



OCCASION

This publication has been made available to the public on the occasion of the 50th anniversary of the United Nations Industrial Development Organisation.



DISCLAIMER

This document has been produced without formal United Nations editing. The designations employed and the presentation of the material in this document do not imply the expression of any opinion whatsoever on the part of the Secretariat of the United Nations Industrial Development Organization (UNIDO) concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries, or its economic system or degree of development. Designations such as "developed", "industrialized" and "developing" are intended for statistical convenience and do not necessarily express a judgment about the stage reached by a particular country or area in the development process. Mention of firm names or commercial products does not constitute an endorsement by UNIDO.

FAIR USE POLICY

Any part of this publication may be quoted and referenced for educational and research purposes without additional permission from UNIDO. However, those who make use of quoting and referencing this publication are requested to follow the Fair Use Policy of giving due credit to UNIDO.

CONTACT

Please contact <u>publications@unido.org</u> for further information concerning UNIDO publications.

For more information about UNIDO, please visit us at www.unido.org

UNITED NATIONS INDUSTRIAL DEVELOPMENT ORGANIZATION

Distr. LIMITED UNIDO/IOD.207 23 August 1978 English

NOTE ON UNIDO ACTIVITIES RELATING TO
PHARMACEUTICAL PRODUCTS IN THE CONTEXT
OF PRIMARY HEALTH PROGRAMMES

International Conference on Primary Health Care,
Alma-Ata, Union of Soviet Socialist Republica,

6-12 September 1978

Prepared by the secretariat of UNIDO

Contribution of pharmaceutical industries in primary health care

An important element in a programme of primary health care is the availability of suitable drugs for preventive as well as curative medicine. In many developing countries, pharmaceutical products are either not available in appropriate quantities or quality or their costs are excessively high. For developing countries as a whole, expenditure on pharmaceuticals accounts for almost half the total expenditure on health care; that is almost three times the proportion found in many developed countries. Even so, the total amount available for health care in developing countries is very limited and it represents only 2% of the Gross National Product (GNP) and between 40%-60% of this expenditure is on pharmaceuticals. In comparison, the developed countries health care budget represents 6%-8% of their GNP from which 15%-20% is spent on pharmaceuticals. 2/ Therefore, large quantities of drugs are donated each year to developing countries in order to supplement the normally available supply. However useful they may be, donations do not provide a basis for a permanent solution to health care problems in developing countries. This requires a long-term programme for the rational development of an integrated pharmaceutical industry, responding to the priority needs for preventive and curative health care.

Measures for the establishment of a pharmaceutical industry in developing countries

2. The first step in the establishment of a pharmaceutical industry should be to ensure that the necessary pre-conditions for a viable industry are met. These include the preparation of a national health policy; arrangements for provision of appropriate medical services; procurement policies; enactment of appropriate drug legislation, including the registration of drugs; setting up quality control facilities, drug production and distribution; and training

^{1/} Study prepared for UNIDO by the Union of the Hungarian Pharmaceutical Industry, February 1978.

^{2/ &}lt;u>Pharmaceutical Industrial Dynamics</u> (Stanford Résearch Institute, Stanford, California, 1976), p.5.

of personnel. The preparation of specific lists of drugs to meet local health needs is an important part of a national health policy; such a list offers the advantage of reducing the number of pharmaceutical products that are to be purchased or produced and concentrating on priority requirements.

- 3. Once a national list of essential drugs is agreed upon, an analysis can be made of the best way to supply them. Some of the drugs may be selected for local manufacture, with the stage from which such manufacture would be undertaken to depend upon the capabilities of the local pharmaceutical industry. In the Second Panel Meeting of Industrial Experts on the Pharmaceutical Industry, convened by UNIDO in Vienna from 28 February to 3 March 1978, the following criteria for the selection were proposed:
- (a) The drug is widely used and/or required by the health authorities to treat diseases prevalent in the country;
- (b) Its efficacy and safety in the treatment of diseases has been demonstrated and the WHO has endorsed its use;
 - (c) The cost per treatment is low enough for the population to afford;
- (d) Local manufacture offers special advantages over import, such as use of available raw materials, saving of foreign exchange, reduction of transport costs etc.;
- (e) A feasibility study of the project indicates that economic production could ultimately be attained, taking into account regional and interregional markets;
- (f) The manufacturing process is appropriate to conditions prevailing in the country;
- (g) The know how for manufacture is available for use, whether patented or not.
- 4. Once such a selection has been carried out and a group of essential drugs has been chosen for local production the level of production will be introduced according to the infrastructure and requirements of developing countries.

