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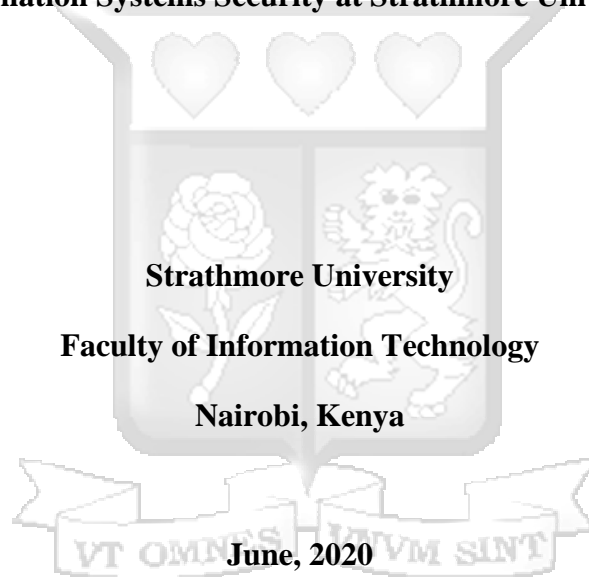
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**BLOCKCHAIN ENABLED DRUG TRACEABILITY SOLUTION: A CASE OF DRUG
COUNTERFEITING IN A PHARMACEUTICAL SUPPLY CHAIN**

Patricia, Tanya Ogwel

**Submitted in partial fulfilment of the requirements for the Degree of Master of Science in
Information Systems Security at Strathmore University**



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Name of Candidate: Patricia, Tanya Ogwel

Signature:



Date:

7th July 2020.

Approval

This thesis of Patricia Tanya Ogwel was reviewed and approved by the following:

Dr. Joseph Sevilla,

Senior Lecturer, Faculty of Information Technology,

Strathmore University.

Dr. Joseph Orero,

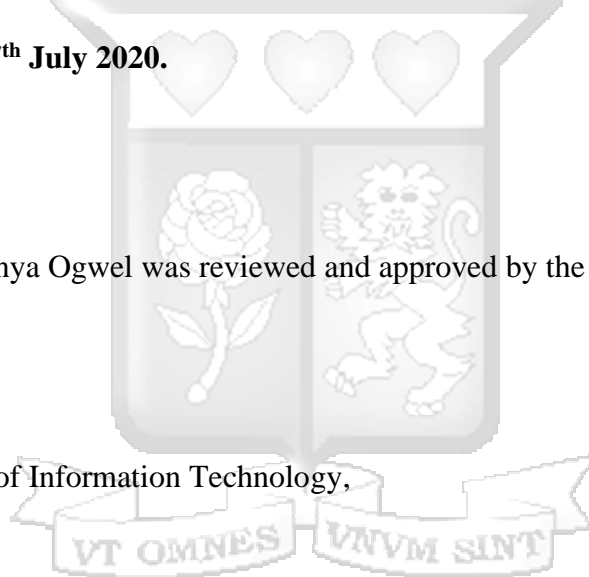
Dean, Faculty of Information Technology,

Strathmore University.

Dr. Bernard Shibwabo,

Director of Graduate Studies,

Strathmore University.



ABSTRACT

The pharmaceutical industry deals with manufacturing, packaging and supply of drugs to the end consumers. Being one of the major industries in Kenya, it plays a big role in the Kenyan economy as well. Most countries are tackling this menace of fake drugs penetrating their markets at a high rate. The drug cartels have embarked on this business and are growing their wings to various parts of the world. The drugs packaging is so similar to the original manufacturer's Product that at first glance one cannot tell the difference between a legit Product and a counterfeit one. Unfortunately, most drug users over the years have been on these fake medications and as a result some of them have not been successful in the treatment of their diseases. In the direst of situations, some patients have aggravated their conditions with the worst-case scenarios resulting to death. The main objective of this dissertation was to come up with a blockchain enabled drug traceability solution that enabled visibility in the supply chain. This solution ensured the drug registered by the company was genuine, and that the end user will be able to see who handled the Product before reaching them. In a way, this will aid in reducing, eventually eradicating the challenge of drug counterfeits in the market. The dissertation area of focus was a pharmaceutical manufacturing company's supply chain setup and the Waterfall Approach was the SDLC (Software Development Life Cycle) approach used. The study devised a solution that can aid in drug traceability of the drug issued to an end user thus a patient in the drug chain. This helped a patient determine if the drug they are purchasing is genuine. The study used blockchain technology to come up with the application.

KEYWORDS: Drug Counterfeits, Drug Traceability, Drug Supply Chain, Blockchain Technology.

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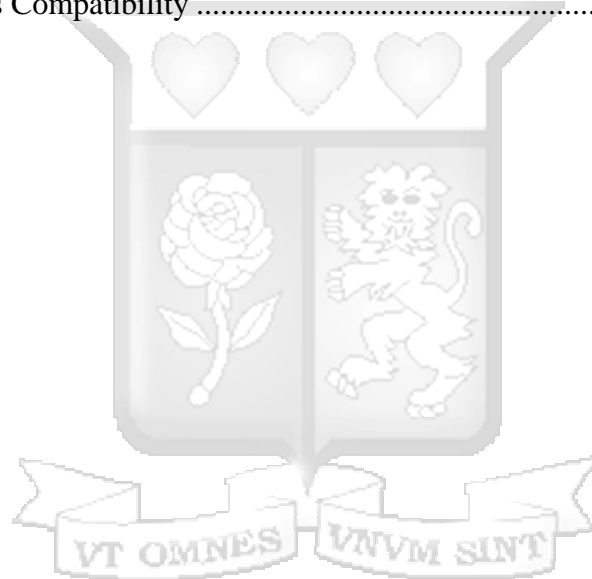
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LIST OF ABBREVIATIONS

API- Application Programming Interface

B2B - Business to Business

BND – Business Network Definition

BNA – Business Network Archive

COMESA- Common Market for Eastern and Southern Africa

CSBWG - Clinical Supply Blockchain Working Group

DEA- Drug Enforcement Administration

FDA- Food and Drug Association

GDP- Gross Domestic Product

IoT- Internet of Things

IP- Intellectual Property

KEMSA- Kenya Medical Supplies Authority

KRA – Kenya Revenue Authority

LTC- LiteCoin

LOI- Letter of Intent

MEDS- Medical Supplies Authority

MOH- Ministry of Health

MVP - Minimal Viable Product

OTC- Over the Counter

P2P- Peer to Peer

PPB- Pharmacy and Poisons Board

RFID- Radio Frequency Identifiers

SDLC- Systems Development Life Cycle

SFDA- State Food and Drug Administration

SGTIN- Serialized Global Trade Item Number

sNDC- Serialized National Drug Code

UN- United Nations



DEDICATION

I dedicate this dissertation to my grandparents and parents. They have been of great support to me in my studies and upbringing.



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CHAPTER 1: INTRODUCTION

1.1 Background of the Study

The pharmaceutical industry in Kenya is an emerging market that is steadily rising. This market constitutes of urban and rural clients not forgetting the government and the private hospitals. Drugs in Kenya are either prescribed or sold over the counter to the customers (patients). It consists of three major players: manufacturers, distributors and retailers. They all play a major role. Kenya is the largest manufacturer of medicine in the COMESA (Common Market for Eastern and Southern Africa), supplying the region with approximately 50% of the region's market estimated 50 pharmaceutical manufacturers (Weru, 2018). Over the years, Kenya has been grappling with drug counterfeiting.

Mombasa has been ranked as a major drug trafficking point. This is due to the ease of access from the far seas via the Indian Ocean. China and India are known for notoriously being major manufacturers of fake drugs that penetrate the market. The drug counterfeiting industry is run by powerful cartels. The continued use of fake drugs threatens the lives of many Kenyans (Peter, 2018).

Counterfeit medicine is fake medicine. It may be contaminated or contain the wrong or no active ingredient. They could have the right active ingredient but at the wrong dose. Counterfeit drugs are illegal and may be harmful to your health (Food and Drugs Administration, 2017). This remark by the USA Food and Drugs Administration kick starts the process of understanding this major challenge on drug counterfeiting.

Kenya has had many cases over the years with regards to the fake drugs menace. Products that were counterfeit versions of medicine for treating hypertension and diabetes were seized in Eldoret, Kenya on the 30th of July, 2009. Inspectors for the Pharmacy and Poisons Board seized the drugs from a local private pharmacy. The drugs were ready for disbursement to the town's health centres. To make matters worse, the drugs were nearly expired by 10 years and others were contrabands (Napb, 2009).

Such situations have many consequences including dangerous side effects or lack of efficacy to the patients using the drugs. In extreme cases it may lead to fatalities. Furthermore, the public in particular the rural community may lose faith in Western medicines and medical health providers

falling back to the traditional ways of administering healthcare thus traditional healers and medicine (Tai, 2011). A patient should experience therapeutic value after taking medicine and this is not the case with the growing cases of counterfeit drugs infiltrating the market.

1.2 Problem Statement

The Pharmaceutical Industry in Kenya has a major issue when it comes to counterfeit drugs. The genuine and fake drug packets have similarities at first glance. A customer (patient) cannot easily differentiate between a counterfeit and legitimate drug by looking at the drug packets. Drug cartels manufacture illegal/contraband drugs without adhering to the legal process and requirements. The fake drugs do not undergo any type of verification or inspection by the drug regulatory body lawfully in charge of drug manufacturing in Kenya – Pharmacy and Poisons Board. Eventually the drugs are distributed to various distributors and retailers in the country consequently, consumers (patients) are exposed to substandard drugs that are not efficient in treating their ailments rather do not have an effect at all.

1.3 General Objective

The main objective of the research was to develop a blockchain enabled drug traceability application for a manufacturer that enables a consumer to identify if a drug administered to them from a retail outlet is legitimate or not.

1.4 Research Hypothesis

The study assumes that a Blockchain enabled drug traceability solution can be used to mitigate the drug counterfeiting problem in the drug manufacturing industry's supply chain.

1.5 Research Objectives

- I. To investigate how the current Kenya pharmaceutical drugs supply chain industry works and understand the drug counterfeiting issue.
- II. To investigate the technologies used to tackle counterfeiting.
- III. To design, implement and test blockchain enabled drug traceability solution.
- IV. To validate that the blockchain enabled drug traceability solution will provide a solution to the counterfeiting problem in the Kenya pharmaceutical drug supply chain.

1.6 Research Questions

- I. How does the Kenya Pharmaceutical drug supply chain industry work?
- II. What are the current technologies used to tackle drug counterfeiting in the drug supply chain industry?
- III. How can blockchain be used to design, implement and test of the solution be carried out?
- IV. Has the blockchain enabled drug traceability solution mitigated the drug counterfeiting issue?

1.7 Scope of the Research

This research was limited to an urban region in Kenya, Nairobi to be specific. The study based their research on a typical Kenyan manufacturer's supply chain consisting of the following stakeholders: the manufacturer, the distributors, the retailers and Customers.

1.8 Limitations of the Research

The development of the solution was based on the IBM Hyperledger Composer and Hyperledger Fabric Blockchain platform. However, the solution had some limitations.

- I. First, it was dependent on the Internet in that the users should always have good Internet connection to access the solution's services.
- II. The solution was able to trace the movement of drugs, which follow a typical supply chains, which are known to the regulatory agency. It cannot track counterfeit drugs that are distributed along routes outside the official supply chains.
- III. The solution was developed and tested in a controlled simulated network; therefore, the results of the studies may not reflect actual performance in real-world deployment.
- IV. The solution was limited to a pharmaceutical manufacturer's Drugs since it was focused on its drug supply chain. However, it is scalable to accommodate a different scenario thus another manufacturer's supply chain.

1.9 Justification of the Research

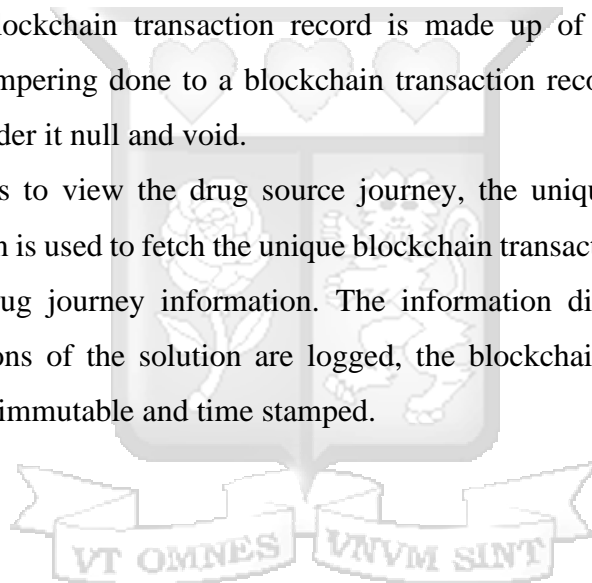
The study sought to address drug counterfeiting in the pharmaceutical industry that has proven to be a major challenge through the use of Blockchain Technology. The circulation of genuine and fake drugs in the supply chain paves way for the possibility of consumers to purchase fake drugs that are

similar to genuine drugs in packaging. A customer is able to verify the source of the drug through their web application portal which performs query actions to the solution's Blockchain.

The Blockchain platform forms part of the solution's echo system that includes a web application which communicates to the Blockchain using an API. With its permissioned nature, the blockchain's transactions are secure since the users of the solution are authorised and given role-based access. The data stored in the blockchain is immutable and of integrity because all the solution's transactions are verified before being committed to the solution's common Distributed Ledger as Blockchain Transaction records by a designated authority. The Ledger's consistency is mandatory.

All transactions on the ledger are sequenced and cryptographically linked together. The hash nature protects the records. Consequentially, preventing modification of blockchain transaction records since the hash of each blockchain transaction record is made up of the previous blockchain transaction's hash. Any tampering done to a blockchain transaction record will distort the whole Distributed Ledger and render it null and void.

When a consumer requests to view the drug source journey, the unique identifier of the drug, allocated during registration is used to fetch the unique blockchain transaction record that carries the data load that displays drug journey information. The information displayed is authentic and trustworthy since the actions of the solution are logged, the blockchain transaction records are cryptographically secured, immutable and time stamped.



CHAPTER 2: LITERATURE REVIEW

2.1 Introduction

This chapter traverses the literature review of similar blockchain enabled solutions that trace drugs down a manufacturer's drug supply chain. It also touches on the anti-counterfeit drug detection technologies that are existent in the market but do not use blockchain technology. A comparison of the technologies will be done and the gap of the solutions realized at the end. Lastly, the study will state its solution's value addition and the literature they will take into consideration. The mission of the pharmaceutical industry is not to treat illness but they do collaborate with doctors in targeting diseases that have already been detected (KenyaPhamTech, n.d.).

2.1.1 Drug Classification

There are various ways of classifying drugs in the pharmaceutical market namely: OTC (Over the Counter), Prescription Drugs and behind the counter drugs. The OTC drugs are medication which the consumer can order by themselves without the aid of a prescription. Prescription drugs are prescribed by a physician and can only be handed to a consumer once the pharmacist reads and interprets the dosage. Finally, the behind the counter drugs are medication that can only be kept by the pharmacist not visible to the public and can only be discharged by them without use of a prescription (Food and Drugs Administration, 2017).

Another classification of drugs is generic drugs and brand-name drugs. Brand-name drugs are originally prepared by the registered manufacturers and released into the pharmaceutical market for consumption. The generic drugs are exact copies of the brand-name drug whereby they have the same ingredients, quantity and performance as the original drug. Their pharmaceutical effects are the same as the brand-name drugs too. However, there is a growing category of drugs making ways into the market called counterfeit drugs. This can comfortably be named as drug counterfeits.

2.1.2 Drug Counterfeiting

Counterfeit according to the Cambridge English dictionary is making something to look like the original of something, usually for dishonest or illegal purposes. Counterfeit medicine is fake medicine. It may be contaminated or contains the wrong or no active ingredient. They could have

the right active ingredient but at the wrong dose. Counterfeit drugs are illegal and may be harmful to your health (Food and Drugs Administration, 2016).

2.1.3 Drug Traceability

Drugs from a manufacturer make many stops before it reaches the retailers. In this process the drug may experience different eventualities such as damage, loss etc. The term traceability means being able to track the drug down the supply chain to the end consumer. One should be able to see how the drug moved considering the timelines and the original identification value should be used to identify this.

2.2 The Pharmaceutical Drug Supply Chain Working and Challenges in Selected Countries

2.2.1 Asia (China)

China has a typical pharmaceutical supply system as demonstrated by Figure 2.1. However, most patients prefer hospital pharmacies over drug retail stores for reasons such as: inconveniences, non-standardized prescriptions and greater assurance of pharmaceutical supply quality (Xuan, 2015).

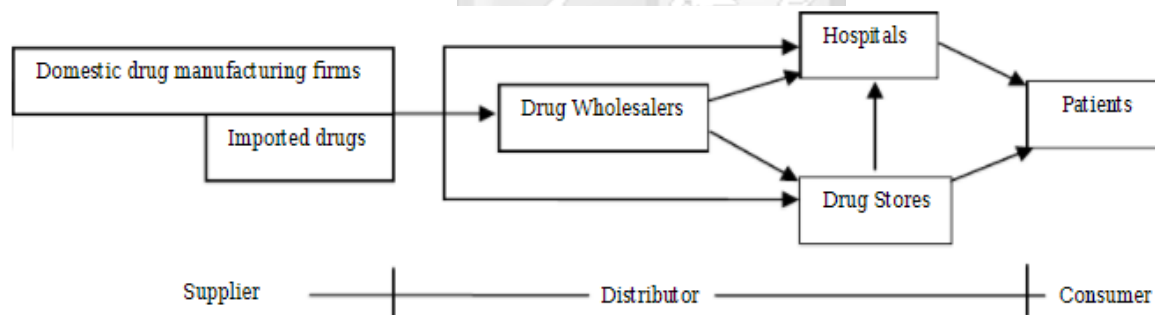


Figure 2.1: China Typical Pharmaceutical Supply System (Xuan, 2015)

Asia is one of the biggest drug manufacturers in the world. However, a lot of counterfeits have been reported to be emerging from the continent. Most of the illegal Products make their way to Kenyan market through the Mombasa ports. Drug cartels make the port their backdoor to sneak in the drugs (Peter, 2018).

Some of the challenges faced in China's pharmaceutical supply chain are:

- I. **Weak Research and Development Intensity:** In China, a higher percentage of pharmaceutical manufacturers are small scale enterprises with a low workforce of around 300 personnel and operating on an estimated revenue of less than 3 million USD per annum. Therefore, it proves a challenge for the firms to support Research and Development in new drugs discovery development and supply due to financial constraints that will not support fully executed programs. This results to the firms engaging in low-value-added activities such as manufacturing, formulating, packaging and distributing generic Products rather than innovation activities. At most, these pharmaceutical firms usually opted for developing generic drugs in order to obtain short-term revenue without going through the burden of high technical innovation (Ni et al., 2017).
- II. **Ineffective supervision of drugs:** The State Food and Drug Administration (SFDA) is an authority put in charge of the drug regulation in mainland China. Its major mandate is to oversee executive and technical monitoring of research, production, selling and usage of drugs in China. However, the body has been hit by a series of corruption cases that saw the dismissal of executive heads. Consequentially, it did not play its role well monitoring the efficacy and safety of pharmaceutical Products (Xuan, 2015).

This challenge also reflects the situation in the Kenyan Pharmaceutical industry. A survey by researchers from the Kenya Medical Research Institute, University of Oxford and the London School of Hygiene and Tropical Medicine unmask a network of bribery. The article sheds light on how drug dispensers bribe the cartel in order to avoid the mandatory drug inspection by the Kenyan Pharmacy Board inspectors (Gathura, 2013).
- III. **Distortion of Price Schedule:** Most pharmaceutical companies use their medical representatives to lobby doctors to prescribe their drugs to patients, by offering financial incentives. The financial incentive is also based on the quantity of the drugs sold. Therefore, this motivates hospital staff to use unnecessary and expensive drugs without strict regulations on drug prescriptions (Xuan, 2015).

2.2.2 United States of America (USA)

The wholesale distributors in USA are licensed and regulated by several government agencies. This includes the Drug Enforcement Administration (DEA) that licenses and inspects pharmaceutical distributors that handle and distribute controlled substances such as narcotics. The U.S Food and Drug Administration (FDA) also inspects and takes action against the distributors who do not act in accordance with the law (Robert, 2005).

In USA, pharmaceutical Products originate at the manufacturer and are shipped to the pharmaceutical wholesale distributor. The wholesale distributor stores the Products according to the manufacturer requirements. Once they receive orders from various healthcare providers, the Products are eventually picked and delivered to them.

Some of the challenges faced in USA pharmaceutical supply chain:

Repacking and Reselling of Drugs: Distributors buy and sell drugs in response to market demand, repeatedly repackaging Products. In wholesale repackaging, illegitimate Products can gain authentic packaging, and clean, authentic packaging is removed and not always destroyed (Buckley, 2013). The research sought to tackle illegitimate drug packaging, this revelation reflects the challenge also faced in Kenya on drug packaging by crude supply chain players.

License Leniency per State: The state pharmacy boards hand distributors with operating licenses. Unethical distributors seek out states clement requirements and move from one state to another when caught in breach of the state's laws (Buckley, 2013).

2.2.3 Africa (South Africa)

South Africa attributes to 0.4% of the global pharmaceutical value. It is by far the largest market in Africa bearing in mind; it has the largest ARV program in the world, with an estimated 3 million people in the public sector and 150,000 in the private sector in their treatment program (Zachary, 2016). Africa continent has become the main destination for the exports from South Africa, thus pharmaceutical Products (Pharma Sector Report, 2017).

Some of the challenges faced in South Africa pharmaceutical supply chain:

- I. **Currency Weakness:** This increases the cost of imported active pharmaceutical ingredients that are key ingredients in the drugs manufacturing process (Pharma Sector Report, 2017).
- II. **Lack of Change:** Inadequate attention to industry transformation is also a major problem in the industry. Technology trends keep on changing and the lack adoption of new ways of drug manufacturing can cause the industry to lag behind (Pharma Sector Report, 2017).

2.3 The Pharmaceutical Drug Supply Chain Working and Challenges In Kenya

The pharmaceutical industry players in Kenya are listed in Table 2.1.

Table 2.1: Summary of the Pharmaceutical Sector and their Respective Roles (Programme for Health, 2014)

ACTOR	ROLES AND RESPONSIBILITIES
PUBLIC SECTOR	
Ministry of Health (MOH)	Policy leadership on pharmaceutical matters, and initiation and supporting of pharmaceutical legislative processes
Pharmacy and Poisons Board (PPB)	Oversight and implementation of regulation of pharmaceutical manufacturing, importing, distributing and retailing establishments, as well as all cadres of pharmaceutical personnel Kenya
Medical Supplies Authority (KEMSA)	Procurement, distribution and warehousing of medicine and medical commodities
PRIVATE SECTOR	
Mission for Essential Drugs and Supplies (MEDS)	Procurement, distribution and warehousing of medicine/medical commodities to non-profit organizations mainly, but also public facilities and selected commercial facilities
Manufacturers	Production and marketing of pharmaceutical commodities. Production in Kenya typically entails buying the active pharmaceutical ingredients and formulating and packaging these into the final dosage forms for consumers

Distributors	Link between manufacturers and retailers. 'Distributors' refers to larger firms that supply retailers directly.
Retailers	Suppliers directly responsible for selling medicines to end users. In Kenya, these include pharmacies (all types of medicines) and general shops (specific pre-packaged medicines classified by law as over-the-counter)
PROFESSIONAL BODIES	
Pharmaceutical Society of Kenya	Representing interests of member retailers in Kenya. Retailers include all personnel with a minimum of a degree qualification in pharmacy from a recognized institution
Kenya Pharmaceutical Association	Representing interests of pharmaceutical technologists in Kenya. Pharmaceutical technologists include all personnel with a minimum of a diploma qualification in pharmaceutical technology from a recognized institution
TRAINING INSTITUTIONS	
Universities	Training of retailers, and supply of interns to manufacturers, distributors and retailers
Mid-level colleges	Training of pharmaceutical technologists, and supply of interns to manufacturers, distributors and retailers

Kenya has an estimated five thousand healthcare facilities countrywide with about seven hundred registered wholesale and one thousand three hundred retail dealers in Kenya, manned by registered retailers and pharmaceutical technologists (Importers in Kenya Report, 2015). Table 2.2 is a representation of the available manufacturing companies.

Table 2.2: An Excerpt of Pharmaceutical Manufacturing Companies in Kenya (The Pharmaceutical Industry in Kenya: Importers in Kenya, 2015)

LOCAL AND MULTINATIONAL PHARMACEUTICAL FRIMS IN KENYA	
Local manufacturers	Cosmos , DAWA , Regal , Universal , Betacare , Sphinks , Njimia
Top multi-nationals in Kenya (by market size)	GSK (UK), Pfizer (US), Novartis (Switzerland), Sanofi-Aventis (France), Roche (Switzerland), Bayer (Germany), Adcock (South Africa), Astra Zeneca (UK), Jansen (Belgium), MSD (UK), Abbot (US)
Local distributors that deal with generics	Glenmark, Laborex (Kenya), Philips, Sunpar (Kenya), Sun, Europa, Harleys, Galaxy, Medox, Lords, Surgilinks, Surgipharm, PSM, Betacare, Njimia, Denk, Pan, Simba, Ranbaxy
Top multi-nationals dealing with generics in Kenya (by size)	GSK (deals with branded and generics), Glenmark, Sun, Ranbaxy, Medser, Laborex, Surgilinks, Philips, Cipla

The companies involved in manufacturing and distribution of pharmaceutical Products in Kenya continues to grow, due to the Kenyan government continued efforts to promote investment in the sector both foreign and local.

The drugs are produced in the manufacturer plants. Later on, dispatched to various distributors upon order and strict instructions on how to stores the drugs. Thereafter, retailers make orders according to their market demand.

Some of the challenges faced in Kenya pharmaceutical supply chain:

- I. **Affordability:** The cost of Production is equally high, forcing the manufacturers to sell the drugs at high prices. These can prove to be a challenge to the common “Mwananchi” who finds the pricing to be too high (Npp, 2010).
- II. **Low Reimbursement Rates:** Manufacturers are not given good reimbursement rates compared to the costs they incurred during Production.

- III. **Counterfeit Drugs:** The market is flooded with fake or substandard drugs. This poses a high health risk to the consumers who are completely unaware of the consequences lurking with the consumption of these drugs (Npp, 2010).
- IV. **Inventory Management:** Pharmacies have a difficult time keeping up inventories in order to isolate recalls and valid stock in order to avoid putting the customer at risk.

Means used in tackling drug counterfeiting in the pharmaceutical drug supply chain

Effective anti-counterfeit technologies are essential since they ensure the safety of the patients consuming the drug. There are various ways of combating counterfeiting. These include cooperation with law enforcement, private investigations, consumer education, taking legal actions on illicit traders and finally use of evolving technologies (Dipka, 2013).

Characteristics of efficient anti-counterfeit technologies

Anti-counterfeit technologies have various characteristics that qualify them as efficient and effective. These characteristics include ease of use of the anti-counterfeit technology, compliance with the existent laws of the land and non-duplicable thus difficult to remove or copy (Dipika, 2013).

2.4 Example of Anti-Counterfeit Technologies Currently Used In the Market

2.4.1 Mass Serialisation

Serialized Global Trade Item Number (sGTIN): This is a unique number which identifies an item. It is created by attaching a serial number to the Global Trade Item Number of the Product. In March 2010 the FDA issued instructions that the Serial Number Identifier (SNI) be placed on the drug prescription at the manufacturer's plant and the Product be repackaged in order to enable tracking. They also requested the use of NDC combined with an eight-digit serial number to come up with the Serialized National Drug Code (sNDC) (Food and Drugs Administration, 2016).

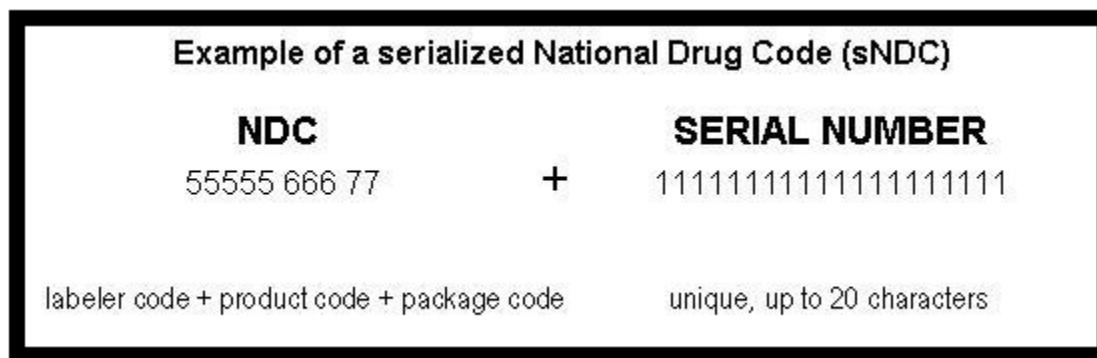


Figure 2.2: Example of sGTIN (Food and Drug Administration Regulatory Information, 2016)

Data Carriers: These are systems used to carry and relay the Product information electronic or human readable format. They are usually represented by a tag, label or mark at the source. The most common format used is computer readable such as two-dimensional (2D) bar codes and Radio Frequency Identifiers (RFIDs) (Food and Drugs Administration, 2016). The reasons are displayed in the Table 2.3.

Table 2.3: Data Carriers (Food and Drug Administration Regulatory Information, 2016)

RADIO FREQUENCY IDENTIFIER (RFID) Vs Dimensional (2D) Barcode		
Features	2D BARCODE	RFID
Direct line of sight requirement	Yes	No
Difficult to duplicate or alter	No	Yes
Readability, robustness (interference with liquids metals)	No	Yes
Cost of tags	Low	High
Tag data storage	Low	High
Bulk tag reading	No	Yes
Initial technology set up cost	Low	High
Eco-system and/or standards maturity	High	Medium
Tag feature's extendibility (ex. Tag with sensors)	Low	High

Global Trade Item Number (GTIN): This is a GS1 (International Standards Development Organization) defined globally unique identification number used to trade items or Products or services. GTIN numbers are allocated by manufacturers in line with GS1 allocation standards and guidelines that ensure the uniqueness of the reference number in every Product (NCPDP, 2010). It can consist of 8 or 12 or 13 or 14 digits. The outer and inner packs are fitted with separate GTINs (NCPDP, 2010).



Figure 2.3: Sample Drug GTIN (NCPDP, 2010)

2.4.2 Major Challenge with Mass Serialisation and Proposed Solution Mitigation

There has been a noted slow uptake of these anti-counterfeit technology by consumers Products sector. This is due to security concerns in that there is a great possibility of replication of the bar codes that can direct consumers to fake websites. The Mass Serialisation technologies suffer the possibility of having their security tags duplicated by unscrupulous drug suppliers. In that, when scanned they will still relay information to one with their application (Megget, 2017).

The solution covers this gap by enabling drug trackability down the supply chain. Furthermore, it offers a security feature that disallows the duplication of bar codes produced at the manufacturer's premise.

2.4.3 Pedigree

This is an electronic file/record that contains information about a drug prescription from the manufacturer's plant down to the retailer. The responsible person at the retailer (pharmacy) must be able to verify that the consignment Products specifics match what is recorded in the pedigree (NCPDP, 2010). This system has been widely adopted because of the almost zero record keeping

failures and less probability of counterfeit drugs involvement (Food and Drugs Administration, 2016).



Figure 2.4: Sample Pharmaceutical Pedigree (Bacheldor, 2007)

2.4.4 Use of Holograms

Normally use a combination of a three-layered security features. Holograms can issue overt first-line authentication and covert features like UV-sensitive inks and scrambled images for the second line of authentication. Furthermore, a new trend of serialisation of holograms as part of the systems so that they combine authentication with traceability. This type of system is linked on security devices that have databases management and tracking ability (Pharmtech Technology, 2008).



Figure 2.5: Example of Holographic Label (Pharmtech Technology, 2008)

2.4.5 Use of Mini Labs

The Kenya Pharmacies and Poisons Board introduced the use of the Raman spectrometers to counter fake drugs in the market. The mini lab equipment is used for testing medicine in the field on the spot. The gadget has the ability of testing content of the medicine directly through the Product's

packaging. This is possible since the gadgets use laser light testing. The device assigns specific chemical signatures to the ingredients present in the drug. The board facilitated the acquisition of the special handheld devices to combat the fake drug distribution menace in the market (Merab, 2017). Figure 2.6 illustrates a sample of the gadgets.



Figure 2.6: Raman Spectrometers (Merab, 2017)

2.5 Blockchain Technology

2.5.1 Introduction

Blockchain is a distributed database solution that maintains a continuously growing list of data records that are confirmed by the nodes participating in it. The data is recorded in a public ledger that also includes the information of every transaction done. The information about every transaction ever completed in blockchain is shared and available to all nodes in the network (Drescher, 2017).

The pharmaceutical industry in Kenya is vast and many players have delved into the manufacturing sector with Glaxosmith and Bayern being among the major players. The pharmaceutical industry has encountered a lot of challenges with drug counterfeiting topping the table.

2.5.2 What is a Distributed Ledger?

This is a data structure type that exists across multiple computer devices that are situated across different locations (Bashir, 2017).

This technology includes the use of smart contracts and blockchain technologies. It comprises of three basic components namely Data Model; this captures the current ledger state, Language of Transaction; it changes the ledger state and Protocol; used to arrive at a consensus among participants

2.5.3 What is a Blockchain?

It is a peer-to-peer distributed ledger built on consensus, combined with smart contracts and other technologies. The distributed ledger forms a chain of blocks, hence the name 'blockchain' (Hyperledger, 2014).

The metadata components of a blockchain consist of the reference to the previous block, proof of work which is also known as a protocol or function that is usually an economic measure to prevent DOS attacks by requiring some processing time from the computer that makes the request, timestamp and the merkle tree root that is a result of hashing all hashes of transactions in a block.

