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A Blockchain-Based Drug Traceability Solution: A Case of Drug Counterfeiting in the Pharmaceutical Industry.

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DECLARATION

This project, as presented in this report, is my original work and has not been presented for any other university award.

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This project has been submitted in partial fulfillment of the requirements of the Master of Science Degree in Distributed Computing Technology of the University of Nairobi with my approval as a university supervisor.

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ABSTRACT

In recent years, poor quality and counterfeit drugs have penetrated the Pharmaceutical Supply Chain (PSC) at an increasingly alarming rate. One factor that has significantly contributed to this surge of fake drugs in the supply chain is the lack of traceability. Therefore, a need arises for the implementation of a solution that would ensure traceability i.e., the product's journey would be visible to all stakeholders within the supply chain. This paper aims to address this problem using a blockchain network that accepts accurate tracking data for monitoring drug commodity movement history. Blockchain allows for distributed peer-to-peer networks where non-trusting members can interact with each other without a trusted intermediary, in a verifiable manner. It is also immutable. Specifically, this study aims at enabling consumers to verify the provenance of their medication.

An exploratory sequential design was adopted for this study. A non-probability sample was used. Google forms were used to collect information from the respondents. A blockchain prototype was developed using the Design Science Research Methodology. Then, virtual interviews were conducted with participants to evaluate the system's functionalities. The developed system traced a given product using its unique ID back to the manufacturer. That way, a product's journey was transparent to all stakeholders within the supply chain. Feedback obtained from respondents suggests that traceability is likely to greatly contribute to reduced instances of counterfeit drugs in the market.

Keywords

Pharmaceutical Supply Chain (PSC), Traceability, Blockchain, Identification (ID), Counterfeit.

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LIST OF ABBREVIATIONS

RFID - Radio Frequency Identification

DoS - Denial of Service

CNT - Calling in the Numeric Token

ID - Identification

PPB - Pharmaceutical and Poisons Board

HPTs - Health Products and Technologies

LMIS - Logistics Management Information System

KEMSA - Kenya Medical Supplies Authority

LMICs - Low- and Middle-Income Countries

OECD - Organization for Economic Cooperation and Development

EAC - East African Community

KAM - Kenya Association of Manufacturers

PSC - Pharmaceutical Supply Chain

SC - Supply Chain

CHAPTER ONE: INTRODUCTION

1.1 Background

The African Community of Practice on Managing for Development Results (2017) claims that piracy and counterfeiting have become a global epidemic, draining resources from businesses and the economy, jeopardizing investments in innovation and creativity, and posing dangers to consumer health and safety. The amount of subpar and fake goods has significantly increased in African marketplaces in recent years. These products include anything from software to textiles to electronics to spare parts to cosmetics to household goods to food.

Original products that are offered under brand names are imitated in product counterfeiting and the trade in counterfeit labels, packaging, and goods. For consumers, entrepreneurs, and traders in African countries, counterfeit goods are becoming problematic. These imitations typically consist of clones or altered products, labeling, and packaging. Unverified dealers produce, process, or provide counterfeit goods by illegally using the ideas and intellectual property of other businesses or people (African Community of Practice on Managing for Development Results, 2017).

The pharmaceutical industry is a complex one that involves numerous diverse players, including producers, national regulators, government departments, distributors, and others. It has been severely impacted by counterfeiting. Fake pharmaceuticals are becoming more and more of a concern nowadays, and the logistical chain from the supplier to the pharmacy is where the weakness comes in. These stakeholders must work collectively to develop the sector. According to Libby Baney et al. (2015), counterfeit pharmaceuticals are usually produced in unsafe settings, increasing the likelihood that contaminants will be mixed into the drug. In many cases, these contaminants include toxic substances like floor wax, chalk, boric acid, road tar, paint, etc. Additionally, counterfeit drugs frequently lack the proper concentration of the active ingredient. In the end, this might cause severe reactions or even death.

Many entities are tasked with protecting pharmaceutical consumers, including governments and pharmaceutical companies. To further analyze this problem and find solutions, a joint global effort is required to safeguard the global supply chain, expand the capacity for quality control, and enhance surveillance.

According to a statistical model created by the London School of Hygiene and Tropical Medicine (2017), fraudulent antimalarial medications are probably responsible for up to 158,000 annual malaria deaths in Africa south of the Sahara. These drugs have significant risks for patients and their families, frequently resulting in severe damage that spirals over time into financial difficulty and, ultimately, death. The threats that counterfeit drugs pose to the world's public health have increased, according to Tim K. Mackey (2018) despite the industry having

already benefited from technological advancements that should ideally stop the spread of fakes. The use and production of counterfeit medications surged by 122% between 2005 and 2010. One in ten medicines supplied in developing nations, according to (Justin D. Evans,2018), are fake; they either have harmful impurities left over from the manufacturing process or improper dosages of the active ingredients. Ozawa et al. (2019) account that according to a recent meta-analysis, 19.1% of all antimalarials tested in low-and-middle-income countries (LMICs), were substandard or falsified. Furthermore, The Organization for Economic Cooperation and Development (OECD), (2008) estimates that the East African Community (EAC) loses over US$500 million in tax revenue annually due to counterfeiting. Kenyan manufacturers are said to be losing up to 40% of their market share to counterfeiters, according to a 2012 research on illegal trade in Kenya by the Kenya Association of Manufacturers (KAM).

Tim K. Mackey (2018) remarks that the inability to ensure the integrity and safety of pharmaceutical companies' global supply chains is a major contributing factor to the proliferation of counterfeit medications. According to Deloitte (2017) the supply chain's information traceability is significantly hampered by the difficulty of sharing information across many stakeholders. Additionally, tracking and linking information to material without bias becomes difficult due to the intricacy of stakeholder interactions. Due to a lack of secure sharing and the fact that information is split across numerous stakeholders, stakeholders can experience difficulty accessing information effectively. According to Towett Ngetich (2021) access to medical product data (through efficient tracking and tracing of medication along its full supply chain cycle) could help prevent incidents like these and further reveal the supply networks and entrants of counterfeit medical items. The existing solutions have struggled to keep up. They include dated methods like barcoding and serialization as well as new advances that aim to enhance pharmacovigilance and post-marketing surveillance of drugs. However, they don't appear to be well-equipped to handle the issue alone. According to a Ministry of Health study (2020) in Kenya, the traceability of health products and technologies (HPTs) throughout the public health supply chain is now carried out by actual visits to service delivery sites, thorough reviews, and reconciliations of documentation, and comparisons of issue data with consumption data. Such audits take a lot of time and resources. For instance, the Kenya Medical Supplies Authority's (KEMSA) Logistics Management Information System (LMIS) lacks real-time stock visibility while in transit. This presents a chance for the market to be flooded with fake or inferior pharmaceuticals.

1.2 Problem Statement

As discussed above, it is clear that counterfeit drugs pose a great challenge in the pharmaceutical supply chain. This negatively impacts the supply chain’s stakeholders from the manufacturers down to the end consumer and hence there is a pronounced need to combat this issue. According to Christo Hall (2012) as counterfeiters' methods improve, there is a constant need for highly effective anti-counterfeit technology. Markers that are clearly visible on a drug's packaging have

traditionally been used to distinguish between genuine and counterfeit ones, however, holograms and other distinguishing features that are affixed to the blister foil, film, or paper substrates of the package are often accurately imitated. Genuine and fraudulent products can appear the same to the untrained eye.

Current technologies presented have not been able to make a significant impact in the fight against counterfeit drugs due to the non-immutable nature of the data stored in the systems which in turn raises the question of the accuracy of data present for auditing purposes. This implies that the traceability of the drugs is therefore affected.

1.3 Research questions

1. What are the requirements for a blockchain solution to tackle the issue of drug counterfeiting?
2. What are the features in consortium blockchain that make it best suited for a pharmaceutical supply chain?
3. How does a blockchain solution contribute to data veracity and traceability?

1.4 Objectives

Main Objective.

> Build a blockchain network that can accept accurate tracking data for monitoring drug commodity movement history through a web application.

Specific Objectives.

1. Investigate the current technologies used to combat counterfeit drugs in the pharmaceutical industry and the processes involved in its supply chain.
2. Build a consortium blockchain on hyperledger fabric that can be integrated with other technologies.
3. Validate the system.

1.5 Scope

Inasmuch as counterfeit drugs have become a complex problem around the globe, the technologies used to a large extent have been used independently. This study aims to design and implement a tool that can combine two technologies e.g., IoT and Blockchain - to enable effective tracking and tracing in the pharmaceutical supply chain.

The study will cover the pharmaceutical stakeholders namely; the manufacturer, the distributor, the wholesaler, and the regulatory authority. The stakeholders covered are based in Nairobi county, Kenya. The sample population will be selected from each stakeholder group for data collection. This study only covers one-way supply and not returns or recalls of assets. The project is to be carried out within a time frame of 3 months or less.

1.6 Assumptions

One presumption is that, in the end, consumers will be willing to check the legitimacy of drug items and report any irregularities they may observe. To do this, it will be necessary to raise awareness, provide training, and a commitment to establish a supply chain environment where genuine medications are available.
Another is that the end consumer is well aware of the trusted outlets for medication and the track and trace process, and is also informed of the government website through which to report cases of counterfeits.

1.7 Significance

The aim of this study is to make sure that pharmaceutical orders can verify that genuine medications are delivered to an authorised personnel at each transfer point, ensure compliance with the right requirements for transportation and asset transfer, and make sure that a mutually verified ledger of all transactions is always available. This refers to each drug's origin along the supply chain. The manufacturers and users of the medications would stand to gain the most if the provenance of every drug in the chain could be established.

For the manufacturer, the elimination of counterfeit drugs from the supply chain would ensure that their brand names' reputations are upheld, and they would not have to face unfair competition. Apart from manufacturing costs, manufacturers also incur other costs in advertising, remuneration of employees, taxes, etc. Counterfeiters, on the other hand, incur very minimal costs but end up taking profit on legitimate business investments (AfCoP, 2017). The end consumer would benefit greatly as well since the elimination of counterfeit drugs would ensure that if a patient acquires their prescription medication from a pharmacy or hospital that is supplied with drugs from the supply chain, the drugs would be authentic. By providing consumers with genuine medication, their exposure to dangerous or ineffective products would be non-existent and as a result, complications resulting from falsified medicines would be removed.

CHAPTER TWO: LITERATURE REVIEW

This chapter begins by looking at the pharmaceutical supply chain to understand the processes therein. In addition, the study seeks to understand how counterfeit drugs are introduced into the supply chain. After this, a review of the relevant literature on the current technologies (both blockchain and non-blockchain) being used to fight against drug counterfeiting is conducted. Furthermore, the challenges of implementing traditional blockchain are discussed. An IoT integrated system is reviewed and the flaws are noted. Finally, a summary is given and the research gap of the study is realized.

2.1 The Pharmaceutical Supply Chain.

Samantha McGrail (2020) asserts that the pharmaceutical supply chain serves as the medium for the processing and distribution of prescription medications to patients. The involvement of numerous stakeholders, including pharmaceutical producers, wholesalers, distributors, customers, information service providers, and regulatory bodies, is mentioned by (Kapoor D et al., 2018).

Production of pharmaceutical products is done in two stages according to Abbas Ahmadi et al., (2018) i.e. primary and secondary stages. Abbas et al. (2018) continue to posit that in the primary stage, raw material is transformed into an active pharmaceutical ingredient (API). After that process, this API is then changed into the final product at the secondary stage. There are more secondary manufacturing plants than primary plants. Subsequently, the final products are packaged in the main distribution centers. The packages are then dispatched to wholesalers and other local distribution centers. Ultimately, the local distribution centers redistribute these products to pharmacies, hospitals, etc. from where patients have easy access to the drugs.

This is shown in Figure 2.1 below.

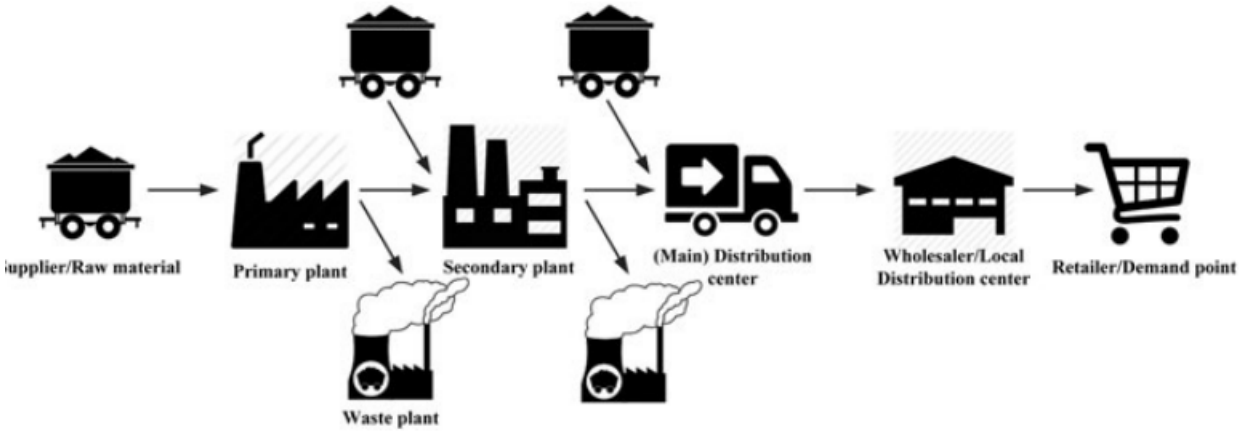


Figure 2.1: This shows the various steps before the final product in the PSC (Abbas Ahmadi et al., 2018).

Lorenzo Cozzella et al. (2012) note that the PSC faces multiple challenges, among them, is the issue of drug counterfeiting. With increasing complexity in the supply chain today, it becomes increasingly complicated to certify each individual supply source. This is a major factor contributing to the fast increase of counterfeiting attacks.

2.1.1 Injection of Counterfeit Drugs into the Supply Chain

For the issue of counterfeit drugs to have become such a deeply rooted problem in the PSC, enabling conditions must have been present, based on Lorenzo Cozzella et al. (2012) explored below are some of these conditions;

I. As the business of counterfeits is booming and becoming more beneficial, the sophistication levels of how the culprits are packaging their products keep rising. Hence it becomes difficult for a non-trained eye to identify between an authentic package and a fake one.
II. Counterfeiters are also finding other ways to penetrate the legal supply chain for instance, by stealing authentic products, mixing them with fake products then diverting and selling them to other markets.
III. An unfolding threat to the pharmaceutical supply chain is the contractors responsible for producing authentic packaging for drugs when they produce extra genuine packaging and sell it to counterfeiters.
IV. Due to rising demand for prescription medication, subpar supply chain management, and the expansion of e-commerce falsified drugs may enter the supply chain.

