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OCCASION

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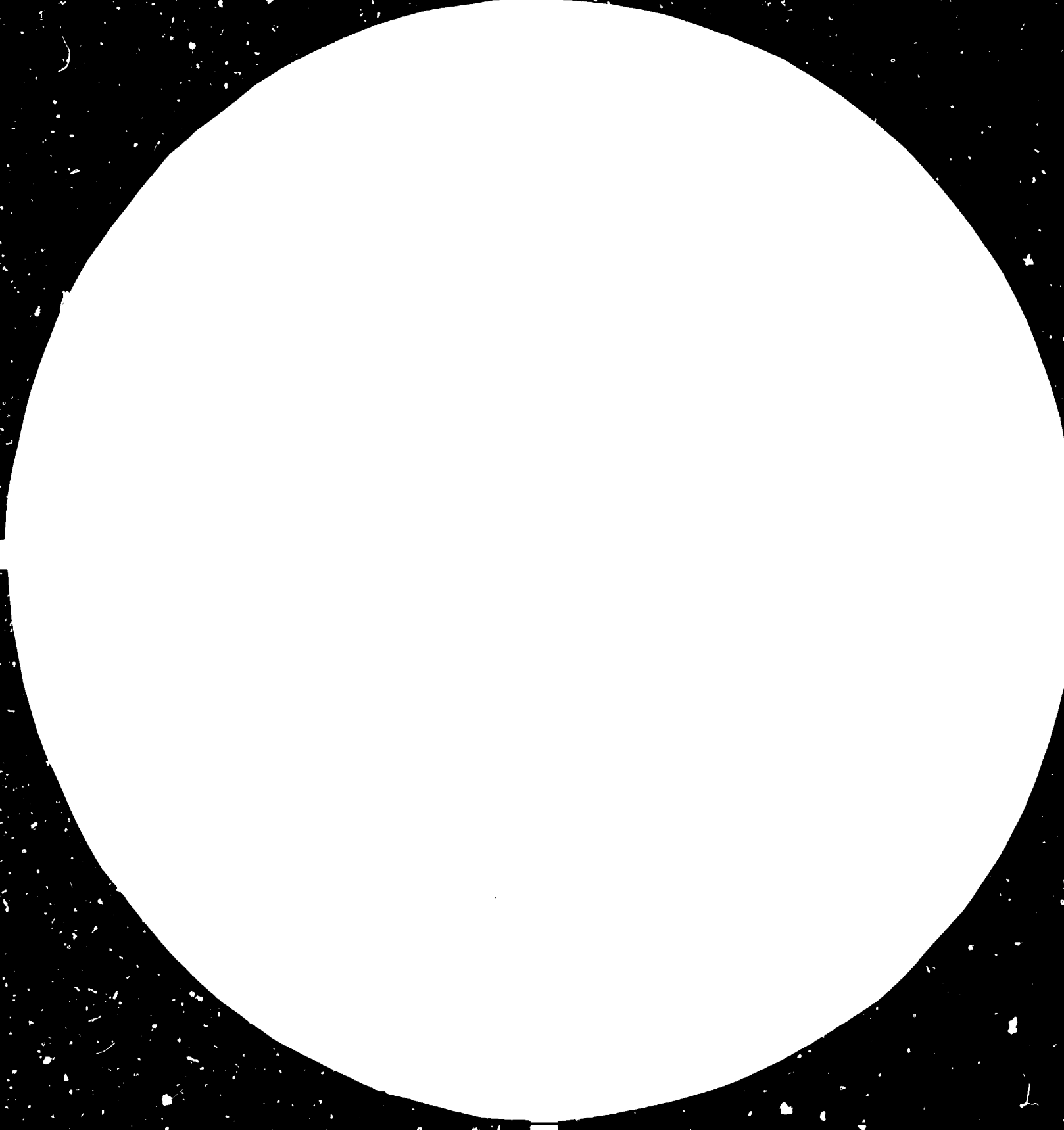
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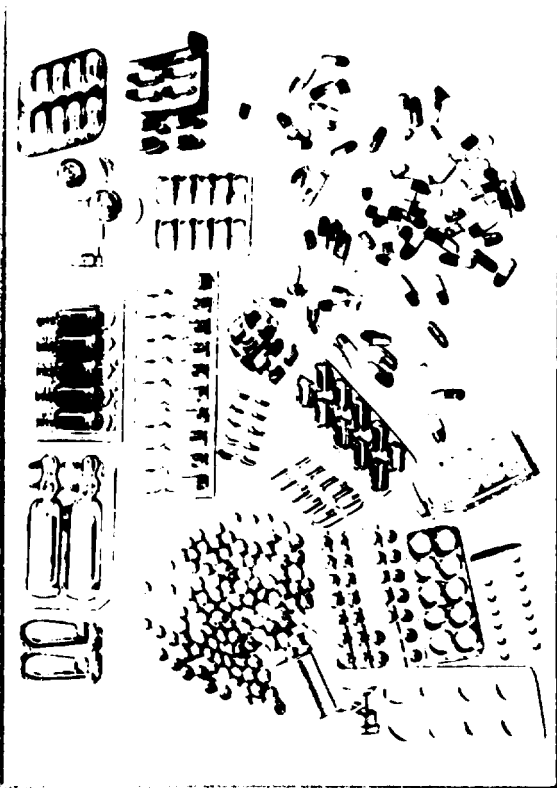


