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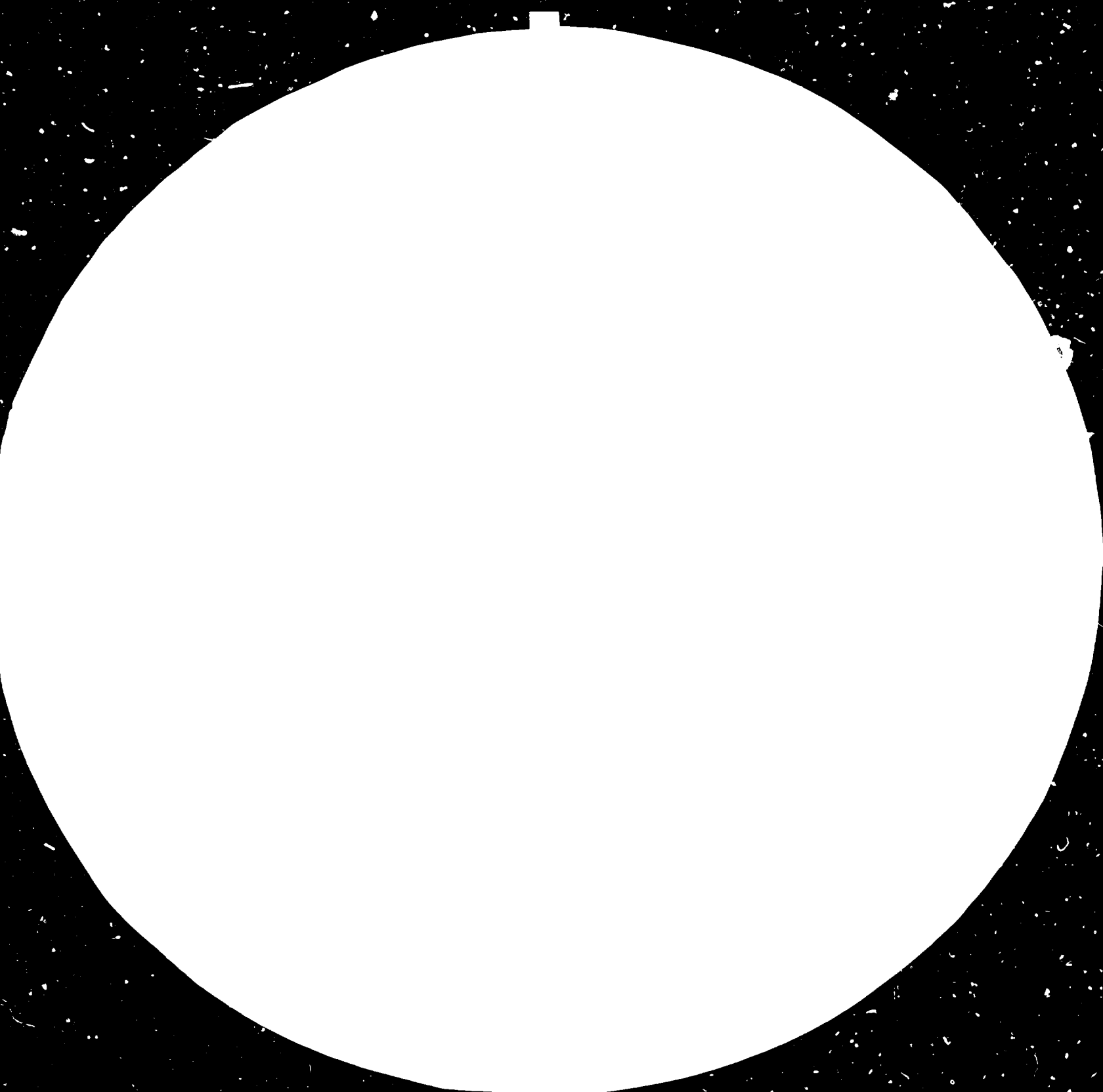