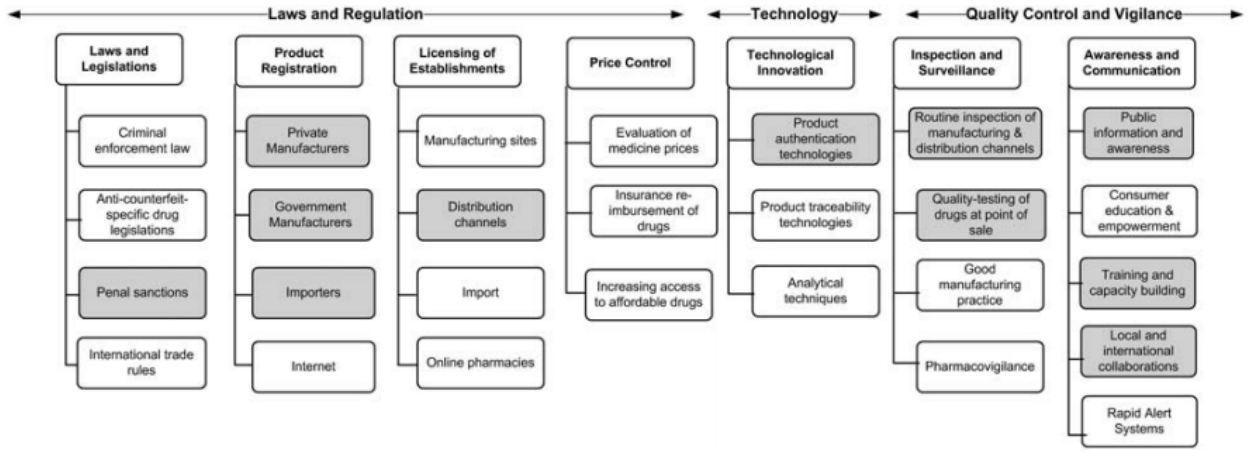


Figure 2.2: The figure above shows a wide framework of different anti-counterfeit strategies that have been employed to fight against falsified medicines (El-Jardali F et al., 2015).

2.1.2 Traceability in the Pharmaceutical Supply Chain

Argentina (n.d.) defines traceability as the ability to trace a product's origin and monitor its location at any given point in the supply chain. Fatima Leal (2021) claims that production lines in the pharmaceutical industry produce a large number of heterogeneous data sets from multiple systems that regulate the production of medicines. By using the batch number or code as a unique identifier and tracking mechanism, these data sets may be able to ensure end-to-end traceability for the release of a pharmaceutical batch. Since the pharmaceutical sector is becoming more and more regulated for the sake of product quality and patient health, auditable systems on production lines are essential. According to Dr. Reddy Gottipolu (2020) traditional information systems, unlike blockchain, fall short when it comes to providing end-to-end traceability in the pharmaceutical supply chain because it is nearly impossible to process much of the product quality-related data using those systems.

Keystones of Traceability

According to Meg Snyder (2016) establishing traceability is based on three main concepts;

1. Serialization

   Daleiden (2016) defines serialization as the creation of a distinct identity for a drug product across one or more tiers of packaging for that product.

2. Track and Trace

   While tracing is more of a historical view i.e., where the product has been or who has owned it, tracking is frequently thought of as having a more forward perspective, or

where a product is right now in the supply chain and capturing information about that product as it goes through the supply chain.

3. Verification

   The potential for verifying data about products or transactions at one or more points in the supply chain after creating a unique identity for the product through serialization or establishing traceability of transactions related to the product (either change of ownership or product movement).

Technologies in use for automated data reading

According to Argentina (n.d.), different technologies are used to transmit unique information about a product and are regarded as cost neutral in various countries.

1. Linear barcoding is widely employed in many industries, and readers are typically used in the value chain for this technology.
2. Two-dimensional barcoding has a higher reading capacity than linear barcoding and enables more information or data to be encoded into a comparatively small space.
3. RFID tags are information-containment devices that transmit data to the reader by transmitting a signal at a specific radio frequency.

2.2 Anti-Counterfeit technologies

With the growing problem of counterfeit pharmaceuticals all over the world, the weak link being the lack of cooperation between the supplier and the pharmacist, several studies have been conducted by organizations, governments, and other interested parties to develop effective strategies to eradicate drug counterfeiting. Other non-blockchain technologies that have been used to foolproof pharmaceutical supply chains have been discussed below.

2.2.1 Barcoding

Premsai Sainathan (2021) reports that barcodes have been widely adopted in the pharmaceutical industry to automate fake product identification at the item level. It is preferred since it is a simple and affordable technology. The drugs are marked with barcodes (that are not just pre-printed) which work towards addressing counterfeit medicines at an item level. A drawback to this though is that it is easy to clone the tags. In addition, a situation may arise where the fake product gets distributed before the original one. Therefore the barcode will catch the original one as a duplicate, and a mistake of capturing a genuine product as a fake occurs. Barcodes also need a line of sight to be properly read, according to (Edmund W. Schuster et al., 2007). Direct reads for large shipments are therefore cumbersome. Barcodes can also only give unidirectional information; they cannot be used to remotely send information like location.

2.2.2 RFID tags

RFID (Radio-Frequency Identification) has been used for tracking and authenticating commodities in the supply chain in a variety of applications, according to (Emil Nilsson et al., 2011). Although RFID opens up new possibilities, it is susceptible to a variety of threats, including eavesdropping, DoS, and cloning. The complexity and level of safety that the system offers correlate with an increase in computational cost.

2.2.3 Calling in the Numeric Token (CNT)

According to Emil Nilsson et al. (2011) the CNT method employs numerical tokens, or ID-codes, linked to the pharmaceutical product. The strategy is governed by three rules.

1. For each product contained inside a specific Lot, the ID codes must be different and generated at random..
2. The identification code shouldn't be a serial number and should be random.
3. The number of possible ID numbers must be at least a thousand times greater than the number of product containers in use.

The number of possible ID numbers must be at least a thousand times greater than the number of product containers in use.

According to Emil et al. (2011) authentic ID codes are kept in a supplier-controlled database. When a buyer wishes to confirm the legitimacy of the product they just bought, they dial the ID-code or numeric token they can find on the container. Customers are informed that a product is genuine if the ID code is a correct number. However, if a previous caller dialed the same ID code, the client is informed that their purchase is a fake. Despite the ease of this approach, a first caller who was unaware may have chosen not to buy the item, leading a second caller to wrongly declare the same legitimate item to be a counterfeit.

2.2.4 Serialization

According to Gary Pond (2020) many nations have passed laws requiring serialization. It is now necessary for product identifiers to be linked to each package in order to guarantee traceability across the distribution supply chain. Although this makes it possible to track the package, it might not be possible to determine if the medication inside is genuine or not, or whether it has been diverted.

2.2.5 Blockchain Technology

Blockchain, as per Ana Reyna et al. (2018) is the system that enables transactions to be validated by a number of untrustworthy actors. It offers a distributed, transparent, secure, auditable, and

immutable ledger. According to Ana et al. (2018) the blockchain provides access to every transaction that has taken place from the system's first transaction and may be verified at any point by any entity. The blockchain protocol organizes data into a chain of blocks, each of which is linked to the previous by a hash reference. Blockchain has been dubbed one of the most revolutionary technologies of all time. Numerous applications have been made in several fields and industries, including finance, medicine, supply chain management, etc (Clement Nartey et al., 2021).

In line with Hajar Moudoud et al. (2019) there are three main ledger types for a blockchain: public, consortium, and private. Anyone can join the network in a public blockchain, and each member is in charge of validating transactions. Only a few members of a consortium maintain the consensus, making it partially decentralized. Consortium blockchain is typically formed by a number of different companies. The private Blockchain only allows network members to access it. It is often implemented by a single corporation or group.

Features of a Blockchain.

Described below are characteristics of Blockchain based on (Clement Nartey et al., 2021).

(i) Decentralized. The system as a whole is distributed. The system will continue to function even if one of its nodes malfunctions or is disconnected from the network.

(ii) Trustless. As a result of the system's complete transparency, nodes on blockchain networks can trust one another.

(iii) Collective Maintenance. The system's nodes and blocks are not maintained by a single entity. Consensus algorithms on blockchains function to establish the veracity of new blocks added to the chain.

(iv) Reliable Database. A copy of the current ledger as it is is sent to each node. As there are more nodes on the blockchain network, the blockchain ledger's reliability often increases.

(v) Anonymity. Nodes can decide to stay anonymous in the network because there is no requirement for trust in the system.

(vi) Immutability. Once data is added to the blockchain, it is stored permanently and cannot be changed.

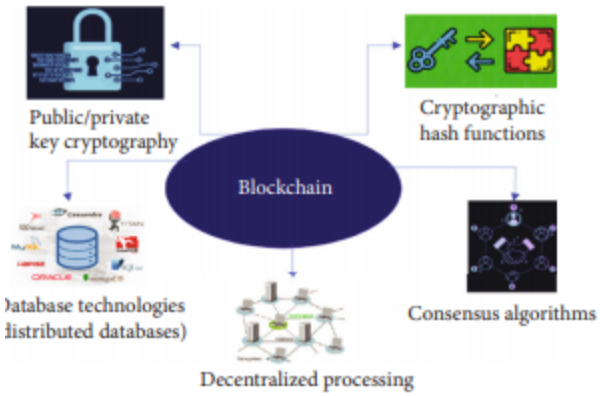


Figure 2.3: Components of blockchain technologies(Clement Nartey et al., 2021)

Every node on the network is given two keys—a public key and a private key—based on the cryptographic principles of the blockchain, according to (Clement Nartey et al., 2021). While the private key is used to approve and sign transactions, the public key serves as the node's distinctive network address. According to Nartey et al. (2021) transaction data is transmitted via peer-to-peer broadcasting, in which each node verifies and validates the transaction before retransmission. Blocks with time stamps are created from valid transactions. In a blockchain, each block's header includes a hash of the block preceding it as well as transactions. A block's hash is dependent on the parent block's hash. The nodes verify earlier transactions as new blocks are transmitted throughout the network. The block is added successfully to the chain of blocks, updating the distributed ledger, if the transaction and its hash are both valid.

Smart Contracts in Blockchain

When certain predetermined requirements and conditions are met on a blockchain network, such as when assets are transferred, a few lines of code called a "Smart Contract" is automatically executed (Abhinav Sangi et al., 2021). Mueen Uddin (2021) asserts that an asset's definition and the transactional instructions for updating the asset are contained in an application program referred to as business logic. To facilitate, authenticate, and enforce rules for reading, storing, and altering key-value pairs or other state information among the network participants, peer nodes generate and execute smart contracts.

Application of Blockchain in the Supply Chain

Gupte et al. (2019) have noted that many sectors have introduced blockchain technology for use in their respective fields. According to Angraal et al. (2017) blockchain technology has been gaining traction in various fields, including the healthcare industry.

Many applications of blockchain in the supply chain have been deployed in the food supply chain, according to the reviewed literature. A few papers, however, have touched on its application in the pharmaceutical supply chain. A shared system of records is necessary for a

conventional supply chain (SC), according to (Ju Myung Songa et al., 2019). There are various governance policies for entities in the SC since there are often competing interests and a lack of trust in the SC. An SC also requires immutable event logs. This is arguably the main factor behind the success of the use of blockchain technology in supply chain management. According to Kelesidis and Falagas (2015) blockchain-enabled solutions can be used to establish an immutable drug traceability system to query source information, manufacturer details, packaging and unpacking process details, and drug consignment-related information. This system would allow for drug tracking from the supplier of the raw materials across manufacturers to broader healthcare ecosystems.

Blockchain in the Pharmaceutical Supply Chain

Xiwei Xu et al. (2018) implemented OriginChain, a project that applies a blockchain application design approach. It is a traceability solution that uses blockchain technology instead of a central database. originChain provides transparent, immutable, traceable data by applying blockchain and designing towards security. According to Xu et al. (2018) the system supports automatic regulatory-compliance verification and adaption in product traceability scenes and is highly available. It is noteworthy, nonetheless, that despite being reliable, the OriginChain system created by Xu et al. for imported product traceability using smart contracts does not specify the precise procedures of the pharmaceutical supply chain. Smith and Dhillon (2019) proposed a blockchain-based mobile agent technology solution for a virtualized pharmaceutical product scenario. By addressing important challenges in managing virtual supply chain risk, they recommend using blockchain technology as a means for fostering trust amongst various supply chain participants. They did not, however, discuss stakeholder security issues.

A challenge in implementing blockchain in the supply chain.

Inasmuch as Blockchain is a nascent technology, it's been gaining traction quite fast. Nonetheless, people that have implemented blockchain have encountered some challenges during the process. Some of them have been solved to some extent while others have not been explored much. Ensuring data quality is considered a challenge in the implementation of blockchain technology. According to UNECE (2020) while one strength of Blockchain is its immutability in data, this can also become a weakness when inaccurate data is pushed into the blockchain. For instance, what ensues in the case that data is inadvertently entered incorrectly? As per Dennis Turpitka (2020) it is more difficult to fix erroneously input data in a blockchain application than it is in a non-blockchain application. Since data on a blockchain can only be updated rather than simply fixed as in a traditional database, it gets more expensive since the more modifications are made, the more transactions need to be processed, which uses up more resources.

UNECE (2020) suggests that data collection needs to be automated in order to maximize the efficiencies that can be achieved. Any discrepancies in the accuracy of data entered will

undermine the usefulness of the system and therefore the adoption of Blockchain technology. Based on Dennis Turpitka (2020) One way to address the challenge of data quality is by granting data access rights selectively. This can be achieved by determining a set of roles with related access rights and assigning roles to all individuals that will interact with the supply chain management system. According to Premsai Sainathan (2021) for pharmaceutical blockchain to be more inclusive and infallible, it needs to eliminate manual data capture. Premsai (2021) posits that using IoT sensors to capture package-level location and storage conditions data together with blockchain to store the data would secure data records and ensure they are irreplaceable. In that way, authenticity is maintained.

2.2.6 IoT integrated Blockchain.

Clement Nartey et al. (2021) note that Blockchain and IoT independently have proven to bring immense advancement to the areas and sectors to which they have been applied. Based on the review of literature conducted for this study, most of the IoT integrated blockchains implemented are for the healthcare sector, i.e., to be used in hospital settings to allow doctors and their patients to share information, prescriptions, etc. From the review so far conducted, the study came across implementations of an IoT integrated blockchain as discussed below. Based on Thomas Bocek et al. (2017) Modum.io AG, a start-up that has implemented blockchain in the pharmaceutical supply chain, came up with a system to track all necessary data during the transportation of medicinal products. They combine IoT sensors with blockchain technology (Ethereum Blockchain Network). Modum.io AG and the University of Zurich (UZH) also develop the sensor devices and their software. The technology ensures the integrity of data and makes it impossible to interfere with records. A smart contract is executed to ensure temperature category compliance upon delivery. These results are communicated back to the receiver and the distributor, they are publicly accessible. Nonetheless, Ethereum is a public blockchain network and therefore does not allow for the privacy of data for competing stakeholders.

The issues of safety, trust, inefficiency, and traceability of pharmaceutical products in the pharmaceutical supply chain have been addressed by (Jianfeng Shi et al., 2019). The technology is built on blockchain and IoT. IoT devices, including radio frequency identification (RFID), sensors, etc., are used to gather data on the status of pharmaceutical items at any time in order to ensure the accuracy of the data. With the aid of blockchain's distributed ledger technology, the system has made it possible to share and store data along the whole supply chain while also guaranteeing its transparency, traceability, and immutability. Finally, the consortium blockchain-based permission control technique was designed to satisfy some data's privacy and confidentiality concerns. According to Shi et al. (2019) the system efficiently promotes data transparency throughout the supply chain, raises the safety of pharmaceutical items, and minimizes manual operation. However, this implementation does not put into consideration the verification of the accuracy of data pushed into the blockchain by the IoT devices.