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PHARMACEUTICALS

Preface

Since 1967, the United Nations Industrial Development Organization (UNIDO) has adhered to its mandate "to promote and accelerate the industrialization of the developing countries" by responding to requests for technical co-operation in all aspects of industry from the Governments of those countries.

This commitment to industrialization as a means of improving the living standards of nearly three quarters of the world's population, which was first outlined in November 1966 by the United Nations General Assembly in its resolution 2152 (XXI), has since been intensified. The Lima Declaration and Plan of Action on Industrial Development and Co-operation, which was adopted by the Second General Conference of UNIDO in 1975, called for an international effort to increase the developing countries' share of world industrial production to 25 per cent by the year 2000. This goal was further emphasized at the Third General Conference of UNIDO, held at New Delhi, India, in early 1980, with the adoption of the New Delhi Declaration and Plan of Action on Industrialization of Developing Countries and International Co-operation for their Industrial Development.

In the series of booklets *UNIDO for Industrialization*, of which this is one, an attempt is made to describe briefly the contribution of UNIDO, through its Division of Industrial Operations, to the industrialization of the developing world and to give examples of what has been done and will continue to be done to accelerate the process.

FINANCING UNIDO ACTIVITIES

The bulk of the costs of UNIDO administration and research, now approaching \$US 48 million annually, is met from the **regular budget** of the United Nations, as are some lesser expenditures reserved for certain advisory and training activities. Once UNIDO achieves the status of a specialized agency within the United Nations family, it will cease to be funded from central sources of the United Nations and will rely on its own budget based upon contributions from its member States.

Technical assistance programmes for projects in developing countries, however, are funded from varied sources, the most important of which are summarized below.

By far the largest share of the field activities of UNIDO, some 70 per cent of the total, is funded from the **United Nations Development Programme (UNDP)**. Thus, a high proportion of UNIDO field projects are subject to UNDP approval before implementation. Since the ultimate source of this money is the contributions of the member States themselves, both developed and developing, it can truly be said that UNIDO field activities are self-help programmes, initiated only at the request of Governments of developing countries and using funds to which many developing countries themselves contribute. These funds are allocated to particular countries from UNDP sources up to a predetermined amount known as the indicative planning figure (IPF). They cover the whole spectrum of United Nations assistance to those countries, industrialization being only one of many programmes needing financial support.

Country programmes normally have a five-year span; and the available funds, which vary from country to country and are weighted in favour of least developed countries, must be allocated to specific projects within a country during the five-year period.

Special Industrial Services (SIS) funds are confined to a narrow range of expert services provided for unexpected high-priority projects that are called for from time to time. The programme is restricted to short-term projects of limited cost, and during recent years \$US 3.5 million has been set aside annually to support it.

The **United Nations Industrial Development Fund (UNIDF)** was created to finance innovative projects, preferably projects having a multiplier effect. The Fund consists of contributions pledged by individual Governments, and in some cases the purpose of the contribution is specified. Pledges are made in convertible and non-convertible currencies.

Trust funds are provided by participating Governments for specific projects to be executed by UNIDO in accordance with agreements reached with the contributing countries. They are used, typically, for technical assistance, expert services and specialist training.