 Three different levels of production could be considered for the production of drugs:

Formulation and packaging

Chemical synthesis based on intermediates

Chemical synthesis based on raw materials

For the last two levels the multi-purpose plant or industrial scale concept could be adopted, according to the market size.

- 5. A beginning for an indigenous pharmaceutical industry might be made with the establishment of simple formulation and packaging facilities based on imported bulk materials. This would require less complicated technology but still offers the possibility of achieving savings of up to 30%-40% in foreign exchange costs of drugs. It would also offer the basis for the creation of an infrastructure for a more developed industry.
- 6. According to the market size and available infrastructure a multi-purpose or industrial scale production based on intermediates or raw materials could be placed. The multi-purpose plant concept, in which a number of small volume products have to be produced, could be utilized. This is mostly the case in developing countries.
- 7. In the past two decades, the value of world annual production of pharmaceuticals increased from \$2.7 thousand million to \$45 thousand million. The developing countries, however, participated very little in this growing industry; they account for only 10% of the total world production of pharmaceutical products. Thus, there appears to be considerable scope for further expansion of this industry in developing countries to meet growing primary health care requirements.

UNIDO activity in the pharmaceutical industry

- 8. Characteristically, the pharmaceutical industry is technology-based and needs well-trained scientists and technicians in a variety of disciplines. Therefore, many of the activities carried out by UNIDO to assist developing countries in the establishment of a pharmaceutical industry have sought to strengthen the technological capabilities of these countries through training programmes, expert group meetings and seminars, and publications as well as specific technical co-operation projects in individual countries or groups of countries.
- 9. The importance of training has long been recognized and special attention given to this area by UNIDO. Every year since 1974, UNIDO, in collaboration with the Belgian pharmaceutical industry, has organized a training programme for technicians from developing countries at Chent University; these programmes have proven very beneficial.
 - 3/ All references to dollars (\$) are to United States dollars.

- 10. UNIDO has also developed several programmes for the transfer of technology in the field of pharmaceuticals, both from developed to developing countries and, increasingly, between developing countries themselves through co-operative programmes of various kinds. For example, in collaboration with the Government of Romania, through the Joint UNIDO/Romania Centre, a mobile unit has been sent to selected countries in Asia and another may be sent to Africa, to transfer technology in extraction of drugs from medicinal plants through on-the-spot demonstrations and training. In co-operation with the Belgian pharmaceutical industry, a programme is being developed for the establishment of a demonstration unit for the production of sterile products in Africa.
- 11. A meeting at the Central Drug Research Institute, at Lucknow, India, in 1976, organized by UNIDO in co-operation with the Government of India, led to recommendations for a number of measures for co-operation between developing countries in the field of production technology and in the use of natural resources, including medicinal plants. Among the follow-up programmes and projects that were elaborated, particular mention is made of a project recently approved for financing under the United Nations Industrial Development Fund for assistance to Cuba in the establishment of a multi-purpose pilot plant facility for the production of a group of drugs using technology from India. This facility will permit the economic production of a number of drugs required in relatively small quantities by using a small number of reactors having versatility of operation. It is expected to be in full operation in 1979 and will be used for demonstration purposes as well as for training technicians from other countries interested in establishing a similar unit for their own use.
- 12. In its programme of technical co-operation activities, UNIDO, often with UNDP resources, has assisted in the establishment of several units for the formulation and packaging of drugs using imported bulk materials; units have been started in Cape Verde, Democratic Yemen, Chana, Guyana, Guinea-Bissau, Haiti, Nepal, Sri Lanka, United Republic of Tanzania and Yemen Arab Republic. In other countries, which have suitable infrastructure and opportunities for large-scale production, UNIDO is providing assistance in the establishment of industrial production.
- 13. UNIDO has also convened expert group meetings, technical consultation meetings and panels of experts to consider various aspects of the pharmaceutical

industry and recommend programmes of action (see bibliography). Recently, for example, UNIDO convened a technical consultation meeting for the production of drugs from medicinal plants. During the last decade, the use of medicinal plants in modern medicine, based on scientific production technology, has been introduced. Since developing countries are rich in such plants, UNIDO has, with the assistance of consultants, drawn up a list of medicinal plants by therapeutic groups and elaborated a programme of production of drugs from such plants. Also, a multi-purpose extraction unit has been developed and introduced to developing countries. The programme was discussed in detail during the recent technical consultation meeting.

