



TOGETHER
for a sustainable future

OCCASION

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



TOGETHER
for a sustainable future

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 publications@unido.org for further information concerning UNIDO publications.

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



17104-E

Distr.
LIMITED
ID/WG.466/23(SPEC.)
17 August 1987
ENGLISH

United Nations Industrial Development Organization

Third Consultation on the
Pharmaceutical Industry
Madrid, Spain, 5-9 October 1987

Issue Paper II

INTERNATIONAL CO-OPERATION RELATED TO: EXCHANGE OF INFORMATION
AND EXPERIENCE; INTEGRATED DEVELOPMENT OF THE PHARMACEUTICAL
INDUSTRY; AND DEVELOPMENT OF PHARMACEUTICAL
ANCILLARY INDUSTRIES

Prepared by
the UNIDO Secretariat

I. 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. National Governments and public authorities are interested in maintaining an adequate supply of drugs at all times to cater for the regular as well as emergency needs of the population. The local pharmaceutical industry plays an important role in keeping the supply at an adequate level and in adapting itself to emergency situations whenever the need arises. 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. Considering the regional character of most of the diseases endemic to the developing countries and the increasingly global character of other new and alarmingly contagious diseases, action to combat the spread of disease and the production of effective drugs to control and eradicate them becomes an international responsibility, warranting the co-operation of all countries. International organizations such as the World Health Organization (WHO), the United Nations Children's Fund (UNICEF), the United Nations Industrial Development Organization (UNIDO) and others can play an active role in fostering such co-operation.

3. The pharmaceutical industry is very dynamic, with continuous development of new products and processes. Moreover, it is extremely research and development intensive, and the development of a new product to the level of commercial application may easily cost more than \$US 100 million and cover a time span of over seven years. The industry is also dominated by a number of powerful transnational corporations that have widely spread production and marketing networks and tight control over production technologies. Very few developing countries could claim to have the capability to provide for their own drug needs through the local production of pharmaceutical formulations, pharmaceutical chemicals and their intermediates. 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, particularly in the area of technology transfer, and between developing countries themselves, in particular in the fields of production, quality control and marketing.

4. 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. A survey of work carried out by the United Nations agencies and other international organizations in this field reveals the immense amount of efforts spent by some countries to achieve the objectives of their national industrial drug policies. ^{1/} The main elements of such policies consist of part or all of the following items:

Preparation of a list of essential drugs based on local needs

Provision for the bulk purchase of generic products based on international competition

Establishment of a local pharmaceutical industry

Planning the acquisition and absorption of foreign technology and the development of indigenous technology, including the promotion of technological R & D

Quality-control legislation

Initiation of measures to regulate unwarranted promotional and marketing practices

Provision of safeguards against unsafe drugs

Setting up mechanisms for price monitoring or control

Legislation of guidelines on foreign investment

Setting up legal and administrative machinery to administer drug policy and a mechanism for co-operation with other countries on drug policy or on some of its constituent components

5. Considering the extreme diversity that exists with regard to the stages of economic development, socio-economic systems and resource availability in the developing countries, international co-operation, interaction between the various models of development and the exchange of experience would help a great deal in streamlining the national industrial drug policies of developing countries. International organizations such as WHO, UNICEF, UNIDO and the United Nations Conference on Trade and Development (UNCTAD) could play an active role in the realization of such regional or international co-operation activities.

6. 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-ordination with other socio-economic activities such as population growth and structure, health and health-related policies, education, infrastructure etc.

7. The availability of drugs at all times 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.

8. The practical tool which has been developed by UNIDO to make effective the application of the above-mentioned integrated approach is embodied in the master plan for the development of an integrated pharmaceutical industry, 2/ which has been applied, for instance, to the specific situation in Algeria. 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.

9. Within the framework of the master plan or parallel to it, subsectoral plans could be developed to deal with a clearly identifiable objective, such as the production of biologicals or an ancillary industry. In this sphere, UNIDO has developed a strategic paper on the production of vaccines and other biologicals in developing countries. 3/ 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;

(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.