The small regular programme of technical assistance provides funds for types of technical assistance that either complement other programmes or do not lend themselves conveniently to alternative means of financing. In particular, this type of funding permits a certain degree of flexibility in spending, since the allocation of the funds available is entirely under the control of the principal policy-making organ of UNIDO, the Industrial Development Board. Programmes are designed to reflect the emphasis on special measures for the least developed countries, on technical co-operation among developing countries and on establishing and strengthening industrial training facilities in developing countries.

Pharmaceuticals

Despite the world's hopes for primary health for everybody by the year 2000, as envisaged in the Alma Ata Declaration adopted by the International Conference on Health Care, sponsored by the World Health Organization (WHO) and the United Nations Children's Fund (UNICEF) in 1978, the harsh reality of today indicates that almost 80 per cent of the population of some developing countries still has no access to modern medicines and depends on traditional forms of medicine and on faith healers.

Per capita consumption of pharmaceuticals varies annually from an estimated \$US 1 in some poorer countries to \$US 50 in highly developed countries; some 45 developing countries still lack even the most elementary pharmaceutical industry. A similar number of developing countries, while maintaining pharmaceutical formulation industries of their own, are totally dependent upon imports for active ingredients. As recently as 1977 the developing world's share of total pharmaceutical production was about 12 per cent, confined mainly to formulation and packaging rather than basic manufacture.

In recognition of the importance of health to society, UNIDO has formulated policies for establishing pharmaceutical industries in developing countries. UNIDO is concerned with principles of production, quality control, transfer of technology, replacement of synthetic chemicals with products from natural sources as far as possible and the promotion of multi-purpose plants for manufacturing active ingredients. In implementing health programmes UNIDO co-operates closely with the World Health Organization (WHO).

Through its Pharmaceutical Industries Unit, UNIDO assists in the founding of new pharmaceutical plants on a turnkey basis, either by use of specialist contractors or by accepting the prime role itself, providing expert services from the planning stage right through to the point of independent production by local enterprises.

UNIDO assists developing countries in producing biomedical equipment and technical devices for the handicapped, beginning with the production of simple equipment in accordance with the readily available WHO designs and progressing to more sophisticated items.

Within the past eight years UNIDO has assisted the pharmaceutical industries of the developing world by its participation in over 150 projects and 40 special studies. International meetings have been convened on 15 occasions. The scope of UNIDO interest is as broad as the industry itself as the following list of UNIDO activities, by no means an exhaustive one, indicates:

- Formulation and packing of dosage forms for human as well as veterinary use
- Processing and formulation of medicinal-plant based drugs
- Processing and production of essential oils from aromatic plants

Basic manufacture of active ingredients through chemical synthesis/
fermentation

Production of:

- Drugs from animal by-products
- Biomedical equipment
- Blood products and blood substitutes
- Immunologicals (vaccines, serums)
- Oral rehydration salts
- Injectable solutions

Management

Maintenance

Reorientation and rehabilitation of existing industrial facilities

Techno-economic studies

Training, including the training of maintenance engineers

Transfer of technology

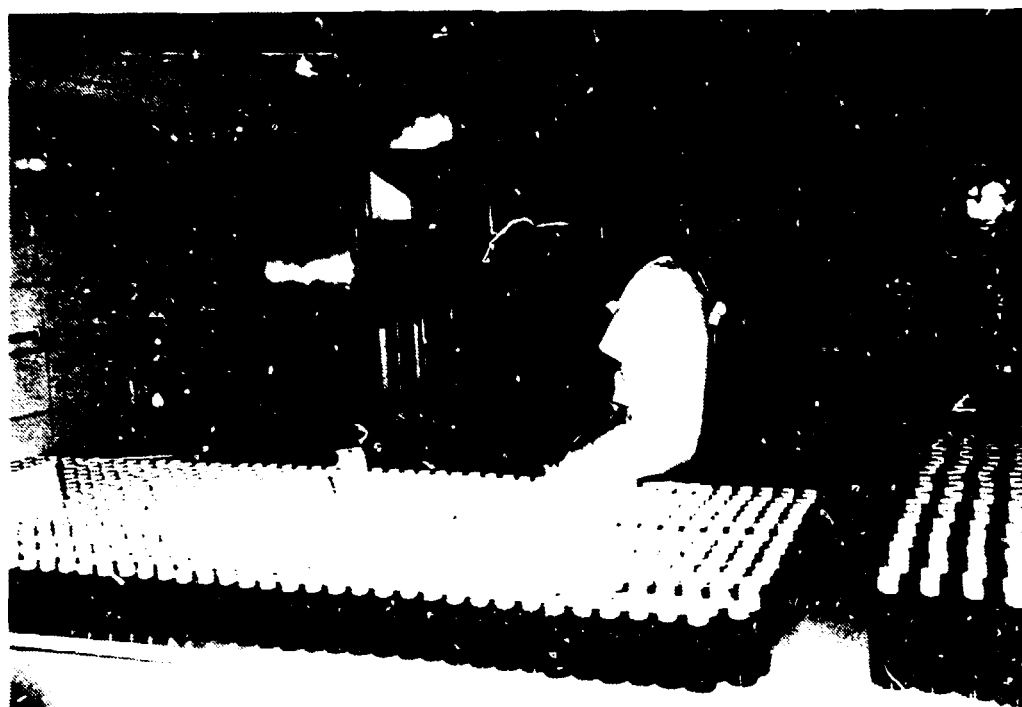
In carrying on all its activities in the field of pharmaceuticals, UNIDO places special emphasis on quality control and good manufacturing practice, without which there can be no safe, acceptable drugs industry.

