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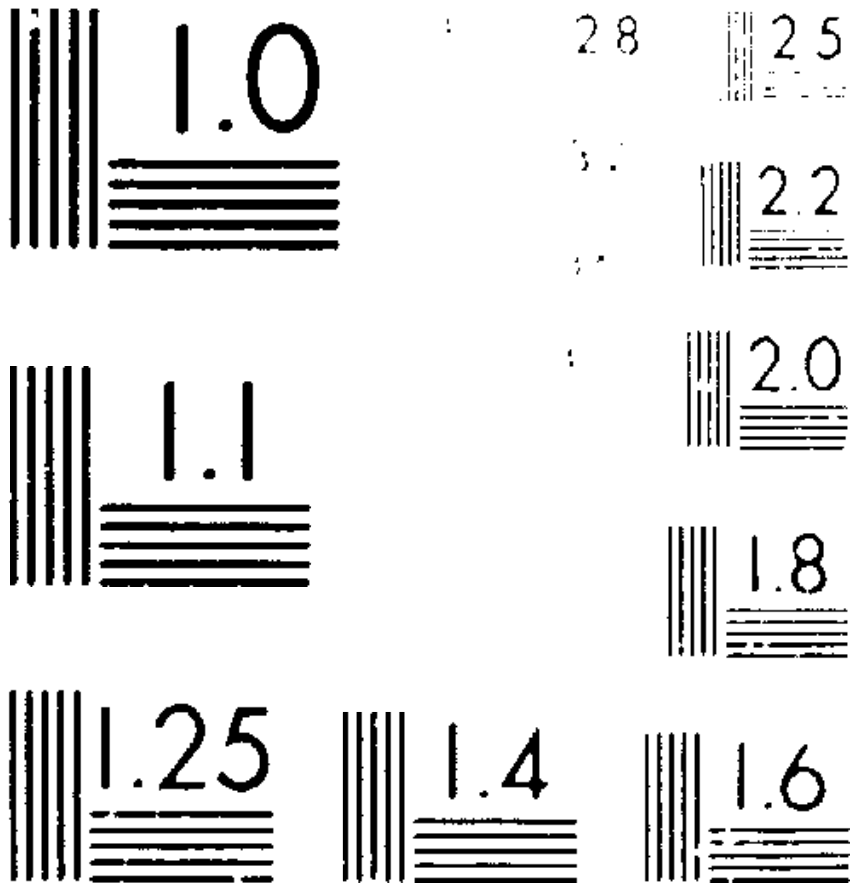
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THE STATUS OF THE PHARMACEUTICAL INDUSTRY IN THE DEVELOPING COUNTRIES IN AFRICA*

