



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

15931

28 October 1966

**PRODUCTION OF PHARMACEUTICAL INTERMEDIATES
AND PHARMACEUTICAL FORMULATIONS**

(Areas not covered by documents
ID/NC 393/1, ID/NC 393/2 and ID/NC 393/4)

Preface

This document has been prepared in accordance with recommendations of the Special Commission on the Pharmaceutical Industry held in Budapest, from 21 to 25 November, 1963. It identifies a number of clauses which are and currently are not included in contractual arrangements for the transfer of technology for the manufacture of bulk drugs/intermediates included in ID/NO. 393/1 list; items which should be included in licensing agreements for the transfer of technology for the formulation of pharmaceutical dosage forms; items which should be included in contractual arrangements for the setting up of a plant for the manufacture of bulk drugs/intermediates included in ID/NO. 393/1 list; the importance of the use of standardizing tools for the development of regulatory tools for the pharmaceutical industry and developing countries.

The texts contained in this reference paper, have been prepared on the basis of the same methodology as applied for the preparation of earlier documents on contractual arrangements, taking into account previous ID/DO and ID/NO. 393/1 documents' work on the matter. The explanatory notes are likewise followed by the relevant illustrative clauses.

It should be noted that with the purpose of standardizing, as far as possible, clauses common to licensing agreements, the same texts are proposed for documents ID/NO. 393/1 (relating to bulk drugs (pharmaceutical chemicals) and intermediates) and ID/NO. 393/3 (referring to formulations). Given the different nature and scope of ID/NO. 393/4 which relates to the setting up of a plant, special illustrative clauses and commentaries have been prepared therefor.

On approval, the new texts are proposed to be appropriately inserted into the revised existing documents. However, in order to preserve consistency and avoid redundancies in some cases (like in settlement of payments corresponding to ID/NO. 393/1 and 3), minor adjustments will be required in connected clauses.

Illustrative clauses 2/

Settlement of payments

The Licensee shall keep true, accurate and legally valid files and books of account or other records containing all data required for the full calculation and verification of the amounts to be paid and the information to be given in the statements provided for herein.

The Licensor may at its sole expense, appoint an independent representative or chartered accountant to review the records referred to above, during the usual business hours, for the purpose of determining the accuracy of the sales reports and the amounts payable by virtue of this contract.

This provision shall survive for one year beyond the termination of the contract or until the Licensor has received all payments to which it is entitled under this contract, whichever is later.

Payment shall be made in the currency provided for at the rate of exchange.

Alternative a: of the last day of the relevant period).

Alternative b: resulting from the average of the highest and lowest official exchange rates occurring during the relevant accounting period preceding the report referred to in

1.4 The Licensee shall pay to the Licensor in (specified country) and (designated legal tender) within (number of days) after the dates of the royalties due hereunder.

1.5 Each royalty payment due under Clause () shall be accompanied by a statement, certified by an authorized official of the Licensee, which shall set forth: (i) the amount of (net sales or other basis for royalties) expressed in the licensee's local currency; (ii) the exchange rate used; (iii) the amount of (net sales or other basis for royalties) expressed in (designated legal tender), (iv) the royalty rate; and (v) the amount of royalties payable in (designated legal tender).

1.6 The exchange rate to be used to determine the amount of royalties payable shall be the (name of rate; e.g. official, financial, etc.) exchange rate prevailing on (date: e.g. last day of relevant period) as quoted in (name of publication). Payments shall be made to licensor by (indicate method of payment; e.g. wire transfer to Licensor's bank account number () at (name of bank)). Payments shall be deemed to be made upon (will vary with method of payment). Payments not made within () days after the payment dates specified in Clause 1.4 shall bear interest at a rate of () percent per annum.

2/ For reflection in document where appropriate.

2. Variation of contract

Changes in circumstances which do not amount to force majeure (see clause 2.1) relating to markets (e.g. appearance of new drugs; radically new legislative conditions), products (e.g. discovery of side or adverse effects or harmful formulations) or in other areas (e.g. modification of legal conditions) may require or make advisable, in the interests of both parties, the revision of the agreed contractual terms. The revision may refer to the contract's object, its duration, price conditions or other particular conditions and modalities for their fulfilment.

In some cases, however, where the new events or changes are transitory or temporary, the suspension of the contractual terms, the suspension of some particular conditions or of their performance may be sufficient.

