security, blockchain will come to the rescue. In the fiscal year 2019-20, Bangladesh's pharmaceutical export revenue was 136 million. Besides, Bangladesh ranks 71st out of 134 countries in the world in terms of global pharmaceutical exports. Renata, the descendent of Pfizer Bangladesh, posted a 26% increase in profit. Its EPS rose to Tk51.94 from Tk41.14 in the previous year. Orion Pharma registered a 41% increase in profit in FY21. Its consolidated EPS rose to Tk4.1 from Tk2.84 in the previous fiscal year. The IBN Sina Pharmaceuticals profit rose by 26%. Its EPS rose to Tk15.66 from Tk12.56 in the previous fiscal year. This is a huge market for the product and as I told you earlier blockchain will have a major impact in securing not only the company's product information but also preventing lickedge of inside information so that the market stays stable.

Competition

Pharmaceutical sector is one of the largest sectors in Bangladesh but sadly there are currently no blockchain solutions that are helping them secure their product or any other valuable information that is leaking through various resources. We believe that our proposed idea will have a major impact on securing the information of the pharmaceutical companies. For instance, the companies must use some kind of security system that is gonna prevent serious hacking or spreading of misinformation or maybe in some cases leaking important information such as the components of some medicines, etc.

Partners

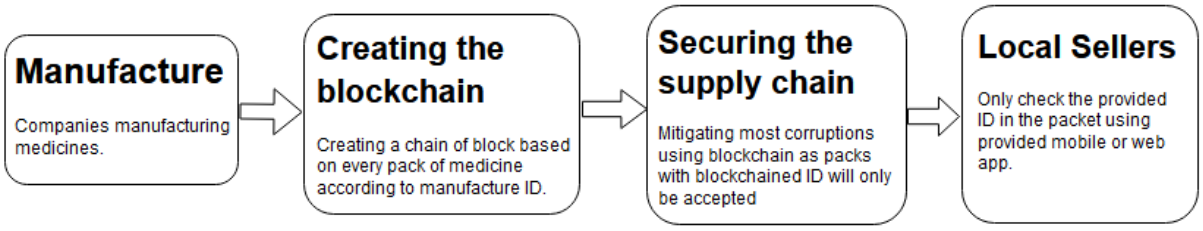
- **Medicine Company :** Various pharmaceutical companies will be the partner of this project as it's securing their supply chain and money.
- **Regulator :** Restoring the reputation of the medical company and encouraging investors to invest again.
- **Bangladesh Medicine Association :** BMA is an organization that would be our partner to ensure the smooth relationship with the companies.
- **Ministry of Health & Family Welfare :** This government ministry would be our partner to maintain the proper secure pharmaceutical supply chain.

Risk Analysis

The viability of our strategy is dependent on pharmaceutical companies enforcing specific standards, not via government regulation, but through incentives, to avoid improper production methods. Our primary objective was to make the system more responsible without relying on legislation, but if there is widespread corruption, we may need to rely on government involvement and policy reforms.
Disintermediation is a popular strategy in today's world. However, bringing about such huge changes in a nation like Bangladesh is difficult at first. So we decided to integrate all such middlemen into our system and then strive to optimize the system for more efficiency and transparency in the future.

Architecture

We work with manufacturers of pharmaceutical products to vendors and provide a way for the owners to verify these assets to the manufacturer.



Choice of Blockchain

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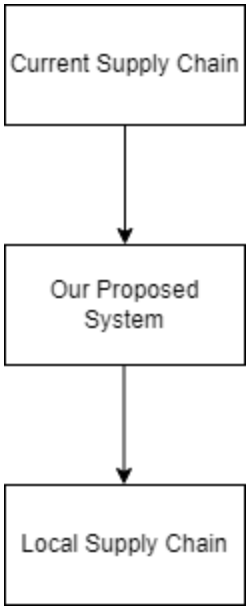
Integration with Existing Systems

Our solution does not change our partners' current methodologies; instead, we just allow them to link their current implementation with our system to make it more efficient and resourceful. We intend to assist issuers in digitally maintaining their own papers, something they do not currently do. Supply chain digitization and the use of digital signatures for verification are standard solutions used in many situations and should not disturb their present working style.

On the other hand, most businesses have some form of legacy system that they use internally to manage their workflow and record accounts, transactions, product history, and so on. They would have to upgrade the system to record a transaction only after it had been accepted by the blockchain through consensus. They may communicate with the blockchain via our API, providing only the essential data as specified by the government, and then returning to their usual process.


Current Supply Chain
Our Proposed System
Local Supply Chain

Governance

We digitally document the information of manufacturers to ensure the authenticity of medicines on our system. However, the issuers are already tracking this information. Because the relevant issuers are already dependably preserving records of the assets, our methodology does not ask them to do anything more than keep the data digitally. We may also rely on them to correctly and consistently represent assets on a blockchain by adding members for monitoring, such as regulators and credit rating organizations.