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. 4/

11. The choice of appropriate materials and the proper production process for the packaging industry needs both a high level of know-how and scientific knowledge in physical and chemical disciplines and production experience. The most important function of these materials is to ensure the quality, safety and efficacy of the final product until it is administered to the consumer. Moreover, the sustained success of such a choice should take into account: the local availability of the materials selected for use; the method of

production and supply, i.e. on the basis of integration with a pharmaceutical plant or supply from another plant; and, finally, the reliability and availability of supply. Considering the fact that most of the pharmaceutical-related ancillary industries are small or medium-scale industries, those industries could have a multiplier effect on the development of local economies and the creation of job opportunities and would also need special incentives. The packaging industry may also serve other sectors of the economy, e.g. agro-industries.

12. The choice of primary packaging materials, i.e. those in contact with the drug, will also depend on the formulations produced. But in most cases these will be made of plastics, glass, metal or a combination thereof. Secondary packaging is mostly paper, carton, plastics, wood, metal etc. Careful consideration would have to be given to the local availability of these materials, otherwise the interruption of imports owing to foreign exchange difficulties could create serious supply problems. Promotional assistance would have to be provided for the ancillary industry in the form of investment support, training and R & D back-up activities. In most cases, the establishment of a national centre dealing with packaging materials industries in general has proved to be most effective in many developing countries.

13. It is recognized that a lack of information on sources of supply of production technologies and raw materials and chemical intermediates for the pharmaceutical industry has hampered its development and that a greater degree of international co-operation is required to remove the obstacles. During the last few years, UNIDO has devised several tools to assist in enhancing international co-operation in the pharmaceutical industry. Of obvious importance in this field has been the publication of the directory on sources of supply. 5/ The publication of this information on sources of supply has helped in establishing new and widening existing contacts between suppliers and producers in both developed and developing countries, particularly between those from the developing countries. Moreover, it has increased international competition and helped in reducing prices.

14. It should also be stressed that it is not enough to reveal new sources of supply but it is also necessary to establish, develop and improve a viable system for the procurement of pharmaceutical chemicals, intermediates and formulations. A well-functioning procurement system is essential for the implementation of the national health delivery system, of which the cost of pharmaceuticals is a major component in developing countries. A well-designed procurement system to secure pharmaceuticals at all levels and whenever they are needed could certainly lead to cost saving, the development and strengthening of local capabilities and a higher degree of self-reliance. UNIDO has prepared a report on this issue, covering such important aspects of a procurement system as marketing, investment, pricing, transport, distribution, modes of payment and the functioning of the procurement process. 6/

15. Another important tool of international co-operation to assist in the transfer of pharmaceutical technologies to developing countries is a survey by UNIDO of some 325 pharmaceutical producers in developed and developing countries to assess the need for and the availability of technology, the willingness to transfer it and the modes and conditions for such transfer. 7/ Moreover, UNIDO has played the role of intermediary: after identifying the need and the availability, UNIDO brings prospective partners into direct contact. It is believed that such a practical approach to international co-operation could and is yielding fruitful benefit to partners from developed and developing countries. In this context, the documentation on contractual arrangements in the pharmaceutical industry prepared by UNIDO, as agreed upon

by a group of experts representing Governments and industry from developed and developing countries, serves the same functional benefits for the development of this industry. 8/

16. 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 developed the concept of a multi-purpose plant for the production of pharmaceutical chemicals in developing countries. 9/ 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. One such plant is already in operation, and another is presently under construction with UNIDO assistance. Co-operation in this field will help in opening the technology package and in building up the technological capabilities of developing countries. It is considered that through this approach the barrier to technology transfer could be removed at a viable cost.

17. Perhaps the most important area that warrants closer co-operation both between developed and developing countries and between developing countries themselves is pharmaceutical research and development, owing to, first, the complexity of the industry itself and, secondly, to the extremely high cost required to develop new products to the commercial level. It could be stated that the organization of R & D in pharmaceuticals and the expectation of any real success in this field is beyond the reach of the great majority of developing countries. Also, considering the incongruity between the needs of developing countries for essential drugs and the pattern of production and R & D facilities, which are mainly located in developed countries, the necessity of having R & D devoted to the needs of developing countries becomes more and more acute. This explains the interest shown by a large number of developing countries and some developed countries in the establishment of a research and development centre for pharmaceuticals. 10/ It is thought that the establishment of such a centre on a co-operative basis to provide information, to train high-level cadres and to improve and develop new process technologies would be an important contribution to the transfer and development of pharmaceutical technology and to the creation of endogenous capabilities in developing countries to find adequate solutions to their own specific problems.