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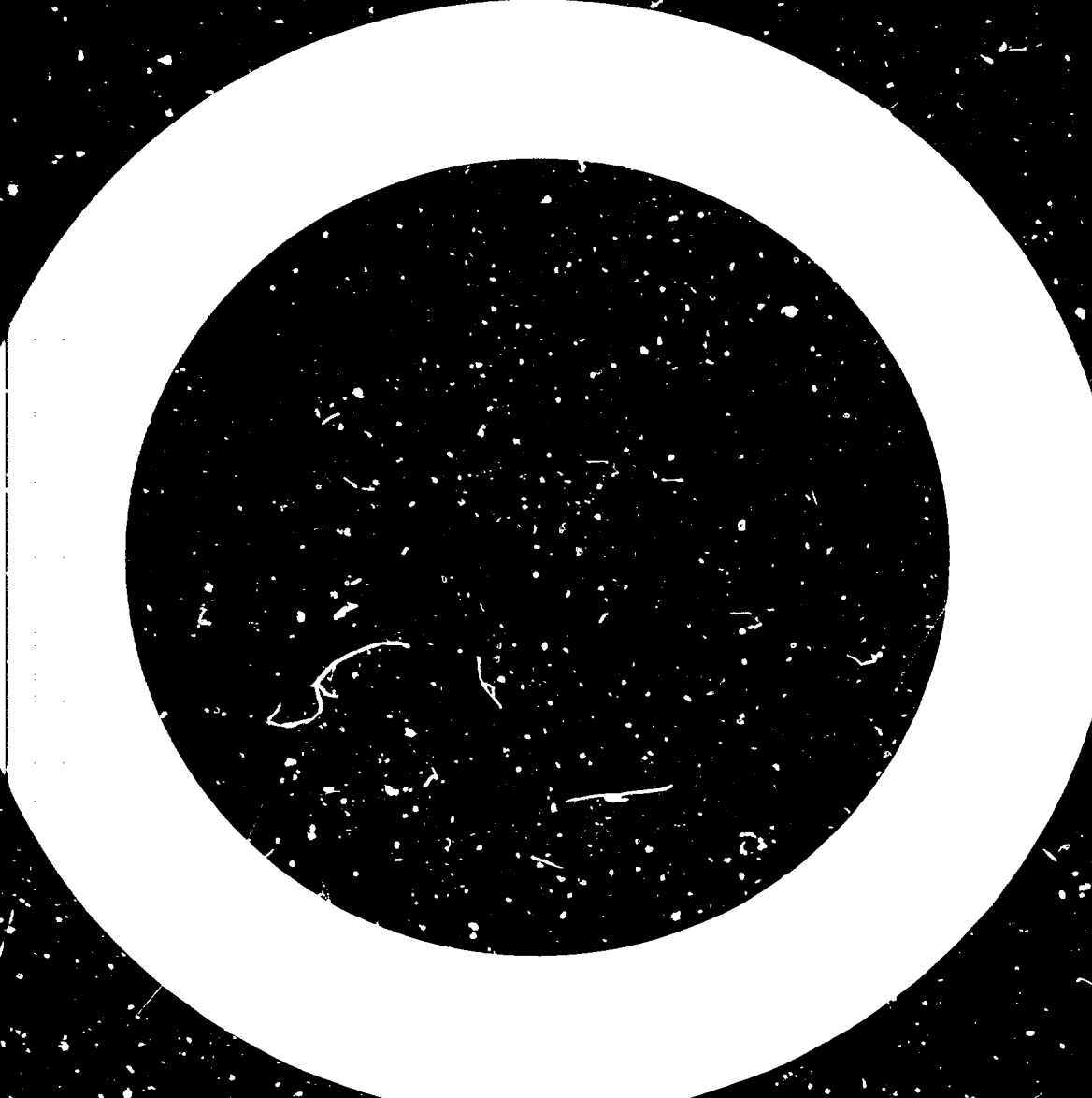

The status of the pharmaceutical industry in the developing countries in Africa

It is well recognized that one of the major components of health care is the supply of drugs both for preventive and curative purposes. However, in many developing countries, especially in Africa, the pharmaceutical products are either not available in appropriate quantities or quality or their costs are unduly high and beyond the reach of most of the people. The national expenditure on health care in the developing countries in general is very limited. For example, in Ethiopia it represented 0.8 percent of GNP in 1978 while the corresponding figure for the Federal Republic of Germany was 8 percent. Consequently the per capita drug consumption in Ethiopia in the same year was US$0.8 compared to US$52 in the Federal Republic of Germany. Apart from this, the expenditure on pharmaceuticals in many developing countries accounts for almost half of the expenditure on health care while it amounts to around 15 percent in the developed countries.

Africa constitutes one of the important regions of the world. The region as such has the lowest consumption of drugs, as can be seen from above, the highest mortality rate and the lowest level of pharmaceutical industry, although Arab Africa is relatively more developed than the other developing countries. (Please see Annex 1).

How long can you depend on donations?