TRANSFER OF TECHNOLOGY

One of the basic principles of the industrial policy of UNIDO is to promote the transfer of technology from developed to developing countries, or sometimes from the more advanced developing countries to the less advanced ones. This policy is nowhere more important than in pharmaceuticals. UNIDO is able to assist in supplying both the less complicated technology of formulation and packaging processes and the increasingly sophisticated technology necessary when production of active ingredients is contemplated.

FORMULATION AND PACKAGING OF DRUGS

Developing countries still lacking a pharmaceutical industry can take as a first step in establishing the industry the formulation of drugs into dosage forms of capsules, tablets, oral rehydration salts, infusions, injectibles etc. A successful example of this approach is found in Ghana, where the Pharmaceutical Division of the Ghana Industrial Holding Corporation (GIHOC), with assistance from UNIDO technical experts, has been able to increase its output of pharmaceutical formulations several times over and to develop a highly profitable unit producing formulations for the domestic market. Further examples may be seen in Cape Verde, Guinea and the island of Zanzibar.



Production of syrups, Cape Verde

MANUFACTURE OF ACTIVE INGREDIENTS

Small-scale production

The larger of the developing countries and those which are already fortunate enough to possess an industrial base will increasingly produce pharmaceuticals on a scale sufficient to satisfy the needs of their people. Countries with very small populations and the least developed countries will be unable to support large-scale industries, either because their domestic market is too small or because lack of technological knowledge and investment potential preclude more than basic production for the present. In such cases UNIDO is able to assist in introducing pharmaceutical techniques, at first, simple formulation and packaging processes; subsequently, active ingredients may be produced by processing locally grown medicinal plants or by using imported raw materials. With this grounding and the guidance of UNIDO specialist personnel, expansion into the more involved fields of fermentation, synthesis, vaccines and serums etc. can be contemplated later.

Industrial-scale production

Developing countries with basic pharmaceutical industries will need first to satisfy their domestic markets, but later can proceed to exporting by expanding their industry to produce a more sophisticated range of products requiring greater technology and large-scale production equipment. Here UNIDO can



Quality control laboratory in a pharmaceutical unit. Guinea

help by providing international experts, by arranging training courses at home or abroad, and by introducing into the plants modern management techniques and quality control standards.

At this stage of development, in particular, the need is for somewhat more sophisticated technology, which UNIDO can supply, and for professional evaluation of the existing production facilities, which may often usefully be reconstructed or rehabilitated to enable them to handle newly introduced processes at a great saving in capital costs.

In the progress to the advanced stages of pharmaceutical production, technology must be constantly reviewed and updated when necessary; UNIDO is able to arrange regular evaluation by its experts, who are familiar with modern technology and methodology.

DRUGS FROM MEDICINAL PLANTS

Among one of the most highly promising fields for a newly established pharmaceutical industry is the extraction of drugs from medicinal plants. Most areas possess a variety of flora long recognized as having medicinal properties, folk medicine having largely been based on the known effects of certain plants. According to a reliable estimate, 25 per cent of all medical prescriptions issued in one major developed country specified one or more drugs derived from medicinal plants, of which more than 30 are named in the list of essential drugs compiled by WHO. Through intensive cultivation or collection in their wild

state medicinal plants constitute an important and relatively cheap source of materials for the pharmaceutical industry.

