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**United Nations Industrial Development Organization**

Interregional Meeting to Prepare for Consultationson the Pharmaceutical Industry

Cairo, Egypt 23-27 January 1979

# REPORT

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## INTRODUCTION

1. The Second General Conference of the United Nations Industrial Development Organization (UNIDO), held at Lima, Peru, in March 1975, recommended that UNIDO should include among its activities a system of continuing consultations between developing and developed countries with the objective of raising the developing countries' share in world industrial output through increased international co-operation. That recommendation was endorsed by the General Assembly at its seventh special session in September 1975. It was being implemented under the guidance of the Industrial Development Board, the policy-making organ of UNIDO.

2. The Industrial Development Board authorized the secretariat to undertake preparations for a consultation on the pharmaceutical industry including preparatory activities at the regional level. Two panels of experts from developing and developed countries were convened in June 1977 and February 1978 and a number of issues suitable for consultations were identified in a preliminary way.

3. The Interregional Meeting to Prepare for Consultations on the Pharmaceutical Industry was convened 23-27 January 1979 at Cairo at the invitation of the Government of Egypt. The Meeting was attended by participants from 12 countries and from 9 regional organizations (annex I).

4. The purpose of the Meeting was to identify priority issues that the developing countries were to discuss with developed countries at consultation meetings.

## CONCLUSIONS AND RECOMMENDATIONS*

### The goals of developing countries in developing the pharmaceutical industry

5. The pharmaceutical industry should make a much more important contribution to health care in developing countries. Many developing countries have no pharmaceutical manufacturing facilities; some have facilities to formulate a limited range of drugs; only a few have facilities for the basic manufacture of drugs.

6. As a result, the availability of drugs, active ingredients and intermediates for drug manufacture depends at present on imports. The growing cost of such imports makes it imperative for most developing countries to consider local formulation or basic manufacture of as wide a range of bulk drugs as possible.

7. At present, very few essential drugs are available in developing countries in sufficient quantities and at a low enough cost to satisfy health needs. The development of a national pharmaceutical industry in these countries is, therefore, a prerequisite for a health care programme that aims to cover the majority of the population.

8. The main constraints to the growth of the pharmaceutical industry in developing countries are inadequate technological capability; lack of qualified and trained personnel; high cost and limited availability of imported bulk drugs and intermediates; scarcity of financing available on terms and conditions suitable for the industry; and absence of well-defined national policies to promote the growth of the industry.

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* It was agreed by the participants that the conclusions and recommendations should be called "The Cairo Declaration".

National policies to facilitate the development of the pharmaceutical industry in developing countries

9. Developing countries have tended to imitate the pattern of supply in developed countries where many different products are sold in different combinations and dosage forms. In addition, many different brands of the same product are produced, often without significant differences in the product's formulation and efficacy. The pharmaceutical industry in developing countries should follow a different pattern concentrating on the local production of the essential drugs that the majority of the population need.

10. To achieve this, there is an urgent need to increase the local production of pharmaceuticals in developing countries keeping the costs within the reach of the majority of the population. The range of products produced needs to be rationalized so that production is concentrated on the essential drugs required to meet national health care needs. An integrated development of the entire system of procurement, production and distribution of pharmaceuticals at the national level appears the best way to achieve this objective.

11. As a first step towards establishing appropriate policies, a developing country should examine in detail its present overall drug requirements as met by imports and local formulation or production with a view to identifying the essential drugs required to meet the national health needs.

12. National policy should aim to make available the essential drugs required by the country and avoid excessive proliferation of different combinations, brands and dosage forms. It should also aim to guide pharmaceutical manufacturing activities to concentrate on producing these drugs most needed by the population. The following methods are suggested and to the extent possible or desirable could be adopted by each country as may be appropriate to its circumstances:

(a) Preparation by the health authorities of a national list of drugs with reference to the WHO Model List of Essential Drugs; 1/

(b) Establishment of a central procurement system of drugs including storage facilities to make available good quality bulk materials at lower prices;

(c) Establishment of a national quality control system;

(d) Establishment of a system for the registration of drug preparations sold in the country;

(e) Adoption of a pharmacopoeia suitable to meet national or regional requirements as appropriate;

(f) Establishment of distribution channels that facilitate supply to all segments of the population;

(g) Selection and regular updating of a number of drugs suitable for local formulation selected from the national list of drugs;

(h) Preparation and regular updating of a national list of active ingredients suitable for local production.

As far as possible, these methods should be implemented through co-operation between developing countries.