- 14. These are examples of some of the activities carried out by UNIDO in recent years to encourage the establishment and strengthening of pharmaceutical industries in developing countries. UNIDO is prepared to offer a wide range of further assistance in this field, not only through the technical co-operation activities financed from the UNDP or the United Nations Industrial Development Fund resources, but also through a range of other activities, such as a programme of advice and assistance in the choice, development or acquisition of technology; the programme of investment promotion activities in co-operation with the World Bank; the programme of technological and industrial information services; and the system of consultations intended to lead to the establishment of new productive facilities in developing countries. Representatives of governments and industry have participated actively in two panel meetings convened by UNIDO as a preparatory stage for sectoral consultations on the pharmaceutical industry.
- 15. In close co-operation with the WHO, UNICEF and other international organizations, UNIDO would welcome opportunities to assist developing countries to establish an integrated pharmaceutical industry for the indigenous production of the drugs that form an essential part of any programme of primary health care.

Bibliography 4

Basic principles for the transfer of technology for the establishment of a pharmaceutical industry in developing countries. (UNIDO/IOD.76)
Limited distribution.

Draft strategy paper on UNIDO pharmaceutical activities. Prepared for UNIDO/WHO Meeting, 11-12 November 1976. (Unpublished)

Establishment of pharmaceutical industries in developing countries. Report and proceedings of expert working group meeting, Budapest, 5-9 May 1969. (ID/35) Sales no.: 70.II.B.13.

The growth of the pharmaceutical industry in developing countries: Problems and prospects. (ID/204)
Sales no.: 78.II.B.4.

Information sources on the pharmaceutical industry. (UNIDO Guides to Information Sources, No. 20, ID/162)

International consultation in the field of establishment and development of pharmaceutical industries: Lectures and theses. Papers presented at a UNIDO conference in Budapest, 17-28 November 1975.

The pharmaceutical industries in the Second Development Decade. (ID/WG.37/2) Limited distribution.

Proposal for co-operation among developing countries in the pharmaceutical industry. Prepared for the Non-Aligned Summit Conference, August 1976. (Unpublished)

Raw materials and local production of contraceptives in developing countries: Global. Report prepared for the United Nations Fund of Population Activities. 23 July 1975. (UNIDO/ITD.346)
Restricted distribution.

Report of the Second Panel Meeting of Industrial Experts on the Pharmaceutical Industry. (ID/WG.267/4/Rev.1)
Limited distribution.

Report on Technical Consultation Meeting on Production of Drugs from Medicinal Plants in Developing Countries. (ID/WG.271/5)

Reports on drugs from the National Drug List which because of their essentiality could be produced in the developing countries. (ID/WG.267/5)
Limited distribution.

The steps involved in establishing a pharmaceutical industry in developing countries. (ID/WG.267/3)
Limited distribution.

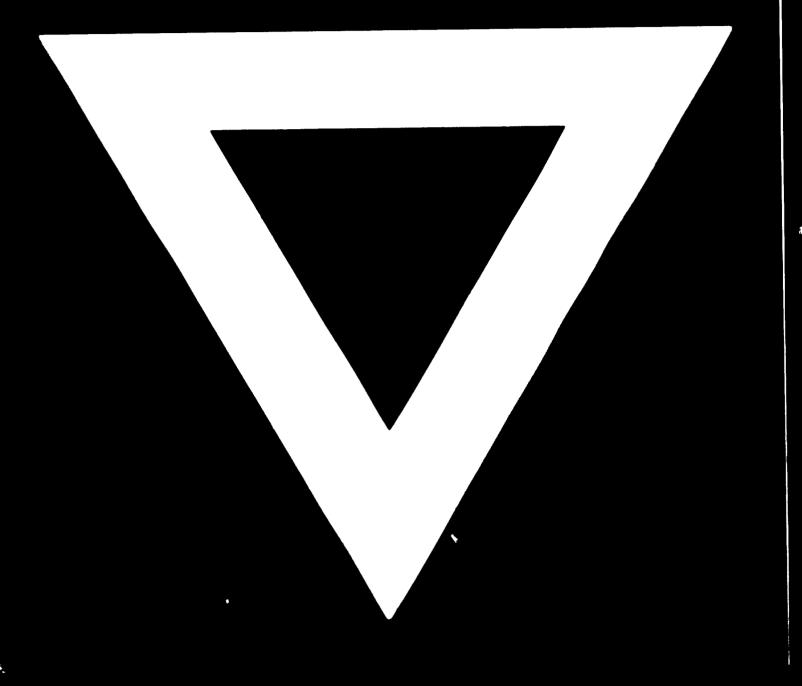
Summary of the Draft World-Wide Study of the Pharmaceutical Industry. (UNIDO/ICIS.74)

Ways of ensuring adequate supplies of chemical intermediates required for the production of drugs in developing countries. (ID/WG.267/2)

Limited distribution.

^{4/} All these documents are by UNIDO. Technical studies of particular plants or countries, which are confidential documents, are not included.

F-656



78.10.3