Table 1: Table showing the differences between blockchain and an IoT integrated blockchain

Traditional Blockchain	**IoT integrated Blockchain**
1. Horizontal integration of information between companies.	Both horizontal and vertical integration of information and material flows in supply chains.
2. Manual data capture	Automated data capture

2.3 Summary

The inclusion of the end-user in the visibility of the product journey should be taken seriously in the PSC. Before drugs reach the end consumer, they go through several actors within the PSC. Counterfeits have multiple ways of infiltrating the PSC. Most studies on combating counterfeit drugs mention traceability. Several authors agree that achieving it would result in a significant change. For this study, a unique identity for the medicine being tracked is required. Immutability is crucial when utilizing medical product unique identifiers to combat pharmaceutical counterfeiting (Adrian Clarke, 2020). There have been many anti-counterfeit technologies including blockchain. Blockchain is favored because it is immutable, transparent, auditable, secure, and distributed. Consortium Blockchain is the most suitable since it can be built and managed by multiple organizations and also has a private aspect to it. A Blockchain-enabled solution is useful in creating drug traceability systems that can be queried for information using the unique identifier.

The solution provided in this study is capable of fighting falsified medicines since it ensures the verification of the unique identifier's authenticity as a crucial step in ensuring the legitimacy of the pharmaceutical product bearing it. This is only based on a comparison with reliable data on legitimate unique identifiers that have been submitted by verified users to a secure repository system as supported by (Adrian Clarke, 2020). According to Sohail Jabbar et al. (2020) it is clear that Blockchain's immutability property has both advantages and disadvantages. The problem arises because errors cannot be fixed in blockchain as they can in traditional databases. Data must be entered into the system accurately the first time. According to Jabbar et al. (2020) developing procedures for confirming the accuracy of data uploaded to the blockchain is a current field of research. To cover this, the solution, therefore, involves a mechanism to ensure the correctness of data i.e., by being selective when assigning roles for data entry as Dennis Turpitka (2020) suggests. Adrian Clarke (2020) adds that in order for verified users to have access to services that enable them to safely encrypt data and store it on a blockchain so that it may be used as evidence, in order for unique identifiers to be utilized as the verifier of authenticity. The study employs the same concept as only verified users from the manufacturer

stakeholder will be able to add the items and ensure they are all uniquely identified. This solution would ensure increased protection of consumers from falsified or poor-quality medication. Their exposure to dangerous or ineffective products would be non-existent and as a result, complications resulting from falsified medicines would be removed. Also, the elimination of counterfeit drugs from the supply chain would ensure that manufacturer brand names' reputations are upheld, and they would not have to face unfair competition as mentioned (AfCoP, 2017).

2.4 Gap Statement

Substantial research has been conducted in an attempt to solve the issue of drug counterfeiting. These studies cover various aspects of the Pharmaceutical Supply Chain. Traceability is considered in most studies to be of significance in the fight against fake drugs. While different technological approaches have been taken to ensure traceability, many researchers agree that blockchain would be highly effective. Ethereum blockchain has been widely used in different supply chains despite the fact that it is public. Most proposed solutions involving hyperledger fabric, a consortium blockchain, have not been implemented at the time of this study. Those that have been implemented mostly cover imported pharmaceutical drugs. It is important to address the traceability of drugs with a system that can share information publicly yet ensure confidentiality between competing organizations. In addition, a solution should be able to accommodate the end consumer in that, the end consumer can view the history of the product. This study comes up with a hyperledger blockchain-based application that facilitates drug provenance in the smallest unit possible for the end consumer.

2.5 Conceptual Model

As discussed above, IoT integrated blockchain technology can achieve both input data veracity and traceability in the pharmaceutical supply chain. This research proposes a model that will ensure the visibility of data along the pharmaceutical supply chain for the various stakeholders involved. The main actors involved in this project are; the manufacturer, drug regulatory authority (DRA), distributor, and finally the wholesaler. The manufacturer procures active pharmaceutical ingredients which they use to create the drugs. The DRA authenticates the drugs and ensures they meet the given standards and hence approves or disapproves them. The distributor receives the drugs from the manufacturer and stores them in their warehouses. The drugs are then transported to registered wholesalers. The wholesalers then redistribute these drugs to retail stores, hospitals, clinics, etc. which serve as outlets for the consumer. The introduction of counterfeit drugs will be detected easily by the actors in the supply chain with the proposed system in use hence cutting down on falsified drugs in the market. The stakeholders involved will play various roles in the IoT-integrated blockchain. The model below illustrates the inputs and outputs to and from the system. The manufacturer for one will be able to create new products with unique identifiers and add their details to the ledger. They will also be able to create distributions and also add details of the origin of the active ingredients used in the

production of the drugs. From the ledger, the manufacturer will be able to track their products along the supply chain up to the wholesaler.

The Drug Regulatory Authority will be able to approve drugs after checking whether they have met the set standards. From the ledger, they will be able to trace the item back to its origin and track it forward to the wholesaler using the unique Id. of the product. The distributor will be able to create distributions, to update the ledger of the storage conditions and location even during transit. From the ledger, they will be able to receive distributions, trace items to their origin, and also track them up to the wholesaler. They will also check for registered wholesalers. The wholesaler will be able to add their company details such as their registration details to the system. Also, they will be able to update their purchase information. From the distributed ledger, they will be able to trace items to their source to confirm the authenticity and also receive distributions.

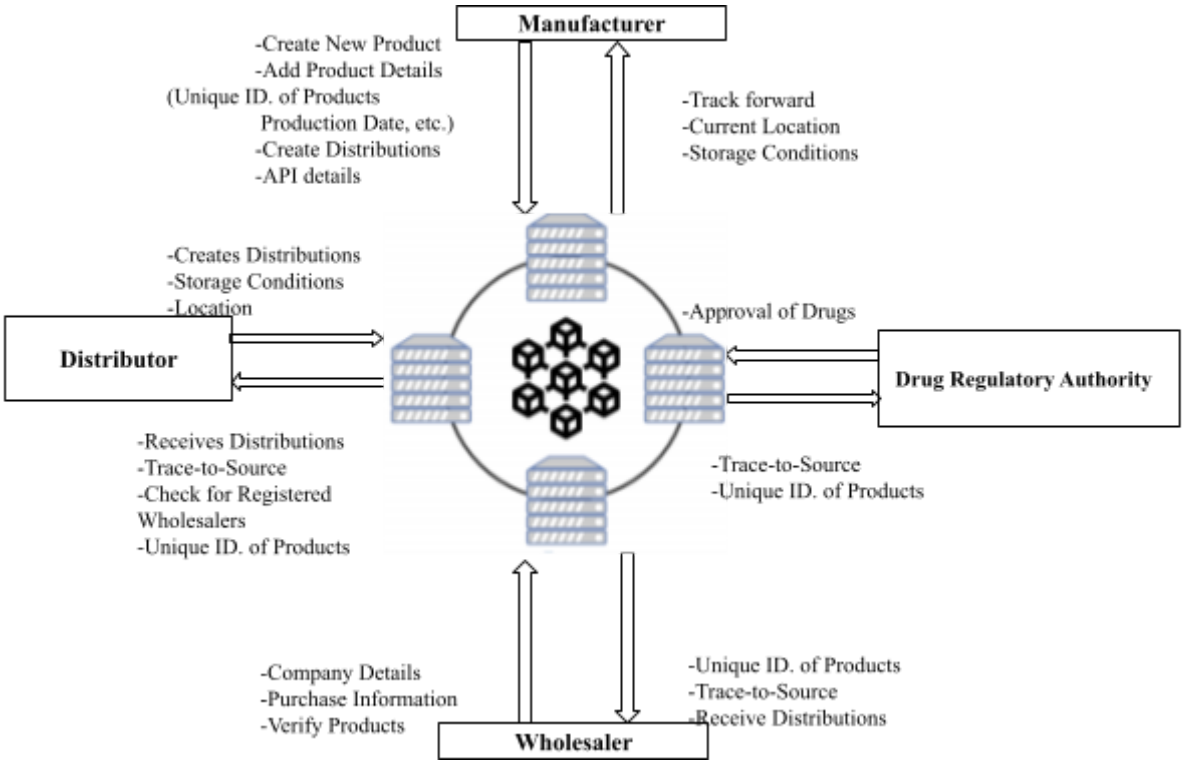


Figure 2.4: The figure above shows the interactions of the stakeholders with the Blockchain.

CHAPTER THREE: METHODOLOGY

This chapter begins by defining the research design adopted for the study. It then introduces the methodology followed for the realization of answers to the research questions. The data collection methods, sources, sampling, etc., and justifications are all discussed.

3.1 Research Design

According to Kerlinger (1986) a research design is a plan, structure, and strategy for an investigation devised to find answers to research questions and manage variance. Because it is utilized when the researcher wants to complement qualitative findings with quantitative analysis, this study has adopted the exploratory sequential design. This two-phase strategy is very helpful for researchers interested in creating new tools, taxonomies, or treatment protocols (Creswell & Plano Clark, 2011).

A framework for developing and testing an instrument on a particular population is provided by the instrument-development design. With this design, the researcher builds the instrument with guidance from the qualitative findings and evaluates it during the subsequent quantitative phase (W. Alex Edmonds & Thomas D. Kennedy, 2017). In this method, the researcher starts with a qualitative research phase. The majority of the qualitative information for this study will come from a review of previous works. After data analysis, a second, quantitative phase is built using the knowledge gained. The qualitative phase is used to develop an instrument that is most relevant for the research sample and to find the best instruments to employ in the subsequent quantitative phase. In the quantitative phase, the researcher is able to test the instrument they have created.

This research project started by reviewing existing literature (qualitative data) to gain insight into the pharmaceutical supply chain process and the parties involved, factors that have contributed to the rise of counterfeit drugs, non-blockchain and blockchain-based technologies that have been used to combat this issue. After this, the research identified the shortcomings of already implemented blockchain solutions. This was of importance since it would advise on a conceptual framework that would bring a solution to the same. In the conceptual framework, system requirements will be defined. The specific requirements for the system such as modules, architecture, components, interfaces, etc will be defined. In designing the system, the focus will be shown on how different components interact with each other and work together to achieve the set objectives. Additionally, when designing the system, the participants (active peers) and their roles are determined. In the case of this research, the active peers will be the manufacturer,

wholesaler, and retailer. The IoT integrable system is then created using the Design Science Research Methodology (described in more detail later in this chapter). This methodology was chosen because a key result of this kind of research is an artifact that resolves a domain problem, also known as the solution concept, which must be evaluated against standards of worth or utility. The artefact will be validated. The functional and non-functional needs of the system will be tested to ensure that all functions achieve the intended outputs. The system will be tested with data input from actual smart labels in a simulated environment so as to tell if the artefact developed based on the proposed framework was working correctly. The main aim of traceability will be achieved if the user is able to query the system for details of a specific drug and get a history of the item. The outcome will be communicated and recommendations made.

3.1.1 Target Population

According to Paul J. Lavrakas (2008) the target population for a survey is the full set of units for whom the survey data is to be utilized to draw conclusions; the target population defines those units for which the survey's findings are intended to be generalized. This study will focus on some of the stakeholders in the pharmaceutical industry. They are as follows: the manufacturer, the distributor, the wholesaler, and the drug regulatory authority.

3.1.2 Sampling

As stated in Ranjit Kumar (2011) sampling is the process of choosing a small number of individuals from a larger group to serve as the foundation for calculating the likelihood that an unknown fact, event, or result will occur in the larger group. A sample, in simple terms, is a segment of the population that interests you. The sample that will be used in this study is a non-probability sample, specifically a judgment sample. This implies that the researcher selects people out of convenience, people that are most likely to have the information desired. People that work with the inventory information systems of the stakeholder organizations will make the most suitable samples for this study.

3.1.3 Sample Size

The size of the sample is a crucial variable that governs the impact of the experiment, as per (Vinayak Bairagi et al., 2019). The appropriate quantity of samples to take is frequently a source of concern for the researcher. In the same way that a small sample size might not meet the needs of the study, leading to less accurate results or incorrect conclusions, a big sample size leads to generalization and lacks precise findings. A viable approach to the sample size in an exploratory sequential mixed method approach, for the qualitative data, is the idea of saturation. When the categories, in accordance with Charmaz (2006) are saturated—that is, when acquiring new data no longer yields novel insights or discloses novel properties—one stops collecting data. At such a point, the sample is adequate.

A member from each stakeholder group will be selected and data collected. If the saturation point is reached, then the sample size is 4, if not, another member is selected from each stakeholder group and the cycle is repeated until the saturation point is met. The number of persons interviewed to reach the data saturation point will make up the sample size. For quantitative data, Han Ping (2019) states that, for the data to be generalized for the entire population, a minimum of 50 individuals are required.

3.1.4 Data Collection

Leonard Bickman et al. (2008) list people, independent descriptive observations of events and activities, physical documents, and test findings as potential primary data sources that are available to researchers. According to Leonard Bickman et al. (2008), when planning for primary data collection, the researcher should take into account the following five important factors: site selection, authorization, the data collection process, accessibility, and other support required. The stakeholders involved in the pharmaceutical supply chain will be the key data sources for this study. Ranging from the manufacturers (GlaxoSmithKline), wholesalers (Transchem), the drug regulatory authority (PPB), and pharma distributors (KEMSA).

For the secondary data sources, the study mostly utilized published reports, journals, and books sourced online and from electronic databases namely; Springer Link, Google Scholar, etc. As reported by John W. Creswell et al. (2018) the steps for data collection include establishing the protocol for recording data, setting the parameters for the study through sampling and recruitment, and gathering data through observations and interviews, documents, and visual materials. This study is expected to use Interviews and Observation as the primary methods of data collection. Interviews are to be conducted with the involved stakeholders in the pharmaceutical industry. Interviews are most likely to be carried out on a video platform. Seeking consent to collect data from the target institutions will be the initial step in the data collection process. Emails are to be used as a medium for requesting interviews with prospective interviewees. Once the integrated system has been developed, observation during the testing phase will be used. The researcher will collect quantitative data through observation whereby they will observe the selected sample population using the system. For instance, the researcher will time the period transactions take to be completed for the different stakeholder organizations.

The research employed a systematic literature review for the literature review section. This is a methodical approach to identifying, assessing, and synthesizing finished works done by researchers, academics, and practitioners as per (Okoli, 2015). There are four stages to the methodology: planning, searching and filtering, reviewing and analyzing, and reporting as per (Amrozi, 2020). The research question and the review process were established during the planning stage. The search terms, inclusion and exclusion criteria, and paper sources make up the review process. The papers are first searched from the source using the queries in the searching and filtering phase, and then they are filtered using the criteria. In the review and analysis step,

each paper is evaluated by reading it and noting everything pertinent to the research question, after which the results are aggregated and organized into categories. The literature review was written based on the final results, which were recorded during the reporting phase.

