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Pharmaceutical Verification and Information System for Authentication of Registered Drugs

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Abstract—

Majority of the world population seek medication on daily basis. The need for pharmaceutical drugs after consultation requires each person to buy or use a drug. The availability of drugs are made possibly by a retailer or druggist in a hospital, pharmacy or any drug related stores licensed to provide easy access to these pharmaceutical resource. In order for consumers to make effective decisions in a drug acquisition process, there is a need to make certain information readily available. The centralization of a mobile system to provide information on registered pharmaceutical products will be of a immerse help to the country and world. Depending on the locality of the user, he/she can research for himself/herself if a drug required to combat a medical dilemma is registered and the information provided fulfils all necessities needed to distribute.

This paper proposed a system that will integrate with all registered drugs and its respective details from the Food and Drugs Authority, Ghana. The paper sets out to provide an intermediate solution to help fight against counterfeit drugs and majorly, unregistered drugs. Our solution allows users to verify the authenticity of the drug about to be purchased and to report otherwise. The Ghanaian drug market is populated with unregistered drugs, counterfeit drugs, expired drugs, unlicensed drugs and expired licensed drugs.

Keywords— drugs safety, pharmaceutical information system, mobile apps

I. INTRODUCTION

With the majority of the world's population seeking required medications for various illnesses and medical conditions day-in-day-out, there is a need for appropriate pharmaceutical drugs. The agencies responsible for regulating and approving these pharmaceutical drugs are doing their best to provide the general population with at least a yearly update of all registered drugs approved for various distributions at local drug stores, hospital pharmacies, private pharmacies and licensed chemical sellers. However, due to challenging factors such as cost of production, middlemen distribution, research and legal issues, accessibility and reliable source of sale, there have been more issues arising from the illegal and unregistered pharmaceutical drugs. There is also no guarantee of an individual seeking medical help through the use of prescription drugs. Records gained after each annual registration will be made available and it will provide the various stakeholders with information regarding pharmaceutical drugs allowed for regulation on the local drug markets and the also the manufacturers responsible for each drug distribution. The stakeholders to make use of the information available include manufacturers, medical institutions, pharmacies and pharmaceutical drug importers, distributors and the general public.

The provision or availability of the system will help the public to be aware of the pharmaceutical drugs that have being approved by the authority in charge. Also, to improve the quality of life by the healthcare community and life in general, and awareness of unregistered and/or fake pharmaceutical drugs to the public and stakeholders. This information of registered pharmaceutical drugs needs to be integrated and made accessible to the majority of population to enable them to view for themselves [1].

Over the years, a number of hybrid solutions have been applied to this problem. In general, they can be classified as employing a combination of stepped-up regulatory enforcement and technological innovation. Being pioneers in technology, industrialized nations have typically enjoyed a good balance between these two key ingredients [2].

Developing nations, however, are comparatively less-endowed and generally not in the position to invest vast amounts in the research and development needed to yield effective anti-counterfeit technologies. Thus, where such countries have chosen to tackle the unregistered pharmaceutical drug problem, stepped up regulatory enforcement (syndicated raids and legal proceedings) is the only deployable tool. Fortunately, the need for technological assistance to the enforcement-only

approach has been identified, and innovators in the first world have developed a number of products. Technologies like Nano-particle taggant, RFID tags and UV-sensitive labels, all require new training and expensive readers currently not present on the developing nation market. Holograms are the leading anti-counterfeit measure, but the mature technology is currently subject to routine counterfeiting due to low cost reproduction equipment. All these solutions will not give the consumer control in checking the validity of the drugs at the point of sale, but a system that can be with them, such as an online system for checking registered pharmaceutical drugs, will aid to an extent [3].

As users of pharmaceutical drugs, being able to identify these unregistered and fake drugs has become very challenging in recent times. What baffles many is why and how some of these fake pharmaceutical drugs find their way on to the market without the knowledge and approval of the FDA. Some even believe that to cover their incompetence, the FDA, once in a while, picks on one of the local companies simply to give the impression that it is working. "In a statement issued on October 8, 2013, Imani Ghana said the FDA could not absolve itself from the apparent retrogressing in quality terms of products by the pharmaceutical companies as it has failed to ramp up its own internal capacity to lift up Ghanaian pharmaceutical companies."[4]

There is also the belief that the regulators have to "review the processes involved in the registration of pharmaceutical drugs in the country including, but not limited to, evaluation of documents/dossiers, average throughput time for registration, risk/analytical assessment reports of pharmaceutical drugs, the entry and clearance of pharmaceutical product at the various points of entry."The Food and Drugs Authority occasionally publishes list of registered drugs but by then the harm of these unregistered pharmaceutical drugs will/have already crippled our healthcare system and markets.

