



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.

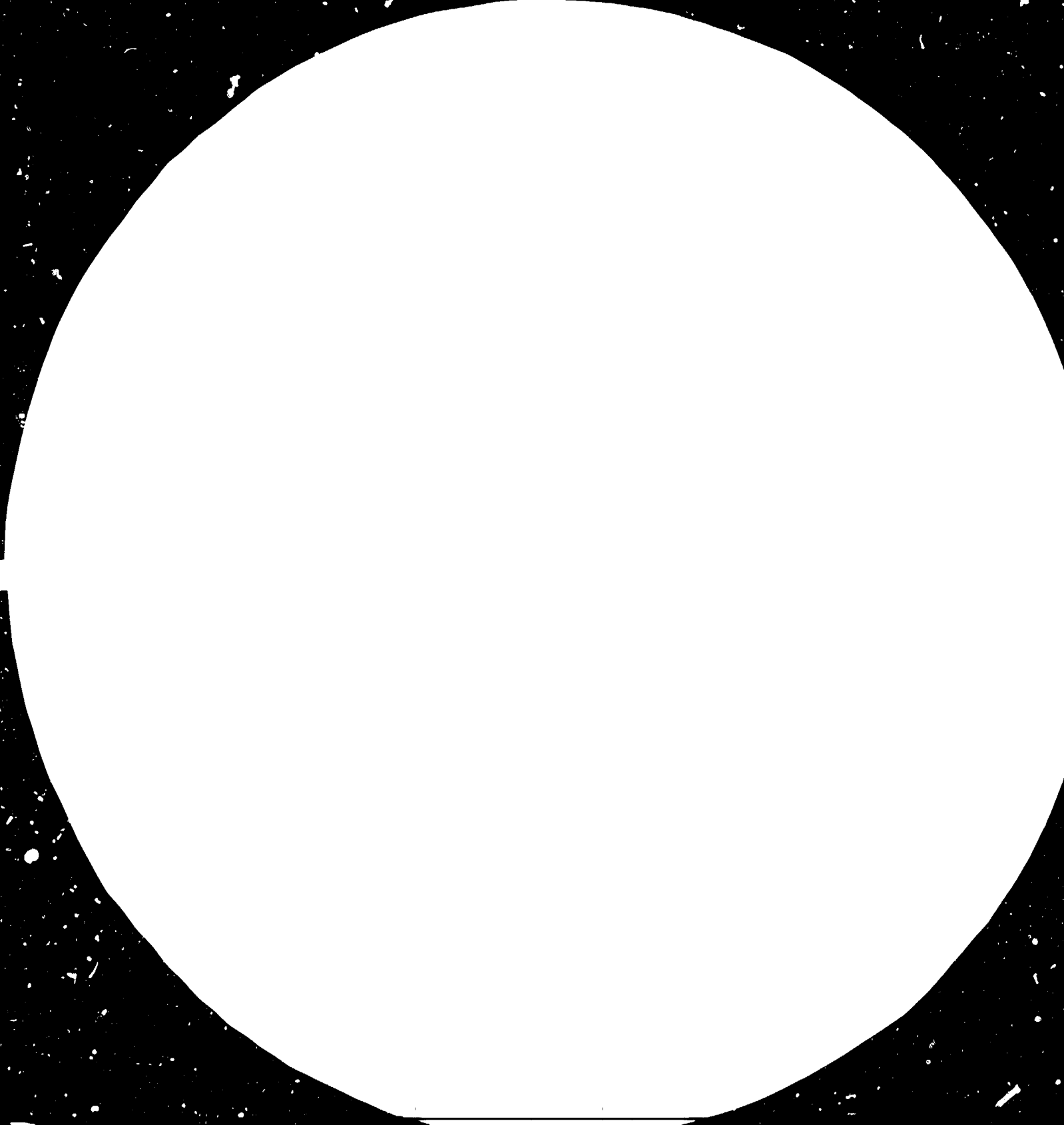
FAIR USE POLICY

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





12824-E



United Nations Industrial Development Organization

Distr.
LIMITED

ID/WG.393/8
1 September 1983

ENGLISH

Second Consultation on the
Pharmaceutical Industry
Budapest, Hungary, 21 - 25 November 1983

AVAILABILITY, PRICING AND
TRANSFER OF TECHNOLOGY FOR
BULK DRUGS AND THEIR INTERMEDIATES

Issue paper *

prepared by
the UNIDO secretariat

* This document has been reproduced without formal editing

V.83-59911

1. Background

In accordance with the recommendation of the First Consultation on the Pharmaceutical Industry and of the Committee of Experts on Pharmaceuticals, UNIDO is presenting to the Second Consultation the background paper on this issue that reports the action and results obtained upon implementation of issues 1 and 3 of the First Consultation (report of the First Consultation: ID/259, paras 1 and 3 to 7).

In addition, and as requested by the First Consultation, "Directory of sources of supply of 26 bulk drugs, their intermediates and some raw materials" has been prepared.

Further, reference papers to complement the main surveys recommended by the Committee of Experts have also been prepared, and which are described in the background paper to this issue.

2. The Document

Report to the Second Consultation; Availability, pricing and transfer of technology for bulk drugs and their intermediates, background paper (ID/WG.393/9).

The main objective of issue 1 of the First Consultation was to discuss the technical and economic aspects of the availability of intermediates and bulk drugs, in order to evolve a better understanding of this topic and assist developing countries in the production of such drugs and intermediates. This issue covers two topics, intermediates required for manufacture of bulk drugs and bulk drugs required for formulations into dosage forms.