The products reach the domestic or export markets either as chemically and biologically standardized extracts or as isolated pure products for use directly as remedies or as base materials for the synthesis of drugs.

Pharmaceuticals can be produced from medicinal plants either in existing processing and manufacturing units or in multi-purpose plants newly installed and specially designed to extract active ingredients from local flora.

UNIDO has initiated the compilation in selected developing countries of an economic mapping system, specifying:

(a) The location of all known medicinal plant species, the quantity available within the spontaneous flora, their cultivation and utilization;

(b) Locations where climatic, soil and water supply conditions etc. indicate that a particular plant species may be expected to thrive in a cultivated state, even though the plant is not indigenous to the area and may be previously unknown there.

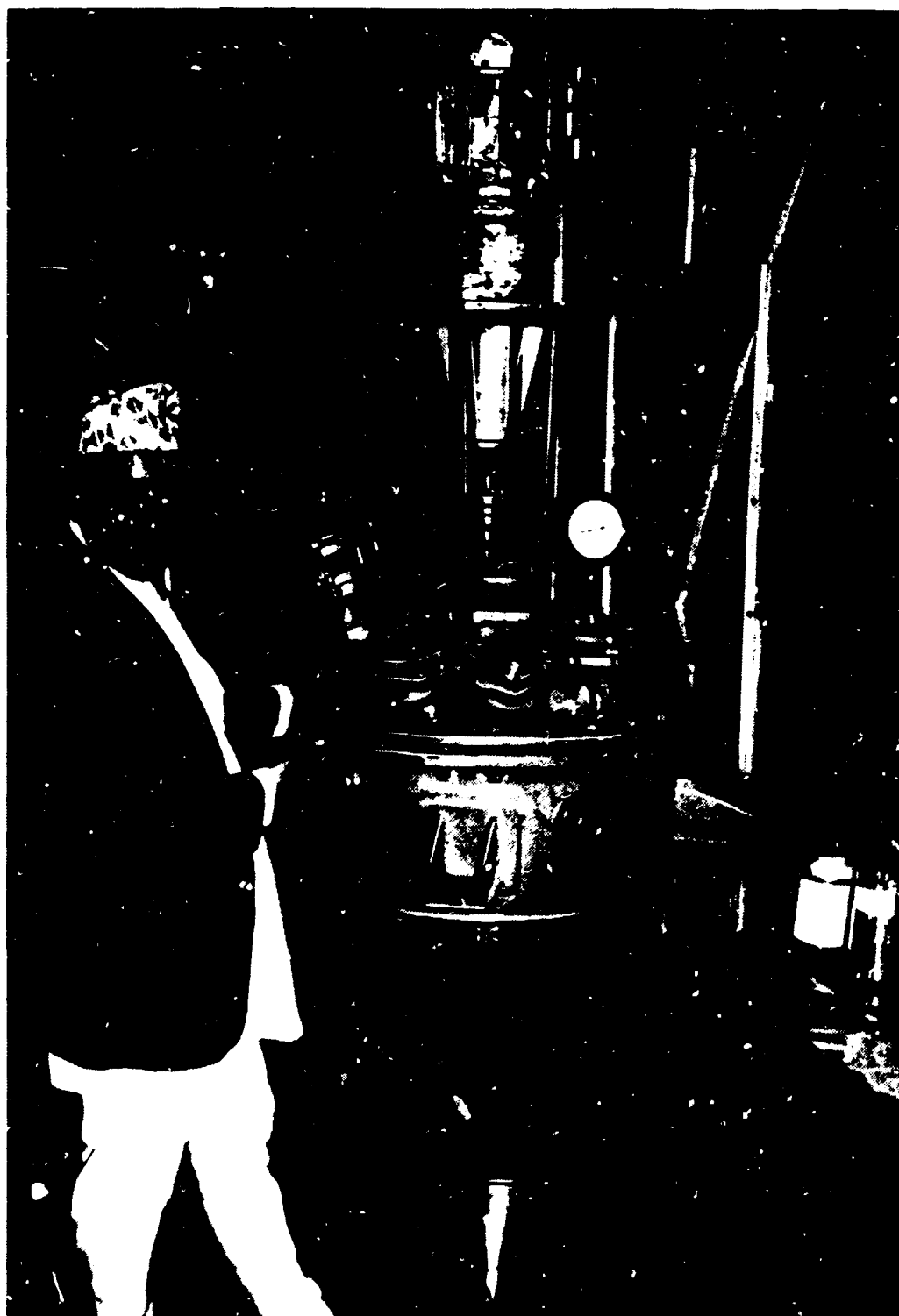
UNIDO is able to assist in all phases of introduction and cultivation of any medicinal plant through to the final extraction of the pure drug.