The following literature sources were used for this review:

I. Google Scholar
II. Scopus
III. IEEE Xplore
IV. Research Gate
V. Elsevier ScienceDirect
VI. Academia
VII. Springer SpringerLink

The search google scholar brought quite a number of unrelated results. 61 papers were deemed relevant results and considered for review. The papers selected were from the year 2015 and above and had to fulfill the inclusion criteria. The exclusion criteria were used to further filter the papers. These keywords were used to conduct the search across these databases: Blockchain, IoT, Blockchain and IoT, Pharma supply chain, Pharmaceutical Industry, Supply Chain, Counterfeit Drugs. The following search strings were used:

1. (Blockchain OR block chain) AND (IoT OR Internet of Things OR Internet of Things)
2. (Blockchain OR block chain) AND (Pharmaceutical Industry OR Pharma supply chain)
3. (Blockchain OR block chain) AND (Supply Chain)
4. (Blockchain OR block chain) AND (Counterfeit Drugs)

The following inclusion criteria were applied:
1. The paper was published in 2015 or later.
2. The paper is written in English.
3. The use of blockchain in the pharmaceutical supply chain is referenced in the title.

The following criteria were applied for exclusion:
1. The paper wasn't published.
2. The paper is not one that has been published in a journal, a book or book section, or a conference.
3. The document is a duplicate.
4. Blockchain and the pharmaceutical supply chain are not discussed in the report.

Skimming the 61 papers produced 17 after filtering with the exclusion criteria. These were the studies closely related to the research problem considered. Relevant papers cited in their reference sections were also downloaded, leading to more material. The abstracts were scanned to determine which papers to read. After identifying the final list of papers, pertinent information

was extracted i.e., the papers identified were reviewed in-depth and analyzed. Notes were formed from them. The review was written based on this. The importance of this review is that it provided data that would be used in forming the requirements of the conceptual model. Moreover, it would aid in the identification of the research gap.

Desk research was conducted for the Pharmacy and Poisons Board since it proved challenging to secure an interview with them. This was for the purpose of understanding how the PPB goes about in the verification of the authenticity of drugs. The search for the documents was done based on the keywords Pharmacy and Poisons Board. Published journals, papers, and other similar sources were used to compile the study materials. The majority of these documents were obtained from the internet. Four documents were found to be useful to the study. Because they were mostly a duplication of one another, data from two of them was used.

3.1.5 Data Analysis

The formation of categories, their application to raw data through coding and tabulation, and the subsequent drawing of statistical inferences are just a few of the closely related procedures required for data analysis, according to (Krishnan Nallaperumal, 2014). The qualitative data collected using interviews will employ narrative analysis whereby the response data is reformulated taking into account the context and different experiences of the various parties (revision of the respondent data by the researcher). The quantitative data collected during testing will be analyzed using descriptive statistics whereby, for instance, the meantime for transactions will be found.

3.2 Design Science Research Methodology

In accordance with Jan vom Brocke et al. (2020) Design Science Research (DSR) is a paradigm for problem-solving that aims to advance human knowledge by developing innovative artifacts. DSR also aims to advance the knowledge bases of technology and science by developing inventive artifacts that address issues and improve the surroundings in which they are used. The DSR methodology developed by Hevner et al. (2004) and Peffers et al. (2007) is used in this study. The DSR implementation by Peffers et al. (2007) divides the approach into six activities:

1. Problem identification and motivation
2. Defining the goals for a solution
3. Design and development of an artifact
4. Solution demonstration
5. Solution evaluation
6. Communication of the solution

3.2.1 Problem identification.

Based on Peffers et al. (2007) the research problem is defined, and the importance of the solution is justified. This activity involves awareness of the state of the problem and the significance of its solution. An extensive review of secondary literature is conducted as part of the problem identification step. The search for the documents is done based on the keywords of the research title e.g., Blockchain, IoT, Blockchain and IoT, Blockchain integration with IoT, Pharma supply chain, Pharmaceutical Industry, Counterfeit Drugs, etc.

Studies that are closely related to the research problem are considered, and the papers cited in their reference sections are downloaded hence leading to more material. The selected documents for the actual review are of the near past (mostly less than 3 years old) so as to ensure access to the most recent and relevant information that is likely to shape future research. A comprehensive literature study is significant not only because of problem identification but also, because it would aid in answering the first research question of the study, 'requirements for an IoT integrated blockchain to tackle the issue of drug counterfeiting.'

3.2.2 Definition of the objectives.

As specified by Peffers et al. (2007) the definition of the problem and knowledge of what is feasible and possible can be used to infer the aims of a solution. The objectives can be qualitative, such as a description of how a new artifact is intended to support solutions to problems not previously addressed, or quantitative, such as terms in which a desirable solution would be better than present ones. According to Peffers et al. (2007) The objectives should be rationally deduced from the problem description. After formulation of objectives, it is possible to come up with the research questions of the study.

3.2.3 Design and development.

An artifact is created. Following Peffers et al. (2007) a DSR artifact can theoretically be any designed object that incorporates a research input into the design. In this process, the desired functionality and architecture of the artifact are determined, and the item itself is then created. This is the phase in which the elements such as modules, architecture, components, interfaces, etc., and the specific requirements for the system are defined. In designing the system, the focus is shown on how different components interact with each other and work together to achieve the set objectives.

Additionally, when designing the system, the participants' (active peers) roles are determined. In the case of this research, the active peers will be the manufacturer, drug regulatory authority, distributor, and wholesaler. Their roles are also defined in the conceptual model. The system will be designed in such a way that the accuracy of data from the smart label is confirmed before the data gets into the system. For the provenance of a product, the unique id will be used for

querying the blockchain from the web-based user interface. The result will be the history of the product since its inception.

The consortium blockchain is developed using the HyperLedger Fabric, an open-source blockchain. A consortium blockchain is preferred primarily because it restricts the number of participants and delegates control to a group of authorized individuals rather than a single corporation. As a result, it offers the effectiveness and security of public blockchains while also allowing for some kind of centralized management, oversight, and security. The system will be run on a web platform, with a user interface provided. The second research question of the study, 'features in consortium blockchain that makes it best suited for a pharmaceutical supply chain' is answered during this phase.

3.2.4 Demonstration.

This exercise demonstrates how to use the artifact to address the problem. This can entail applying it to an experiment, a simulation, a case study, or other pertinent tasks (Peffers et al., 2007). The researcher will demonstrate the use of the artefact to a selected sample of the involved stakeholders.

3.2.5 Evaluation.

In line with Peffers et al. (2007) the evaluation gauges how well the artifact contributes to a resolution of the problem. This task entails contrasting a solution's goals with the outcomes that were actually obtained when the artifact was used in its intended setting. Evaluation can take many different formats depending on the artifact and the problem venue. The researchers can choose to move on to communication and leave further improvement to following projects after this activity or return to step three to try to increase the effectiveness of the artifact as per (Peffers et al., 2007). Testing and evaluation are important since it establishes whether the system delivers according to the users' requirements. The tests to be carried out are determined and performed in this phase. The selected sample will be based on the saturation of data collected as explained in the sampling section. The significance of this is that it answers the third research question of validating the system.

3.2.6 Communication.

Here, all pertinent stakeholders are informed of the problem's details as well as the designed artifact. According to Peffers et al. (2007) depending on the research goals and the audience, appropriate communication methods are used. The outcomes of the testing demonstrate whether the system met its objectives. The main conclusions of the study that came from the techniques used to obtain and examine the data are presented in the results section. It offers these conclusions in a logical order without bias or author interpretation.

This section details how the system works, whether it managed to meet its objectives, and the user's experience after interacting with the system. For the system in this study, whether the system was able to attain traceability as its main aim. Communication will be done in the form of a report that will be distributed to the sample population.

3.3 System Validation

First, the system will be tested in a simulated environment to check whether it meets the requirements of a blockchain system. The ability of all the participating organizations to trace drugs in the supply chain will be confirmed. The system's ability to combat counterfeits will be weighed by considering a scenario whereby bad actors introduce imitations into the supply chain.

Second, a demonstration of the system to respondents. This exercise will be carried out by arranging a zoom meeting with 3 respondents. They will be given a demonstration of the transactions on the web application. Afterward, they will be interviewed and asked to cite their opinions regarding the system based on some factors. These factors are as follows; user-friendliness, drug traceability, and the possibility of the solution's success.
The interview questions are designed based on (Bryn Farnsworth, 2021). Initially, the goal of the interview is established, then the target audience is identified, questions are developed - the study will opt to use open-ended questions, and finally, the question sequence and layout are designed.

3.4 Ethical Concerns.

a. Avoiding Bias
   Bias occurs when the researcher intentionally hides the findings in the study or highlights something disproportionately to its actual existence (Kumar, 2005).

b. Obtaining Consent
   In many areas, gathering data from a subject without their knowledge is regarded as unethical. According to Kothari (1985) informed consent infers that subjects are adequately informed about the information that is needed from them, why it is being sought, what will be done with it, how they are expected to participate in the study, and how it will affect them either directly or indirectly. Consent must be voluntarily offered and uninfluenced in any way.

c. Information Gathering
   A respondent may feel pressured by the request for some information. Some information sought may be considered confidential by the respondent. Inasmuch it is acceptable to ask questions, it is best to do so after seeking informed consent from the respondent.

CHAPTER FOUR: RESULTS AND DISCUSSION

This chapter begins with the results of the study by presenting the responses from the questionnaires issued. It then looks at the blockchain network creation process and its web application that provides the users with a friendly interface to interact with the blockchain. Later on, testing of the APIs is discussed. The discussion section then follows. Finally, the validation and summary close the chapter.

4.1 Presentation of Results

Google forms were utilized by the study to obtain data from ten producers, distributors, and retailers who were randomly selected. The respondents were located within Nairobi County. Results were generated by analyzing the questionnaire responses. The study's research questions from section 1.4 were addressed using the findings. The integration of multiple functionalities into the overall results helped to shape the application's system design.

4.1.1 Questionnaire

A structured questionnaire was used to obtain data from the study's target respondents. The respondents were majorly retailers. The sample size used for this study is 10. The sample size was selected based on saturation theory as stated by Charmaz (2006) in the methodology chapter above. Most studies that use saturation are qualitative and the sample size mostly ranges between 9-17 respondents (Hennink et al., 2021). Detailed below are the questions that were included in the questionnaire as well as an analysis of their responses.

I. Methods used to check for drug quality after the acquisition

This question was meant to find out whether the wholesalers/retailers have ways to check for the quality of drugs purchased e.g. by testing the components in the lab. From the responses, most of the wholesalers and retailers do not have their own scientific lab testing means for checking the quality of drugs acquired. They rely on the Pharmacy and Poisons Board (PPB). The researcher did not manage to interview PPB personnel, therefore, methods used by the PPB were sought from secondary sources and the respondents of the study. The researcher discovered that the PPB issues licenses to manufacturers of pharmaceuticals and also makes sure manufacturers follow good manufacturing practices as per (Pharmacy And Poisons Act, 2012). Based on Pharmacy And Poisons Act (2012) a national quality laboratory is used as a facility for;
(a) the analysis and testing of pharmaceuticals, as well as any components or substances utilized in their production, as well as any potential manufacturing, processing, or handling processes. Drug and medical substance quality control is also ensured.
(b) conducting pharmacological evaluations and other chemical, biological, biochemical, physiological, and other analyses.
(c) testing pharmaceuticals and medicinal substances that are both imported and locally produced in order to ascertain if they adhere to the established requirements.

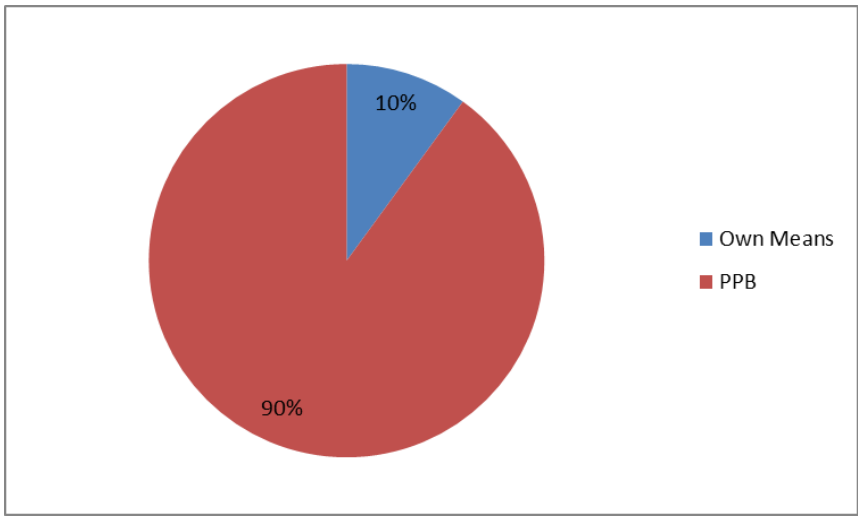


Figure 4.1: The pie chart above represents the methods the respondents use to check for drug quality.

II. Contact with counterfeit drugs

The respondents were asked whether they have handled counterfeit products on their premises. This was significant because the study's main goal was to comprehend the problem of drug counterfeiting in the pharmaceutical sector. 37% claimed to never have handled fake drugs while 63% cited having handled them. It is evident that a majority of respondents have encountered fake drugs hence the conclusion that counterfeit drugs are a threat facing the Pharma industry.

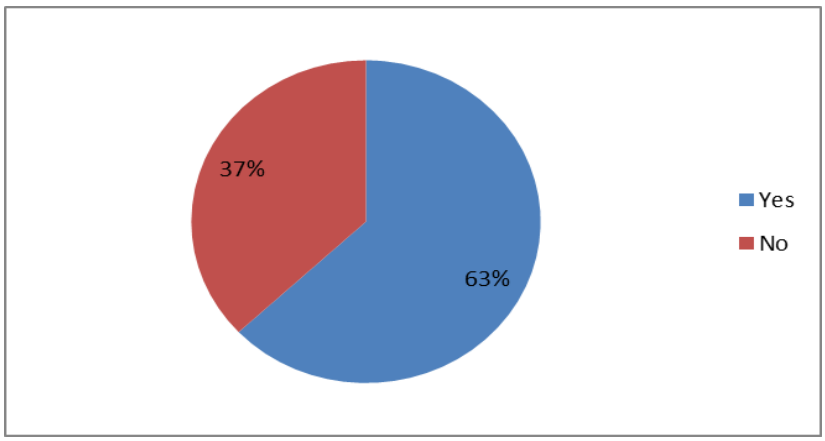


Figure 4.2: The figure above shows the rate of encounters with fake drugs.

III. The likelihood of counterfeit drugs injected into the Supply Chain being branded in a strikingly similar manner as the ones from authentic suppliers.

This question was answered only by the respondents that were certain they have handled fake products. This was crucial since it would shed light as to whether the branding of these fake products is a contributor to their increase in the supply chain since the untrained eye is unable to differentiate and hence does not report such cases. The majority of the respondents agreed.

