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INTERNATIONAL COOPERATION IN DEVELOPMENT  
OF PHARMACEUTICAL INDUSTRY - EXCHANGE OF INFORMATION  
AND EXPERIENCE\*

Background Paper

Prepared by

UNIDO Secretariat

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## I. Introduction

The objective of an industrialization process in a developing country is the creation of a coherent national productive system. Pharmaceutical sector is health related and provides products that are essential to the immediate welfare of the population which cannot be replaced by other products. At present, more than 75% of the world population are living in developing countries whereas their share in the world consumption of pharmaceuticals is about 17% and the production share is the same or even less. In some geographic regions the actual production has gone down in the recent past and more specifically smaller national enterprises with limited financial facilities are affected. The past two Consultations of UNIDO on this sector have identified a number of factors to promote the development of pharmaceutical industry in the developing countries in support of the global strategy of "Health for all by the year 2000" adopted by World Health Organization in its resolution WHA 34.36 of 22 May 1981.

The demand for pharmaceuticals in developing countries will increase considerably in future to improve the global standard of living and the health of population. Therefore, there will be need to increase the supply of pharmaceutical products to developing countries and encourage local production. In order to achieve the goal of development of pharmaceutical industry and to assist solving the problems associated with its development, international cooperation in this sector becomes imperative.

This paper examines ways and means of eliciting international cooperation in attaining the objectives of development of pharmaceutical industry in the developing countries to supply the drugs uninterrupted, save foreign exchange, move towards industrialization, establish testing laboratories, achieve diffusion of technology and develop manpower.

## II. A general review: Problems and role of international cooperation

The pharmaceutical industry differs from most other fields of chemical industry. The major characteristic related to the production of the therapeutic materials include great variety and highly developed processes involving complicated steps, biotechnology steps are employed in addition to chemical synthesis, batch processes are more frequent than continuous processes, quality control and assurance is of paramount importance. The availability of technology is one of the prima factors in the development of this industry as it is indeed a complex factor.

Furthermore, the pharmaceutical industry is characterized by a high rate of obsolescence of its products owing to the discovery and development of new therapeutic substances more safe and with less side effects or of less costly substitutes and because of users development of immunity to certain products. Therefore sustained and concerted efforts to improve and modify the technology used and to manufacture new products is going on. Genetic engineering is bringing about change and opening up of opportunities. Biotechnology is aiming to improve and simplify processes, lower costs of production and replace limited/expensive natural sources.

The developing countries can keep abreast with the global development in the sector and be a party to such development processes only through international cooperation and with the assistance of pharmaceutical companies and Government research institutes that can afford R&D expenditure involved. In particular, large manufacturing units in developed countries which have established research laboratories and spend large portion of their revenues on R&D are the main sources of information on improved processes, strains, new drugs and scientific information for medical and pharmaceutical professions. Besides the R&D, cooperation is needed in planning, setting up, operation, quality control, marketing and development of manpower, related to the pharmaceutical industry.

The subject is vast, the problems are varied. But there is no doubt that the solution to the problems can be found through international cooperation. Though South-South cooperation is becoming increasingly important option for developing countries, nevertheless it cannot be regarded as a substitute for full North-South cooperation but only as a complementary strategy to be pursued. In essence, North-South and South-South cooperation play an important role in domestic development of industry and for developing countries to obtain greater benefits from such collaboration, guidance is necessary in this sophisticated industry.

For a meaningful involvement, an in-depth study of factors such as policies and regulations, technologies, investments, management methods and technical expertise would be necessary.

In view of the complexity of the subject, the scope of this paper is being restricted to only two aspects, namely: I. Exchange of experiences and II. Exchange of information, since among other elements these two are considered essential tools for the domestic development and operations of pharmaceutical industry, specifically in regards to pharmaceutical formulations, pharmaceutical chemicals and biologicals.

#### The issues of exchange of experiences and information

##### 1. Exchange of experiences

To deal with the issues of exchange of experiences, a two tiers approach at (i) policy level and at (ii) industry level should go long way in achieving the desired results of upgrading the skill and improving the efficiency for the healthy development of the domestic pharmaceutical industry.