13. To achieve this, there must be a parallel development of the chemical and packaging industries, including industries manufacturing capital equipment.

The need for a new framework for international co-operation in developing the pharmaceutical industry

14. So far the pharmaceutical industry in developing countries has been developed mainly with the co-operation of pharmaceutical enterprises in developed countries, which are the main sources of supply of technology and manufacturing know-how, and one or more of the following trends in the development of the industry have resulted:

(a) Local formulation of a wide range of branded drug preparations not always well adapted to national health needs;

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1/ See The Selection of Essential Drugs, Technical Report Series No. 615, (Geneva, World Health Organization, 1977).

(b) Insufficient development of integrated production of drugs from intermediates or local raw materials because of limited or tied access to technology available in the world;

(c) High prices for imported intermediates;

(d) Inadequate local processing of raw materials obtained from developing countries for world markets;

(e) Full or majority ownership of local manufacturing facilities by multinational corporations, which has prevented the growth of manufacturing facilities under majority local ownership;

(f) Limited transfer of technological capability to national employees;

(g) Inadequate expenditure on research to develop new drugs suitable for the health needs of developing countries whose population will be 75 per cent of the world's total population by the year 2000.

15. A new framework for international co-operation should be established which takes account of the developing countries' goals to establish an integrated industry that gives priority to producing a broad range of essential drugs. This framework should comprise two elements: (a) greater co-operation between developing countries; and (b) greater co-operation between developing countries and pharmaceutical enterprises in developed countries.

Greater co-operation between developing countries

16. The main elements of the programme include:

(a) Greater use of technology available in developing countries for the formulation of drugs and production of active ingredients;

(b) Obtaining supplies of basic chemicals and intermediates available in developing countries;

(c) Pooling of production capacities and increased exchange of pharmaceutical products;

(d) Joint research and development, in particular on drugs derived from plant, mineral and animal resources;

(e) Providing technical training facilities in developing countries.

This programme should be supported by UNIDO, particularly by the establishment of regional pharmaceutical development centres.

17. The following specific areas are suitable for co-operation in establishing and operating plants to formulate drugs and manufacture active ingredients:

(a) Facilities for training manpower in the operation of plants, good pharmaceutical manufacturing practice, research and development, quality control, and marketing and distribution;

(b) Provision of technical know-how, including, in the case of antibiotics, a supply of strains of micro-organisms;

(c) Assistance in the preparation of feasibility studies and other forms of consultancy;

(d) Design and engineering of plants including turn-key projects;

(e) Supply of machinery and equipment;

(f) Supply of bulk drugs, intermediates and chemicals for basic manufacture;

(g) Advice on projects to develop a packaging industry.

When requested UNIDO should help to arrange co-operation in the above areas.

Greater co-operation between developing countries and pharmaceutical enterprises in developed countries

18. The programme should comprise:

(a) Recognition of the developing countries' need to concentrate on the production of a broad range of essential drugs reflecting national priorities and requirements;

(b) Development of integrated production of bulk drugs from intermediates or local raw materials;

(c) Development of national technological capabilities;

(d) Readiness to increase expenditure on research and development to improve health care in developing countries;

(e) Full support for the transfer of technology from one developing country to another for the production of essential drugs;

(f) Readiness to negotiate guidelines suitable for a licensing agreement for the transfer of technology for the production of active ingredients from intermediates and raw materials and formulation of drugs.

19. Initially such co-operation for the integrated production of bulk drugs from intermediates or local raw materials might concentrate on the list of illustrative twenty essential drugs (annex II) which were selected from the WHO Model List of Essential Drugs[1]. These drugs are needed in very large quantities in developing countries. For many of these drugs, the main part of the expansion of world markets will be developing countries and for some of them the entire market is in developing countries.

Issues that might be considered at the First Consultation Meeting

20. The First Consultation Meeting should consider how international co-operation can help to establish local facilities in developing countries for the basic manufacture of the active ingredients of essential drugs as well as for their formulation. While national policy could help to facilitate the development of the pharmaceutical industry in developing countries by the preparation of a national list of drugs, a system for quality control and registration of drugs, and where necessary, central procurement and the establishment of a distribution system etc., the three specific aspects requiring discussion and agreement at the Consultation Meeting are:

(a) The role that can be played by greater co-operation between developing countries;

(b) Guidelines suitable for a licensing agreement for the transfer of technology for basic manufacture of the active ingredients of essential drugs and formulations;

(c) The availability of, and pricing scheme for, intermediates and bulk drugs.

