MAKERERE UNIVERSITY

A VERIFICATION SYSTEM FOR MONITORING DRUG AUTHENTICITY IN THE SUPPLY CHAIN

BY

BIS GROUP 18

DEPARTMENT OF INFORMATION SYSTEMS

SCHOOL OF COMPUTING AND INFORMATICS TECHNOLOGY

COLLEGE OF COMPUTING AND INFORMATION SCIENCES

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APPROVAL

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Signed .....

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DEDICATION

We dedicate our work to our dearly beloved families and our class mates for the good and endless support, guidance along with prayers availed to us by many during the course of our studies which have made a great contribution to our project.

We also dedicate our work to our supervisor Dr. Namatovu Hasifa the entire staff of the college of computing and informatics science for they have contributed to what we are today. May the Almighty God bless them abundantly and also fill back the pockets for those who have supported us financially.

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ABSTRACT

The main purpose of this research project was conducted in reference to understanding the big problem of counterfeit drugs in the supply chain. A thorough review on literature and other research techniques were used on how counterfeit drugs are being distributed in the market, how they are produced and who disturbs them giving us an understanding of the big problem.

A study was to carried out in Kampala throughout the drug supply chain sampling out key players like joint medical stores and national medical stores as one the large-scale wholesalers, CIPLA quality chemicals and MTK chemicals as the two manufacturing companies and some three (3) small-scale wholesalers. A number of research techniques were used in the study such as questionnaires, and planned interviews were used on the selected groups. The collected data was then summarized and the study showed that 100% of the respodents that from manufacturing companies had have a manual system that tracks drug distribution to first line of distribution and the picture on the right showed that from both respodents the system they use is a manual system, secondly 100% that the manufacturers currently are using holograms and graphical images in protecting their brands from counterfeiters.

And it was on these findings that we designed a supply chain management system to provide a better monitoring and authentication of the genuine drugs on the Ugandan market.

CHAPTER ONE

1.0 Background

Counterfeit drugs have gradually become a very big challenge in the whole world posing a serious public health risk and concern especially to consumers. Leaving no country untouched all around the continent from North America and Europe, through the Sub-Saharan Africa and Latin America South East Asia and is no longer a problem limited to developing and low earning income countries. (WHO, 2018). In Africa, about 100,000 deaths a year in Africa are linked to counterfeit drug trade and 30% of drugs in some parts of Africa, America, Asia and Latin are fake, according to the World Health Organization. The World Health Organization estimates tens of thousands of children die because of the $30bn spent on counterfeit drugs (WHO, 2013). In Uganda a number of cases of counterfeit drugs have been reported and investigated for example in a 2009 raid, conducted by Interpol and the WHO-supported group IMPACT (International Medical Products Anti-Counterfeiting Taskforce), and discovered five (5) tons of fake drugs in the central and eastern districts of the country (Gaurvika and Joel, 2012). In addition, of recent in 2017 the National Drug Authority (NDA) issued alerts over two cancer drugs being sold on the Ugandan market from a hawker near the Uganda Cancer Institute (UCI). After impounding a hawker who selling these drugs to patients on the 4th July, 2017, The drugs included Avastin (bevacizumab), a first line drug in the treatment of ovarian cancer and Sutent (Sunitinib malate), a medicine often used to treat progressive tumors of the digestive system, the pancreas, and the kidneys. (Emmanuel. A, 2017). According the World Health Organization (WHO, 2018) "defines counterfeit medicines are those which are 'deliberately and fraudulently mislabeled with respect to identity and/or source". The labelling and packing are often imitated to perfection making it impossible to tell its fake with a naked eye, with this kind of duplication even the original manufacture can at times not be able to distinguish between fake and genuine product.

The supply chain is one process through which drugs undergo to reach the final consumers. (Javid, Mohammad, Parvez, 2017). The success of medicines management cycle will depend upon the ability to reliably and consistently supply the standard quality medicines at affordable rates to health facilities at all levels of the healthcare system. Pharmaceutical supply chains are different because they usually have large and extended global pipelines requiring high levels of product availability with high uncertainty in supply and demand. In order to sustain and expand the successful interventions, these supply chains need to be made more robust and flexible through better management and increased investment of resources to achieve supply chain optimization. However, many countries for example do not routinely monitor supply chain systems and report on their performance. This in itself is a significant indicator of suboptimal performance. Even if monitoring does occur, it is often based on periodic survey data for a limited set of indicators. An assessment about the performance of supply chains is constrained by a number of factors including lack of data and the presence of many confounding factors that impact medicine availability, in particular, financing. This greatly evidences a great opportunity for counterfeit drugs in the markets

With the aim to eradicate the problem many methods are being used such as Multi-national control efforts, and agencies e.g. the Word Health Organization, United Nations, European Union, Africa- and Asia- wide issues, National Issues or control efforts focused on specific nation states or sub-regions within one nation state, including state government control programs Pharmacy control efforts focused on pharmacists and the pharmacy retailer Internet security Studies concerning pharmaceutical products purchased online via internet suppliers, drug analysis and verification techniques Studies related to techniques for analyzing pharmaceutical products or packaging, e.g. chemical analyses of active pharmacological ingredients, packaging inspection methods (William, Cormac, Mycroft and Gabriel, 2016). However, in developing countries despite such efforts by international bodies together with several government awareness campaigns against counterfeit drugs, there is continued circulation of these fake products mainly due to poor regulatory controls. Consumer ignorance and self-medication as well creates and room for the practice to continue. It is on these efforts that we capitalize to offer a supply chain management system to provide a better monitoring and authentication of the genuine drugs on the Ugandan market

1.1 Problem statement

Counterfeit Drugs is still a big challenge in the pharmaceutical business thriving in Uganda today with markets being flooded with fake and poor-quality drugs (Mark Davison, 2011; Jaramogi P, 2011). These drugs make up over 70% of drug stock supplied in the market, which poses a big threat to the health and economy of Uganda, Anie, K (2018). This outrageous out pouring of counterfeit drugs is causing long-term health consequences and even death. World Health Organization in 2016 estimated that about 100,000 deaths a year in Africa were linked to counterfeit drugs, (Jocelyne.S, 2013). These products are also causing economic setbacks with an estimated $30b spent by African countries including Uganda on counterfeit drugs annually according to WHO in the Guardian publication (November 2017). This growing atrocity has provided the need to study and come up with a more technical approach to combat the circulation of counterfeits in the drugs market. Hence, it is on that background that this study is geared towards offering a mobile verification system to help combat the circulation of counterfeit drugs through the supply chain.

1.2 Main Objective

The main objective of this project is to develop system a verification system for monitoring drug authenticity in the supply chain.

1.2.1 Specific Objectives

1. To gather and analyze the current system and validate requirements for the new system.
2. To design the system architecture using requirement specification from first phase.
3. To Implement the system

1.2.2 Outcomes/significance

This study aims to develop a system that will assist suppliers, distributors, wholesalers, and interested parties verify and monitor the authenticity of drugs. In the already ongoing campaign to combat, the circulation of counterfeit drugs in the Ugandan market, and therefore it will be of great significance:

1. **To the manufacturing companies**

The verification system for monitoring drug authenticity in the supply chain will help drug-manufacturing companies protect their brands against counterfeit drug manufacturer and as a result, it will save manufacturers from making losses

2. **To the consumers**

It will help protect consumers from using counterfeit drugs that is a threat to millions of innocent lives. This verification system will also save consumers a lot of money since it will protect them from purchasing counterfeits this is because this verification system will cut the quantity of counterfeit drugs circulating in the market.

1.2.3 Scope of study

The study will be carried out in Kampala, focusing on the drug supply chain from the leading pharmaceutical drug manufacturing companies to the retailers and large scale wholesalers.

System scope

The study will focus on developing a system using a real time verification technique to monitor and verify the authenticity of drugs in a supply chain. The system will enable drug distributors, retailers wholesalers and authorities interact with the authentic drug database to monitor, verify and combat circulation of counterfeit drugs in the market.

Time scope

The study will cover a period of 4 months and 12 days within which a system will be developed and tested for applicability.

CHAPTER TWO

LITRETURE REVIEW

2.0 Introduction

This literature review is conducted with the aim of looking at the problem by comparing different literature about the global phenomenal on the circulation of counterfeit drugs and the impact it imposes to the community, and, look at the current methodologies being used to overcome the problem. This part is going to be categorized in three, the impact posed by counterfeits drugs, reasons why the problem is still prevailing some of the measures currently used to overcome the problem.

2.0.1 Definitions

In a global perspective, developing and developed countries take up different forms in defining what constitutes counterfeit drugs, which presents a huge challenge since what might be considered counterfeit in one country might not be so in another country (Deising, 2018). However, according to the World Health Organization (WHO),"counterfeit medicines are grouped into three categories and are defined as follows: Substandard: Also called "out of specification", these are authorized medical products that fail to meet either their quality standards or specifications, or both Unregistered/unlicensed: Medical products that have not undergone evaluation and/or approval by the National or Regional Regulatory Authority (NRRA) for the market in which they are marketed/distributed or used, subject to permitted conditions under national or regional regulation and legislation, Falsified: Medical products that deliberately/fraudulently misrepresent their identity, composition or source" (WHO, 2017).