2.5.4 Blockchain History

Blockchain technology is most used in the development of Bitcoin cryptocurrency. It is the decentralised managing technique of Bitcoin, designed for issuing and transferring money for the users of Bitcoin currency. This technique supports the public ledger of all Bitcoin transactions that have taken place, without any third party controlling it (Drescher, 2017).

2.6 Blockchain Transactions

These are records of events that are secured cryptographically with a digital signature that are verified. In blockchains, cryptography plays a major role in the security of the blockchain. It proves that a transaction was initiated by a particular person and also links transactions in a block in a tamper –proof way. This is also proven by the immutability of the transactions recorded on the blockchain (Bashir, 2017).

2.6.1 Difference between Blockchains and Databases

A blockchain is a write-only data structure whereby every new block is appended to the blockchain by linking it to the previous block's hash. A hash is a cryptographic signature that uniquely identifies a block. Blockchains were designed for decentralised applications (Nathan, 2020).

In a relational database, data can be manipulated. The database administrators can make changes to the database at any time provided they have access rights. Furthermore, they were designed for centralised applications where a single entry controls the data.

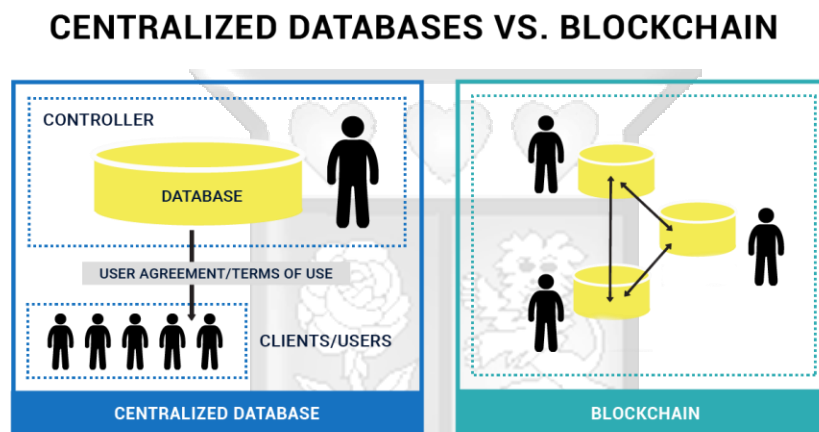


Figure 2.7: Difference between Centralised Database and a Blockchain (Nathan, 2020)

2.6.2 Types of Blockchains

- I. **Public Blockchain (Permissionless):** A public blockchain network is completely open and anyone can join and participate in the network. The network typically has an incentivizing mechanism to encourage more participants to join the network (Jayachandran, 2017).
- II. **Private Blockchain (Permissioned):** This requires pre-verification and permission from the parties in the network in order to join the network. Businesses who want to set up a private blockchain will always set up a permissioned network. The decision to either join a public or private blockchain is motivated by the use case at hand. Most business must vet the new partner before agreeing to engage with them. In the case of supply management for example, some parties will not be comfortable dealing with a party which is not vetted. Therefore, each

member of the consortium will require permission from the rest to complete a transaction with the new party (Jayachandran, 2017).

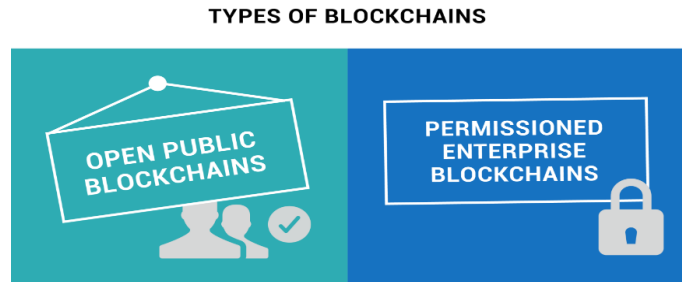


Figure 2.8: Types of Blockchains (Nathan, 2020)

2.6.3 Understanding Peer-to-Peer Network Architecture

Also known as P2P, is network created when two or more computers are connected and share resources without going through a central server (Cope, 2002). Peers (Computers in the network) contribute to the storage and power needed to upkeep the network. P2P networks are considered to be secure as they do not have a single point of attack as opposed to the central server network whereby a single entry endangers the whole network.

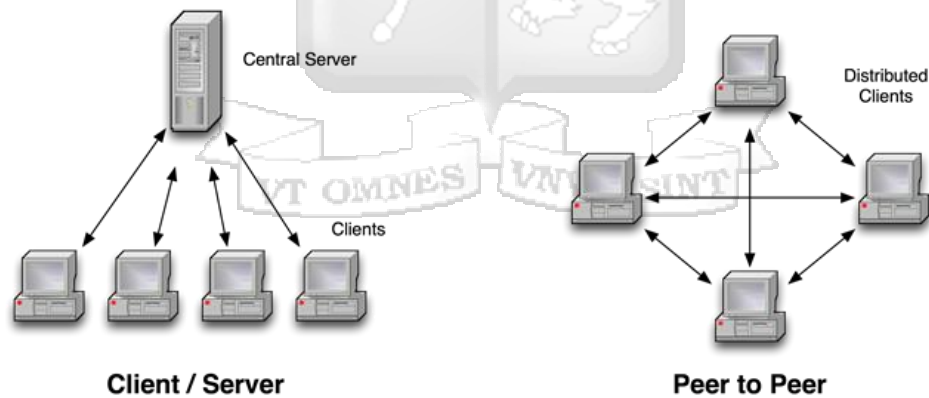


Figure 2.9: Difference between server-based and P2P Network (Fordhancyberculture, 2013)

2.6.4 Smart Contracts

These are self-executing contracts with the terms of agreement between a buyer and a seller being directly written in line of code. They also provide language transactions that allow the state of the ledger to be modified (Bashir, 2017).

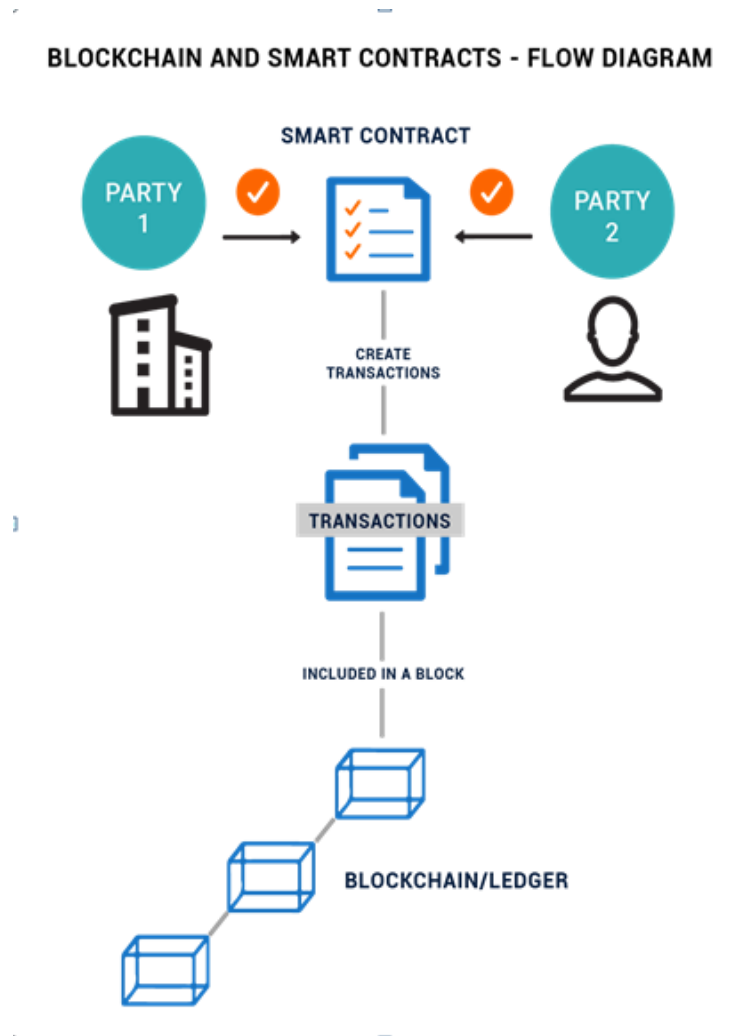


Figure 2.10: Illustration of a Smart Contract (Boschi, 2018)

2.6.5 Blockchain Security

In a blockchain network, a group of transactions is combined into blocks of transactions which are connected to each other in the chain using the hash record of the previous block. The immutability aspect of a blockchain is seen in the security mechanism that is set in a way that the farther the block is located along the chain (older) the more protected from changes is data contained in the block. In

the event an attacker attempts to modify any block, the local registry will automatically be invalid since the hash values inside the header of the next block will be different. There is no transaction that can successfully join the chain without being validated by nodes and new transactions create a complexity that locks out hackers. For any hacker to succeed, he or she must hack every 'block' but there are millions of them (Bodrova, 2017).

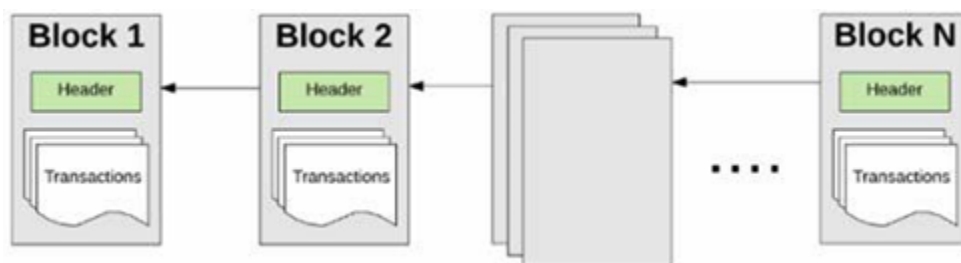


Figure 2.11: Blockchain systems chain structure. (Bodrova, 2017)

2.6.6 Advantages of Blockchain Technology

Blockchain technology brings forth many benefits. Some of the benefits are data that is stored on the chain code is immutable and has been verified by all nodes. Secondly, the data in the blockchain is of integrity since the nodes are trust worthy and participate in verifying the data. Each block's header includes a hash of the block's transactions, as well as hash of the prior block's header. All transactions on the ledger are sequenced and cryptographically linked together. The hashing and linking of the blocks make the blockchain secure. Even if one node hosting the ledger was tampered with, it would not be able to convince all the other nodes that it has the 'correct' blockchain because the ledger is distributed throughout a network of independent nodes. Lastly, blockchains have timestamp ability, whereby every transaction is recorded and the time is marked for accountability purposes (Bashir, 2017).

2.6.7 Disadvantages of Blockchain Technology

The blockchain technology has its limitations too. One, Throughput; the potential throughput of issues in the Blockchain networks is currently maximized to 7 transactions per second. Secondly, Latency; the time to make a block and confirm the transaction takes a lot of time. Lastly, Size and Bandwidth; the size of a block is big and also the time taken to transmit the same is long thus is a limitation to the whole process (Bashir, 2017).

2.7 Uses of Blockchain

2.7.1 Cryptocurrency

This is a digital asset designed to act as a medium of exchanged using cryptography to secure the transactions and to control the creation of additional units of currency. Bitcoins introduced in 2009 were the first among many cryptocurrencies existing. Bitcoins use decentralised control as opposed to centralised money for banking system. The decentralised control is related to the use of bitcoin's blockchain transaction database in the role of a distributed ledger (Coinstorm, 2019).

2.7.2 Blockchain Technology in Kenya

The emergence of blockchain market in Kenya was warmly welcome by different players in both the private and public sector (Kariuki, 2017, September 12).

The following sectors depict how blockchain will revolutionize the sector:

- I. **Transport Sector:** The National Transport and Safety Authority (NTSA) has launched a Product called e-service that operates on a shared blockchain platform. E-service allows sharing of critical information among state agencies such as the Kenya Police Service and the Kenya Revenue Authority. This information includes vehicle ownership, insurance status and inspection (Odhiambo, 2017, September 14).The study further stated that Kenyan motorists should have electronic stickers for their cars. This will be verified by a special gadget. The main aim of this implementation will be recovery of stolen cars and phasing out old vehicles from the Road.
- II. **Public Health Sector:** Kenya's Seven Seas Technologies and Japan's Toyota Shusho are implementing a blockchain programme that will see ninety-eight public hospitals be able to monitor patient data (e.g patient history) from a single smart platform. This will aim at eliminating the manual noting of patient health history as it was the order of the day (Kariuki, 2017, September 12).

Furthermore, the blockchain programme will create a hub whereby doctors and nurses in remote areas can seek counsel in circumstances that need consultation. Secondly, the administration of certain specialised treatment services such as MRI will be performed centrally. Thus, it will be less costly for patients since their data will be readily accessible from a repository that can be accessed from the same portal. Lastly, the smart platform will

enable scrutiny of diagnostic notes by other doctors to avoid lone decisions (Odhiambo, 2017, September 14).

- III. **Security:** The database of the National Registration of Persons Bureau will be linked with the manned Closed-Circuit Television (CCTV) cameras by the Kenya Police Service. This is an initiative by the Ministry of Interior & Coordination of National Government to allow recognition of persons by using the blockchain technology (Odhiambo, 2017, September 14).
- IV. **Real Estate:** Land Layby Kenya Ltd is ready to launch a minimal viable Product (mvp) for Africa's first multinational Blockchain powered land registry early 2018. The platform shall use 'Harambee Token' as a digital key to access it. This will eliminate the unnecessary intermediaries, hidden costs and time taken to perform transactions. Furthermore, it will also eradicate manual errors, duplication of the verification process and improve data security (The Standard Reporter, 2017).
- V. **Kenya Police:** The Kenya Police Force has implemented and is actively using an Immutable Digital Occurrence Book for transparency and account in recording incidents at police stations countrywide. However, blockchain technology is yet to be fully verified as the prime technology, however the characteristics of the solution match characteristics of a blockchain environment (Cryptoguru, 2019).
- VI. **Kenya Revenue Authority:** The body responsible for collecting taxes in Kenya was challenged by the Blockchain and Artificial Intelligence Task Force of Kenya, a committee setup by the Cabinet Secretary of Kenya, Hon. Joe Gicheru to lead the way in the adoption of emerging technologies. The Task Force suggested that KRA should search for areas where it can apply blockchain technology (Mbaka, 2019).

Blockchain is not a solution to all the problems in the tax system, it could potentially be applied to reduce the administrative burden and collect tax at a lower cost, helping to narrow the tax gap (Mark et al, 2017).

2.8 Other Blockchain Enabled Solutions

There are various solutions based on the blockchain technology in the market. Walmart is our first example. "Consumers today want more transparency about where and how a Product came to be. If you could track and pinpoint where that came from faster, you could alleviate all that and ensure

consumer confidence continues” These are the words of Frank Yiannas, the Vice President of food and safety at Walmart after they rolled out the trial version of the IBM Hyperledger project. Walmart partnered with IBM to come up with a blockchain application that could track Chinese pork, in their supply chain (Hackett, 2017, August 22).

Secondly, we have, InsurETH. It enables one to insure their flight directly with an Ethereum smart contract; this contract is resolved automatically on the Ethereum blockchain. Third, we have Visa B2B Connect. In mid-2018, Visa Card will launch a blockchain based business to business payments service. This is a platform designed to give financial institutions a secure, fast and predictable way to process corporate cross-border B2B payments (Visa, 20). The Banco de Santander bank is also looking to use blockchain applications for banking transactions, including international payments for individuals and corporations. Technology experts at the company are supervising 20 employees at a lab in Madrid who are experimenting on how the online ledger technology can be used for international payments like audits, compliance and transactions within capital markets (Castellanos, 2018).

On the other hand, Kodak in partnership with WENN Digital came into a licensing partnership. They launched the KODAKOne images rights management platform and KODAKCoin. KODAKCoin is a photo-centric cryptocurrency that empowers photographers to take better control in image rights management. Furthermore, the KODAKOne platform that is based on Distributed Ledger Technology (DLT) that creates an encrypted digital ledger of rights ownership for photographers to register both new and archive work that can be licensed within the platform (Prisco, 2018).

Lastly, a Nairobi-based B2B platform for kiosks and foods stalls in Africa teamed up with IBM to come up with a blockchain-enabled micro financing for Food Kiosk owners. The blockchain platform enables the loaning procedures to be pellucid to all parties in the network, thus the lending bank down to the borrower’s banks and the loan applicant. Secondly, they performed a pilot in 2017 in 220 shops in eight weeks. The pilot processed more than 220 loans via mobile phones that averaged around 30 dollars. This led to increased order size by 30 percent and profit for each trader by 6 percent (IBM, 2018).

2.9 Current Blockchain Enabled Drug Traceability Solutions in the Market

- I. **Mediledger Project:** Chronicled a Blockchain and IOT firm teamed up with Chronicled Inc a life science consultancy to come up with a track and trace blockchain project. The project known as the Mediledger Project is aimed at preventing counterfeit medicine from entering the drug supply chain. Other Partnerships to this project include Genentech, Pfizer, AmerisourceBergen and McKesson Corporation. The major goal for this project in the event of success will enable everyone from drug makers to eventual drug users to have a record of the drug movement down the supply chain (Vanyukevich, 2017, September 21).

The Mediledger solution enables the drug manufacturers, distributors and dispensers to have a system that is interoperable in that it can identify the originating manufacturer's GTIN/Serial Number as authentic. Secondly, it detects exceptions when inventory is in transit automatically. Lastly, puts an end to counterfeit Products penetrating the USA market. The system will be able to identify if an illicit item enters the trusted network.

- II. **SophiaTX:** SophiaTX and Riyadh-based Company signed an LOI (Letter of Intent) confirming a partnership between the two businesses on the design and development of blockchain pharmaceutical logistics and transport solution (SophiaTX, 2020).

SophiaTX aims at integrating with a company's current SAP Software Product. This will allow the pharmaceutical companies to write their Products directly to the SophiaTX's blockchain addressing the issue of counterfeiting, drug traceability and track ability (Jaroslav, 2017).

The major pointers for the SophiaTX software are the integration with an existing company's ERP, CRM and any other database. Secondly, SophiaTX contains integration APIs to SAP and other enterprise applications (SophiaTX, 2020).

BlockRx Pharma Ecosystem: Operates on hyperLedger Sawtooth and is built on a system that contains three components namely: The Blockchain, BlockRx Token and Advanced Digital Ledger (ADLT). Companies that adopt the BlockRx use the ADLT to translate the data in the ERP to the blockchain in place. The main aim for BlockRx is to link systems that are not communication ready with each other and create a communication path that satisfies regulatory and business requirements. Through focusing on the creation of the network of

trust, BlockRx provides the solutions for facilitating the exchange of information (BlockRx, 2020).

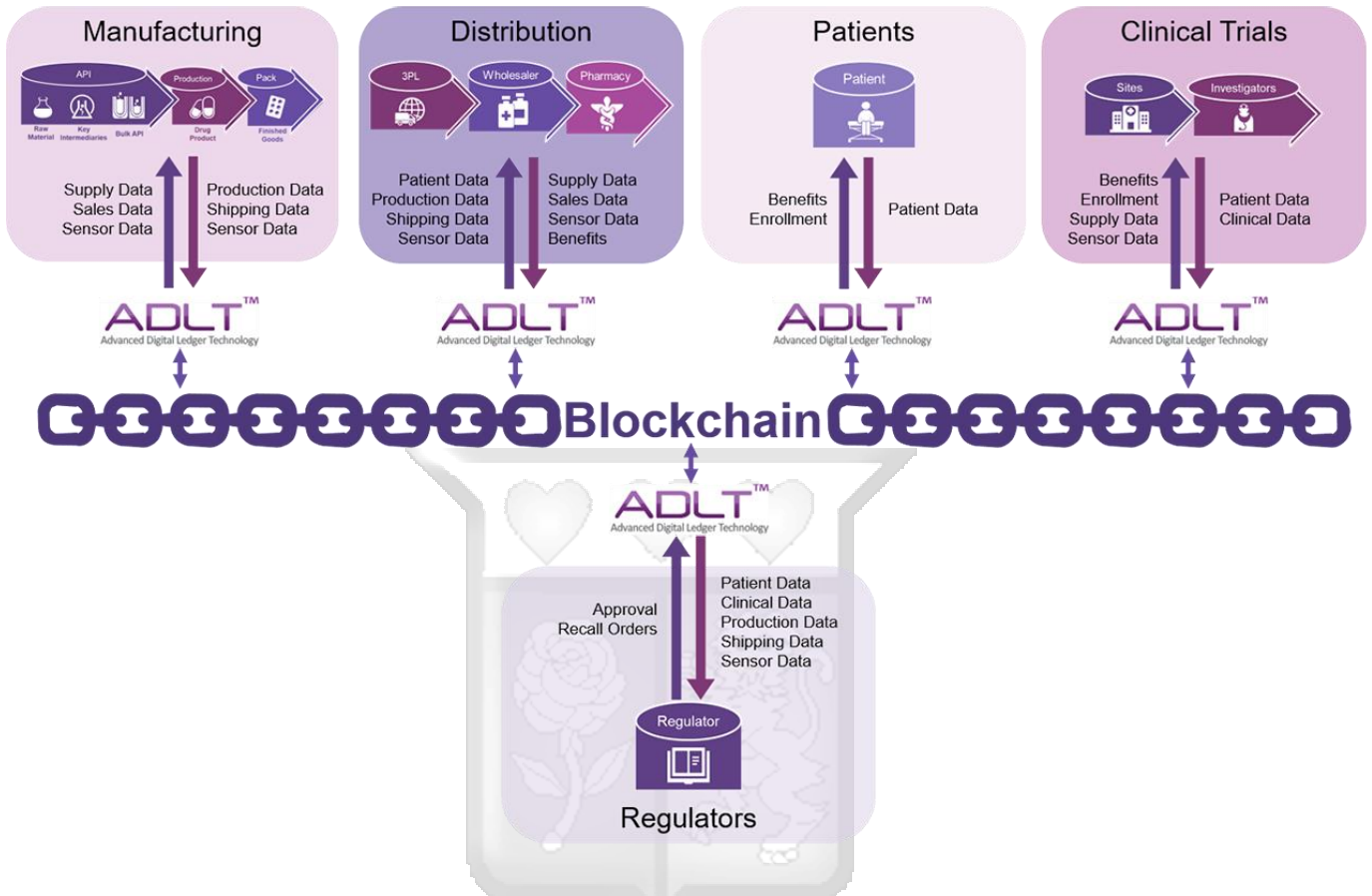


Figure 2.12:BlockRx Work Flow Illustration

The major pointers of the BlockRx software are the trade partners can share data in a transparent environment. Thus, they can validate each transaction and everyone has a unique identify that controls who can see their information. This helps offset the financial burden of regulatory compliance. Lowers the cost of bringing drug to the market (BlockRx, 2020). Secondly, BlockRx acts as a link between a Pharma Company’s ERP and the rest of the supply chain. It behaves as a portal whereby a Pharma Company can view and integrate a trusted partner’s data (BlockRx, 2020).

- III. **Modum.io System:** This is a combination of blockchain technology and sensor devices (Mod). The sensors take note of the change in environment while the Products are in transit. In the case of change of ownership of the goods, the sensor data is corroborated against the predefined conditions in the smart contract specified for that blockchain. The contract

determines if the current conditions satisfy the ones set by the sender/clients/regulator and triggers notifications containing the information to the sender and receiver at the same time (Modum, 2017).



Figure 2.13: Modum Workflow (Modum.io Systems, 2017)

The major pointers of Mod are the use of Mod sensors in the transportation of their Products in order to monitor the temperature of the goods before their next destination. The receiver therefore accepts the Products and the data is written to a blockchain which is publicly accessible and immutable. Secondly, the EU guidelines on Good Distribution Practice (GDP) regulation (GDP 2013/C 343/01) section 9.2 states that; “If a deviation such as temperature deviation or Product damage has occurred during transportation, this should be reported to the distributor and recipient of the affected medicinal Products (European Commission Report, 2013). A procedure should also be in place for investigating and handling temperature deviation.” Therefore, once in the blockchain the report of the temperature deviation is reported both to the sender and receiver (modum_io, 2016).

- IV. **BlockVerify:** This is a company that utilises blockchain technology to improve anti-counterfeit measures in different industries and have a positive impact on them. BlockVerify can identify counterfeits, diverted goods, stolen merchandise and fraudulent

transactions. It has a package for the pharmaceutical industry whereby they can track drug supply down the chain and ensure that the end users receive the authentic Products (BlockVerify, 2020).

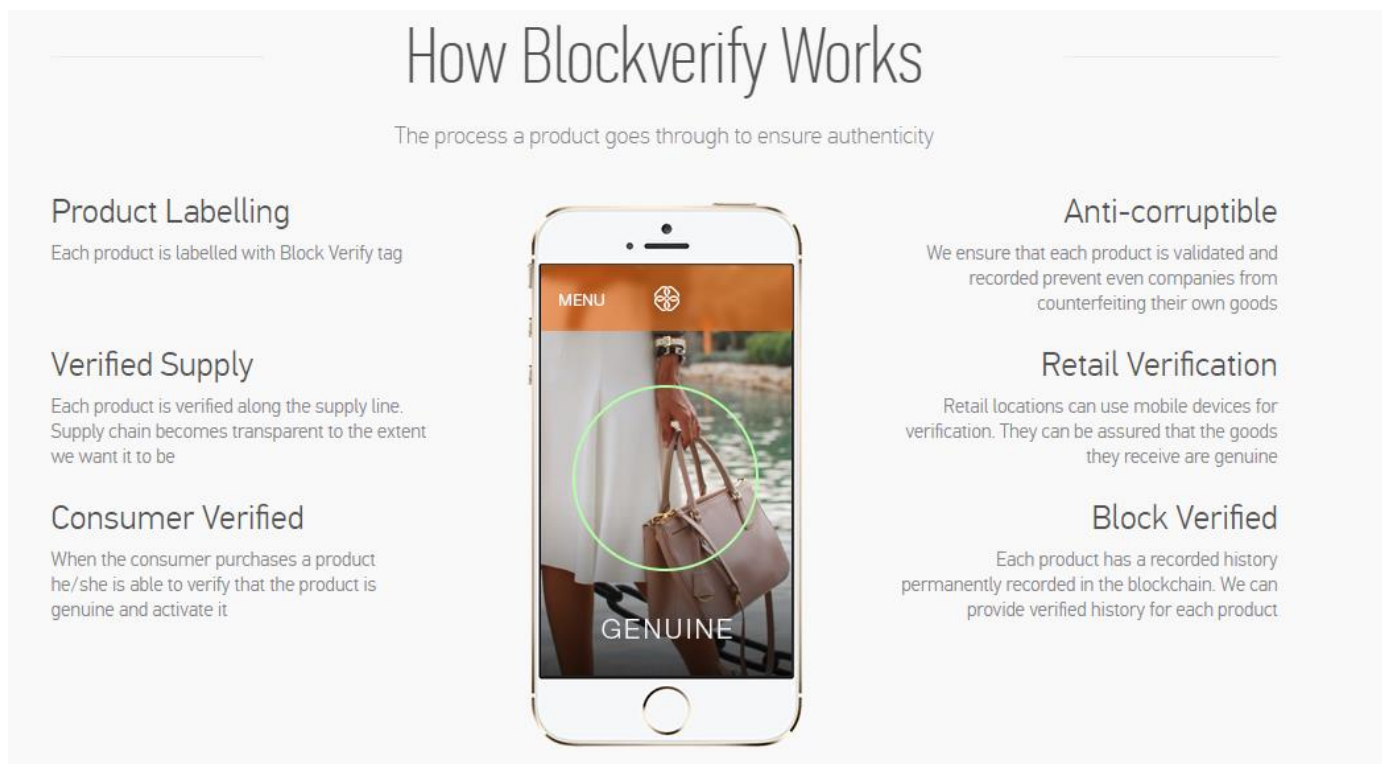


Figure 2.14: Snapshot of Blockverify Workflow (Blockverify, 2020)

The major pointers on BlockVerify are one can scan and verify Products online or offline. Secondly, 2G data metrics and RFIDs tags encrypt serial numbers of the Product that are placed on the Products thereafter a mobile phone is used to scan them. Lastly, it can be easily integrated using APIs with existing solutions (Deloitte, 2016).

2.10 Blockchain Adoption in the Pharmaceutical Industry

- I. **KitChain:** LedgerDomain developed the application called KitChain using its LedgerDomain Selvedge server. The LedgerDomain Selvedge server is based on Hyperledger Fabric. KitChain enables corporations like Pfizer to track shipments of packaged medicines. The participants can see when a delivery is sent and received. However, tracking logistics is probably just the first step in this larger project called the Clinical Supply Blockchain Working Group (CSBWG) that was created to address a range of challenges in

the pharmaceutical clinical supply chain. The CSBWG groups is a consortium of Pfizer, Biogen, IQVIA, GlaxoSmithKline, Merck & Co., UCLA, Thremo Fisher, Almac Group and Marken. The ultimate vision is to have a seamless user experience for supply chain managers, clinical sites and patients to track and trace investigational Products from point of manufacture to acknowledgement of consumption by patients. Secondly, a fully auditable and transparent system that allows all stakeholders to have direct access to a trusted source of validated data (Chad et al., 2019).

- II. **PharmaLedger:** This is a Blockchain Enabled Healthcare project that consists of 29 partners from 10 EU Member States, including 12 large pharmaceutical companies. The PharmaLedger project will create a Blockchain-based framework for the efficient digitization of the healthcare industry. The goal of the project is to provide a widely trusted platform that will support the design and adoption of Blockchain-enabled healthcare solutions while accelerating delivery of innovation that will benefit the entire ecosystem, from manufacturers to patients (Morris, 2020).



Figure 2.15: PharmaLedger Consortium (Morris, 2020)

2.11 Value Proposition of the Solution

2.11.1 Gap Not Addressed by the Current Anti Counterfeit Technologies in the Market

As mentioned in section 2.4, mass serialisation, pedigree and use of a hologram are some of the anti-counterfeit technologies used in the drug supply chain as track and traceability options. The solutions in section 2.4 do not provide a definite way of conducting open transactions. There is no solution

that encourages transparency between the industry actors (manufacturer, distributors and retailers) thus by allowing each other to keep the same copy of the record as the rest. This imposes that an actor in the supply chain is unaware of where their Products came from, yet they are no sure way of establishing where the Products they are currently handling will be delivered. Thus, drug traceability and track ability prove to be an issue. Consequentially, the end consumers will also not have a way of verifying the source of their purchased drugs.

In Kenya, as shown in section 2.7, blockchain technology is making its entrance into the market. The Kenyan industrial sector is still warming up to the new technology, with tech companies throwing their weight behind research and start-ups. The most popular method used in Kenya to mitigate illegitimate pharmaceutical practices in Kenya is the display of Ministry of Health Safety Codes in a pharmacy. The code will enable the end consumer to verify via an SMS application if the pharmacy is licensed to run or not (Astariko, 2016).

Lastly, at the moment, blockchain Research and Development has not been fully adopted and exploited in Kenya. Therefore, the dissertation looks at proving the concept as an early adopter of the technology in a Kenyan pharmaceutical manufacturer's supply chain scenario.

2.11.2 Benefits of Using Blockchain Technology in Pharmacy Supply Chain

There are quite a number of benefits of using the blockchain technology in the pharmaceutical supply chain. These include:

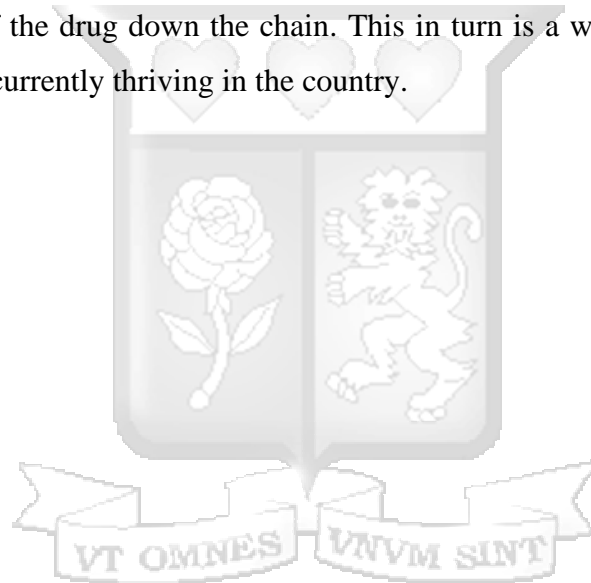
- I. **Authenticity:** Verification that the authentic drugs are handed over to an authorised party at each transfer point, the data relayed in the blockchain is immutable and time stamped, a joint verifiable ledger of all transactions is available at all times.
- II. **Security:** This is guaranteed since the information is verified by respective actors before being transmitted. The transactions are performed by various actors in the blockchain network
- III. **Transparency:** Information is accessible to any actor in the chain and all additions reflect on everybody's ledger.
- IV. **Compliance:** Blockchain technology gives value add to a pharmaceutical supply chain by allowing ways of adding compliance and governance in the supply chain.
- V. **Inventory Management:** Blockchain reduces the risk of expiration of drugs through proper ledger management by the blockchain.

2.11.3 Challenges of Using Blockchain Technology in Pharmacy Supply Chain

Not forgetting, there are quite a number of limitations of using the blockchain technology in the pharmaceutical supply chain. The disadvantages are regulatory uncertainty, lack of technology maturity, data security concerns and lack of industry acceptance.

2.12 Conclusions

The study took into consideration the literature on blockchain technology on the classical characteristics of a blockchain. It also aimed at coming up with a solution that integrates blockchain technology to mitigate the drug counterfeiting issue in the Kenyan pharmaceutical supply chain scenario. The consumer of the Product will know the Product's journey whereas the manufacturer also sees the movement of the drug down the chain. This in turn is a way of combating the drug counterfeit menace that is currently thriving in the country.



CHAPTER 3: RESEARCH METHODOLOGY

3.1 Introduction

The dissertation explored various steps that were adhered to when studying the research problem. The research involved finding out the drug counterfeiting challenges that the pharmaceutical industry is facing at the moment and how a blockchain enabled solution could improve the drug traceability along the supply chain.

