

NAFDAC INFORMATION SYSTEM FOR PRODUCT REGISTRATION

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Abstract— The study aims at designing an information system to enhance the registration of products with ease and effectiveness for NAFDAC(National Agency for food and drugs Administration and control) as a case study. This study emerges as a result of the shortcomings discovered in the registration of product in NAFDAC such as typographical error, time consumption, lack of durability and safety of files and inadequate manpower. To design the system, the mode of operation of NAFDAC was enquired with other vital details. The system is design to suit the needs of the users. It also describe the functionality imbedded in the product registration system application, the components, how it operates, its' relevance and future development. Visual basic 6.0programming language was used in other to achieve the required objectives. The systems has been designed, tested and implemented it successfully.

Index Terms—NAFDAC, Information system, computerized database, Fake drug, Testing

I. INTRODUCTION

Technology has advanced rapidly over the years and a result of this the use of computer for registering product has become very easy and less stressful (Jayasuriya, 2007). According to World Health Organization (2006), the rapid usage of computers has changed the ways in which works are done in different sector of industries, so it is important to know that the computer is a good tool to assist in solving these problems.

With the rapid establishment of various companies in Nigeria it is necessary to computerize the product registration process so that it will be easy and faster which will help to reduce the spread of illegal and substandard product which had once led to the untimely death of 84 promising Nigeria children in 2008 it is of utmost importance that product such as food, drugs, cosmetics, water and chemicals are registered before they are advertised and distributed in Nigeria.

The modes of operation of NAFDAC are thus:

- i. All Unregistered companies dealing with health product such as foods, drugs, cosmetics, medical devices, chemical, detergent and package water brings a copy of their company's details to the NAFDAC Zonal offices close to them;

- ii. The NAFDAC officials evaluate and record their details and request for a sample of their product for experimentation;
- iii. After conducting the experiment if the product is good NAFDAC approved the product and attached a registration number and also a certificate of registration to the product; and
- iv. This registration number is attached to all the container or case of this particular product before it can be freely distributed in the country.

Initially, the standard of regulation and registration was to ensure the pharmaceutical quality of medicative products, but subsequently, current developments have led to the evolution of technological systems for the production of quality medicinal product and to ensure public safety as well. The production of these counterfeit drugs is a dilemma that has no straightforward prevention remedy. However, experts in counterfeit eradication are of the opinion that whilst measures can be taken to antagonize the negative effects of counterfeit drugs on the public, preventing the manufacture and production of these drugs completely is almost impossible and therefore needs further exploit (Jayasuriya, 2007).

Nevertheless, suggestions in place by the developed nations to mitigate drug counterfeiting include the use of automated product registration systems, public awareness of genuine products and track and trace technology systems. Jayasuriya (2007) reveal that automated product registration systems facilitate the identification of products that are illegally authorized to be commercialized.

In agreement to this reveal, WHO (2010) has developed guidelines that can assist the developing countries to create simple and efficient product registration systems using computerized databases, enabling assurance that marketing authorizations are coherent with their national drug policy. Furthermore, WHO (2010) stresses that preparation and printing of certificates for genuine products registration and licenses should be automated. Also, this provides a fast and efficient input and output of data, which reduces the registration processing time (WHO, 2010).

A suggestion by (Liang, et al., 2005), is to allow these systems easy access by users, send report using email, fax and phone, and to use single site for data collection and coordination. However, while WHO (2010) acknowledges that these automated product registration systems provides an effective way of reducing the amount of clerical errors that abound to most previously used manual systems which could

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cause duplicate registration number, high security standards must be implemented to avoid the system from being compromised.

One of the feasible conclusions that could be obtained is that, an automated registration system seems to be a better solution to the developing countries such as Nigeria that still register company drugs manually. The task now at hand is to create a prototype of an online registrar system for the NAFDAC that automates the registration process and also create public awareness of the genuine products.

A. Statement of Problem

The method used in NAFDAC Zonal office for product registration, the following problems were discovered. It is time consuming and also tedious to both the NAFDAC officials and the companies' owners. The cost of transportation is expensive and greater number of staff is needed for data collection and recording which result to greater cost of running the organization.

The present system is limited because of inadequate space to store ever increasing document that are not yet computed. This method does not allow for durability and safety of files because they could be easily misplaced, torn or destroyed before they are computed.

The insurgence of fake/counterfeit, substandard and other unwholesome regulated products in societies gave the leadership of the agency tough time. It has been demonstrated by a number of studies that medicine induces morbidity and mortality are the major problem of which health professionals and the general public are becoming aware.