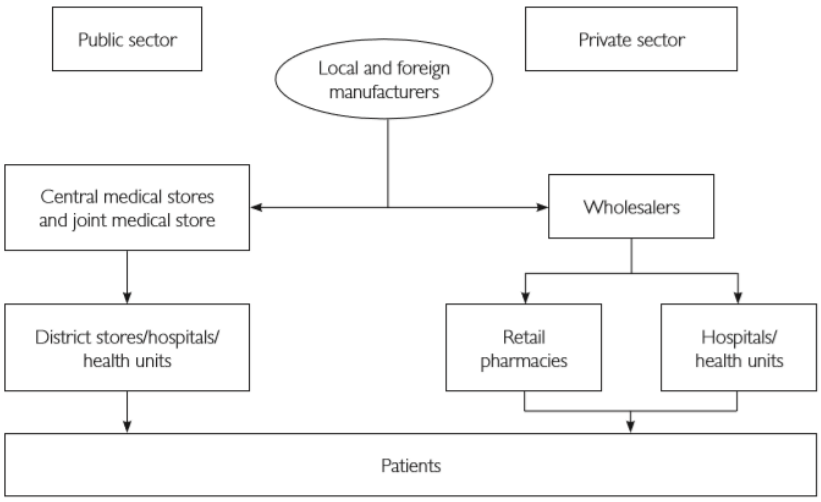
2.0.2 Uganda's pharmaceutical industry and the Supply of medicines

Uganda's pharmaceutical market has an estimated value of US$ 276 million, of which 90 per cent of the medicines are imported, mainly from India and China, and 10 per cent produced by local manufacturers. The imported medicines and health supplies account for 5.4 per cent of Uganda's total imports (UPMA, 2010). Medicines are supplied through both the public and the private sectors and there are non-governmental organizations (NGOs), faith-based organizations (FBOs) and international aid agencies involved in the procurement and distribution of medicines and health supplies. (UNIDO, 2010)

Uganda has a total of 11 licensed local pharmaceutical manufacturers, 477 registered pharmacies and over 4,370 chemist shops. The National Medical Stores (NMS) are responsible for the procurement, storage and distribution of medicines and health supplies for the public sector, while the private sector is served through a chain of wholesale and/or retail pharmacies, chemist shops, and private clinics (UNIDO, 2010). Most imported medicines (about 90 per cent of consumption within the public health sector, including NGOs and/or faith based health units and hospitals) are distributed through the National Medical Stores (NMS) and the Joint Medical

Store (JMS) as wholesalers and local manufacturers also sell medicines to NMS and JMS. In addition, the larger manufacturers either manage their own distribution systems or contract licensed private sector subsidiaries as wholesalers. Distribution to end-users is through over 477 pharmacies, about 5,263 registered chemist shops, 1,500 clinics, and 114 hospitals (in 94 districts).

Distribution of medicines, health supplies in Uganda's public, and private sectors



2.0.2 Impacts of counterfeit drugs

Counterfeit drugs present social, economic and health impact to the consumers, manufacturers and the governments. This for a long time has been a global phenomenal affecting both developed and developing countries with numerous atrocities being reported in recent years all around the world. To the consumers, counterfeit drugs can be harmful to their lives if they contain toxic ingredients as it happened in 2013, were an estimated 122,350 deaths of children under the age of 5 years in the sub-saharan-africa in 39 countries was because of consuming fake antimalarial drugs (Renschler *et* al*;* 2015). Another scenario of drug poisoning between November 2008 and February 2009, occurred in Nigeria where 84 children died from acute kidney failure brought on by the industrial solvent diethylene glycol in teething syrup (Akuse et al., 2012; Polgreen, 2009). The contaminated product, My Pikin, was registered with the Nigerian regulatory authority and made in Lagos, the national manufacturing hub (Akuse et al., 2012). Inspectors traced the problem back to deliberate fraud by a chemical dealer in Lagos, eventually leading to 12 prosecutions (Poisoned teething drug arrests, 2009; Polgreen, 2009). As well as having accurate doubts about individual pharmacies, consumers in places where fake drugs circulate have reason to lose faith in the public health system. A recent systematic review suggests that patients across a range of developing countries already have poor perceptions of the health system,

especially the technical competence and clinical skills of the staff and the availability of medicines (Berendes et al., 2011).

These drugs Increase Antimicrobial resistance if they do not contain active pharmaceutical ingredients (API). Antimicrobial resistance (AMR) now recognized as a major threat to global public health (Pisani, 2015). According to (Abdul-Aziz *et* al. 2015) "If poor quality medicines contain less than the intended API, pathogens can become exposed to drug concentrations in the 'mutation selection window'—high enough to exert a selection pressure but too low to kill all of the pathogens" with these mutation the pathogens can multiply and spread. Counterfeit drugs also has physiological effect to patients making them lose faith in the healthcare, which broadens the gap for organized crime according to (Newton, 2006, 2010; Mackey and Liang 2011; Karunamoorthi 2014). Some more recent reports suggest that falsified antiretroviral drugs may circulate in African countries. In September 2011, falsified and substandard versions of the triple combination therapy Zidolam-N surfaced in Kenya, many samples molding and crumbling in the packages (Taylor, 2011). A year later, in Tanzania, the regulatory authority uncovered falsified antiretrovirals at a district hospital (Athumani, 2012). These failures put HIV patients at risk for disease progression and favor the selection of resistant virus strains (WHO, 2003). As their viral loads increase, these patients are also more likely to transmit the infection, impeding efforts to control the virus.

Similarly, counterfeit drugs have had a huge impact on the pharmaceutical industry. This is largely because the counterfeit drug market is becoming more lucrative and attracting more investors than the legit drug market and, experts estimate that the sale of counterfeit drugs is growing at twice the rate of legitimate pharmaceuticals (Kristina Acri, 2018). Consequently, the global pharmaceutical industry faces an estimated loss of up to US $75 million annually (WHO, 2016). Additionally, counterfeiting forces legitimate players to incur increase costs of securing the supply chain, investments in anti-counterfeiting technologies and public relation in a bid to repair the reputational damages and avoid potential liabilities (Kristina Acri, 2018), This make the production of pharmaceutical products expensive.

In a larger sense, trade in falsified and substandard medicines undermines not just the health system but also all public institutions. Corruption in the health system can cause patients to assume the drug supply is substandard (BBC, 2012). The UNODC described the traffic in fake drugs as both as cause and an effect of political instability, explaining, "Living in a society where such widespread and serious fraud can occur undermines confidence in government, but the effects are so diffuse and uncertain that they are unlikely to generate an organized political response" (UNODC, 2009). In many parts of the world, falsified and substandard medicines further erode the already weak political infrastructure that allows them to circulate, part of a vicious cycle of poverty and crime.

2.0.3 Why the problem is still prevailing

Counterfeiting drugs has been hard to fight despite the WHO launching the International Medical Products Anti-Counterfeiting Taskforce in 2006 (IMPACT), this is because it's a crime carried out using deception and other

techniques typical of organized crime and yet health authorities are not equipped to adequately address the situation (Burns, 2006). Continued circulation of counterfeit drugs is majorly due to weak regulation policies (Lui *et al*, 2016). Among other factors include; high drug prices, value added tax, prescription of drugs without registration, lack of public awareness, weak enforcement of legislations and flexibility in the current legal framework (Saurabh et al; 2014). The above reasons are coupled with vulnerable supply chain and the emergency of online pharmacies. It is estimated that 50% of the drugs for sale on the internet are fake and even though the online dispensaries might look legitimate (WHO, 2015). Another big problem is that patients taking ineffective drugs die of apparently natural causes, making these products more difficult to identify. Ineffective medicines often contain benign ingredients, such as chalk, pollen, or flour, instead of medicinal chemicals. More dangerously, some contain substances intended to mask the illness and feign treatment, such as paracetemol added to fake antimalarials to lower fever. (Buckley and Gostin, 2013).

2.0.4 Over view of the current solutions to drug counterfeiting

The continued production of counterfeit drugs and its potential harmful effects has called for a global unity against this dangerous activity. Numerous measures to combat drug counterfeiting such as legal actions on illicit traders, countermeasures using technologies, consumer education and information, private investigations, and cooperation with enforcement agencies are being used (Dipika Bansal *et el;* 2012).The need for sophisticated anti-counterfeit technology is ever growing as the practices of counterfeiters become increasingly advanced. Technology as a countermeasure must necessarily improve, especially in reaction to what is a multifarious problem. There is the manufacturing concern, to ensure brand protection and reinforce intellectual property rights for pharmaceutical companies, and the health concern, with the potential for counterfeit drugs to lead to mortality. (Christo .H, 2012). Currently some of the technologies used in the pharmaceutical industry include:

Overt Visible features

These are feature intended to enable end-user to verify the authenticity of a pack. These feature are applied in such a way that they cannot be reused or removed without being defaced or damaged on the pack so that they cannot be recycled with fake contents giving a fake impression of authenticity. Such features include Holograms, Optical Variable devices (OVD), color security shifting inks and films, security graphics and sequential product numbering.

Covert Features

These are features mainly used to enable brand owners to identify counterfeited products and the public is not aware of them nor are they capable of verifying these features. The features must be had to detect, copy or duplicated without specialized knowledge. If publicized, covert features will lose some if not all of their security value and for this reason such techniques are not be disclosed in detail in this paper.