3.2 Research Design

The literature review section of the dissertation addressed the following research questions: how the Kenya Pharmaceutical drug supply chain industry works, the current technologies used to tackle drug counterfeiting in the drug supply chain industry and the gap being closed. This chapter touches on the methodology that was used and its steps thus; requirements analysis, system design, system coding, testing and implementation.

3.3 Research Methodology

The Waterfall Model was adopted for the solution development since each phase of the project should be completed before commencing to the next phase. To note, these steps are sequential thus data from the last phase proves handy to the next phase. There are five stages that are represented in the Figure 3.1.

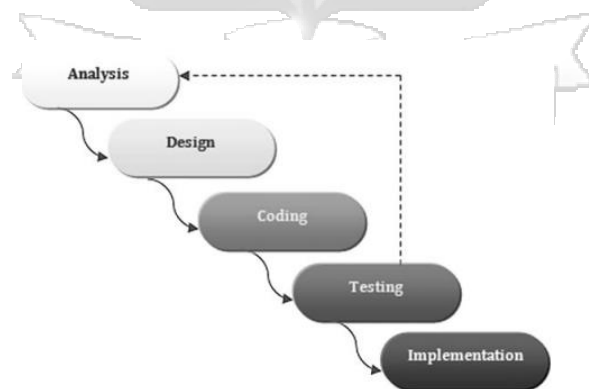


Figure 3.1: Stages of a Waterfall Model (Issa, 2015)

3.4 Requirement Analysis

This is the first phase of the software development process. It entails analysing the requirements of the system and the expected results. Requirements analysis was used to reveal important information like what the end client needs, the tools to be used to test and develop the application and identification of any other requirement needed to make the development process a success.

3.4.1 Location of Study

The study focused on Nairobi County, as the area is densely populated with drug manufacturing companies as shown in Table 3.1.

Table 3.1: Leading Manufacturing Companies in Kenya (Pharmaceutical Companies in Kenya, 2013)

LEADING PHARMACEUTICAL MANUFACTURING COMPANIES IN KENYA		
1.	Alpha Medical Manufacturers	Nairobi
2.	Aventis Pasteur SA East Africa	Nairobi
3.	Bayer East Africa Limited	Nairobi
4.	Beta Healthcare (Shelys Pharmaceuticals)	Nairobi
5.	Cosmos Limited	Nairobi
6.	Dawa Pharmaceuticals Limited	Nairobi
7.	Didy Pharmaceuticals	Nairobi
8.	Diversey Lever	Nairobi
9.	Eli-Lilly (Suisse) SA	Nairobi
10.	Elys Chemical Industries Ltd	Nairobi
11.	Glaxo SmithKline	Nairobi
12.	High Chem East Africa Ltd	Nairobi
13.	Ivee Aqua EPZ Limited	Athi River
14.	MAC's Pharmaceutical Ltd	Nairobi
15.	Manhar Brothers (Kenya) Ltd	Nairobi
16.	Norvatis Rhone Poulenc Ltd	Nairobi
17.	Novelty Manufacturers Ltd	Nairobi

18.	Pfizer Corp (Agency)	Nairobi
19.	Pharmaceutical Manufacturing Co(K) Ltd	Nairobi
20.	Pharmaceutical Products Ltd	Nairobi
21.	Philips Pharmaceutical Limited	Nairobi
22.	Regal Pharmaceutical Ltd	Nairobi
23.	Universal Pharmaceutical Limited	Nairobi

3.4.2 Target Population

The target population consisted of a manufacturing, distributor and retailer representatives. This group aided in identifying the system requirements. Furthermore, gave more information about the working of their supply chains.

3.4.3 Sampling Strategy

The study used simple random sampling method as its sampling strategy. Random pharmacies around Nairobi West shopping centre, Madaraka shopping centre, Langata shopping centre and CBD Accra Road and Tom Mboya street were used for the data collection. The motivation for selecting these pharmacies was the dense population that visit these premises.

3.4.4 Sample Size

There are 5,840 registered pharmacies in Kenya with Nairobi county leading with 1,850 followed by Central at 870, South Rift Valley comes third with 610 chemists, Coast (590), Nyanza (470), North Rift (460), Lower Eastern and Western tie with 330 chemists each, Upper Eastern (270) with South Rift coming last at 60 chemists (Angela, 2019).

The study used confidence level of 95% and confidence interval 10% to have a sample population size of 91. This population well represented the retailers in the location of focus.

This formula aids in estimating the true value of a population since its selection process is simple. Simple random sampling method thus $n = (Z_{\alpha}^2 p(1-p)) / d^2$ was used. Disseminating the formula; Z is the value (1.96 for 95% confidence level), p is the population (1850) and d is the confidence level, expressed as decimal (.05 = +-5) (Frerichis, 2015).

Table 3.2: Sample Population Size of Pharmacies in Nairobi

Population	Confidence Level of 95%		
Confidence Interval	5%	10%	12%
Pharmacies (1850)	318	91	64

3.4.5 Data Collection

Structured interviews were used to collect data from 6 manufacturing companies: Universal Pharmaceuticals Limited in Kikuyu Township, Kiambu County, Dawa Pharmaceuticals Limited in Baba Dogo Road, Industrial Area, Philips Pharmaceuticals Limited on Mombasa Road, Elys Chemical Industries Limited on Enterprise Road, Industrial Area and Cosmos Limited on Rangwe Road, Industrial Area. A representative from the companies was used to collect data on the manufacturing company’s operations and its drug supply chain. Secondly, the study reviewed a couple of case studies in order to analyse specific issues within the boundaries of the research topic environment. Lastly, the dissertation used questionnaires to gain more information from select pharmacies. The sample size selected for the exercise was 91 outlets as arrived at by the random sampling size calculation in section 3.4.4. Find the sample of the retailer questionnaire and manufacturer interview questions in Appendix A section A.1 and A.2.

3.5 System Design

This phase commenced after the completion of the requirements analysis phase. This is the process of elaborating the elements of a system like the components and modules, architecture, interfaces of the components and finally the data that goes through the system. This phase is meant to meet the needs or requirements of the system in order to facilitate a well running system (Kenpro, 2012).

Object oriented analysis was used to ensure that all requirements are analysed and modelled (Kenpro, 2012). The study used Unified Modelling Language (UML) a graphical language for visualizing, specifying, constructing and documenting the artefacts of a software-intensive system (Padmanabhan, 2012). It was used to come up with the following system models:

- I. **Context diagram:** Used to smoothen up the developing process model of the system. It is the highest level of representation of a system (Ibrahim, 2010).

- II. **Use case diagram:** It demonstrates various ways a user can interact with the system. It summarised the details of the system and actor's interaction with the system (Padmanabhan, 2012).
- III. **System sequence diagram:** Also known as event diagrams was used. It describes interactions among classes in terms of message exchange overtime. The objects communicate with each other in terms of a sequence of messages (Padmanabhan, 2012). The Sequence diagram helped in knowing how the system will behave and to discover potential responsibilities of a class in the process of system modelling.
- IV. **Wireframes:** They were designed using Balsamiq Software. This aided the developer to have a clear view of how the interfaces looked. A wireframe is a layout of a web page that demonstrates what interface elements will exist on key pages (Lim, 2012).

3.6 System Coding

This phase entails the actual development of the system from the designs mentioned in section 3.4. The study developed a blockchain based web-based application.

3.6.1 Blockchain

The blockchain was developed using IBM Toolkit called Hyperledger Composer and was deployed on the Hyperledger Fabric platform as a single organisation. The blockchain platform was used to store the transactions made by the actors in the network. A blockchain Hyperledger Composer REST API was exposed for interaction with the blockchain. The main reason for choosing the IBM Toolkit as a tool of development was it is an open source tool (Hyperledger, 2014). Secondly, the IBM toolkit has ready technical support from its official site. Lastly, it was cost friendly to use the open source tools.

3.7 System Testing

The system underwent the following tests to ensure that the user requirements were met:

3.7.1 Functional Test

The system's functional and non-functional requirements were tested against the new system. This ensured that every line of code executed and ensured that every function produced the expected outcome.

3.7.2 Compatibility Test

The blockchain web application was tested against the following browser versions:

- Safari - OS X 10.9 Mavericks to macOS 10.12 Sierra Versions.
- Mozilla Firefox – all versions.
- Google Chrome – all versions.

This ensured that the solution developed could coexist with existing enterprise solutions.

3.7.3 Users Test

The study identified some users from the sample size identified in section 3.4.4 above to test the application. Questionnaires were used to perform the test on aesthetics, user friendliness and acceptability. See Appendix A section A.3 for a sample of the user test questionnaire. Their feedback was essential for the refinement of the system. This test ensured that the user was able to use the blockchain web application without hitches. This in turn confirmed to the designer that the end user requirements were being met.

3.8 System Deployment and Maintenance

Deployment of the solution was eventually done after the developers and the users gave the green light to operate the system. A manufacturing company's pharmaceutical supply chain setup was used in piloting the solution. Therefore, continued enhancement and service of the solution will be done according to the user needs.

3.9 Validation

The study's hypothesis on whether a blockchain enabled drug traceability solution can be used to mitigate the drug counterfeiting problem in the drug manufacturing industry's supply chain was tested by issuance of validation questionnaires. The population used for the validation came from the random sampling size illustrated in section 3.4.4. Their satisfaction with the solution was gauged from their responses. Also, the responses determined if the study had solved the problem. The questionnaire sample is found in Appendix A section A.4.

CHAPTER 4: SYSTEM DESIGN

4.1 Introduction

This chapter includes the design of the solution's architecture, the presentation of context diagrams, sequence diagrams, use case diagrams and wireframes.

4.2 Data Analysis

4.2.1 Manufacturer Interview

The study collected data from 6 manufacturing companies these are: Universal Pharmaceuticals Limited in Kikuyu Township in Kiambu County, Dawa Pharmaceuticals Limited on Baba Dogo Road in Industrial Area, Philips Pharmaceuticals Limited on Mombasa Road, Elys Chemical Industries Limited on Enterprise Road, Industrial Area and Cosmos Limited on Rangwe Road in Industrial Area. Each company had one representative interviewed by the study using structured interview questions. The structured interview is based on a questionnaire with a sequence of questions, asked in the same order and the same way of all subjects of the research, with little flexibility available to the researcher. The study used narrative analysis method to analyse the data collected via interviews. See Appendix A, section A.1 for the structured interview template (Edward, 2013).

Manufacturer Interview Narrative Data Analysis

I. The actors in the drug supply chain

This question was meant to infer the types of actors in the manufacturer's drug supply chain. The most common actors according to the responses were:

- I. The Drug Manufacturers
- II. Distributors
- III. Retailers (pharmacists).

II. The working of the drug supply chain

This question was meant to find out the working of the manufacturer's drug supply chain. According to the findings, there were common trends on drug movement. These included:

- I. Most respondents relayed that drugs originated from a registered drug manufacturer, assigned to a wholesaler and finally to the retailers.
- II. In some scenarios, the manufacturers supplied drugs directly to retailers in their drug supply chain.

III. The major challenges facing the drug supply chain in terms of counterfeiting

This query focused on getting wind of the obstacles faced by the drug manufacturers down their supply chain. The most prevalent challenges were:

- I. The presence of counterfeit drugs in their drug supply chains. First, the respondents reflected the heavy presence of fake drugs circulating the industry using their brand names. Therefore, it is quite a task to differentiate between the real and fake brands. Patients are oblivious of the dangers they are exposed to when they consume such substances.
- II. Authorities colluding with drug cartels. Corruption is rampant in the industry, whereby, the cartels pay huge amounts of money to authorities to go scot free in tight situations.
- III. The presence of untrained personnel operating local pharmacies. The basic knowledge on how to decipher a drug's brand name and comparing the content to the approved industry standards is also a challenge to industry.

IV. The technologies currently used to tackle counterfeiting in the drug supply chain

This question enthralled on the various technologies present in the manufacturer's drug supply chain. The respondents cited various techniques used to counter drug feigning. These included:

- I. Use of the SMS service through a health safety USSD Code -21031. The Pharmacy and Poisons Board introduced this technology to help the public ascertain if a pharmacy outlet they are dealing with is registered with them.
- II. The respondents cited the use of machines for rapid testing of the drugs on the spot. These are mini-labs that enable quick testing of the drug's ingredients on the spot in the field to confirm they are genuine or not.

V. **Methods of getting alerts on counterfeited drugs**

This query sort to look at methods used to get alerts on counterfeit drugs. The respondents cited that formal complaints were launched through:

- I. Emails
- II. Complaint boxes in their respective stations.
- III. Some customers alerted them of counterfeit drugs through Short Message Services.
- IV. Phone calls.

4.2.2 Retailer Questionnaires

The dissertation used Google forms to collect information from 91 randomly sampled retailers in section 3.4.4. The retailers were located around Nairobi West Shopping Centre, South C Shopping Centre, South B Shopping Centre, Madaraka Shopping Centre, Langata Shopping Centre, Central Business District Accra Road, River Road and Tom Mboya Street. The reason for picking these areas was that the customer traffic was high. The questionnaire responses were analysed using Google analytics tool. Results were used to answer research questions stated in section 1.6 of this dissertation. The overall results contributed to the system design of the application through integration of various functionalities.

Retailer questionnaires google data analysis

The data collected was analysed using the Google analytics tool. The dissertation targeted randomly sampled 91 respondents who were to give adequate feedback using Google Forms. The response rate for the data collection exercise was 101. See sample of the questionnaire in Appendix A section A.2.

I. Current customer traffic in a day

The dissertation sought to find out the number of customers a retailer had in a day. The customer traffic data was key to the study since the traffic for consumers in a regular store in a day, assisted the study to have an idea of the solution's querying frequency in a day in the event of deployment of the platform. 38.6% of the respondents had customer traffic between 51-100 customers, 27.7% had between 31-50 customers, 19.8% had between 0-30 customers and 13.9% had over 100 customers in a day. Figure 4.1 reflects the findings.

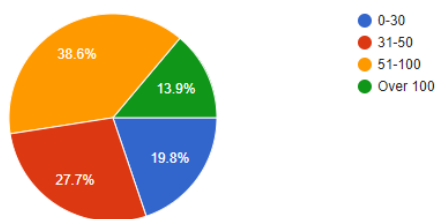


Figure 4.1: Current Customer Traffic Results

II. The possibility of handling fake drugs (yes/no)

The respondents were requested to cite if they had ever handled fake drugs in their premises. This data was important since it contributed to the study whose research objective focused on understanding the drug counterfeiting issue in the industry. 62.4% of the respondents cited that they have handled fake drugs in their pharmacies whereas 37.6% of the respondents had never handled. Figure 4.2 shows the results.

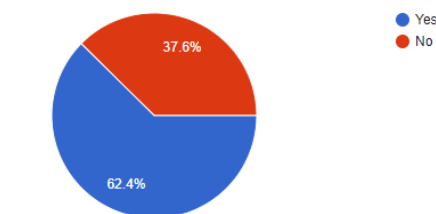


Figure 4.2: Results on Fake Drugs Handled by Retailers

III. Likelihood of the fake drugs to come from the drug suppliers' line (yes/no)

This question was only answered by respondents who affirmed that they have ever handled fake drugs in their premises. The dissertation sought to know if the fake drugs were from the retailer's drug supplier's brand. The data obtained from this question motivated the study to explore the various anti-counterfeit technologies used to tackle drug counterfeiting by looking at major industry players and their implementations. 61.4% of the respondents confirmed that the drugs were from their regular drug supplier's brand name whereas 38.6% of the respondents said the drugs did not bear their supplier's brand name. Figure 4.3 is a visual representation of the response.

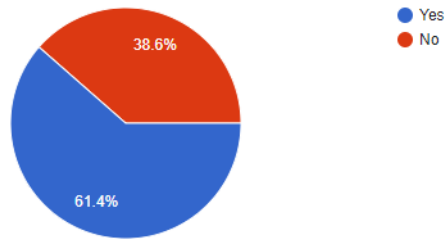


Figure 4.3: Results on Whether the Drugs were from Regular Supplier

IV. **Methods used to assure customers that the drugs purchased are legitimate**

The respondents were requested to cite the various techniques used to assure customers that the drugs they were buying were legitimate. The study used this data to assist them in revealing the various techniques currently used to prove authenticity and secure customers' trust in the market. There were quite a number of methods used by the retailers to convince their customers. These are:

- I. The use of the quality assurance certificate as a measure of authenticity of the drugs.
- II. A majority of the respondents stated they get their supplies only from a specific manufacturer. Furthermore, they make their orders straight from the source.
- III. The respondents cited that customer feedback was of major value to their service and quality assurance. The feedback was taken seriously and any complaint about a drug was handled strictly.
- IV. They taught their customers on ways of checking for important seals, watermarks and company logos.
- V. **Counterfeit drug reporting mechanisms present (phone/call/sms/other)**

The dissertation looked to get feedback on the methods customers used to report any anomaly with the drugs they purchased, with major focus on the avenues they used. The data guided the study on the existing fraud alert communication channels and the most preferred method. 51.5% of the respondents said their customers used the brand's email address, 27.7% used Short Message Service, 18.8% used phone calls, 1% stated they used the customer complaints portal and 1% used the complaints box. Figure 4.4 shows the visual presentation of the findings.

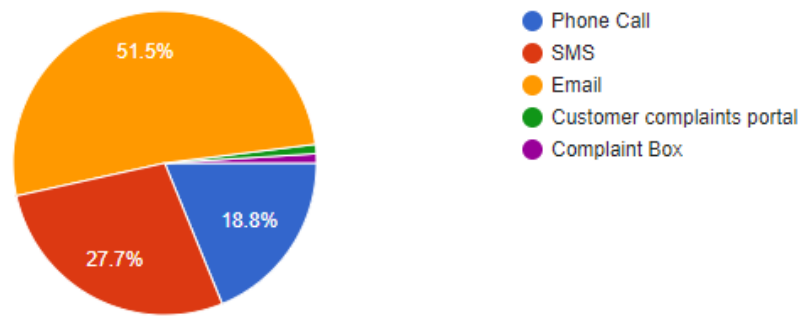


Figure 4.4: Results on the Reporting Channels

4.3 Conclusions from the Data Collection and Analysis

The responses from the data collection exercise were highly appreciated and informative. The data collected played a major role in deciding whether the solution was viable or not. The key features of the system were polished based on these findings. The findings acquired from this exercise were:

- I. The retailers encountered fake drugs in their supplies with a majority of the brand names mimicking the original manufacturers' brand names.
- II. The retailers had no steady technique to assure the customer of the authenticity of the drug.
- III. Most retailers cited a big influx of customers on a normal business day.
- IV. The retailers mostly used email and SMSs to communicate to their suppliers on rogue medicine stocks in their premises.

4.4 Requirements Analysis

The requirements were obtained from the manufacturing company representatives, distributors and retailers interviewed. Different data collection tools were used to elicit data. Through analysis, the requirements were identified and categorised into functional and non-functional requirements.

4.4.1 Network Users

The following are the users of the Blockchain Network:

- **Network Administrator:** The individual in charge of setting up the Blockchain Network and managing the Network's resources. The Network Administrator is an independent entity.
- **Manufacturer:** The company that manufactures medicine and trades with the distributors in the Blockchain Network.
- **Distributor:** The manufacturer's client.
- **Retailer:** The Distributor's client.
- **Customer:** The Retailer's client.

Other Key Words

- **Product:** A Unit of Medicine in the Blockchain Network. This describes the packet in which the medicine is packaged in. An asset in the blockchain.
- **Batch:** A set of Products created by a Manufacturer.
- **Barcode:** Unique representation of the data in machine readable form of the handlers of the Products down the supply chain. The barcode is linked to the unique identification number of a Product. The information embedded in the barcode is the source of Product details. The barcode is printed on a Product's casing.

4.4.2 Functional Requirements

The following are the functional requirements the solution users have to meet to successfully operate the blockchain.

NETWORK ADMINISTRATOR

- I. Ability to set up the Blockchain Network Environment.
- II. Ability to add Blockchain Network users (Manufacturers, Distributors and Retailers) to the Blockchain.
- III. Ability to view transactions made by the Blockchain Network users. (Only user with this privilege).

MANUFACTURER

- I. Ability to register a Product and capture its information in the blockchain.
- II. Ability to create and view Product Batches for distribution in the Blockchain Network.
- III. Ability to transfer Products to a Distributor. (Transfer of Ownership).
- IV. Ability to view the registered distributors on the blockchain.

DISTRIBUTOR

- I. Ability to view the Products assigned to them.
- II. Ability to transfer Products to a Retailer. (Transfer of Ownership)
- III. Ability to view the registered retailers on the blockchain.

RETAILER

- I. Ability to view the Products they have received from a distributor.
- II. Ability to mark Products as sold whenever a customer purchases a unit. This enables scanning by the customer.

CUSTOMER

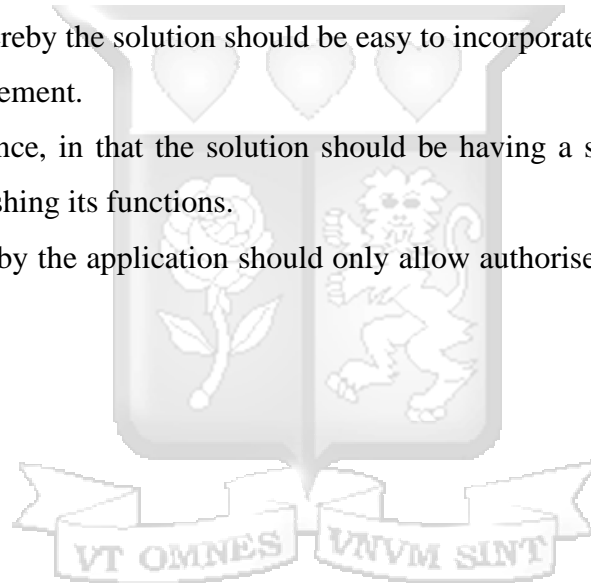
- I. Verification of Product Source. A customer should be able to establish the source of a Product through scanning the bar code generated by the manufacturing company during packaging.

- II. Reporting of illegitimate drugs to the manufacturer via email when a customer handles tampered packaging.

4.4.3 Non-Functional Requirements

These are requirements that are not important to the core functions of the application but cannot be ignored since they improve the user experience. These requirements include:

- I. Usability, thus the application should be easy to use and interact with. The user should not find any difficulty in the operability of the application.
- II. Reliability and availability whereby the application should have consistent performance and available to perform tasks requested by the user.
- III. Scalability, whereby the solution should be easy to incorporate additional features in the event of enhancement.
- IV. Good performance, in that the solution should be having a satisfactory response time while accomplishing its functions.
- V. Security, whereby the application should only allow authorised and authenticated users to operate it.



4.5 System Design

4.5.1 Overview Working of the Solution

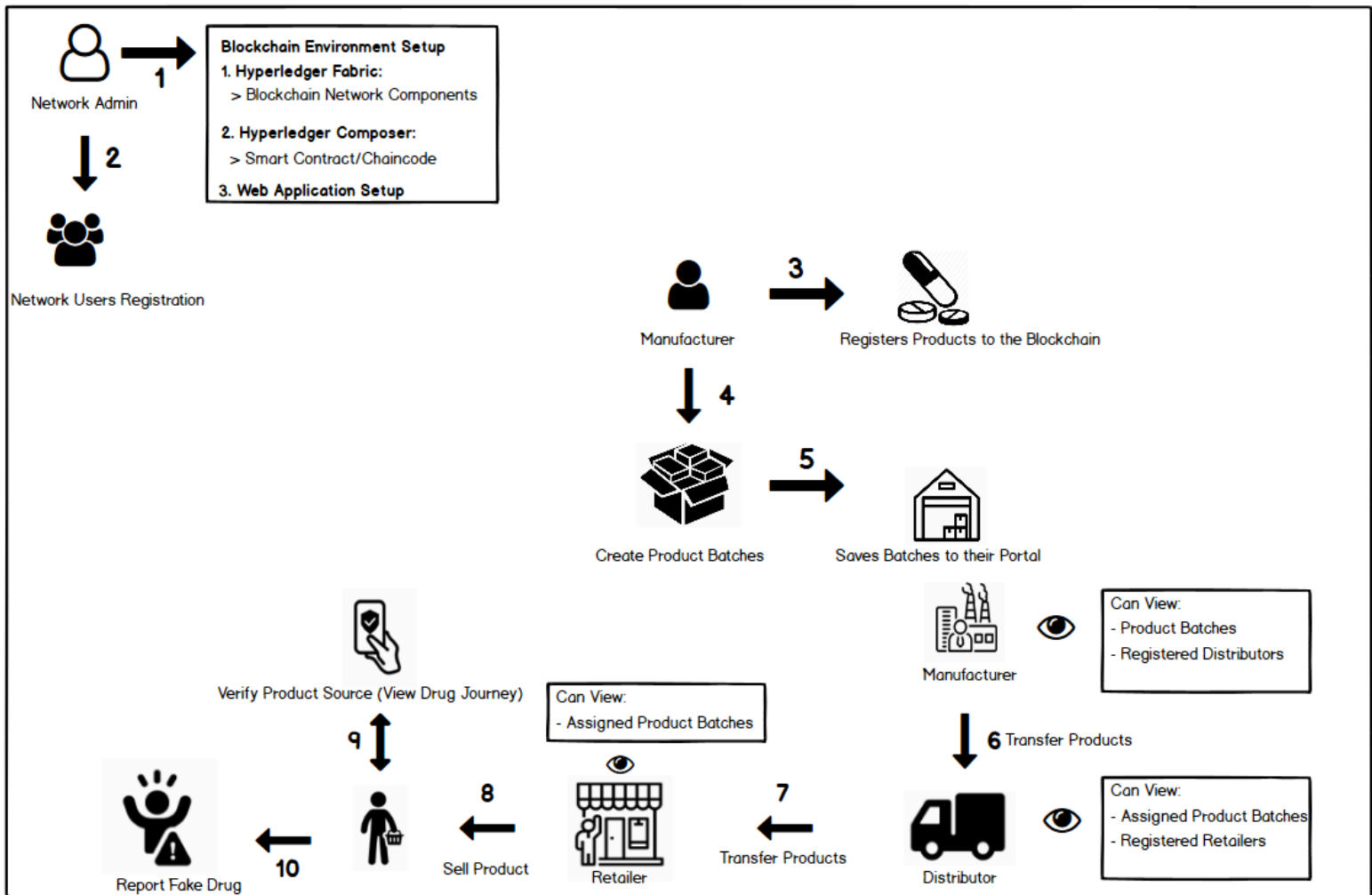


Figure 4.5: Overview Working of the Solution

The Network Administrator is the superior user of the solution since they are charged with the responsibility of setting up the Blockchain Network. Thereafter, the Network Administrator registers the users of the Blockchain through a web application portal. Other activities performed by the Network Administrator are monitoring the Blockchain Transactions Logs and the illegitimate drug reports by customers.

The Manufacturer registers Products to the Blockchain. Once the Products have been registered as assets in the Blockchain Network, they are grouped into Batches by the Manufacturer. A Batch contains several units with unique identifiers.

The Manufacturer can view the Products Batches they have created and the registered Distributors in the Blockchain Network. The Manufacturer transfers Products to a Distributor by selecting the Type of Product from the Batches created and specifying the number of units.

Similarly, the Distributor can view the Products they have received and the registered Retailers in the Blockchain Network. They can transfer Products to Retailers. Once the Retailer sells the Product to a Customer, the consumer can verify the drug source by scanning the barcode printed on the packet and viewing the Product Journey. In the event of a fake Product, the Customer is prompted to report through their end of the application.

4.5.2 Overall Solution Architecture Design

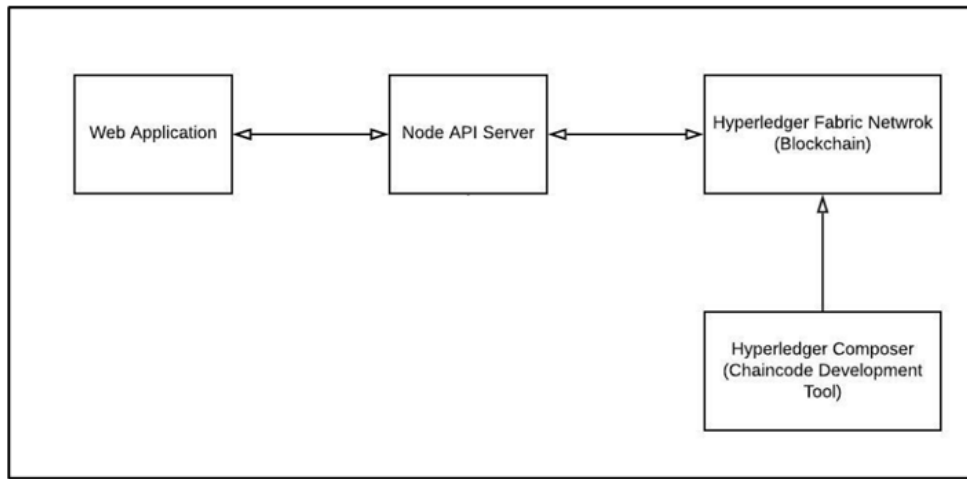


Figure 4.6: Overall Solution Architecture Design

- I. **Web Application:** Front End Web Application to be used by the Network Users to interact with the Blockchain.
- II. **Node API Server:** A Restful API (Application Program Interface) that uses HTTP requests to GET, PUT, POST and DELETE data to the blockchain. Enables external components to access the Blockchain.
- III. **Hyperledger Fabric Network:** Blockchain Backend Platform.

IV. **Hyperledger Composer:** Tool for developing Blockchain Network Framework including Chain code (Smart Contract) Development.

4.5.3 Blockchain Design

4.5.3.1 Development Environment Tools

- I. **Hyperledger Composer:** Tool used to quickly come up with a framework that contains the blockchain network files (Hyperledger, 2020). This constitutes the business logic (smart contract/chaincode) that runs on the blockchain and REST APIs that expose the blockchain logic to web or mobile applications
- II. **Hyperledger Fabric v1.2:** An open source enterprise-grade permissioned distributed ledger technology (DLT) platform. Some major features are a ledger, smart contract, blockchain network and the participants that perform transactions. The platform has a modular architecture designed whereby its core is configured to meet the diversity of enterprise use case requirements (Hyperledger, 2020).
- III. **Ubuntu Linux v18.04.2** (Canonical Ltd, London, United Kingdom) LTS with Intel Core i5-8500 @ 3.00 GHz processor (Intel, Santa Clara, CA, USA) and 8 GB memory (Ubuntu, 2020).
- IV. **Docker engine v18.06.1-ce**, (Docker, San Francisco, CA, USA): Provides the docker running environment (Docker, 2020).
- V. **Docker Compose (v1.13.0, Docker):** Provides the Integrated Development Environment (IDE) to configure docker images and containers in the virtual machine (Docker, 2020).
- VI. **CLI Tool:** Consists of Composer CLI tool that enables developers and administrators to deploy and manage smart contracts and Hyperledger Fabric SDK that generates APIs that expose the blockchain logic to web or mobile applications (Hyperledger, 2020).
- VII. **NPM (version 5.x):** The package manager for the Node JavaScript platform. It puts modules in place so that node can find them, and manages dependency conflicts intelligently (Npm, 2020).
- VIII. **Node v8.0:** Node version managers allow you to install and switch between multiple versions of Node.js and npm on your system so you can test your applications on multiple versions of npm to ensure they work for users on different versions (Nodejs, 2020).
- IX. **Browser:** Google Chrome

- X. **Library and Framework:** Boot Strap and jQuery are used to help in prototyping the frontend of the web application in order to provide a more user-friendly way to visualize the information (Bootstrap, 2020).
- XI. **Programming Languages:** Node JS for constructing RESTful APIs which the client web application can use to interact with the server. An end user can invoke the APIs functionalities through HTTP requests such as GET and POST. HTML & JavaScript were used to develop Web Application Front End.

4.5.3.2 Hyperledger Technologies Integration - Blockchain Backend Design

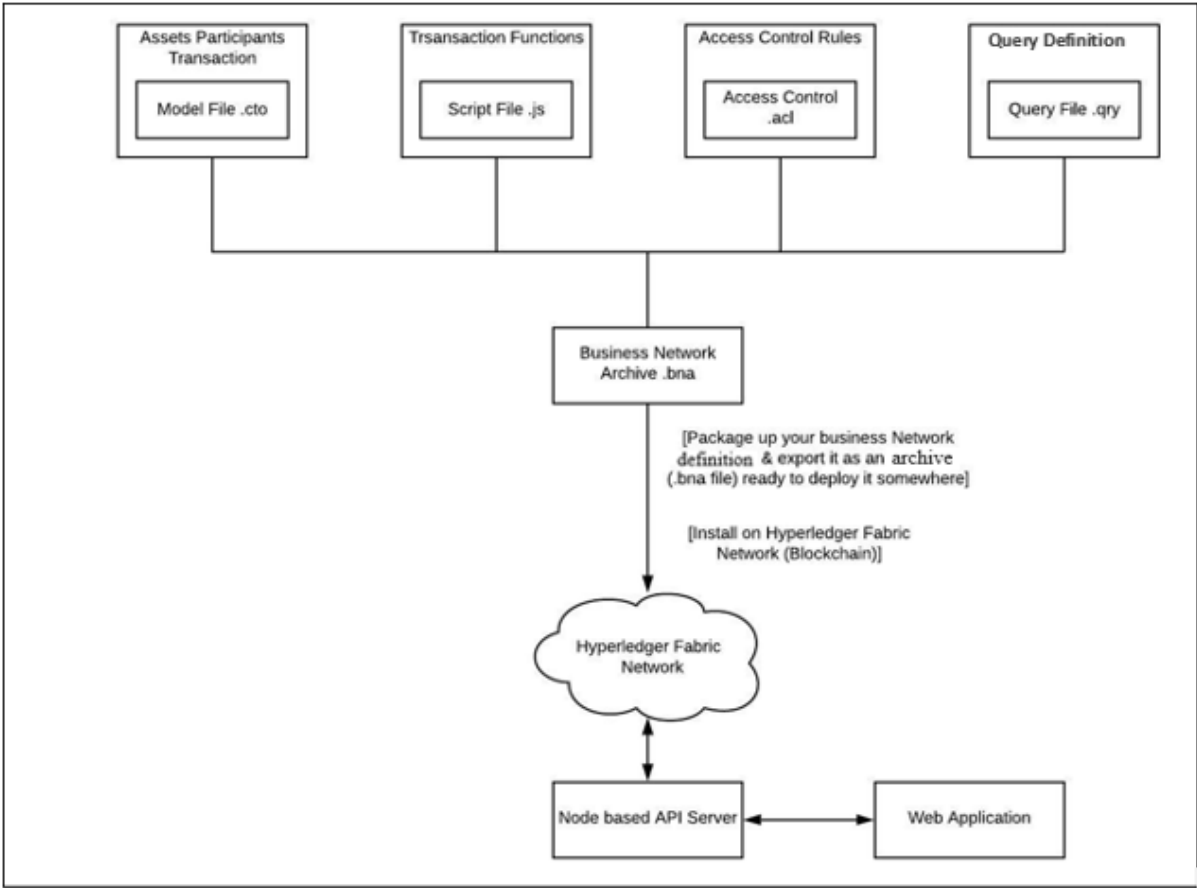


Figure 4.7: Display of the Hyperledger Technologies Fusion

The Hyperledger Composer tool packages the Data Model, Script, Query and Access Control files into a Business Network Archive (BNA) file that is deployed in the Hyperledger Fabric environment. The BNA file therefore, forms the chaincode otherwise known as the ‘Smart Contract’. The smart

contract is designed to make it easier to integrate the blockchain applications with the existing business systems.