21. As regards the contents of the guidelines, some relevant clauses that might be included as guidelines for the preparation of a licensing agreement for the transfer of know-how involving sophisticated technology in the pharmaceutical industry were discussed. In order to facilitate

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2/ Ibid.

concrete discussions at the Consultation Meeting, UNIDO should prepare a detailed draft of the contract form as well as guidelines for its use by the parties. Participants should assist UNIDO in this task by contributing contracts and their experience.

22. The Consultation Meeting should consider a further issue relating to the mobilizing of financing for the establishment of facilities for the formulation of drugs and for the basic production of active ingredients from intermediates and raw materials. The aspects of this issue requiring discussion and agreement are:

(a) Guidelines on the criteria for evaluating the investment required;

(b) Recommendations on the terms and conditions of financing of such investments addressed to Governments and national and international financing institutions. (Countries receiving taxes from the profits of multinational enterprises exporting drugs to developing countries should be particularly sympathetic to this recommendation.)

23. The specific role that UNIDO can play in facilitating co-operation on all the above issues should be considered by the Consultation Meeting.

24. It is further suggested that some Governments contributing to the United Nations Industrial Development Fund may increase their contribution and allocate part of such contributions to the Fund for the purchase of technology for the production of essential drugs on behalf of the developing countries. In addition, Government contributions to UNDP could be allocated for use by UNIDO for the same specific purpose.

25. The participants of the Meeting agree to assist UNIDO with the preparations for the Consultation Meeting.

## I. ORGANIZATION OF THE MEETING

26. The Meeting was opened by His Excellency Professor Dr. Hamdouh Gabr, Minister of Health of the Government of Egypt. He described the development of the pharmaceutical industry in Egypt, pointing out that while in 1952, 90 per cent of the drugs required were imported, today Egypt produces 80 per cent of its requirements worth LE 120 million. The number of drugs in the market had been reduced from 22,000 in 1952 to 2,500 in 1975. The industry currently employed 30,000 persons. A start had been made on the production of bulk chemicals, but so far only 15 per cent of those required were manufactured locally. Therefore, Egypt still required foreign technology for the production and synthesis of bulk drugs.

27. The Minister also praised the significant role that UNIDO played in helping developing countries to establish a pharmaceutical industry and other industries. He stressed the importance of the developing countries' striving to increase their share of world production in that and other industrial sectors.

28. A. Tcheknavorian-Asenbauer, Chairman of the UNIDO internal task force established to prepare for consultation on the pharmaceutical industry, was Chairman of the Meeting. When introducing the agenda, she described the current stage of development of the pharmaceutical industry in the developing countries. She also stressed the need for an integrated development of the procurement, production and distribution of pharmaceuticals in order to ensure that essential drugs were made available to the majority of the population at reasonable prices.

## Adoption of the agenda

29. The following agenda was adopted:

1. Consideration of the background paper "Assessment of the pharmaceutical industry in developing countries; its potential and the national and international action required to promote its development" (ID/WG.292/2).

2. Identification of priority issues that should be discussed at the First Consultation Meeting.

3. Adoption of the report.

## Documents

30. The documents considered by the Meeting are listed in annex III.

## Adoption of the report

31. The report of the Meeting was adopted on Saturday, 27 January 1978. At that point, representatives of each region confirmed their full support for the Conclusions and Recommendations.

## II. SUMMARY OF DISCUSSION

### Stage reached in the development of the pharmaceutical industry and constraints on its growth

32. The Meeting recognized that developing countries were at different stages in establishing a pharmaceutical industry and that the constraints on the growth of the industry were different at each stage. Three principal groups were identified:

(a) Developing countries with little or no pharmaceutical manufacturing activity;

(b) Developing countries with facilities to formulate a range of drugs;

(c) Developing countries with facilities to manufacture some of the active ingredients as well as formulate drugs.

33. For many of the first and second group of countries, the resources made available for health care from the national budget were limited. The lack of trained personnel was a serious constraint. Many countries were small countries with limited markets, imports were unrestricted and in most countries procurement was not centralized. As a result, a proliferation of different pharmaceutical products were sold on the market, most of them imported. Another constraint in many countries was the lack of a well-defined national policy for the development of the pharmaceutical industry. The local formulation industries found that prices of imported bulk drugs and raw materials were often too high. Many countries found that it was not always easy to obtain suitable formulation technology on reasonable terms.

