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SOME CONDITIONS AND PREREQUISITES FOR ESTABLISHING PHARMACEUTICAL INDUSTRY IN DEVELOPING COUNTRIES 1/

by

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The Soviet Union, rendering technical assistance to developing countries in creation of national economy, also takes part in establishing pharmaceutical enterprises in these countries.

This co-operation is accomplished in the following ways:

- participation of Soviet Designing Institutes in preparation of initial designing data by organizations of developing countries.
- project designing,
- delivery of production equipment, control instruments and materials,
- supervision over construction and installation,
- commissioning of plants,
- training of personnel at pharmaceutical plants in the USSR and developing countries.

Such collaboration was carried-out up to now mainly in construction of State Pharmaceutical enterprises.

Therefore, our recommendations, concerning the cardinal conditions and prerequisites for establishing national pharmaceutical industry, are based mainly on the experience gained in this field.

We would like to define that when speaking of independent Pharmaceutical Industry of developing countries we mean mainly enterprises with completed production cycle of various pharmaceuticals in bulk form or processed into ready-made drugs, starting from initial raw materials.

Pharmaceutical enterprises, manufacturing ready - made drugs from imported active substances in bulk form or penultimate products, which after one or two stages of synthesis, carried out at a plant in the developing country, are transformed into the final product, are not fully independent, as they will always depend on import.

Construction of such enterprises, from our point of view, may be considered as the first stage of establishing the national pharmaceutical industry prior to the time, when its own production of main raw materials is organized.

From the other side, even in enterprises producing active substances it is reasonable to provide special Finishing blocks for their processing into formulations and manufacture of ready-made drugs, in order to increase economic efficiency of the plant.

It is meant, that the rest of raw materials, which production is inexpedient, because of small demand or economic inefficiency, may be imported from other countries.

Our experience in designing pharmaceutical enter - prises in a number of developing countries in Asia and

Africa makes it possible to elicit some general conditions and prerequisites for establishing national pharmaceutical industry in such countries.

First of all, in our opinion, it is feasible to aspire to establish ones own production of such pharmaceuticals, which are the most important for Public health service of the given country for medical treatment of widely spread diseases, for instance:

- sulpha drugs.
- anti-TB drugs,
- essential antibiotics as well as additive or second row (reserve) antibiotics.
- preparations for treatment of gastric - intestinal diseases (e.g.chloramphenicol),
- drugs for treating some diseases typical of the given country, for example, filariasis, leprosy, etc.

Our experience shows, that to ascertain the expediency of establishing a national pharmaceutical industry it is necessary that, prior to designing, a thorough technical and economical survey of the pharmaceutical plant or a separate production unit construction in the given country should be made.

The results of this survey determines, to a considerable extent, the feasibility of a pharmaceutical enterprise establishing, profitableness of its operation and competitiveness of the manufactured goods.

The most important element of these studies is preliminary determination of the possibility to supply the pharmaceutical industry with raw materials, since the

availability of a local sources of main bulk raw materials is the key-stone of its independence of foreign markets and, hence, economic stability.

In this connection we would like to dwell on the main kinds of raw materials used in various branches of the pharmaceutical industry.

Chemicals are basic raw materials for production of various pharmaceuticals, obtained by chemical synthesis.

To this kind of raw materials are referred products of the heavy chemicals industry, such as acids, alkalies, some of the inorganic salts, gaseous products, organic solvents, as well as a number of intermediates, produced by organic synthesis from coal-tar distillation products and petrochemicals.

Therefore, to establish a large scale production of the most important synthetic drugs in a developing country, it is expedient primarily to organize local fabrication of essential products of heavy organic synthesis and intermediates on their base. The same is true for antibiotics.

It is considered, that organization of the bulk chemicals and other raw materials production is not meant as an end for itself for the pharmaceutical industry and that its requirements will be met "including", together with chemical, textile, and food industries , as they are relatively small.

Some pharmaceutical plants, as well as the majority of small scale production units, may be based on imported raw materials, if market prices of the given country for

imported raw materials and process know-how make able to produce pharmaceuticals at cost prices competitive with imported into the country by foreign firms.

Establishing local production of the main chemicals and organic intermediates is one of the most important prerequisites for raising profitableness and competitiveness of the synthetic drugs production, if other considerations, such as ensurance of independence from foreign markets, regardless of production cost , are predominant.

In developing countries vegetable raw materials are generally considered more available for fabrication of many pharmaceutical preparations, as the flora of these countries in most cases includes various kinds of medicinal plants, containing active substances, required for manufacturing of a number of phito-chemical preparations - galenics, alcoloids, glycosides, etc.

Organization of collection of wild grown medicinal plants and special farms for cultivation of medicinal plants or utilization of agricultural wastes seems, at first sight, simple and less troublesome task than construction of chemical plants for the production of bulk chemicals, intermediates and pharmaceuticals by organic synthesis.

