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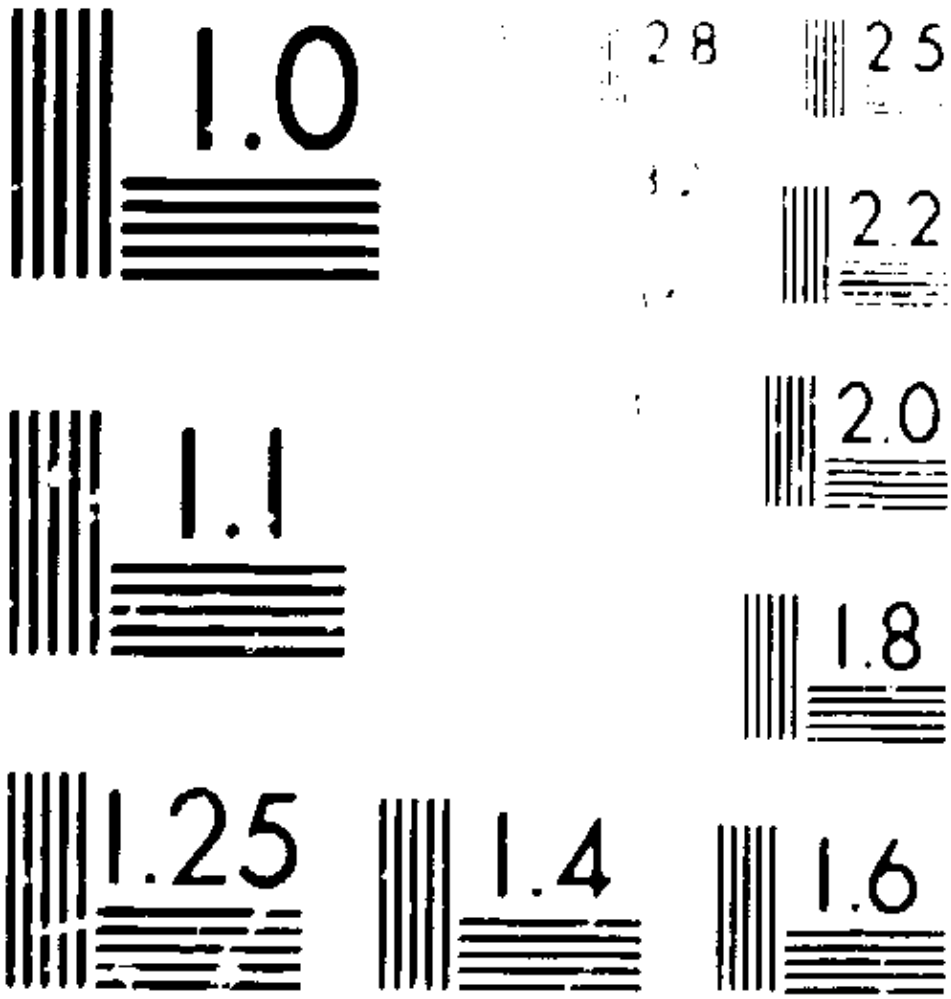
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CONTRACTUAL ARRANGEMENTS FOR THE PRODUCTION OF DRUGS·

Issue Paper

prepared by
the UNIDO Secretariat

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Issue Paper on Contractual Arrangements for the Production of Drugs

1. Background

In accordance with the recommendation of the First Consultation on the Pharmaceutical Industry UNIDO, in cooperation with the Ad-hoc Panel of Experts, is presenting to the Second Consultation three main documents on contractual arrangements relating to the transfer of technology in the pharmaceutical industry:

a) Items which could be incorporated in contractual arrangements for the transfer of technology for the manufacture of those bulk drugs/intermediates included in UNIDO's illustrative list.

b) Items which could be included in licensing arrangements for the transfer of technology for the formulation of pharmaceutical dosage forms.

c) Items which could be included in contractual arrangements for the setting up of a plant for the production of bulk drugs (or intermediates) included in UNIDO illustrative list.

Annexure A presents the UNIDO List of 26 Essential Drugs.

In this context, and as requested by the First Consultation, an additional reference paper "Relevant topics to be taken into account in the preparatory phase of technology transfer arrangements for the production of pharmaceuticals" has also been prepared. In addition, a reference paper on "Summary of industrial property protection on pharmaceuticals in developing countries" has been prepared as requested by the Ad-hoc Panel.

2. The Documents

A. Items which could be incorporated in contractual arrangements for the transfer of technology for the manufacture of those bulk drugs/intermediates included in UNIDO's illustrative list (ID/WG.393/1)

This document includes items which could be incorporated in contractual arrangements while negotiating transfer of technology for the manufacture of those bulk drugs and intermediates included

in the UNIDO illustrative list; it is addressed in particular to enterprises in developing countries which are able and willing to increase the range of bulk drugs (or intermediates) locally produced.