Several developing countries in Africa have been depending on the good will of industrialized countries and donations of pharmaceuticals for preventive as well as curative purposes. While such donations did help to some extent, they are inadequate to remedy the situation with regard to the availability of pharmaceuticals. Further, most of the biologicals being produced in the developed countries are primarily to sustain their immunization programmes. When once the need for certain types of immunization no longer exists in the developed countries, they may stop producing the concerned vaccines and sera. Further, due to increased pressure on the national budgets on account of increase in national expenditure, the developed countries may no longer be able to

continue such donations. In such a situation, the developing countries which have been depending on donations over the years find themselves in a precarious situation, where they would be unable to sustain even their limited immunization programmes. Thus, continued dependency on good-will and donations is not a lasting solution of the problem.

What is the solution?

It is for the developing countries of Africa to rise to the occasion and find a lasting solution. In this connection, it may be pertinent to recall as to how developed countries faced the energy crisis. Many of these countries which have virtually no oil resources of their own had enormous trade deficits due to the steep escalation in the cost of oil imports. They solved the problem through measures such as economising the oil consumption, rehabilitating the use of coal and finding substitutes for oil. It will be appreciated that they solved the problem primarily on account of their initiative and readjustment. Similarly the developing African countries themselves have to solve the problem regarding the availability of pharmaceuticals.

Without such a lasting solution, the slogan "Health for everyone by the year 2000" stays merely as an emotional one. To translate this into action, the necessary links have to be forged. The establishment of local production of pharmaceuticals will be the obvious step to take in order to remedy the situation.

Industrial Policies

No matter whether it is a laboratory, medium scale unit or an industrial scale production - the industrial policies will have to be built into the production unit at every stage and these include industrial design, energy aspects, adaptation of technology, etc. Flexibility has to be built into the design to accommodate changes in the pattern of production as may become necesary from time to time. While planning, it is necessary to make provision for future expansion. It has also to be ensured that the technology used is not only suitable to the environment but is adequate to render the operations viable.

The requirements of energy no doubt assume great importance. In many developing countries, the power supply is often interrupted and this can cause heavy losses to production, particularly in the case of sterile products. To avoid this situation, it would be necessary to provide a stand-by generator. Similarly, the availability of water both in respect of quantity and quality has to be ensured. Special attention has to be paid to the design of ventilation, especially for the units engaged in the manufacture of sterile products. Good pharmaceutical manufacturing practices (GMP) will have to be built into the local production. Another important aspect is the availability of skilled personnel, which is a common problem to many of the countries in Africa. It would, therefore, be necessary to plan manpower and technical skill development alongside the establishment of local industry. It may be necessary to select a group of products for local production in order to render the operations economically viable. Thus the pharmaceutical industry has to be planned like any other industry, of course with additional safeguards as described above.

Apart from above, there are other factors which have to be kept in mind while establishing local production. For example, the production of pharmaceuticals has to be considered from the humanitarian angle and not merely as a commercial proposition. While considering the cost of production of the end product, it has to be recognized that this would depend amongst others on the factors influencing the cost of inputs, many of which may be outside the control of the country concerned. The aspect of infrastructure is equally important. Whereas in Asia and Latin America, many transnational corporations have established their subsidiaries, there are very few such subsidiaries in Africa. In other words, outside investment is not forthcoming in this region. One of the reasons for this is the absence of adequate infrastructure and skilled personnel for the establishment of the pharmaceutical industry.

Wherever proper attention was not paid to the above factors, the industry suffered a severe set back. The optimum utilization of raw materials, manpower and energy and taking into account the environmental aspects contribute to the success of the industry. In the past there have been cases in Africa in which scant attention was paid to some of the above factors and the industry did not make progress beyond the simple formulation and packaging based on imported raw materials.

Overemphasizing the obvious things

It is quite obvious that quality control is a 'must' in the pharmaceutical industry and this has to be built into the production unit right from the raw material stage through to the finished product. However, this aspect is often over emphasized to an extent that the developing countries in several cases are scared to take up local production. It will be appreciated that there is no need to overdo this in such a manner. Further quality control must be enforced in the case of imported pharmaceuticals with the same rigidity as in the case of local production. In practice, however, local production alone is singled out for this purpose and rarely any control is exercised on imported pharmaceuticals. This in its turn works to the detriment of local industry. In view of this, it is necessary to enforce quality control measures in the case of imported pharmaceuticals and extend it to local production.