Serialization / Track and Trace Technologies

These are the feature in fighting counterfeits. Track and Trace Technologies are technologies involving assigning a unique identifier to each stock unit during manufacturing and remains with it through the supply chain until consumption. The identifier will normally include details of product name, description, lot number, expiry date and others. It simply take the form of a unique pack coding which enables access to the same information held on a secure database to authenticate the pack.

In a brief conclusion, our application has NFC scanner which will enable the consumers scan and verify the drugs. In case a product is scanned and it is flagged as a counterfeit, the consumer will be prompted to report the incident providing the location where it has taken place. The report is delivered to the National Drug Authority and action will be taken.

The app also provides a live chat with the application developers incase consumers have any questions.

CHAPTER THREE

METHODOLOGY

3.0 Introduction

This is a description of methods chosen to achieve the objectives of the proposed system. The methodology goes on to describe the techniques of data collection that will be employed in the research study of the proposed application. As (Carter and Little, 2007) put it out that, methodologies justify methods, which are to be used to collect data and analyses it. The methods that shall be applied to achieve the project objectives include interviewing respondents, and questioners.

3.0.1 Area of study

The study is to be carried out near Kampala at joint medical stores and national medical stores as one the large-scale wholesalers, CIPLA quality chemicals and MTK chemicals as the two manufacturing companies and some three (3) small-scale wholesalers.

3.0.2 Sample size

A number of people are involved in the process manufacturing and distribution of drugs to the final consumer. Therefore, this study is targeting two (2) operations manager from two manufacturing companies, with 6 managers of whom 3 are from big pharmaceutical wholesalers and 3 are from small pharmaceutical wholesalers giving us a sample size of 8 respondents.

3.0.3 Sampling Technique

During this research, random sampling method shall be used, during this process, a few respondents sample size shall be approached information will be gathered through interviews and use questionnaires. This method will enable the research team acquire more information on the existing system and will provide insights in relation to problem in question.

3.0.4 Data collection methods and tools

This research was conducted by means of a literature study and empirical research. The phase of data collection began after the research problem had been defined and research design/Plan lay out. In this study, data was collected from both primary and secondary sources. Secondary data collection was done by going a thorough review and analysis of research works and reports produced by Individuals, NGOs and the governments about the issue of counterfeit drugs in Uganda and international level. Questionnaires, interviews were also used for collecting qualitative and quantitative data that provided concrete conclusions and recommendations for the study.

3.0.5 Interviewing

The interview method of collecting data involved presentation of oral-verbal stimuli and reply in terms of oral-verbal responses. Face to face, interviews were conducted during the field study from the respondents' offices with interest of getting to know the current how counterfeits affects the key stakeholders and the current methods they use in fighting counterfeits. Several numbers of players in the distribution and supply chain were also interviewed because this is where counterfeit penetrates to the legitimate market. Some staff from one drug manufacturing company was also interviewed. This method was chosen to enable collection of first hand data from the target respondents.

3.0.6Questionnaires

In this method, set preset questions were distributed to the target respondents to capture their opinions and views. Questionnaires helped us in gathering data to determine how the proposed system should be developed and the most pressing issues regarding the question in study.

3.1 System development

This phase shows how the various parts of the proposed system was arranged to form a complete system. This was achieved by using the system development life cycle (SDLC) detailing the all stages of system development from requirement specification, Systems analysis, system design, implementation and testing.

3.1.2 Data analysis

This section describes process of inspecting, cleansing, transforming, and modeling data that was derived from the study carried out during the research process with the goal of discovering useful information, suggesting conclusions, and supporting decision-making.

Study one aimed at investigating analyzing the data collected from various respondents basing on the given questionnaires about the efficiency of the existing systems whether they comprehend with the existing system, and whether there should be introduction of a mobile platform. To analyze the answers /data collected, we shall apply context analysis to examine the data from the field survey in order to obtain deep insight into the phenomenon.

Excel and descriptive statistics will be used to analyze the interview guide items relating to phenomenal.

3.1.3 System design

System design defines the architecture, modules, interfaces, and data for a system to satisfy specified requirements. It will show the different techniques of data processing in order to demonstrate the levels of design that include architectural, conceptual, logical and physical design.

Architectural design

The architectural design is to show the design of the system architecture that describes the structure, behavior and more views of the system.

Conceptual and Logical design

The logical design of a system pertains to an abstract representation of the data flows, inputs and outputs of the system. This is often conducted via modeling, using an over-abstract and sometimes graphical model of the actual system. In the context of this system, designs include.

Data flow diagram: we used data flow diagram to describe the systems process flow, data stores and show all external entities of the system and how they communicate and produce resources to user.

Entity relationship diagram: we used entity relationship diagram to represent user requirements, visualize the system and also represent entities and their relationships with each other.

Context diagram: we used a context diagram to define the scope of the system and entities.

Physical design

The physical design relates to the actual input and output processes of the system. This is explained in terms of how data is input into a system, how it is verified /authenticated, how it is processed, and how it is displayed. In physical design, the following requirements about the system are decided. Input requirement, Output requirements, Storage requirements, Processing requirements, System control and backup or recovery.

3.1.4 System implementation

This involved putting together various elements of the system. The system will be implemented using the different tools, hardware and software. The following tools will be used to achieve the above; the system was implemented using the Hyper-Text Markup Language (**HTML**) that is user friendly was used in developing the user interface. CSS was also used for making the interface more attractive. **PHP**: (Hypertext processor) this is widely used open source general purpose scripting language that is especially suited for web development and can be embedded into HTML. This will used to connecting the interfaces to the MySQL database. **MYSQL**: (structured query language) this tool has a very large database management system and will be used for data storage. This software will be used to design a database, because it is light and scalable.**JAVA**: This will be used this for implementing the Mobile Application

3.1.5 Testing and Validation

Testing of the system was done after the implementation provide stakeholders with information about the quality of the system. The system was tested with the aim of getting feedback regarding its functionality, performance, usability and that it meets the user requirements.

CHAPTER 4

4.0 System Analysis and Design

This chapter highlights the identified requirements of the system by analyzing the data gathered for designers to design the system satisfying the requirements and testers to verify that the system satisfies requirements. It describes every input into the system, every output from the system, and every function performed by the system in response to an input or in support of an output. Analysis the data and the information that was collected, we were able to derive some of the user specifications, functional, nonfunctional requirements that guided us in the development and implementation of the system.

4.1 System Study

Facts about the strength and weakness of the current approaches being used by manufactures to fight counterfeit drugs in the supply chain were gathered by the project team and it was confirmed that the current approaches include:

Overt Visible features

These are feature intended to enable end-user to verify the authenticity of a pack.

Strength	**Weakness**
User verifiable	Require user education – not always widely understood
Newer technologies more secure	May be easily mimicked
Can add decorative appeal	May add significant cost
Can be a deterrent to counterfeiters	May rely on covert features for authentication
	May be re-used or refilled
	May give false assurance

Covert Features

These are features mainly used to enable brand owners to identify counterfeited products and the public is not aware of them nor are they capable of verifying these features.

Strength	**Weakness**
Can be simple and low cost to implement	Need strict secrecy – "need to know"
Needs no regulatory approval	If widely known or used, may be easy to copy
Can be easily added to or modified	More secure options add supply complexity and cost
Can be applied in-house or via component suppliers	If applied at component suppliers, greater risk of compromise

Data Analysis

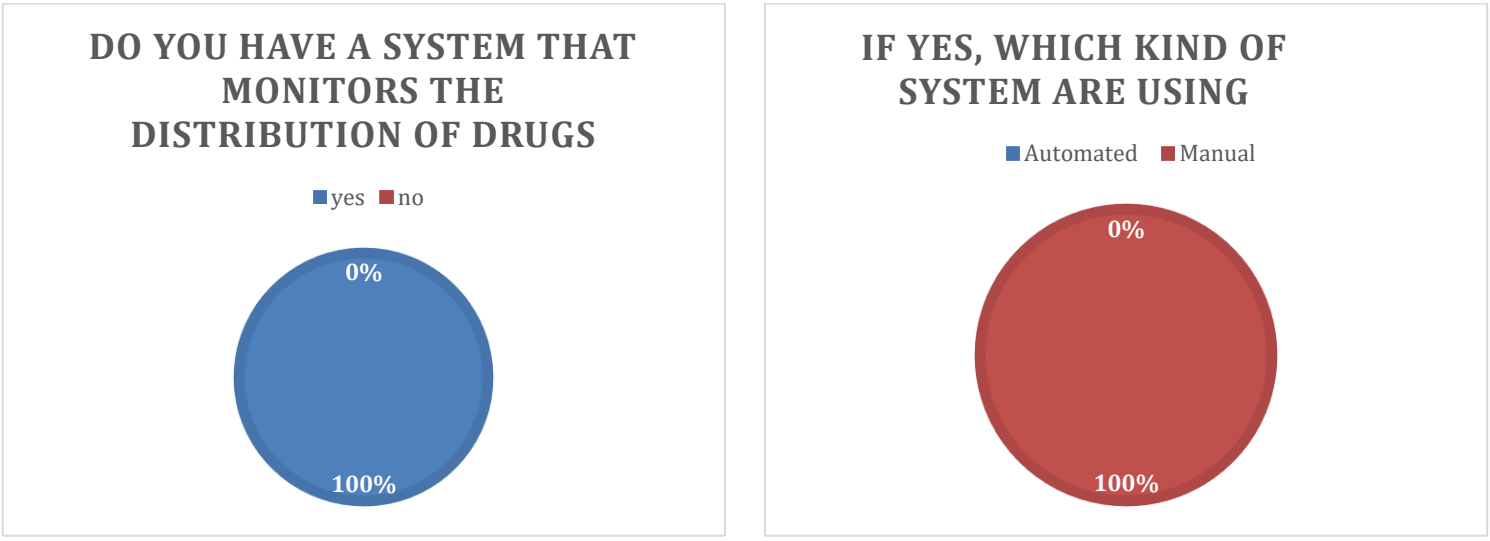


Figure 1: show the Response on whether there is an existing system that monitors drug distribution and which kind of system

From figure 4.1 the picture on the left showed that 100% of the respodents that from manufacturing companies had have a manual system that tracks drug distribution to first line of distribution and the picture on the right showed that from both respodents the system they use is a manual system.

