REPORT

ON

STUDENT INDUSTRIAL WORK EXPERIENCE SCHEME (SIWES)

JUNE - AUGUST 2019

AT

NEIMETH INTERNATIONAL PHARMACEUTICALS

PLOT 16, AKANNI DOHERTY LAYOUT, OREGUN INDUSTRIAL ESTATE, OREGUN

LAGOS, NIGERIA

PRESENTED BY

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DEPARTMENT OF PHARMACOLOGY AND THERAPEUTICS

AFE BABALOLA UNIVERSITY, ADO-EKITI, EKITI

BEING A REPORT SUBMITTED TO THE SIWES CO-ORDINATOR DEPARTMENT OF PHARMACOLOGY IN PARTIAL FULFILLMENT OF THE REQUIREMENTS PHA408

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DEDICATION

This report is dedicated foremost to Almighty God for his favour, mercy and grace upon my life especially during my 3 months SIWES programme at Neimeth International Pharmaceuticals.

Special dedication also to my parents and siblings for their relentless love and support towards me during the course of my SIWES training and their contribution to making it a successful one.

To God be the glory!

ACKNOWLEDGEMENT

My appreciation goes to the Industrial Training Fund for their foresight in putting this program in place and also to the Department of Pharmacology, Afe Babalola University, Ado-Ekiti, for providing a platform on which I was engaged on the training.

I am grateful to The Neimeth International Pharmaceuticals, Oregun, Lagos for providing me with such an opportunity to be exposed to various research methods and in depth understanding of quality survey and good manufacturing practice.

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To my fellow interns; Benita, Aleemat, Chidinma, Timeyin and others thank you all for making my stay at Neimeth an exciting one.

To my parents and siblings thank you all for your moral and financial support. I cannot wish for a better family.

I am deeply indebted to God almighty, the giver of all wisdom, knowledge and understanding without whom I would have achieved nothing at all.

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ABSTRACT

The Students Industrial Work Experience Scheme (SIWES) is a skills training programme designed to expose and prepare students of universities and other tertiary institutions for the Industrial Work situation they are likely to meet after graduation. The training was done at Neimeth Interanational Pharmaceuticals, Oregun, Lagos between the period of June and August 2019. This report contains information of the industry where the training was undertaken. The description of work carried out includes research survey and good manufacturing practice from raw materials to finished goods. The technical experiences and skills acquired are also outlined briefly.

CHAPTER ONE

1.1 INTRODUCTION

Overview of the Student Industrial Work Experience Scheme (SIWES)

The Students' Industrial Work-Experience Scheme (SIWES) was initiated in 1973 by the Industrial Training Fund (ITF). This was in response to the mandate given to the ITF, through Decree 47 of 1971, charging it with the responsibility of promoting and encouraging the acquisition of skills in the Industry and Commerce with the view to generating a pool of trained indigenous manpower sufficient to meet the needs of the economy. The scheme was designed to expose student to the industrial environment and enable them develop occupational competencies so that they can readily contribute their quota to national, economic and technological development after graduation.

Consequently, SIWES is a planned and structural program based on stated and specific career objectives which are geared towards developing the occupational competencies of participants.

1.2 AIM/OBJECTIVES OF SIWES

The Industrial Training Fund's Policy Document No. 1 of 1973 which established SIWES outlined the objectives of the scheme. The objectives are to:

- Provide an avenue for students in institutions of higher learning to acquire industrial skills and experience during their course of study;
- Prepare the students for industrial work situations that they are likely to meet after graduation;
- Expose students to work methods and techniques in handling equipment and machinery that may not be available in their institutions;
- Make the transition from school to the world of work easier and enhance students' contacts for late job placements;
- Provide students with the opportunities to apply their educational knowledge in real work situations, thereby bridging the gap between theory and practice;
- Enlist and strengthen employers' involvement in the entire educational process through SIWES.