What are the priorities?

The aspect of establishing local production of pharmaceuticals has to be tackled in a systematic manner on the basis of certain priorities.

(i) Vaccine and sera. 'Prevention is better than cure'. So the immunization programme has considerable significance for Africa. With relatively less investment, facilities can be established for the production of vaccine and sera required for sustaining the immunization programmes on a continuous basis. In this connection, the modular type of construction can be implemented in a relatively shorter period than the traditional method (6 months vs. 36 months) in the absence of building materials such as cement and steel. In the case of modular project, the guarantee can be given on a turnkey basis.

(ii) Utilization of medicinal plants based on modern technology. The extraction of drugs from medicinal plants constitutes a highly promising field for a newly established pharmaceutical industry. Many developing countries in Africa possess a variety of flora long recognized as having medicinal properties, folk medicine having largely been based

on the known effects of certain plants, of which more than 30 are named in the list of essential drugs selected by WHO. Through intensive cultivation or collection in their wild state medicinal plants constitute an important and relatively cheap source of materials for the pharmaceutical industry.

Pharmaceuticals can be produced from medicinal plants either in existing processing and manufacturing units or in multipurpose plants newly established to extract active ingredients from local flora. The developing countries thus instead of exporting medicinal plants could process them for domestic use or for export at greatly enhanced values.

(iii) Production of pharmaceuticals and drugs. Based on the availability of infrastructure, raw materials, technical skills, markets and the industrial criteria, the developing countries can be broadly grouped into three categories as indicated below:

I. The first group primarily comprises the Least Developed Countries where there is no pharmaceutical industry or where there exists such an industry it is in an elementary form and such countries are:

Angola
Benin
Botswana
Burundi
Cape Verde
Central African Republic
Chad
Comores
Gambia
Guinea-Bisau
Lesotho
Malawi
Mali
Mozambique
Niger
Rwanda
Somalia
Sudan
Uganda
Upper Volta

Zaire

In the above countries a beginning can be made with the simple formulation and packaging of pharmaceuticals in dosage form where such an industry does not exist. These countries can also take up the extraction of medicinal plants for export.

As a first step in the development of a national drug industry, it is necessary for every country to prepare a list of drugs which are essential to the well-being of the majority of its population. The essential drug list drawn up by WHO can be taken as a basis for the preparation of such lists for each country. This list also will be useful for taking up the production of pharmaceuticals in dosage form. However this list should be reviewed taking into account the industrial policies mentioned above.

(b) The second group consists of countries where there exists some elementary form of a pharmaceutical industry a. . these include:

Cameroon
Ethiopia
Ghana
Guinea
Nigeria
Morocco
Senegal
United Republic of Tanzania
Zambia

The existing formulation industry such as tabletting can be expanded. New industrial units can also be planned to take up the production of intravenous fluids and injectables-

Before taking up the expansion of the existing formulation industry and entering into more sophisticated operations such as the production of intravenous fluids and injectables, it is again necessary to consider the industrial policies described above.

c) The third group comprises countries where there is an adequate

base for the pharmaceutical industry and some progress has been made in the backward integration into the manufacture of active ingredients and these include:

Algeria
Egypt
Ivory Coast
Kenya
Zimbabwe

Having a well-established pharmaceutical formulation industry, skilled personnel and the market, it is appropriate that the countries in this group should take up the backward integration of the production into the manufacture of bulk drugs or active ingredients based on chemical intermediates or raw materials. For this purpose UNIDO identified 26 essential drugs out of the model list of essential drugs drawn up by WHO and this list has been approved by WHO. The selection of these drugs is also in line with the criteria laid down by the UNIDO Panel of Industrial Experts for the Production of Drugs in Developing Countries (Please see Annex II). These drugs are used widely in the developing countries for treating diseases prevalent in these countries. The developing countries also constitute large markets for many of these drugs. The technology involved in the production of these drugs is relatively more sophisticated than that involved in the formulation of drugs and is available with the Transnational Corporations, countries with centrally planned economies, smaller companies in the developed countries as well as in some of the developing countries.