18. An International Centre for Genetic Engineering and Biotechnology, with components in New Delhi, India, and Trieste, Italy, has been pioneered by UNIDO and established by member States on a co-operative basis. In addition to its activities in other areas, the Centre is expected to assist in the development of new fields of activities relevant to the pharmaceutical sector.

II. ISSUE 2: INTERNATIONAL CO-OPERATION

19. Issue 2 has three parts, namely:

Exchange of information and experience

Integrated development of the pharmaceutical industry (master plan for the development of the pharmaceutical industry, multi-purpose plant for

the production of pharmaceutical chemicals, model programme for the production of biologicals, industrial drug policy, research and development centre)

Development of pharmaceutical ancillary industries.

Separate background papers covering these three main areas for international co-operation have been prepared by the UNIDO Secretariat to facilitate the presentation and discussion of this issue at the Third Consultation on the Pharmaceutical Industry.

20. It is recognized that, in view of the strategic importance of the pharmaceutical industry and its impact on national health delivery systems, Governments should play a leading role in all stages of its development. Although the direct responsibility of Governments in setting out general plans for the implementation of a national health policy is unquestionably accepted, the delicate relationship of this with the industrial drug policy and particularly with the local pharmaceutical industry, including enterprises from both private and public sectors, is not always well understood. The success of a local pharmaceutical industry would depend to a large extent on the adoption of a clear policy linking national health and national industrial drug policies and consequently on the support that would be afforded by the Government to the local pharmaceutical industry. Such support would have to balance the need to make the most effective and cost-efficient drugs available to the population through the national health delivery system and at the same time the need to ensure the development of the local pharmaceutical industry. In this regard, a national industrial drug policy could be adopted whereby elements of investment, import prices and other major policy issues are considered under a system of government incentives supporting the development of local industry. Other factors such as technology transfer, manpower development, patents and licensing and other relevant factors that would build up local capabilities in this sector would also have to be included in the industrial drug policy programme, to be legislated and implemented under government supervision.

21. Interaction and the exchange of experience between various developed and developing countries and between developing countries themselves, owing to the diverse socio-economic structures, health delivery systems and differing levels of economic and social development, would enrich each country's experience. Governments in developed and in developing countries play the major role both in setting up and in the implementation of their national health and industrial drug policies. They too would have to play the same leading role in the establishment of proper mechanisms for regular consultation at the regional and international levels and to explore the possibilities of policy co-ordination at the subregional and regional levels. United Nations agencies such as WHO, UNIDO, UNCTAD, UNICEF and others could help in the realization of international co-operation in this field.

22. 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 retooling 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.

23. The Third Consultation may wish to consider appropriate measures to be taken for the development of the pharmaceutical industry through co-operative action in the areas discussed below.

Exchange of information and experience

24. Considering the importance of having data and information available to determine the demand and sources of supply for pharmaceutical products, process technology, research and development, manpower training, investment and other factors having bearing on the development of the pharmaceutical industry in developing countries, consideration may be given to the establishment of such national infrastructural facilities as mentioned below. Also keeping in view the vital importance of a flow of information at the regional and international levels, its impact in improving and enriching local capabilities and the equal impact of the exchange of experience on this development, action may be considered on the ensuing:

(a) The establishment of national centres for information, training and research and development in the pharmaceutical industry;

(b) The establishment of federations/associations of pharmaceutical producers in regions where these do not exist, with particular reference to Africa;

(c) The preparation and dissemination of awareness booklets containing a brief account of and statistical data relating to the activities of:
(i) subregional, regional and international federations, associations and pharmaceutical development centres in the developing countries; and
(ii) international organizations, institutions, agencies and pharmaceutical industry development centres concerned with the pharmaceutical industry, including those interested in providing consultancy services;

(d) The organization and periodic convening of interregional meetings of representatives of the industry from subregional, regional and interregional federations/associations to review current activities and co-ordinate future co-operation projects;

(e) The adoption of a regular programme for holding expert meetings at the policy level to exchange experience in various fields related to pharmaceuticals, such as the preparation of a master plan, industrial drug policy, human resource development, pricing and procurement and marketing of pharmaceutical chemicals and biologicals and research and development activities;

(f) The establishment of pharmaceutical and packaging technology research institutes and enhanced linkage between science and technology institutions to production sectors in this field;

(g) The organization of workshops devoted to technical management, covering operations, quality control, specifications, technological improvement and other aspects in which the experience of pharmaceutical production units in different countries could be exchanged;