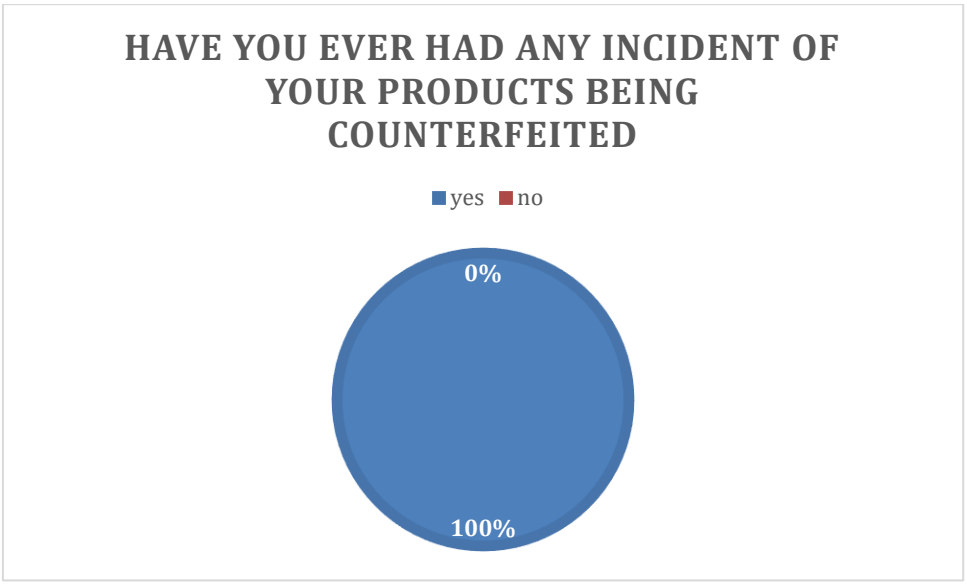


Figure 2: Response on whether there have been any incidences of counterfeit drugs

According Figure 4.2 the respondents agreed 100% that they have ever had their products duplicated by other people.

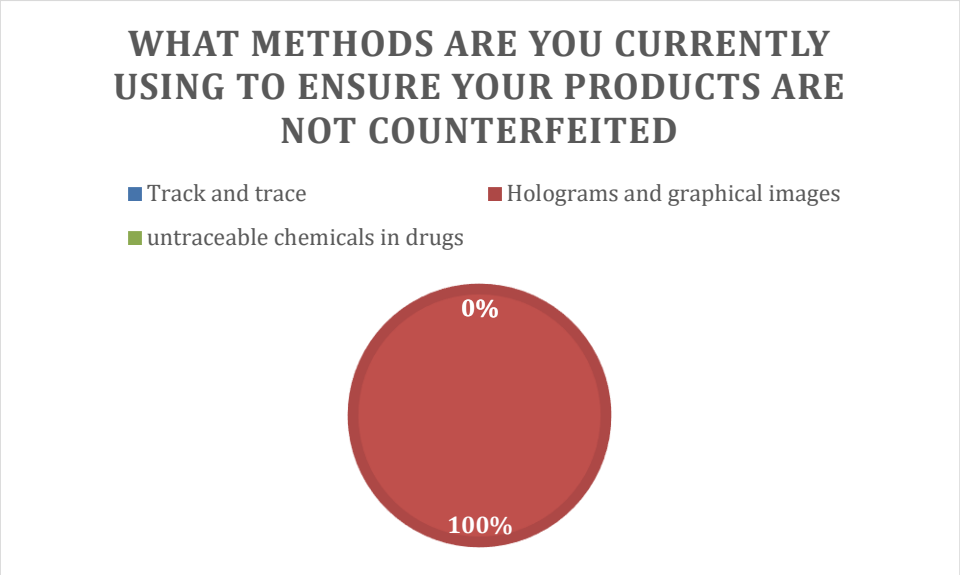


Figure 3: Response on the measures currently being used to ensure that the drugs are not counterfeited

From the results from data, collected figure 4.3 showed 100% that the manufacturers currently are using holograms and graphical images in protecting their brands from counterfeiters.

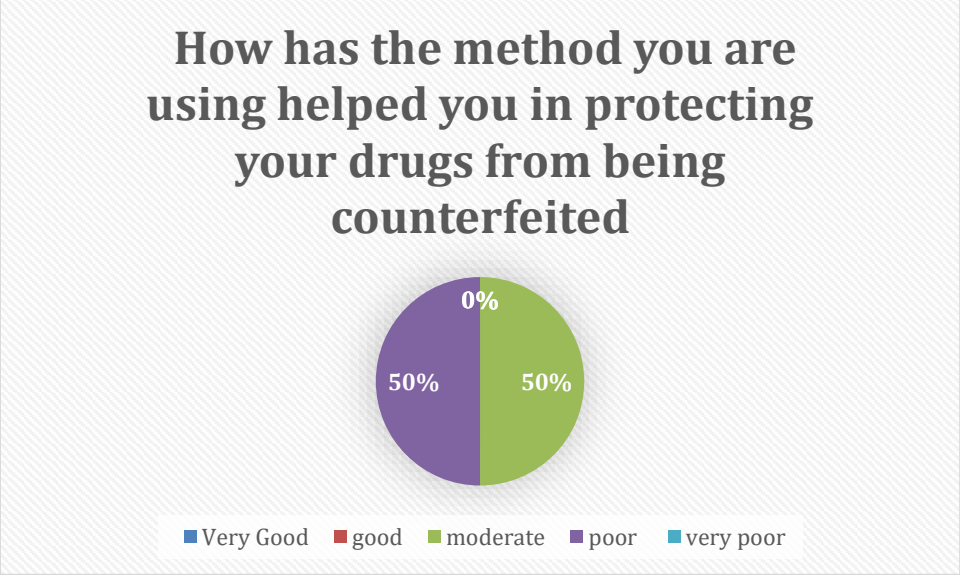


Figure 4: Response on how the current method been helpful in protecting drugs from being counterfeited

4.1 User requirements for the application

The application should:

1. Should be able to scan a tag on drug container.
2. User should be able to register and log in into the system.
3. User should be able to receive notification from the system about scanned container
4. User should be able to update database of drugs and tags.
5. User should be able to generate reports of tags and results from the process.
6. System should be user friendly to the users

Functional Requirements

Functional requirements define the various functionalities expected of the system.

1. The system should enable users to scan the electronic tags on drug containers.
2. The system should authorize registered users to access the system.
3. The system should send feedback to the user about the drug batches scanned.
4. The system should help manufacturers generate of the results of the different batches scanned.
5. The system should allow manufacturers update database of drugs and tags before drugs are distributed.

Non-Functional Requirements

1. User must first login into the system to be able to use it.
2. A tag must be scanned before a request can be approved.
3. Clicking the Approve button moves the request to the Approval Workflow.
4. All personnel using the system will be first trained.
5. The database will have a functional audit trail.
6. The system will limit access to authorized users.
7. Members of the Data Entry group can enter requests but cannot approve or delete requests.
8. Members of the Managers group can enter or approve a request but cannot delete requests.
9. Members of the Administrators group cannot enter or approve requests but can delete requests.

System Design

This chapter defines the architecture, components, modules, interfaces, and data required of the system to satisfy the specified system requirements. In this phase, the following tools where used: architectural design, process modeling, data modeling and database design.

Architectural Design

Architectural design is concerned with understanding how a system should be organized and designing the overall structure of that system. It is the critical link between design and requirements engineering, as it identifies the main structural components in a system and the relationships between them. This system is comprised of a mobile application to be hosted on a user's phone that communicates to a database server. The user on his/her mobile device opens the application and scans the NFC tag on the drug batch. During the verification process, a query is made to database checking whether there is a similar ID in the database similar to that scanned from the tag, and if the ID is there, a query is made to the database requesting for details about the drug which are then displayed to users phone confirming the authencity of the drug batch while if the ID is not in the database the users will receive a message of no drug detail found.