(iv) Manufacture of Drugs in a Multipurpose Plant.

In many of the developing countries, smaller quantities of a variety of drugs are required. In such cases, a multipurpose plant is suitable for the manufacture of a number of products either sequentially or to some extent simultaneously, using single/double series equipment. Further, in such a plant sophisticated automation is generally not required. A plant of this type will also involve relatively lower investment and the average life of such a plant is also higher.

An additional advantage in the case of a multipurpose plant is that it is versatile enough to take care of new products for which the technology might be under development. In other words, flexibility is built into the design of the multipurpose plant to cope with the varying and ever changing demands of the pharmaceutical market. The design also facilitates a substantial increase in the capacity of the plant by additional investment. Presently, UNIDO is establishing a multipurpose plant for the manufacture of 240 tons per year of 15 synthetic drugs in Cuba based on the technical know-how from India.

(v) Technical co-operation amongst developing countries (TCDC). This also brings up the potentialities of technical co-operation amongst developing countries (TCDC). Som of the developing countries are relatively more 'advanced' than others in the technological field and they would be in a position to assist the sister developing countries in this field. The UNIDO project for the establishment of a multi-purpose plant in Cuba mentioned above illustrates the scope in the field of technology transfer amongst developing countries.

Conclusions: In the foregoing, an effort has been made to make the issue of pharmaceutical industry transparent. Now it is for the governments of African countries to decide upon the course of action which they would like to take in order to find a lasting solution to the problem of non-availability of pharmaceuticals to meet the requirements of their health care programmes. It is realized that no country can ever be truly independent in this sector. However, it is feasible to attain a large measure of self-sufficiency through local production and utilize the scarce foreign exchange resources available to import bulk drugs and active ingredients, specialty pharmaceuticals, etc. UNIDO has the requisite experience and expertise to assist the developing countries in their endeavours to establish local pharmaceutical industry and is willing to assist. (Please see Annex III).

Production level of certain essential drugs in developing countries

COUNTRIES / Africa	Ampicillin	Aspirin	Benhenium hydronaphtoate	Catgut	Cetrimide	Chloroquine	Clofazimine	Diaminodiphenylsulphone	Diethylcarbamazinecitrate	Digitalis glycosides	Ethambutol	Insulin	Isoniazid (INH)	Mebendazol	Metronidazole	Paracetamol (acetaminophenol)	Parachloromethoxylenol	Penicillin Benzyl	Penicillin Pheroxymethyl	Pepsin	Phtalylsulphathiazole	Phtalylsulphacetamide	Pinerazinecitrate	Primaquine	Reserpine	Rifampicin	Sennosides	Streptomycin	Sulphacetamide	Sulphadimidine	Sulphadiamine	Sulphadimethoxine	Sulphaguanidine	Sulphanilamide	Sulphamethiazole	Sulphamethoxypyridamin	Sulphamoxol	Sulphasomidine	Sulphaphenazole	Sulphapyridine	Tetracycline	Tolbutamide	Triplesulpha	Research and Development Facilities
Algeria																																											
Angola																																											
Chad	1	1	1		1	1	1	1	1	1	1	1	1	1	1			1	1			1		1		1	1	1				1			1					1			
Egypt		5		5						2						5		3						2					5	5			5	5						3	5		x
Ethiopia	1	1	1		1	1	1	1	1	1	1	1	1	1	1	1	1	1	1		1		1	1	1		1			1	1			1	1	1					1	1		
Ghana	2	2				2			2				2		2	2			2						2					2			2	1		2					2	2		
Guinea	1	1				2							1	1				1					2										1			1					1			
Morocco																																												
Mozambique	1	1				1		1		1			1	1	1	1			1				1		1	1						1				1					1			
Nigeria																																												
Rwanda		2																2												2	2			2							2			
Sudan																																												
Tunisia						2										2		2	1		1				1					2			2							2			
United Republic of Tanzania	1	2				2										2		2	1		1				1					2			2							2			
Upper Volta																																												
Zambia																																												