CHAPTER TWO

2.2 DESCRIPTION/HISTORY ON NEIMETH INT'L PHARMACEUTICALS

Neimeth International Pharmaceuticals located Plot 16, Akanni Doherty Layout, Oregun Industrial Estate, Oregun, Lagos. Neimeth International Pharmaceuticals Plc. is the resultant Company from the Mazi Sam I. Ohuabunwa led Management-Buy-Out of the 60% equity holding of Pfizer Inc. New York, USA in Pfizer Products Plc. This Management-Buy-Out took place in May 1997 when Pfizer Inc. in pursuit of its global repositioning strategy, divested 60% equity in Pfizer Products Plc. in favour of the existing management

Before the brand name Neimeth International Pharmaceuticals Plc., the company had operated in Nigeria for 40 years, manufacturing, marketing, and distributing Pfizer brands of pharmaceutical and veterinary products in tablets, capsules, ointment/cream, powder, injectable, and oral liquid forms. During the 40-year period (1957-1997), the company established the first pharmaceutical manufacturing plant in Nigeria at Aba, which was destroyed during the Nigerian civil war. It then set up and opened the most modern pharmaceutical plant in the West African sub-region in 1976 at Oregun, Lagos. These represent great milestones for a company that started as a trading venture in 1957 at a location in Ebute Metta, Lagos.

VISION: To be the leading **pharmaceutical** company and a leader in Corporate Nigeria, through the achievement of excellence in delivering competitive and high quality products and services.

MISSION: Our performance will be driven by our resolve to be the number one pharmaceutical company in Nigeria, maintaining enviable employee welfare scheme, through the provision of quality products and superior returns to all the stakeholders while adding value to indigenous research.

CHAPTER THREE

3.1 SOME LABORATORY EQUIPMENT AND THEIR USES

1. PIPETTE: Pipette is a laboratory tool commonly used to transport a measured volume of liquid, often as a media dispenser.
2. OVEN: Oven is used for the drying, sterilizing, and dehydration of samples. Operating temperatures range is up to 235°C.
3. WEIGHING BALANCE: Weighing balance is an instrument which is used to determine the weight or mass of an object.
4. MORTAR & PESTLE: Mortar & Pestle is used to grind up solid chemicals into fine powder and crush solids into smaller pieces.
5. VERNIER CALIPER: Vernier caliper is for measuring the distance between two opposite side of a surface. It can measure the internal and external dimension and even height of an object with accuracy.
6. DESICCATOR: Desiccator is used to protect chemicals which are hygroscopic or which react with water from humidity.
7. pH METER: pH meter is used in buffer preparation to measure the acidity and alkalinity of a solution.

3.2 ACTIVITIES CARRIED OUT

3.2.1 SALES & MARKETING DEPARTMENT

A survey was carried out on the availability of Neimeth Int'l Pharmaceuticals products in retail pharmaceutical stores and customer demand with the distribution of a questionnaire. I designed the questionnaire for this survey. The findings from the survey will be summarised below.

Availiabilty of Neimeth International Pharmaceuticals Product in Retail Pharmaceutical Stores and Customer Demand in Alagbole-Ojodu, Lagos

Abstract

Successful marketing of pharmaceuticals can improve consumer welfare by increasing incentives for research and development (R&D) investment and by providing guidance to research and development to make it more consistent with consumer preferences[1]. Pharmaceutical promotion is likely to be particularly valuable because information plays a key role, is highly technical, and can change rapidly. Even consumer advertising can potentially improve health[1].

This survey was conducted in Alagbole-Ojodu, Lagos to assess for presence of Neimeth International Pharmaceuticals products in the vicinity as well as customers' demand for the product. Study was conducted between 25th June 2019 to 29th June 2019, with a total of 11 pharmaceutical retail stores were surveyed using the Researcher Developed questionnaire. The collected data was analysed using the SPSS version 23 (SPSS Inc.).

Results shows that Neimeth antimalarial product (Nimartem) was present in 5 of the pharamaceutical stores while none had Antimal. Moreover, all the pharmaceutical stores had Pyrantrin, Normoretic, Tiocosid/Gyno-tiocosid and NCP. Also, none of the pharmaceutical stores surveyed had Flucosyd, Urah, Hibilon, Nimetol. In addition, all pharmaceutical shop surveyed had at least one other non-Neimeth product available for all the classes of drugs/products produced by Neimeth International Pharmaceuticals. Finally, customers **always** demanded for Normoretic in all the pharmaceutical retail stores, Pyrantrin in 10, NCP in 5, Flexodene and Obron 6 each in 1 of the pharmaceutical retail stores surveyed. Unfortunately, customers **never** requested for Urah and Pancemol in 10 of the pharmaceutical retail stores. In summary, although Nimartem was available in some of the

pharmaceutical retail stores but the demand is poor, this calls for urgent market strategy to create awareness.