Alternative clause 2/

2. Variation of contract

2.1 Each party shall notify the other of any event or circumstances which may jeopardize the performance of the Contract, or any particular condition thereof.

2.2 Upon such notice, the parties shall open negotiations in order to find a mutually agreeable agreement for the suspension of any condition or performance under the Contract, or for the amendment of the terms thereof.

2.3 Any amendment to this Contract shall be established by a written addendum duly signed by the parties, and shall be considered an integral part of the Contract.

Unless and until the parties amend the Contract in accordance with the provisions of Clause 2.3, all of the provisions of the Contract shall remain in full force and effect.

3. Subcontracting

The Licensee may need, or wish, to partially subcontract the production of the Products provided for in the Contract.

In this case, the Licensor would generally request safeguards in connection with two aspects.

On the one side, subcontracting should not reduce Licensee's obligations and responsibilities, vis-à-vis, for instance, quality control and specifications fulfillment.

On the other side, and as far as the agreement includes confidential information which is to be transferred to the subcontractor, it is necessary to specifically provide for the confidentiality obligation to be observed by the latter.

3/ For reflection in document where appropriate.

Illustrative clauses 2/

3. Subcontracting

3.1 The Licensee may select, under his responsibility, subcontractors to undertake some of the manufacturing or promotional activities related to the Products. Subcontracting will not affect or reduce in any manner Licensee's obligations arising out of this Contract.

3.2 In cases in which subcontracting involves the transfer of Confidential Information to Subcontractors, the Licensee shall obtain from such subcontractors a written agreement not to disclose or divulge Confidential Information which is the subject of this Contract. The Licensee shall transfer to the Subcontractor only that of the Confidential Information which is necessary for the Subcontractor to perform its duties.

3.3 The Licensor may object the Licensee's choice of subcontractors, in case they are direct competitors of the Licensor.

Any subcontracting shall be subject to prior written consent of the Licensor.

4. Insurances

Agreements for pharmaceutical formulations may, depending upon the circumstances, provide for the insurances to be taken out by the parties. Though clauses thereon are not indispensable, they may protect the parties against consequences of unexpected events and contribute to the success of the contractual relationship.

The Licensor should provide, for instance, insurance policies for his staff deputed to the Licensee's plant, and both parties might effect insurance in respect of their own property and personnel. It might be important, in particular, to obtain coverage as regards to claims made by or on behalf of their employees grounded on injuries - eventually death - arising out in connection with the contract's performance.

Illustrative clauses 2/

4. Insurances

4.1 The Licensor and the Licensee shall effect insurance in respect of their own property and personnel, respectively. Such insurance shall cover in particular any claim that may be made by or on behalf of their employees alleging injury or death arising out as a result or in connection with the performance of this Contract.

4.2 The Licensor shall be responsible for taking out an insurance policy for his staff, working at the Licensee's Plant, and when required by the Licensee, shall submit adequate proof that such insurance is in force.

2/ For reflection in document where appropriate.

5. Notices

In order to avoid misunderstandings and difficulties among the parties, clear and efficient procedures for notices should be established.

Though in general it is advisable to convey notices by registered airmail, they may be anticipated through telex or cable means.

5.1. Illustrative clauses 1/

Notices

Any notice to be given by the Licensor or Licensee shall be conveyed by registered airmail to the following address:

Licensor:
Licensee:

When deemed appropriate, the notice may be transmitted by cable or telex, provided that it is confirmed in accordance with 5.1. Telex and cable numbers are as follows:

Licensor:
Licensee:

When any such notice is sent by registered mail post it shall be deemed to have been duly served following the expiration of (.....) days after the date of effective posting.

Either party may, by notice to the other party in writing, change its postal address, cable address, or telex address for receiving and for forwarding such notices.

In order to facilitate communications between the parties, the following persons are authorized to receive notices and documents relating to the execution of this Contract:

Licensor:
Licensee:

1/ For reflection in document where appropriate.

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

Subcontracting

The awarding of contracts of the nature considered in this document is subject to the experience and qualifications of potential contractors and to limitations as to their assignment to or execution by sub-contractors.

Subcontracting should not affect the overall contract of responsibility of the Contractor. The Contractor shall be responsible for the selection of sub-contractors and for their performance. The Contractor shall be responsible for the design, start-up, tests, etc. In this case, the Contractor may directly subcontract the execution of work not requiring his special experience or qualifications.