34. For the third group of contries, the main concern was to broaden the range of active ingredients produced from intermediates and raw materials. A common constraint was the lack of availability, and high price, of imported intermediates and raw materials. The foreign technology required to relieve this constraint was not always available

on suitable terms and conditions. A parallel development of the chemical and packaging industries was also needed. In large countries, there was a need to begin local production of the equipment and machinery used by the industry. Facilities for local research and development should be encouraged and local personnel should receive extensive training in order to develop the country's technical capabilities.

Ways to facilitate the growth of the pharmaceutical industry

35. The Meeting recognized that a harmonization of policies was required to promote the growth of the pharmaceutical industry in developing countries. Among the steps that should be considered, the following were mentioned:

(a) To establish whenever necessary, a health-care programme that aimed at health for the whole population by the year 2000 and practical programmes to implement it within a specific time frame;

(b) To allocate a higher proportion of budget funds and foreign exchange for health-care programmes;

(c) To prepare a national list of essential drugs;

(d) To regulate imports and guide local production to make available the essential drugs included in the list;

(e) To establish centralized procurement and distribution systems when needed;

(f) To encourage local production by protective measures;

(g) To establish a registration system and gradually abolish the use of brand names;

(h) To establish training facilities for national personnel;

(i) To strengthen facilities for quality control;

(j) To establish facilities for research and development;

(k) To regulate prices for pharmaceutical products.

36. Many participants indicated that their countries had difficulty in obtaining access to technology. Other participants stressed the importance of regular supplies of bulk drugs at reasonable prices. It was therefore suggested that consultations might consider the following issues:

(a) Access to the technology suitable for the environment of developing countries at a reasonable price;

(b) Assured availability of bulk drugs, intermediates and other raw materials at reasonable prices.

Co-operation between developing countries

37. The Meeting examined the opportunities for increased co-operation between developing countries. It felt that countries with experience (group 3) could provide useful assistance to other developing countries (groups 1 and 2). A major constraint on developing such co-operation was a lack of information on the capabilities developed in the more advanced countries in the pharmaceutical industry.

38. It was therefore suggested that:

(a) The more developed of the developing countries should make available to other developing countries information on the availability and price technology, raw materials, equipment etc., the latter could approach them for assistance if they wished;

(b) Developing countries should adopt a charter whereby their formulation and bulk drug manufacturing plants would be open to visitors from other developing countries;

(c) The more developed of the developing countries should be ready to provide experts to other developing countries to render technical assistance at minimum cost;

(d) Before seeking assistance, developing countries should have taken some of the preliminary steps mentioned above to establish centralized procurement and quality control laboratories etc. so that the co-operation could be effective for this purpose.

39. Co-operation at the government level might include harmonization of national drug registration systems; adoption of a unified pharmacopoeia on a regional basis; reduction of tariffs and taxes on drugs manufactured within the region; when purchasing drugs, preference should be given to the offers of other developing countries; pooling of capabilities to undertake research and development; and co-operation in developing uses of local resources such as medicinal plants. In all of the above areas, UNIDO should help to identify opportunities for co-operation, receive project proposals, introduce suitable partners and, when requested, assist in the implementation.

Co-operation between developing and developed countries

40. The observer from IFPMA pointed out that the best way to facilitate the growth of the industry was to provide incentives for the flow of technology, and not to create disincentives by reducing the life of patents, abolishing brand names and trade marks etc. He also pointed out that pharmaceutical enterprises from some developed countries had made a big contribution in the training of personnel in developing countries, particularly in the field of quality control.

41. It was pointed out that a number of developing countries had on going co-operation with countries with centrally planned economies for purchasing bulk drugs and intermediates and technology.

Priority issues for the First Consultation Meeting

42. It was further recognized that the developing countries would continue to need a flow of technology to develop their pharmaceutical industry in order to serve the health needs of three quarters of the world's population living in such countries. It would be a pity if enterprises in developed ccuntries took a narrow view of their own interests and were unwilling to provide that technology on reasonable terms to those countries where it was so badly needed.

43. A dialogue between the developing and developed countries at the First Consultation Meeting could consider where those interests were complementary and where they conflicted. A practical basis could then be found for co-operation that would lead to a more rapid development of the industry in developing countries.

44. In order to make such a discussion on common interests more specific and produce concrete and useful results, it was felt that the main issues to be considered should be:

(a) A model form of agreement for licensing of technology;

(b) A scheme to determine the price at which bulk drugs and intermediates were sold to developing countries;

(c) Ways to overcome difficulties faced in financing pharmaceutical industry projects in developing countries.

The preparation of a model form of agreement for the licensing of technology in the pharmaceutical industry

45. The participants reviewed some relevant clauses to be included in a licensing agreement proposed by a participant (annex IV ). Some participants suggested a number of modifications (annex V).