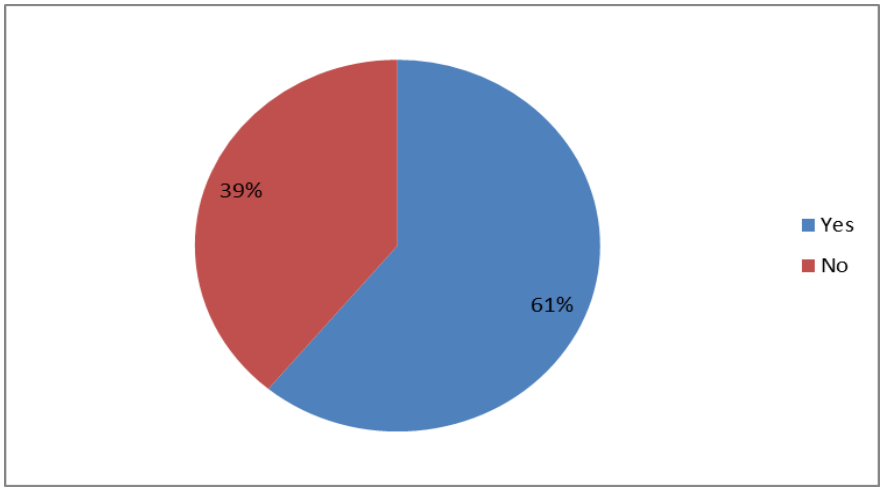


Figure 4.3: The figure above relates the branding of drugs and drug counterfeiting.

IV. The approximate number of parties the drugs go through before getting to the retailer

The question was meant to infer the parties the drugs pass through in the supply chain before reaching the retailer and finally the end consumer. This would help in relating the parties to the counterfeit drug issue, i.e. whether an increase in the number of parties that handle drugs before getting to the consumer increases the risk of injection of fake drugs into the supply chain. The respondents further cited the drug regulatory authority (PPB) has an inspectorate that ensures they follow the issued guidelines for effectual, proper handling, storage conditions, and distribution of products.

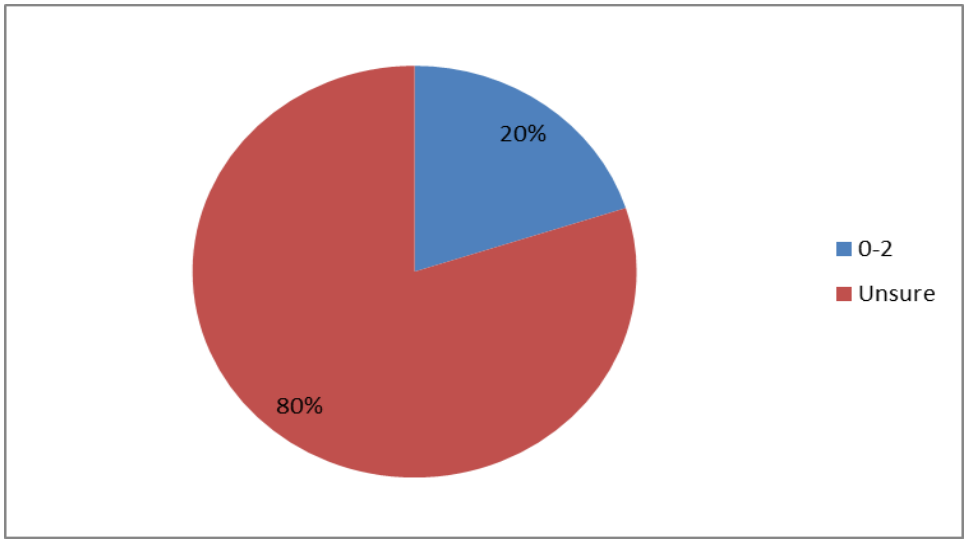


Figure 4.4: The figure above illustrates the number of individuals/organizations the drugs go through before reaching the retailer and finally the consumer.

V. Opinion on whether improving drug traceability will be effective in minimizing the cases of counterfeit drugs in the supply chain

This question was aimed at confirming whether there is a need for a more effective solution to address the issue of drug traceability. Most of the respondents agreed.

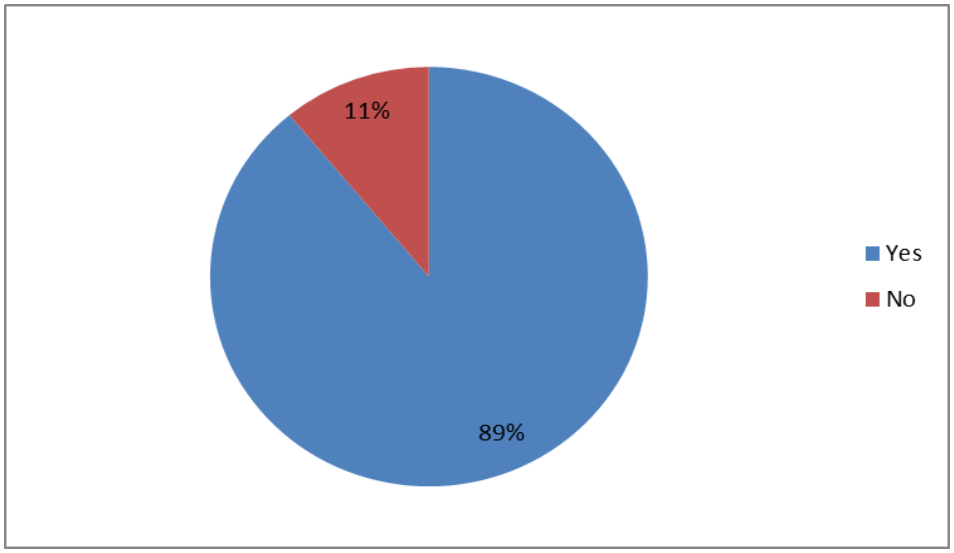


Figure 4.5: The pie chart above represents the views of the respondents on improving the traceability of drugs along the supply chain.

VI. Channels of distribution

The question sought to look at the channels of distribution of drugs before getting to the end consumer. The respondents cited that they rarely view the distributors as a separate organization since most of the time, the manufacturers/wholesalers have their own means of distribution. Therefore, getting a sample from the distributors was unfeasible. For this reason, this study decided to remove the distributor from the independent organizations. However, this could be pursued more when furthering this study. The channels of distribution were similar for the respondents. It was established that the drugs originate from a registered drug manufacturer, then a wholesaler, and finally to the retailers. However, it was noted that in some cases, manufacturers supplied drugs directly to retailers.

4.1.2 Setting up the Blockchain Network

The network in this study consists of one peer per organization and one orderer. The process begins by setting up the development environment. The developer installs the required prerequisites; Git, cURL, Docker, Docker Compose, Hyperledger Samples, Binaries, and Docker Images. Hyperledger Fabric is then downloaded and installed. Before a transaction is committed to the blockchain ledger, the peers verify it. They also store the blockchain ledger. The order in which endorsed transactions are included in new blocks is decided by ordering nodes. The blocks are subsequently sent to peer nodes, which add them to the blockchain ledger.

The network was set up locally via the ubuntu terminal. The process consists of several steps. A few of them are discussed below.

i.) Creating the network components

The network created consists of several components i.e. the orderer node, peer nodes, the certificate authorities, couch database, and CLI containers. To configure and manage identities within the blockchain network, certificates and key material are generated by the Hyperledger Fabric Certificate Authority (CA). The Fabric CA client registers node and user identities with the CA of each organization. A Membership Service Provider (MSP) folder is generated for each identity. According to Hyperledger (2020) the MSP folder contains each identity's certificate and private key, as well as information on the identity's role and membership in the organization that operates the CA. Once the organization's crypto material has been generated, the peer and orderer nodes of the network are brought up. When starting the network, the genesis block - the first block in the network, is generated. This is illustrated below.

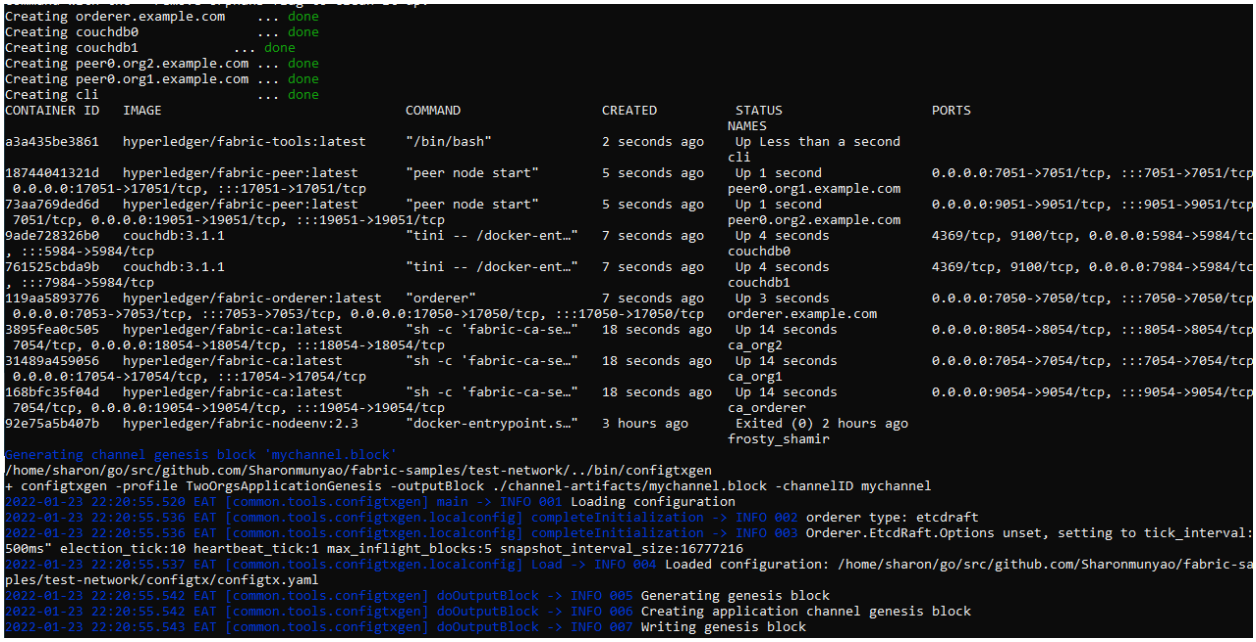


Figure 4.6: The figure above shows the components created during the process of bringing up the network.

ii.) Creating the Channel

The channel is the layer of communication between the various organizations within the network. The transactions between organizations take place on the channel.

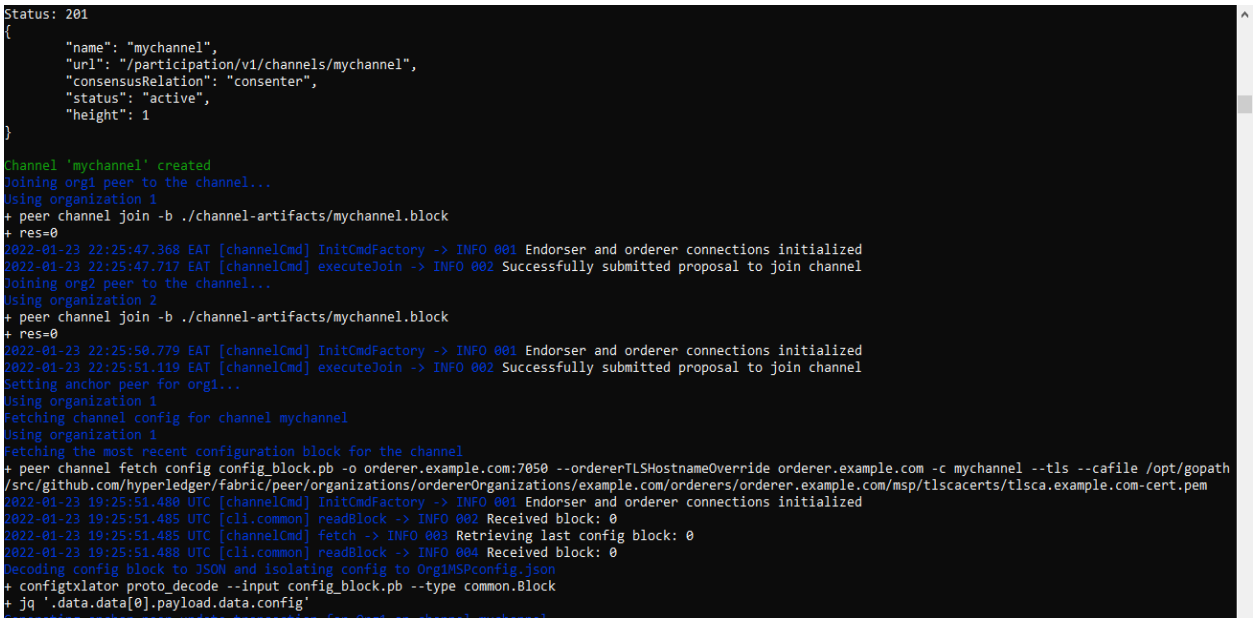


Figure 4.7: ‘mychannel’ channel creation during the blockchain setup.

iii.) Deploying the Chaincode on the channel

According to Hyperledger (2020) the business logic that governs an asset on the ledger is stored in the chaincode (smart contract). Chaincode is run by peers. The chaincode is written in JavaScript. The chaincode is packaged in order to be installed on each organization's peers. As per Hyperledger (2020) the chaincode is defined on the channel after it has been installed on the peers. Once the chaincode definition is committed to the channel, the chaincode is initialized and invoked to put initial data on the ledger. The chaincode is deployed to the channel and then utilized to communicate with the blockchain ledger and endorse transactions. Part of this process is illustrated below.

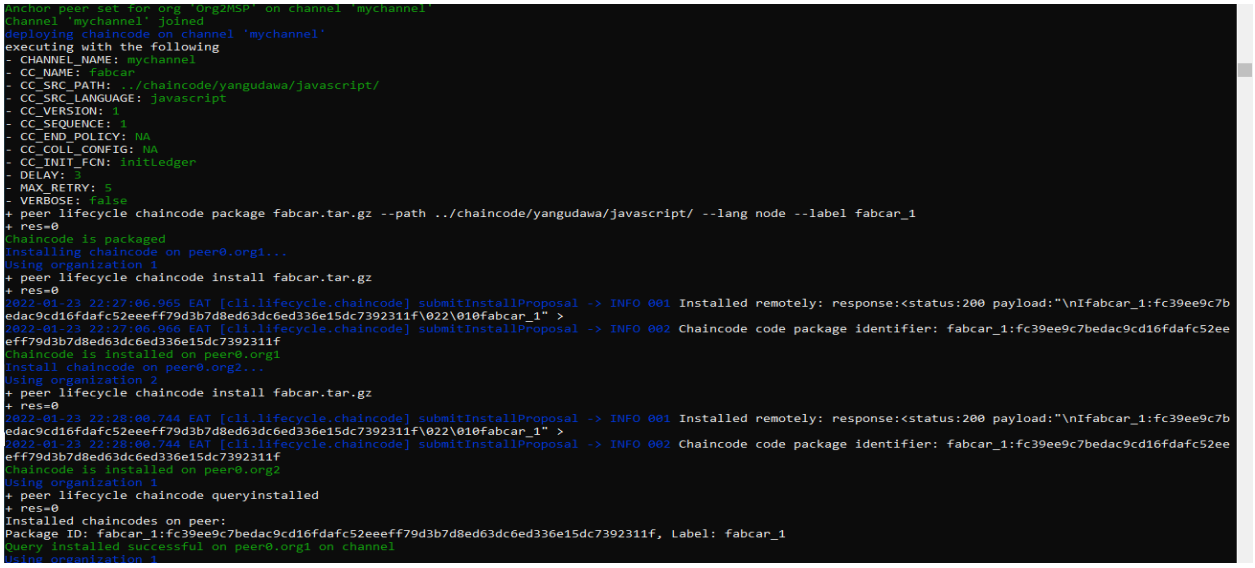


Figure 4.8: Javascript chaincode deployment in the ‘mychannel’ channel.

