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RESEARCH AND DEVELOPMENT CENTRE
FOR INFORMATION, TRAINING AND DEVELOPMENT
OF PHARMACEUTICAL TECHNOLOGY*

Background Paper

Prepared by

UNIDO Secretariat

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Introduction

The development of local pharmaceutical industry has been identified by the developing countries as one of the important steps needed to improve their health pattern and the economics of their health system. The past two Consultations on the pharmaceutical industry have provided a forum to discuss issues related to the development of this industry with a view of enhancing the capabilities of the developing countries in this field. Previous issues have covered aspects such as development of industrial policies, infrastructure, manpower, technology acquisition and transfer as well as Research and Development. Facility for basic as well as applied pharmaceutical research and development is practically non-existent in most developing countries. In few cases where it does exist interaction between basic and applied research is not fully ensured. It is universally recognized that while industrial R + D aims mainly at getting new products, basic research done in universities and research laboratories provide the seed for commercial technologies a decade later. It is also well known that the time and cost involved in developing and turning out one new pharmaceutical product from the laboratory to the commercial marketing exceeds ten years and needs tens or hundreds of millions of US dollars, which is beyond the reach of most developing countries.

One viable way for developing countries to take part in such important activities could be through the pooling of technical and economic resources towards setting up an R + D Centre for information, training and development of pharmaceutical technology. Recognizing the significance of Research and Development and the limitations and handicaps with which most of the developing countries suffer in this sphere of activities the Second Consultation on the Pharmaceutical Industry agreed that to assist developing countries, UNIDO might, at the request of interested countries, undertake a feasibility study and subsequently convene an intergovernmental meeting to consider the establishment of a process research and development centre. Such centre would inter alia provide services to interested countries in: acquiring and assessing technologies for their pharmaceutical sector; developing manufacturing processes to fit their specific needs; providing reference quality control for raw materials, intermediates and pharmaceutical chemicals; helping to develop the medicinal plant industry and organizing training courses.

2. Government of Portugal offer to host a Centre

In 1983 the Government of Portugal expressed its interest to host the establishment of Research and Development Centre for information, training and development of pharmaceutical process-technology. In 1985 the Portuguese authorities reconfirmed the offer and expressed their readiness to immediately assist interested developing countries through a joint programme for which the Government will provide facilities of its National Laboratory for Industrial Engineering and Technology at Quduz de Baixo.

3. Preparation of Prefeasibility Study for R+D Centre

In the light of the foregoing UNIDO prepared a prefeasibility study on the establishment of such a Centre in order to ascertain the economic and technical viability of such a project; The purpose of this study was as follows:

- establish the objectives of the Centre;
- define the scope and programme of activities of the Centre;
- identify the location and the size of the potential market for the activities of the Centre;
- identify and define various operational alternatives for the Centre;
- define the facilities, staff and organization of the Centre;
- establish the timetable for the implementation of the Centre;
- evaluate the implementation and operating costs of the Centre;
- evaluate the financial viability of the Centre;
- identify and suggest various financing schemes to provide the required funding.

The study comprises 3 volumes, Volume I gives an executive summary dealing with the Centre's objectives, proposed activities and programme implementation alternatives, institutional status, investment and operating costs and recommendations, Volume II deals with potential market, activities and description of the Centre and Volume III deals with financial and legal matters pertaining to the establishment of a Centre.

The study dwells at length with the overall objectives of assisting the developing countries in responding to their needs in health care, keeping in view the specific objectives of assisting in the development of their technological capabilities, human resources and national pharmaceutical production to support and improve the economics of health and foster co-operation among developing countries. The programme covers all aspects related to pharmaceutical formulations, pharmaceutical chemicals and drugs based on medicinal plants.

The study provides various modules with detailed description of activities and programmes, investment and operating costs, equipment and personnel etc. The estimates of investment costs for the alternative modules reflected in the study range from 3.7 to 12.4 million US\$ and that for operating cost range from 3.7 to 7.7 million US\$ during the first year of operations and 4.3 to 9.6 million US\$ during the tenth year of operation of the centre. It deals with the proposal of the centre being a non profit-making but self sustaining entity. It proposes that funds required for implementation may be obtained from official banking and financial institutions, grants from the host country, grants from member countries or foundations, etc. The operating cost of the centre as proposed by the study is to be covered by the income generated from the sales of its services to those developing countries whose economic situation allows them to do so, to any other interested party and from yearly contribution from member countries. While making proposals on the institutional status for the centre the study proposes the following

three possibilities: establishing the centre as (a) an independent international body under multilateral convention ratified by interested Governments, (b) as a subsidiary of UNIDO, (c) an institution under the auspices of the host country, either linked to UNIDO or as a foundation with other Governments contributing towards it.

4. UNIDO enquiry, Member States Response on the Matter

The executive summary of the prefeasibility study was forwarded to Governments of member states accredited to UNIDO in order to assess their views on the matter as a whole and the degree of their interest in participating in this Centre.

In response to the above referred enquiry from UNIDO 67 Governments have so far responded on the subject. 37 have expressed positive interest in the establishing of the Centre, 3 having indicated that they are not in favour of the Centre, while 27 have asked for more information.

UNIDO is, at present, planning to convene a meeting in September 1987 between the representatives of Governments who have expressed interest in the establishment of the Centre. The member states will be requested to consider terms of references, the modalities of operation as well as financing schemes of the centre.

A report on the conclusions and recommendations of this intergovernmental meeting would be submitted to the Third Consultation for consideration and advice to UNIDO on the next steps to be taken on the subject.