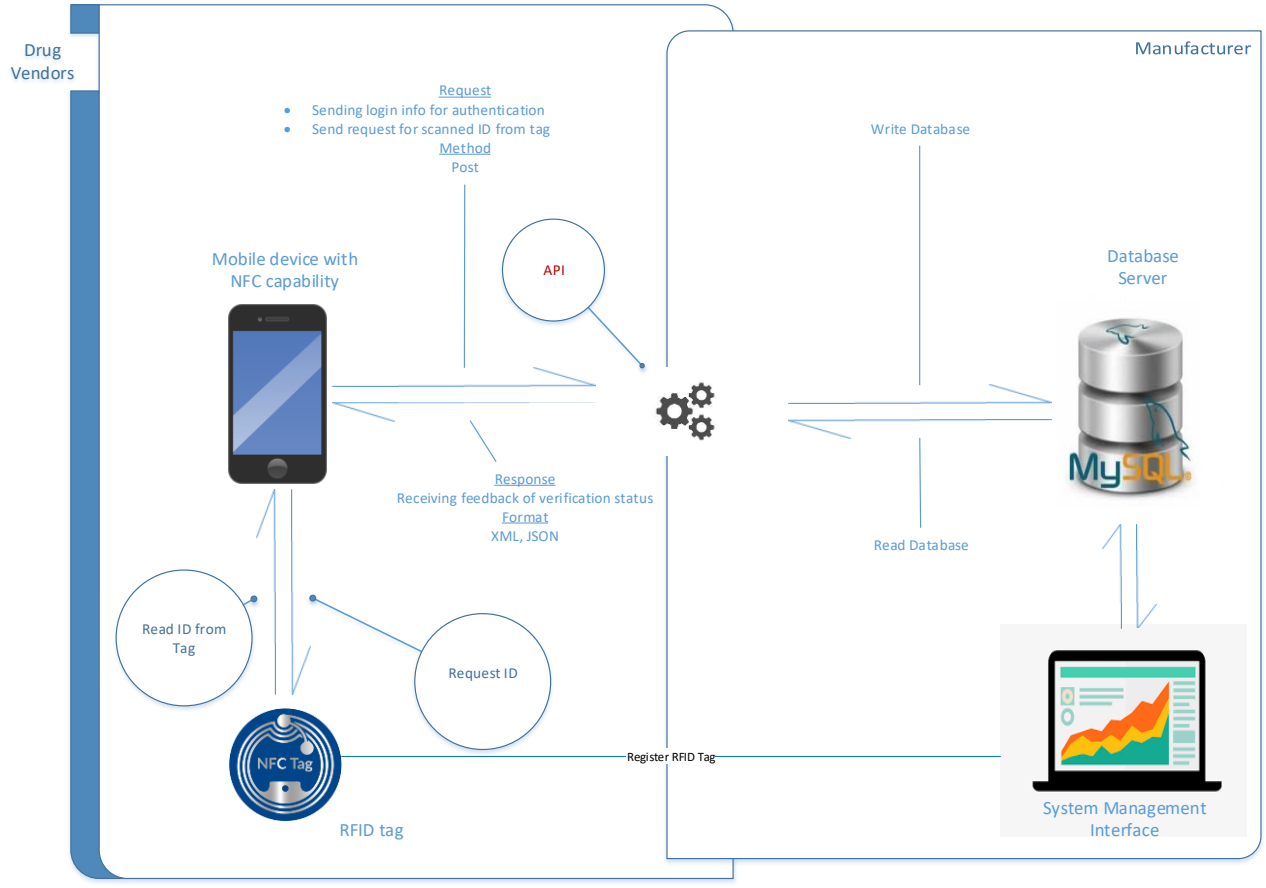


Figure 5: Architectural Design

Process Modeling

A context diagram and data flow diagram were used to illustrate the activities that are performed and how data moves in the system.

Symbols used

Entity

Data store

Processs

Data Flow

Context Diagram

A context diagram is high level view of the system that is to be developed, external entities the will interact with the system and the movement of data from the system to the external entities and from the external entities to the system