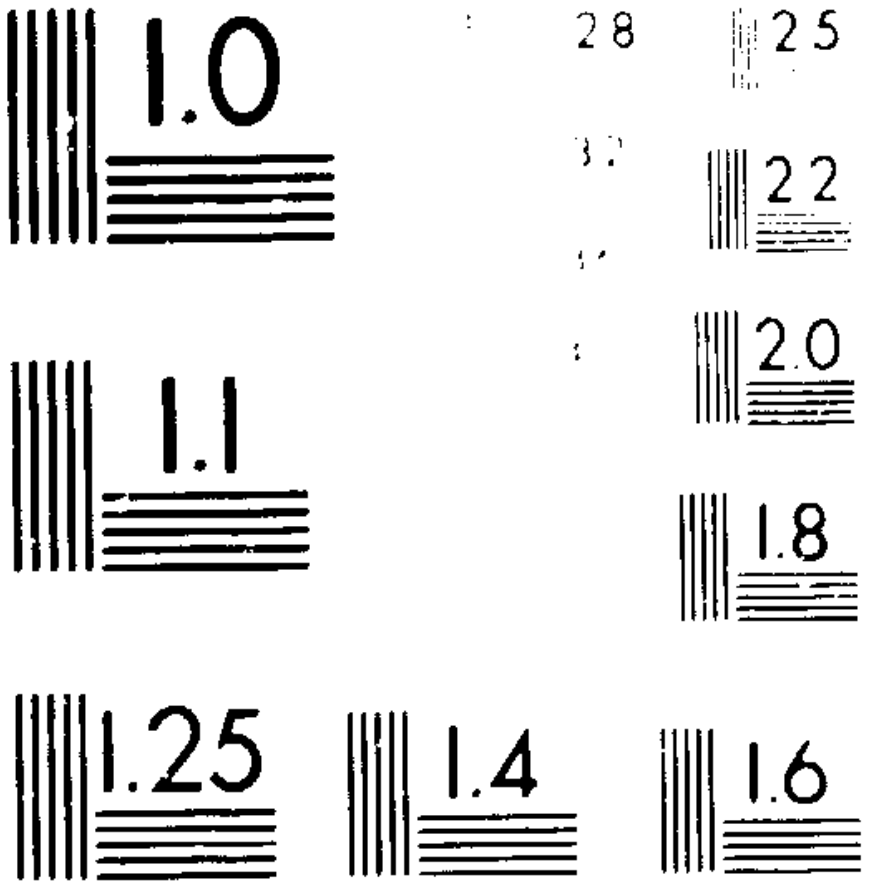

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UNIDO EXPERIENCE IN IMPLEMENTING PHARMACEUTICAL PROJECTS IN DEVELOPING COUNTRIES*

prepared by

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1. Introduction

In a previous paper some aspects of establishment of pharmaceutical industry in developing countries have been discussed. The aim of that study was to give guidance throughout the different stages of development of national pharmaceutical industries highlighting the specific characteristics of each stage. It has been also shown how the different stages of establishment of pharmaceutical are interrelated and especially how the national pharmaceutical policy determines the pharmaceutical production in developing countries.

Based on the UNIDO's experience in developing countries, the prerequisite for the development of a pharmaceutical industry seems to be neither the size of domestic market nor the availability of skilled manpower. The crucial aspect is the government's political decision to promote the development of national pharmaceutical industry. Pharmaceutical projects have been successfully finalized with UNIDO assistance in developing countries of wide range of population. For example, in Africa, both the pilot plant for production of dosage forms in the Cape Verde Islands of 300,000 population and the unit for production of oral rehydration salts in Mozambique of 11 million population show economic viability.

The aim of this paper is to list and discuss the most typical problems by which the governments of developing countries and UNIDO are envisaging during the implementation of a pharmaceutical project and to give recommendations to prevent them. Each stage of the development of a pharmaceutical industry has its own difficulties and therefore they are discussed accordingly. Finally it should be mentioned that the examples given in the following paragraphs have been selected from interim or final reports of different UNIDO projects without referring to the actual source, according to the consecutive stages of implementation. All the reports and documents used, however, are listed as references.

2. Pharmaceutical policy

The promotion of the pharmaceutical industry in an actual stage of development may require a specific pharmaceutical policy of the government. As far as possible this policy should be in accordance with the national health and industrial policies, and it includes drug policy and pharmaceutical industrial policy.

In many developing countries the first and basic obstacle is that the pharmaceutical policy, if it exists at all, does not secure adequate conditions for the development of a national pharmaceutical industry and in that way it passively encourages foreign investment. On the other hand, the foreign investment is advantageous since it creates a healthy competition for the developing domestic pharmaceutical industry.

There is no national formulary of drugs and/or the list of the essential drugs has not been established. Without these documents, an economic production programme providing the widest coverage to people with the most relevant essential drugs at minimum cost is impossible to establish. It should be noted, however, that in order to guarantee the economic viability an industrial approach has to be also applied, considering all the techno-economic factors leading to a more diverse production programme, the so-called "mixed-product approach".

Changes of the economic situation of developing countries may result in political changes, and these may be reflected in the development of pharmaceutical industry. As a result of the changing government or only the replacement of some high government officials, there may be a delay in implementation of the project. This in many cases can be significant and may take even years. In one instance the implementation of a project was delayed for several years as changes in the government altered the project concept which in turn brought about changes in the layout and design of the manufacturing unit. Sometimes there is not only a delay of implementation, but at any stage after conception, projects can be cancelled owing to political changes in a country.

