DRUGS MANUFACTURE IN NIGERIA

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It would be necessary before delving into the details of the manufacture of drugs to explain that what takes place in Nigeria is what is generally referred to as secondary production. This is the manufacture of different dosage forms from raw materials for use by patients. Primary manufacture which in effect is the making of raw materials i.e. antibiotics and steroids etc. manufacture, does not take place in Nigeria presently. In secondary production, facilities that are generally installed in Nigeria include that for the manufacture of dosage forms like tablets, syrups, powders, suppositories, gelatin capsules and injections etc. The operations are of necessity on a small scale when compared with the operations in Europe or America because industry in Nigeria is still in its infancy. Most of the examples that I cite today are derived from my past experiences at Glaxo Nigeria Limited in Apapa and the Glaxo Associates in the U.K.

What is involved in Drug Manufacture

Before one thinks that he wishes to manufacture anything he must possess the generally recognised materials of men, machines and money (not necessarily in that order of priority). The same is true in Nigeria in setting up a drug manufacture outfit. Also more important in Nigeria is the location of the factory which controls the easy availability of the main materials and the ease with which the product will reach the market for sale. The infra-structure required include;

- (i) good roads to the factory and from it
- (ii) good and adequate water supply
- (iii) provision of reasonable electricity supply and
- (iv) adequate buildings and surroundings.

The location of the factory therefore, in Nigeria, must of a necessity be in an urban area so that it can adequately obtain the necessities. Big cities like Lagos, Ibadan, Kano and Benin City are those which are now supporting the nucleus of what we hope to be the manufacturing industry for drugs in Nigeria.

I have assumed that one has raised the necessary finance, adequate for the business, from the bank for industry or from commercial banks and perhaps from promised loans from friends, relations or other financiers. Let us also assume that one has obtained suitable consultancy and recommendations on the site and the plan of the factory and also on the personnel with the necessary technical know-how to manage the business. What more does he need? His know-how from personnel employed must include the following disciplines

- Production
- Marketing
- Transport and Warehousing.

Of course one man may think that he knows enough about all these to constitute by himself these areas of knowledge or that he can find time to supervise others to do the job but I will like to say that he is only looking for trouble. What are the problems in these different

sections? I shall briefly touch on the marketing and transport problems while I leave the production and warehousing aspect for full treatment later.

Marketing

One asks himself the question—shall I make products made by other people to an official standard e.g. Aspirin, Codeine; shall I make a product of my own trade name but similar in activities to those of other people e.g. trade mark names; or shall I make a product of both to keep my machines running.

Why do I want to manufacture? I may have already acquired enough following for my products from the marketing base already established.

I may have a product similar to a fast selling product and feel mine would also do well.

I may simply wish to manufacture, thinking I shall make more profit than just importing and selling.

If one is an entrepreneur he will be well advised not to commence his production by making trade mark products which are completely new in the market. He will have a task in achieving acceptance of these products, an uncertain future for his machines and therefore his profitability, should acceptance be slow; and certainly at the end of the day heart break. If on the other hand he makes official preparations which he could definitely sell under the official names, he will make less profit because his margins will be under pressure from competitors already established in the business.

At Glaxo the first lot of products made commanded reasonable margine and of course had an already established clientele.

Under marketing you consider sales including the detailing force, how to keep them mobile and remunerate them. How to deliver your products. How to control all these forces within your budget and advertise your OTC products to the public may not be an easy matter. You cannot manufacture therefore till you have a minimum but reasonable sales from your product lines.

Production

The hallmark of a good production manager is that he keeps his machines running for most of the time thereby fully recovering his overheads. Once the investment of capital in the buildings and machines and the labour all required in production have been made, there is a constant expense in the account book of the cost of these; whether production takes place or not. If however, production is kept at its optimum, at the end of the day a profit would probably have been made after deducting all the expense from the sales price of the goods. This assumes you sell what you make. A production man in Nigeria trains his staff as we did in early 60's, he supervises them more closely than when they are already skilled. He is constantly inside the factory explaining and answering questions and at the end of the day when the factory shall have closed he will stay behind to do his paper work. The paper work involves:

- (i) Ordering his raw materials, the powders and liquids he uses as starting materials.
- (ii) Ordering his packing materials, the bottles and cartons etc.
- (iii) Ordering spare parts for his machineries to keep the machines from breaking down always while in production.
- (iv) Posting the materials that have been used or have just arrived into his record cards.
- (v) Checking his production plan for the next day in the light of his achievement on the day just finished.

He may of course have staff to do all these if he likes but, he must remember they will cost him money and unless his scale of operation is very large he cannot afford all that. We had the minimum of staff for operating machines, production and packaging and I was the sole office clerk and manager for many years. We also have accounting help from the Sales organisation. Part of the production manager's problems, apart from manufacturing, is storage of the materials which he has ordered, and for which he needs a storekeeper who must take care of these and the finished products.