##### (i) Policy level

###### (a) The Policies and Regulations:

The policies and regulations are formulated and enforced. These instruments are intended to protect the health of the population which include steps such as regulations to control potential health hazards resulting from the introduction of new drugs, suitable prices for the benefit of consumers and to limit social security costs.

The objectives of the policy makers behind the regulations aim at the following:

- to ensure adequate supplies of quality pharmaceuticals at low prices
- to secure maximum capital investment in technically advanced facilities
- to encourage the growth of local pharmaceutical and auxiliary industries to meet local needs and to induce vertical integration for the production of pharmaceutical chemicals and intermediates, i.e. increasing the sophistication of the local industry, starting with packaging, the working up to pharmaceutical dosage forms and ending with manufacture of pharmaceutical chemicals and their intermediates
- to achieve export potential

The regulatory mechanism generally used in regulating production and sales of pharmaceuticals include:

- Adoption of quality assurance systems implementation (good laboratory practices, manufacturing practices and promotional and supply practices)
- Pricing policies
- Restrictions to certain degree related to patents, trade marks and/or brand names
- Consideration of generic as well as brand drugs
- Restrictions on specific products
- Check on trade policies by application of high tariff on pharmaceutical formulation specialities to curb imports
- Identification, restriction and control on investment facilities
- Adoption of "open door policies" for foreign investment
- Awarding of status of "national interest industry" and thus granting important fiscal and financial incentives
- Granting permission for high prices for pharmaceutical formulations local manufacturers in order to encourage development of backward integration to manufacture pharmaceutical chemicals and intermediates and conduct R&D activities entailing basic research and research in process know-how
- Adoption of priority attitude to immunization programme and organize infrastructure and local production of particularly the classic one for which developed countries have no needs and developing countries need those immunologicals.

(b) Mechanisms for cooperation:

Exchange of experiences on mechanisms of cooperation such as grants for purchase of machinery and equipment, joint venture and other arrangements, loans, exchange of technology and knowhow, training of manpower academically in institutes as a prelude to training in industry, research and expert services.

(ii) Industry level

Exchange of experiences at manager level for production of both pharmaceutical chemicals and pharmaceutical formulations can materialize through expert group meetings and seminars, visits etc. The subject can include:

- Experiences of plant design, construction, plant and machinery and operation
- Experiences on operational problems
- Experiences on technology and costs
- Experiences on technological adaptation
- Experiences on repair and maintenance - engineering services
- Experiences on quality assurance problems
- Experiences on development of competent management

2. Exchange of information

The subject can include areas such as:

- On pharmaceutical chemicals and drugs as regards specifications of raw materials, finished products, prices and market trends, inputs
- On new products
- On sources of products
- On equipment and machinery
- On production technology, suitability, adaptation, innovations
- On quality assurance aspects
- On drug side effects and their treatment and necessary precautions to eliminate those drugs or limit their use, role of control agencies in dissemination of information
- Management and marketing aspects
- Export promotion techniques
- Trade opportunities facilitating technological collaborations.

These regulations, regulatory mechanisms and other points cited above must be looked from positive standpoint. The spirit of give and take should not be divorced. The attitude should be that of understanding in order to have long term advantages. The problems should be well studied and actions planned accordingly. The long term development needs well considered thoughts as they could lead to availability of high technologies, finances, development of local manufacture and export markets.

In order to promote the development of pharmaceutical industry, the Third Consultation on the Pharmaceutical Industry may like to consider a programme of action for implementation to strengthen the international cooperation.

III. Programme to strengthen international cooperation

An integrated, comprehensive, global and dynamic approach to development lies in cooperation between North and South, and within the South. UNIDO has a catalytic role in generating positive interaction between the partners and fostering a coordinated approach to development and industrialization in the

developing countries. Results, however, would depend on the actions of developed and developing countries themselves. For meaningful results UNIDO draws the attention of the developed countries to bear in mind the impact their policies have on the industrial development of the South. At the same time, UNIDO requests the developing countries to also turn to the manifold problems that exist within their own boundaries.

There is a definite role to be played by the industry, governments in developed and developing countries, regional and international organizations in fostering South-South and North-South cooperation.

The participants of the Third Consultation may consider proposals regarding the establishment of programmes of cooperation and their financing.

The two areas identified in this document for cooperation are in fact deeply related to the already ongoing issues of Availability, Pricing and Transfer of Technology for the Pharmaceuticals.