Network Membership Governance

1. **Member on and off boarding:** We intend to begin with a single pharma company and the issuers that their clients utilize to authenticate their collateral.We will gradually integrate more issuers into the system to employ various types of collateral.Other companies can join the system by agreeing to the network's regulations and obtaining authorization from the government's regulatory authorities.

2. **Ownership of Data:** Companies have complete custody of their customer data in the system and only share a portion of it with regulators and other companies to establish customers' trustworthiness.

3. **Approval structure:** When customers join the network, they agree to share (read-only) purchaser asset data with the company. Companies examine these assets and record their issued credits before granting access (read-only) to other companies and regulators, to just the data deemed required by regulators.

4. **Permission structure:** The complete system will be operated by the Ministry of Health and Family Welfare and The Directorate General of Drug Administration (DGDA)(Smart Contracts). They will set the necessary database head in the pharmaceuticals platform to enter data. They can delete data after the quantity comes to zero to place new data. It will optimize the memory. This system will be transparent. People can see how many medicines they have bought and how many are left. It will help them to ensure their rights on original medicines and the government will receive taxes from pharmaceutical companies. It will boost our pharmaceutical business and they can earn their target from medicines.

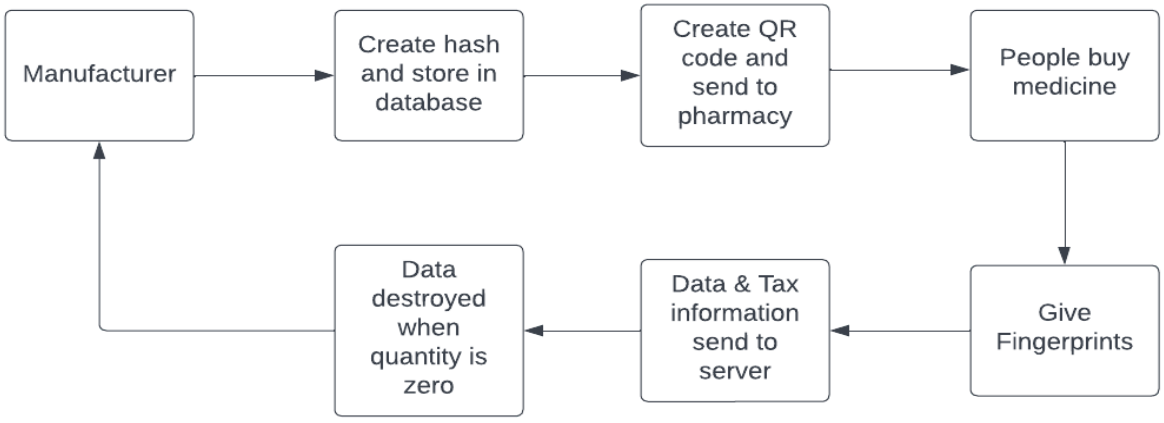
5. **Risk optimization:** The full system will be monitored by smart contracts. They will create validator nodes for each package and destroy the hashes when it’s expired. Every node will be owned by smart contracts and competitors and third parties might be blocked from transacting on this system or risk being restricted from using certain functionalities. Blockchains employ cryptographic functions such as hashing algorithms and public-key cryptography to ensure the integrity of the overall system and guarantee safety.

Business Network Governance:

1. **SLA Management :** Companies ,sellers and customers all agree to disclose the relevant data as specified above. While doing so, they must provide uptime of 99.5 percent ,turn around time of less than a minute (should be renegotiated every quarter based on increasing complexity and technological advancements), and average time to answer in 30 second minutes if a problem arises during checking. If any entity fails to respect the agreement, the authorities may take severe action (fine, expulsion from the system or other legal actions).
2. **Regulatory and Legal Compliance:** There are many types of organizations with various types of regulation.The Directorate General of Drug Administration (DGDA) under the Ministry of Health & Family Welfare, Government of the People's Republic of Bangladesh, is the Drug Regulatory Authority of the country.
3. **Business Management Structure:** Companies are allowed to conduct their own operations, with the exception of disclosing more data as defined by authorities.

Technology Infrastructure Governance:

1. **Model of distributed maintenance:** Manufacturers will create medicines and send them to the smart contracts. They will implement blockchain technology to create hashes and store those hashes in QR codes. Then it will be sent to pharmacies. When someone buys medicine, shopowner will scan a QR code and both of them have to give fingerprints. Once you give fingerprints, data and tax information will be sent to the server. When the medicine quantity is empty, the hash will be destroyed. This is how we can ensure original medicines for all and tax for the government.