Interestingly, most of these companies have advertisements of the apparently fake drugs running on radio, television and in newspapers on daily basis. As a result, there are so many ways of ascertaining the availability of particular pharmaceutical drugs at any drug outlet. This leads to situations where majority of the population seeking healthcare solutions to variety of health problems not being able to cure themselves efficiently and effectively. There is currently no centralized system of checking list of registered and unregistered pharmaceutical drugs when needed. Depending on the locality of the user, he/she can research for himself/herself if a drug being purchased is registered and has fulfilled all necessities needed to distribute and sell to the Ghanaian population. .

II. LITERATURE REVIEW

The World Health Organization (WHO) defines counterfeit medicine as one, which is deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging. Counterfeit drugs are packaged and labelled to look like actual brand name drugs or generic drugs. This false packaging is to deceive you into thinking that you are buying a legitimate product.

Counterfeit medicines and other health products can have harmful effects on patients' health, including death in worst-case scenarios. These fake products are also detrimental to public health, efforts to deal with disease in countries, which are already stretched thin with limited resources for health care. The counterfeiting of medicines has been a problem for at least two decades in many countries around the world. As international markets expand and become globalized, the problem has extended to all countries and regions; even though it remains more prevalent in developing countries. The increase in the commercial use of the Internet has also contributed to a growth of the problem as many fake products are sold illegally on unauthorized web sites. The counterfeit drugs industry is estimated to be worth $200 Billion a year. The sale of counterfeit drugs kills up to 10,000 Africans each year and creates between 2 to 5% tax losses for governments around the world.[5] The World Health Organization (WHO) estimates that counterfeit drugs are associated with up to 20% of the one million malaria deaths worldwide each year. [6].

Drug counterfeiting is the highest weapon of terrorism against public health, as well as an act of economic sabotage. If you use a counterfeit drug, you may be at risk of serious health problems, including unexpected side effects, allergic reactions, or a worsening of your health condition. These can occur because a counterfeit drug may[7]:

- Be contaminated with harmful substances.
- Contain the wrong active ingredient, which may not treat your condition or may cause unwanted side effects.
- Have too little or none of the active ingredient, which will be insufficient to treat your condition.
- Have excessive active ingredient, which can cause unwanted and potentially dangerous side effects.
- Be packaged in phony wrapping, which may have incorrect directions on how to use the medication.
- Fake drugs are worse than the combined scourge of malaria, HIV/AIDS and armed robbery put together. This is because malaria can be prevented, HIV/AIDS can be avoided and armed robbery may kill a few at a time, but counterfeit/fake drugs kill in mass.

- The social problem posed by hard drugs, cocaine, heroin etc. cannot also be compared with the damage done by fake drugs, because illicit drugs are taken out of choice, and by those that can afford them, but fake drugs are taken by all and anybody can be a victim.
- Fake drugs have led to treatment failures, organ dysfunction or damage, worsening of chronic disease conditions and the death of many citizens. The situation tends to become so bad that even when patients are treated with genuine antibiotics, they no longer respond due to resistance induced by previous intake of fake antibiotics.

A new global campaign by the United Nations Office on Drugs and Crime (UNODC) was launched on the 14th day of January, 2014 to raise awareness among consumers of the $250 billion a year illicit trafficking of counterfeit goods. The campaign – 'Counterfeit: Don't buy into organized crime' – informs consumers that buying counterfeit goods could be funding organized criminal groups, puts consumer health and safety at risk and contributes to other ethical and environmental concerns. The campaign urges consumers to 'look behind' counterfeit goods to boost understanding of the serious repercussions of this illicit trade. - UNODC Press Release[8].

III. SYSTEM DESIGN AND IMPLEMENTATION

The system architectural model encompasses different components of the system, technologies and concepts employed, which include, web services technology used to implement other service principles. SDLC principles and software project management techniques were engaged in the development process. Rapid Application Development (RAD) was used the software building process [9].

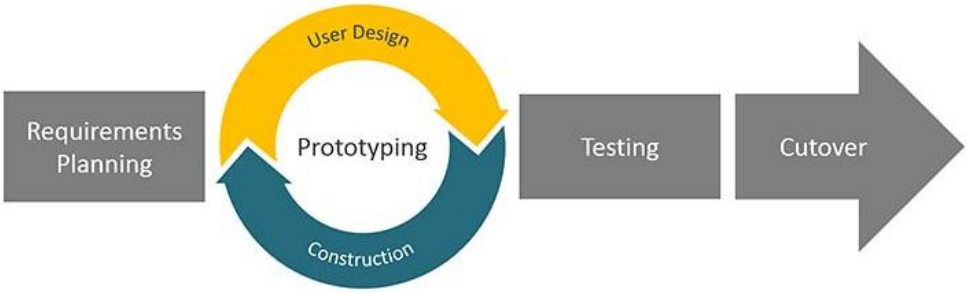

Fig. 1 Stages of the Rapid Application Development

With the RAD we considered the following[10]:

- Requirements planning phase – we combined elements of the system planning and systems analysis at this phase of the Systems Development Life Cycle (SDLC) as it is a generic standardised approach at this level. Discussions and approvals were made on business needs, constraints, project scope, and system requirements.
- User design phase –interactions were made users so as to meet their needs and also with systems analysts and we develop models and prototypes that represent all system processes, inputs, and outputs.
- Construction phase – We built the application at this phase with more focus on program and application. This covered programming and application development, coding, unit-integration and system testing.
- Cutover phase – A delivery of the built system was made at this phase.