The main objective of issue 3 of the First Consultation was the transfer of technology to enable the integrated production from raw materials to intermediates to bulk drugs of the 26 essential drugs included in UNIDO's list.

Upon the recommendation of the First Consultation, a Committee of Experts in Pharmaceuticals was convened in October 1982 to discuss the above issues.

Concerning the availability and pricing topic, the Committee acknowledged the major impact which prices of intermediates play in drug production and formulation manufacture, and which prices of bulk drugs play in formulation manufacture. However, the Committee did not arrive at a pricing mechanism linking cost of intermediates with cost of drugs. Instead, it recommended alternative solutions to this topic as follows:

- a) production of bulk drugs and intermediates in developed countries to meet the collective requirements of interested developing countries;
- b) production of bulk drugs and intermediates in developing countries through transfer of technology. Hence this topic was included into issue 3;
- c) to assist in particular the least developing countries in the manufacture of formulation of bulk drugs into dosage forms.

A survey on the collective requirements of drugs and intermediates of selected developing countries raised several questions from replying countries while giving limited information on their drug requirements.

A survey of availability of technology for transfer to developing countries turned out 14 replies out of 130 addressees covering 17 out of the 26 essential drugs in UNIDO's list and 2 intermediates. However, the technology offered was based on imported intermediates - which problem of price and availability is still unsolved -, technology to manufacture intermediates seem to be non-available, and the desired upstream manufacturing integration from raw materials to bulk drugs could not be achieved.

Despite the above disappointing outcome, UNIPJ continued its search and eventually became successful in identifying some independent research-based technology holders willing to transfer technology for the production of 21 out of the 26 essential drugs in UNIDO's list.

A directory of sources of supply of 26 essential bulk drugs, their intermediates and some raw materials was prepared in order to inform developing countries about a range of sources of supply which would assist them in obtaining their requirements of drugs and intermediates, and to improve their negotiations on procurement.

3. The Issue

This issue covers three parts namely basic drug manufacture, formulation and national drug policy. Participants at the Second Consultation are invited to advise UNIDO on actions to be taken in each of the parts under discussion.

A. Basic drug manufacture

As reported in the background paper to this issue, no pricing mechanism for intermediates and bulk drugs could be found by the Committee of Experts. The Committee considered that the more logical alternative for improving the availability and pricing of the above products in developing countries was through domestic production in those countries. To achieve this goal, transfer of technology is the critical factor.

So far UNIDO has not been successful in identifying suitable technologies for the production of intermediates. The Secretariat would continue its endeavours to dialogue with major technology holders and to make available to interested developing countries the information currently obtained or subsequently received.

Bearing in mind the spirit generated by the Committee of Experts for solving this issue through domestic production and despite minimal achievement with major technology holders, UNIDO was successful in identifying some independent research-based technology holders having technological capability and production capacity, and which agree to transferring technology for intermediates and bulk drugs production according to the requirements of developing countries.

A group of these technology holders have complete technologies for 21 out of the 26 essential drugs included in UNIDO's list. According to them, some of the technologies are already in commercial production in both developed and developing countries. This group has informed UNIDC about their technologies including terms and conditions for its transfer to developing countries.

Some developing countries have already indicated their technology requirements for the domestic production of several of the 26 essential bulk drugs including: (i) chemical synthesis from raw materials and from intermediates, (ii) drug production by fermentation and (iii) drug production from biological sources.

The advice of the Second Consultation is sought on the following:

- a) co-operation between developed and developing countries such as through the offer for transfer of technology made by the independent technology holders, whereby feasibility studies could be prepared in collaboration with the above technology holders. Thereafter negotiations between the parties could be initiated and the results could be reported to the next Consultation.
- b) as an alternative approach to transfer of technology from current technology holders, co-operation among developing countries in areas such as applied research and development may be desirable

for the longer term development of technologies from raw materials to intermediates to bulk drugs, according to the health needs of developing countries. A feasibility study leading to the establishment of such research and development centre could be prepared to enhance the technological capabilities of developing countries.

B. Formulation into dosage forms

To help promote the development of the pharmaceutical industry in particular in the least developed countries, a directory of sources of supply of 26 essential drugs was compiled. However, the directory neither ensures the availability of bulk drugs at reasonable prices nor covers the majority of drugs required by the health needs of developing countries.

The advice of the Second Consultation is sought on the following:

- c) The directory is currently restricted to 26 drugs which are a fraction of WHO's essential drug list. Information on additional sources of supply for a larger number of bulk drugs would improve the bargaining of developing countries on drug procurement. Therefore, an extended coverage of the directory to include the entire WHO's list of essential drugs could be prepared. Thereafter, a data collection system may be established to update the expanded directory periodically, and make available this information to interested developing countries on request.

- d) To provide practical assistance in particular to the least developed countries, technical profiles on formulations including the design and layout of model production units have been prepared. Thereafter, the technical profiles could be upgraded to industrial profiles by completing the necessary techno-economic appraisal, to be followed by specific project preparation upon request of individual developing countries.

C. National drug policies

As reported in the background paper, a case study of four developed and developing countries was carried out concerning the national drug policies and its impact on the development of their pharmaceutical industry.

In view of the important role played by those policies in guiding the development of the pharmaceutical industry, the advice of the Second Consultation is sought on the following:

- e) The carrying out of more comprehensive case studies on national drug policies and the preparation of guidelines thereof.