46. It was agreed that in order to assist UNIDO in the basic task of preparing a model, the participants would send to the UNIDO secretariat within two months: (a) a copy of a complete negotiated contract from their country; and (b) specific suggestions for clauses that they wished to be included in the model to be drafted by UNIDO.

47. It was further suggested that UNIDO should prepare a comparative study of a number of existing contracts to single out all the issues that were relevant. It was pointed out that any model contract UNIDO drafted would have to be updated; it would also have to be adapted to the particular circumstances of each country.

48. It was stressed that the duration of patents should be reduced and the period over which royalties were paid by the licensee should be limited. Such payments should not continue after the licensor had recovered his expenses in developing the technology sold.

Pharmaceuticals derived from medicinal plants

49. The representative of OAU stated that in some developing countries:

(a) More than 70 per cent of the population used traditional methods and herbal medicine;

(b) The medicinal flora of the developing countries represented an extraordinary richness for improving the health of the vast population of such countries; nevertheless synthetic drugs were being promoted for use by the population at their expense at an alarming rate.

50. Collaboration and more efforts were needed for the support of research and development on the use of medicinal plants and traditional medicines. That needed not only co-operation between the developing countries but also the support of UNIDO, WHO, and other donor agencies.

51. Systematized and multi-disciplinary studies were required to generate a forum for modern scientific investigations that would secure the popular medical knowledge in the developing countries and achieve and establish an effective exchange of knowledge, personnel, investigation and developing projects, for the full utilization of medicinal plants and traditional medicines.

Annex I

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## Annex II

## ILLUSTRATIVE LIST OF ESSENTIAL DRUGS RECOMMENDED BY THE MEETING FOR LOCAL BASIC PRODUCTION OF ACTIVE INGREDIENTS FROM INTERMEDIATES AND RAW MATERIALS*

### ANALGESICS

Acetylsalicylic acid

### ANTI-INFECTIVE

#### Anthelmintics

Bephenium

#### Antibacterials

Ampicillin
Benzylpenicillin
Phenoxymethylpenicillin
Tetracycline
Sulphadiazine
Sulphadimidine

#### Antifilarials

Diethylcarbamazine

#### Antimalarials

Chloroquine
Primaquine

#### Antileprotics

Dapsone
Clofazimine

#### Antiprotozoals

Metronidazole

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* This illustrative list was selected from the WHO Model List of Essential Drugs using the criteria suggested by the Second Panel of Industrial Experts on the Pharmaceutical Industry organized by UNIDO.

Annex II (contd.)

Antituberculosis

Ethambutol
Isoniazid
Streptomycin

CARDIOVASCULAR DRUGS

Antihypertensive drugs

Reserpine

Cardiac glycosides

Digoxin
Digitoxin

## Annex III

### LIST OF DOCUMENTS

| | |
|---|---|
| Assessment of the Pharmaceutical Industry in developing countries, its potential and the national and international action required to promote its development<br>UNIDO secretariat | ID/WG.292/2 |
| Report of the Panel Meeting of Industrial Experts on the Pharmaceutical Industry - July 1977 | UNIDO EX.24 |
| Report of Second Panel Meeting of Industrial Experts on the Pharmaceutical Industry - March 1978 | ID/WG.267/4 |
| Steps involved in establishing a Pharmaceutical Industry in developing countries<br>UNIDO secretariat | ID/WG.267/3 |
| Ways of ensuring adequate supplies of chemical intermediates required for the production of drugs in developing countries<br>UNIDO secretariat | ID/WG.267/2 |
| The Growth of the Pharmaceutical Industry in developing countries; Problems and prospects | ID/204 |
| The selection of essential drugs - Report of a WHO Expert Committee - World Health Organization, Geneva 1977 | Technical Report Series 615 |

Annex IV

RELEVANT CLAUSES TO BE CONSIDERED IN A LICENSING AGREEMENT *

Between :

Licensor
Manufacturers of Pharmaceutical Products,
whose registered office is situated at
.....
(hereinafter called".....")

of the one part,

And :

Licensee
a company formed under the laws of
.....
(hereinafter called ".....")

of the other part.

The following has been agreed upon.

* This document is reproduced in the form that it was presented to the Meeting by a participant without alteration or editing.

ARTICLE 1

Licensor grant to Licensee the right to manufacture and market in.....,
their products mentioned in Appendix I attached hereto and such other Pharmaceutical products as may be agreed in writing between the parties hereto from time to time (hereinafter referred to as the "Products") for a period of five years commencing on the date what the first product is launched on the market.