The requirement specification entails adequately defining the functionality of a system and the functionality of the system however was placed in two categories:

- Functional requirements
- Non-functional requirements
- The functional requirements of the system include the following modules:
- UI Layer (HTML5/CSS3/JS/PHP)
- Domain Logic (JS/MySQL)
- Native Implementation
- WAMP / XAMPP: software that serves as a host server on a local machine.

A. Use Case Diagram

TABLE I USE CASE DIAGRAM

Use Case	**Description**
Login	The admin enters an assigned user name and a password to have access to the system
Logout	An admin who has logged in successfully exits the system at his/her own convenience by pressing the log out button.
Change Password	An admin who has entered the system successfully re-enters his/her current password and then enters the new password, after meeting the requirement he/she can now proceed by clicking the change password button.
Search for Registered Drug	The external user can easily search for the registered drugs in the system.

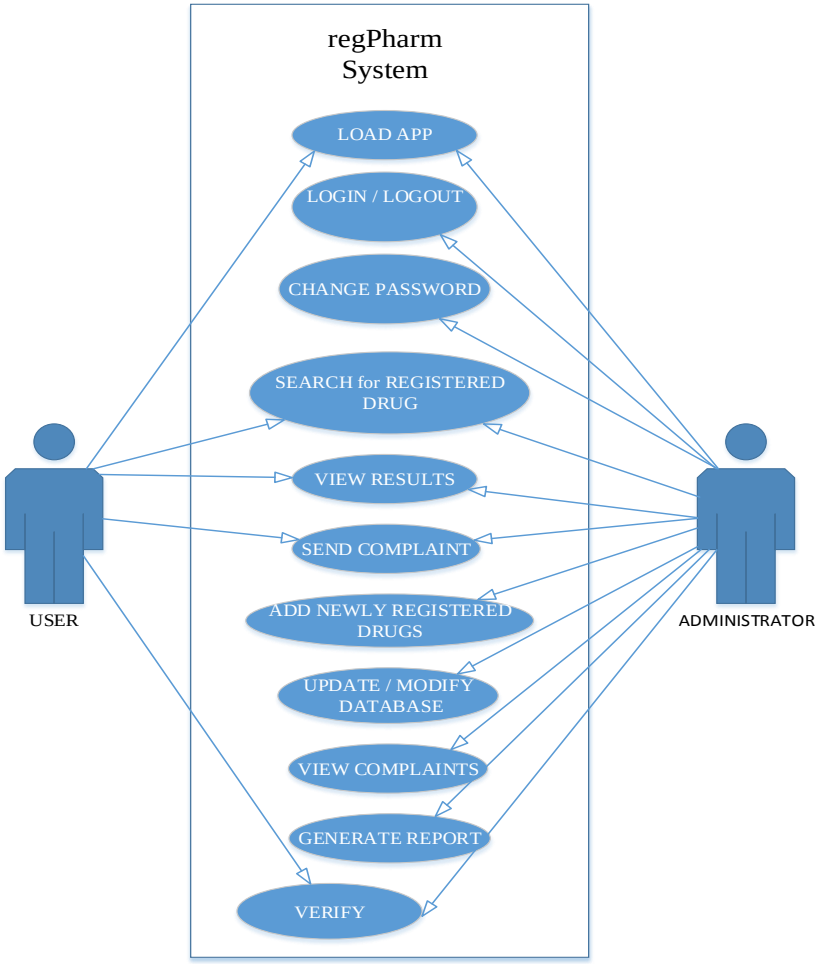

Fig. 2 The Use Case Diagram

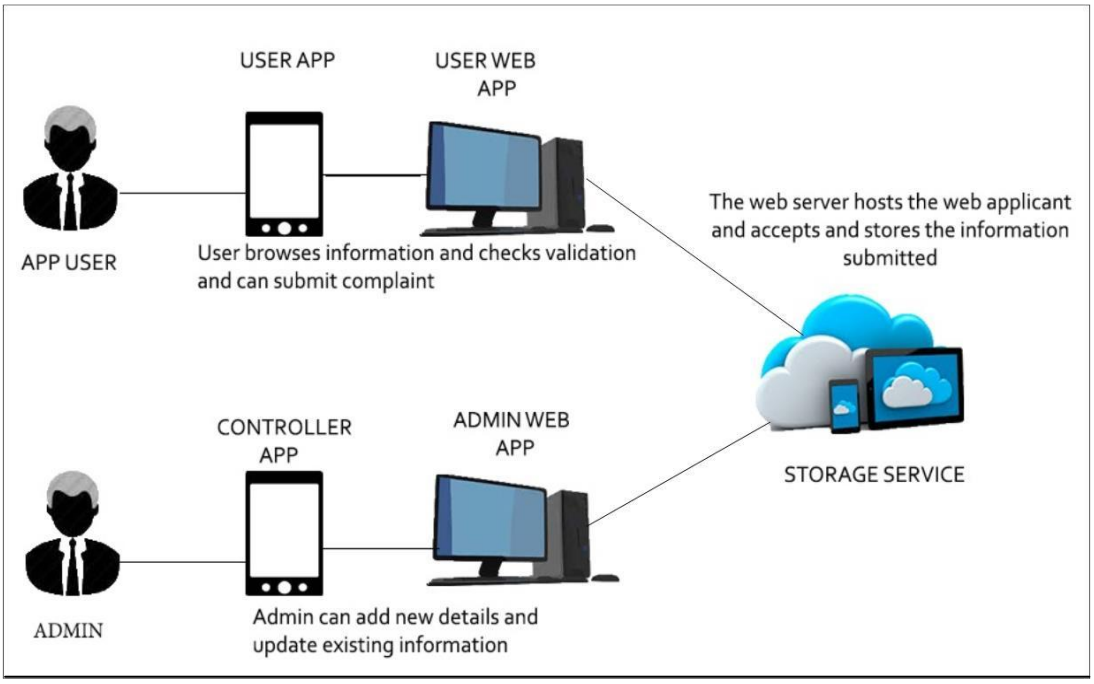

Fig. 3 The System diagram

From the above diagram, a user runs the application from an internet enable Smartphone or tablet running an Android mobile operating system. The user can then browse for registered pharmaceutical drugs and also verify if the drug is legit to be sold on the pharmaceutical market or not. The user can equally access the web app over a desktop computer connected to the internet which then connects to a server for exchange of data and information. The administrator also has a controller application as well as the admin web application to sign in to the back end.