4.5.3.3 Hyperledger Fabric Blockchain Network Components

Hyperledger Fabric has a highly modular and configurable architecture, enabling innovation, versatility and optimization for a broad range of industry use cases including banking, finance, insurance, healthcare, human resources, supply chain and even digital music delivery (Hyperledger, 2020).

The following are the components of a Hyperledger Fabric Blockchain Network:

- I. **Assets:** These are tangible (e. g Products) or intangible (e. g contracts) items that can be exchanged in a blockchain network. They are a representation of Products in the blockchain, with state changes which are recorded as transactions on the ledger.
- II. **Consortium:** Two or more companies that come together to join a blockchain network.
- III. **Network Members:** They consist of the Network Administrator, Manufacturer, Distributor and Retailer. These are companies that came into an agreement to form a consortium (private blockchain network) that is only accessible if you are a member of the network.
- IV. **Chaincode:** Otherwise known as the Smart Contract defines the business logic of a Blockchain Network. It is a program in Node.js that handles the business logic agreed to by the members of the network. It defines the assets of a network, the transaction instructions of modifying the assets, enforces the rules for reading or modifying the ledger of the blockchain.
- V. **Ledger:** This a sequenced, tamper-resistant record of all state transitions in the blockchain network. The ledger is comprised of a blockchain ('chain') to store the immutable, sequenced records in blocks, as well as a state database to maintain current fabric state. There is one ledger per channel. Each company maintains a copy of the ledger from the channel they belong to. The Blockchain Network consisted two channels.
- VI. **Nodes/Peers:** The companies join the network using peers. Peers are communication entities in a blockchain network. They receive blocks of generated transactions, which are subsequently validated before they are committed to the peer's copy of the ledger. Peers are

important to the blockchain network because they host ledgers and smart contracts of the blockchain. All peers in a channel maintain an exact copy of the ledger.

Types of peers:

- I. **Orderer Peer:** Orderer peer is considered as the central communication channel for the Hyperledger Fabric network. Orderer peer/node is responsible for a consistent Ledger state across the network. Orderer peer creates a block from transactions made and delivers that to all the peers.

Orderer is built on top of a message-oriented architecture. There are three options that can be used to implement the Orderer peer:

- **Solo:** Suitable for development. Single point failure. Solo is not used for in a Production-ready network.
- **Kafka:** Production-ready Hyperledger Fabric Blockchain networks use Kafka as the Orderer implementation. Kafka is messaging software that has high throughput fault tolerant feature.
- **Raft:** This is a crash fault tolerant (CFT) ordering service based on an implementation of Raft protocol. Raft follows a “leader and follower” model, where a leader node is elected (per channel) and its decisions are replicated by the followers.

The study used Raft in implementing the Orderer Node for the Blockchain Network.

- II. **Anchor Peer:** Anchor peer is configured at the time of Channel configuration. In Hyperledger Fabric you can configure secret channels among the peers and transactions among the peers of that channel are visible only to them.

Anchor peer receives updates and broadcasts the updates to the other peers in the organization. Anchor peers are discoverable. So, any peer marked as Anchor peer can be discovered by the Orderer peer or any other peer.

- I. **Committing peers (Network Administrator, Manufacturer, Wholesaler, Retailer):** Every peer node in a channel is a committing peer. It receives blocks of generated transactions, which are subsequently

validated before they are committed to the peer node's copy of the ledger as an append operation. All receive the same block generated by the Orderer Node per transaction.

II. **Endorsing Peer:** Peers can be marked as Endorser peer (Endorsing peer). Upon receiving the “transaction invocation request” from the Client application the Endorser peer:

- **Validates** the transaction. Check certificate details and roles of the requester.
- **Executes** the Chain code (Smart Contract) and simulates the outcome of the transaction. But it does not update the ledger.

The endorsing peer can either approve or disapprove the transactions committed to it by the Web Application. The Endorser node executes the Chain code (Smart Contract) so there is no need to install Chain code in each and every node of the network which increases the scalability of the network. The Hyperledger Fabric validation of transactions and communication of the current ledger state to all nodes are done by different nodes thus the endorsing peer node and orderer node. Therefore, the Orderer node will duplicate the same blocks to all Peer Node that will update their current Ledger. Figure 4.8 demonstrates the same.

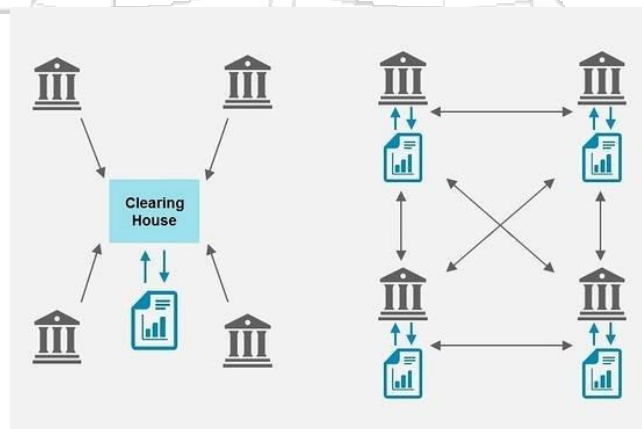


Figure 4.8: Orderer Node Distributes the same Blocks all Peer Nodes of the Blockchain Network.

This feature gives the Hyperledger Blockchain Platform an edge over other Blockchain Technologies when it comes to performance since different nodes handle these functions.

- I. **Client (Web application):** A component connected to a peer on the Blockchain Network. It avails a user-friendly front end that allows a user to create and invoke transactions in the blockchain network.
- II. **Channel:** A private “subnet” of communication between two or more specific network members, for the purpose of conducting private and confidential transactions. Each channel is an independent chain of transaction blocks containing only transactions for that particular channel. The network participants connect to a channel through their peers.
- III. **Access Control List (ACL):** It is part of a channel’s configuration. ACL manage access to peer resources by referring to the agreement undertaken by each member for the blockchain network.
- IV. **Membership Service Provider (MSP):** It manages identity and permissioned access for network participants. Public Key Infrastructure (PKI) is used to generate cryptographic certificates for use in the network. A PKI is comprised of Certificate Authorities (CAs) who issue digital certificates to Network Members, who then use them to authenticate themselves in the messages they exchange in their environment. The MSP is governed by policies which are also agreed upon when the organization is joined to the network.
- V. **Transactions:** These are Operations invoked on the chain code that when successful, the chain code executes the specified function - which may involve modifying the corresponding state of the ledger and returning an output.
- VI. **Consensus:** Consensus is only achieved when a node needs to validate a Batch of transactions and add them as a new block to the blockchain.
- VII. **Endorsement Policy:** These are conditions agreed upon by members of the network on how to validate transactions. Usually followed by peers during validation.
- VIII. **Blocks:** A block contains an ordered set of transactions. It is cryptographically linked to the preceding block and in turn it is linked to subsequent blocks. Blocks are created by the orderer node and validated by peers.
- IX. **State Database:** This Database represents the latest state of the blockchain. The state is stored persistently and updates to the state are logged. Stored in. The solution used a CouchDB.

- X. **Privacy:** The Immutable ledger is made available exclusively to participants of the Blockchain Network. The Blockchain Transaction Logs are available only to authorized members of the network. The privacy settings are determined by the policies guiding the network.

4.5.3.4 Blockchain Network Architecture

The architecture displayed in Figure 4.9 represents a high-level view of the Blockchain Network components used in the solution. The blockchain network is for a pharmaceutical supply chain that runs its business logic on the Hyperledger Fabric platform.

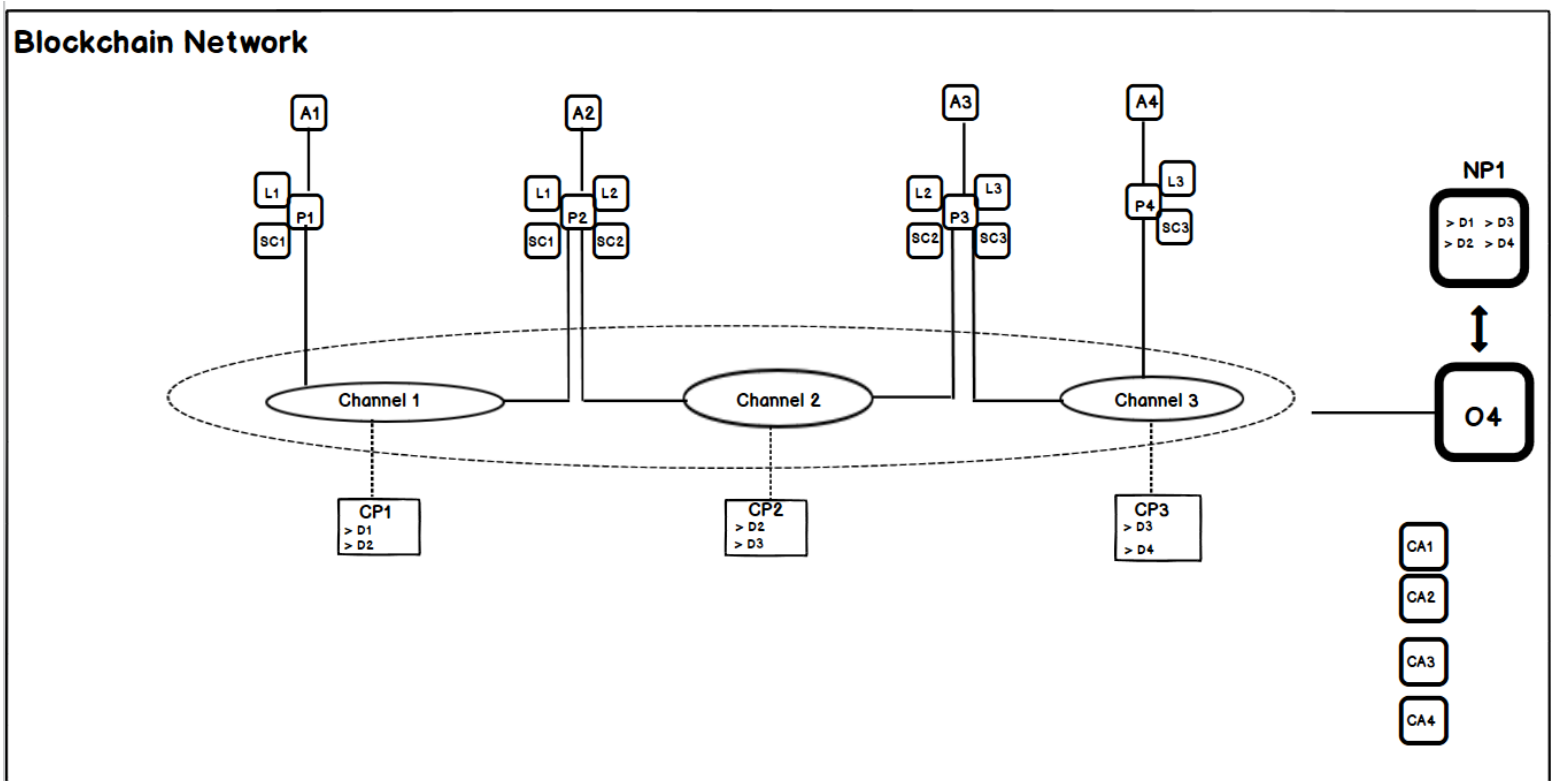


Figure 4.9: Solution's Blockchain Network Architecture

Table 4.1: Description of the Blockchain Network Components

O4	Orderer Peer		NP1	Network Policy 1
D1	Network Administrator		A1	Client Application for Network Administrator (D1)

D2	Manufacturer		A2	Client Application for Manufacturer (D2)
D3	Distributor		A3	Client Application for Distributor (D3)
D4	Retailer		A4	Client Application for Retailer (D4)
P1	Peer Node 1		L1	Ledger 1
P2	Peer Node 2		L2	Ledger 2
P3	Peer Node 3		L3	Ledger 3
P4	Peer Node 4		CP1	Channel Policy 1
CA 1	Certificate Authority for Network Administrator (D1)		CP2	Channel Policy 2
CA 2	Certificate Authority for Manufacturer (D2)		CP3	Channel Policy 3
CA 3	Certificate Authority for Distributor (D3)			
CA 4	Certificate Authority for Retailer (D4)			
SC1	Smart Contract 1			
SC2	Smart Contract 2			
SC3	Smart Contract 3			

Figure 4.9 displays the Blockchain Network topology for the solution. The Network consists of 4 user roles: Network Administrator, Manufacturer, Distributor and Retailer (represented as D1, D2, D3 and D4) in the Channel Policies (CP1, CP2 and CP3). These four departments have jointly written into an agreement of Network Policy (NP1) that D1 will set up and initialize a blockchain network.

The Network Users also agreed to have private communication among themselves despite being in the same network. Therefore, the Blockchain network will have three channels. Some of the reasons cited by the participants during the research was the need to have Product Price privacy.

The channels were created to enable the Network Users relate in trade. Therefore, the following are the Channel Participants:

- **Channel 1:** D1 and D2 (Network Administrator and Manufacturer).
- **Channel 2:** D2 and D3 (Manufacturer and Distributor)
- **Channel 3:** D3 and D4 (Distributor and Retailer)

The Channel 1 is governed by the policy rules established by D1 and D2 specified in the Channel Policy 1 (CP1). The same with CP2 and CP3, the participants create the rules for their Channel Policy.

Channel 1 is controlled by Peer 1 (P1) and Peer 2 (P2), which host Smart Contract 1 (SC1) and Ledger 1 (L1). Channel 2 is managed by Peer 2 and Peer 3 where Smart Contract 2 (SC2) and Ledger 2 (L2) are hosted. Channel 3 is managed by Peer 3 and Peer 4 where Smart Contract 3 (SC3) and Ledger 3 (L3) are hosted.

The Ordering Service (O4) acts as a Network Peer Manager that can create a channel or allow other peers to join the specific channel. It also supports the communication within channels C1, C2 and C3, for the sake of ordering transactions into blocks per channel.

Network Users access the Blockchain Network using Client Applications A1, A2, A3 and A4. Client Applications A1 and A2 can use Peer 1 (P1) to connect Channel 1 (C1) whereas A2 and A3 can access Channel 2 (C2). A3 and A4 accesses Channel 3 (C3). Each of the departments (D1, D2, D3 and D4) are associated with a permanent Certificate Authority (CA), for example, client application A1 belongs to D1 which is issued by Certificate Authority CA1. CA issues Public Key Infrastructure (PKI) based certificates to network members.

4.5.3.5 Blockchain Backend Set Up

- I. **Constructing the Chaincode:** The smart contract is designed and implemented using the Hyperledger Composer. The smart contract consists of a data model, script, access control rules and query file definitions. The tool also models the Network Users definitions (Network Users) and Network Assets (Units of Medicine/Products).
 - **Data Model File:** This is whereby the detailed structure of the State Database is defined. The Products, network users and their interaction. Events are also described in this file in the same way as assets or network users. They are usually

included in the transaction processor functions to be emitted as part of a transaction.

- **Script File:** The script file specifies the transaction process functions that act on assets and participants to either create, update or delete properties on assets and participants.
- **Access Control Rules:** The access control file describes assets or groups of assets and defines the Network Users who can perform operations according to their role in the network.
- **Query File:** The Queries are written in a bespoke query language and are defined in a single query file within a smart contract definition. By using queries, data can be easily extracted from the blockchain network. Queries contain a description and a statement.

II. **Generation and deployment of the Business Network Archive (BNA) File:** The smart contract content (Chaincode) is developed in a Business Network Definition (BND) File and packaged into Business Network Archive (BNA) file for deployment in the Hyperledger Fabric Blockchain environment.

The study used Hyperledger Composer to come up with the chaincode/smart code (business logic) of the solution. Once the chaincode was ready for deployment in the Hyperledger Fabric environment, it was packaged in a BNA file and deployed.

III. **Blockchain Network Configuration**

Amongst the major considerations while putting up a Blockchain Network is to identify the components of the network.

The following are the Network components of the Blockchain Enabled Drug Traceability Solution that were setup:

- I. **Certificate Authority (CA) Configuration:** The Fabric CA client is used to register and enrol identities. It creates Certificates Authorities (CAs) of the Network. This was the first component that was deployed in the Network on the Network Administrator Node. The certificates normally identify who can administer a node. The first CA otherwise known as the “Enrolment CA” was created for the Network Administrator. It was used to generate certificates for the other Network Users thus the Manufacturer, Distributors and Retailers.

The Network will use a Transport Layer Security Certificate Authority (TLS CA) to generate TLS Certificates for the other nodes in the Network. The TLS Certificates are used to secure communication in the Network through preventing Man in the Middle Attacks. The study will deploy the TLS Certificate Authorities first and will use its root certificate to bootstrap the enrolment CA.

The Network Administrator will register and enrol with the enrolment CA, (their node will get its signing certificates that identify it when it attempts to sign its actions) and with the TLS CA (it will get the TLS certificates it uses to authenticate its communications).

The TLS CA and the Enrolment CA will share the same database to allow a one-time registration which allows the node identity (Network Administrator) to only be registered once and enrolled by CA server separately. The dissertation will have one Enrolment CA (Network Administrator Node) and three TLS CAs for the Manufacturer, Distributor and Retailer Nodes.

II. Register and Enrol Network Administrator Identity and MSP (Message Service Provider): The first step is to register and enrol the Network Administrator Identity and create their MSP structures needed to define the components in the Blockchain Network. Once the Network Administrator identity has been registered, it is enrolled by assigning it a username and password. The Network Administrator will be used to set up the other Network Components such as the three peers, the chaincode installation and the channels.

The Fabric CA will also generate two certificates for the Network Administrator. A Public Certificate (signcert) known to the members of the Network and a Private Key stored in the Key Store folder, that will be used to sign actions taken by the Network Administrator.

Furthermore, the Fabric CA will generate an MSP file for the Network Administrator. The MSP file will contain the Public Certificate and the root of trust for the Network Administrator's Certificate Authority. Hyperledger Fabric CA is the default Certificate Authority component, which issues PKI-based certificates to network members. The other users are joined to a network by adding its Membership Service Provider to the network.

- III. **Register and Enrol the Blockchain Network Nodes Identities:** The other users of the Network are the Manufacturer, Distributors and Retailers. The Network Administrator given the privilege of enrolling users to the Network in its CA configuration, registers and enrolls the identities of the users to the Blockchain Network with the Enrolment CA and the TLS CA. It is in this process that the Network Users are assigned usernames and passwords. The Manufacturer, Distributor and Retailer will be assigned the role of a Peer Node in the Blockchain Network.

The MSP structure (Local Peer MSP) will be created once the Peer Nodes have been created and used to bootstrap the nodes. The MSP is referred to as Local MSP since the permissions assigned to it are only applicable at the node (local) level.

- IV. **Deploying the Network Nodes:** Once the Certificate Authorities and the MSPs have been configured, the Network Administrator creates the Network Nodes.

Peer Nodes

This is a network entity that maintains a ledger and runs chaincode containers in order to perform read/write operations to their ledgers. Peers are owned and maintained by its member in this case each Network User will have their own peer. A peer receives ordered state updates in the form of blocks from the ordering node to maintain their state and their ledger. They expose a set of APIs that enable the Network Administrators and Client Applications to interact with them. The Network Administrator will enrol the Peers in the Blockchain Network with their CA and Local Peer MSP. The study will setup four peer nodes for the Network Administrator, Manufacturer, Distributor and Retailer identities. The four peers will be endorsing and committing peers.

Ordering Node (Orderer)

In the Blockchain Network, to update a transaction, a single peer cannot perform this process on its own. Updating requires the consent of other peers in the network. A peer requires other peers in the network to approve a ledger update before it can be applied to its peer's local ledger. This process is called consensus. In this process, transactions are ordered and bundled into a block. The orderer node is responsible for creation of the genesis block. A genesis

block is the first block in a Blockchain (Hyperledger, 2020). Orderer peer creates the blocks and delivers that to all the peers. These blocks eventually form the Blockchain.

The orderer implementation for the Blockchain Network is Raft. A crash fault tolerant (CFT) ordering service based on an implementation of Raft protocol. Raft follows a “leader and follower” model, where a leader node is elected (per channel) and its decisions are replicated by the followers. Therefore, the lead node in the Blockchain Network is the Orderer Node.

The study used one ordering node for the Blockchain Network that was configured by the Network Administrator to:

- Collect proposed transaction updates.
- Order the Transactions in the Blockchain Network: The ordering service puts the transactions into a strict order and peers will use this order when validating and committing transactions.
- Package proposed ledger updates by the peers into Blocks ready for distribution to the other nodes, where they are then committed to the ledger. The peers will independently validate the blocks and ensure consistency of their ledgers.

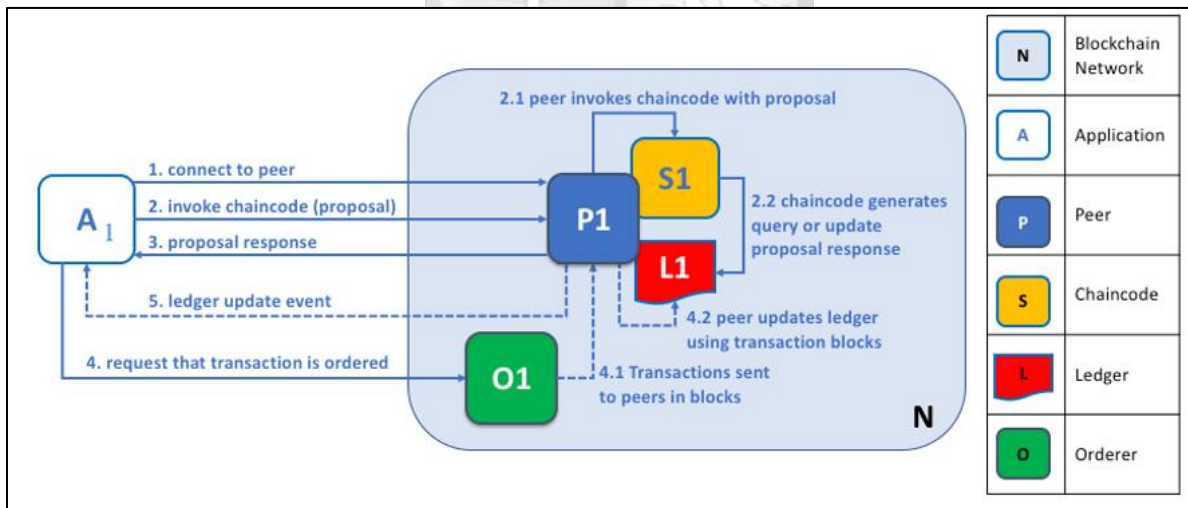


Figure 4.10: Demonstration of how a Web Application interacts with a Peer Node (Hyperledger, 2020)

V. **Setting Up Blockchain Network Policies:** These are a set of rules that determine how decisions are made in the Blockchain Network and specific results are reached. Hyperledger Fabric is a permissioned blockchain and the users are charged with the responsibility of deciding how the governance management of the network will be done before the Blockchain Network is launched. The members of the Blockchain Network also must collectively agree to changes to resources such as the smart contract or the channel before they are implemented.

The study followed the Hyperledger Fabric Policy Hierarchy to come up with policies for the solution. See Figure 4.11.

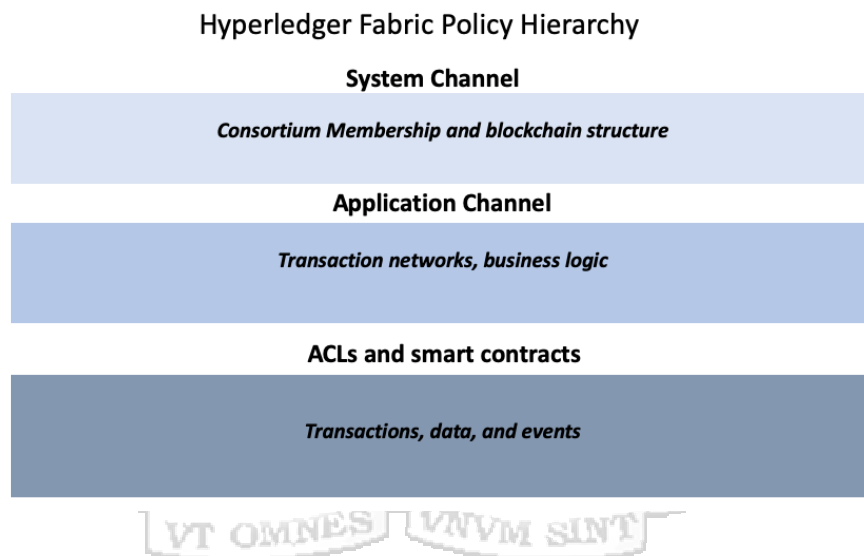


Figure 4.11: Representation of the Hyperledger Fabric Policy Hierarchy (Hyperledger, 2020)

VI. **Setting Up the Channels:** The Channels in the Blockchain Network were used as private “subnet” of communication between two network members, for the purpose of conducting private and confidential transactions (Price Privacy).

It consists of:

- Endorser/Committer Peers
- Smart Contract
- Orderer Node
- Distributed Ledger
- State Database

According to the policies set up for members in the Blockchain Network, the Network Administrator (Peer Node 1 – P1) and the Manufacturer (Peer Node 2 – P2) will have access to one channel. Whereas, Manufacturer (Peer Node 2 – P2) and Distributors (Peer Node 3 – P3) access to one channel. Distributors (Peer Node 3 – P3) and the Retailers (Peer Node 4 – P4) will have access to another channel.

Therefore, the study configured three channels that had completely separate ledgers. This is because in the network policies the members would prefer a level of confidentiality with respect to sensitive information (Product Price Privacy). This is well displayed in the Blockchain Network Architecture in Figure 4.9.

VII. **Configure the Distributed Ledger:** The ledger for the Blockchain Network will store the history of transactions in the Blockchain Network and keeps track of current value of the state of objects in this case the Networks Assets (Products).

The ledger in this solution consists of:

- I. **World State:** This is a database that contains current values of a set of ledger states. It enables an application to directly access the current value of a state rather than calculating by going through a whole transaction log. The world state can change frequently, as states can be created or updated. The ledger states are represented as key pairs. For example, in the Drug Traceability Solution, once the Network Administrator registers an asset (Product) to the Blockchain, the world state in the ledger will look like: { Key = Product Record 1, Value = {type: Amoxillin, Drug Information: 100ml, owner: Manufacturer} }

The world state is often queried to retrieve objects in line with the client application request. The world state is implemented in a CouchDB database environment.

- II. **Blockchain:** The blockchain is a historical record of the facts about how the objects arrived at their current states. The blockchain has recorded every previous version of each ledger state and how it has been changed. The blockchain contains a sequential log of interlinked blocks, where each block

contains a sequence of transactions, each transaction representing a query or update to the world state. Each block's header includes a hash of the block's transactions, as well as hash of the prior block's header. All transactions on the ledger are sequenced and cryptographically linked together. The hashing and linking of the blocks make the blockchain secure. Even if one node hosting the ledger was tampered with, it would not be able to convince all the other nodes that it has the 'correct' blockchain because the ledger is distributed throughout a network of independent nodes.

The study will have three ledgers in their Blockchain Network that represent the current state of the objects in the three channels created.

- IV. **Develop the Client (Web Application):** The client application represents the entity that acts on behalf of an end-user. It must connect to a peer for communicating with the blockchain. Client applications create and thereby invoke transactions.

The study came with a web application that allows the end users under different identities to invoke transactions to the Blockchain.

The web application will be used by the Network Users to access ledgers and the chaincode through the peer nodes of the network that are designed for their roles. Through a peer connection, applications can execute chaincode to query or update a ledger. The Hyperledger Fabric APIs enables the web application to connect to the peers, invoke the chaincode to generate the transactions and submit transactions to the network, which will then be ordered, validated and committed to the ledger of the channels. The peers validate a transaction before committing it to their ledgers. Once the ledgers are updated, the peers generate events to the Web Application to signify completion of the transaction request.

The client application uses Hyperledger Fabric SDK to interact with the Hyperledger Fabric network. Chaincode installed in peers causes to initiate transaction invocation request. All the peers maintain their one ledger per channel that they are subscribed to in the Hyperledger Fabric Client (HFC) SDK that provides a powerful and easy to use API to interact with a Hyperledger Fabric blockchain.

4.5.3.6 Blockchain Execution Processes

Registration, Enrolment and Blockchain Network Access

For a system user to access the system, they should have registered and enrolled their identities. In order to obtain the identity of the users, the Network Administrator will submit the registration request to the Enrolment Certificate Authority (CA) that issues a secret for the enrolment process.

The Enrolment request is then sent from the client (web application) to the CA passing the enrol ID and secret fetched from the registration process. The CA will pass the Enrolment Certificate along with the Public Key.

In response, the CA passes the Enrolment Certificate (ECert) along with the public key. The ECert is used to request for the Transaction Certificate (TCert), and the transaction CA passes the TCert along with the private key for signing the transactions. Once a user has been enrolled then will they access the blockchain platform. A summary of this process is relayed in Figure 4.12.

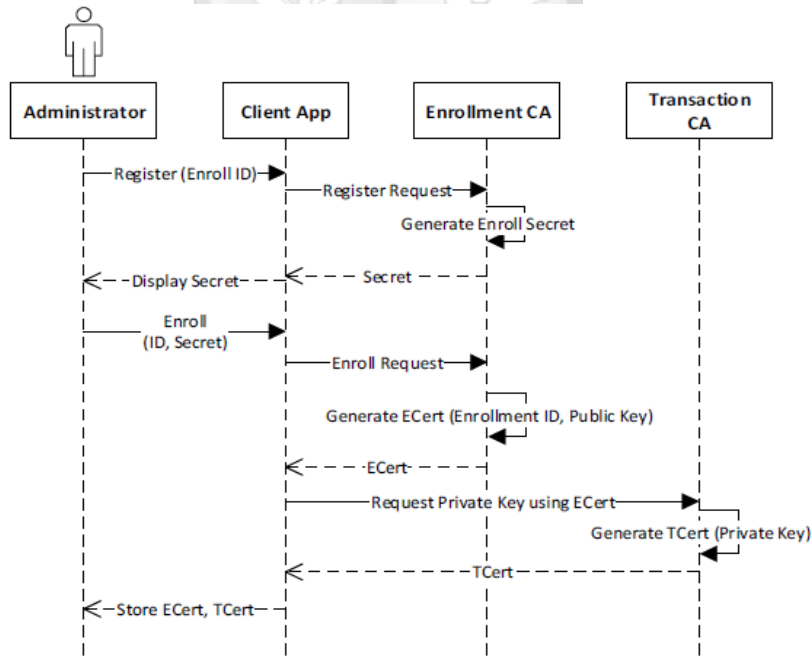


Figure 4.12: Summary of the Enrolment Process

Transaction Processing

There are various operational processes performed in order to submit a transaction for registering a Product (unit of medicine) and adding the Digital Record in the blockchain. The Manufacturer will generate a transaction proposal request using the POST method to invoke the smart contract function on the endorser peers. This is done when they input the Product registration details through the client application (web application). The smart contract is then executed to produce transaction results and the set of these values are passed back to the client. The client application verifies the proposal responses according to the endorsement policies and broadcasts the endorsed transactions to the orderer node. The orderer node orders them chronologically by channel and creates blocks of transactions per channel. The blocks of transactions are delivered to all peers on the channels for validation. Each peer appends the block to their chain, updates their ledgers and the Digital Record are saved to their current state database. Finally, an event is emitted to the client application to inform the Manufacturer that the Digital Record is created in the blockchain. To register Products in their portal, the Manufacture registers the Products and its Product Information. The Product is Uniquely identified by a Serial Number. These actions are done through their web application portal. This is the same process for all transaction processes. Lastly, an event is emitted to inform the Manufacturer that the Digital Record has been created and the transaction has been recorded to the blockchain. See Figure 4.13.