3. Feasibility study

According to UNIDO's experience the feasibility study is generally carried out and without shortcomings. In developing countries, however, without adequate or with outdated pharmaceutical policy the feasibility study should recommend the establishment of such a policy, as a prerequisite of any development in this specific subsector of industry.

4. Engineering phase

The effective project management is essential for good planning, thorough design, completion on time and within budget resources. It is, however, the efficiency which is often lacking in developing countries and since most of the shortcomings and bottlenecks occur in this stage it is important to discuss them in detail.

5. Allocation of funds

As soon as the government has signed the project, funds should be allocated for the construction work. Both convertible and non-convertible inputs are required. In many cases, because of some unforeseeable reason the government is not able to allocate funds for the project, which can be the main cause of delay. It might happen that a construction work scheduled for one year can be completed only in 4-5 years due to this delay at the start. It should be noted that as soon as any delay is noticed the schedule of implementation should be rephased.

6. Specific requirements for pharmaceutical manufacturing facilities

The pharmaceutical manufacturing facilities shall meet the requirements of GNP, which may result in a higher percentage of convertible currency input than is experienced in other subsectors of construction industry. It should bring to the government's attention that the requirements for a pharmaceutical plant is different from those for any other manufacturing facilities. For this reason the construction materials available locally cannot be used, and the import of these materials will increase the convertible currency portion of the budget, which consequently may lead to a further delay in the implementation.

7. National counterpart

The national counterpart or project manager should be appointed as soon as the implementation of the project is started. The project manager should coordinate between the licensor and contractor. If the project manager is replaced for any reason it may affect the implementation of the project since the new manager will not be in possession of information which is necessary and not on file.

8. Lack of competitive construction industry

In many developing countries, there are only a few companies which have the competence for the construction of a pharmaceutical production unit. Even there are cases where there is no real choice since only one single construction company exists. If there is no competitive construction industry, there is no price ceiling and this surcharge will place more constraints on the allocation of funds. On the other hand if a construction company receives contracts under such favourable terms, it may be driven beyond its capacity, causing a new source of delay in the construction work.

9. Equipment

The above delay from varying sources brings about problems especially with regard to equipment. It may be that equipment is procured according to the original schedule but the construction is not proceeding on time, and therefore the equipment cannot be installed, and is stored, unpacked. In one case on record the equipment remained unpacked for five years owing to delay in completion of the construction work. In tropical climates in particular the equipment may become rusty or even obsolete. Furthermore, it is possible that during this prolonged implementation the production programme of the manufacturing unit could also be changed, with the result that completely different equipment would be required to that previously purchased.

10. Trained personnel

Personnel trained for production may lose experience and skill gained during the training course as these were not required due to delay in implementation, resulting in loss of money, time and effort and the necessity for the course to be repeated.

11. Experts

Experts contracted for a fixed-term cannot complete their tasks if the construction work is not ready on time. For example if a production expert arrived according to the schedule prior to completion of the construction work but because of unforeseen circumstances this could not be completed, time would be wasted and the period for the trial runs would be shorter.

12. Production phase

The bottlenecks of this phase are again financial in nature. To run a production plant hundreds of different materials are needed which cannot be procured locally and allocation of convertible currency is required. These materials consist of a wide range of active substances and auxiliary materials for the formulation of dosage forms, packaging materials and spare parts for equipment. Chemicals and auxiliary materials are also required for the quality control. As a rule the above materials should be procured in advance and stored in sufficient quality and quantity to meet the demand of production for at least half a year.

It would result in a tremendous drawback if the government changed the management during the production phase. If that occurred, the experience gained by the management since the conception of the project and during the training would be completely lost.

13. Summary

Based on the UNIDO's experience in developing countries, the prequisite for the development of a pharmaceutical industry seems to be neither the size of domestic market nor the availability of skilled manpower. The crucial aspect is the government's political decision to promote the development of national pharmaceutical industry.

Summarizing the UNIDO's experience in implementing pharmaceutical projects in developing countries it seems to be that the longest delays are occurring during the engineering phase. Due to the delays, not only time is lost, but in most cases this runs parallel with direct wastage of financial resources, manpower and equipment. As indirect wastages one can count the funds which could be saved if the production unit was in operation. Finally, it would be difficult to express the loss of such values as interest and motivation of personnel due to the long delays in completion of the project.

Based on the above UNIDO has come to the conclusion that the use of prefabricated units (or modules) are recommended for the construction work instead of the conventional techniques. According to an estimate of a feasibility study in a project the use of prefabricated units would save 40% of the total investment and the project could be completed in 6 months, instead of 3 years. Even though these figures are optimistic they do demonstrate the main advantages of this new technique.

If the government did not accept this proposal and kept itself to the conventional construction techniques, UNIDO would add its contribution only when completion of construction and engineering works were assured. In such a way UNIDO could be used more economicaly both in developing of trained manpower and equipment required.

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