The manufacturing includes compounding, processing, subdividing and packaging of the Products.

ARTICLE 2

(a) Licensor agree to the manufacture and marketing of the Products under.....trade marks and trade names or under Licensee trade names or under pharmacopeal names at the option of Licensee.

(b) Licensor agree that the Products shall be packed and marketed by Licensee according to the prevailing laws of the country of Licensee.

(c) Licensee undertake to pay all costs and charges for maintaining the registration in the Licensee's country of their trade marks during the term of this agreement.

(d) Licensor agree to furnish all relevant data required for registration of Product in the Licensee's country.

ARTICLE 3

(a) Licensor agree to grant Licensee the "Know-How" to manufacture the following raw materials as soon as Licensee advises Licensor of their readiness to manufacture them:

1. .....
2. .....
3. .....

(b) Licensor do not object for the manufacture of bulk or finished product with any local manufacturer the Licensee's country authorities would indicate, pending the

approval of the local manufacturers for those products Licensor have already committed.

(c) Licensor shall prohibit their subsidiaries, agents and licensees from selling preparations covered by this agreement in Licensee's country.

ARTICLE 4

licensor grant to Licensee the right to export or re-export the Products covered by this agreement to territories as specified in Annex.....

ARTICLE 5

licensor will indemnify Licensee against damages and losses incurred due to patent infringement on the use of know-how furnished by the Licensor.

ARTICLE 6

(a) Immediately after this agreement has been signed and approved by the Licensee's country, Authorities, Licensor will forward to Licencee the "Know-How" of the Agreement Products and raw materials agreed upon.

(b) Licensor and licensee will exchange full reports and information concerning all improvements of manufacturing methods and packing.

(c) Licensor shall further keep Licensee posted on technical improvements in the manufacture, control and packaging of the Products.

(d) Licensor shall assist licensee in solving any technical problem which might appear in the course of manufacturing, packing, control, analysis of the Products and product development.

(e) Licensee, on their part, shall be entitled to delegate at their expense, one or several representatives of their personnel to the Licensor's laboratories, with a view to practising their manufacturing, packing, controlling or analytical processes and in such case Licensor shall lend their assistance to enable those representatives to learn of manufacture or analyse or pack pharmaceutical products in Licensee's country to the same standard

and under the same conditions as Licensor's Products during the pending of Agreement. If for the manufacture of the Products additional machinery equipment eto. is needed, Licensor will, for the sake of purchasing and installation advise Licensee to the best of their knowledge and put their experienoe at Licensee's disposal and will forward all technical assistance related to the manufacture of the Products.

(f) Licensor shall be entitled to send to Licensee's country at their expense, their technical delegate to Licensee's establishment to control the processes used and make sure that their methods and the means of improving them are duly applied.

(g) Licensee will start by manufacturing in their laboratories three successive small batches of the Products following Licensor's production instructions and will submit to Licensor samples of these batches for investigations, control and approval, Licensor on their part, agree to proceed with this control within the shortest possible time, and upon approval by Licensor, Licensee will proceed to manufacture, launch and sell the Products without further permission from Licensor. Licensee on their part, will supply Licensor whenever asked for samples of the Products. If such samples are not approved by Licensor, then Licensee agree to withdraw the corresponding batches of the Products for sale.

(h) Licensor guarantee that Licensee, based on the Know-How shall obtain Products oonforming to specifications within a specified time.

(i) Licensor in the event of failure to prove the guarantee within the specified time shall compensate Licensee liquidated damages amounting to not more than.....

ARTICLE 7

Licensor and Licensee undertake not to disclose to any third party any information, except where such information is by law required by Governmental Authorities, concerning the relations between Licensor and

Licensee, production, control and sales methods and technical and clinical data exchanged or evolved by cirtue of this agreement. Further, Licensee will ensure that employees having access to the aforementioned information undertake to preserve the secrecy of the information.

ARTICLE 8

(a) Licensor shall receive annually in Licensor's country, after publishing Licensee's annual balance sheet, a net royalty, a maximum amounting to 5% (five per cent) calculated on Licensee's net wholesale price of the Agreement Products and on raw materials used in the manufacture of the Agreement Products. Remittance of royalty shall be effected in Licensor's currency or in any convertible currency.

Royalties shall be paid against complete "Know-How" being complete descriptions of the methods of manufacture, specifications and control of the Products, active ingredients, raw materials, packing materials and ausiliary materials agreed upon as well as technics in general in order to ensure a perfect production as indicated in Annex.....