Explanation of Table:
1. Imported finished
2. Formulated locally
3. Manufactured from late intermediates
4. Manufactured from early intermediates
5. Manufactured from local raw materials
x. Research and Development Availability
Blank: data not available
Source: Country studies

ILLUSTRATIVE LIST OF 26 ESSENTIAL DRUGS FOR WHICH FACILITIES FOR THE LOCAL MANUFACTURE OF ACTIVE INGREDIENTS SHOULD BE ESTABLISHED IN DEVELOPING COUNTRIES

ANALGESICS

1. Acetylsalicylic acid
2. Paracetamol

ANTI-INFECTIVE DRUGS
Anthelmintic drugs

3. Mebendazole
4. Piperazine

Antibacterial drugs

5. Ampicillin
6. Benzyl Penicillin
7. Erythromycin
8. Sulphadimidine
9. Tetracycline

Antifilarial drugs

10. Diethylcarbamazine

Antileprosy drugs

11. Dapsone

Antimalarial drugs

12. Chloroquine
13. Primaquine

Antituberculosis drugs

14. Ethambutol
15. Isoniazid
16. Streptomycin

CARDIOVASCULAR DRUGS
Antihypertensive drugs

17. Hydralazine
18. Propranolol
19 Reserpine

DIURETICS

20. Furosemide

ANTI-DIABETICS

21. Insulin

ORAL CONTRACEPTIVES

22. Ethinylestradiol + levo-norgestrol.

IMMUNOLOGICALS

23. Blood and Blood fractions

VITAMINS

24. Ascorbic acid
25. Hydroxocobalamin
26. Retinol

Annex III

ACTIVITIES OF UNIDO IN THE PHARMACEUTICAL INDUSTRY SECTOR

During the past ten years, UNIDO has been engaged in the development of the pharmaceutical industry in the developing countries through the provision of technical assistance for the establishment, expansion and improvement of this industry. This comprises the fielding of international experts, provision of equipment, transfer of technology and providing expert services from the planning stage right through to the point of independent production by local enterprises. UNIDO is also concerned with the overall policies of the pharmaceutical industry as for example, the organization of the First Consultation on the Pharmaceutical Industry in the course of which problems hampering the growth of this industry in the Third World were discussed. The follow-up action of this consultation is under implementation.

The activities of UNIDO in the African Region cover practically all the facets of the pharmaceutical industry ranging from the simple packaging of pharmaceuticals in dosage form to the sophisticated production of intravenous fluids, active ingredients and injectables. Amongst the countries where such programmes have either been implemented or under implementation are Cape Verde, Guinea-Bissau, Botswana, Burundi, Rwanda, Uganda, Cameroon, Ghana, Guinea, Tanzania, Zanzibar and Zambia. The project in Cape Verde consists of a unit for the production of simple pharmaceutical formulations and a Quality Control Laboratory, while the unit in Zambia concerns the production of intravenous fluids. With the technical assistance provided by UNIDO, the pharmaceutical division of GIHOC increased its production several times and became one of the most profitable units of GIHOC.

In the field of medicinal plants, a mobile unit equipped with facilities for testing and extraction, sponsored by the Joint UNIDO-Romania Centre, surveyed Botswana, Burundi, Rwanda, Uganda and Tanzania to identify medicinal and aromatic plants which will form the raw materials for the local pharmaceutical industry producing extracts and active ingredients. In this connexion it is pertinent to mention that according to an estimate, 25 per cent of all the prescriptions issued in the USA every year contain one or more drugs from plants. In Cameroon UNIDO is assisting in the rehabilitation of a vegetable oil plant for the extraction of tabernosine alkaloid for use in medicine.