The traditional pattern has been for developing countries to export their medicinal plants in an untreated form to the highly developed countries, where they are processed into alkaloids, hormones etc. for sale on the domestic or export markets at greatly enhanced values. It is by no means unusual for the value of the derivatives of medicinal plants to exceed tenfold the original cost of import. By transfer of suitable technology and the introduction of appropriate pharmaceutical equipment this pattern could be changed, to the great advantage of developing countries.



Rauwolfia serpentina: plant source for the production of the therapeutically valuable drug Reserpine

A current example of using equipment originally fulfilling a different function but adapted to process medicinal plants with the help of UNIDO is to be found in Cameroon, where the alkaloid substance tabersonine is being extracted from locally grown voacanga seeds. Tabersonine is used in the synthesis of the drug Vincamine. It is conceivable that sometime in the future,



Pilot plant for the production of pharmaceuticals from medicinal and aromatic plants, Nepal

based on the work of a UNIDO project, tabersonine, or an extract enriched with the alkaloid, will be exported instead of the raw seeds as at present.

UNIDO can also help with the design and supply of special production units for extracting essential oils from aromatic plants for medical and technical purposes by distillation. The assistance in this field is similar to the type of UNIDO assistance in projects concerning medicinal plants.

DRUGS BASED ON FERMENTATION

The case for establishing units producing antibiotics is a strong one and has the fullest support of UNIDO. Manufacture of antibiotics involves fermentation technology normally based on special forms of microbial cultures, for which the raw materials are mainly agricultural products available in most developing countries. Other raw materials can easily be imported as necessary. Production of antibiotics can be considered when an adequate base for the pharmaceutical industry already exists. UNIDO is ready to assist in establishing a fermentation complex, thereby helping to ensure the availability of these vital pharmaceutical substances, which are in great demand in developing countries.

MULTI-PURPOSE PLANT

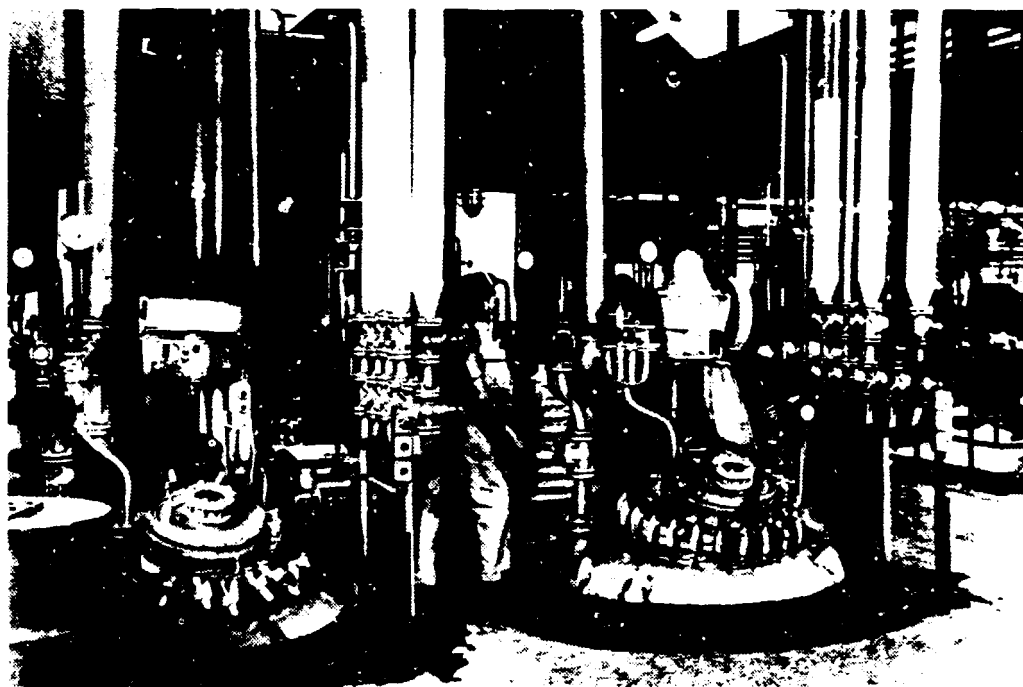
The scale of production needed in a developing country will depend primarily on the size of the domestic market; hence most of the least developed countries require the production of a range of products in limited quantities only. To meet this need, UNIDO is promoting the multi-purpose plant, which permits a variety of drugs to be produced in small quantities from the same manufacturing unit. Multi-purpose plants are particularly suitable to the needs of countries in which the sophisticated technology necessary for large-scale production of drugs from raw materials and intermediates is either not available or unsuitable in local conditions, and where insufficient investment funds exist for large-scale plants.