The materials ought to be stored under a proper storage condition e.g. Vitamin, and antibiotics in cool conditions (air conditioning) which would be monitored by taking regular daily temperature readings. The dates for expiry of these materials must be kept in view to ensure only acceptable materials are used in production. The containers must be adequate for the purpose of storage; the analytical evaluation of the raw materials are done before use. A work-sheet which sets out the identity of the material to be used in manufacture must be of an established formulation which would yield products of stable form from which accurate regualr dosage can be given over its life span. The weighing of the materials must be supervised and the processing must be by standard processing instructions which shall not change unless a thorough revaluation of the finished product is repeated.

The supervision of the process is important, to ensure the life of the product to expiry. On completion of the processing, analytical check of active principles again is required in the laboratory before packaging is commenced.

Packaging

A standard packaging sheet that will set out the components of packing is agreed and it is essential for consumer products that this should not be changed in any way without adequate plans to inform the customers, otherwise doubts about the authenticity of the products will occur. Many fast selling products of many companies are now being copied at the moment with impunity though still on a small scale. The number of personnel involved in the different stages of the production will be dependent on the following factors:-

- 1. The type of product being made
- 2. The quantity of product being made
- The machinery involved in the manufacture (it will be wise to use the most simple machine because of the problems of maintenance).

 The number of product lines that will be manufactured.

It is possible to do a theoretical man-hours demand for any or all the product lines and make allowance for the various unforseen occurrences e.g. electricity cuts, lateness of staff due to road congestion, sickness of staff leading to absenteeism from duty etc. Some products require a minimum number of personnel before the line can be run. These products which are team-work-line products always obtain priority treatment in the case of insufficient people because a reduction in the labour content of the line cannot be undertaken; it is therefore important for a small manufacturer to organise his work as best as possible for the very minimum of staff.

Warehousing and Transporting

When the products have been made according to the agreed worksheet and process instructions, passed by the Analytical laboratory it must now be stored in the warehouse to await actual request from customers. No amount of care taken in the manufacture will be of value if the storage condition of the finished product is not adequate. Due care therefore should be taken to ensure adequate storage is established since the product may stay in the manufacturer's warehouse or the distributors warehouse for a considerable length of time of its life before being required for use by the patient after a sale has been made.

An experienced warehouse man is essential to reduce the losses in the warehouse from:

- (a) damages and breakages
- (b) pilferages
- (c) improper rotation of products (Always use the maxim of first product in first product out).

Records should be able to show the time the materials are put into stock, the average monthly usage of it and therefore obtain an estimate of stock excess to requirements before life to expiry is reached. These will help in the ordering of future stock against budget to reduce losses of this type to absolute minimum. The ordering method adopted in keeping adequate stock to requirement can be various:

- (1) minimum stock level ordering method can be used. Here a specific minimum of materials in stock will triger off an order for an economic ordering quantity of the material or
- (2) time lag period of ordering may be used, i.e. orders are placed regularly on a fixed date only or
- (3) a combination of both the above methods. It is important not to run out of stock otherwise labour will be paid for doing little or no work.

Whatever method is used it must be able to conserve money while giving adequate stocks of the material for use in production.

Both materials for use and finished product for sale must be moved from one position in the town to another. It would be necessary to control these movements to ensure that the conditions under which they take place do not detract from the quality of the product in the final state. Different packages therefore need to be examined to decide which one will be adequate for

the type of material being transported. A decision choosing tins or bottles with or without cartons, etc. will be dependent on the cost factor as well as amount of protection that can be obtained the price and the product involved.

All the points enumerated must be evaluated within the framework of Government Legislations as follows:—

- Factory Act—Chapter 66 of the Laws of the Federation of Nigeria—which sets out minimum statutory requirements under the headings Heatlh, safety, welfare, etc. for an establishment employing ten or more persons and involved in manufacturing.
- 2. Pharmacy Legislations
 - (a) Dangerous Drugs Act—Chapter 48 of the Laws of the Federation of Nigeria—which sets out to control dealings in Dangerous Drugs.

- (b) Pharmacy—Chapter 152 of the Laws of the Federation of Nigeria—Fully known to us all.
- (c) Pharmacists Act 1964
- (d) Foods and Drugs Decree 1974.
- (e) Customs Tariff Decrees and a host of others which affect the commercial life of a company under the 1968 Companies Decree.

I have attempted to cover the major points that must be noted and studied to enable manufacture of drugs in Nigeria to be done with minimum headaches, but cannot state that there are enough details in the above. These should be sufficient however to inform an entrepreneur who wishes to establish a drug manufacture organisation to appreciate the need for advice from technically qualified sources and not feel that he can do it all himself.

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