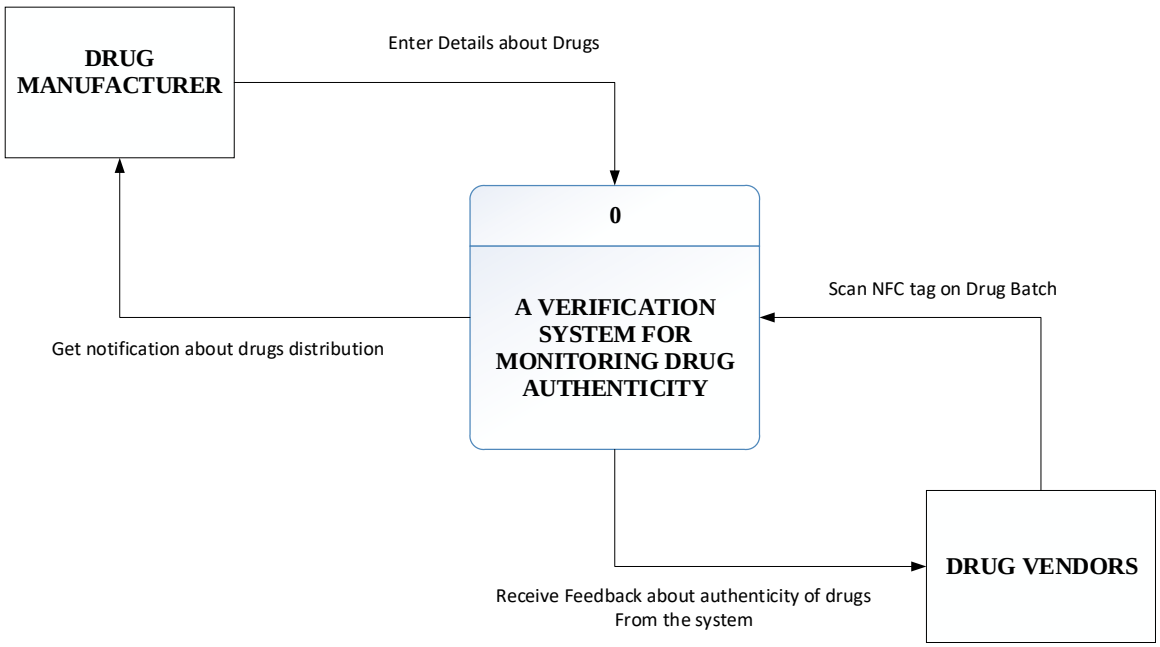


Figure 6: Context Diagram describing the major actors of the system

Level 1 Data Flow Diagram

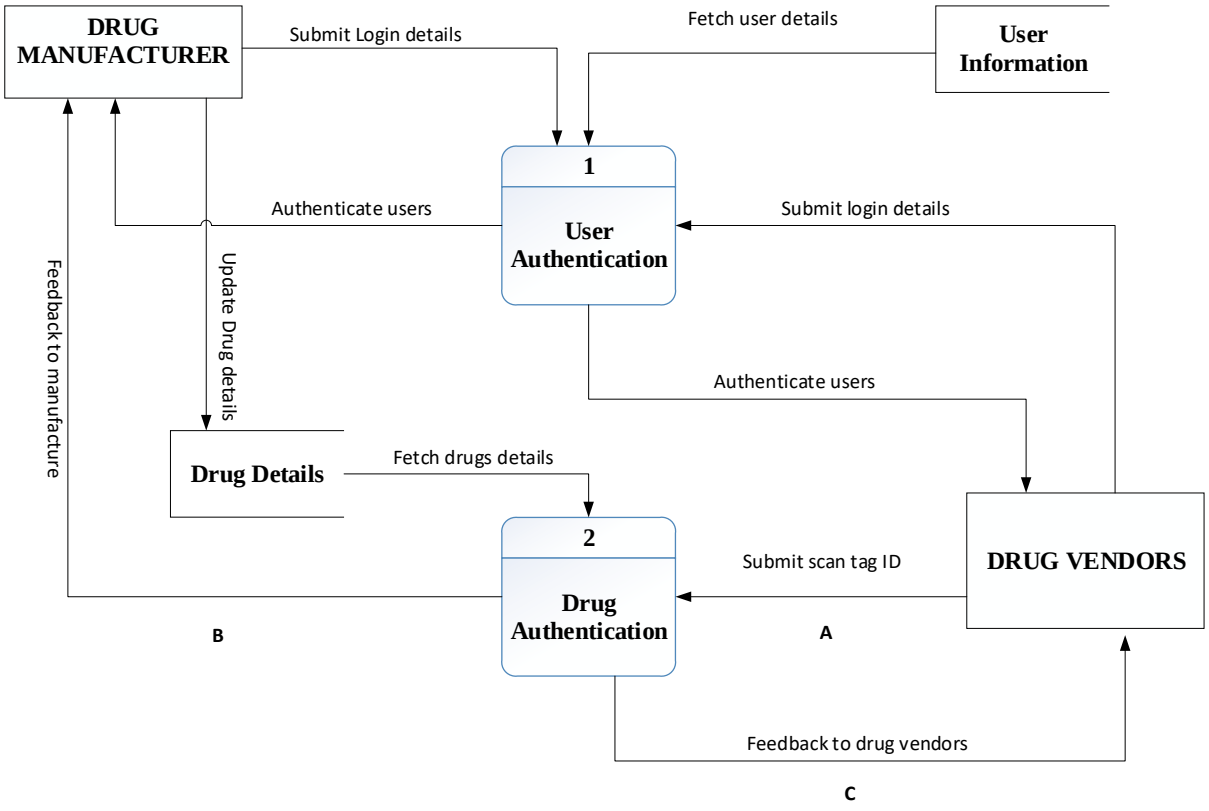


Figure 7: Level 1 Data flow Diagram

Level 2 Data Flow Diagram

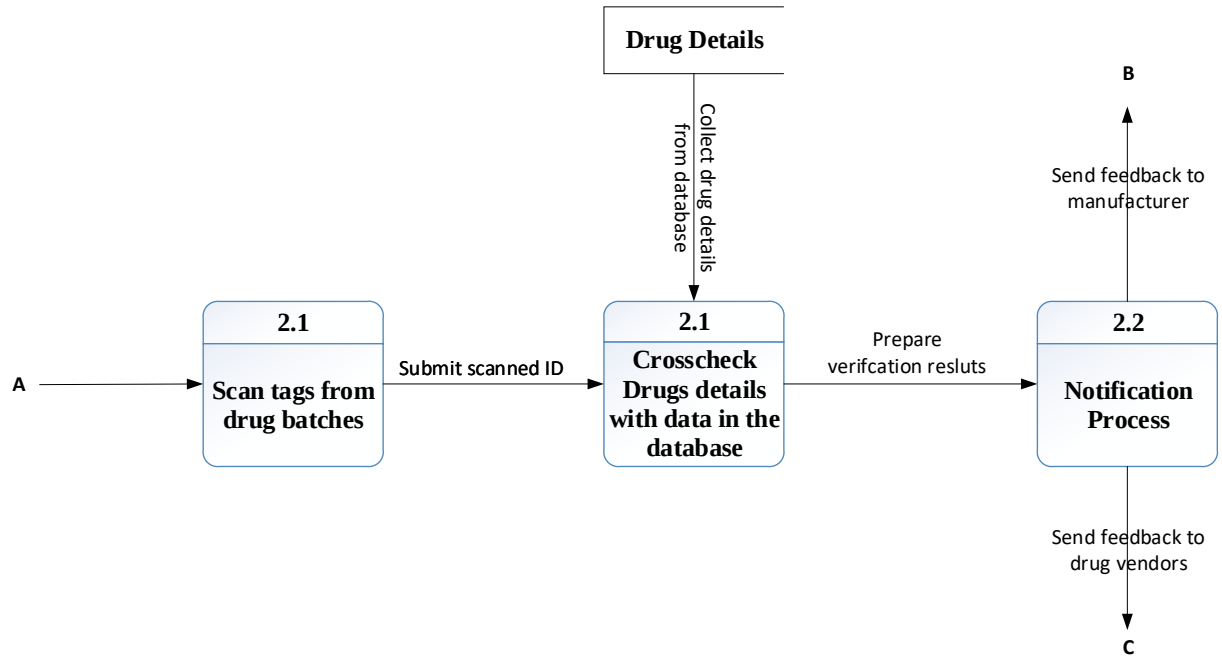


Figure 8: Level 2 Data flow Diagram

Description of the level 1 and Level 2 Data Flow Diagrams

The Tables below give a Description of all design objects used in developing the system and these include processes, data flows, data stores, entities involved in the system.

Description of process

Process	Description
User authentication	This is the process for verifying users before access system resources
Scan tags	This is the process of capturing data from drug batches for verification
Drug details verification	This is the process where scanned details are crossed with drug details in the database
Notification process	This the process where the users are given feedback about the verification status

Description of Entities

Entity	Description
Systems Admin	
Drug manufacture	These are people that manufacture drugs
Drug Vendors	These are people who buy the drugs from the manufacture

Description of Data Stores

Entity	Description
Drug Details	Data store of details about the system
User information	Data stored about the users

Data Modeling

Data modeling is the formal way of representing the data that is used and created by a business system.It shows the people, places and things about which data is captured and the relationships among them. Data modeling looks at identification of entities and the characteristics of those entities. The data requirements in table below show the entities, their description and attributes.

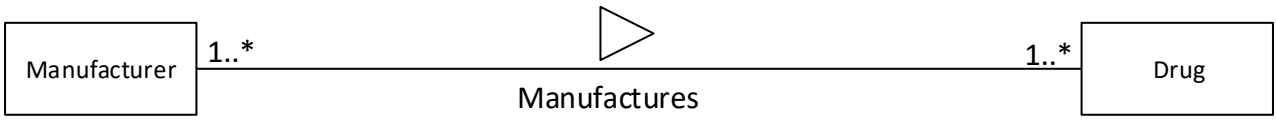
Data Requirements

Entity	Description	Attributes
Manufacturer	Stores information about a person who has the necessary skills to administer healthcare and health advice	Manufacturer_ID Company_ID Telephone Email Address
Drug Vendor	Stores information about a person who uses the system to verify drugs when they are procuring drugs	Drug_ID DrugName Manufacture_Date Expiration_Date Manufacturer_ID
Drugs	Stores information about details of the drugs	Vendor_ID Vendor_Name UserName Password V_telephone V_Email V_address
Tag	Stores the ID that is scanned to verify the drugs	Tag_ID

Logical database design

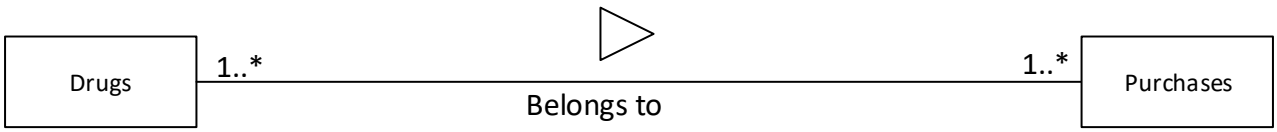
Logical database design is the process of deciding how to arrange the attributes of the entities in a given business environment into database structures, such as the tables of a relational database. The goal of logical database design is to create well-structured tables that properly reflect the systems environment.

Modeling relationship between entities



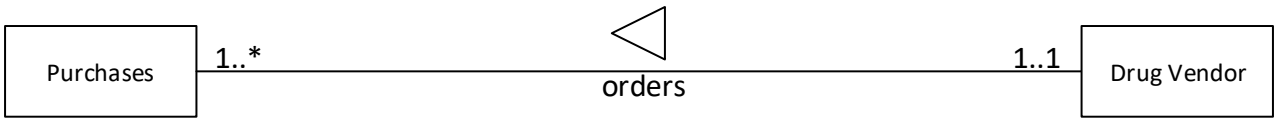
Relationship between Manufacturer and Drugs

A Manufacturer manufactures one or more drug types, but one drug is manufactured by one manufacturer



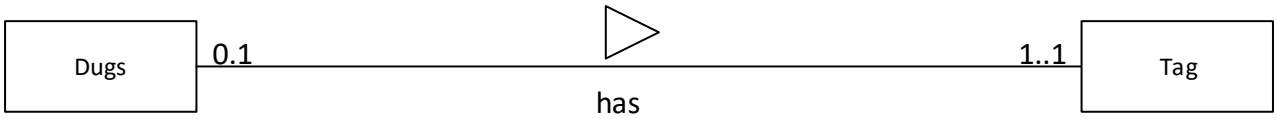
Relationship between Drugs and Purchases

A Drug can belong to one or more purchases, but one purchase can comprise one drug type.