4.1.3 System Implementation

The solution is a web application called Fabdawa that integrates blockchain technology. The Fabric Gateway Software Development Kit (SDK) is used to allow the application to interact with the blockchain network. The Hyperledger Fabric Client SDK provides simple APIs to interact i.e., submit transactions or query the contents of the ledger, within the Blockchain network.

The blockchain comprises four actors namely; the Network Admin, Manufacturer, Wholesaler, and Retailer. In line with Hyperledger (2020) the application uses a connection profile to configure a gateway that handles all network interactions. The fabric SDK is used by the

application to communicate with the network. It follows some steps to submit a transaction as highlighted below;

a. An identity is selected from the wallet.
b. A connection to a gateway is established.
c. Access to the network.
d. A transaction request is constructed for the smart contract.
e. Submission of the transaction to the network.
f. Processing of the response.

Communication between the web application and the blockchain takes place via the exposed APIs. The APIs are used to invoke and query transactions within the blockchain. The web application's front-end and back-end were both developed using Javascript. MySQL database was used to store the system users' data.

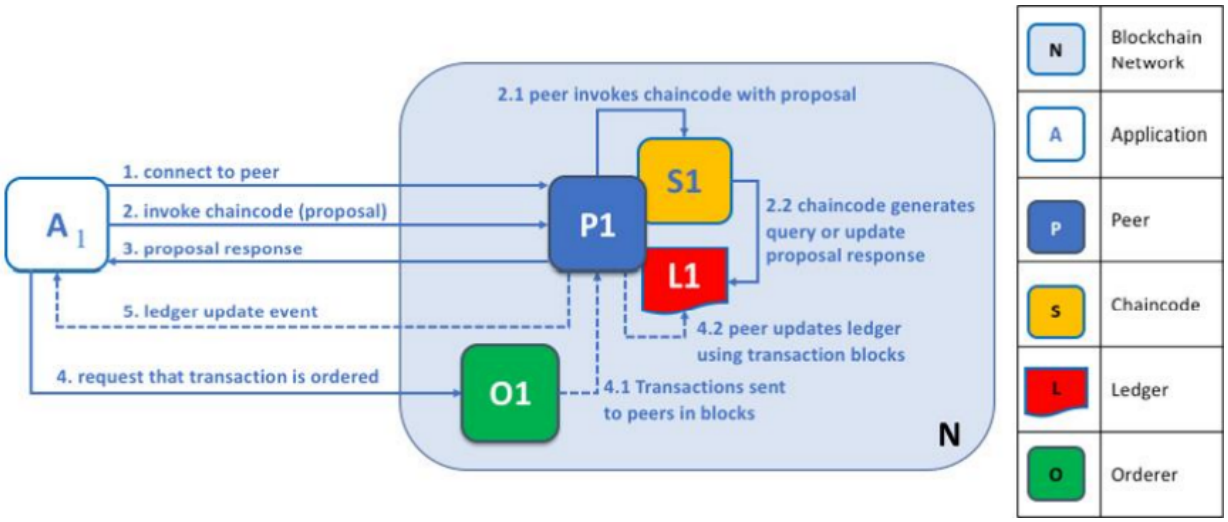


Figure 4.9: An illustration of the interactions between a peer node and the web application (Hyperledger, 2020)

Peers independently execute transaction proposals, returning responses that have been endorsed. Connection to the peer is established first by the application. Above, based on Hyperledger (2020) application A1 generates a transaction proposal that it transmits over the channel to peer P1. P1 executes S1 using the transaction proposal generating transaction response which it endorses. Application A1 receives the transaction's endorsed response. The ordering of the transaction is then requested by Application A1. Peer P1 receives the ordered block from orderer O1. Upon processing the block, peer P1 adds a new block to ledger L1 on P1. The ledger L1 has

been continuously updated on peer P1 after this process is finished, and it may then notify the connected application that the transaction has been processed.

Web Application Features

Network Users login page

The users log in to the system using their email and password. See the figure below.

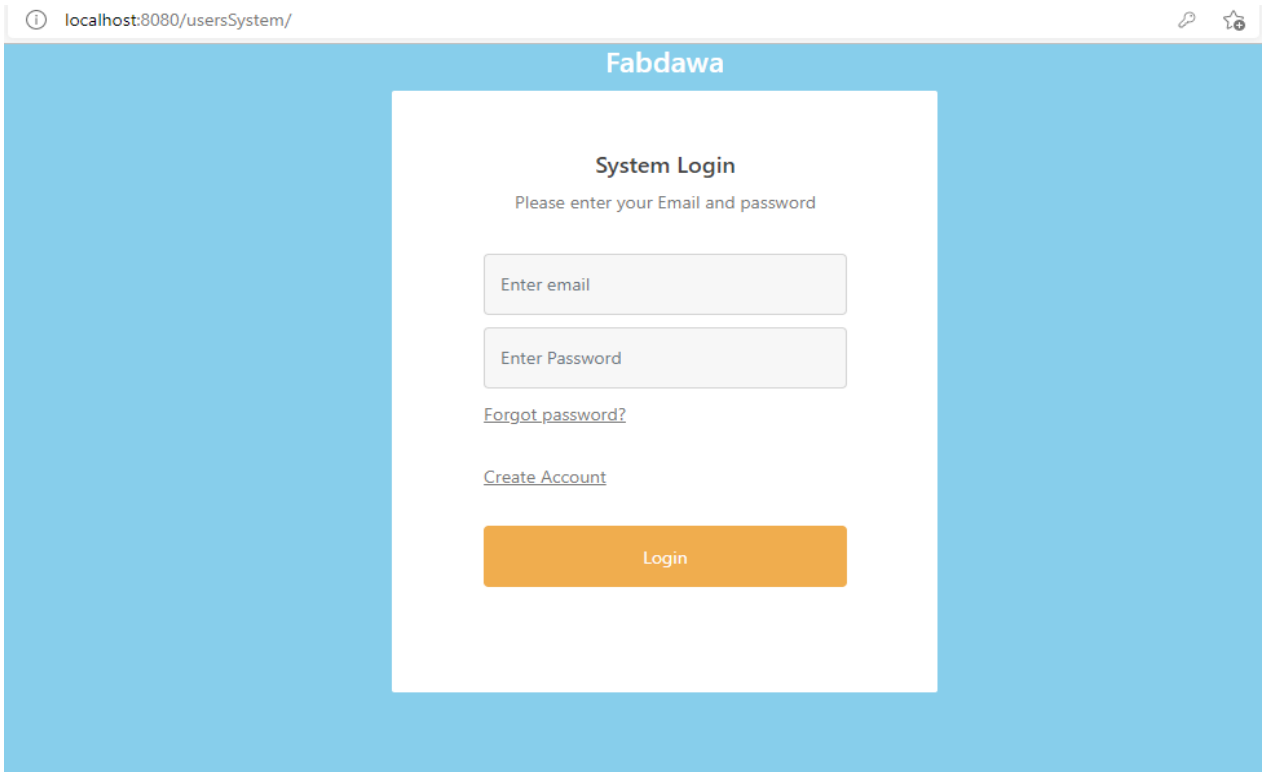
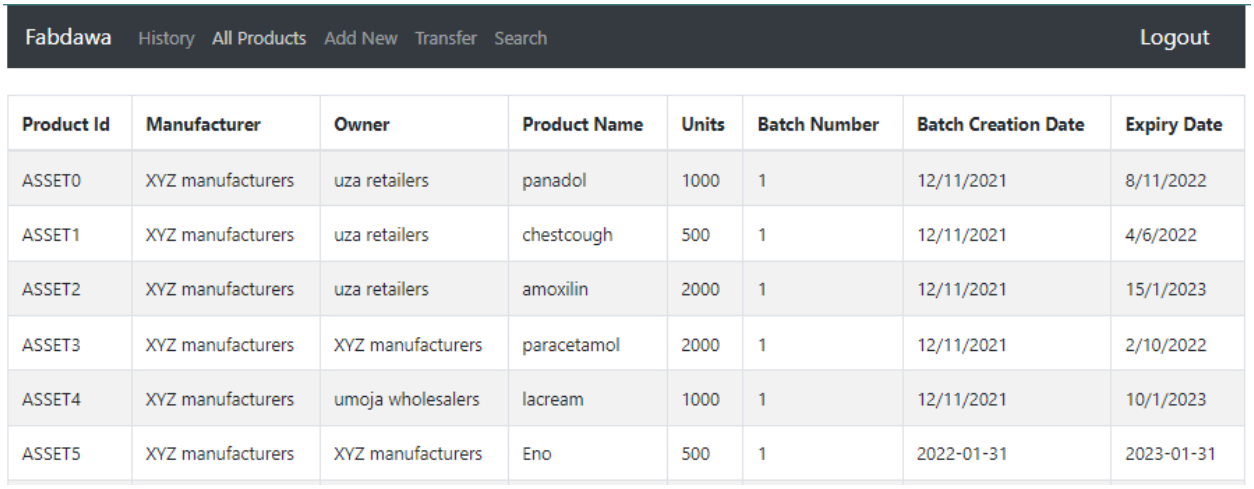


Figure 4.10: The figure above shows the user account creation and login page.

View all products page

Information on every product (asset) that is registered in the blockchain can be accessed here. See the figure below.



Product Id	Manufacturer	Owner	Product Name	Units	Batch Number	Batch Creation Date	Expiry Date
ASSET0	XYZ manufacturers	uza retailers	panadol	1000	1	12/11/2021	8/11/2022
ASSET1	XYZ manufacturers	uza retailers	chestcough	500	1	12/11/2021	4/6/2022
ASSET2	XYZ manufacturers	uza retailers	amoxilin	2000	1	12/11/2021	15/1/2023
ASSET3	XYZ manufacturers	XYZ manufacturers	paracetamol	2000	1	12/11/2021	2/10/2022
ASSET4	XYZ manufacturers	umoja wholesalers	lacream	1000	1	12/11/2021	10/1/2023
ASSET5	XYZ manufacturers	XYZ manufacturers	Eno	500	1	2022-01-31	2023-01-31

Figure 4.11: All assets in the blockchain are displayed here.

Transfer of Ownership

The web application provides the user with an interface to change ownership of an asset from their organization to another.

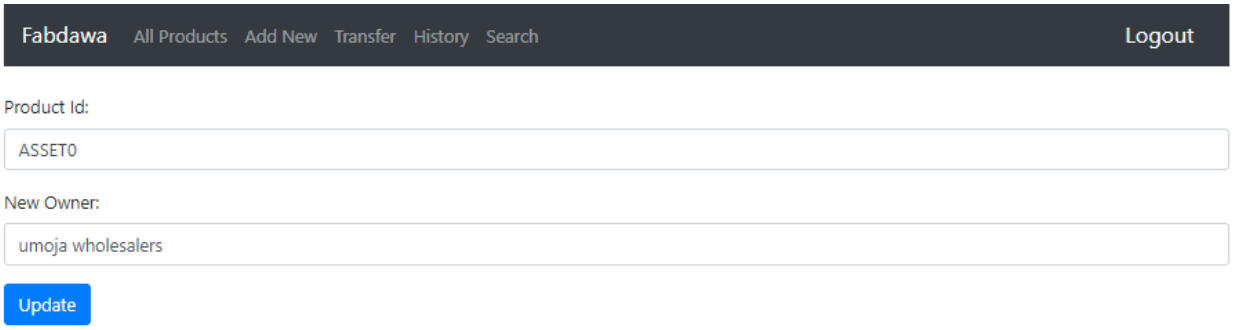


Figure 4.12: The figure above shows an asset changing ownership.

Product registration

The manufacturers on the blockchain are able to create and register new items on the blockchain. The product id and other information are added using a form as shown below.

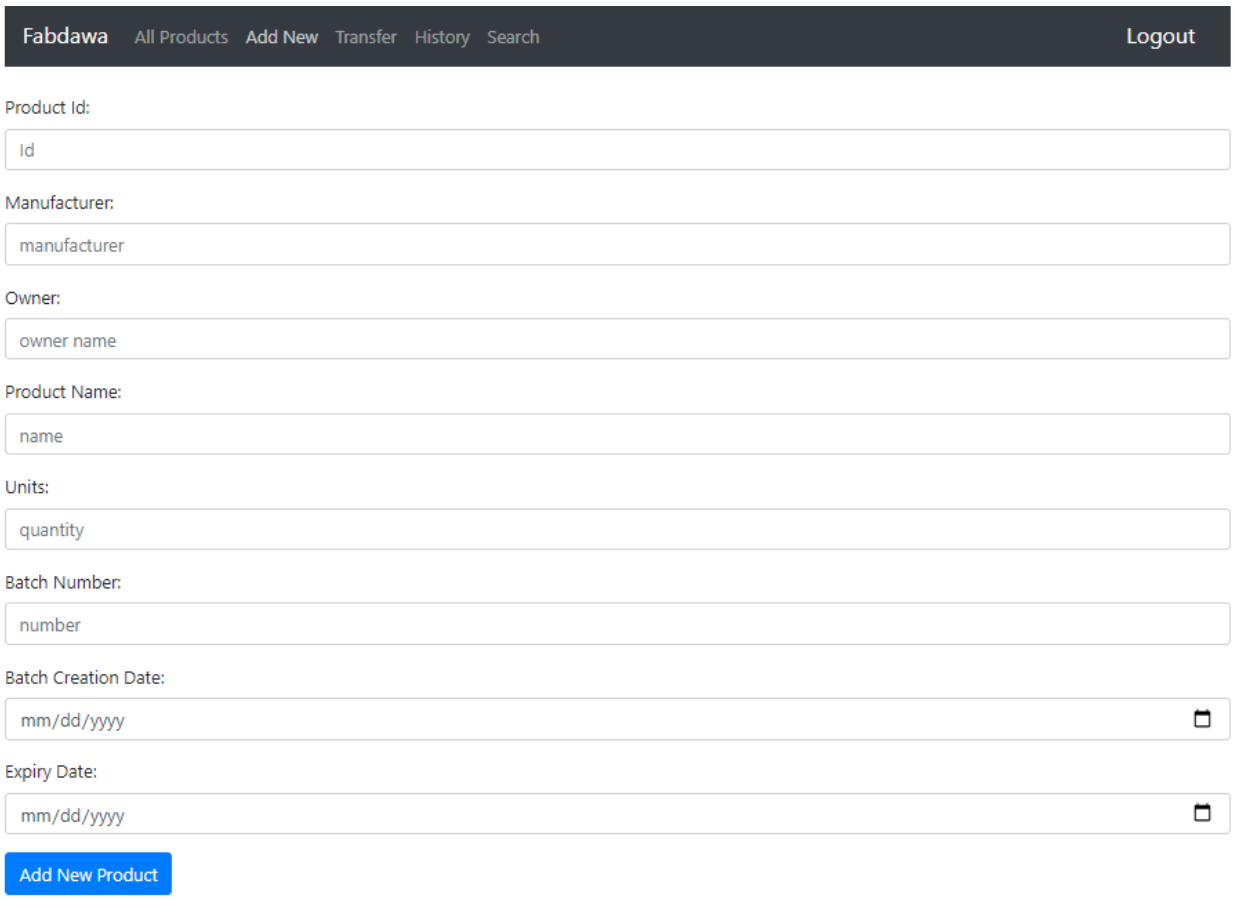


Figure 4.13: Form used to add a new asset to the blockchain.