UNIDO is able to provide expert help in establishing small-scale units in such areas.

TECHNICAL CO-OPERATION AMONG DEVELOPING COUNTRIES

The programme of technical co-operation among developing countries (TCDC), which UNIDO regards as especially important, has particular relevance to the pharmaceutical industry when the necessary technology and investment requirements for mass operations are lacking. In the pharmaceutical field, as in others, UNIDO is active in providing experts to advise and assist Governments in the transfer of technology to developing countries and in the pooling of regional industrial capacity and capabilities.

UNIDO is assisting in establishing a multi-purpose pharmaceutical plant at a cost of \$US 2 million at Havana. Besides producing pharmaceuticals for the Cuban market and for export to neighbouring countries, the plant will facilitate the training of key personnel for the Caribbean region and, it is confidently expected, will later make useful contributions to the development of drugs production technology. Technical know-how is provided entirely from India's Sarabhai Research Centre. This UNIDO-inspired example of technical co-operation between India and Cuba may be of relevance to other countries.



Multi-purpose pilot plant for the production of synthetic drugs in Cuba-plant model

REGIONAL CENTRES FOR PHARMACEUTICAL DEVELOPMENT

UNIDO plans to establish a series of regional centres for pharmaceutical development are now well advanced. Such centres will constitute the backbone of the emerging industry, providing an efficient infrastructure base and acting as "trouble-shooter" in diagnosing and solving industrial problems. They will concentrate on industrial design appropriate to regional and local needs and on valorization of raw materials. A centre serving Asian countries is to be established at Hyderabad, India, with the UNDP contributing \$US 1.7 million already earmarked for India.

The centres will be equipped with pilot-plant facilities for training and will be concerned with pooling of pharmaceutical capabilities of developing countries within their regions for research and development (R and D) activities and for the evaluation and development of technology.

QUALITY CONTROL

In any UNIDO pharmaceutical programme a quality control system is introduced as an essential safeguard in the production of drugs. Quality control laboratories of varying sizes have been set up in many countries to replace or strengthen existing inspection systems that do not meet the industrial need for the constant testing of raw materials, in-process materials and finished products. The help of UNIDO in introducing and maintaining quality control facilities especially in factories can ensure safe and efficient production.



Central analytical laboratory for pharmaceuticals, Guinea

TRAINING

In promoting the industrialization of developing countries, the policy of UNIDO has always been that training should be practice-oriented and as far as is feasible carried out at the work site. Training to a very high standard is essential to the pharmaceuticals industry, since skilled personnel are essential and the end-product must be of high quality.

The bulk of industrial training must be carried out in the home country. Initially it is usual to rely on the international experts recruited by UNIDO, who will normally integrate their training schedules with their industrial functions and thus impart the required level of skills to local personnel in the course of their work. Then, progressively, the international experts will be replaced by trained local personnel until eventually the industry achieves self-sufficiency in training.

The importance of training abroad, however, must be stressed. By this means key personnel become familiar with the most modern methods and technology under the guidance of instructors experienced in every phase of production of pharmaceuticals. UNIDO is able to arrange training of individuals or groups in industrialized or advanced developing countries. When necessary, fellowships lasting from one to several months can be granted to enable key management personnel to keep abreast of the latest developments in pharmaceuticals.

Global training, unrelated to the usual fellowship projects, is also undertaken with the assistance of UNIDO. In such cases groups of trainees nominated by the Governments of developing countries are selected, with the help and advice of UNIDO, by the authorities of the countries in which training is to be given to participate in intensive courses at the cost of the host Governments, after which they return to contribute to the technological advance of their home countries. At present such schemes are being provided by the Governments of Belgium, France and Romania. For instance Romania has offered such specialist training in the utilization of medicinal and aromatic plants in the production of pharmaceuticals.