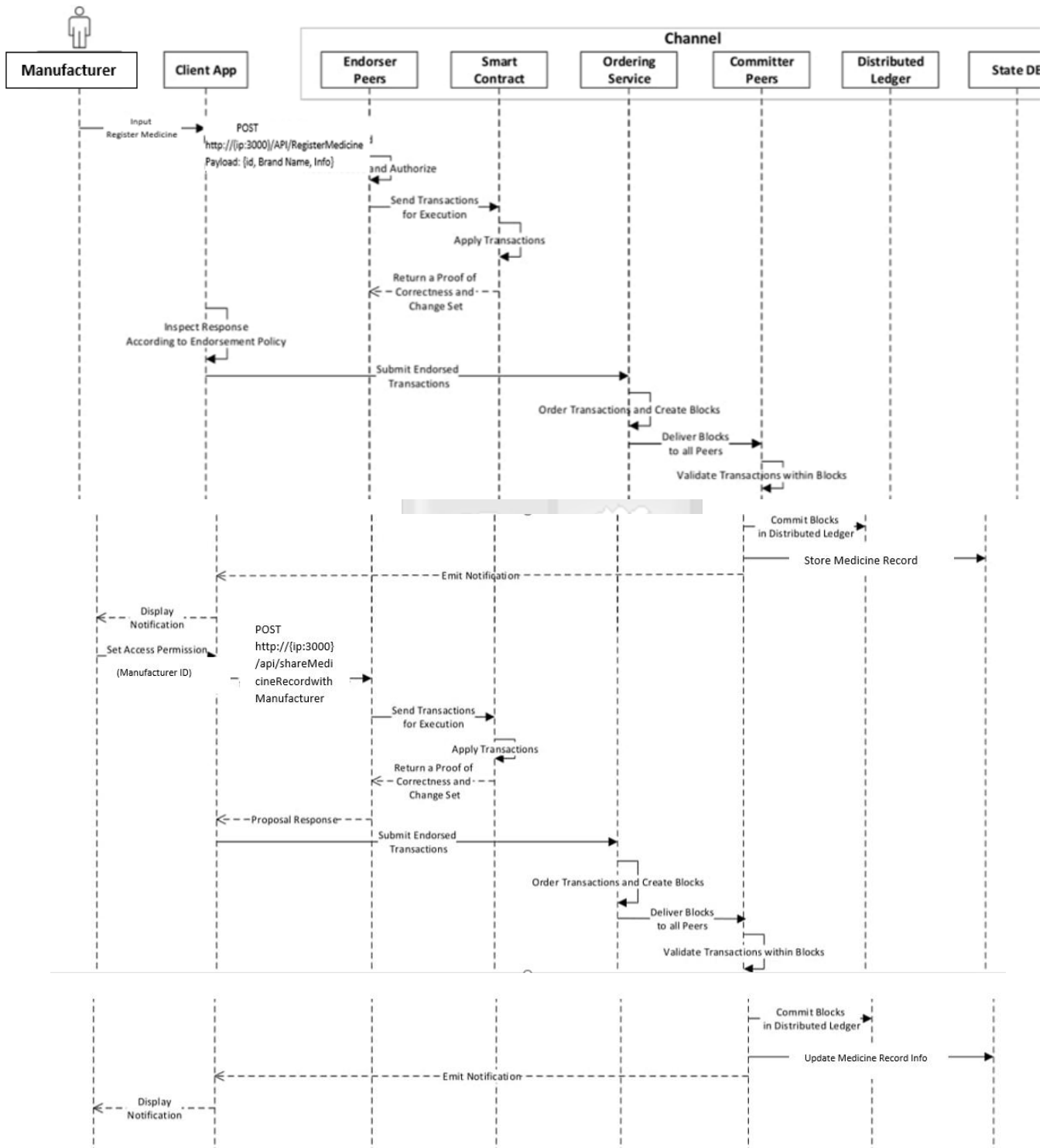


Figure 4.13: Digital Record Generation and Sharing in the Blockchain

Querying the Blockchain

The Manufacturer queries the Medical Record from the state database using the unique Serial Number, this is done by requesting the API endpoint using the GET method. All the peers in the Blockchain Network keep a local copy of the ledger that are consistently updated whenever the Peer Nodes commits transaction records from the blocks delivered by the Network's orderer node to their channel. Therefore, the query result of the Medical Record by the Manufacturer is returned immediately. See the summary in Figure 4.14.

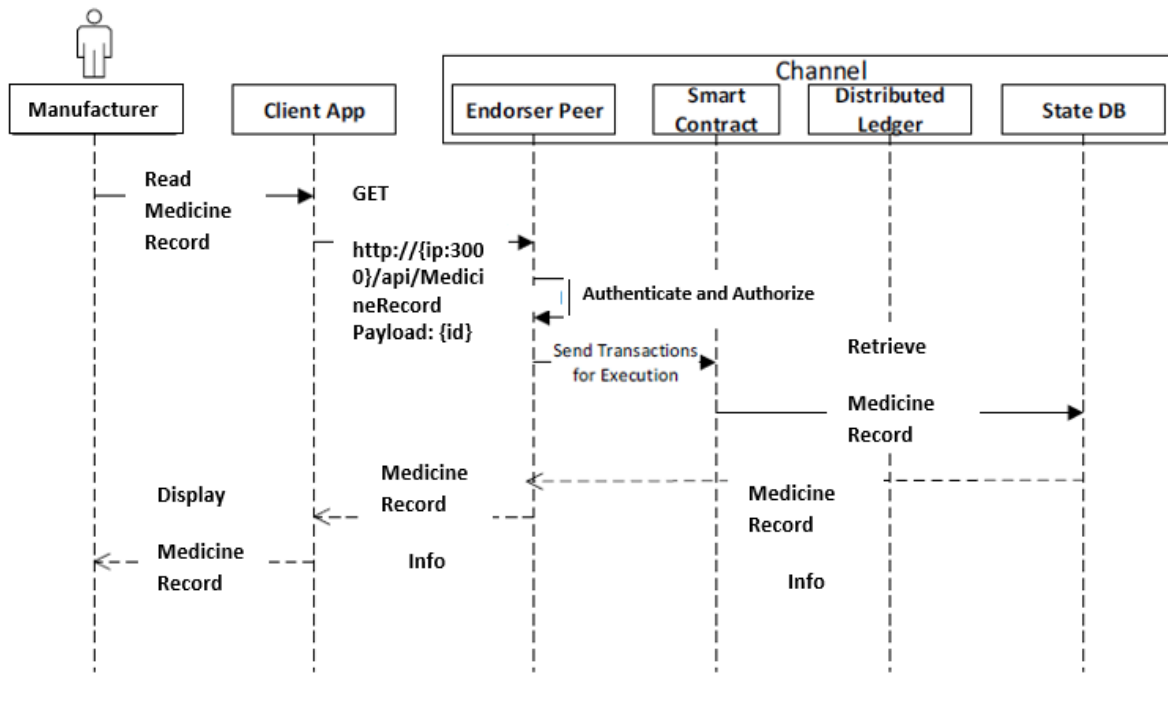


Figure 4.14: Execution procedures for a Manufacturer to query the shared Digital Record

4.5.3.7 Operations Design

I. Web Application Interface - Network Administrator

- **Log in:** The Network Administrator **Logs In** to the system and is able to access their **dashboard**.
- **User Registration:** The Network Administrator will register Manufacturers, Distributors and Retailers to the Blockchain.
- **Blockchain Transactions Log:** The Network Admin is able to view the blockchain transactions that have taken place in the blockchain.
- **View illegitimate Drugs Reports:** The Network admin can view the fake drugs report. The report can be in any kind, provided it makes representation sense.

II. Web Application Interface – Manufacturer

- **Log in:** The Manufacturer **Logs In** to the system and is able to access their **dashboard**.
- **Product Registration:** The **Manufacturer** will **Register Products** to the Blockchain. In this registration stage of the medicine, the solution captures the following details:
 - Manufacturer Name
 - Product Name
 - Product ID (Autogenerated for the Products in the Batch)
 - No. of Units assigned
 - Batch No. (Autogenerated)
 - Batch Creation Date & Time (Autogenerated)
 - Batch Expiry Date & Time (To be selected)
- **Batch Created View:** The Manufacturer can view the Batches created. Also, they can:
 - **View Batch Products:** When they **view** the **Batch Products**, they can see more information about the Batch and the Products contained in the Batch can be seen and identified by **unique codes**.
 - **Product Out View:** The manufacturer is able to view the Products they have transferred to the distributors.

III. Web Application Interface - Distributor

- **Logs In:** The Distributor **Logs In** to the system and is able to access the **dashboard**.
- **Products In View:** The distributor can view the Products they have received from the Manufacturer. Also, in this view they can:
 - **View Details:** When they **view the details**, the Products contained in that record can be seen and identified by **unique codes**.
 - **Transfer:** The distributor selects the **record** from which they would like to **transfer Products from**. Then, select the retailer, insert the quantity to be assigned to them.
- **Batch Out View:** The distributor is able to view the Products they have transferred to the retailers.
 - **View Details:** Ability to see more information about the Product.

IV. Web Application Interface - Retailer

- **Log In:** The retailer **Logs In** to the system and is able to access the **dashboard**.
- **Products In View:** The retailer can view the Products they have received from the distributor.
- **View Details:** Ability to see more information about the Product.
- **Mark Product as Sold:** The Retailer will mark the Product as sold in the system once a customer purchases the unit of medicine. This also acts as security for the bar codes produced in the solution.

V. Web Application Interface Role - Customer

- **Scanning of Barcode:** The customer scans the Barcode of a single unit of Product bought from a pharmacy.
- **Product Journey View:** Once the customer **scans the bar code**, they are able to **view** the Product's journey from the Manufacturer > Distributor > Retailer.
- **Report illegitimate Drug:** The customer to use a form that captures the details and send it to a dedicated the Manufacturing Company's email address. It captures:

- Retailer Company Name
- Drug Name
- Location (Auto capture)
- Picture of the Medicine
- Comments

4.5.4 Context Diagram

This is the highest-level of the system (Level 0). A context diagram was used to represent five external actors (Network Administrator, Manufacturer, Distributor, Retailer and Customer) that interacted with the blockchain. Figure 4.15 demonstrates the actions performed by each actor and the system response (Ibrahim, 2010).

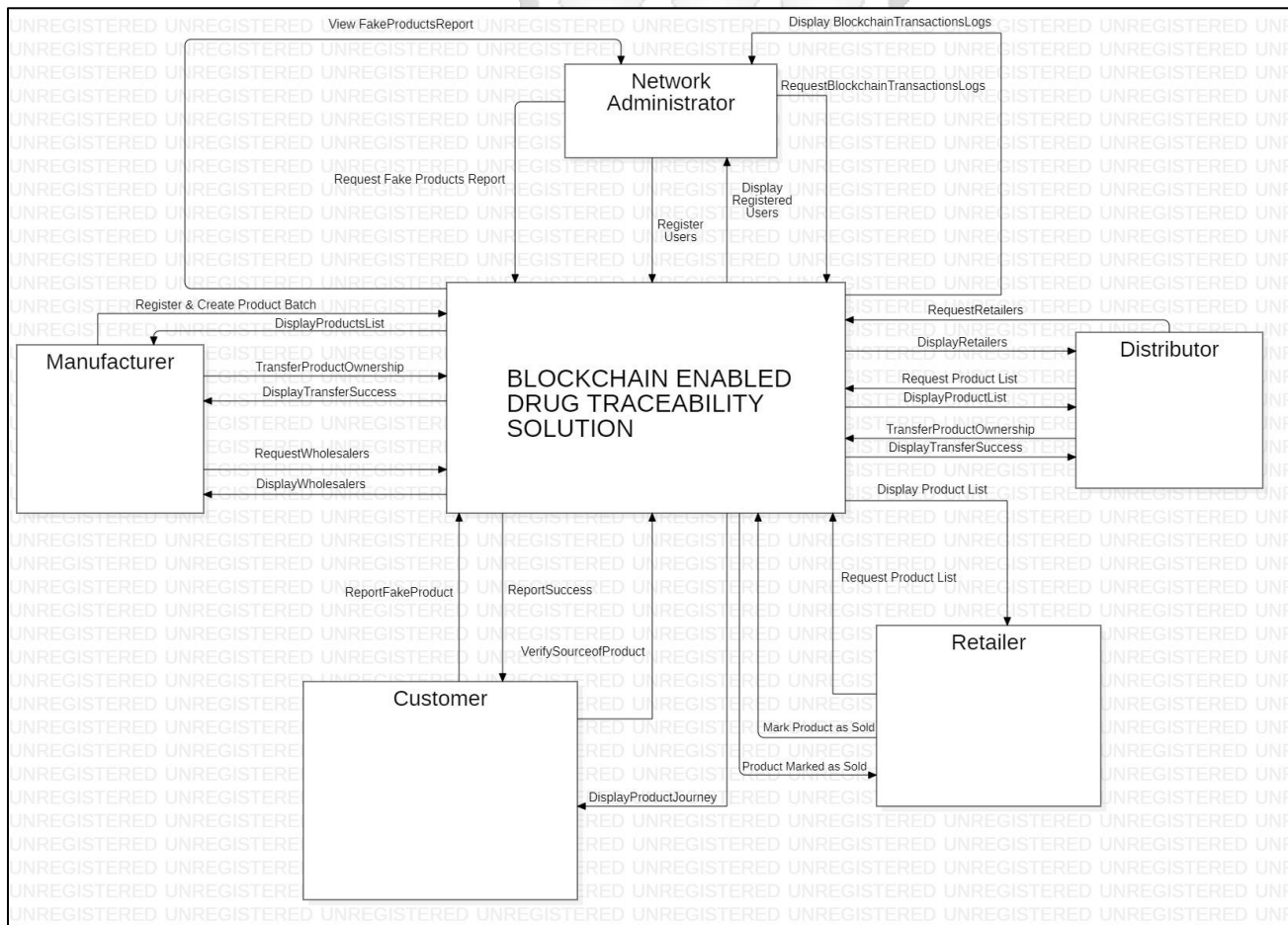


Figure 4.15: Solution's Context Diagram

4.5.5 Sequence Diagram

Sequence diagrams helped in knowing how the system would behave and to discover potential responsibilities of a class in the process of system modelling Kenpro (2012, August 22). The solution had five external actors (Network Administrator, Manufacturer, Distributor, Retailer and Customer) in the sequence diagram to show the flow of the system. Figure 4.16 demonstrates the solution’s sequence diagram.



Figure 4.16: Solution’s Sequence Diagram

4.5.6 Use Case Modelling

A use case model was used to demonstrate how the network administrator, Product custodian, manufacturer, distributor, retailer and customer interacted with the system. Figure 4.17 displays the solution's Use Case model.

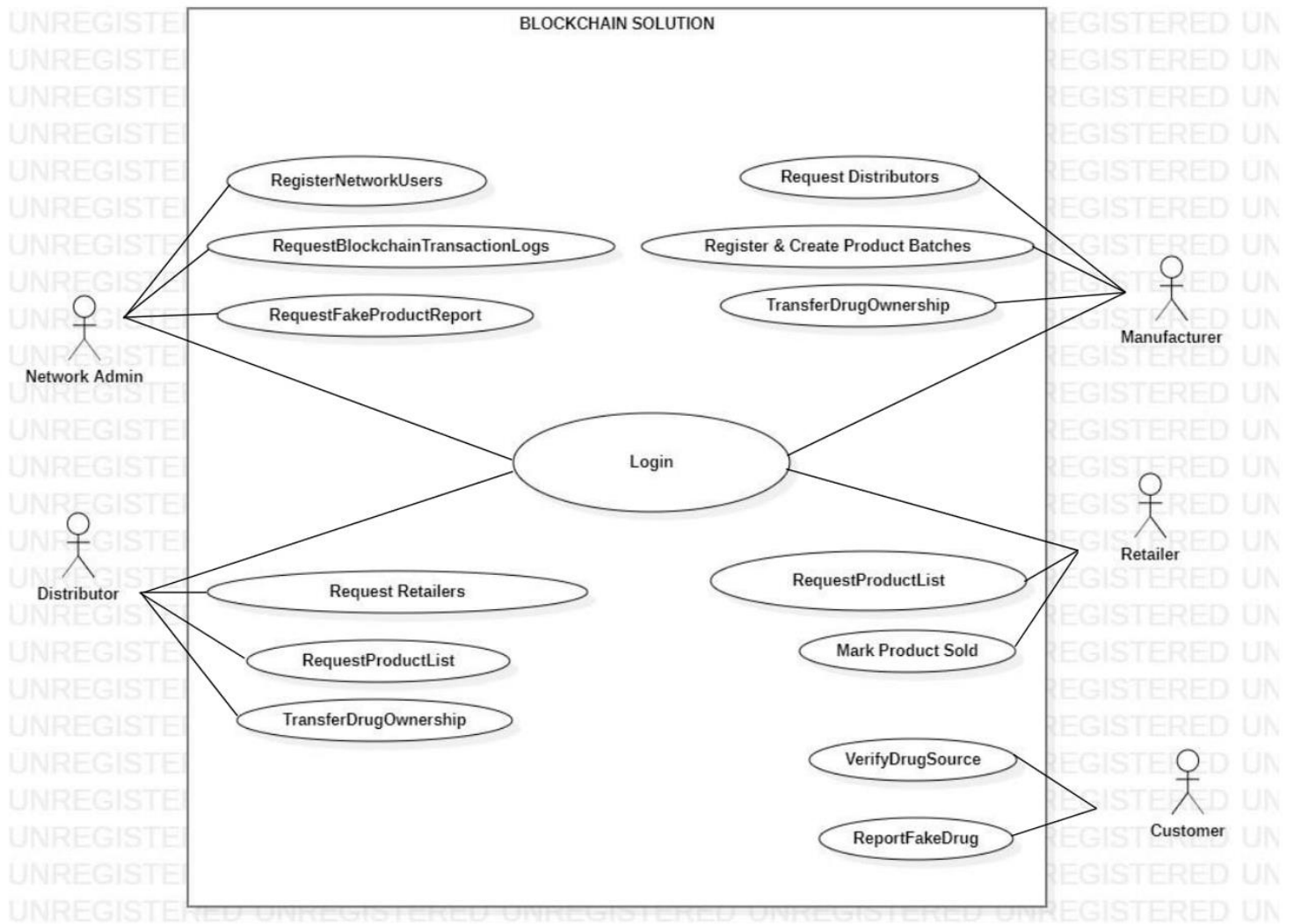


Figure 4.17: Solution's Use Case Model

Table 4.2 explains the various functionalities by the Blockchain Network in the Use Case Diagram in Figure 4.17.

Table 4.2: Solution's Blockchain Use Case Description

Use Case Name	Register Network Users
Description:	The Blockchain Network Users are registered to the Blockchain by the Network Administrator.
Primary Actors:	Network Administrator
Precondition:	The Network Administrator should capture the company name.
Post condition:	The Network Users are added to the blockchain.
Typical case of Events Actor Response	System Response
<ul style="list-style-type: none"> ▪ Register Network Users 	<ul style="list-style-type: none"> ▪ Network User has been registered.
Use Case Name	Request Blockchain Transactions Log
Description:	The Network Administrator can retrieve Transaction Logs for the Activities in the Blockchain Network.
Primary Actors:	Network Administrator
Precondition:	The Network Administrator should request to view the Blockchain Transactions Log.
Post condition:	The Network Administrator views the Blockchain Transactions Log.
Typical case of Events Actor Response	System Response
<ul style="list-style-type: none"> ▪ Request Blockchain Transactions Log 	<ul style="list-style-type: none"> ▪ Display Blockchain Transactions Log
Use Case Name	Request Fake Product Report
Description:	The Network Administrator can view the Fake Product reports submitted by the customers.
Primary Actors:	Network Administrator
Precondition:	The Customer needs to submit a Fake Product Report.
Post condition:	The Network Administrator Views the Fake Product Report.

Typical case of Events Actor Response ▪ Request for Fake Product Report.	System Response ▪ Display Fake Product Report.
Use Case Name	Request List of Distributors
Description:	The Manufacturer can view the list of Distributors in the Blockchain Network.
Primary Actors:	Manufacturer
Precondition:	The Distributors must have been registered by the Network Administrator.
Post condition:	The Manufacturer views the registered Distributors in the Blockchain Network.
Typical case of Events Actor Response ▪ Request for List of Distributors.	System Response: ▪ Display List of Distributors
Use Case Name	Register & Create Products
Description:	The Manufacturer registers the Products to the Blockchain and creates Batches.
Primary Actors:	Manufacturer
Precondition:	The Products must be registered by their Brand Name and Information to the Blockchain and identified uniquely with a Serial Number. Thereafter Batches are created.
Post condition:	The Manufacturer view the Products created together with their Batches.
Typical case of Events Actor Response ▪ Request for List of Products. ▪ Request for List of Batches.	System Response: ▪ Display List of Products ▪ Display List of Batches
Use Case Name	Transfer Product Ownership
Description:	The Manufacturer can transfer a Product (s) to a Distributor.
Primary Actors:	Manufacturer

Precondition:	<ul style="list-style-type: none"> ▪ The Product must have been registered and created for a Batch. ▪ The Distributor should have been registered to the Blockchain by the Network Administrator.
Post condition:	The Manufacturer is able to transfer a Product to a Distributor.
Typical case of Events Actor Response <ul style="list-style-type: none"> ▪ Request for List of Distributors. ▪ Request for List of Batches. ▪ Request to transfer Products to Distributor. 	System Response: <ul style="list-style-type: none"> ▪ Display List of Distributors ▪ Display List of Batches ▪ Transfer Products to Distributor
Use Case Name	Request List of Retailers
Description:	The Distributor can view the list of Retailers in the Blockchain Network.
Primary Actors:	Distributor
Precondition:	The Retailers must have been registered by the Network Administrator.
Post condition:	The Distributor views the registered Retailers in the Blockchain Network.
Typical case of Events Actor Response <ul style="list-style-type: none"> ▪ Request for List of Retailers. 	System Response: <ul style="list-style-type: none"> ▪ Display List of Retailers.
Use Case Name	Request Product List
Description:	The Distributor request to view the list of Products assigned to them by the Manufacturer.
Primary Actors:	Distributor
Precondition:	The Products must have been registered to the Blockchain Network by a Manufacturing Company.
Post condition:	The Distributor should view the List of Products assigned to them by the Manufacturer.
Typical case of Events Actor Response <ul style="list-style-type: none"> ▪ Request for List of Products assigned to them. 	System Response: <ul style="list-style-type: none"> ▪ Display the Product List

Use Case Name	Transfer Product Ownership
Description:	The Distributor can transfer a Product (s) to a Retailer.
Primary Actors:	Distributor
Precondition:	<ul style="list-style-type: none"> ▪ The Product must have been registered by a Manufacturer. ▪ The Retailer should have been registered to the Blockchain by the Network Administrator.
Post condition:	The Distributor is able to transfer a Product to a Retailer.
Typical case of Events Actor Response	System Response:
<ul style="list-style-type: none"> ▪ Request for List of Distributors. ▪ Request to transfer Products to Retailer 	<ul style="list-style-type: none"> ▪ Display List of Retailers ▪ Transfer Products to Retailers.
Use Case Name	Request Product List
Description:	The Retailer request to view the list of Products assigned to them by the Distributor.
Primary Actors:	Retailer
Precondition:	The Products must have been registered to the Blockchain Network by a Manufacturing Company.
Post condition:	The Retailer should view the List of Products assigned to them by the Distributor.
Typical case of Events Actor Response	System Response:
<ul style="list-style-type: none"> ▪ Request for List of Products assigned to them. 	<ul style="list-style-type: none"> ▪ Display the Product List
Use Case Name	Mark Product as Sold
Description:	Once the Retailer sells the Product to the Customer, they mark it as sold in the system to enable the customer to scan the barcode of the Product during Source Verification.
Primary Actors:	Retailer
Precondition:	The Product must have been sold to a customer.
Post condition:	The Product is marked as sold once the Retailer sells it to a Customer.

Typical case of Events Actor Response ▪ Request for Marking Product as Sold	System Response: ▪ Product Marked as Sold
Use Case Name	Verify Product Source
Description:	The Customer will verify the source of the Product by scanning the barcode on the Product's packet.
Primary Actors:	Customer
Precondition:	The Product must have been marked as sold by the Retailer.
Post condition:	The Customer is able to view the Product's journey.
Typical case of Events Actor Response ▪ Request to Verify Product Source.	System Response: ▪ Display Product's Journey.
Use Case Name	Report Fake Product
Description:	The Customer is able to report a fake Product together with more information on the same.
Primary Actors:	Customer
Precondition:	The Customer should get the Product from the Retailer store.
Post condition:	The Customer should be able to report a Fake Product.
Typical case of Events Actor Response ▪ Request to report Fake Product	System Response: ▪ Fake Product reported.

4.5.7 Wireframes

Wireframes were used to model the solutions web application user interfaces. Prototyping is essential in determining the ease of use of an application (Robert, 2015). The dissertation used Balsamiq Wireframes to design the web application wireframes.

Web Application Wireframes

The system users will need a **Username** and a **Password** to access the Blockchain Network. See Figure 4.18.

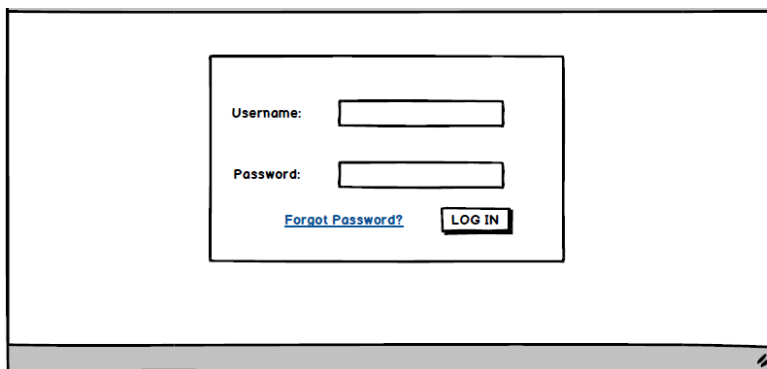


Figure 4.18: Login Page

NETWORK ADMINISTRATOR

The Network Administrator accesses their **Landing Page** (Dashboard) once they log in. See Figure 4.19.

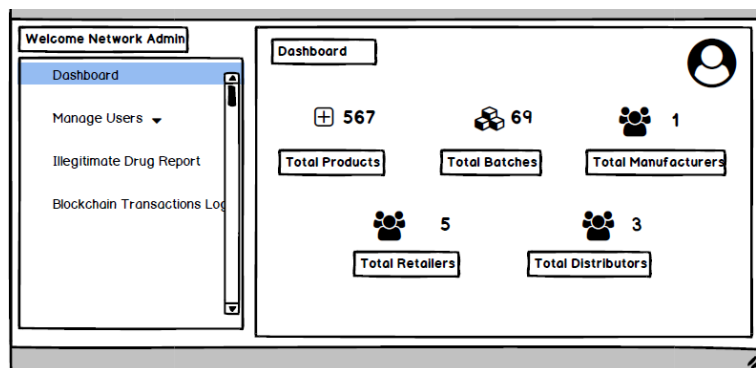


Figure 4.19: Network Admin Landing Page

They are able to see the **list of Registered Network Users** on their right pane. See Figure 4.20.

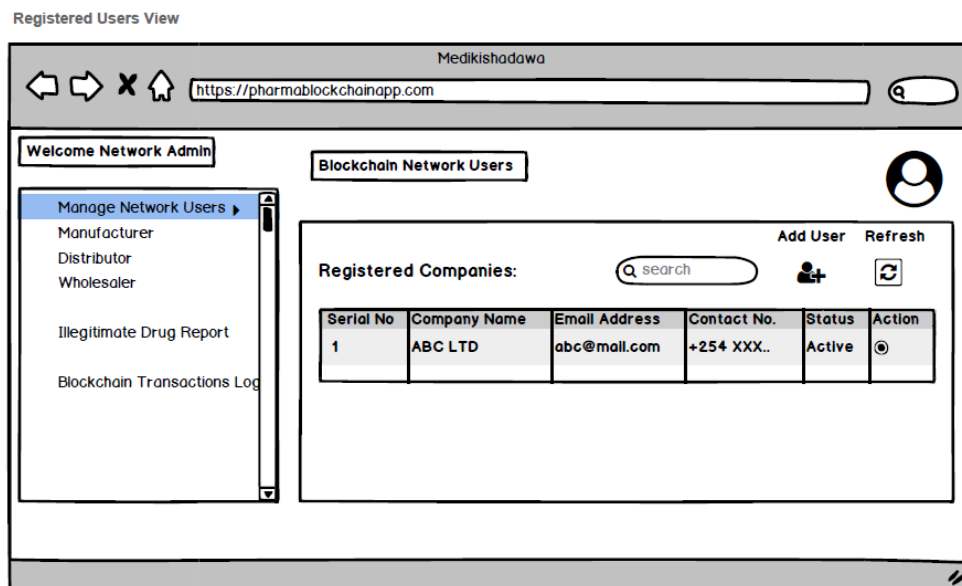
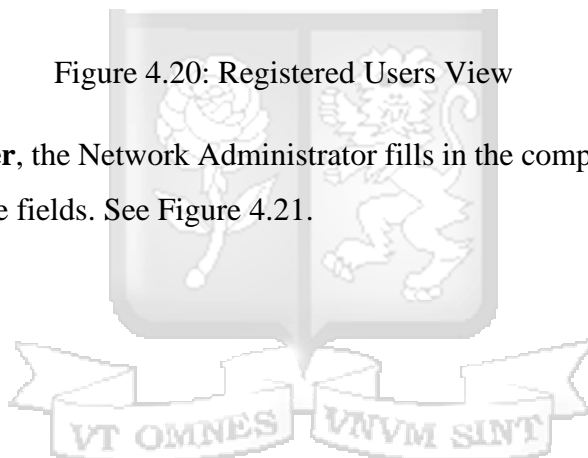


Figure 4.20: Registered Users View

To **register a Network User**, the Network Administrator fills in the company details. They click on **Save** once they fill in all the fields. See Figure 4.21.



Medikishadawa

https://pharmablockchainapp.com

Welcome Network Admin

Create Manufacturer

Dashboard

Company Profile

Manage Users

Manufacturers

Distributors

Retailers

Illegitimate Drug Reports

Blockchain Transactions Log

Company Representative Detail

First Name:

Last Name:

Username (Email):

Password:

Confirm Password:

Contact Number:

Company Details

Company Name:

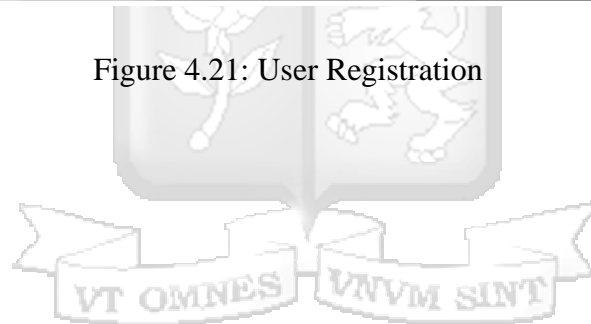
Company Address:

Company Logo

Certificate of Registration:

Status (Active/Inactive):

Figure 4.21: User Registration



As the Blockchain Network interactions continue, their will be transactions created and logged by the Blockchain. The Network Administrator will check the Blockchain's Activities from the **Blockchain Transaction Log View**. See Figure 4.22.

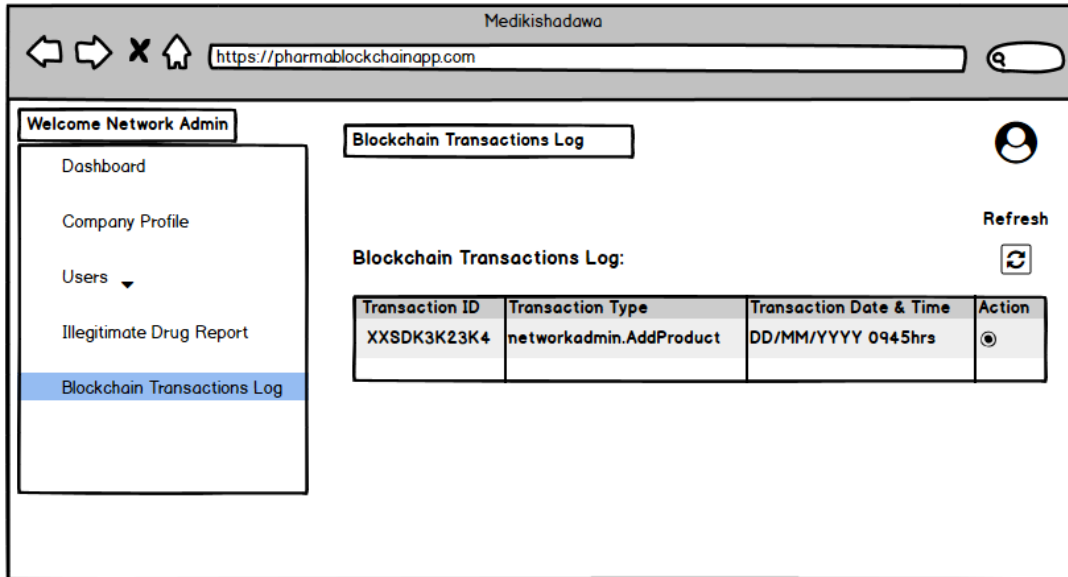


Figure 4.22: Blockchain Transactions Log

If a Customer reports an illegitimate drug the Network Administrator will be able to view the Report Logs from the **Illegitimate Drug Report View**. See Figure 4.23.