3.2.2 MANUFACTURING PLANT

3.2.2.1 RAW MATERIALS SECTION

Raw materials are supplied to the industry at the raw material warehouse. Every raw material that comes into the warehouse is documented and issued a Raw Material number for identification. Using the industry specification data, when a raw material is being tested it's labeled with a Yellow sticker "Under test" and after the test has been done, it's labeled with a green sticker "Approved" or a red sticker "Rejected" if it fails the specification.

3.2.2.2 PRODUCTION SECTION

This is divided into two; Wet and Dry section.

Wet Production is where all liquids, ointments are produced. Dry Production is where all tablets, capsules and caplets are produced.

Production is the process of drug manufacturing and can be broken down into a range of unit operations, such as blending, mixing, granulation, milling, coating, tablet pressing, filling and others. The Pharmaceutical manufacturing process has precise requirements and manufacturing guidelines for good quality, therefore, it is necessary that pharmaceutical manufacturing equipment complies with good manufacturing practices.

In the pharmacy, the active ingredients and excipients for a drug production are weighed, then taken to the production floor. The work surfaces in areas where materials are weighed and dispensed should be smooth and sealed, permitting their proper cleaning.

In wet production, liquids are frequently charged and discharged from containers. Liquids are separated based upon their physical properties (e.g., density, solubility and miscibility). Liquids are mixed in compounding operations to produce solutions, suspensions, syrups, ointments and pastes. Liquids are often transferred between storage vessels, containers and process equipment during pharmaceutical manufacturing operations. After the production of a liquid drug, it is moved from the storage vessels through a pipe to the filling room.

In dry production, solids are frequently charged and discharged from containers and process equipment in pharmaceutical manufacturing operations. Dry and wet solids are granulated to change their physical properties with the use of a granulator. Water- or solvent-wet solids are dried with the aid of a dryer. After drying, the dried solids are milled to change their particle characteristics and produce free-flowing powders. This is then blended to produce homogeneous mixtures. Dry solids are compressed or slugged to compact them, changing their particle properties. Compressed or molded tablets contain mixtures of drug substances and excipients. These tablets may be uncoated or coated with solvent mixtures or aqueous solutions. Capsules are soft or hard gelatin shells. Tablet presses, tablet-coating equipment and capsule-filling machines have different designs and features.

After production, the finished dosage-form products may be packaged in many different types of containers (e.g., plastic or glass bottles, foil blister packs, pouches or sachets, tubes).

3.2.2.3 WORK – IN – PROCESS SECTION

In-process quality control tests are simply routine checks that are performed during production and packaging. These tests are carried out before manufacturing process is completed to ensure that quality products are met before they are approved for consumption and marketing. This section is divided into two; Production and Packaging

- Production

The following are to be carried out during the manufacturing process;

- Checking the weight variation for tablets and capsules at 30 minutes interval of production.
- The disintegration test, dissolution test, hardness, friability of the tablets will be checked at least during the beginning, middle and end of the production.

▪ Disintegration test: This test is provided to determine whether tablets or capsules disintegrate within the prescribed time when placed in a liquid medium under the experimental conditions. Complete disintegration is defined as that state in which any residue of the unit, except fragments of insoluble coating or capsule shell, remaining on the screen of the test apparatus or adhering to the lower surface of the discs, if used, is a soft mass having no palpably firm core.

▪ Dissolution test: The amount of drug substance that goes into solution per unit time under standardized conditions of liquid/solid interface, temperature. The principle is

to know the therapeutic effectiveness during product development and stability assessment.

- Friability test: It's a laboratory technique used to test the durability of tablets during packing processes and transit.
- Hardness test: is used to test the breaking point and structural integrity of a tablet prior to storage, transportation, and handling before usage.
- Leakage test: It's used in the pharmaceutical industry to check the integrity of tablet strips, blister packs and small bottles.

- Physical test is also carried out on random selected drugs.

This physical test includes the length, width, diameter and thickness of the drug. The instrument used to achieve this is a Vernier caliper.

N.B- "Stability test" is a test carried at 3 months interval after drugs have been produced and released into the market till it expires, to know if it's still suitable for consumer consumption. All the production tests will be carried out on the product.

- Packaging

- Line clearance is done.
- When the products are being packaged, it is recorded at 30mins intervals on the record of inspection sheet.

For tablets & capsules; Check that the blisters are sealed properly, ensure the expiry date and LOT number are very visible both on the blister and pack, ensure the blisters packaged are not more or less than the required.