(h) The optimization of the use of existing training facilities in developing countries to organize training programmes for personnel in such areas as project implementation, production techniques, plant operation, the implementation of a quality assurance system, the development of specifications for raw materials and finished products, technical management and audit and maintenance of pharmaceutical plants;

(i) The establishment of maintenance improvement programmes to enhance capacity utilization, including the preparation of improved maintenance manuals, the introduction of new techniques of maintenance such as preventive maintenance, management of spare parts etc. making maximum use of the experience of developing countries in this field;

(j) The organization of mutual exchange of visits of personnel from developing countries at the plant level in order to benefit from each other's experience in the pharmaceutical sector;

(k) The stimulation of an exchange of technical information with the ultimate aim of establishing regional networks as regard specifications for raw materials, finished products, production technology, information on new products, sources of supply, procurement and prices, equipment and machinery, management and marketing aspects and export promotion techniques;

(l) The provision of information regarding the capabilities to manufacture pharmaceutical equipment and machinery and exchange of experience in this field;

(m) The promotion of interregional trade in raw materials, intermediates, finished pharmaceuticals and packaging materials in collaboration with UNCTAD so as to facilitate and enhance technological collaboration;

(n) The establishment of contacts on a permanent basis with international organizations such as UNIDO, WHO and UNICEF to exchange information on all pertinent aspects related to the sector. These organizations may be called upon to assist in setting up, rehabilitating or strengthening national quality control facilities for pharmaceutical and biologicals units. These organizations may also assist enterprises in improving the standard of their manufacturing plants through technical audits;

(o) Taking advantage of the facilities and strengthening mutual capabilities from the services of International Centre for Genetic Engineering and Biotechnology.

25. International organizations, such as UNIDO, WHO, UNICEF, UNCTAD and others, could contribute to the development, implementation and co-ordination of some of the activities mentioned above within their financial capabilities and if so requested.

Integrated development of the pharmaceutical industry

26. 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 at the Third Consultation 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 preparing pharmaceutical production strategies, based on 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, biologicals and ancillary materials etc., taking due account of the experience of developed and developing countries in this regard;

(d) Soliciting the assistance of international organizations in drawing up such plans and in organizing investment forums for their implementation.

Development of pharmaceutical ancillary industries

27. Considering the importance of the pharmaceutical-related ancillary industries (the providers of inputs to the health sector) in the development of pharmaceuticals and in order to identify the constraints, potential and advantages of adopting an integrated approach towards their development, participants at the Third Consultation may consider focusing the discussion on the following:

(a) The need to elaborate a development strategy for the pharmaceutical-related ancillary industries, accompanied by appropriate incentives to ensure their initial success and to allow domestic producers to gain mastery over the operation and development of ancillary industries;

(b) The advantages of establishing national institutes or centres for development of packaging materials, which would undertake R & D on packaging, set out standards and specifications, train local manpower and arrange contacts with the appropriate regional and international organizations;

(c) Studying other possible forms of international co-operation between developed and developing countries and between developing countries themselves to further the development of pharmaceutical and ancillary industries in developing countries through greater contributions by international, regional and bilateral technical and financial institutions.

Notes

1/ "Factors having a bearing on industrial drug policies: synopsis of studies made by United Nations agencies" (ID/WG.466/6 (SPEC.)).

2/ See background document ID/WG.466/16 (SPEC.).

3/ See "Model programme for the production of vaccines in developing countries" (UNIDO/IO.2).

4/ See "Development of the pharmaceutical related ancillary industries in developing countries, with special reference to packaging materials" (ID/WG.466/17 (SPEC.)).

5/ "Directory of sources of supply of pharmaceutical chemicals, intermediates, some raw materials and biologicals - based on the WHO Model List of Essential Drugs" (ID/WG.466/1 (SPEC.)).

6/ "A study to assist in improving management skills for the procurement of pharmaceutical chemicals, their intermediates and drugs (pharmaceutical formulations)" (ID/WG.466/21 (SPEC.)).

7/ "Availability, pricing and transfer of technology for pharmaceutical chemicals and their intermediates" (ID/WG.466/8 (SPEC.)).

8/ See ID/WG.393/1, 3 and 4.

9/ "Multi-purpose pilot plant for the production of pharmaceutical chemicals" (ID/WG.466/7 (SPEC.)).

10/ "Research and development centre for information, training and development of pharmaceutical technology" (ID/WG.466/20 (SPEC.)).