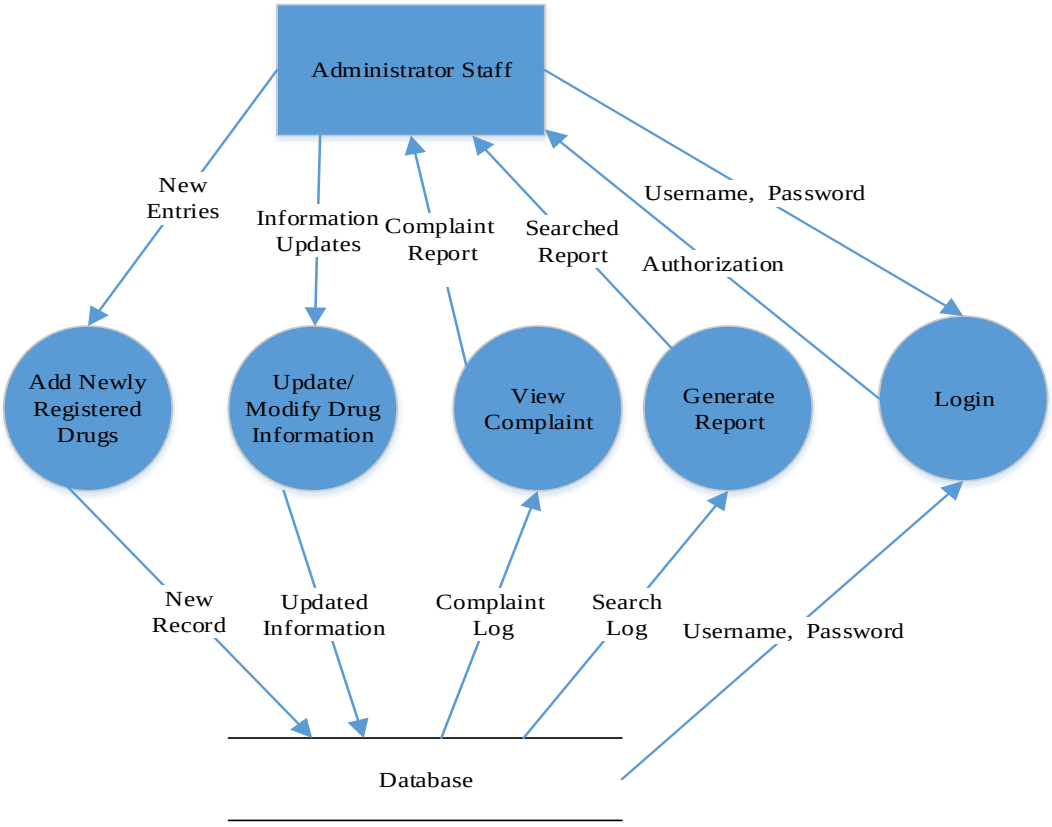

Fig. 4 The Data Flow Diagram for Administrator

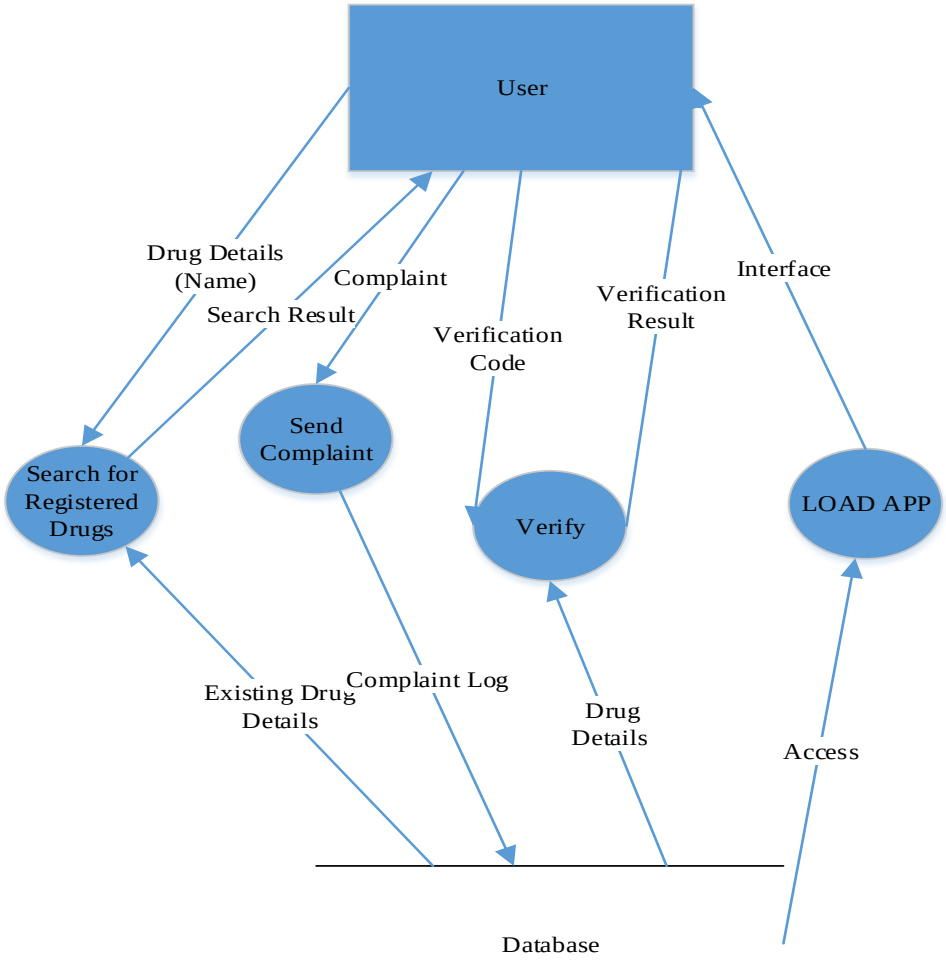

Fig. 5 The Data Flow Diagram for User

The data flow diagram described and analysed the movement of data in a system. The transformation of data from input, through processing, to output, may be described logically and independently of physical components associated with the system.