For Liquids & ointments; Check that the containers are good, ensure proper cap sealing and labelling.

- Temperature and relative humidity of rooms (production & packaging floor) are checked three times daily, this is due to the nature of drugs which can affect their effectiveness if produced or stored in a temperature high or less.

3.2.2.4 QUALITY CONTROL SECTION

1. WATER ANALYSIS TEST

Before the commencement of any work on daily basis, the water is tested.

Procedure

A. Potable water: this includes; Before filtration water, After filtration water and Dechlorinated water

Reaction: to 10ml of water, add 2 drops of phenolphthalein, the water sample remains colourless.

This potable water is then tested for presence of zinc and residual chlorine.

B. Purified water: this includes; Deionised source, Storage tank, Deionised lab water, Production water, Recycling loop water

This purified water is then tested for presence of calcium, CO2, oxidizable substances.
Conductivity: conductivity measurements are carried out for the water samples using a conductivity meter.

C. Engineering water: softened water

The hardness of this water is analysed.

D. General Test Conducted for Potable, Purified and Engineering water

The amount of Chloride and sulphate is analysed in this section.

pH: The pH meter is to be used for the measurement of pH

N.B:- This comprehensive water analysis is carried out every Monday, but for the rest of the week pH, conductivity and residual chlorine are analysed.

2. DETERMINATION OF A DRUG ACTIVE CONSTITUENTS USING THE HPLC

HPLC (High Performance Liquid Chromatography)

High-performance liquid chromatography or high-pressure liquid chromatography (HPLC) is a chromatographic method that is used to separate a mixture of compounds in analytical chemistry and biochemistry so as to identify, quantify or purify the individual components of the mixture.

Basic Principle: HPLC utilizes different types of stationary phase (typically, hydrophobic saturated carbon chains), a pump that moves the mobile phase(s) and analyte through the column, and a detector that provides a characteristic retention time for the analyte.

Chromatographic Conditions: such as the wavelength, flow rate, column are evaluated depending on the compound.

Calculation:

$$\text{Unknown Compound(mg/g)} = \frac{\text{Area of sample}}{\text{Area of standard}} \times \frac{\text{Dilution of standard}}{\text{Dilution of sample}} \times \text{Potency of standard}$$

3.2.2.5 GOOD MANUFACTURING PRACTICES (GMP)

Good manufacturing practice (GMP) is a system for ensuring that products are consistently produced and controlled according to quality standards. It is designed to minimize the risks involved in any pharmaceutical production that cannot be eliminated through testing the final product. The main risks are: unexpected contamination of products, causing damage to health or even death; incorrect labels on containers, which could mean that patients receive the wrong medicine; insufficient or too much active ingredient, resulting in ineffective treatment or adverse effects. GMP covers all aspects of production; from the starting materials, premises and equipment to the training and personal hygiene of staff. Detailed, written procedures are essential for each process that could affect the quality of the finished product. There must be systems to provide documented proof that correct procedures are consistently followed at each step in the manufacturing process - every time a product is made.

CHAPTER FOUR

4.1 OBSERVATIONS

- As a student, my first observation was the cognition of the difference between the school environment and the work organization.
- I also observed that safety was so important and it could be seen as the primary goal of every staff of the institution.
- Neatness was also a key attribute in carrying out duties as well as in dressing.

4.2 PROBLEMS ENCOUNTERED

- Due to the cost of some equipment, industrial training students weren't allowed to have access to some equipment.
- The distance of work place from home.

CHAPTER FIVE

5.1 RECOMMENDATION

I use this means to make the following recommendation concerning the training of students in the Industrial Attachments.

- I would like to recommend that the Pharmacology curriculum in Afe Babalola University be adjusted such that practical related to the course starts in 200level, so that students have a familiar approach before embarking on the Industrial training.
- Allowances should be paid to students during the SIWES program, just like NYSC and not after. This would help in a great deal to handle some financial problems during the training.

5.2 CONCLUSION

The student industrial work experience program really was a huge success and a great time of acquisition of knowledge and skills in the pharmaceutical industry. The SIWES program exposed me to how a research survey is carried out, a good working environment, good facilities and solving health issues for the betterment of the environment. During the course of the training, Neimeth staff and other IT colleagues gave me an ideal knowledge of team spirit, work ethics and other good qualities as a student and a scientist.