2. **Data Entry:** Smart contracts will allow members to data entry for each pharmaceutical. They will have access to the necessary information and after a medicine quantity comes

to zero, it must be destroyed. This cycle will run and new hashes secure the data as well as ensure original medicine to all.

3. **Framework for utilizing industry standards:** In this project, we have assessed and recognized the demand of using Hyperledger, which is an open source project used as a framework.

   Founded by the Linux Foundation in 2016, Hyperledger framework is mainly designed as an environment system where different communities and individual developers can collaborate on blockchain technologies. The result of this cooperation is a set of blockchain tools for building financial, healthcare, banking, IoT, supply chain, and other projects.

   Generally the members who use and develop it fund it.

   The framework is based on the "umbrella strategy" which means the project is not one tool but a set of libraries, instruments, frameworks, and interfaces. The most well-known and commonly used Hyperledger frameworks are:

   - **Hyperledger Sawtooth**.
   - **Hyperledger Iroha**.
   - **Hyperledger Fabric**.
   - **Hyperledger Burrow.**

   But to solve this problem, we are focusing on Hyperledger Fabric.

   Hyperledger Fabric: Hyperledger Fabric is one of the blockchain projects within Hyperledger. Like other blockchain technologies, it has a ledger, uses smart contracts, and is a system by which participants manage their transactions. Where Hyperledger Fabric breaks from some other blockchain systems is that it is private and permissioned. Created by IBM, this is the most famous instrument among all Hyperledger frameworks. Fabric is a great solution for creating highly scalable apps which is our initial target.

   In addition, Hyperledger provides developers with tools to help them create, manage, and terminate Hyperledger frameworks.

   As we've mentioned, Fabric is used more often than any other Hyperledger framework. Its popularity can be explained by its many advantages, including:

   1. A client application initiates the transaction flow by sending a transaction proposal to peers in each organization for approval.

   2. The peers confirm that the submitting client is who they say they are and that they have the permission to submit the transaction. Then they replicate the planned transaction's conclusion, and if it matches what was predicted, they provide the client an endorsement signature.

   3. The client accumulates peer endorsements and delivers the transaction to the ordering service after it has received the required number of recommendations as determined in the endorsement policy.

4. Finally, the ordering service verifies that the transaction has the required number of endorsements to comply with the endorsement policy. The accepted transactions are then chronologically ordered and packaged into blocks, which are ultimately sent to peer nodes inside each organization. The ordering service sends fresh blocks of transactions to peer nodes, who perform final validation on the transactions in that block. The new block is then added to the ledger, and the ledger's state is modified as a result. The new transactions have been completed and committed.

Process of te Fabric:

Each cartoon of medicine will have a block. The block will have three parts:

- Headers: will include the data of the supply chain.
- Company Information: The middle part of the block will have information about the import, manufacturer, ingredients etc.
- Tail: Date stamp and Location stamp.

For headers,

- Headers will be fixed and include data of “Importer”, “Manufacturer”, “ Distributors”, “Retail”.
- Headers will be used to verify each chain.
- On verification, meta data from the headers will be removed and the block will be updated.
- If the chain is broken, the block will be detected as invalid and DGDA servers will be notified.

For package information,

- Will be generated using importer, manufacturer, distributor and retail location information.