B. Items which could be included in licensing arrangements for the transfer of technology for the formulation of pharmaceutical dosage forms (ID/WG.393/3)

This document provides general guidelines and concrete drafting proposals for the negotiation and conclusion of licensing arrangements related to the formulation of pharmaceutical forms. These guidelines have general application to all those drugs contained in WHO's model list of essential drugs, including those on UNIDO's illustrative list. This document is intended to cover two main situations, on the assumption that the licensee wishes to set up a new formulations unit, and requires the licensor to provide the process know-how and basic engineering, and a situation where the licensee already operates a plant for formulations and requires the licensor to supply process know-how for new products.

C. Items which could be included in contractual arrangements for the setting up of a plant for the production of bulk drugs (or intermediates) included in UNIDO's illustrative list (ID/WG.393/4)

This document is intended to provide guidance for the negotiation and drafting of engineering contracts for setting up a plant for the production of bulk drugs and for intermediates or for the addition or adaptation of a plant in operation when new products or new technologies are introduced.

The documents as presented are the outcome of a thorough and careful examination by the Ad-Hoc Panel of Experts whose recommendations and discussions are reported in its background paper (ID/WG.393/7). In each of its constituent parts, the documents reflect the consensus agreement of the Ad-Hoc Panel.

All three documents include, when appropriate:

(i) Elements to be taken into account in the negotiation and drafting of the clauses;
(ii) Technical aspects, and particularly difficulties that may be faced at the negotiating phase and implementation of the agreement;
(iii) Concrete examples, wherever possible, relating to fermentation, synthesis and extraction processes;
(iv) Recommendations as how to deal with the particular issues;
(v) Possible clauses and variations thereof.

The illustrative clauses provided in the documents are presented as examples that could be used to achieve the purpose of the agreements; these clauses, however, should not be considered as being exhaustive on covering all possible situations that can arise in transfer of technology.

3. The Issue

The material contained in the three documents is the first attempt to provide negotiating parties, with a practical instrument adapted to the requirements of the sector at hand and to the specific needs of enterprises in developing countries.

The originality and value of these documents as instruments for negotiation is due to the fact that they represent in themselves the product of a negotiation, incorporating thus experience and up-to-date knowledge of contractual arrangements in the pharmaceutical industry.

However, whilst fulfilling the mandate given to UNIDO by the First Consultation the preparation of the three documents on contractual arrangements is not an end in itself; in the view of participants at the Second Consultation, further improvements may be required and applicability to specific projects may also have to be ascertained.

Further, the Ad-hoc Panel recommended the preparation of two additional documents on this issue, which recommendation is hereby presented to the Second Consultation for its consideration.

Participants at the Second Consultation are thus invited:

i) to review and approve the content of three contractual documents;

ii) to advise UNIDO on further steps to be taken in order to improve or complete the material presented in (i) above, with a view to evolve contractual documents of more general applicability;

iii) to advise UNIDO on the preparation of a document on "Items which could be included in turnkey contractual arrangements for the setting up of a plant for the production of bulk drugs (or intermediates) included in the UNIDO illustrative list";

iv) to advise UNIDO on the preparation of a document containing "arrangements for technical assistance for the formulation of pharmaceutical forms".

ANNEXURE A

Illustrative UNIDO List of 26 Essential Drugs

A. ANALGESICS

1. Acetylsalicylic acid *
2. Paracetamol

B. ANTI-INFECTIVE DRUGS

Anthelmintic drugs

3. Mebendazole
4. Piperazine

Antibacterial drugs

5. Ampicillin *
6. Benzylpenicillin
7. Erythromycin
8. Sulfadimidine *
9. Tetracycline *

Antifilarial drugs

10. Diethylcarbamazine *

Antileprosy drugs

11. Dapsone *

Antimalarial drugs

12. Chloroquine *
13. Primaquine

Antituberculosis drugs

14. Ethambutol *
15. Isoniazid *
16. Streptomycin

C. BLOOD PRODUCTS

17. Plasma fractions

D. CARDIOVASCULAR DRUGS

Antihypertensive drugs

18. Hydralazine
19. Propranolol
20. Reserpine

E. DIURETICS

21. Furosemide

F. DRUGS AFFECTING THE BLOOD

22. Hydroxocobalamine

G. HORMONES

Antidiabetic agents

23. Insulin

Oral contraceptives

24. Ethinylestradiol/Levonorgestrel

H. VITAMINS

25. Ascorbic acid
26. Retinol

Note: This list was prepared by UNIDO in consultation with WHO. The classification and nomenclature was updated according to WHO's "The Use of Essential Drugs", Technical Report Series No. 685, 1983.

* Selected 9 priority drugs for which sources of supply are limited (report: UNIDO/PC.33)