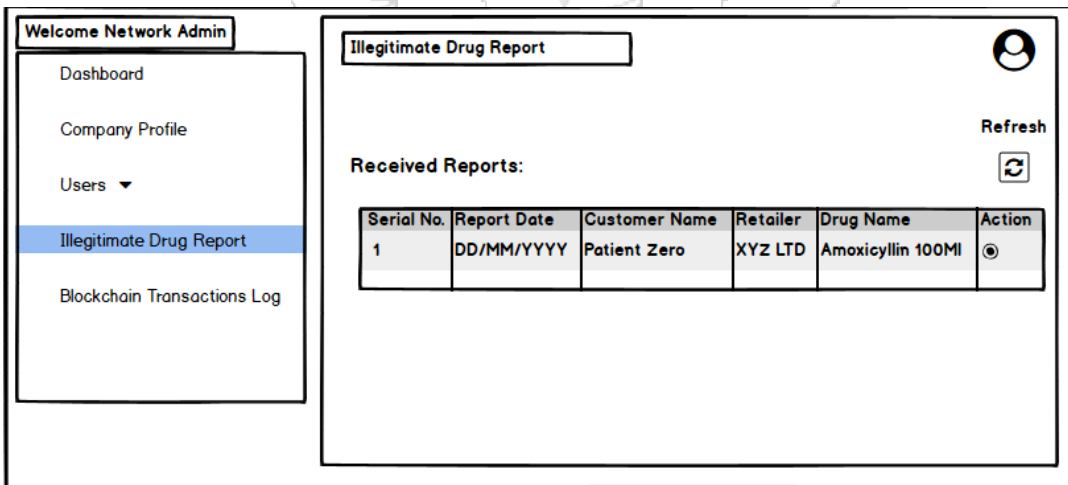


Figure 4.23: Illegitimate Drug Report View

MANUFACTURER

The Manufacturer **Logs In** and accesses their dashboard. See Figure 4.24.

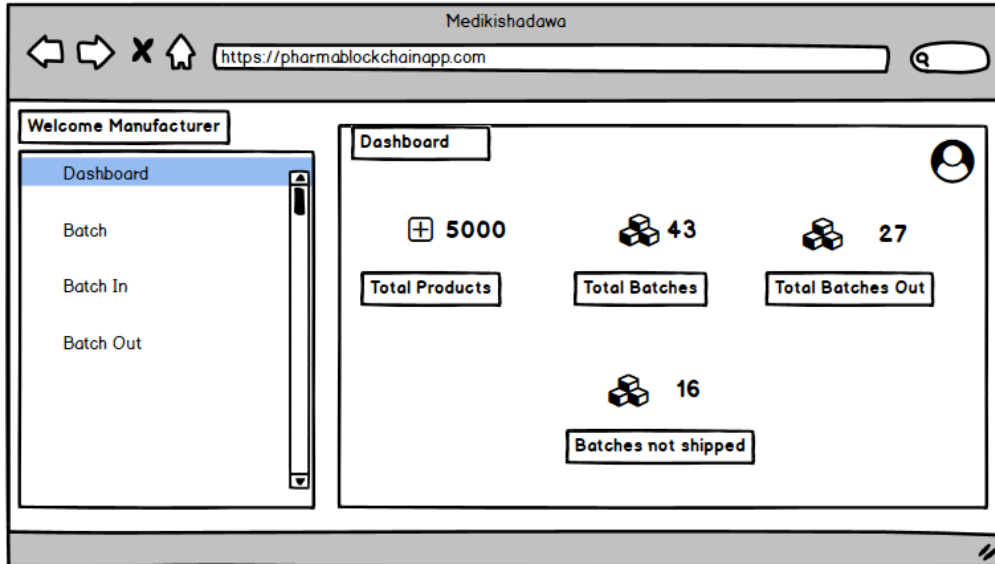


Figure 4.24: Manufacturer's Landing Page

To **register** Products in the Blockchain Network, the Manufacturer fills in the Product Registration Form and clicks **Save**. See Figure 4.25.

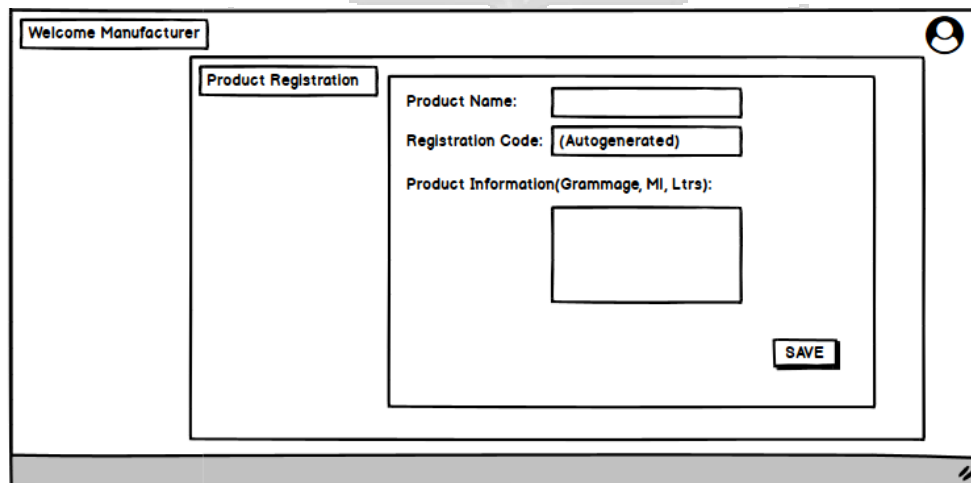


Figure 4.25: Product/Medicine Registration View

The Manufacturer can view the **List of Registered Products** in the Blockchain Network from their portal. See Figure 4.26.

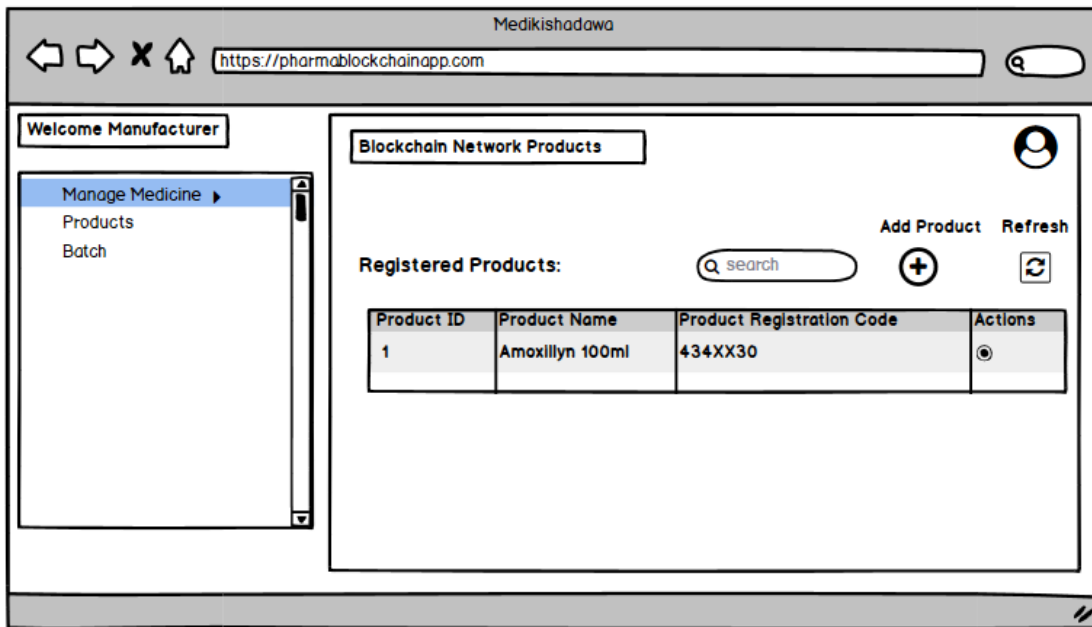
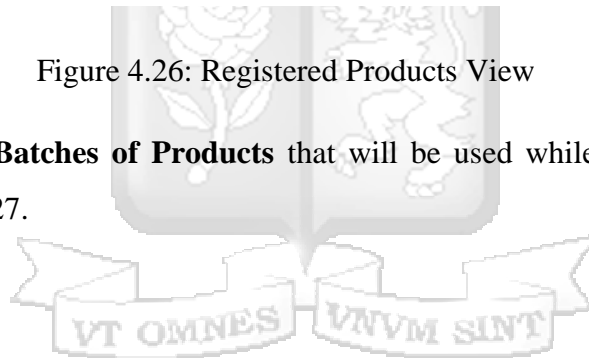


Figure 4.26: Registered Products View

The Manufacturer **creates Batches of Products** that will be used while transferring Products to Distributors. See Figure 4.27.



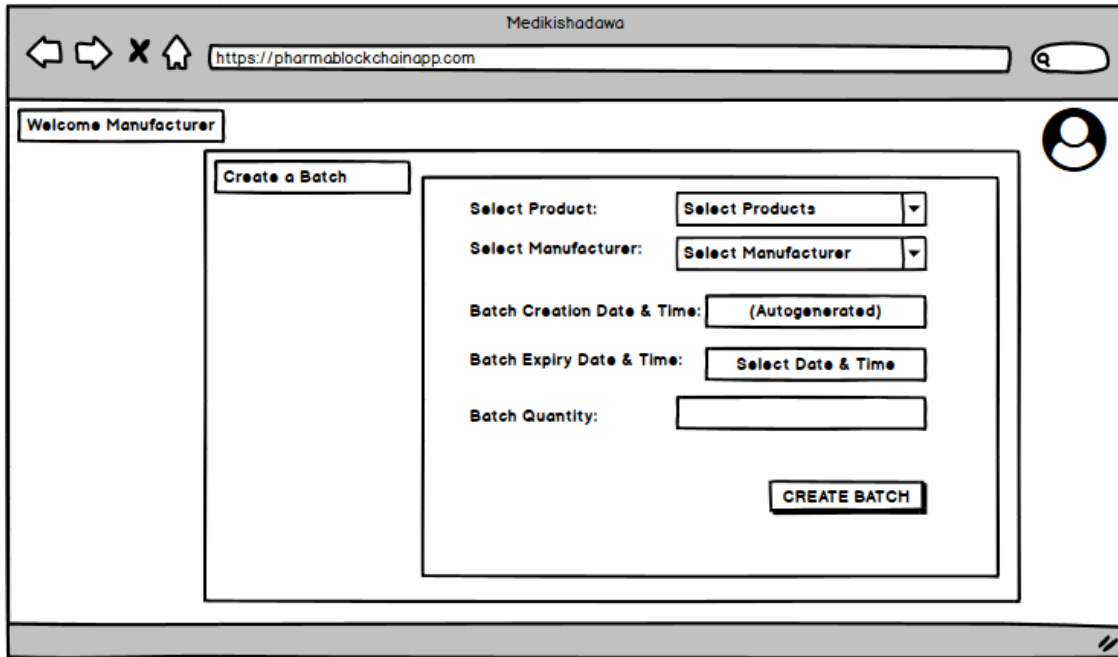


Figure 4.27: Batch Creation

They can also **view** the list of **Batch of Products** they have created. See Figure 4.28.

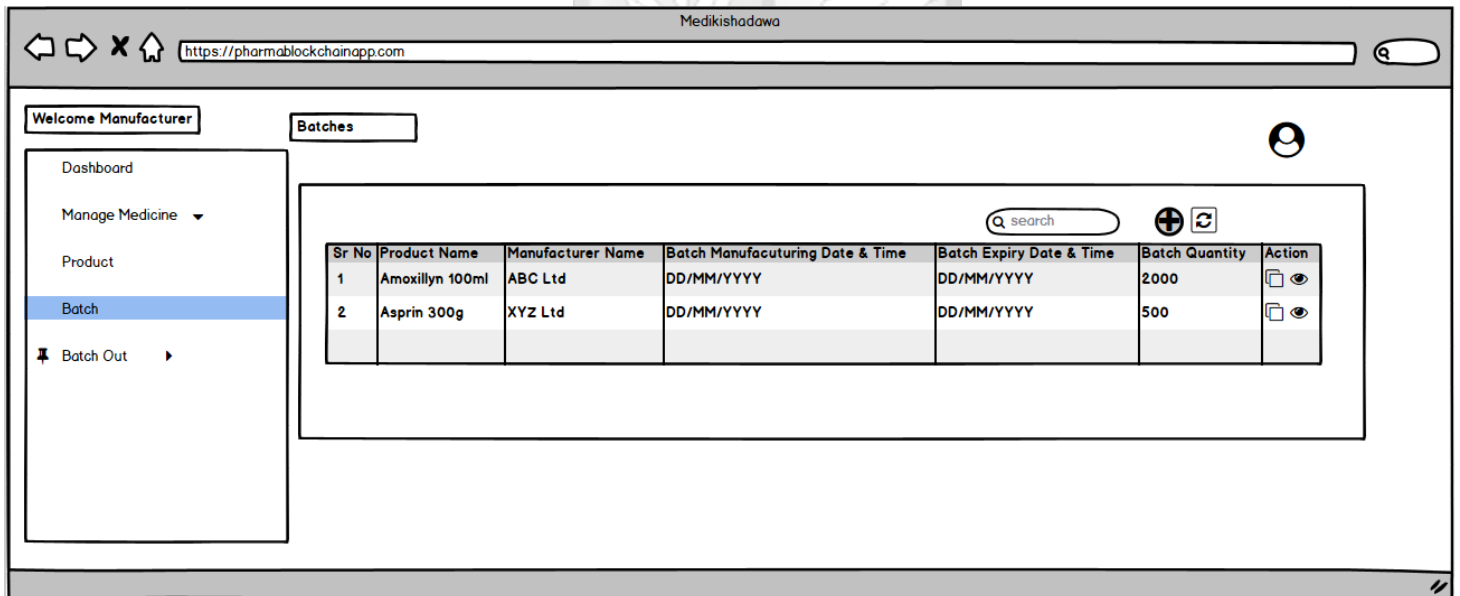


Figure 4.28: Registered Batches List- Manufacturer

To **Transfer Products** to a **Distributor**, the Manufacturer **selects the Batch** they intend to transfer from by clicking on the **Distribute Batch icon** in Figure 4.28 above. Thereafter, select the Distributor who will be assigned Products from the Batch selected. They insert the **quantity** of Products to send and click **Batch Out**. See Figure 4.29.

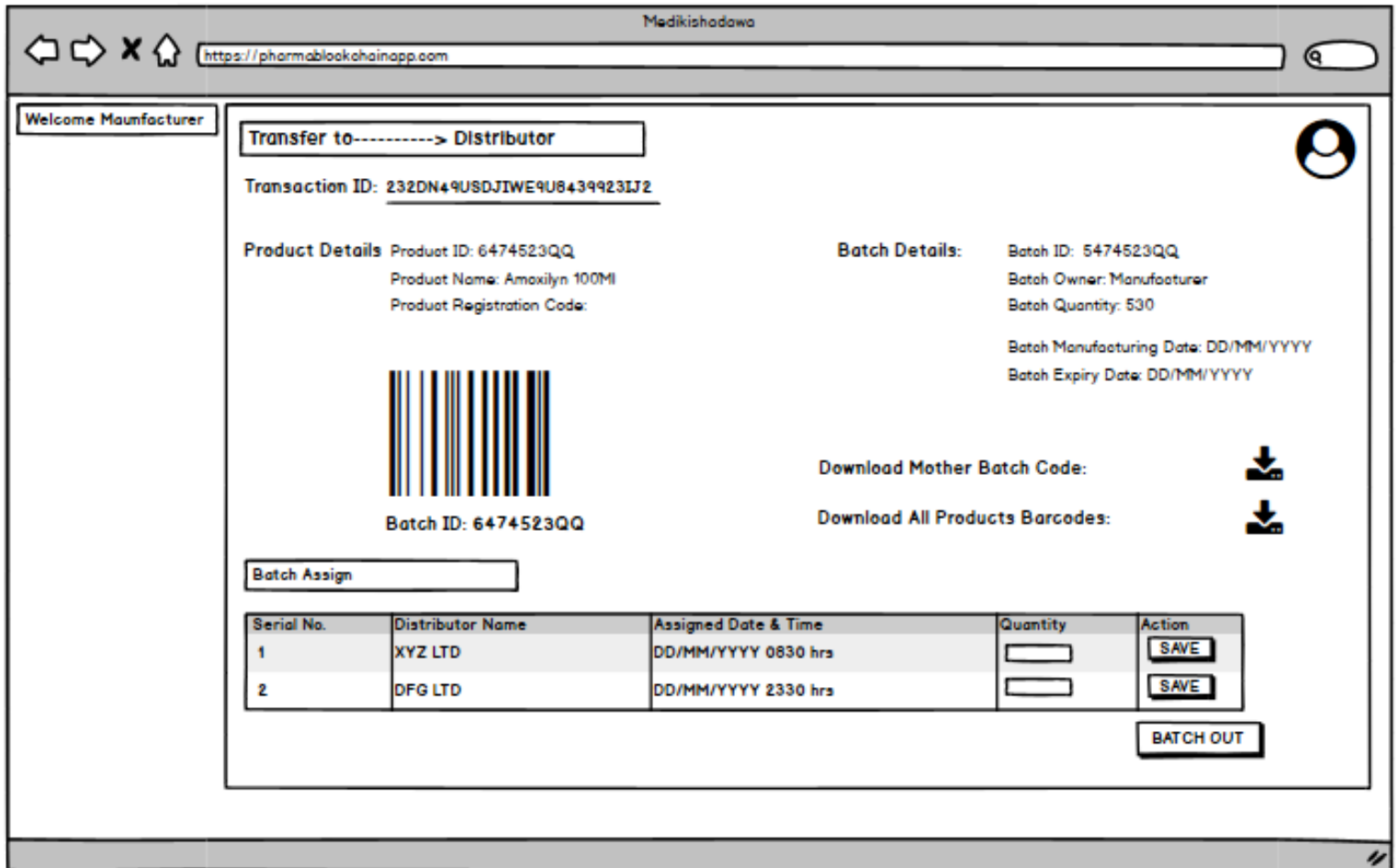


Figure 4.29: Manufacturer Product Transfer

DISTRIBUTOR

The Distributor can **view** the **Products** they have received from the Manufacturer. To further view the Batch details, they click the eye-like icon on the Batch record. See Figure 4.30.

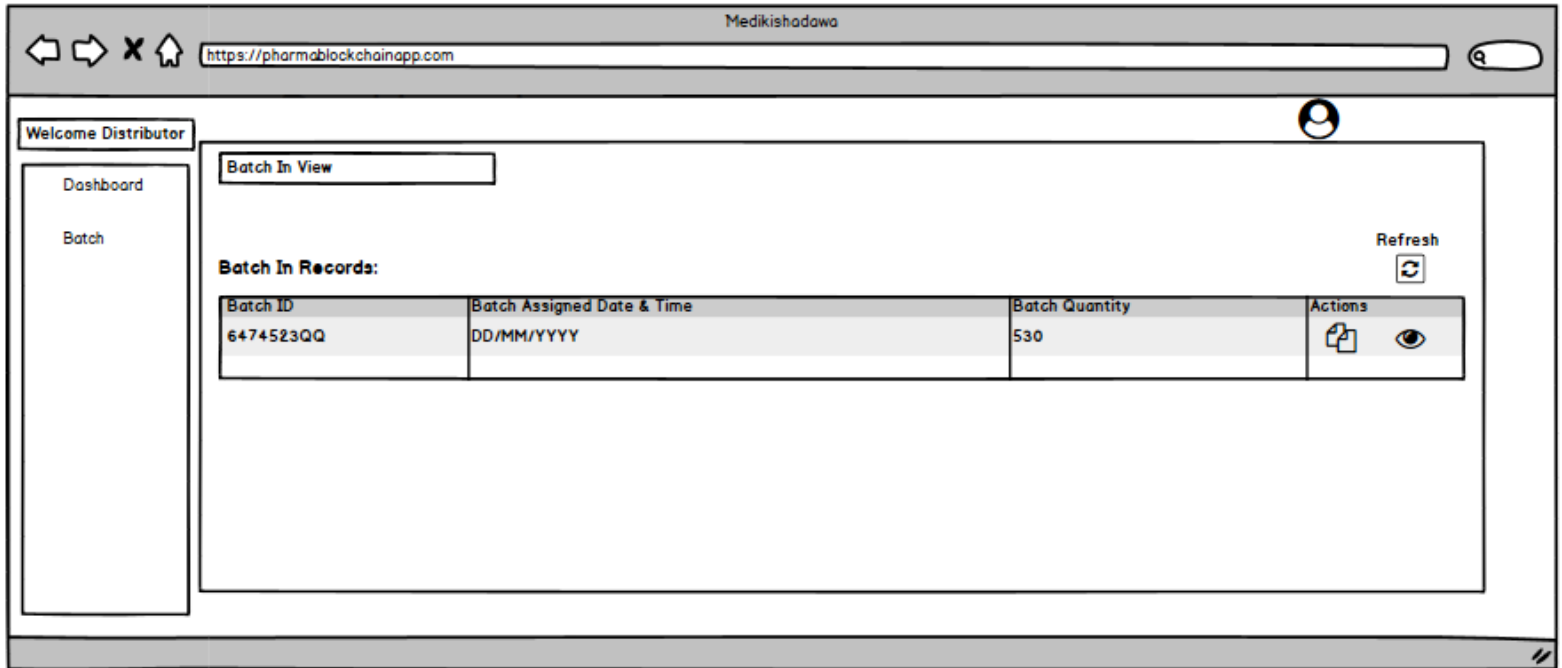
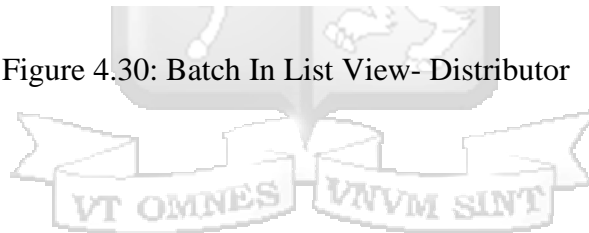


Figure 4.30: Batch In List View- Distributor



To **Transfer Products** to a **Retailer**, the Distributor selects the record they intend to transfer from by clicking on the **Distribute Batch icon** in figure 4.30 above. Thereafter, select the who will be assigned Products from the Batch selected. They insert the **quantity** of Products to send and click **Batch Out**. See Figure 4.31.

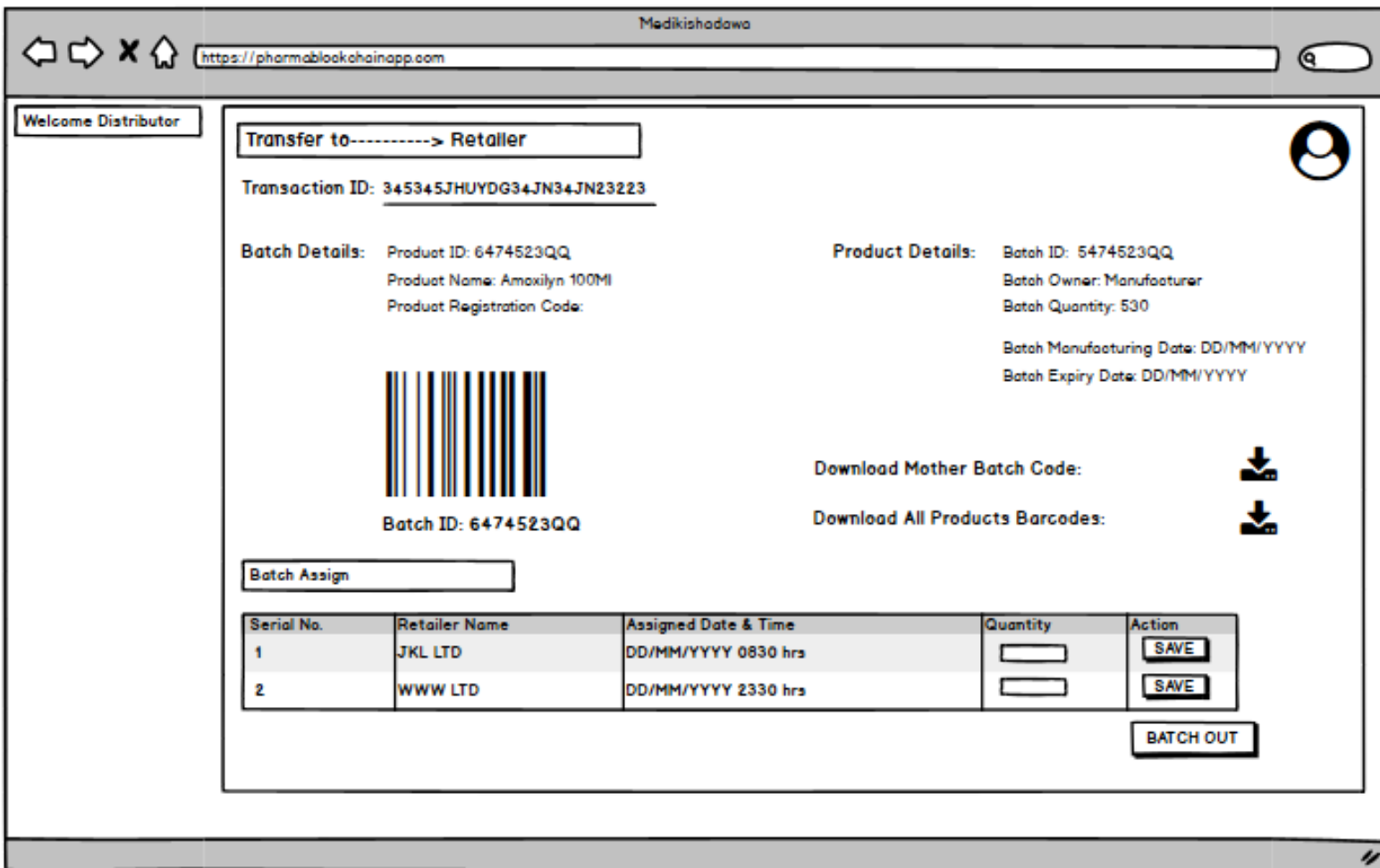


Figure 4.31: Distributor Product Transfer

The Retailer **sells** the Products to a Customer. Once the customer has purchased and wants to **verify the Source of the Drug**, the Retailer has to enable the scanning of the Bar Code by the customer by **marking the Product as sold** in the system. See Figure 4.32.

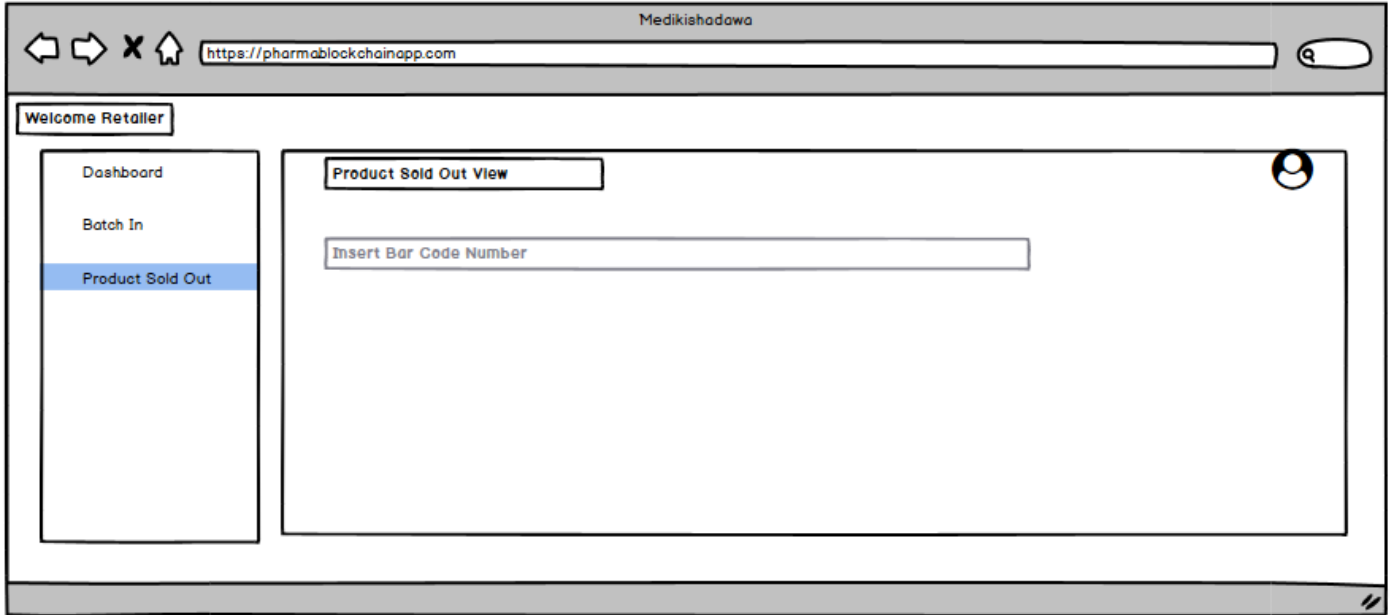


Figure 4.32: Retailer Product Sold Out View

Thereafter, the Customer will **Insert the Web Application URL** that will avail the **Bar Code Scanner** that allows them to see the Product Journey of the drug they have purchased. See Figure 4.33.

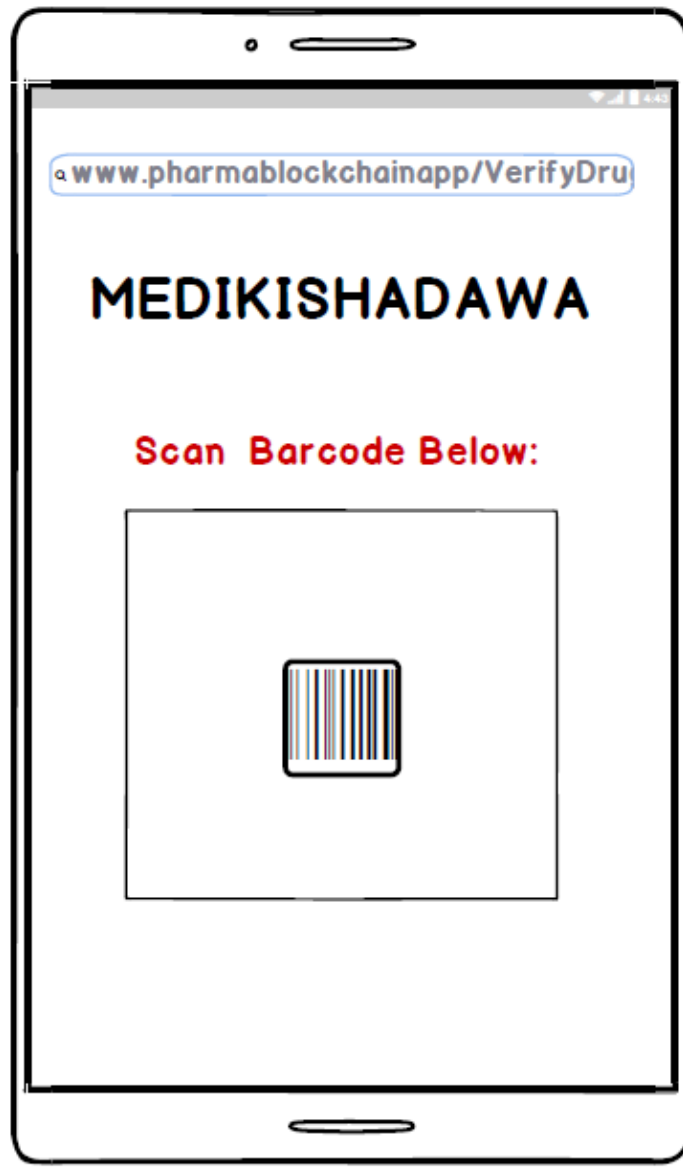


Figure 4.33: Customer Drug Source Verification View

The **Product Journey** of a drug **verified** by a Customer will be displayed as seen in Figure 4.34.



Figure 4.34: Product Journey View

In the unfortunate event a Customer purchases a **fake Product**, they can report using their side of the web application and avail further information about the incident. See Figure 4.35.

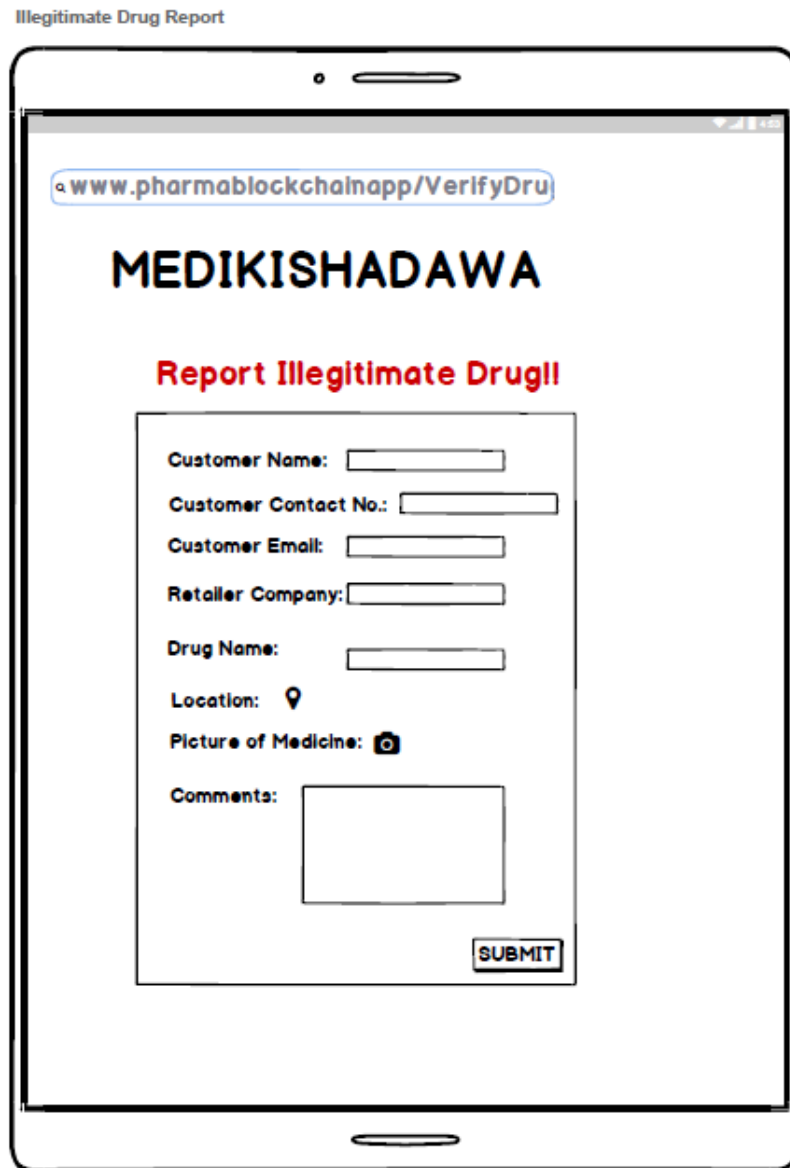


Figure 4.35: Illegitimate Drug Report View

CHAPTER 5: SYSTEM IMPLEMENTATION AND TESTING

5.1 Introduction

This chapter concentrates on application development environments, implementation, testing and validation. It also focuses on the implementation of various system requirements and functionalities needed by application to function.