Resting upon experience, we may say, that such an opinion is not always true and a thorough field survey of raw materials of vegetable origin availability is necessary for specific conditions of the developing country in question.

Such study should have for an object the revealing of sources of wild-grown herbs, possibility of organizing

their cultivation at specially arranged farms, cost of collection, preliminary treatment and transportation in order to evaluate at what reasonable price they could be delivered to the pharmaceutical plant.

In this aspect, a typical example may be given of a would be constructed phito-chemical plant for the extraction of caffeine from tea prunning in one of the developing countries, when due to increase of expected prunning cost by several times against the previously planned one, it turned out in the course of additional studies that such a production is not expedient.

The cost of caffeine obtained under the circumstances from tea prunning exceeded the synthetic one.

Besides, when studying the profitableness of phito-chemical production, it is also necessary to take into consideration the prices of chemicals and organic solvents, their availability, and other factors existing in the country.

The availability and cost of chemical raw materials and solvents may in their turn influence the selection of the production know-how, and also the solvent used as extraction agent.

For instance, in the above mentioned case the replacement of prunning by tea wastes and chloroform solvent by dichloroethane approximates cost price of caffeine produced from vegetable raw materials to the cost price of synthetic caffeine.

Considering the usually bad transportability of ve-

getable raw materials, because of small volume weight, and often unsatisfactory condition of roads in developing countries, that cause high transport expenses, pharmaceutical phito-chemical plants should be brought nearer to the sources of raw materials(for example, to plantations).

Some pharmaceutical plants are large scale manufacturing enterprises with high requirements for electric power, water, steam and may discharge considerable amounts of industrial effluents, therefore their auxiliary services represent an important problem which is to be considered when working-out construction problems of many of the pharmaceutical plants and, first of all, antibiotics, large-scale synthetic drug plants etc. in developing countries.

Many developing countries are situated in the hot climate regions where rivers dry up during the hot period of the year, that's why providing a pharmaceutical plant with water and the discharge of industrial effluents meet considerable difficulties in such countries.

Thus, in order to supply water to the plant it is often necessary to build special intake stations for water purification and delivery to the plant as well as to provide the plant with complex water chilling and recirculation systems, that raises additional running expenses and affects the cost price of the product.

Industrial effluents of Pharmaceutical plants require, as a rule, some preliminary treatment at the plant and sub-

sequent complete purification usually together with domestic faecal effluents at Biological treatment plants where they are brought to the condition allowing their discharge into water basins or irrigation systems.

These installations are also complex and costly in operation.

Pharmaceutical plants consume a considerable amount of electric power for carrying-out the production process, ventilation of production premises as well as for chilling recirculating water and air conditioning.

Power supply sources in developing countries usually have insufficient capacity and, besides, it is necessary to construct power transmission systems for considerable distances to the plant site.

As a rule, construction of auxiliary services for pharmaceutical plants in developing countries is entailed with technical difficulties and requires considerable additional expenses that are to be taken into account prior to plant construction and site selection.

Other problems which, from our point of view, are to be considered when evaluating the constructing a pharmaceutical plant in developing countries and selecting the plant location, are transportation of raw materials and finished products as well as availability of labor and technical personnel.

Taking into account the fact that production of Pharmaceutical plants is usually shipped to a great number of consumers, it is desirable that large plants with great

turnover are located in points with railway siding. For smaller plants, service roads, connected with highways are sufficient.

If the pharmaceutical plant is not situated in the outskirts of a city, a township is to be established near the plant site (observing required sanitary break) in order to ensure a constant labor contingent,

Considering the lack of skilled labor of required specialities in the majority of developing countries we recommend, according to our experience, building of special training centres within the territory of the township for timely labor training.

Building of the township and training centre is to be carried out simultaneously or even somewhat earlier than the plant itself.

When studying problems connected with equipment supply for pharmaceutical plants it is reasonable to consider the possibility of fabrication in the given developing country of some kinds of process equipment.

Experience shows that certain equipment, for example pumps, electric motors, transformers, various reservoirs of mild steel, heat exchangers etc, which is unreasonable to transport from afar, may be fabricated at local plants, while more complicated equipment is to be supplied from industrially developed countries.

Therefore, it is recommended along with equipment deliveries to provide for the supply of required spare parts in sufficient quantities and for a sufficient length of

time, and in some cases even reserve sets of equipment.

When developing the problems of establishing pharmaceutical enterprises in the given country the economics of production should be considered as a deciding factor.

Generally, developing countries ask for technical collaboration in construction of Antibiotics and Synthetic Drugs plants.

It is noteworthy, that as a rule, the authors of such inquiries do not fully realise all the aspects of establishing ones -own pharmaceutical industry - complexity of production processes, the necessity of providing all the above mentioned prerequisites, but are guided mainly by considerations of humanitarian order and the desire to restrict foreign currency expenditures for purchasing imported drugs.

To meet their demand for drugs many developing countries with small population need relatively small plants which potentially may prove to be unprofitable in operation.