B. Objectives of the Study

The main objective of this research work is to make improvement on the design of information system for product registration. The specific objectives are:

- i. To reduce the time spent and stress involved on product registration;
- ii. To introduce an online registration for new customer intending to register their product and communicate the procedures involved in product registration process; and
- iii. To publish list of acceptable industries that has been approved and list of fake industries dealing in some items.

C. Significance of the Study

Due to the stress involved in registering product such as food, drugs, cosmetics, water, and chemicals to both preventive and curative health care. An application has been incorporated into the NAFDAC websites that enables online registration of product so as to reduce the stress. This innovation makes those that are physically challenge and those whose company are far from the NAFDAC zonal office to register their product through the use of internet thus, making NAFDAC activities more efficient by reducing delays in registration and also save the companies intending to sell drugs and other substance like food and chemicals the stress of going to NAFDAC office for registration since it can be done online. In addition, it reduces the insurgence of fake/counterfeit, substandard and other unwholesome regulated products in our society.

II. LITERATURE REVIEW

The Decree setting up NAFDAC mandated it to regulate and control the importation, exportation, manufacturer, advertisement, distribution, sale and use of food, drugs, cosmetics, medical devices, bottled water and chemicals. This implies that any person wishing to engage in any of the above activities must require the Agency's development guidelines for its operations (Hansen et al., 2014).

A. Product Registration Mechanism

The following mechanisms are put in place to ensure that product registration by NAFDAC is safe and the quality guaranteed Hansen P.R. et al (2014).

i. Documentation

This is aimed at ensuring that the products are coming from statutorily recognized establishment (Hansen et al, 2014).

ii. Screening Of Product Samples

Samples are screened for adequate labeling information, suitable name and address of the manufacturer, packaging materials, ingredient list and direction for use etc. (Hansen et al, 2014).

iii. Inspection Of Establishment

This is necessary to ensure that the factory manufacturing the products is operating a satisfactory manufacturing practice (GMP) so as to build safety into the production process and eliminate contamination (Hansen et al, 2014).

iv. Laboratory Evaluation

All products for registration are evaluated at the agency's laboratories to ensure that they are safe and not adulterated with dangerous substances. For new drugs, clinical trials and conducted before the products are registered (Hansen et al, 2014).

v. Registration Of Regulated Products

NAFDAC Decree No. 15 of 1993 as amended by Decree No. 20 of 1999 defines regulated product as processed foods, medicines for human and animal use, cosmetics, medical devices, detergent, packed water and chemicals. For the benefit of everyone, and in other to promote compliance with the law it is necessary to draw attention to the most fundamental and very important provision of the law, which prohibits the manufacture, importation of unregistered products.

For the avoidance of doubt, registration of every regulated product is made mandatory by the drugs and related product Decree No. 19 of 1993 as amended by Decree No. 20 of 1999 which provides that no processed food, drug, cosmetics, medical devices or packaged water shall be manufactured imported, exported, advertised, sold or distributed in Nigeria unless it has been registered in accordance with the provision of the Decree or regulation made under it. To understand why the law insisted on regulation of all regulated product by NAFDAC, it becomes necessary to elaborate on the purpose of the registration as agency established to protect the public from any harmful effect of unwholesome processed food, medicine, cosmetics, packaged water and chemicals.

B. THE IMPACT OF THE CIRCULATION OF FAKE DRUG

The impact of the circulation of fake drugs and other product is very harmful. The problem is indeed more serious than the effect of hard drug in Nigeria. The impact

of the proliferation of fake drugs can be summarized as follows:

- i. The consumption of fake drugs has resulted in increasing mortality and morbidity of patients to the drugs being administered;
- ii. Erosion of the credibility of our health system: The exposure of patients to sub therapeutic of antibiotic has resulted in the loss of confidence in health care practitioners and health system; and
- iii. Dent on the image of our health system, Nigerian company has been major drugs suppliers to several countries in West Africa sub-region. However, with increasing incident of fake drugs in Nigeria market, most of the countries have banned the importation of drug from Nigeria.

C. Implication of Fake Drugs

The Tide (2014), Drug faking is the greatest evil of our time and the highest weapon of terrorism against public health, as well as an act of economic sabotage:

- i. The evil of fake drugs is 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 robbers may kill a few at a time but counterfeit/fake drug kills in mass; and
- ii. The social problem posed by hard drugs, cocaine, heroin etc. cannot also be compared with the damage done by fake drug, because illicit drugs are taken out of chronic, and by those that can afford them, but fake drugs are taken by all and anyone can be victim.