South-South cooperation, regional cooperation among developing countries in the pharmaceutical industry

Because of similar problems and level of development, the developing countries ought to be in a good position to transfer and exchange experience, expertise and information. The following points need consideration:

- There should be proper coordination between developing countries both at policy and industry level in order to cover the exchange of views on handling specific problems related to the development of pharmaceutical industry.
- While sharing of experiences and other limited resources is an important component of cooperation between developing countries, the collective approach to any of the problems faced by those countries in developing their pharmaceutical industry should help them in obtaining improved facilities such as better information resources, improved training programmes, more detailed technical seminars etc.
- The Third Consultation may consider that in order to strengthen cooperation between developing countries in matters relating to pharmaceutical industry, UNIDO should as a first step assist in the establishment of close cooperation between existing sub-regional, regional and international associations or federations of pharmaceutical enterprises and pharmaceutical industry centres concerned with the development of pharmaceutical formulations, pharmaceutical chemicals and biologicals in the developing countries.
- The participants at the Third Consultation may also consider that assistance be sought in establishment of federations or associations of pharmaceutical enterprises in regions where these did not exist with particular reference to Africa.

To further the above objectives: UNIDO's assistance may be asked



- (a) to prepare, publish and widely disseminate an information booklet containing a brief account of and statistical data relating to the activities of:
  - (i) All sub-regional, regional, international federations, associations, pharmaceutical industry development centres in the developing countries
  - (ii) all international organizations, institutions, agencies and pharmaceutical industry development centres concerned with the pharmaceutical industry including those interested in providing consultancy services
- (b) To help to organize periodically interregional meetings of representatives from sub-regional, regional and interregional federations, associations to review current activities and propose new activities and projects of cooperation in all sub-sectors of pharmaceutical industry including immunologicals.
- (c) To organize workshops on different aspects of technical management covering operational and technological problems of pharmaceutical formulation, pharmaceutical chemical and biological production plants in which experiences of pharmaceutical production units in different countries could be exchanged.
- (d) To initiate action for organization of training programmes for personnel making full use of the existing training facilities in developing countries. The training should cover areas such as project implementation and quality assurance systems implementation (good manufacturing practices, operations, quality control, technical management and audit and maintenance of pharmaceutical plants).
- (e) To assist regional organizations to establish a maintenance improvement programme that would improve capacity utilization. The programme should include preparation of improved maintenance manuals, introduction of new techniques of maintenance such as preventive maintenance, management of spare parts etc. The experiences of developing countries having pharmaceutical manufacturing plants should be drawn up in preparing the programmes.
- (f) To organize visits of personnel of developing countries to plants of other developing countries with more experience in the pharmaceutical sector.
- (g) To stimulate an exchange of technical information as regard specifications of raw materials, finished products, production technology, information on new products, on sources of supply, on procurement and prices, on equipment and machinery, on management and marketing aspects and export promotion techniques.
- (h) In collaboration with UNCTAD to promote interregional trade in raw materials, intermediates and finished pharmaceuticals so as to facilitate and enhance technological collaboration.

- (i) The policy makers in Governments should establish contacts on permanent basis with international organizations like UNIDO and WHO to exchange information.

The Third Consultation may consider that:

- UNIDO's assistance may be sought to formulate a programme for immediate action and establish an adhoc committee to coordinate the implementation of the programme
- An in-depth study of additional areas for cooperation between developing countries not covered above may be made.

#### North-South cooperation

To achieve the objectives enumerated in the paper, it is recognised that North-South cooperation has a vital role to play; thus

- Government policies regarding incentives, protections and financing arrangements etc. are very important instruments
- All topics of technical services are an important area for cooperation where developed countries' long experience could be of immense value
- Assistance in the development of competent manpower - training
- Transfer of technological developments to developing countries
- Information, experience on R+D in all segments of the industry covering processes product development, safety etc.
- Sharing of experiences in the manufacture of equipment and machinery
- Exchange of experiences which was found to be necessary in achieving targets and avoiding non-viable projects
- Exchange of commercial information.

The Third Consultation may consider the issue and make appropriate recommendations on the implementation of work programme on the lines enumerated above and as deemed appropriate.