Thus, preliminary work out of all aspects (technical and economical backgrounds) of the future pharmaceutical plant establishment in the conditions of the given developing country acquires particular importance.

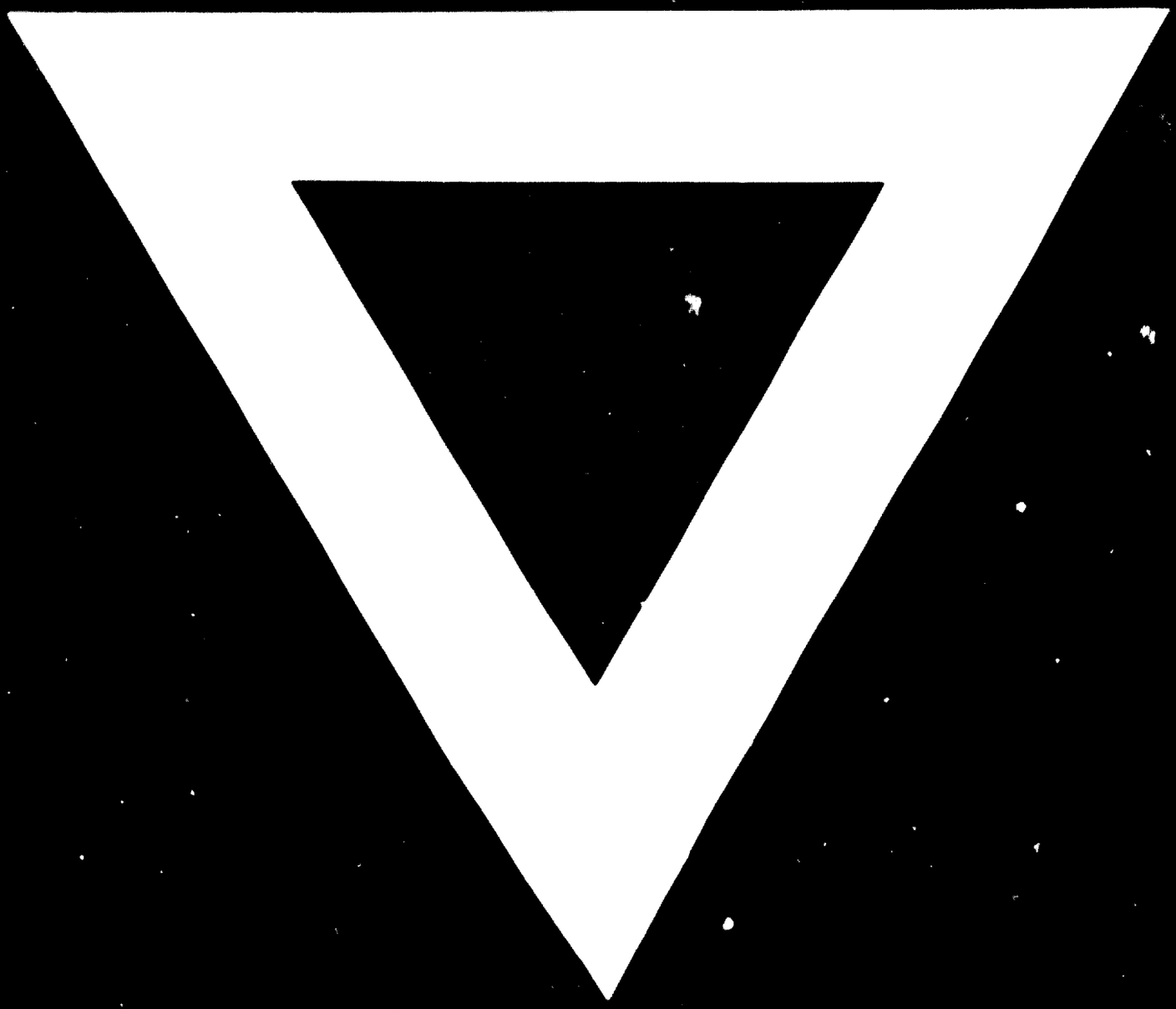
These aspects include capacities and kinds of finished products and their ready-made forms, considerations of process know-how, evaluation of tentative capital investments, terms of construction and expected economic efficiency of the Project.

Besides , it is also necessary to take into account

the availability or possibility of establishing a local construction organization that would favour the project realization on the shortest schedule, as any delay in construction lowers considerably the supposed efficiency of capital investments.

The most important criterion of economic efficiency of a pharmaceutical plant construction, as any industrial Enterprise, is ex-factory cost price of the finished product (in bulk form or as ready-made drug, depending on the enterprise feature)in comparison with the local and world market prices, profitableness and competitiveness of the production.

Thorough preliminary technical and economical survey of all above mentioned aspects and evaluation of the most expedient ways of their implementation in the concrete conditions of the given country allow, as shows our experience, to plan with a certain degree of reliability the establishment of profitable national pharmaceutical industry in developing countries.



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