Table 2: Registering a Product in the Blockchain

Utilized use case	Adding a new Item to the Blockchain
Test Parameters	Register a Product in the Blockchain
Expected Behavior	Successful display of Registered Product
Observed Behavior	Successful displayed Registered Product
Test Outcome	Pass

Tracing an asset

As a product moves along the supply chain, it changes ownership between the parties involved. When the end consumer purchases the product and scans the smart label attached to it, this is the page that displays the results. It clearly informs the consumer of how the drug has moved along the supply chain. This is key since it supports what Dr. Reddy Gottipolu (2020) reports in the literature review section. The user can scan a QR Code printed on the packaging of the drug or type the asset ID into the 'Product Id' field to access the history. Below is an example of a QR Code when scanned displays the history of a product with the unique identification 'ASSET0' and an illustration of the results acquired after either scanning the code or typing the Product Id.

Figure 4.14: QR Code opening to http://localhost:3001/api/GetFabdawaHistory/ASSET0

Table 3: Product history in the Blockchain

Utilized use case	Tracing a product in the network
Test Parameters	Viewing the history of an item using a unique ID
Expected Behavior	Successful display of product history
Observed Behavior	Successful display of product history
Test Outcome	Pass

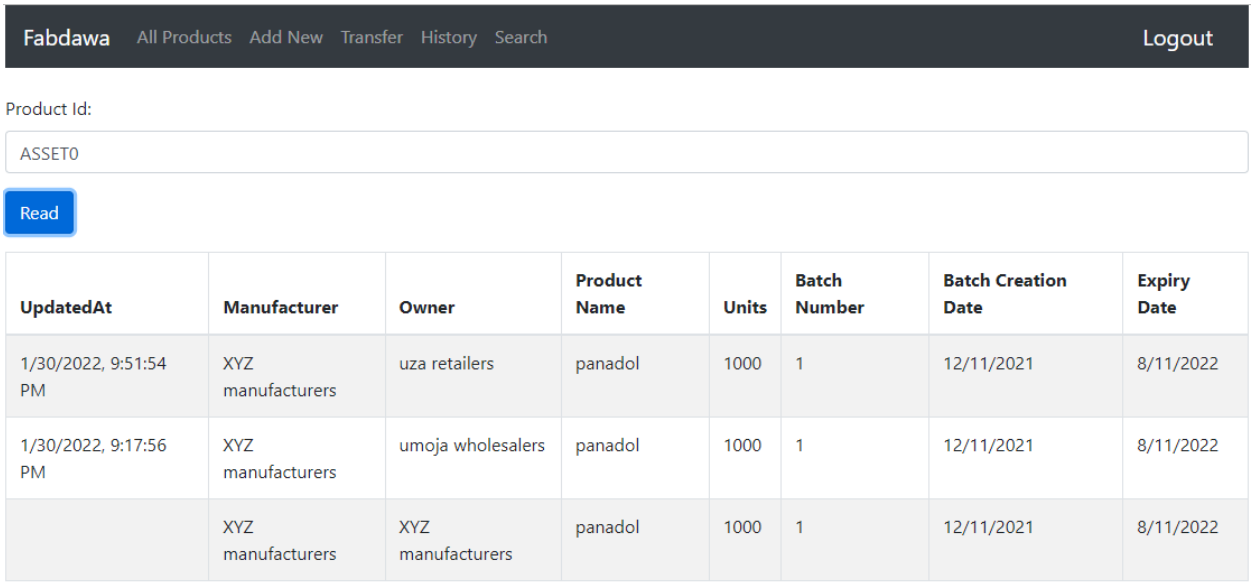


Figure 4.15: Results after querying an asset's history in the network.

4.1.4 API Testing

The APIs were tested using the postman application.

Create API

This is used to add new assets to the blockchain. It displays a success message and the transaction id once the asset is created.

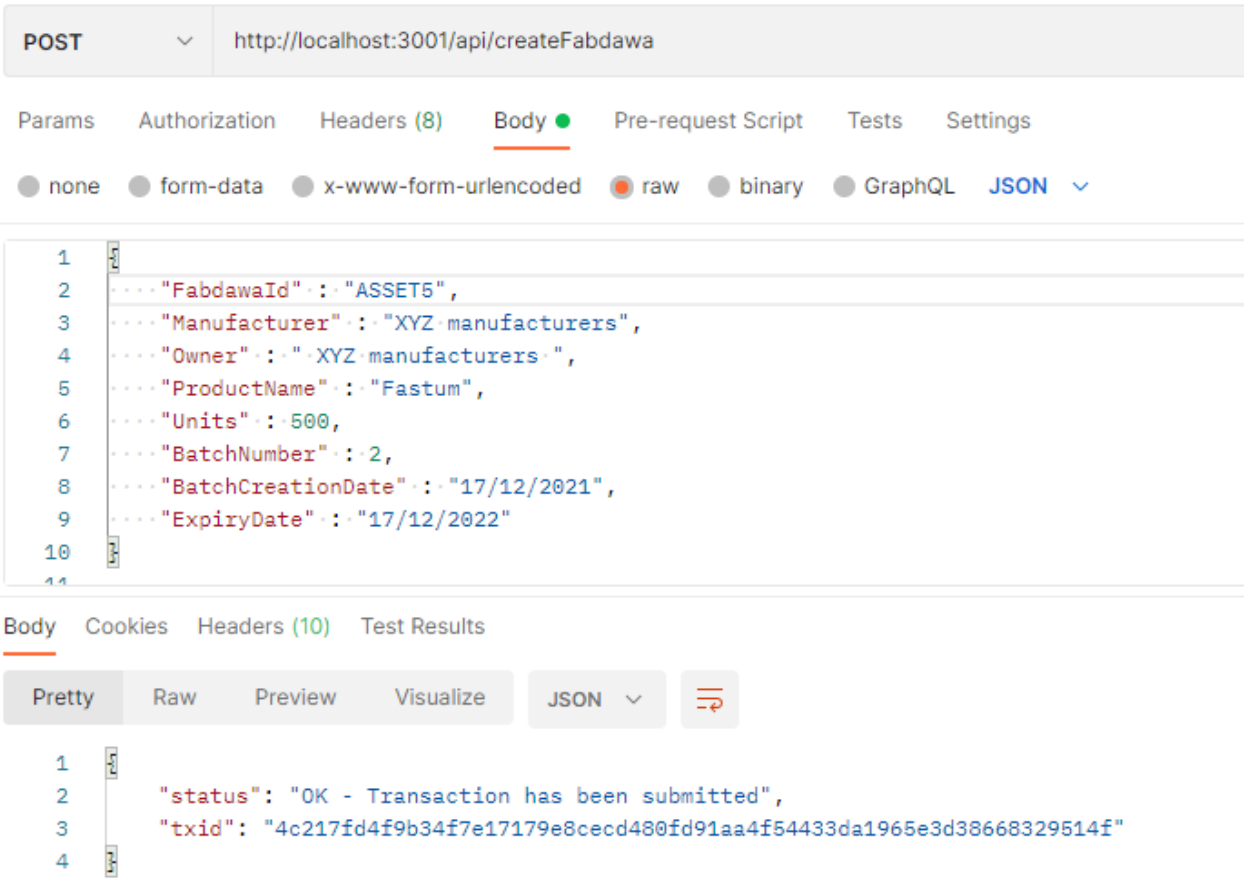


Figure 4.16: Response received after testing the ‘create asset’ API.

Read API

This API is used to query for a particular asset's details using the unique id. It returns a JSON response of the same.

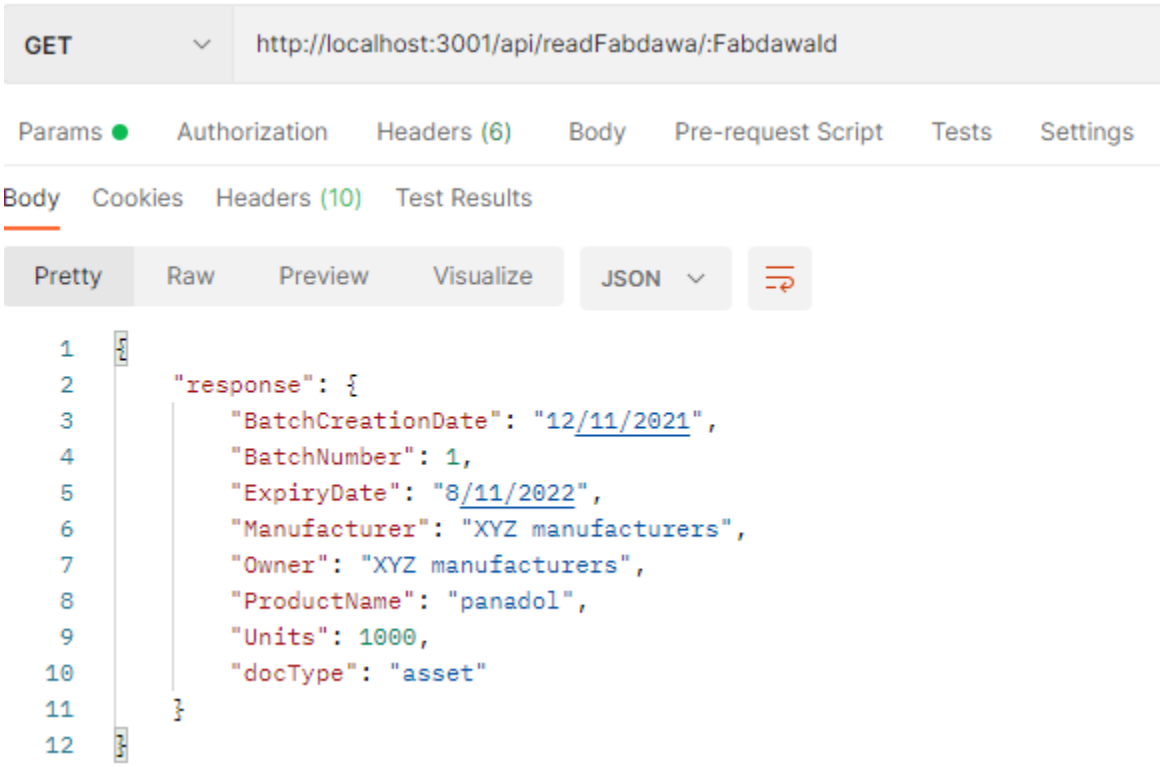


Figure 4.17: JSON response showing information of asset queried using unique id.

Transfer API

This enables the change of ownership of the assets within the blockchain from one organization to another. See the figure below.

Figure 4.18: The figure above shows the parameters required during the testing of the API.

Search History API

Since the asset constantly changes ownership during its lifecycle within the blockchain, it is important to ensure that the history can be traced back to the manufacturer. The transfer API ensures that the product can be traced in the supply chain. It presents results in JSON that distinctively show the different owners of the asset up to the current owner.

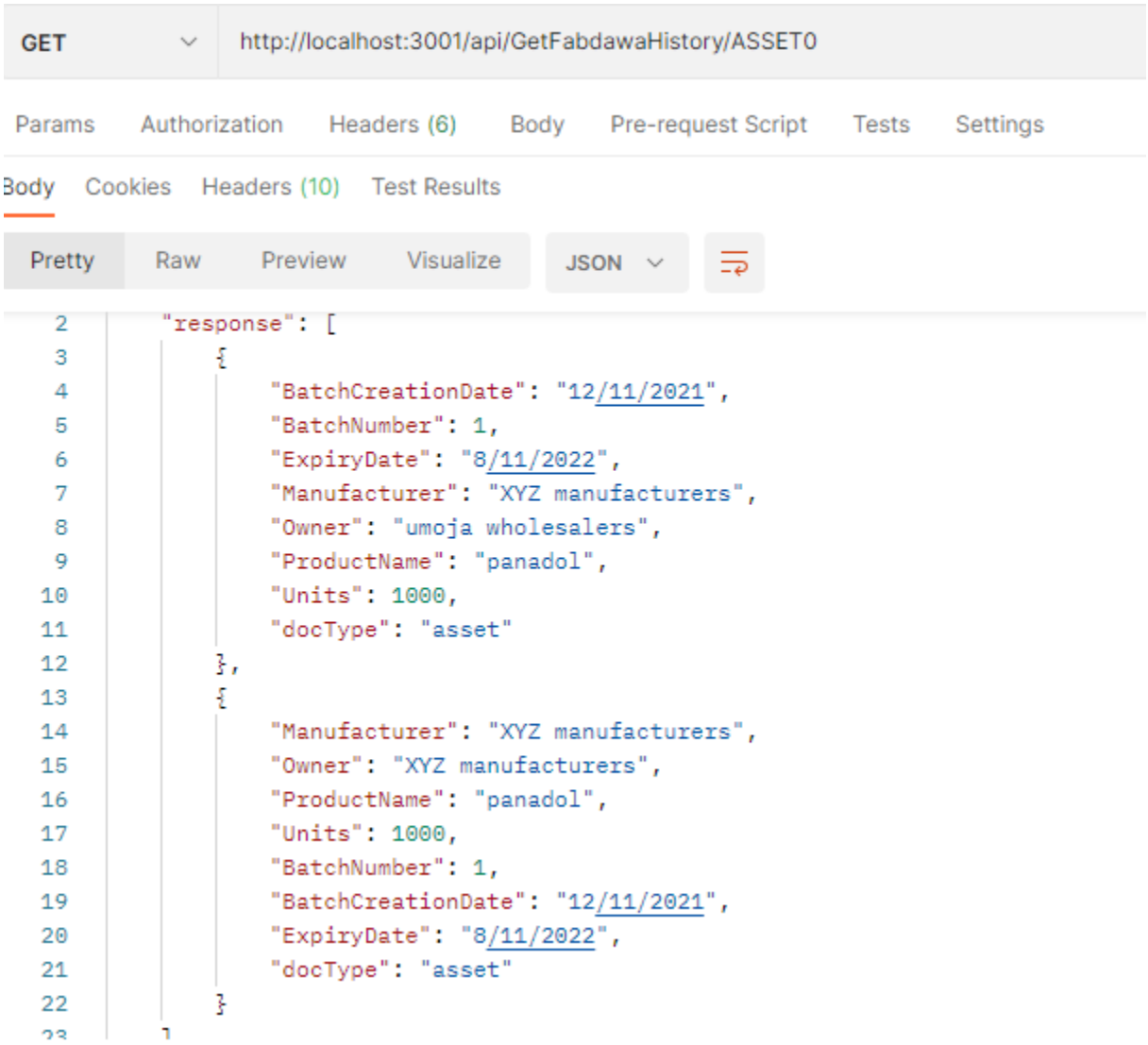


Figure 4.19: Results show the change in the owner field for the asset.