(b) These royalties shall be payable annually according to a statement drawn up by Licensee and certified to be correct by one chartered accountant. Licensor shall be free to appoint an auditor or a delegate at Licensor's expense for checking the amount of the royalty.

(c) Licensee undertake to furnish Licensor with quarterly sales reports containing information on the number of the packings sold of each type and size manufactured by Licensee. A revised annual statement containing a summary of the quarterly sales reports shall reach Licensor not later than the 31st of March of the following year.

ARTICLE 9

As regards purchase of raw materials, a governmental organization is presently handling all imports of pharmaceutical specialities, raw materials as well as medical requisites in Licensee's country. Said organization is setting tenders for raw materials and importing at the lowest possible prices from the world repute suppliers. Licensee thus,

is not allowed to import pharmaceutical specialities, raw materials or even medical requisites for their own account except through said organization.

Bulk raw materials will preferably be purchased from Licensor at world competitive prices. If purchased from other manufacturers, Licensor will be ready to establish their conformity with international standards or to standards to be decided by both parties.

ARTICLE 10

This agreement or any future amendments will not come into force unless approved by all concerned governmental authorities and will be subject to all Licensee's countries legislation during the duration of its validity.

ARTICLE 11

(a) The term of this agreement shall extend five years from the date at which the first product is launched on the market unless sooner terminated and will thereafter be automatically prolonged from year to year, unless one of the parties cancel the agreement by a registered letter despatched not later than six months preceeding expiration of the agreement.

(b) Either party shall have the right to terminate this agreement on six months' notice in writing to the other party after a breach of any provision of this agreement by the other party unless such breach is remedied within such six months' period.

(c) If one of the contracting parties after a period of three years from the day when the medical registration for the first product is obtained, finds the continuation of this agreement to be unfavourable to such party, he will have the right upon six months' notice in writing to the other party forwarded by registered mail to terminate this agreement.

(d) Licensee agree that except with the prior consent in writing of Licensor they will not apply trade marks or trade names covered by this agreement to any products manufactured or marketed by them after the termination of same.

ARTICLE 12

All disputes in connection with this agreement shall be submitted to the arbitration of the International Chamber of Commerce in Zurich, Switzerland, under and in accordance with its rules in force at the date of the

arbitration.

The law to be applied is that of the defendant.

ARTICLE 13

This agreement shall inure to the successors of licensor and the successors of Licensee but shall not be assignable by any of the parties.

ARTICLE 14

This agreement is made in duplicate, each party possessing one copy.

ATTEST

Licensor

Address

ATTEST

Licensee

## Annex V

## COMMENTS ON SOME RELEVANT CLAUSES TO BE INCLUDED IN THE PROPOSED GUIDELINES FOR THE LICENSING OF TECHNOLOGY IN THE PHARMACEUTICAL INDUSTRY TO BE DRAFTED BY UNIDO

The participants considered a document entitled "Relevant clauses to be considered in a licensing agreement" and made the following comments:

Article 2a: third line: after trade name include "generic"

2c: put licensor as first word instead of licensee.

Article 3a: First two lines to read: "The licensor agrees to grant the licensee the latest know-how in the licensor's possession to manufacture the following products as soon as .....

3b: Stop after the word "indicate" in line 3 and delete the revised.

3c: The purpose and drafting of this clause needs to be clarified.

Article 4 : One participant defended this clause. Another participant was of the view that the permission of the countries mentioned in the annex should be obtained before this clause was adopted.

Article 5 : To be revised with legal advice.

Article 6a: Delete the words "Agreement" and "and raw materials".

Article 6b: Add "free of charge" after "exchange".

Article 6c: Add at the end of clause "during the period of the agreement"

Article 6d: After the word "installation" add the word "thereof".

Article 6e: Instead of "their expense" read "the licensee's expense";
instead of "delegate" read "experts";
instead of "applied" read "approved by both parties".

Article 6g: Line 11 after "such samples" insert "do not correspond to the specifications".

Article 6h and 6i: Should be merged: add to the last line of (h) after the work "time" the following "and in the event of failure to prove the guarantee, the Licensor shall compensate the Licensee" and delete sub-clause (i).

Article 7 : To be revised by legal experts and additional clause to be considered that would permit transfer to a third party on mutually agreed terms.

Article 8 : To be redrafted; it was suggested that a group of specialists be convened to study the question of royalties.