5.2 Implementation Environment

The blockchain's hardware environment was set up and hosted on a Digital Ocean Cloud droplet of 4GB Ram, 80 GB HDD and 2 vCPU. The software environment of the blockchain was set up using the Hyperledger Composer Platform and Hyperledger Fabric Platforms, open source tools provided by IBM. The specifications for the Blockchain environment set up are Operating System Ubuntu Linux 18.04 LTS (64 Bit), Docker Engine: Version 18.06.1 -ce, Docker Compose: Version 1.13.0, Node 8.9, npm v5.x and VScode editor.

5.3 System Implementation

The solution implemented is a Web Application integrated with a blockchain known as *medikishadawa*.

5.3.1 Web Application - Blockchain Based Solution

The blockchain has five actors as mentioned in section 4.4.1; the Network Administrator, Manufacturer, Wholesaler, Retailer and Customer. The web application communicates with the blockchain through the REST APIs exposed. The APIs are used to query the blockchain for various actions.

Working of the Web Application

Network Users Login Page

All the Network Users log into the system using a **Username** and a **Password**. See Figure 5.1.

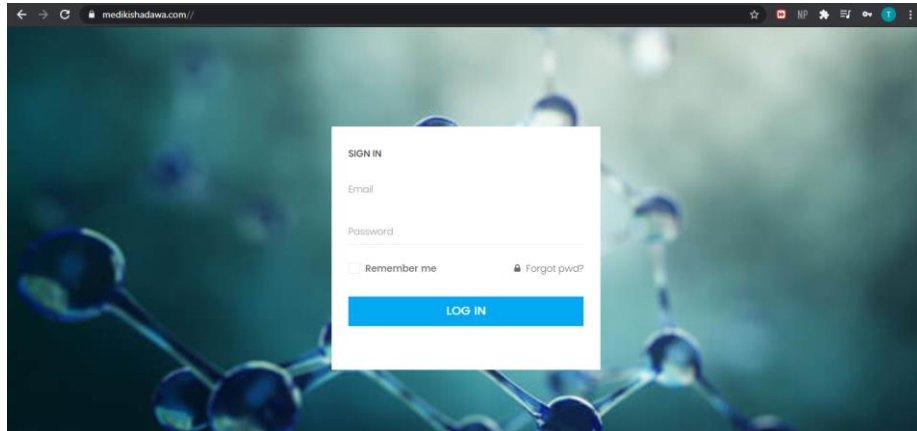


Figure 5.1: Solution's Log In Page

Network Administrator Dashboard

The Network Administrator is responsible for setting up the Blockchain Network. Once they Log In to the system, they will see their dashboard (Landing Page). See Figure 5.2.

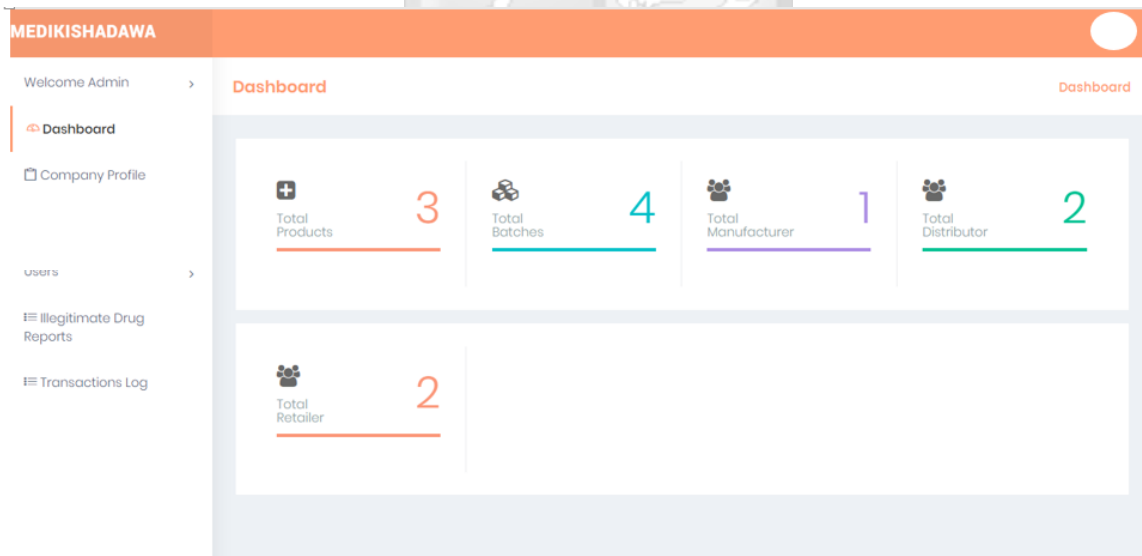


Figure 5.2: Network Admin Dashboard

Network Users Registration

The Network Administrator registers users to the Blockchain Network by Clicking on **Users**. The Roles for the Network will be displayed in a drop-Down Menu. See Figure 5.3.

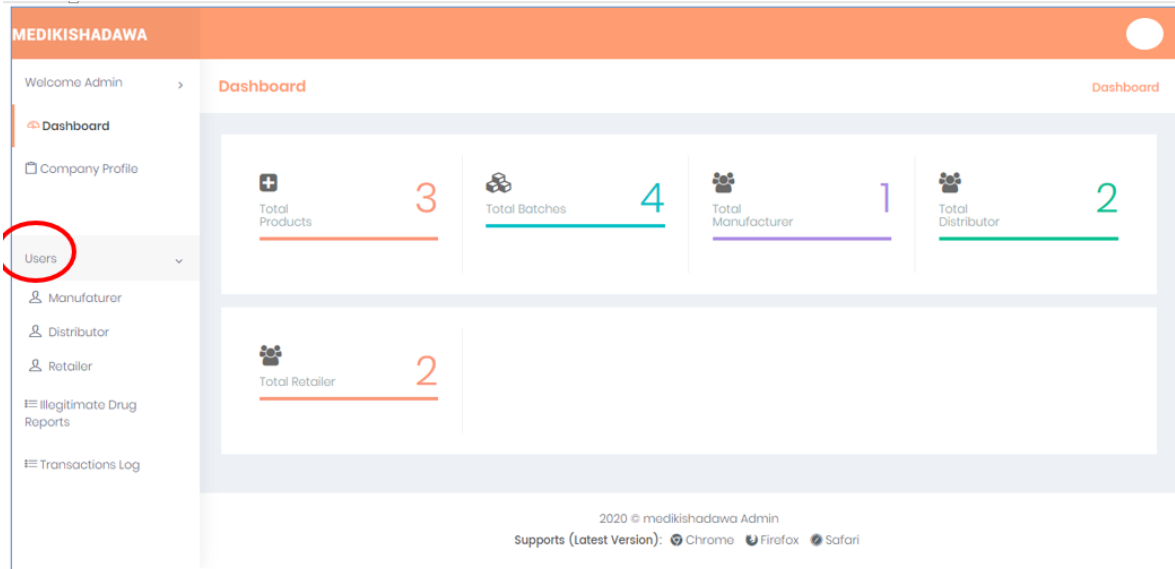


Figure 5.3: Network Users Registration Page

The Network Administrator will insert the Company's details in a registration form. See Figure 5.4.

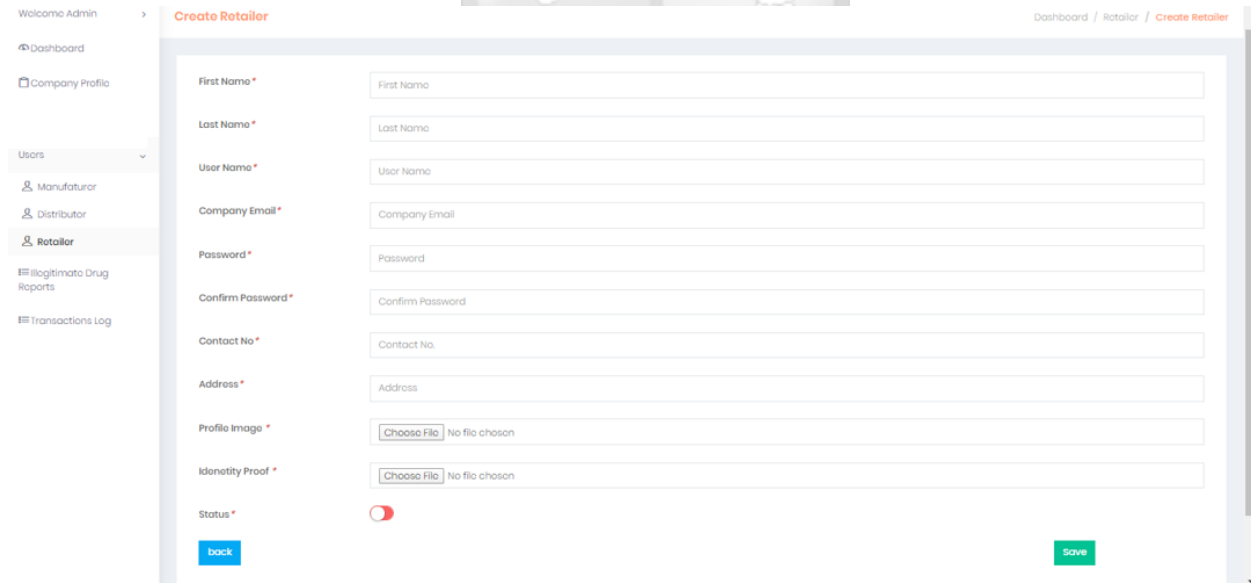
The image shows a web form titled 'Create Retailer'. The form is located in the main content area of the dashboard, with the breadcrumb 'Dashboard / Retailer / Create Retailer' visible at the top right. The form contains the following fields: 'First Name *', 'Last Name *', 'User Name *', 'Company Email *', 'Password *', 'Confirm Password *', 'Contact No *', 'Address *', 'Profile Image *' (with a 'Choose File' button and 'No file chosen' text), 'Identity Proof *' (with a 'Choose File' button and 'No file chosen' text), and 'Status *' (with a red toggle switch). At the bottom left of the form is a blue 'back' button, and at the bottom right is a green 'save' button.

Figure 5.4: Registration Form

Products Registration

Once a Manufacturer is added to the Blockchain Network, they can therefore add their Products to the Blockchain Network. This is done by registering the Product Name and other information on the Product Registration Portal. All Manufacturing Companies in the Blockchain Network have a right to add their Products to the Blockchain. See Figure 5.5.

The screenshot shows a web interface for 'MEDIKISHADAWA'. The top navigation bar is orange with the logo on the left and a user profile icon on the right. Below the bar, the page title 'Create Products' is displayed in orange. A breadcrumb trail shows 'Dashboard / Products / Create Products'. On the left, a sidebar menu lists: 'Welcome Manufacturer >', 'Dashboard', 'Company Profile', 'Manage Medicines >', 'Product' (highlighted), 'Batch', 'Illegitimate Drug Reports', and 'Transactions Log'. The main content area contains a form with three input fields: 'Product Name *' (with placeholder 'Product Name'), 'Product Registration Code *' (with value '978958'), and 'Product Information *' (with placeholder 'Product Information'). At the bottom of the form are two buttons: a blue 'back' button and a green 'Save' button.

Figure 5.5: Product Registration



Batch Creation

A Manufacturing Company also creates Product Batches to the Blockchain for ease of transfer to Distributors in the Blockchain Network. See Figure 5.6.

Welcome Manufacturer > > **Create Batch** Dashboard / Batches / Create Batch

PRODUCT DETAILS

Product ID	Product Name	Product Registration Code

Select Product*

Select Manufacturer*

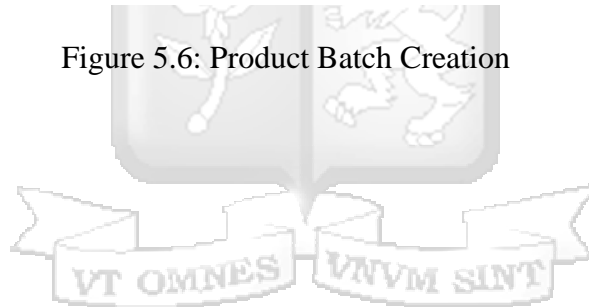
Batch Date*

Batch Expiry Date*

Batch Quantity*

[back](#) [Save](#)

Figure 5.6: Product Batch Creation



Transfer of Ownership: Manufacturer to Distributor

The Manufacturer transfer Products to a Distributor by Clicking on Batch icon. The list of Product Batches will appear on the right pane. He selects the Product by Brand Name and Batch. Thereafter, clicks Distribute Batch Icon. See Figure 5.7.

The screenshot displays the 'MEDIKISHADAWA' application interface. The top navigation bar includes 'Welcome Manufacturer' and 'Batches'. The left sidebar contains a menu with 'Batch' highlighted by a red circle. The main content area shows a table of batches with the following data:

Batch ID	Batch Manufacturing Date & Time	Batch Expiry Date & Time	Batch Quantity	Action
62229	Tue Apr 14 2020 15:54:00 GMT+0200 (Central European Summer Time)	Wed Apr 15 2020 15:54:00 GMT+0200 (Central European Summer Time)	100	[Batch Icon] [View Icon]
785022	Wed Apr 15 2020 08:33:00 GMT+0200 (Central European Summer Time)	Thu Apr 16 2020 08:34:00 GMT+0200 (Central European Summer Time)	60	[Batch Icon] [View Icon]
926224	Wed Apr 08 2020 18:27:00 GMT+0200 (Central European Summer Time)	Thu Apr 09 2020 18:28:00 GMT+0200 (Central European Summer Time)	20	[Batch Icon] [View Icon]
982601	Sun Apr 12 2020 19:25:00 GMT+0200 (Central European Summer Time)	Mon Apr 27 2020 20:25:00 GMT+0200 (Central European Summer Time)	500	[Batch Icon] [View Icon]

The interface also includes a search bar, a 'Show 10 entries' dropdown, and pagination controls (Previous, 1, Next). A red arrow points to the 'Batch' icon in the action column of the second row.

Figure 5.7: Product Transfer to Distributor

The Batch Details are displayed with the list of Distributors at the bottom of the window. The Manufacturer then selects the Distributor they want to transfer the Products to, inserts the Quantity and clicks Batch Out. See Figure 5.8.

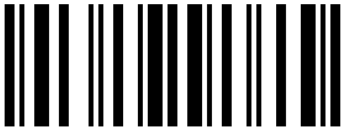
Distribute Batch Batch
Dashboard / Batches / Distribute Batch Batch

Transaction Id

#785022

Product Details

Product Id : 173619
 Product Name : Panadol Cold Cap 500g
 Product Registration Code : 40757



785022

Batch Details

Batch Id: 785022
Batch Owner: ABC Manufacture
 Batch Quantity : 60

Batch Manufacturing Date : 📅 Wed Apr 15 2020 08:33:00 GMT+0200 (Central European Summer Time)
 Batch Expiry Date : 📅 Thu Apr 16 2020 08:34:00 GMT+0200 (Central European Summer Time)

Download Mother Batch Barcode
Download Batch All Products Barcode

Batch Assign

#	Distributor Name	Assigned Date & Time	Quantity	Action
1	Willie Lewis	Wed Apr 15 2020 09:14:44 GMT+0200 (Central European Summer Time)	<input type="text" value="60"/>	<div style="text-align: right;"> Save batch out </div>
1	Walter Menard		<input type="text" value="0"/>	<div style="text-align: right;"> Save batch out </div>
Total Quantity			60	

2020 © medikishadawa Manufacturer

Supports (Latest Version): Chrome Firefox Safari

Figure 5.8: Batch Details and Transfer Page

Transfer of Ownership: Distributor to Retailer

The Distributor receives their Products in Batches from the Manufacturer and they can view them in a list. To transfer Products to a Retailer, the Distributor selects the Product Brand Name and the Batch they will transfer from and click the Distribute Icon. See Figure 5.9.

The screenshot displays the 'Batches' management page in the MEDIKISHADAWA system. The page header includes the company name 'MEDIKISHADAWA' and a user greeting 'Welcome Willie'. The main content area shows a table of batches with the following data:

Batch ID	Batch Assigned Date & Time	Batch Quantity	Action
62229	Tue Apr 14 2020 16:04:05 GMT+0200 (Central European Summer Time)	50	[Distribute] [View]
785022	Wed Apr 15 2020 09:00:38 GMT+0200 (Central European Summer Time)	60	[Distribute] [View]
926224	Wed Apr 08 2020 18:39:06 GMT+0200 (Central European Summer Time)	15	[Distribute] [View]
982601	Tue Apr 14 2020 14:45:20 GMT+0200 (Central European Summer Time)	500	[Distribute] [View]

The interface also features a search bar, a 'Show 10 entries' dropdown, and pagination controls (Previous, 1, Next). A red arrow points to the 'Distribute' icon in the Action column for the batch with ID 785022.


Figure 5.9: Product Transfer to Retailer

The Distributor therefore views the Batch Details and a List of Retailers in the Blockchain Network. The Distributor selects the Retailers they are transferring to the Products, inserts the size and click on Batch Out icon. See Figure 5.10.

Distribute Batch Batch Dashboard / Batches / Distribute Batch Batch

Product Details

Product Id : 173619
 Product Name : Panadol Cold Cap 500g
 Product Registration Code : 40757



785022

Batch Details

Batch Id: 785022
Batch Owner: ABC Manufacture
 Batch Quantity : 60

Batch Manufacturing Date : 📅 Wed Apr 15 2020 08:33:00 GMT+0200 (Central European Summer Time)
 Batch Expiry Date : 📅 Thu Apr 16 2020 08:34:00 GMT+0200 (Central European Summer Time)

Batch Assign to Retailer

#	Retailer Name	Assigned Date & Time	Quantity	Action
1	Darryl Ingram		<input type="text" value="0"/>	<input type="button" value="Save"/> <input type="button" value="Batch out"/>
1	Annex Retail Ltd		<input type="text" value="0"/>	<input type="button" value="Save"/> <input type="button" value="Batch out"/>
Total Quantity			0	

2020 © medikishadawa Distributor
 Supports (Latest Version): Chrome Firefox Safari

Figure 5.10: Batch Details and Transfer Page

The Retailer receives Product Batches from the Distributor. They can view the list of Product Batches as seen in Figure 5.11.

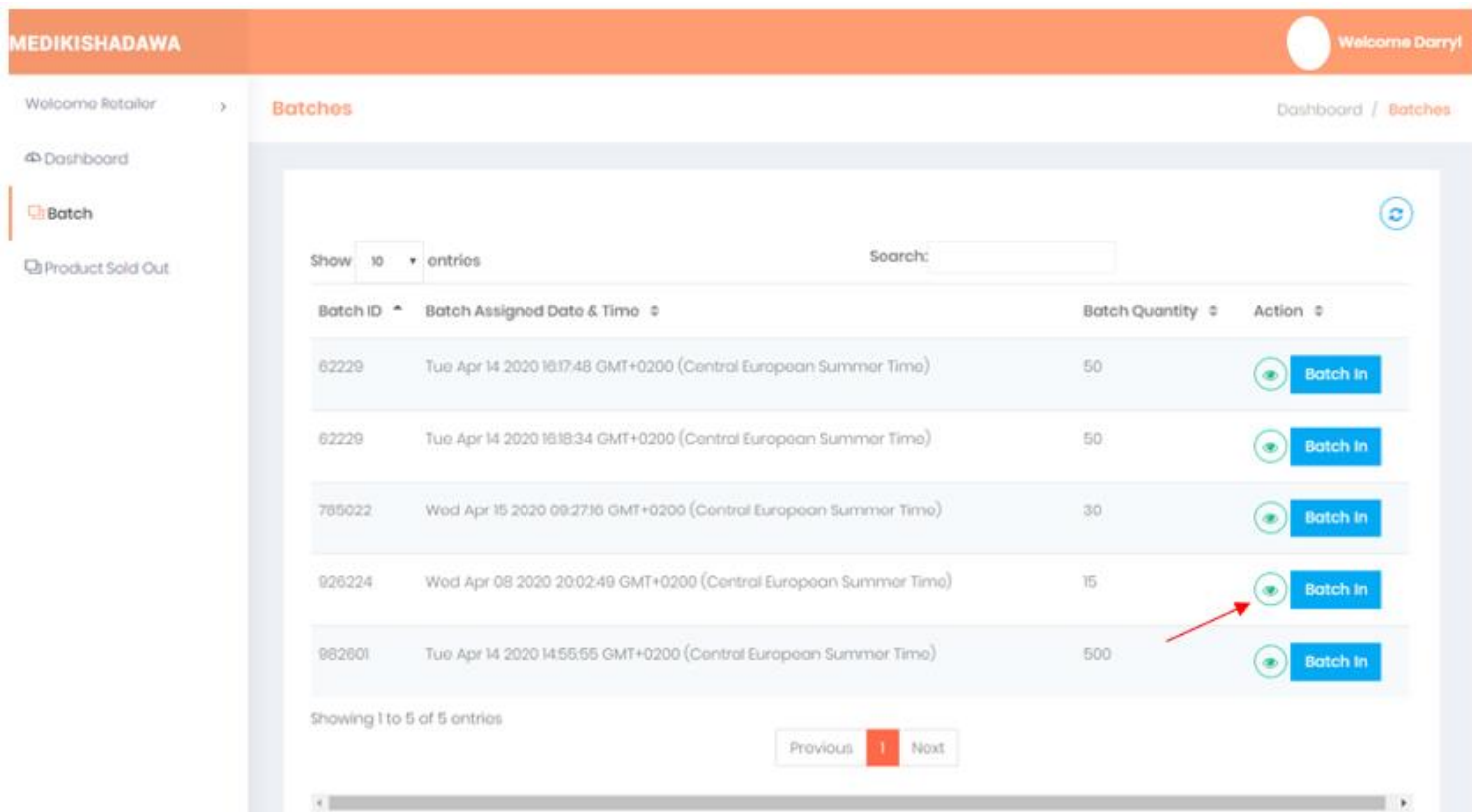


Figure 5.11: Retailer Product Batch List

By clicking the View icon. The Retailer can further look at the Products contained in a Batch. They are represented by their Unique Serial Numbers. See Figure 5.12.

Batch Products (15) ✕

926224 66663311	926224 8363583	926224 61353066	926224 60363656
926224 83516066	926224 32330330	926224 3611363	926224 16136611
926224 03383666	926224 66663211	926224 83236631	926224 66363125
926224 35131653	926224 6353620	926224 13683332	

Figure 5.12: Product Batch Details Items

Product Sold Out

The Retailer marks a Product as sold by scanning the Barcode on the Product's packet. The Retailer searches for the Barcode by inserting the number in the field shown in Figure 5.13 and marks it as sold by scanning the bar code that will appear. This functionality allows the Customer to scan the Barcode and view the Product Journey from their side of the application.

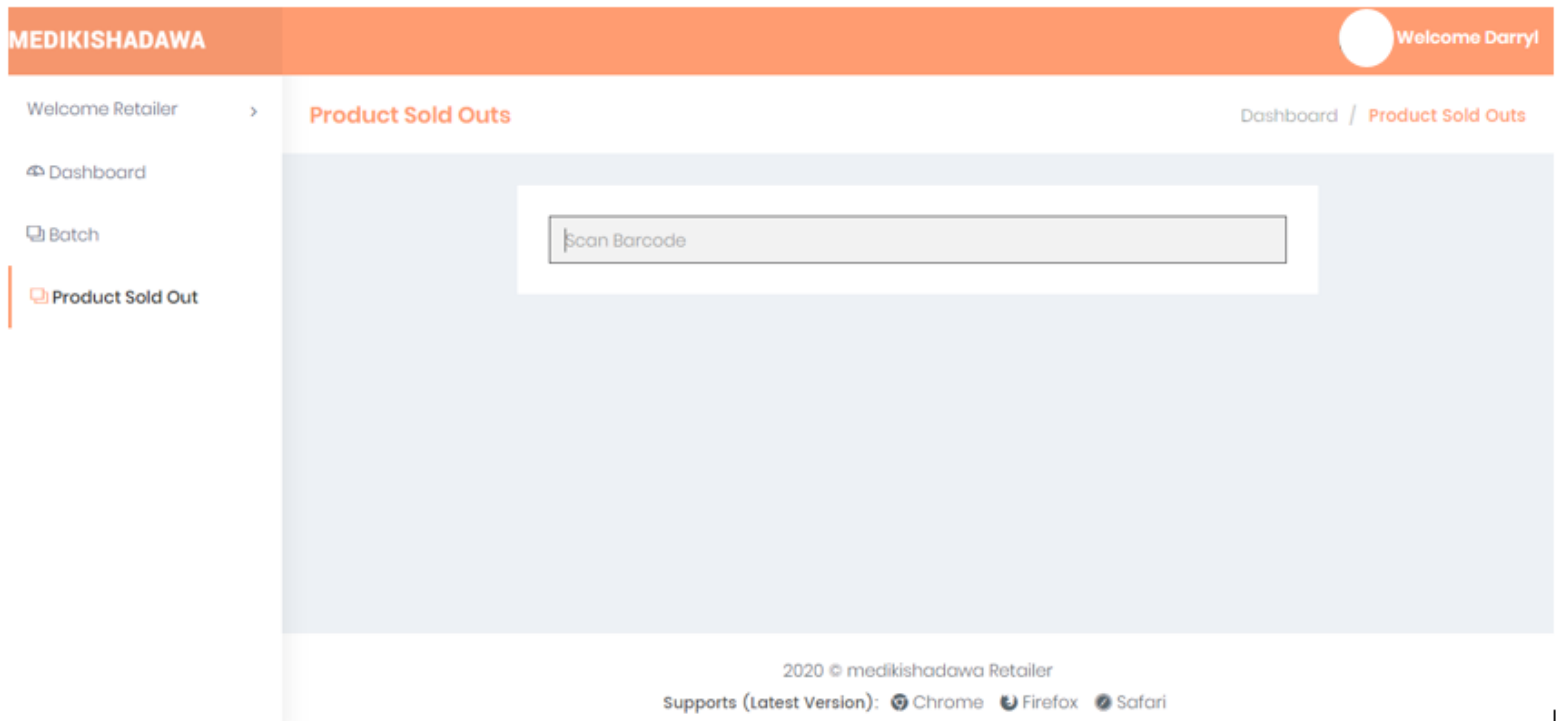


Figure 5.13: Retailer's Product Sold Out Page

Customer Product Source Verification

The Customer can view the Product Journey from their web application side. They insert the application's URL and can either scan the barcode or insert the barcode number in their portal. By clicking barcode, the barcode scanner will open and allow them to verify the drug source. See Figures 5.14 and 5.15.

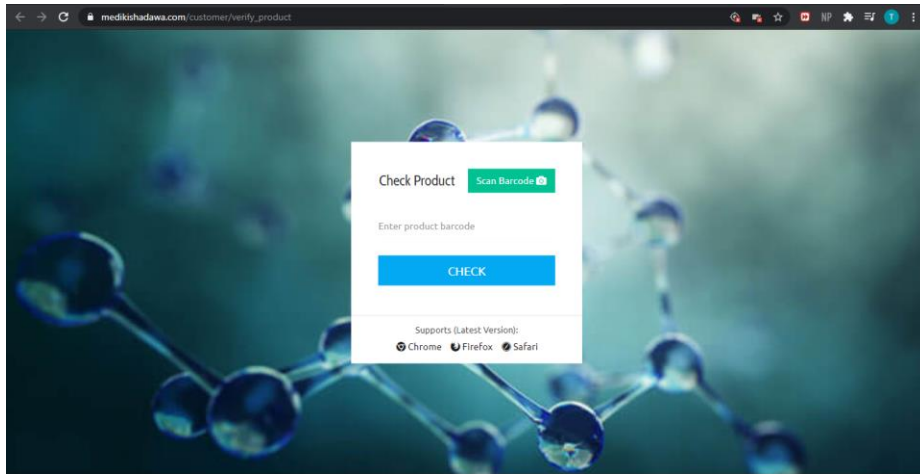


Figure 5.14: Customer's Barcode Scanning Page

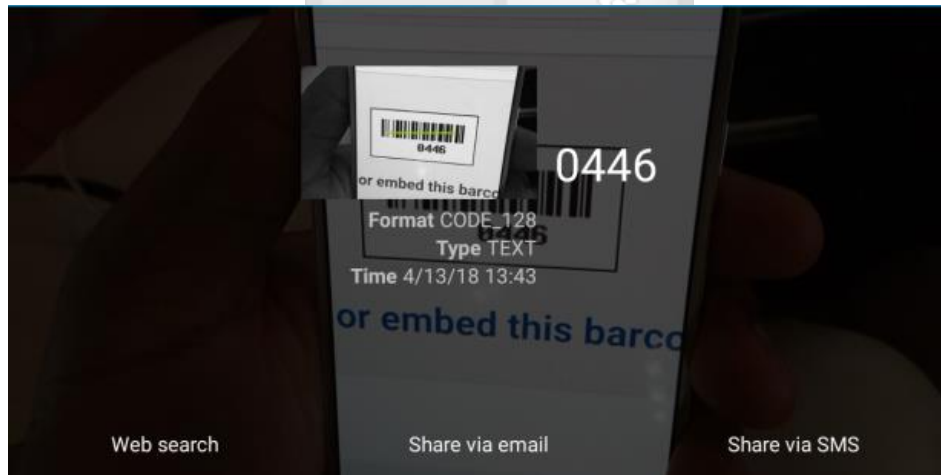
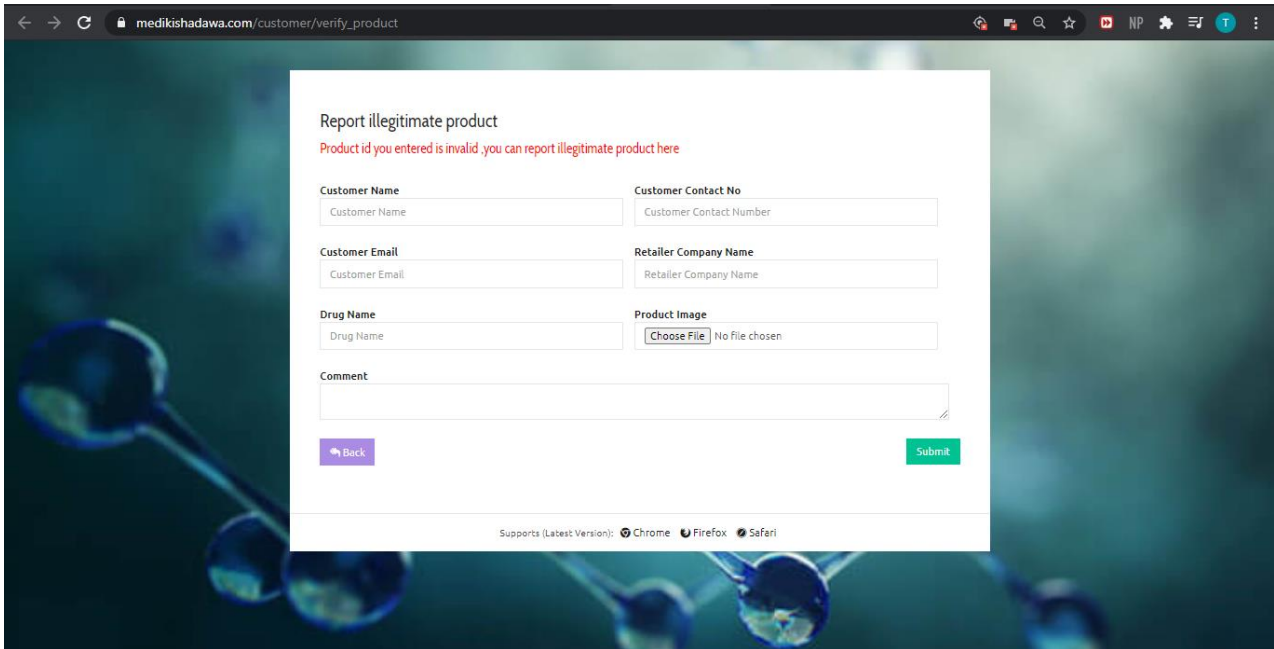


Figure 5.15: Scanning of the Barcode

Fake Drug Reporting

In the event of an illegitimate drug, the web application will not scan the barcode and will prompt the Customer to report the incident. See Figure 5.16.



The screenshot shows a web browser window with the URL `medikishadawa.com/customer/verify_product`. The page title is "Report illegitimate product". Below the title, a red error message states: "Product id you entered is invalid ,you can report illegitimate product here". The form contains several input fields:

- Customer Name:** Input field with placeholder "Customer Name".
- Customer Contact No:** Input field with placeholder "Customer Contact Number".
- Customer Email:** Input field with placeholder "Customer Email".
- Retailer Company Name:** Input field with placeholder "Retailer Company Name".
- Drug Name:** Input field with placeholder "Drug Name".
- Product Image:** File upload field with a "Choose File" button and the text "No File chosen".
- Comment:** A large text area for user input.

