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**BASIC PRINCIPLES FOR THE TRANSFER OF TECHNOLOGY FOR THE
ESTABLISHMENT OF A PHARMACEUTICAL INDUSTRY
IN DEVELOPING COUNTRIES**

presented by
the secretariat of UNIDO
at the
Consultation Meeting on Transfer of Technology
and Technical Know-how between Developing
Countries in the Field of Pharmaceutical industries
India, 22 April - 4 May 1976.

An increasing number of developing countries want to establish their own pharmaceutical industries. However, this industry is based upon very highly sophisticated disciplines:

- Sciences - medicine, pharmacology, chemistry, biochemistry
- Technology - syntheses, production, fermentation, sterilization, packaging
- Economics - costs, prices, marketing and advertising
- Legal affairs - patents, licensing, import and export regulations
- Fiscal affairs - import duties, taxes, royalties
- Education and training of professional personnel and skilled labour

Since most developing countries lack the necessary sophistication in these disciplines, they may find it very difficult to establish a pharmaceutical industry. However, quite strong reasons exist for developing countries to explore their possibilities for establishing this industry, some of which are:

- To reduce dependence upon the external supply of needed drugs
- To save foreign exchange
- To industrialize

A pharmaceutical industry in a developing country should be established in accordance with its growth in the above-mentioned disciplines; therefore, the desired transfer of technology must be accompanied simultaneously with corresponding development of the other disciplines. UNIDO is, among other organizations and agencies, assisting and advising the developing countries and feels that a continuous exchange of experience among these countries may encourage the establishment of new projects and enable managers to avoid mistakes made earlier.

The basic principles involved in establishing a pharmaceutical industry in a developing country are analysed below.

Main characteristics of the pharmaceutical industry

The transfer of pharmaceutical technology is strongly influenced by four main characteristics of the industry:

- Concentration of production within a few countries
- Concentration of research and development
- Dominant position in the market of the major companies
- Pricing practices due to high cost of research and development and promotion

Therefore, a successful transfer of technology will be based upon a thorough understanding of the particular problems a developing country will confront because of these characteristics.

Production of pharmaceuticals had a tremendous growth rate during the last 10 years, but about 70-80 per cent of production was concentrated in the United States of America, Japan, Federal Republic of Germany, France and Italy. The pharmaceutical industry in developing countries is also concentrated within a few countries such as India, Mexico, Brazil and Egypt.

Research in and development of pharmaceuticals is expensive, but essential for the long-term growth of the industry. For the time being research and development are performed mainly by the major companies of the developed countries. (To introduce to the market a new drug, 7-10 years of research and development is necessary at an approximate cost of \$US 10,000.)

Trade and marketing have expanded also very fast during the last 10 years. It is noteworthy that the marketing expenditures are higher than the expenditures for research and development.

The major companies possess a high degree of market power enabling them to obtain the prices needed to achieve the desired return on their investment.

A realistic approach to the transfer of pharmaceutical technology

A developing country wishing to minimize its dependence on external production of pharmaceuticals must find a way to achieve an efficient transfer of pharmaceutical technology. A possible approach is outlined below.

Step I - analysis

As a first step an analysis of the health needs of the country concerned must be made. This analysis, using generic names, will also result in a list of essential drugs a country must have to meet its health requirements.

The number of drugs on that list will be only a very small fraction of the drugs actually marketed, thus enabling the developing country to concentrate on meeting the basic pharmaceutical needs.

Step II - evaluation

To obtain the essential drugs, a developing country may choose from among several possibilities. It may:

Import the drugs

Import the bulk materials and packaging

Import the bulk materials and formulating and packaging

Produce pharmaceuticals out of imported or domestic raw materials or intermediates

Except for the simple import of drugs, the above-mentioned possibilities require a transfer of technology, which is rather simple in the case of packaging and formulating, but far more complex and difficult in the case of production. With the decision to embark on the production of pharmaceuticals, all facts regarding marketing, research and development, quality control and pricing should be considered.

UNIDO may assist in the development and planning of such projects.

Step III - search for low-cost transfer of technology

During the last two years, UNIDO has studied the ways of effecting the low-cost transfer of pharmaceutical technology that will effectively meet health requirements.

The following methods are recommended:

(a) Transfer of technology of production processes already used and available within developing countries. This type of transfer may be successfully achieved through an exchange of know-how among the developing countries;

(b) Transfer of technology of production processes using expired patents or patents made available by pharmaceutical companies at low cost;

(c) Transfer of technology on a regional and co-operative basis to enable the costs to be shared among participating countries.

Practical recommendations

The above-mentioned approach to the transfer of pharmaceutical technology could be implemented on a national or regional basis. Countries with a large domestic market may choose a transfer of technology on a national basis through bilateral arrangements or in co-operation with, for example, UNIDO. Countries with a rather small domestic market may undertake a regional and co-operative development of a pharmaceutical industry.