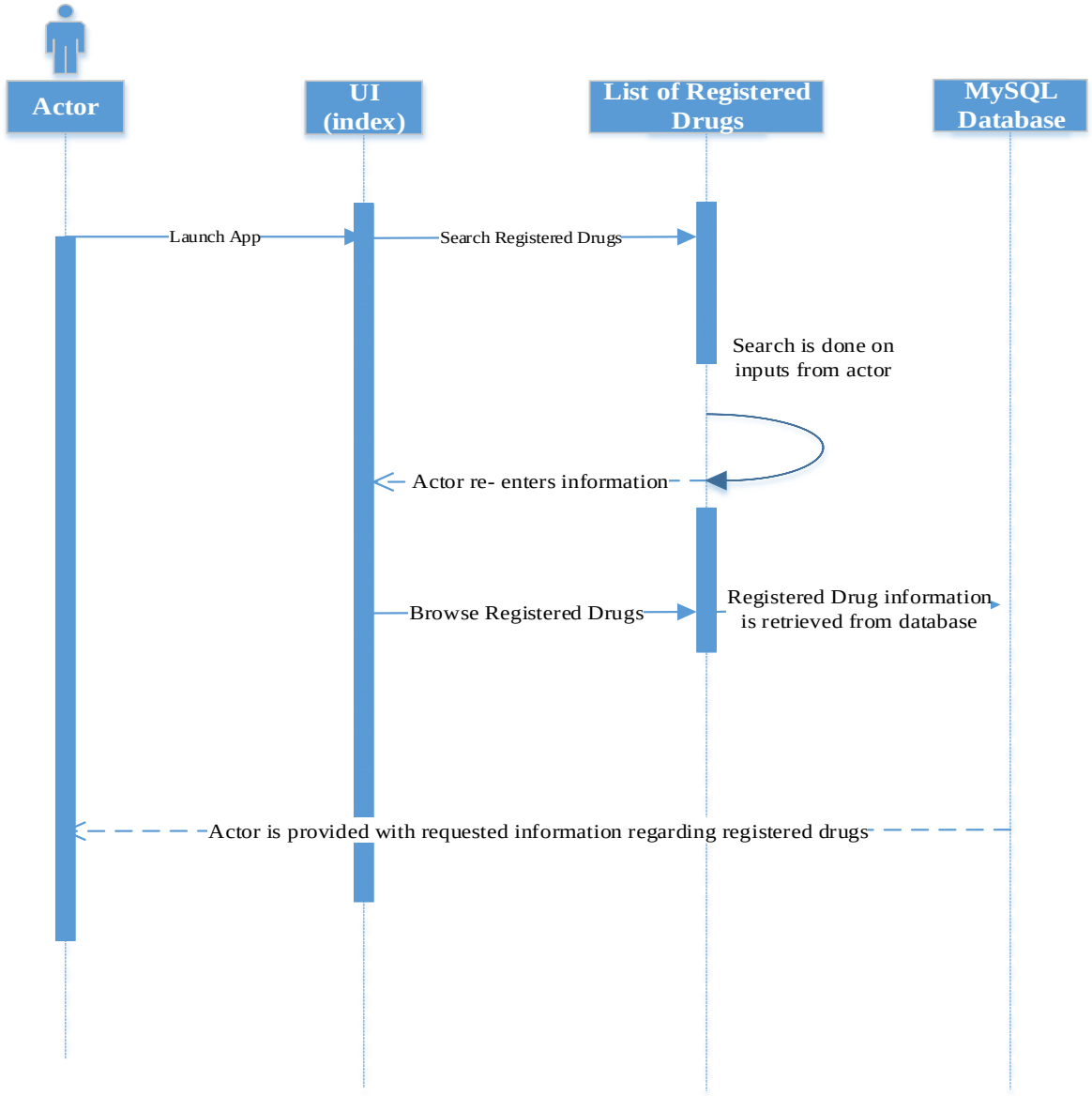

Fig. 6 The sequence diagram

The sequence diagram modelled the collaboration of objects in this project based on a time sequence. The sequence diagram is a UML standard for presenting objects interacting with one another and it shows how each process interacts with the other and the order in which they interact. This illustrates how a user interacts with the system. An actor represents the system user. When the actor opens the application, the actor is taken to the landing page of the application, which is the index.html page, basically, the Home page of the application. The actor can then navigate to other pages to retrieve required information.

IV. RESULTS

The 2012 statistics from ITU indicates that has mobile penetration rate is on the increase. This increase has been made possible by mobile usage; the increase rate now shows that more people are getting access to the internet through their mobile devices. This shows that the market is ready for the type of product that the group has been developed and mobile apps.

Prototyping was extensively used by the team in developing the client application i.e. the mobile application. The first iteration of the prototype which is called "mVerify Alpha" builds. Subsequent prototyping iterations is called “mVerify Beta" builds was used to resolve the issues and to bring performers closer to the final build. The second prototype that was designed for consumers to verify their pharmaceutical drugs whether is registered was based on Mobile App (Android). This build allowed users with smart phones running the Android mobile operating system verify if a pharmaceutical drug package attached with a sticker unique code is keyed into the field given will show the results after a click.

Fig. 7 Revealing and Verifying code

The User Interface of the application software.