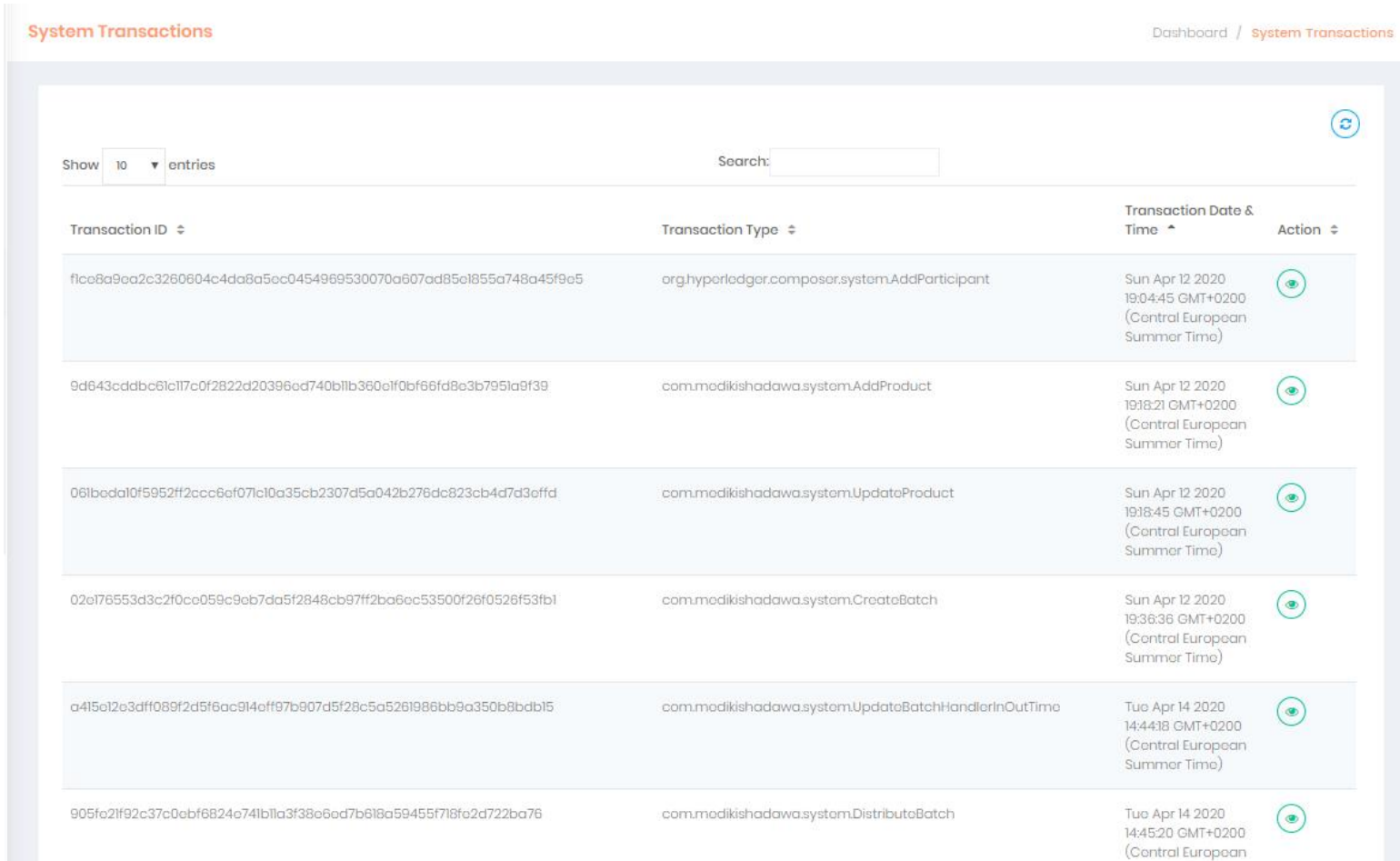
At the bottom of the form, there are two buttons: a purple "Back" button and a green "Submit" button. Below the form, a footer indicates browser support: "Supports (Latest Version): Chrome Firefox Safari".

Figure 5.16: Fake Drug Reporting Form



Blockchain Transactions Logs

The Network Administrator can view the transactions that occurred in the Blockchain invoked by the Network Users. In their portal, the click Blockchain Transaction Logs and the record of actions are displayed. See Figure 5.17.



The screenshot shows a web interface titled "System Transactions". At the top right, there is a breadcrumb "Dashboard / System Transactions". Below the title, there is a "Show 10 entries" dropdown and a search box. The main content is a table with the following columns: Transaction ID, Transaction Type, Transaction Date & Time, and Action. Each row represents a transaction with a unique ID, a type (e.g., "org.hyperledger.composer.system.AddParticipant"), a timestamp (e.g., "Sun Apr 12 2020 19:04:45 GMT+0200 (Central European Summer Time)"), and an action icon (a green circle with a white eye).

Transaction ID	Transaction Type	Transaction Date & Time	Action
f1ce8a9aa2c3260604c4da8a5ec0454969530070a607ad85e1855a748a45f9e5	org.hyperledger.composer.system.AddParticipant	Sun Apr 12 2020 19:04:45 GMT+0200 (Central European Summer Time)	
9d643cddbcb61c117c0f2822d20396ed740b11b360e1f0bf66fd8e3b7951a9f39	com.modikishadawa.system.AddProduct	Sun Apr 12 2020 19:18:21 GMT+0200 (Central European Summer Time)	
061bedal0f5952ff2ccc6ef071c10a35cb2307d5a042b276dc823cb4d7d3effd	com.modikishadawa.system.UpdateProduct	Sun Apr 12 2020 19:18:45 GMT+0200 (Central European Summer Time)	
02e176553d3c2f0ce059c9eb7da5f2848cb97ff2ba6ec53500f26f0526f53fb1	com.modikishadawa.system.CreateBatch	Sun Apr 12 2020 19:36:36 GMT+0200 (Central European Summer Time)	
a415e12e3dff089f2d5f6ac914eff97b907d5f28c5a5261986bb9a350b8bdb15	com.modikishadawa.system.UpdateBatchHandlerInOutTime	Tue Apr 14 2020 14:44:18 GMT+0200 (Central European Summer Time)	
905fe21f92c37c0ebf6824e741b11a3f38e6ed7b618a59455f718fe2d722ba76	com.modikishadawa.system.DistributeBatch	Tue Apr 14 2020 14:45:20 GMT+0200 (Central European Summer Time)	

Figure 5.17: Blockchain Network Transaction Logs

The Network Administrator can go further and view the Block Details of a Transaction by clicking on the view icon on the Transactions Log list. See Figure 5.18.

The screenshot shows a web interface with a breadcrumb trail: "Dashboard / System Transactions / View System Transaction". Below this, the "Transaction Id" is displayed as "#136e68a92a01fd93e16071f7a4cdab6afde79cc41d3eacbba447f2dd38d51ea8". The main section is titled "Transaction Details" and contains a JSON object representing the transaction record. The JSON includes fields for class, transactionId, transactionType, transactionInvoked, participantInvoking, identityUsed, eventsEmitted (a list of event objects), and transactionTimestamp.

```
{
  "$class": "org.hyperledger.composer.system.HistorianRecord",
  "transactionId": "136e68a92a01fd93e16071f7a4cdab6afde79cc41d3eacbba447f2dd38d51ea8",
  "transactionType": "com.medikishadawa.system.AddProduct",
  "transactionInvoked": "resource:com.medikishadawa.system.AddProduct#136e68a92a01fd93e16071f7a4cdab6afde79cc41d3eacbba447f2dd38d51ea8",
  "participantInvoking": "resource:org.hyperledger.composer.system.NetworkAdmin#admin",
  "identityUsed": "resource:org.hyperledger.composer.system.Identity#c3e0e0b9368bb70129772570f19663d98400d0788e69d0c74c75e412ded92fc",
  "eventsEmitted": [
    {
      "$class": "com.medikishadawa.system.ProductAdded",
      "creator": "ADMIN",
      "productName": "Amoxicillin",
      "productRegcode": "541358",
      "productInformation": "5 mg",
      "addedDateTime": "2020-04-08T16:06:36.412Z",
      "product": "resource:com.medikishadawa.system.ProductAsset#109893",
      "eventId": "136e68a92a01fd93e16071f7a4cdab6afde79cc41d3eacbba447f2dd38d51ea8#0",
      "timestamp": "2020-04-08T16:06:35.973Z"
    }
  ],
  "transactionTimestamp": "2020-04-08T16:06:35.973Z"
}
```

Figure 5.18: Transaction Details (Block)

All the transactions invoked by the Network Users are ordered into Blocks to form the Blockchain. The peer nodes that represent the Network Users in the Blockchain maintain the consistency of their ledgers and update the current state databases. In the event of a security breach in the Blockchain, for example, a peer tampers with its ledger, the other peer nodes in the Blockchain Network will not accept the updates from that peer since they had verified and committed blocks from the Orderer Node. This makes the Blockchain model secure for storing transaction details for the Pharmaceutical Supply Chain.

5.4 Testing

This section illustrates how the testing was done for both the web application. The test focused on four main areas, functionality tests, usability tests and compatibility tests.

5.4.1 Functional Testing

This test was carried out to ascertain if the system design and implementation was a success or not. Assorted use cases of the solution were tested and the results were either passed as success or fail. Herein are a sample of the various test cases performed and their outcomes.

Test Identifier 1: Register a Network User to the Blockchain

Table 5.1 displays results of test identifier whose main task was to register Network Users to the Blockchain. The observed and expected behaviour were consistent. Test Identifier 1 passed the trial and the outcome was deemed successful.

Table 5.1: Registering a Network User

Utilized Use Case	Assigning a Trader Unit of Medicine
Test Parameters	Register a Network User to the Blockchain
Expected Behaviour	Successful registration of the Network User.
Observed Behaviour	Network User registration was successful.
Test Outcome	Pass

Test Identifier 2: Registering a Product in the Blockchain

Table 5.2 displays results of test identifier whose main task was to register a Product in the blockchain. The observed and expected behavior were consistent. Test Identifier two passed the trial and the outcome was deemed successful.

Table 5.2: Registering a Product in the Blockchain

Utilized Use Case	Scanning a Unit of Medicine
Test Parameters	Register a Product in the Blockchain
Expected Behaviour	Successful display of Registered Product
Observed Behaviour	Successful displayed Registered Product

Test Outcome	Pass
--------------	------

5.4.2 Compatibility Testing

This test was undertaken to ensure that both the blockchain web application was compatible with existing platforms. The solutions web application was tested on existing Android and iOS Version platforms and web browsers.

Android Platform Testing

Table 5.3 shows the tests conducted on predefined and locally available Android platforms.

Table 5.3: Android Platform Versions Compatibility

Android Platform	Compatible
Android 9.0	Yes
Android 8.0 and 8.1	Yes
Android 7.0 and 7.1	Yes
Android 6.0 and 6.0.1	Yes
Android 5.0 and 5.11	Yes
Android 4.14	Yes

iOS Platform Testing

Table 5.4 shows the tests conducted on predefined and locally available iOS platforms.

Table 5.4: iOS Platform Versions Compatibility

iOS Platform	Compatible
iOS 13.0	Yes
iOS 12.0	Yes
iOS 11.0	Yes
iOS 10.0	Yes
iOS 9.0	Yes
iOS 8.0	Yes

Web Browser Testing

Table 5.5 shows the testing done on available and commonly used web browsers.

Table 5.5: Web Browsers Compatibility

Web Browser	Compatibility
Safri - iOS	Yes
Mozilla Firefox – Version 4 and above	Yes
Chrome – all versions	Yes

5.4.3 User Testing

The potential end users of the solution thus the manufacturer, wholesaler and retailer were involved in the usability test phase. This select group represented the target population who will use the solution. 59 respondents managed to create time to be a part of the testing exercise.

Acceptance

User acceptance test was used as a measure of the solution's success. 72.9% of the users who accepted to participate accepted the solution for use in a manufacturer's drug supply chain. 27.1% did not accept the solution meaning there were some features about the solution that they wished to be done differently. Therefore, since a majority of the respondents accepted the solution, this test was deemed successful. Figure 5.19 illustrates the results.

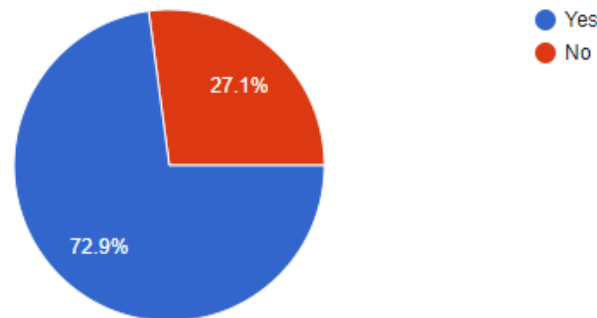


Figure 5.19: User Test: Acceptability Results

User Friendliness

The ability of the solution to easily be learned and used easily was tested by the potential users. 71.2% of the potential users indicated that the solution was easy to learn and use, 18.6% stated it was fair and 10.2% cited it bad. Figure 5.20 illustrates the findings.

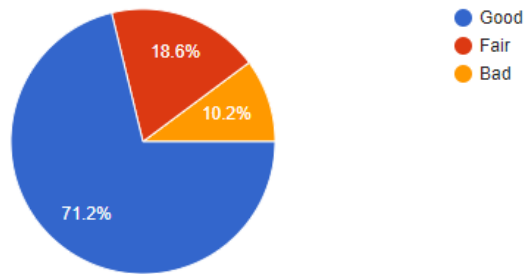


Figure 5.20: User Test: User Friendliness Report

User Interface Aesthetics

The look and feel of the solution to the users was tested in this phase. 67.85% of the users stated the solution was attractive whereas 22% cited it was fairly attractive. Lastly, 10.2% mention it was not attractive at all. Figure 5.21 illustrates the results.

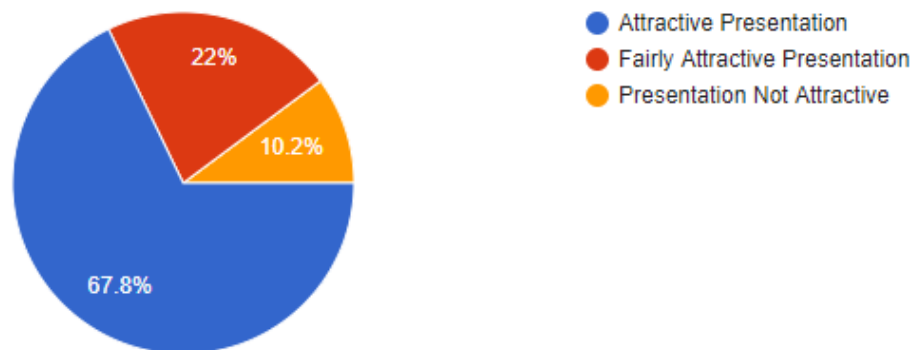


Figure 5.21: User Test: User Interface Aesthetics Results

Functionality

The system functionalities were tested by the potential users of the solution against the user specifications. 72.9% of them pointed out that they were very satisfied with the solutions functionality. This means that the developer achieved most user requirements specification and functionalities. 27.1% indicated that they were not satisfied with the solution's functionality meaning that some of the user's requirements were not met entirely, propelling the developer to refine the system. Figure 5.22 illustrates the report.

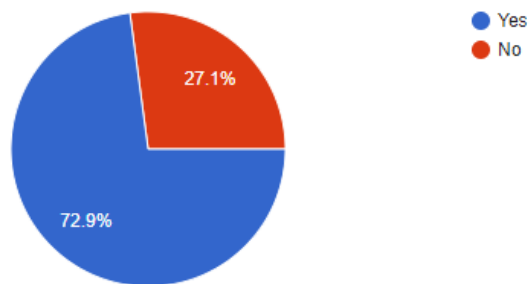


Figure 5.22: User Test: Functionality of the System

5.5 Validation

This exercise was done through distributing validation questionnaires to a willing group of potential users that included manufacturers and retailer. The response rate for the validation exercise was 71. The respondents were requested to cite their opinions on the systems validity based on the following questions:

5.5.1 Fake Drugs Identification

The dissertation asked the respondents if fake drugs could be identified using the solution. 67.6% cited yes whereas 32.4% stated it would not. The latter generally mentioned the incorporation of lab tests and scientific knowledge to qualify a drug as fake. Figure 5.23 illustrates the findings.

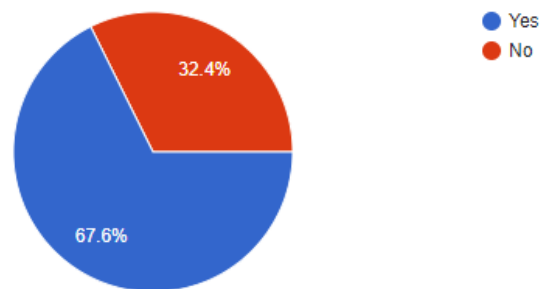


Figure 5.23: Results on Solution Identifying Fake Drugs

5.5.2 Satisfaction with Drug Traceability and Counterfeit Reporting

The respondents were asked if they were satisfied with the solution as far as drug traceability and counterfeit reporting is concerned. 63.2% said they were satisfied with the drug traceability solution whereas 36.8% mentioned they were not. The latter would have preferred the solution being developed differently. Figure 5.24 illustrates the results.

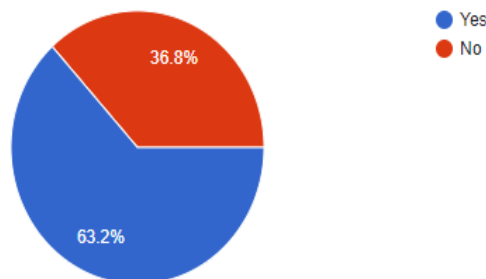


Figure 5.24: Results on Solution Tracing Drugs in the supply chain

5.5.3 Application's Functionalities Success in Solve the Counterfeiting Problem

The respondents were requested to cite if the solution's functionalities solve the counterfeiting problem faced in the drug manufacturing supply chain. 66.2% said Yes whereas 33.8% said No. This indicated that the solution's functionalities solved the drug counterfeiting problem. Figure 5.25 illustrates the responses.

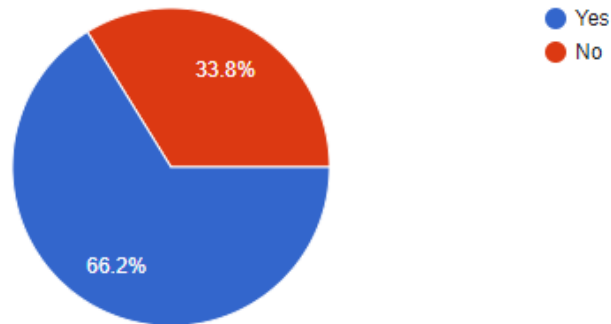


Figure 5.25: Solution's Satisfactory Report

5.6 Summary

The information used in the implementation stage was provided by system requirements formulated in the requirements gathering and analysis stage in chapter 3 above. The study also considered the research objectives and questions in order to ensure that the solution implemented and attained the user requirements provided by the users. The overall dissertation adhered to all the research objectives. The research was completed in time for ample testing and user feedback.

CHAPTER 6: DISCUSSIONS

6.1 Introduction

The motivation of the dissertation was to review how the Kenyan Pharmaceutical Industry drug supply chain works, understand the drug counterfeiting issue, find out the technologies used to tackle counterfeiting problem, discover whether blockchain technology can address the gap that is not catered for by the current anti-counterfeit drug detection solution in the market, design, test and implement a blockchain enabled drug traceability solution and finally to validate if the solution developed mitigated the gap. The research findings helped to identify the working of the pharmaceutical industry together with the technologies used to tackle drug counterfeiting in the market. Furthermore, the findings helped the dissertation to settle on the blockchain technology as a platform to develop a solution for the gap identified. This chapter will describe the findings, achievements, how the objectives were attained, highlight the advantages of the solution in tackling drug counterfeiting in comparison to the systems in place and lastly, portray the limitations of the solution.

6.2 Findings and Achievements

An assessment of the literature review reflects that anti-counterfeit solutions used to combat drug counterfeiting include the use of pedigree, holograms, mass serialization and mini labs. The non-blockchain solutions thus pedigree, holograms, mass serialization and mini labs do not offer a transparent way of conducting open transactions. Therefore, the industry actors in a drug supply chain (manufacturers, distributors and retailers) do not have a common platform to keep track of the transactions that occur consistently. This exacts that the drug supply chain actors will be unaware of where their Products came from and who is handling them down the chain. This is an issue since there is no accountability on the drugs traces and tracks. Consequentially, the end consumer will not have a way of verifying the source of the drugs they are purchasing.

Secondly, the dissertation also found out the available blockchain chain enabled drug traceability solutions available in the market. These included: Mediledger, SophiaTx, BlockRx Pharma Ecosystem, Modium.io System and BlockVerify. The study also used a blockchain platform to develop the drug traceability solution however; it incorporated a mobile application running on an Android platform. The Blockchain enabled drug traceability solutions mentioned above have one

limitation; they lack a functionality that fosters the security of the bar code scanning feature. The study recommends printing of the bar codes with protective papers such as infrared thermal paper or copper paper labels. These are protective papers, custom made for manufacturing companies to avoid duplication of the bar codes by dubious drug suppliers. In an effort to enhance their solution's security, the study developed a mark off functionality whereby the Retailer will mark the Product as sold from their application's side in order to allow their customer to view the Product's journey down the supply chain. In the event of a duplicate bar code, the Customer will not be able to scan the barcode to unveil the Product's journey therefore, being prompted to report the incident.

6.3 Discussion of Research Objectives

This section will highlight how the research objectives were achieved with regards to the blockchain enabled drug traceability solution developed. The dissertation identifies the existing anti-counterfeit drug traceability solutions in the market both blockchain enabled and non-blockchain. This knowledge was derived from research based on journals, website, e-books, books, user feedback and the existing solutions limitations. A blockchain web-based application was designed and developed with an adopted technique from the literature review and system analysis sections. The guidelines in the development were the research objectives.

The first objective in section 1.5 was to find out how the current Kenya pharmaceutical drug supply chain industry works and understand the drug counterfeiting issue. The study identified the workflow of a typical drug supply chain and the actors involved in it. The actors consisted of the Manufacturer, Distributors, Retailers and Customers. Most drugs originated from the manufacturer and the drug movement down the chain was to the Distributor then the retailer and lastly to customer.

The second objective was to find out the technologies used to tackle drug counterfeiting problem. Section 2.4 points out the drug anti-counterfeit technologies currently being used in the market. Further section 2.4 explains their working and main features. Section 2.8 focuses on the current blockchain enabled drug traceability solutions in the market and their working.

The third objective sought to find out whether blockchain technology can address the gaps that are not catered for by the current anti-counterfeit drug detection technology solutions in the market. In section 2.10.2 illustrated the benefits of using blockchain technology in the pharmaceutical drug supply chain. Furthermore; section 2.10.1 tackled the gap that other anti-counterfeit drug detection

technologies could not close. Section 5.5 the validation of the solution is a testament from the user response on the working of the blockchain technology in mitigating the counterfeit problem.

The fourth objective was to design, test and implement a blockchain enabled drug traceability solution. This was covered in chapter 4 (System Design) and chapter 5 (System Implementation and Testing). This objective was achieved through designing the a blockchain based web application. The web application was developed using HTML and Java Script Languages and the Blockchain platform was developed using IBM's Hyperledger Composer and Hyperledger Fabric platforms.

The fifth objective was to validate that the blockchain enabled drug traceability solution will provide a solution to the counterfeiting problem in the Kenya pharmaceutical drug supply chain. All tests were performed in section 5.4, with functionality test measuring if the system worked as it should. The compatibility test measured the solution's rapport with various Android and iOS versions. The blockchain web application also under went testing with the different web browsers. Lastly, user testing was done whereby the solution's user friendliness, acceptability and aesthetics were put to test. The solution passed all tests and met the requirements. Section 5.5 addressed the validity of the system with the end users being requested to cite the ability of the solution to trace drugs down the drug supply chain. Moreover, the solution's functionalities ability to solve drug counterfeiting problems.

6.4 Advantages of the Solution as Compared to the Current System

The solution has quite a number of advantages as compared to the current system. To begin with, there is a permanent record of transactions done in the blockchain. Immutability of data is a key feature of this solution. This encourages transparency and accountability. Secondly, integration of the bar code security feature. Third, it is a convenient tool for manufacturers, so as to protect their Products in their drug supply chain. If every manufacturer had a blockchain enabled drug traceability solution, follow up will be easy and counterfeit cases will be well tracked.

6.5 Limitations of the Solution

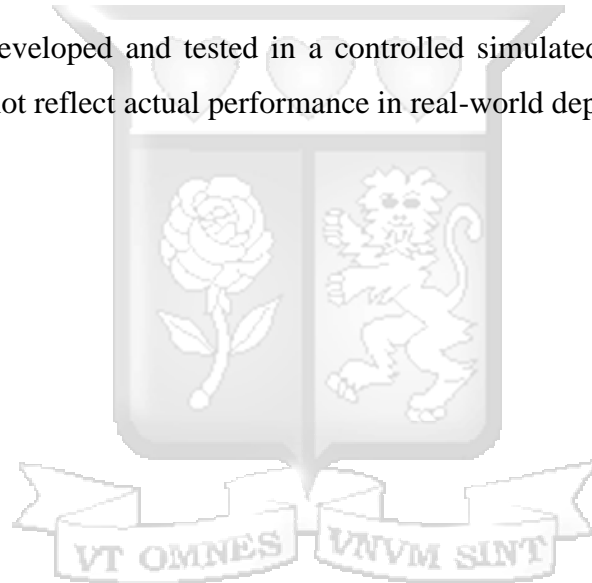
The solution has some limitations. First, the use of blockchain technology in the pharmaceutical supply chain industry can be met by regulatory uncertainty challenge. There are no regulations outlined on the use of a blockchain technology therefore, it is a venture that may kick off well but eventually gain some legal and political challenges.

Secondly, blockchain being a new technology, the industry is not fully ripe for it. Kenya is at the knowledge quest stage and many industry players are getting to learn more about blockchain technology. It is safe to say adoption of the solution will be slow.

Third, lack of industry acceptance. As we know, the drug supply chain industry is flooded with rogue moguls. The introduction of the solution may mean lack of business for some individuals. Therefore, such individuals may use their position of influence to frustrate the acceptance of the solution.

The proposed system is able to detect only the movement of drugs, which follow an official supply chains, which are known to the regulatory agency. It cannot track counterfeit drugs that are distributed along routes outside the official chains.

Lastly, the solution was developed and tested in a controlled simulated network. Therefore, the results of the studies may not reflect actual performance in real-world deployment.



CHAPTER 7: CONCLUSIONS

7.1 Conclusions

The Kenyan pharmaceutical drug supply chain working and challenges were reviewed in the research with major focus on drug counterfeiting. The dissertation sought to mitigate the drug counterfeiting menace crippling the industry. Literature of various drug anti-counterfeiting technologies in use in the market was studied. Some blockchain enabled drug traceability solutions were also reviewed and the study sought to pin point the gap left by the solutions. The study found out that the solutions did not have a feature that gives the different actors who handled the drug down the supply chain. The researcher also collected data from respondents both in the drug manufacturing industry, distributors and retailers. The data helped the study to identify the traffic in regular retailer stores, the possibility of handling fake drugs and the reporting mechanisms in place to channel the complaints. Most respondents cited that they handle a large consumer base in a day meaning they have huge storage of drugs. This indicated active reception of drugs from suppliers. The findings also pointed out that the retailers have ever handled fake drugs and they had simple methods to report such incidents.

As a result of the findings discussed above, a blockchain enabled drug traceability solution was developed. The solution consisted of a Blockchain based web application running on the IBM Hyperledger Composer and Fabric platforms. The key features of the solution were the ability to store immutable data, trace the source of a drug and ability to detect and report the drug counterfeit incidences.

According to the statistics from the user and validation tests, it is in order to say that the solution satisfies the user and functional requirements. Therefore, the research objectives were attained since the acceptability rating amongst the target users was positive.

7.2 Recommendations

This system can be adopted on a large-scale network if stakeholders in the Kenyan Pharmaceutical industry came to a consensus, in terms of having a common network on a blockchain platform for their drug supply chain. This would enable each and every stakeholder in the market to be in the know of the country's drug supply chain working and familiarise with each other. This in turn will encourage transparency in terms of being able to log transactions of a drug manufacturing company

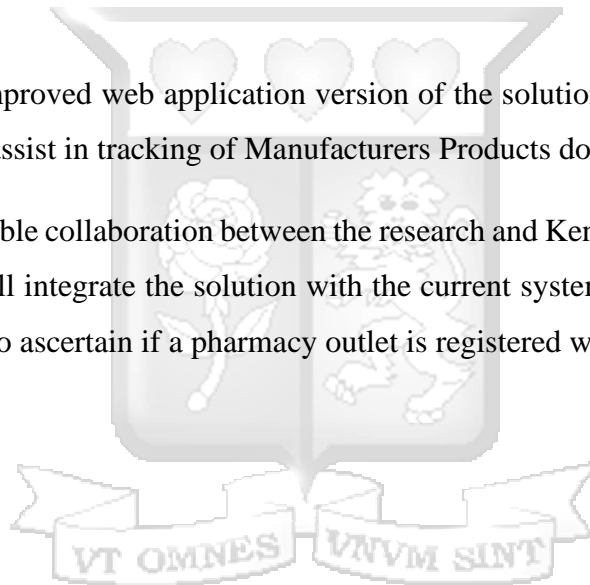
which everyone in the network can see. Moreover, constant verification and authentication of the blockchain network actors before joining the network. This will mitigate the possibility of having rogue suppliers in the industry.

Secondly, to the Government of Kenya. Blockchain technology research is the next game changer alongside Big Data and Internet of Things (IOT). Research institutions should be funded to carry out analysis on these fields. Big industries in Kenya will eventually benefit from this technology as long as Information Technology lead researchers take it upon themselves to spearhead these researches. Additionally, continued research sponsorship from the Kenyan Government will be a plus to this venture.

7.3 Future Work

With more research, the improved web application version of the solution can be adopted in a real industry environment and assist in tracking of Manufacturers Products down their supply chains.

Finally, there can be a possible collaboration between the research and Kenya Pharmacy and Poisons Board. This partnership will integrate the solution with the current system whereby customers can use a USSD Code -21031 to ascertain if a pharmacy outlet is registered with the board or not.



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APPENDIX A

A.1 Manufacturer Site Visit Interview Questions

1. Kindly state the actors in your drug supply chain?

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2. How does your drug supply chain work?

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3. What are the major challenges facing you drug supply chain in terms of counterfeiting?

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4. Are there any technologies used to tackle drug counterfeiting in your drug supply chain? (Yes or No, If No Explain)

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5. How do you get alerts on your drugs counterfeits in you drug supply chain?

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A.2 Retailer Questionnaire (Operations Background Information)

1. What is your customer traffic in a day?
 - a) 0 – 30
 - b) 31 – 50
 - c) 51 – 100
 - d) Over 100

2. Have you ever handled fake drugs?
 - a) Yes
 - b) No

3. If you answered **Yes** in question 2, was the drug from your drug supplier Brands?
 - a) Yes
 - b) No

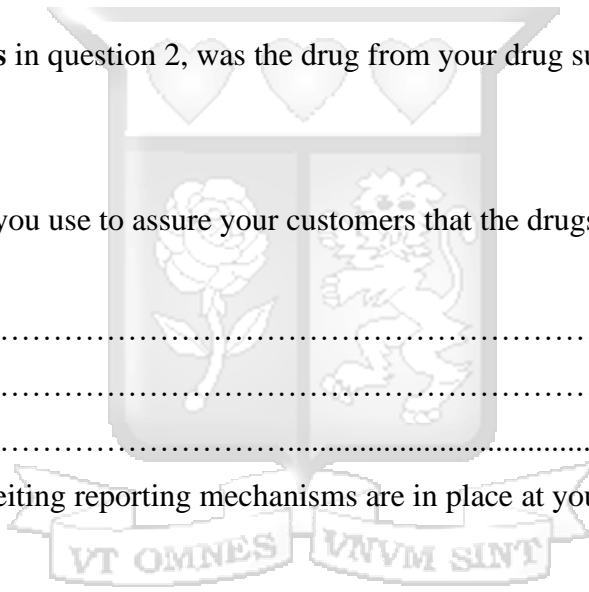
4. What technique do you use to assure your customers that the drugs you are selling are authentic?

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5. What drug counterfeiting reporting mechanisms are in place at your premise?
 - a) Phone Call
 - b) SMS
 - c) Email
 - d) Other



A.3 User Testing Questionnaire

1. Can the medikishadawa solution be used in your drug manufacturing supply chain?

- a) Yes
- b) No

2. How do you rate the user friendliness of the solution?

- a) Good
- b) Fair
- c) Bad

3. How is the look and the feel of the solution attractive?

- a) Attractive Presentation
- b) Fairly Attractive Presentation
- c) Presentation Not Attractive

4. Did the solution meet your requirements?

- a) Yes
- b) No

A.4 Validation Questionnaire

1. Can fake drugs be identified?

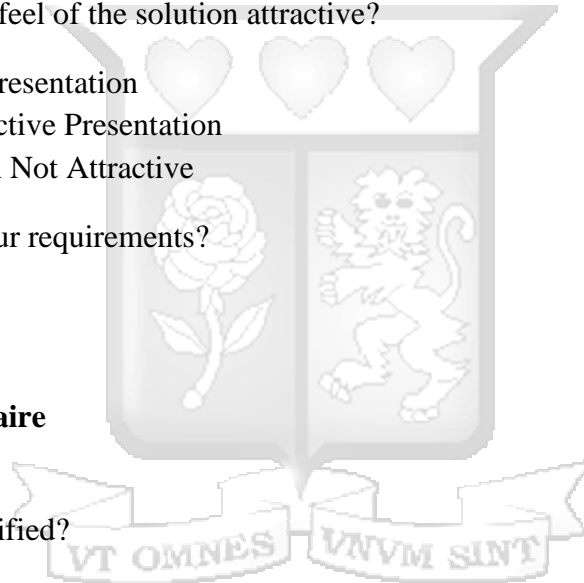
- a) Yes
- b) No

2. Are you satisfied with the application as far as drug traceability and counterfeit reporting is concerned?

- a) Yes
- b) No

3. Do the application's functionalities solve the counterfeiting problem faced in the drug manufacturing supply chain?

- a) Yes
- b) No



APPENDIX B

B.1 Turn It in Report

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