In conclusion, UNIDO strongly recommends the following:

- (a) Creation of a programme of co-operation among developing countries to speed up the establishment of a pharmaceutical industry in these countries;
- (b) Evaluation of expired patents, with due regard paid to the list of drugs essential to the countries involved;
- (c) Co-operation between developing countries and producers to obtain low-cost licences for drugs no longer in their production programmes.

The role of UNIDO role is to provide assistance to the developing countries, upon request, in the transfer of technology and related activities such as:

Analysis and advice

Project evaluation and planning

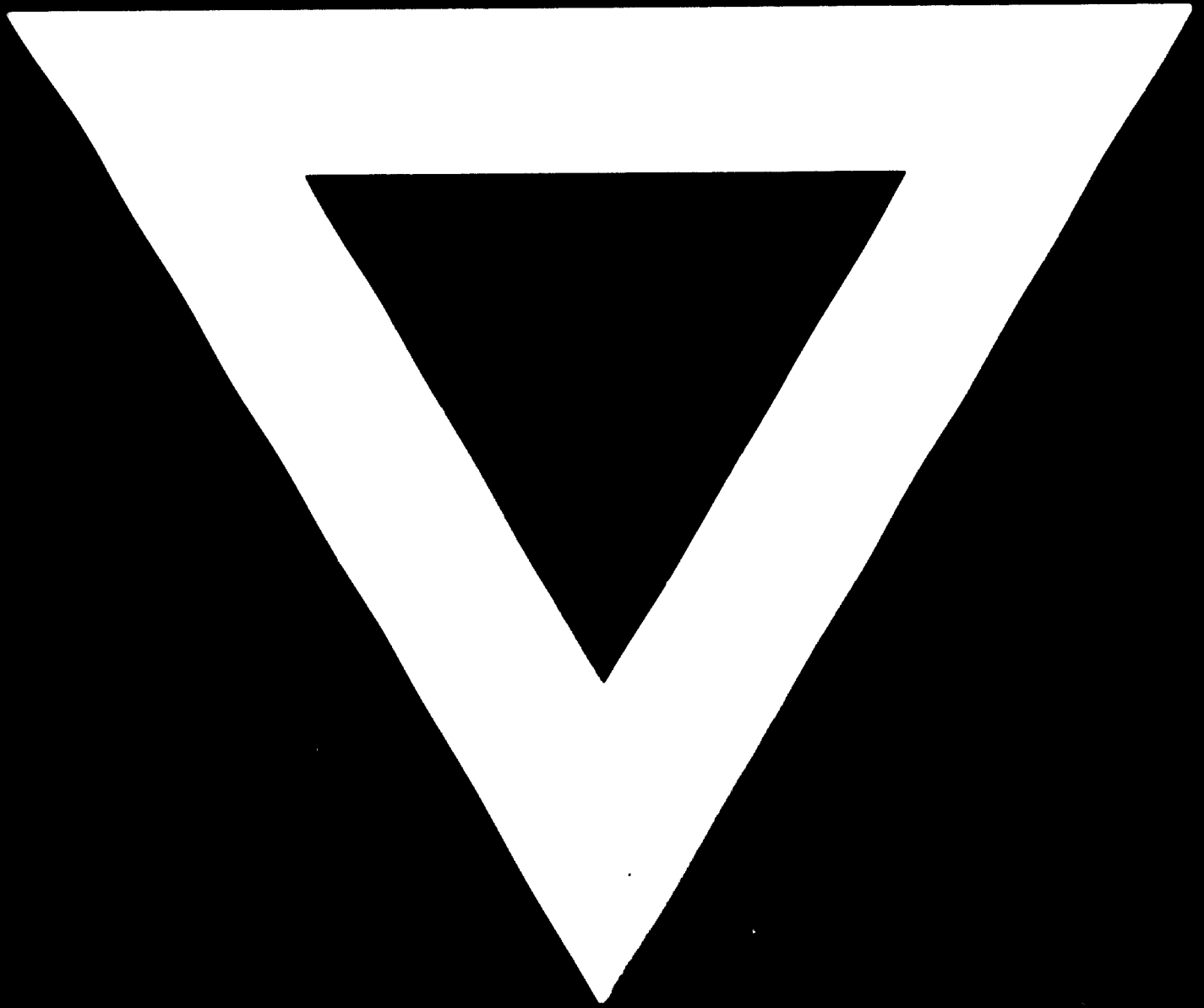
Co-ordination of exchange of know-how among developing countries

Co-ordination of negotiations for the utilization of expired patents and low-cost licensing

Development of a programme of co-operation among developing countries to accelerate the growth of the pharmaceutical industry



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