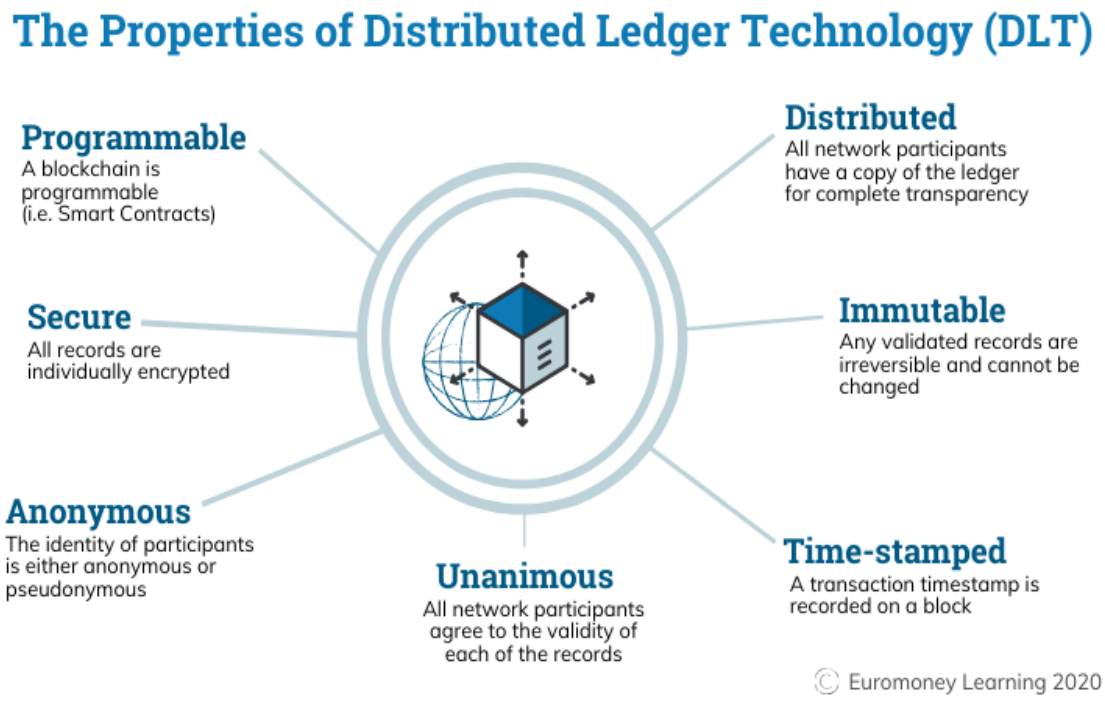
For tails,

- Date stamp and Location stamp will be included to ensure pinpoint tracing with perfect accuracy.

Every step, when the package is received, a mobile app will be used to verify the package. On each step, the block will be regenerated to ensure maximum security. If the supply chain is broken at any point, the package will be terminated and no party will receive any remuneration, also, will be detected as supply frauds.

4. Technology Adoption and Assessment: Hyperledger Fabric is an open source business-grade permissioned distributed ledger technology (DLT) platform that offers certain important advantages over other popular distributed ledger or blockchain systems. It is targeted for usage in enterprise contexts.

For this case our ledger will be built following the given diagram,



Taken from:https://www.euromoney.com/learning/blockchain-explained/what-is-blockchain

For deploying blockchain in our proposed plan, the following adoption will take place,

Programmability: Our hyperledger fabric is fully programmable. We can use the smart contract as NID numbers to make it safe and secure. It has to be programmed from scratch using the framework in order to deploy with full security.

Security: All records are individually encrypted and there is no way to decrypt back.

Anonymous: The identity of the participated individuals are secure and
Unanimous: All network participants have to agree to the validity of each of the records to accept the product. If the product is not verified, the vendor will not receive any revenue
Time-stamped: A transaction timestamp is recorded on a block to track accurate timing.

Immutable: Any validated records are irreversible and cannot be changed. If changed, the whole block is corrupted and fraud will be caught on spot.

Distributed: All network participants will carry a copy of the ledger as a hashing according to the blockchain algorithm. It will have proper transparency.

Valuation and Distribution

Initially for starting our work we need to contact the giant pharma companies and the government. To initiate this service at product level and release it in the market place we need more manpower and technology .For that we will be needing around 20 lakhs . This 20 lakhs will be used for-

- Upgrading our service
- For buying different digital services which will be needed to integrate our system
- Enforcing manpower in our project
- Developing a user friendly web app
- Dynamic marketing purpose
- Issuing license and other formalities

The equity of the company will be equally distributed among the founders where The founders will be the decision makers .A minimum percentage can be given to the Government in required terms where they have to fund us to initiate this project.Other investors can be a part of the company with equity by funding and providing proper monitorization.

Revenue

Our key customers are pharmaceutical firms and the government. The majority of fraudulent drugs are placed onto the market under the brand names of major pharmaceutical corporations. These corporations must bear the consequences of contamination in their products. Again, many pharmaceutical businesses do not pay their fair share of taxes to the government. Our system will guarantee that the proper product is on the market and will assist enterprises in tracking their goods. Essentially, it will keep the supply chain history, and no merchants will be allowed to sell things that are not real, otherwise they will be penalized.

To generate money, we will rely on a subscription revenue model in which any pharmaceutical businesses interested in verifying the authenticity of their goods in the market can enter into a contractual relationship.

The government can learn about each company's transaction history and make a reasonable amount of tax cuts from the corporations in a transparent manner. The government will pay for this service on a contractual basis in order to assure the taxation of all products and provide transparency to this sector.

Our secondary consumers are hospitals and clinics that wish to provide their patients with high-quality care. They might pay on an annual basis to ensure the legitimacy of the mass items used in their hospitals and clinics.

Conclusion

Blockchain brings data security with enhanced and perfect verification and authorization. Development process may take a medium range of time but implementation will bring about a massive change and improvement in the industry. About the revenue fraud, blockchain ensures the revenue that the government receives properly which is currently and most often falls into the wrong hands and never received by the government. Blockchain is a solution to corruption for our Digital Bangladesh.