D. Good Manufacturing Practice Assessments in Developed Nation

Good manufacturing practice (GMP) is a system for ensuring that products are consistently produced and controlled according to safe quality standards appropriate to their intended use and as required by the product specification. It is design to minimize the risks inherent in any product production that can be eliminated completely through testing of the final product as observed by Tide (2014). These risks could be:

- i. Unexpected contaminated products, causing damage to health or even death;
- ii. Incorrect labels, which could cause confusion or mix up and also misinform consumer; and
- iii. Use of inappropriate containers, which can interact with the product to dangerous environment factors resulting in production degradation. GMP covers all aspects of product from the starting material, premises and equipment to the training and personal hygiene of staff.

E. The Importance of Good Manufacturing Practice (GMP)

- i. Poor GMP may result to poor quality regulated product.
- ii. Poor quality medicine and other regulated product not only a health hazard, but a waste of money for both government and other individual consumers. A drug that contains little or none of the claimed ingredient due to poor e GMP will not produce the intended therapeutic effect.
- iii. Most countries will only accept import and sale of medicine that have been manufactured to internationally recognized GMP.

- iv. GMP boosts export of product for a country (The Tide, 2014)

III. RESEARCH METHODOLOGY

The proposed system is based on correcting the short coming of product registration, most part of the operation in the organization is now automated and by this we need to have a system which can correct and give a detail of all registered records and also different levels of registration. By this, we hope to have a system tightly secured in handling the operations that are necessary through the use of password to eradicate the flow of fake product via regulation and control.

A. Feasibility Study

The software is technically feasible due to the fact that all technical equipment required by the programmer are available and it does not involved the use of sophisticated hardware and software which might be very difficult if not impossible to have access to. The program is also economic because the researcher needs not to spend much on buying equipment. Hence it is economic in nature since customer will have easier access to computer anytime and anywhere.

B. Functional Specification

This study is aimed at justifying the importance of electronic data processing system, the use of computers in simulation of product registration and regulation. This product registration software that is proposed is made of several simple programs designed around a simple database management system with each function module available to execute a task. The program is designed to suit users in the case of operations, navigation and interaction. Some of the tasks to be carried out which were divided into different program modules are written below:

- i. Verification registration
- ii. Drug/Food product registration
- iii. Update of additional products
- iv. Delete of registered products
- v. Reports of registered Drugs/Food products.
- vi. Reports of registered companies

C. System Analysis

Presently NAFDAC is making use of a system in product registration. The disadvantages of this system are thus:

- i. The registration is only carried out in NAFDAC Zonal Office;
- ii. It is time consuming and also tedious to both the NAFDAC officials and the company's owners;
- iii. There are typographical errors made by the NAFDAC official in computation as a result of computing so many information and also not understanding what was writing in the company's document;
- iv. The present system is limited because of inadequate space to store ever, increasing document that are not yet computed; and
- v. This method does not allow for durability and safety of files because they could be easily misplaced, torn or destroyed before they are computed owing to the fact that files needs to be collated before they are computed.

The Proposed system is designed to resolve this limitation some of the advantages of the proposed system are:

- i. It saves the cost of transportation to NAFDAC zonal office for registration;

- ii. Its reduces the stress of paper work since files can be sent online;
- iii. It reduce the rate of typographical errors since information is computed by the companies owners themselves and not the NAFDAC officials;
- iv. Its enables easy updating of companies information since there is easy access to the site;
- v. It also reduce the rate of man power since the company's owners can compute the information themselves thereby reducing NAFDAC the cost of employing more workers; and
- vi. The system is user friendly such that you don't need any professional training before you can fill the form.

D. System Design

The proposed system is designed to suit the needs of the users and they are written in codes that can drive the program. A choice of programming language is made for easy understanding and also to save time for the programmer. The purpose of design is for the program to be organized into a logical order. When the program design is completed, it is given a desk check to see whether it is feasible and will produce the predicted result.

E. System Requirement

The design phase is very important in any system development for efficient and successful implementation of the system.

The design of the new system may be considered under the following:

- i. The output it must produce;
- ii. The input it needs to produce these output;
- iii. The operations it must use to produce the output;
- iv. The resources it must use to produce the output; and
- v. Operational and system control;

It is therefore essential that users should be aware of and utilize the system's requirement model for optimum system performance.

i. Minimum Hardware Requirements

Processor	:	Pentium microprocessor
Processor Speed	:	233MHz
RAM	:	64MB
Hard Disk	:	35MB
Key Board	:	104 keys

ii. Software specification

Database	:	MS access
Server	:	Wampserver2.2
Browser	:	Internet Explorer 6.0 up, Firefox, Opera etc.
Programming Language	:	VISUAL BASIC
Graphic Design:		CorelDraw and PowerPoint
Display resolution		should be 800 by 600 pixels and above.