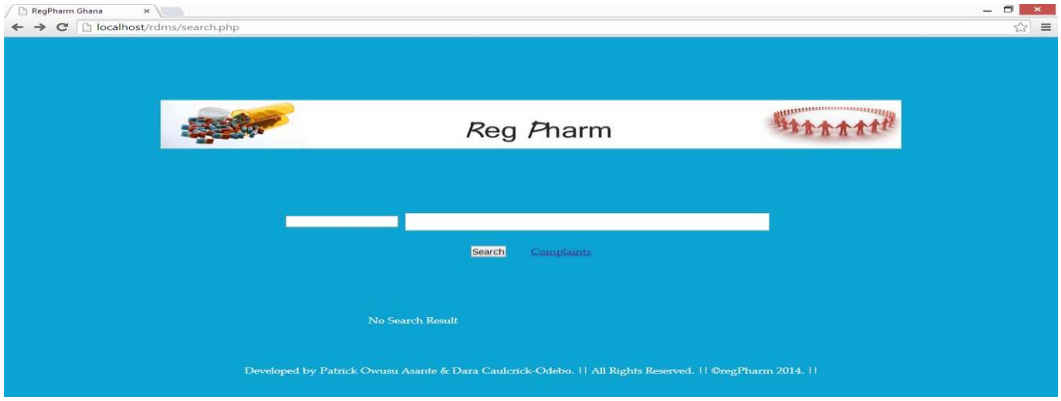

Fig. 8 Search Page

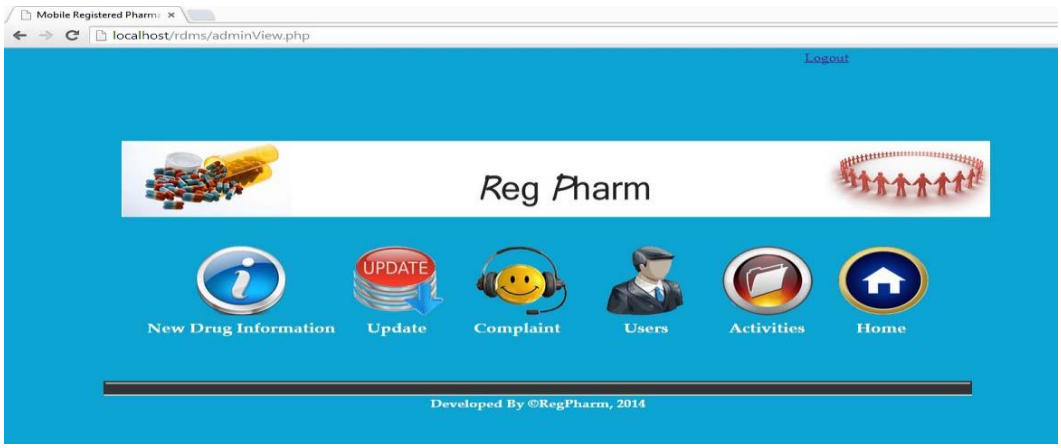

Fig. 9 Admin Switchboard Page

The search link takes you to the search page, which allows the user to search the database for drugs that have been registered with the FDA and the admin page links us to entry for drug and manufacturer information page, update page, admin panel (complaint) and user logs.

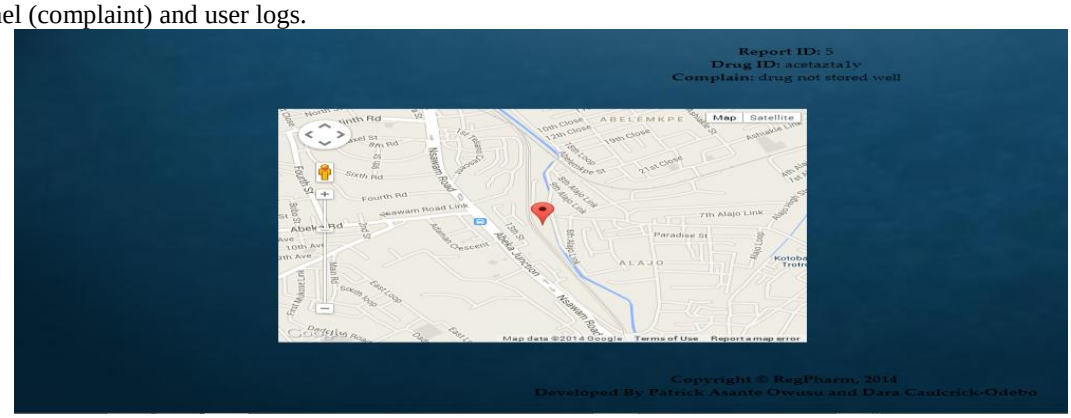

Fig. 9 View Location Page

After users have sent in complaints about unverified drugs, the admin can view the location in which the report was sent from to help locate pharmacies or hospitals that market or sell these counterfeit and/or unregistered drugs.