4.1.5 Validation

With the permissioned blockchain, coordination was made easier for the organizations involved and provided them visibility of their operations. Pharmaceutical firms in the network have the capacity to keep track of their suppliers, verify the quality and credibility of their supply chain, and maintain strict quality control. Each entry is encrypted separately, and because all changes are validated by the nodes, the network will detect any effort by any of the users to change data. Invalid node certificates, drug-related input discrepancies, and timestamp abnormalities are among the anomalies that the system could reliably detect along the supply chain.

After the purchase of a drug, the QR code once scanned by the consumer revealed the history of the product. Because scanning a replicated smart tag reveals the history of the original item, a consumer can determine if the scanned tag is a copy and, if so, the drug is almost certainly counterfeit. For example, if a medication package with a duplicate smart tag states that the distributor/wholesaler sold the drug to uza retailers for direct consumer sale, but the consumer discovered it being sold at a different retailer, say ABC retailer, the consumer could conclude that the smart tag was a fake. One conclusion to draw is that the QR code was duplicated, alerting the consumer to the possibility of a counterfeit drug. The authenticity of the product will be questioned if the last location does not match the purchase location. Once the manufacturer is notified, the counterfeit drugs are recalled from the supply chain. Any drug whose provenance cannot be established is labeled as counterfeit.

What did the users say about the system after the demonstration? User-friendliness. This targeted the ability of the system to be easily learned and the ease of use by the potential users. 60% stated that it was easy to learn and use, 20% indicated that it was fair while the remaining 20% cited it as poor meaning that their requirements were not met entirely.
Drug traceability. The respondents were asked if they were content with the solution as far as traceability is concerned. 60% agreed that they were content with the solution, and 20% stated that they were not. The remaining 20% said that they would rather have some more functionalities added before using it for traceability.
Solution’s success in solving drug counterfeiting. The respondents were asked for their opinion on whether the system was likely to significantly minimize the counterfeit drugs in the pharmaceutical supply chain. 60% agreed while 40% did not. The latter mentioned that they strongly advocated for scientific lab tests to prove whether a drug was fake or not.

4.2 Discussion

It is evident that most wholesalers and retailers do not have ways to confirm the components of the drugs they receive either directly/indirectly from the manufacturer. From the responses, they majorly rely on the Pharmacy and Poisons Board. One of the reasons might be that they lack the necessary lab equipment for testing the drugs. Another might be because they acquire a wide

variety of drugs which makes it difficult to confirm each batch received. Out of the two sources cited on the procedure followed by the PPB when checking for the quality of drugs, both agree that scientific lab testing is used. This is done on samples, not the entire batch of drugs. Drawing from this, if there are any counterfeit or poor-quality drugs in the received batches that end up not comprising the test sample, they will easily penetrate the market without being detected.

From the results, it can be seen that the drugs move through different parties along the supply chain, normally more than two before reaching the consumer. Considering that pharmaceutical drugs change hands multiple times before reaching the consumer, each transaction then poses an opportunity for fake or substandard products to infiltrate the market (Institute of Medicine of the National Academies, 2013). An effort to ensure that there is traceability whereby a consumer can view all parties that have handled the drug along the supply chain would therefore be valuable to the consumer. Most of the respondents have similar channels of distribution and it is notable that a big percentage ensure that the manufacturers that supply them are registered in an effort to minimize counterfeit drug entry into the market.

The respondents that cited not having come in contact with counterfeit medicines were few compared to the ones who had not. This number could reduce even further. Since the branding of fake drugs was noted to resemble a great degree the authentic ones, as confirmed by Christo Hall (2012) in chapter one, it is highly likely that most people who thought they had not encountered fake drugs at some point have come across them and mistakenly identified them as originals. Moreover, the results agree that improved drug traceability would go a long way in minimizing cases of fake medicines. This is also supported by Fatima Leal (2021) as discussed in the literature review of this study.

The API for adding an item to the network accepts some parameters including a unique identifier for every new item. In case the manufacturer tries to use the same identifier for different products, they receive no valid responses from the peers within the network and hence the transaction returns a failure. The create API utilizes the HTTP POST method to submit transactions to the ledger. This API is only used by the manufacturer in this case since they are the only ones allowed to create new assets and add them to the distributed ledger. Once the manufacturer updates the ledger, it is automatically updated for all organizations in the same channel i.e. the wholesaler and retailer.

During the transfer of ownership, the transfer API is called. It uses the HTTP POST/PUT method to submit the transfer transaction. Once the transaction is accepted, the world state of the ledger changes, and hence the asset is assigned a new owner. This API is used by the manufacturer and the wholesaler. When say for instance a wholesaler wants to transfer a batch of drugs to a retailer, this API is called which in turn invokes the chaincode for this particular transaction. Once this transaction is successful, it is registered on the distributed ledger. The retailer then is

able to query the blockchain and confirm that ownership has been changed to them. Thomas (2021) uses restful APIs that return JSON and can be consumed by applications of integrating organizations.

A feature in the application that considerably aids drug traceability is the history component which shows the journey of a drug from the manufacturer to the retailer that sells it to the end consumer. Each packet containing the drug is required to have a unique identifier e.g., ASSET0. The history API can be called by any of the organizations within the network. It uses the HTTP GET method to query the ledger. With the information from this transaction, the consumer would be able to trace back to the origin of the drug. This would ensure end-to-end traceability as supported by Fatima Leal (2021) due to the unique identification of drugs. The end consumer, however, does not need to use the web application for them to access the history of the product. Therefore, each packet has a different QR Code printed onto it. Each QR Code contains the URL to the history component of the application and the unique id of the product as a parameter. Therefore, once a consumer scans the code e.g., using a smartphone, it opens the history of that specific product. Other systems have used QR Codes in a similar manner to store information that links to a web application (Chipman, 2013).

The main aim of this study was to build a blockchain network that can accept accurate tracking data for monitoring drug commodity movement history. It is correct to mention that this was achieved and the system delivered on its expectations. Three people who would act as the end consumers were asked to scan the QR Code and give their thoughts. One said that it was simple to use while another noted that it was easily accessible since no additional device was required (a smartphone with a scanner was enough). The third noted that this code was unique for the specific asset in question.

4.2.1 The Final Model

The researcher was unable to get in touch with a member of the Pharmacy and Poisons Board for the interview. Therefore, the researcher did not get to understand in-depth the operations of the PPB. For this reason, some changes were made to the system model. This is illustrated below.

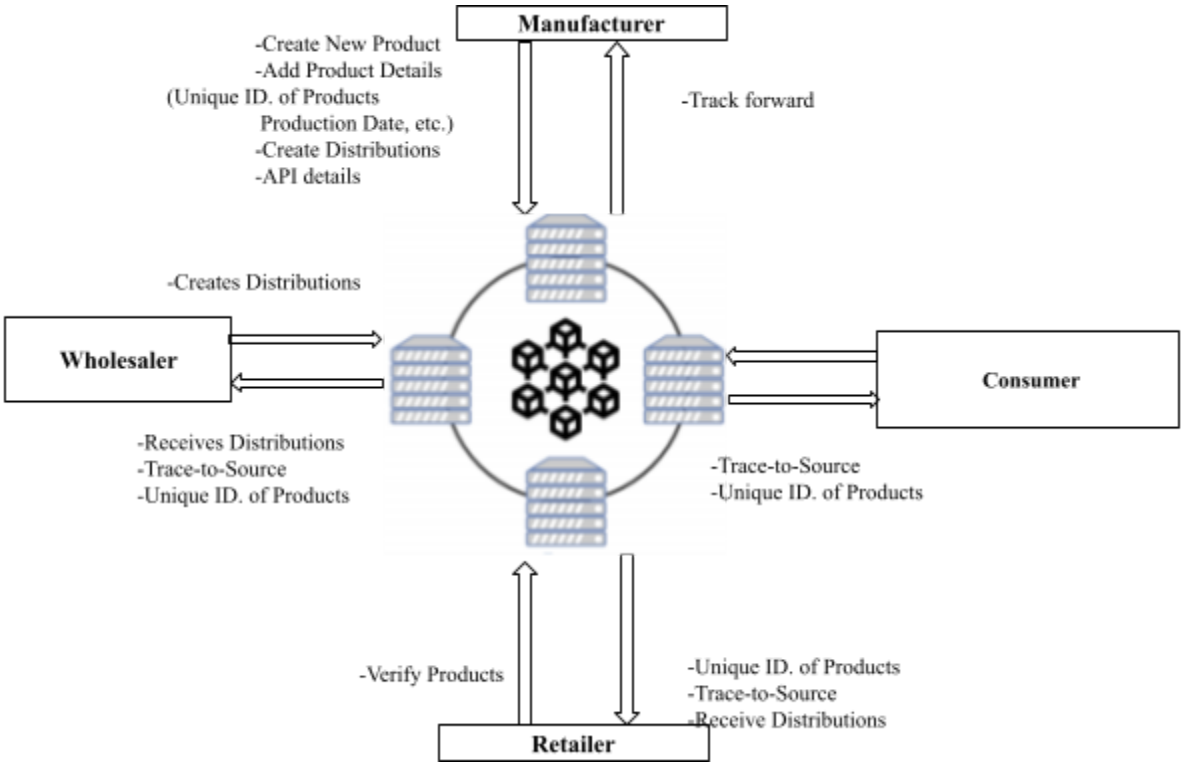


Figure 4.20: The figure above shows the interactions of the stakeholders with the Blockchain.

CHAPTER FIVE: CONCLUSIONS

5.1 Summary

The pharmaceutical industry has considerably been affected by the drug counterfeiting menace it continues to face. The purpose of this research was to come up with a solution to mitigate the flow of counterfeit drugs in the PSC. Anti-counterfeit technologies currently in use were studied in an extensive literature review. The researcher also collected data from actors within the PSC, majorly retailers. This data was aimed at understanding the processes within the Kenyan pharmaceutical supply chain and also the mechanisms in place to check for drug quality.

After the literature review and data analysis, it was clear that a solution with a traceability feature that covered up to the end consumer would be of significance in combating fake drugs. The study came up with a blockchain-enabled drug traceability solution. Feedback from the respondents after illustrating to them how the system works and validation tests imply that user and functional requirements were met. It is in order to conclude that the objectives of this study were met.

5.1.1 Requirements for the blockchain solution to tackle the issue of drug counterfeiting

For the solution to be viable, the data stored in the system needed to be immutable. This was achieved since this is the nature of data in a blockchain. Secondly, the provenance of drugs. This solution provided the user the ability to trace the drug back to the source. Lastly, the integrability of the blockchain. Since it was not feasible to use RFID cards and readers with the prototype, the study adopted the use of QR code technology to check whether the system was integrable. This proved to be a success.

5.1.2 Consortium Blockchain Suitability For a Pharmaceutical Supply Chain

A consortium blockchain is preferred primarily because it restricts the number of participants and delegates control to a group of authorized individuals rather than a single corporation. As a result, it offers the effectiveness and security of public blockchains while also allowing for some kind of centralized management, oversight, and security. The concept of channels is unique to Hyperledger Fabric. These channels provide distinct divisions between business logic and data privacy policies among various system stakeholders. The solution presented in this study utilizes one channel for all the stakeholders hence making all data accessible to all stakeholders. The

solution, however, can be modified to use both public and private data/transactions when the need arises in the participating organizations by creating different channels. Finally, the blockchain is collectively maintained,i.e., all the organizations are responsible for the data in the blockchain.

5.1.3 Data veracity and traceability in a blockchain solution

In this study, data veracity was achieved by involving a mechanism to ensure the correctness of data i.e., by being selective when assigning roles for data entry. Unique identities are used to verify authenticity, and authenticated users are given access to services that let them encrypt and store data on the blockchain in a secure manner. Only verified users from the manufacturer organization are able to add any items and ensure they are all uniquely identified.
Traceability was also attained since the history of a product could easily be queried using its unique identifier. End-to-end traceability is achieved since the product journey is visible from the source to the end consumer.

5.2 Limitation

The solution does not apply to drugs that do not have a unique identifier or a tag, say a QR code. It was noted that some drugs are sold apiece i.e., without being in a packet/sachet. The developed application would therefore not assist consumers to verify the authenticity of drugs sold without having a unique ID.

Additionally, the system can only identify drug movements that adhere to the official distribution networks that are recognized by the drug regulatory authorities. It is unable to trace fake medications that are distributed outside of authorized channels.

The results of this research may not accurately represent how the system will work in a real-world setting because it will be built and used in a controlled context.

5.3 Recommendations for further work

Different channels can be created so as to introduce the private aspect of the consortium blockchain for the participating organizations. This would be of importance since organizations that need to share confidential information between themselves would do so without the worry of everyone accessing the same.

Data on how drug distributors operate could be obtained. This would give further insight into the logistics of the shipping procedure and clarify whether or not counterfeit drugs were introduced into the PSC during transit. This would also ultimately lead to their inclusion in the application.

With more research, the improved web application version of the solution can be adopted in a real industry environment where the Kenyan Pharmaceutical industry stakeholders would maintain a blockchain platform for their drug supply chain in turn increasing transparency within the PSC. This would assist in product provenance. In this way, stakeholders that have been left out could all be included in the solution.

More research on the suppliers of the pharmaceutical product's primary stage of manufacture could be done (where raw material is transformed into an active pharmaceutical ingredient). This would eliminate the chance of counterfeits being introduced into the raw materials, ensuring the manufacturing of genuine active medicinal ingredients.

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APPENDICES

Appendix 1: Questionnaire

This form is aimed at collecting information regarding the Pharmaceutical Supply Chain in Kenya in order to understand the processes involved. Information collected here will only be used for educational purposes.

1. Most of the drugs in your supply chain are?
   Imported
   Locally Manufactured
   Other…

2. Do you audit your suppliers?
   Yes
   No

3. Approximately how many parties do the drugs go through before getting to you?

4. How do you check for drug quality after acquisition?

5. What are your channels of distribution? (e.g. brokers)

6. How do you manage your channels of distribution?

7. What are the activities involved in distribution? (e.g. warehousing)

8. Are there some enabling conditions for the injection of counterfeit drugs in the Supply Chain?
   Yes
   No

9. If your answer is 'Yes' in the question above, please mention these conditions

10. Who are your key customers?

11. What kind of information do you share with your suppliers?

12. Have you come into contact with counterfeit drugs?
    Yes
    No

13. What are the measures you have employed to curb the infiltration of counterfeit drugs in the supply chain?

14. At some point, have you had to recall any drugs from the market after realizing they were counterfeit?
    Yes
    No

15. In your opinion, could improved drug traceability minimize the cases of counterfeit drugs in the supply chain?
    Yes
    No