Article 8a: The following comments were made:

(a) Payments should be more frequent not "annually";

(b) Instead of "wholesale price" read "ex factory price";

(c) Line 4 replace "and" by "a";

(d) Line 5 delete "Agreement".

Article 8b: Same comment as (a) above.

Article 8c: Examine whether "quarterly" rather than "annually" is feasible.

Article 8g: Delete first paragraph;
Include the principle that the licensee has the right to buy at world competitive prices from international suppliers.

Article 11c: Delete.

Article 11d: Rewrite in a positive way.

Article 12 : Revise clause to adapt centre of arbitration to laws of the country of licensor and licensee.

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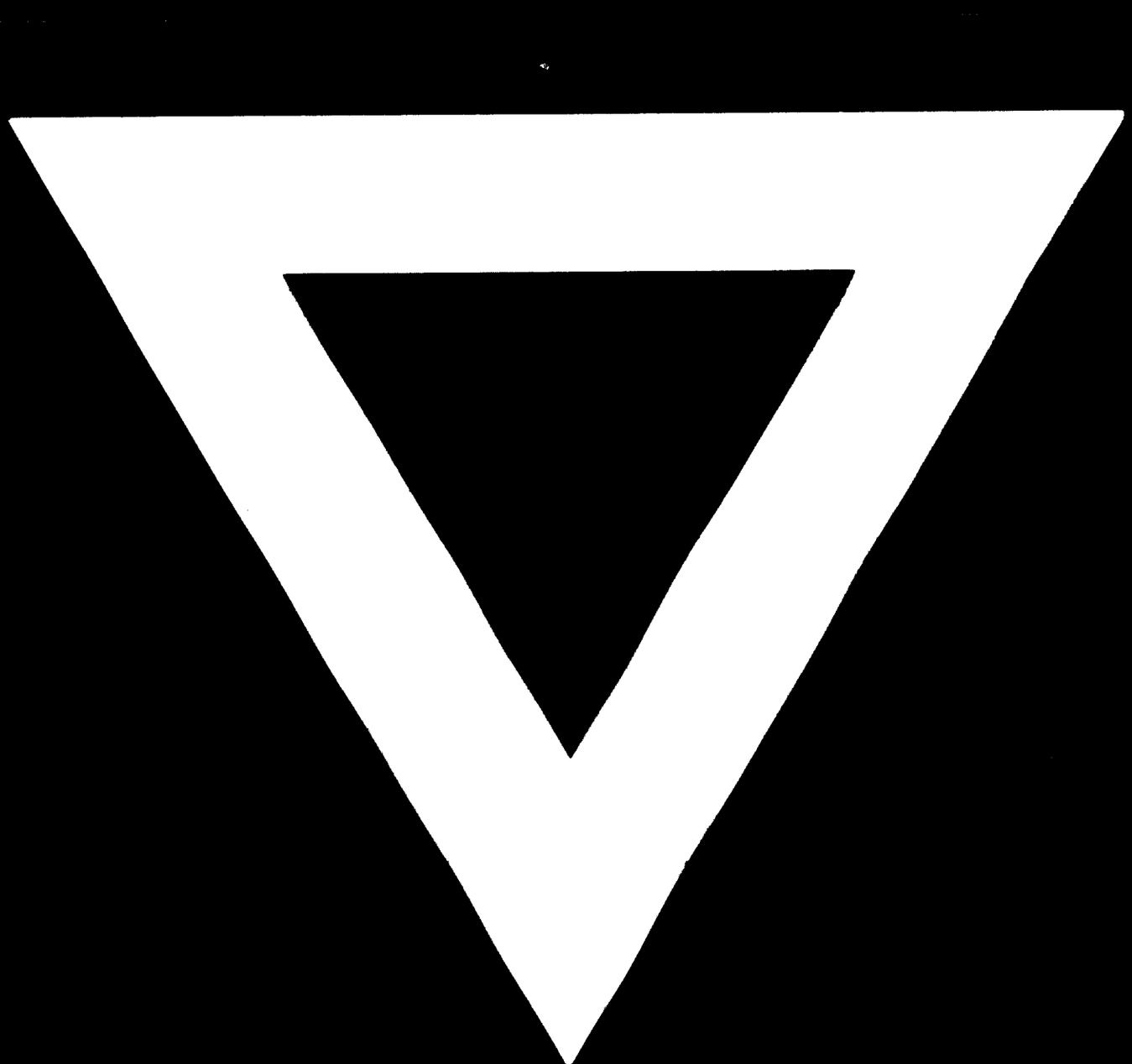

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