The program can function in the following operating systems: Win 98 or Win Me; Win NT 4.0; Win 2000 Professional; Win Xp; Window Vista; Window 7and; Window 8.

F. Output Design

The output details that are needed to satisfy the system objectives are listed and described below. These details include: i) Company's details; ii) Product details; and iii) Registration details.

G. Input Design

The input data for the software design for the various processes are gotten from the relevant stakeholders of food and drug registration. Each record in the database contains unique information about the record that is described. The input data is entered via the keyboard, which is subsequently stored in the database. Data collected include: i) Company's report; ii) Product report; and iii) Administrative user account.

H. Program Design

The modular programming approach, also known as the bottom programming was used in carrying out the program design for the application package and design for the following modules:

- i. Verification registration;
- ii. Drug/Food product registration;
- iii. Update of additional products for companies;
- iv. Delete of registered products;
- v. Reports of registered Drugs/Food products; and
- vi. Reports of registered companies

The list of registered companies the program is design in such a way that before the access of the registration forms or menu, a password is required.

IV. SYSTEM IMPLEMENTATION AND PROGRAM

A. System Testing

Testing is defined as any activity aimed at evaluating and attribute or capacity of a program or system and that it meets its required results. There are many types of testing strategies such as black box; white box testing that can be used to test a system. Black box testing is used for functional testing; because this method of testing is more concerned with the input and output (external environment) of the system.

B. System Maintenance

System maintenance is essential to the smooth running of the system. This is vital to be in order and avoid unwanted breakdown of both hardware and software, which can lead to system operational delay. The following practices are necessary for maintaining the system.

- i. Regular backup of files on the hard disk to external storage devices.
- ii. Regular scanning of hard disk and other drives for viruses.
- iii. Proper use of the system (i.e. the starting up and shutting down of the system properly to avoid data file corruption)
- iv. Servicing the computer as at when due.
- v. Cleaning the system regularly to avoid dust infection.

C. Program Module Specification

The program modules that make up the product registration software are as shown below:

Table 1: Product registration software modules

S/N	PROGRAM MODULE NAME	MODULE FUNCTION
1	MAIN MENU	Module that carries other menus of the program.
2	VERIFICATION MENU	Module that generate the application for verification registration.
3	DRUG/FOOD MENU	Module that generate the application for drug/food registration.
4	UPDATE AND DELETE MENU	Module that update and delete products.
5	REPORT MENU	Module that generate the report of all product registration.
6	EXIT MENU	Module that close all programs.

D. Program Implementation Phase

The implementation phase is the phase where the new system will be tested or carried to check for the quality of the required new system. The method of implementation that was employed in this project is known as “Parallel Implementation.”

In addition, Parallel implementation is an implementation that is done simultaneously, i.e. the new and old system are carried out in a specific time frame. If the new system meets up the required objective of the organization goal, then the old system will be faced out, else the old system will be returned back.

E. Data Type/Database Structure

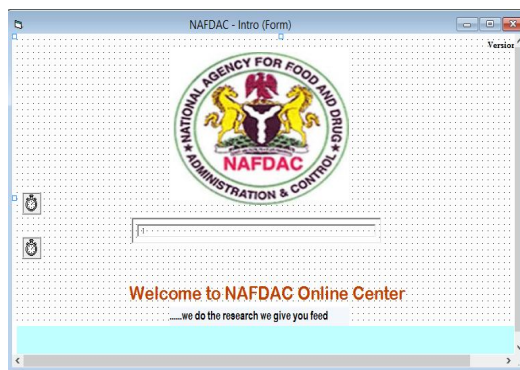
The database design for this program consists of the table listed below.

Table 2: PRODUCT REGISTRATION TABLE

FIELD NAME	DATA TYPE
Company Name	Text
Business Name	Text
Office Address	Text
Branch Address	Text
Email	Text
Website	Text
Number of Staff	Number
Telephone	Number
Fax	Number
Premises Registration No	Text
Certificate of Reg. No	Text
Product category	Text
Product Type	Text
Component used in product	Text
Certificate of manufacturer	Text
Certificate of product	Text
Product Name	Text
Brand Certificate No	Number
Registration Fee	Number
Date of Registration	Date and Time

i. Welcome page

The screen below shows the welcome page of the system



ii. Log in Procedure

To register your product, search product, verify product and view product, just access the server by keying in the URL on your browser. After accessing the product registration website, you must identify yourself. This is done by entering your “Online User Name” and “Password” in the box as shown below.

Furthermore, in solving the problem of insufficient stationary to keep the records, the organization should provide adequate material for the department in charge, considering the purchase of more computer system as priority could solve the problem of inadequate system to do the job. Qualified staff should be employed and a continuous in-house training organization for the staff.

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