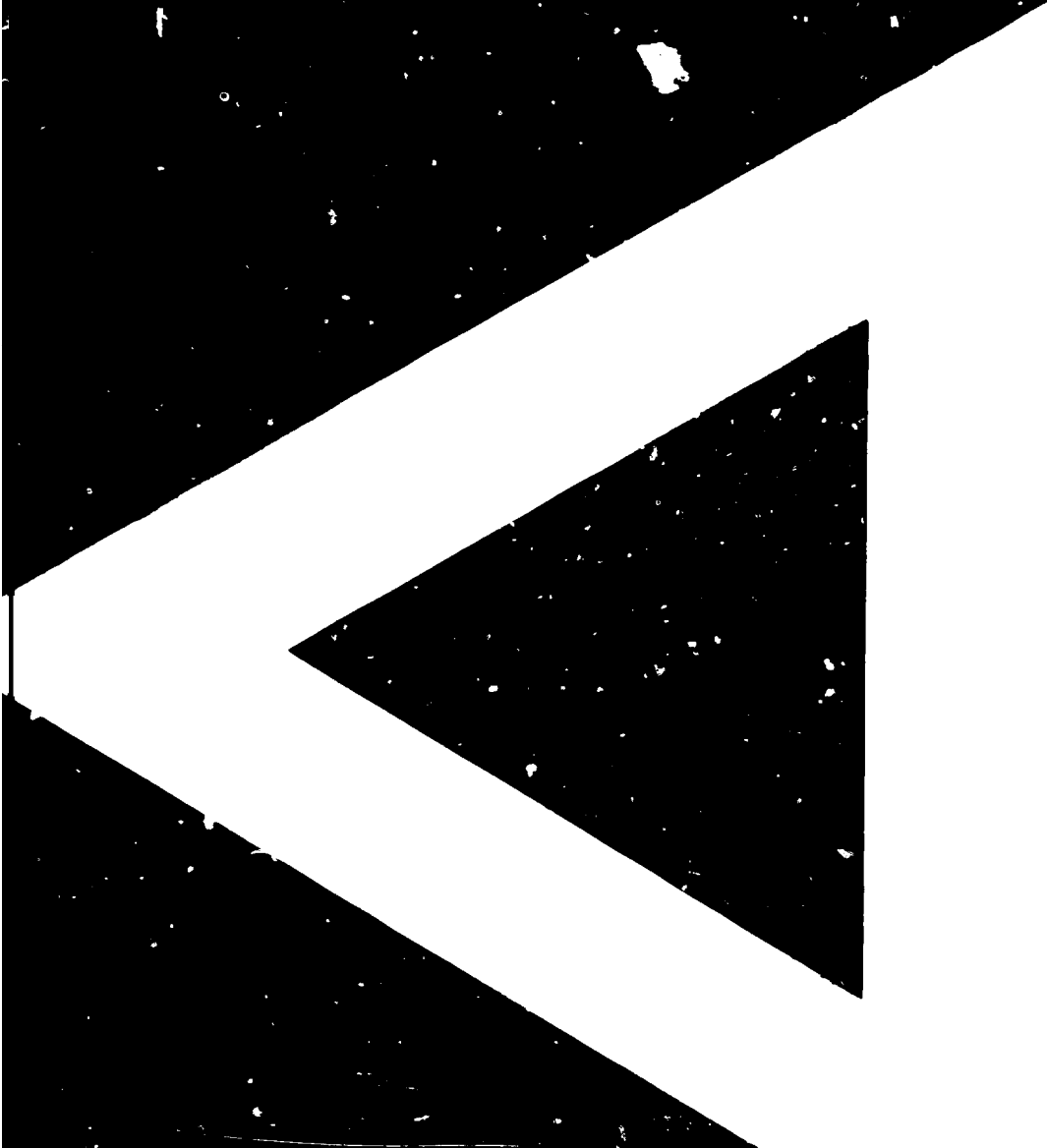
Conferences, workshops and seminars, too, are convened in a variety of countries, attended by selected personnel from the pharmaceutical industries of the developing world. Costs are normally met jointly by the host country and UNIDO.

For further information on UNIDO activities in the field of pharmaceutical industries, contact:

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