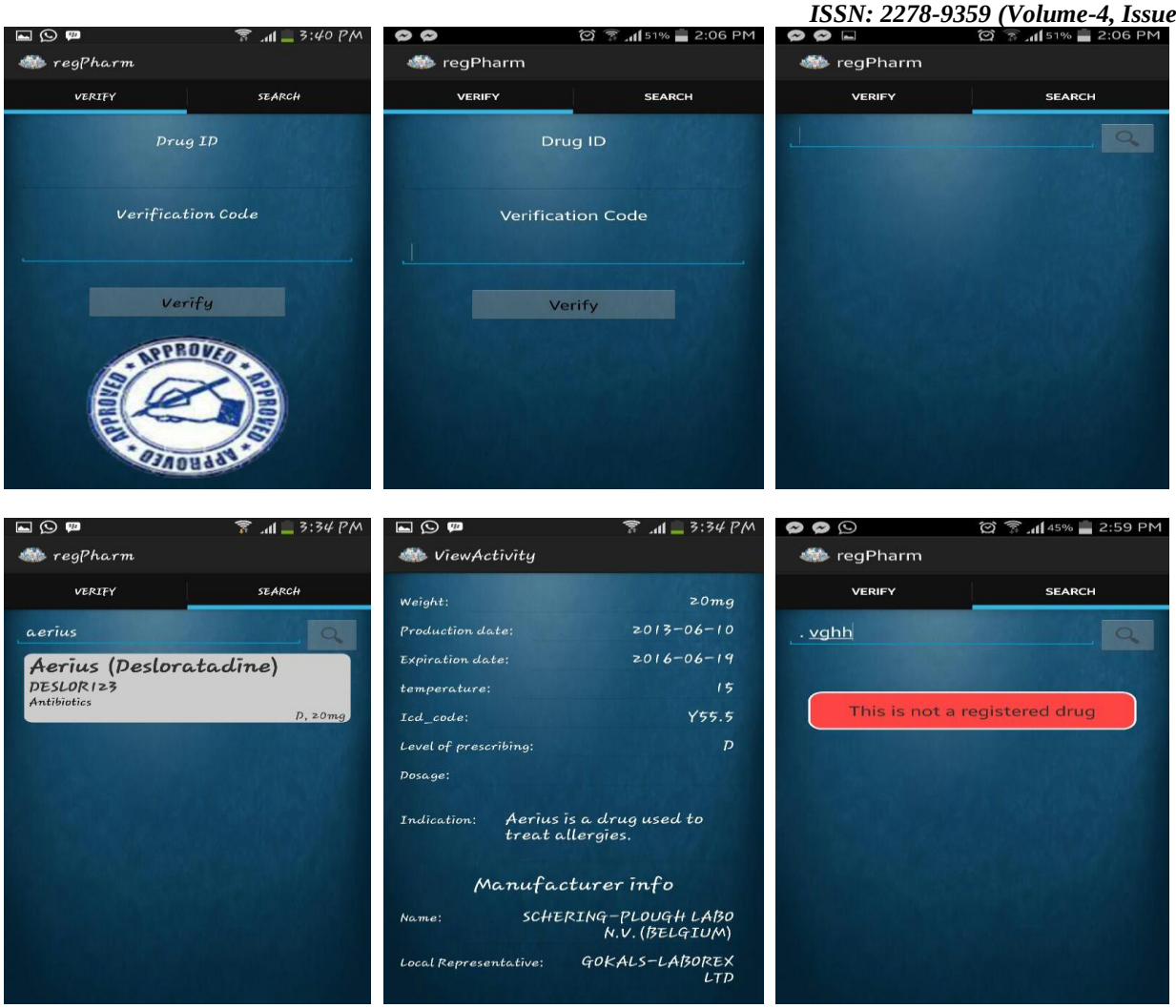

Fig. 10 Mobile Verification Pages

The mobile verification app was developed for smart phones and implemented successfully. For successful adoption of the Pharmaceutical Drug system, there was the need for the group to understand how the users will easily adopt interaction with the systems.

The group identified two key factors and these are:

- Easy to use UI design on both server and mobile application.
- Fast and seamless application feedback.

The application was develop with these factors as a standard.

The application worked and looked similar on a variety of different browsers. The testing was done on the most popular browsers which are:

- Mozilla Firefox
- Google Chrome
- Microsoft Internet Explorer
- Opera
- Safari

The administrative application was tested on the major browser platforms, to ensure that the user experience is uniform throughout the different browsers. The application was tested on a native browser and the popular Operamini mobile browser on a mobile device with Internet capabilities. The layout of the web application loaded beautifully with all the colors, button and logo of the application.

V. CONCLUSIONS

The global counterfeit problem is still on the rise. It was discovered that, when a good relationship is developed between drug product manufacturers, consumers and the government, it would lead to a successful implementation drug verification systems. The system is designed to be beneficial to all stakeholders and there is a need for it to be standardized for identifying drug products. Drug labels are supposed to be tagged or coded with standardized IDs in centralized and open system systems that are made easily available for different devices such as mobile apps, sms

gateway. We also acknowledge the fact that places with no telecommunication network access (Internet Access) will not have access to our system but by using web app to check the validity of the product and hence have to do it via sms gateway.

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