Relationship between Purchases and Drugs Vendors

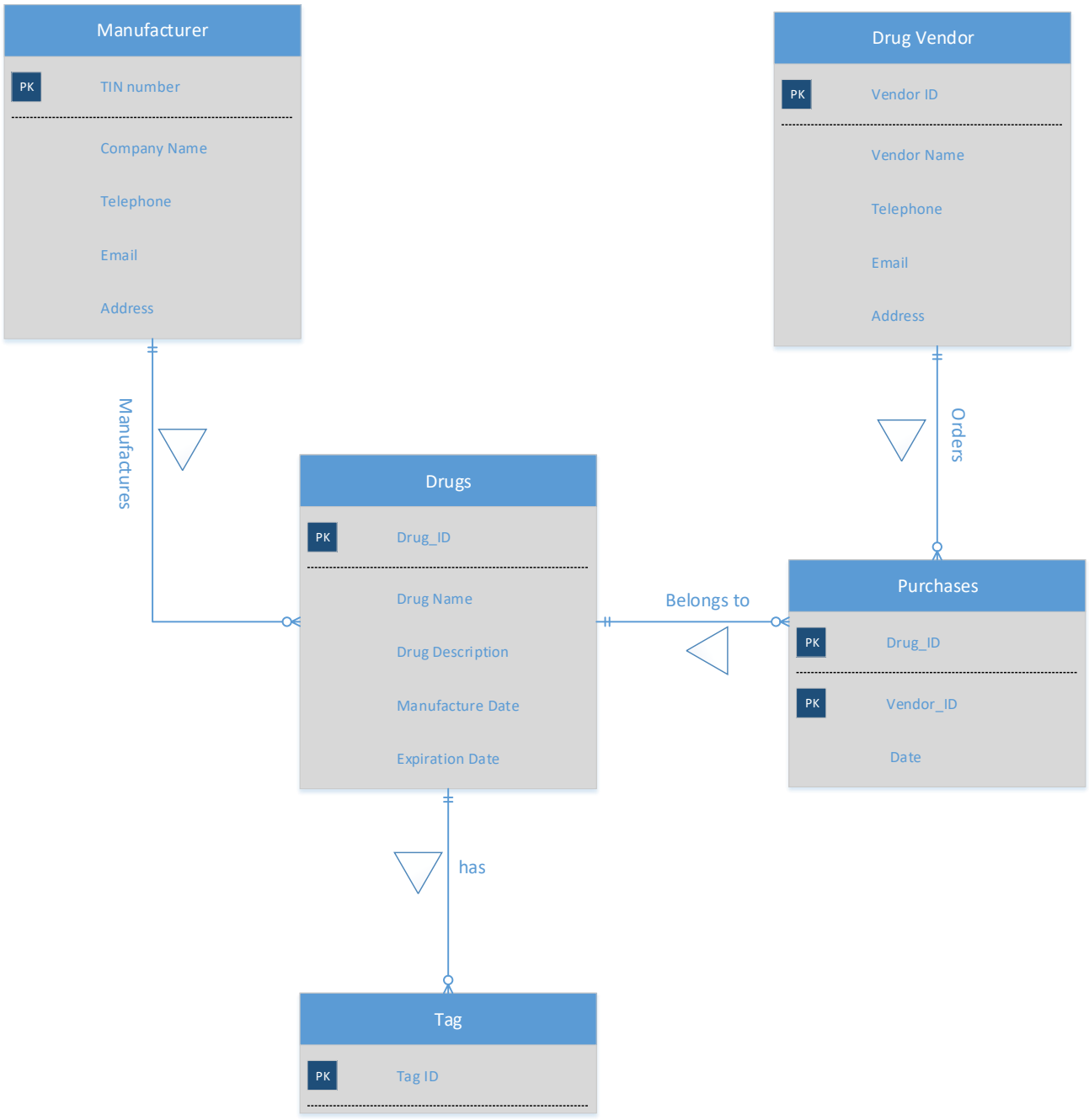
A drug vendor can order one or many purchases, while a purchase can belong to only one drug vendor



Relationship between Drugs and Tags

A drug can have one tag at a time, while a tag can belong to only one drug.

Entity Relationship Diagram
For
A verification system for monitoring drug authenticity



Physical Database Design

Physical database design translates the logical data model into a set of SQL statements that define the database.

Physical Data Model			
Table	**Column**	**data type**	**Notes**
Manufacturer	Manufacturer_ID Company_ID Telephone Email Address	int varchar(50) int varchar(50)	Primary Key
Drugs	Drug_ID DrugName Manufacture_Date Expiration_Date Manufacturer_ID Tag_ID	int varchar(50) date date int int	Primary Key Foreign Key Foreign Key
Drug_Vendor	Vendor_ID Vendor_Name UserName Password V_telephone V_Email V_address	int varchar(50) varchar(50) Password int varchar(50) varchar(50)	Primary Key
Purchases	Purchase_ID Drug_ID Vendor_ID Purchase_Date Verification_status	int int int date varchar(50)	Primary Key Foreign Key Foreign Key
Tag	Tag_ID	int	Primary Key

CHAPTER FIVE

Implementation

5.0 System implementation

This section aims at demonstrating the system features and their functionalities through a prototype. Several technologies have been used to come up with the end system that have been used to test the attainment of the user requirements in the beginning of the project research

5.1 Implementation tools

The Mobile Based Drug Verification Application was implemented using a number of technologies which include PHP, WAMP server, XML, Android Studio and JAVA as explained below:

XML was used to design the user interface layout grids, structures and responsiveness, of the interface features while interacting with the application user.

PHP (HYPERTEXT PREPROCESSOR)

We used this technology for server side scripting thus connecting the database to the application interfaces, and querying the database for different activities or functionalities of the application.

The language was also useful in modeling the JSON (JavaScript Object Notation) strings.

JSON (JavaScript Object Notation)

The JSON was useful in the application during the process of making database calls that generate multiple records, which needed to be parsed into JSON objects that make it easier to link them to lists view resources

Java

We used java to formulate various computational classes, methods and functions that were vital in achieving the expected performance of the application as well as linking of the XML interfaces and creating objects that helps to reduce on multiple reputation of code.

WAMP SERVER

This is a windows framework combining different applications but running on a windows platform such as Apache web server, MySQL database application and PHP which we used to query the database in fulfillment of the different functionalities of the application.

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5.2 System testing

Test objectives

1. The objective of the test was to ensure that the designed system works according to user requirements specified in the Requirements specification document.
2. The final product of the test is system that fulfills the suggestions raised after the testing phase.

Test Assumptions

- User data is required before testing the application.
- The user must have knowledge of how to use a Smartphone.
- Users' must be connected to the internet.
- The Test Team should be provided with access to test environment and a data bundle.
- All the defects would come along with a snapshot.
- Test and preparation activities shall be maintained by Project Team.
- The defects should be tracked through use of exception handlers.
- Project team reviewed all the test deliverables.
- The project team will provide test planning, test design and test execution support.
- Test team will manage the testing effort with close coordination with the Project Team.
- The system will be treated as a black box; if the information shows correctly online and in the reports, it will be assumed that the database is working properly.
- The Test Team must perform functional testing of the whole system.

Test plan

Unit Testing

The goal was to isolate each part of the application and show that the individual parts are correct in terms of requirements and functionality. Individual units of source code were tested to verify the inputs to the expected outputs.

Integration Testing

The goal here was to monitor how each of the individual modules of the system work as a whole.

Compatibility Testing

This was a testing done to find out whether the system is compatible with hardware and other software where it's going to be installed on.

Features that were tested

- **Application launch**

The user clicks on the app icon on their Smartphone to enable him/her get to the home page.

- **Scan NFC Tag**

The user clicks the button to see whether his able to scan the E-Tag

- **Verification**

The user should be in condition to submit a Barcode scan or serial number to be verified

- **Sending of counterfeit alert**

The user must be able to send a counterfeit alert to the responsible party.

Testing Tools and Environment used

Test Server: Firewall

Network: Mobile internet connection

Test Device setup: Phones with android operating system 4.4

Bug Reporting: A bug reporting tool will be provided to the testers to record faults in the system.

Test cases

Test cases

Cases -1Registering user

Purpose: To ensure that users can register to be able to use the system.

Input: Enter user Data

Pass

1. User enters there registration data in the registration interface
2. The user then submits the data which is validated and the stored in the database
3. Then user receives success message for their registration.

Fail criteria

1. User enters there registration data in the registration interface
2. The user then submits the data which is validated and the stored in the database
3. The user then gets an error message saying “registration failed try again”

Cases -2User Login

Purpose: To ensure that users can register to be able to use the system.

Input: Enter user Data

Pass

1. User enters there login data in the login interface

2. The user then submits the data which is validated and then used to authenticate the user
3. Then user receives success message for their login and dashboard for them to carry out the next task.

Fail criteria

1. User enters there login data in the login interface
2. The user then submits the data which is validated and then used to authenticate the user
3. The user then gets an error message saying “login failed”.

Cases -3 Scan NFC Tag

Purpose: To ensure that the Tag can be scanned using a camera and sent to the servers for verification.

Input: Scan NFC tag ID

Pass

1. User clicks on the scan Tag button
2. The scanned tag ID is compared with the ID in the database.
3. Then the user receives information verifying that the drug is genuine

Fail criteria

1. User clicks on the scan tag button.
2. The scanned ID is queried with database
3. The user then gets an error message saying “verification failed, send counterfeit alert

System validation

This involves presenting the system to the users to check and verify its applicability and gather feedback whether it meets user requirement and functionality. The feedback was analyzed and incorporated in order to redesign the drug verification system.

CHAPTER SIX

Limitations, Conclusion, Recommendation and Future works

6.0 Limitations

There were limitations faced during the development of this project among which included;

1) We had limited knowledge of JAVA and Android studio since the researcher was only introduced to them in only one semester. This contributed to the delays in development of the application hence not complying with the agreed dates of delivery.

2) In addition to that, it was expensive to finance the project from personal funds. A lot of funds were spent on the investigation of the existing system, mainly in form of transportation and communication in the process of linking up with the respondents and friends. Other big expenses were in terms of purchasing relevant software plus printing the drafts and final copies.

3) We also got a challenge of denial of information from majority of the study organizations we had chosen to carry out our research which would lead as to the development of the proposed application

6.1 Recommendation

1) We recommend all parties in the fight against counterfeit products to use serialization as it aone the best and effective ways to fight counterfeit products.

2) On side of government we recommend the National Drug Authority to come up with a policy of registering all drugs both from outside countries and those locally manufactured to be verified before consumption in a bid to fighting counterfeit drugs.

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6.2 Conclusion

The Drug Verification system was aimed at verifying and monitoring drug authenticity in the supply chain in a bid to help combat the circulation of counterfeits in the drug market through the supply chain. This system also helps notify the local drug manufacturers about imposters by sending a notification when a counterfeit drug is detected.

