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Interregional Meeting on Co-operation among
Developing Countries for the Development of
the Pharmaceutical Industry

New Delhi, India, 19-22 March 1990

DEVELOPMENT OF AN INTEGRATED PHARMACEUTICAL INDUSTRY*

Prepared by
the UNIDO Secretariat

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Introduction and Background

1. Products of the pharmaceutical industry play a strategic role in sustaining the general health and well-being of the population, which is essential for the performance of their social and economic activities. Herbal medicines are vital in the health care programme for a large segment of the world population, especially in developing countries; in many cases they bridge the gap between availability of and demand for medicine. The local pharmaceutical industry plays an important role in keeping the supply at an adequate level. In order to achieve health and the industrial goals at the national level, close co-operation and co-ordination between those responsible for health, industry and manpower development policies is needed.

2. Very few developing countries could claim to have the capability to provide for their own drug needs through the local production of biologicals, pharmaceutical formulations, pharmaceutical chemicals, their intermediates, and drugs based on medicinal plants. The economic feasibility of producing most essential drugs would require a level of demand far beyond the absorptive capabilities of a large number of developing countries' markets. The effective development of the pharmaceutical industry would thus require active co-operation between developed and developing countries, as well as between developing countries themselves.

3. Moreover, in order to allow the healthy development of the local pharmaceutical industry and at the same time fulfil national health objectives, a delicate balance must be struck to accommodate both objectives through pricing mechanisms and other systems of incentives. In fact, in most countries that have established a pharmaceutical industry, it was found necessary to develop a national industrial drug policy within the framework of the national health policy in order to achieve harmony between the short- and long-term objectives of both those policies.

4. Considering the complexity of the pharmaceutical industry and its environment, an integrated approach to its development needs to be adopted in which the industry is viewed in the context of its socio-economic, technological and all other related aspects of development instead of as an isolated activity related to the establishment of a single production unit. It would thus be necessary to look into factors that have some bearing on the development of the industry in question without necessarily being within its boundary. In such an approach, the technically and economically motivated backward or forward integration of various industrial activities would need to be considered as well as co-ordinated with other socio-economic activities such as population growth and structure, health and health-related policies, education, infrastructure, etc.

Integrated development approach

5. The availability of drugs to cope with needs of the population is a strategic necessity that can hardly be evaluated in economic or financial terms. In order to improve the economy of production and to ensure a consistent level of supply, however, it becomes attractive if not essential to integrate the pharmaceutical industry with the national productive system in such a way as to obtain the necessary inputs it requires from within the country in the form of raw materials, chemicals and intermediates, auxiliary materials, packaging materials, research and development support activities, manpower development schemes, etc. Such an approach would provide a tightly knit production chain with a maximum degree of internal economic and technological self-sufficiency and complementarity.

6. The practical tool to make effective the application of the above-mentioned integrated approach is formulating a master plan for the development of an integrated pharmaceutical industry. The master plan is a general concept that takes on a specific character when applied to the concrete situation of each developing country. Basically, it provides for the estimation of the demand for drugs and tries to equate it to supply, with particular emphasis on the promotion and development of local sources of supply. It is a working tool for technical experts, financial specialists, planners and decision makers, containing pertinent data and recommendations needed for the creation, rationalization and development of a local pharmaceutical industry. It further makes transparent to all concerned the basic conditions and requirements, the interdependence of ancillary industries, the necessary infrastructure, the appropriate institutional framework and the corresponding legal provisions and procedures. The master plan clarifies the long- and short-term goals and identifies specific investment projects for their attainment. The plan can become part of the national development plan and be integrated in the national health care policy.

7. It has been recognized that the most effective way in which the development of the local pharmaceutical industry in developing countries could be achieved is through the integrated approach, whereby the industry is viewed within the framework of a national development policy/national health development plan/national industrial drug policy plan and that it is manifested in a master plan outlining the development objectives of this industry in the long and medium terms. A critical analysis of the demand and the availability of local resources to meet this demand sets the basis for the development of local sources of supply to meet the expected demand for all types of drugs and services and associated industries, taking due account of the cost effectiveness, strategic objectives and long-term national economic development goals. In the analysis of existing sources of supply, special emphasis is given to the rehabilitation of existing productive assets, their retocoling or expansion and the installation of new production capacities, backed up by thorough feasibility studies indicating the amount of investment, the type of technology and government regulations and incentives required for their implementation.

8. Within the framework of the master plan or parallel to it, subsectoral plans could be developed to deal with a clearly identifiable objective, for instance the production of biologicals. To illustrate matters in this sphere, UNIDO has developed a strategic paper on the production of vaccines and other biologicals in developing countries. In that paper, the adoption of a three-step approach for the production of vaccines and other biologicals in developing countries is proposed, namely (a) the establishment of quality-control facilities and the import of ready-to-use doses; (b) local filling and packaging operations based on imported bulk vaccines; and (c) local production of bulk vaccines. This approach would thus allow for the gradual building up of local capabilities in production, quality control and marketing fields for this type of products.

9. In the case of pharmaceuticals, progressive development involves repackaging of formulated drugs, production of dosage forms, and production of pharmaceutical chemicals from intermediates and raw materials. Considering the difficulty of obtaining process technology for the production of pharmaceutical chemicals in developing countries, on the one hand, and the poor economic viability of producing such chemicals for a limited market, on the other, UNIDO has encouraged the concept of a multi-purpose plant for the production of pharmaceutical chemicals in developing countries. The

multi-purpose plant concept is a viable approach for developing countries that wish to enter into the flexible manufacture of a number of pharmaceutical chemicals in quantities compatible with the requirements of the local market. Even more important, it creates the physical facilities for the transfer of technology and know-how and the training of local personnel in chemical synthesis and research and development capabilities.

10. The creation of a viable industrial sector with ample potential for self-sustained growth in a country or a region calls for the parallel development of all of the mutually complementary and supportive activities, including ancillary industries. Moreover, the cost of imported packaging and other materials for ancillary industries constitutes an important element of the cost of production of pharmaceuticals in developing countries. Local production of these materials would have obvious advantages for the pharmaceutical and the general industrial development of developing countries, particularly in view of the shortage of foreign exchange and their indebtedness. The promotion and development of pharmaceutical-related ancillary industries, such as those producing paper, cardboard, glass, plastic and metal-based packaging materials, offer specific benefits to the pharmaceutical industry.

Consideration of steps leading to an integrated development of the pharmaceutical industry

11. In order to adequately identify the constraints, possibilities and advantages involved in developing an integrated approach to the development of the pharmaceutical industry within the framework of national health delivery systems of developing countries, participants may consider focusing the discussion on the following:

(a) The need to study the totality of requirements for the development of the pharmaceutical industry (technology, infrastructure, manpower, investment, etc.) and how these requirements can be met in short, medium and long terms;

(b) The necessity of formulating pharmaceutical production strategies, based on the assessment of national health requirements, the availability of local resources and with due consideration to regional production and export potential and the development of an industrial policy that support domestic production and stimulates exports;

(c) The advisability of initiating steps towards the formulation of a master plan for the development of an integrated pharmaceutical industry covering the production of pharmaceutical chemicals, formulations, drugs based on medicinal plants and factory-produced herbal medicine, biologicals and ancillary materials, etc., taking due account of the experience of developed and developing countries in this regard;

(d) The need to request assistance of international organizations in drawing up such plans and in organizing investment forums for their implementation.