Objectives of the project included

a) To develop verification system for monitoring drug authenticity in the supply chain.
b) To gather and analyze the current system and validate requirements for the new system.
c) To design the system architecture using requirement specification from first phase.
d) To Implement the system

The development of the drug verification system helps vendors to user their Smart phones to verify the authenticity of a drug being dispatched before purchasing in a bid to combat the circulation of counterfeit that would otherwise poise huge health threats to the final consumer.

It also enabled us to identify several loopholes that favor continued circulation of counterfeit drugs in the market

6.3 Future works

Currently, the drug verification system can provide information about whether a dug is authentic or not. However, in future, the system can have much other functionality added to it for example; Drug characteristics, manufacturer's details and pharmacovigilance etc. It can also be integrated with other government parastatal like Uganda National Bureau of standards (UNBS) and National Drug Authority (NDA)

6.4 Appendix

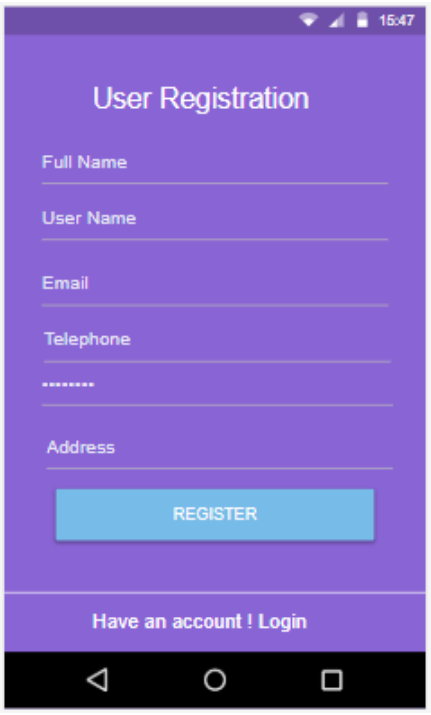

Figure 9: A screen shot of user registration form for the mobile based verification system

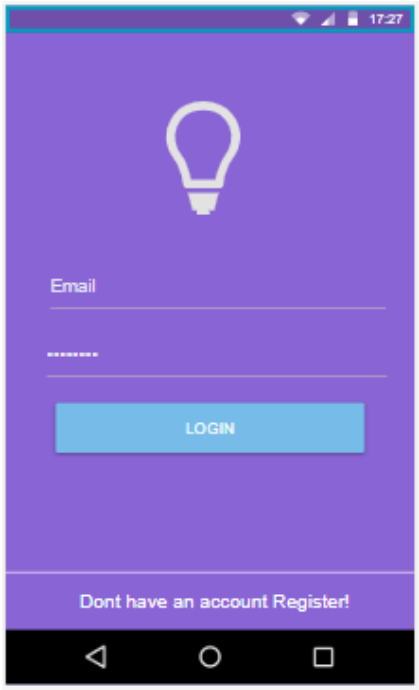

Figure 10: A screen shot of the user login page

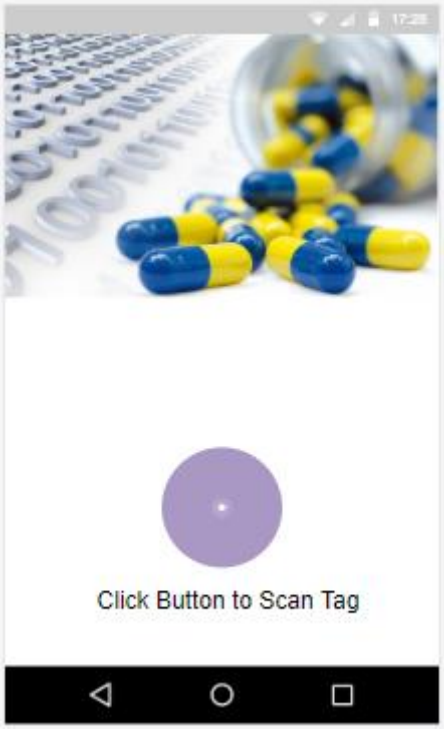

Figure 11: A screen shot showing where a user taps to scan NFC tag

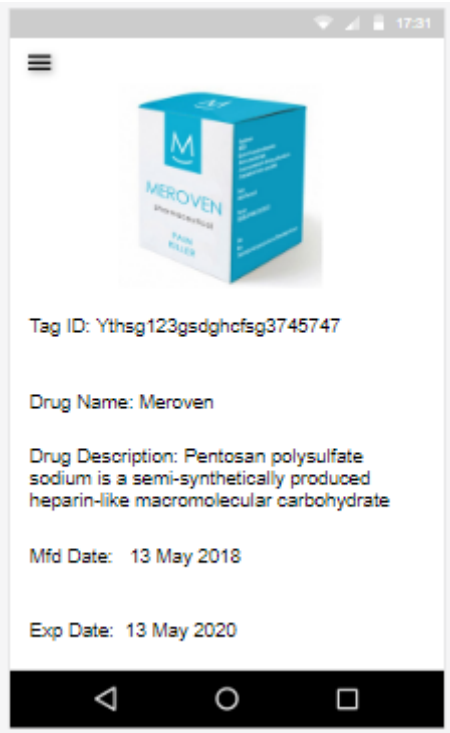

Figure 12: A screen shot showing the drug information after the tag has been scanned

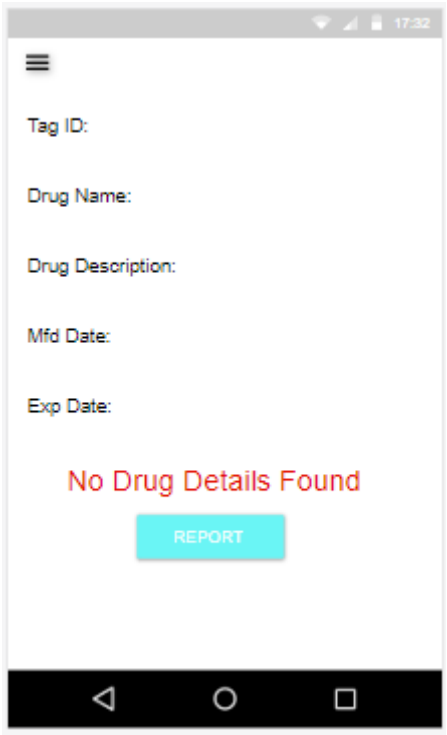

Figure 13: A screen shot returning "No drug detail found and an option to report"

6.5 References

Emmanuel A. (2017).Daily Monitor.*Counterfeit cancer drugs sold in Uganda*. doi: https://www.monitor.co.ug/News/National/Resistance-looms-as-Ugandans-consume-more-fake medicines/688334-1413306-5kobj6z/index.html

Javid et *al*. (2017). Medicines Management in Hospitals: *A Supply Chain Perspective*.

Jocelyne Sambira. (2013).Counterfeit drugs raise Africa's temperature. doi: https://www.un.org/africarenewal/magazine/may-2013/counterfeit-drugs-raise-africa%E2%80%99s-temperature

William L. et *al*(2016). Public health interventions to protect against falsified medicines: a systematic review of international, national and local policies.

Denis B. et *al,* (2018). The Untold Story about Counterfeit Medicines and Its Effects on the Right to Health in Uganda. doi: http://www.peah.it/2018/09/the-untold-story-about-counterfeit-medicines-and-its-effects-on-the-right-to-health-in-uganda/

WHO (2010). Bulletin of the World Health Organization .*Growing threat from counterfeit medicines. 88(4)* doi: http://www.who.int/bulletin/volumes/88/4/10-020410/en/

Linus M. et *al,* (2016). Public Awareness and Identification of Counterfeit Drugs in Tanzania: A View on Antimalarial Drugs. Vol.2016 doi: http://dx.doi.org/10.1155/2016/6254157

Combating Counterfeit Drugs: A Report of the Food and Drug Administration. https://www.fda.gov/downloads/drugs/drugsafety/ucm169880.pdf

Gianmarco B.et *al* (2015). Survey of techniques for the fight against counterfeit goods and Intellectual Property Rights (IPR) infringement.

Kristina Acri (2018). They cost us billions and they can kill: Counterfeit drugs are invading Canada .doi: https://business.financialpost.com/opinion/they-cost-us-billions-and-they-can-kill-counterfeit-drugs-are-invading-canada

Akuse RM, et *al* (2012). Diagnosing renal failure due to diethylene glycol in children in a resource-constrained setting. *Pediatric Nephrology*.

Berendes S, et *al (2011)*. Quality of private and public ambulatory health care in low and middle-income countries: Systematic review of comparative studies. PLoS Medicine.

Athumani R. (2012). Tanzania:Tanzania Daily News.*Factory closed over fake ARVs*.

Polgreen L. (2009). New York Times. *Children are killed by medicine in Nigeria*.

Taylor P. (2013). Fake HIV medications uncovered in Kenya.
Retrived from: http://www.securingindustry.com/pharmaceuticals/fake-hiv-medications-uncovered-in-kenya/s40/a1095.

Buckley GJ et *al* (2013).Countering the Problem of Falsified and Substandard Drugs.
Retrived from: https://www.ncbi.nlm.nih.gov/books/NBK202526/

Christo Hall, (2012).Technology for combating counterfeit medicine.
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4001489/

doi: 10.1179/204777312X13419245939485