In accordance with the principles set out at the UNIDO Round Table meeting in Morocco on pharmaceutical industry, subcontracting should, to the maximum extent possible, rely on Purchasers' country firms or individuals. In this way, the Contract's execution may enhance the local technical capabilities and, in general, attain some developmental objectives.

Illustrative clauses #/

1. Subcontracting

- 1.1 The Contractor shall be responsible for the selection of sub-contractors. The Contractor agrees and acknowledges that notwithstanding anything to the contrary expressed, the Contractor shall assume complete responsibility for all the terms of warranty and guarantee provisions and such other criteria established in this Contract.
- 1.2 The Contractor shall not sub-contract the whole or any part of the Work and or services relating to the design of the Plant, Start-Up, operation or any tests of the Plant (as defined in the Contract) without the written consent of the Purchaser.
- 1.3 The Contractor may sub-contract any other work or services under the Contract, provided the Purchaser is advised of all such sub-contracts. The Purchaser shall have the right to prequalify and evaluate all firms or persons bidding for such sub-contracts, at the time of signing of the Contract or thereafter, and to object the Contractor's choice of subcontractors, in case they are direct competitors of the Purchaser or by other justified reasons related to their industrial or commercial reputation and solvency.

#/ For reflection in document where appropriate.

13.1 Wherever possible, subcontracts are to be awarded to firms or individuals in the Purchaser's country.

The Contractor shall obtain from the Subcontractor a written undertaking that the Subcontractor will comply with the terms and conditions of the Contract as though it were the Contractor.

Management and Technical Advisory Services

In cases where the Purchaser's personnel has little industrial experience or competence to undertake the management of the Plant operation, it might be necessary to ensure the rendering by the Contractor, of management assistance services from provisional to final acceptance. This would generally require the assistance of Contractor's production and maintenance (mechanical and instrumentation) engineers to be selected, as far as possible, among those who participated in the actual start up and initial operation of the plant.

If the Purchaser desires, in view of the circumstances and the actual capabilities of its own personnel, to extend management assistance services after final acceptance, a separate agreement may be required, in order to specify the Contractor's responsibilities as distinguished from those provided for in the original Contract.

Illustrative clauses 1/

2/ Management services

2.1 The Contractor shall manage the operations of the Plant following the Mechanical Completion as specified in Article 13. The management of the Plant by the Contractor shall cease upon the successful completion of the Performance Guarantee Tests and Provisional Acceptance by the Purchaser.

2.2 The Contractor shall provide management assistance services to the Purchaser from Provisional Acceptance until the Final Acceptance. The Contractor shall provide necessary Site personnel in accordance with Article 2.3 hereunder.

2.3 The Contractor's staff required to accomplish management assistance services in accordance with Article 17.2 above shall consist of

1/ For reflection in document where appropriate.

The number and type of Contractor's personnel to be maintained at Site for the purpose of maintenance services shall be as far as practicable be satisfactory to both Contractor and Purchaser from the personnel who have been considered for the actual start-up and operation of the plant up to and including the Performance Guarantee tests.

Personnel maintenance personnel as the requirement of Article 2.3 shall be subject to the following conditions:

1. Maintenance of personnel levels at all times to meet the needs of the plant.

2. Maintenance of personnel levels at all times to meet the needs of the plant.

3. Maintenance of personnel levels at all times to meet the needs of the plant.

4. Maintenance of personnel levels at all times to meet the needs of the plant.

5. Maintenance of personnel levels at all times to meet the needs of the plant.

In every case where the Contractor's personnel at Site are involved in any damage to Plant and/or Equipment, as a result of their negligence, the Purchaser's representative at Site shall be informed forthwith in writing.

2.5 In the event that the Purchaser so desires, he may retain part or all of the personnel covered by Article 2.3 for an extended period, not to exceed (.....) months after Final Acceptance of the Plant, on terms and conditions to be mutually agreed in advance and the payment of an additional fee to be agreed upon with the Contractor. The Purchaser may exercise this option not later than the expiry of months following Provisional Acceptance.

The Contractor's personnel shall remain at the Site for such extended period only if an agreement as to the terms and conditions of their retaining has been reached.

Contract variations and cost

The site and nature of the agreement dealt with in this document, together with the fact that the Contractor has accepted the responsibility and other relevant obligations relating to the purchase order by the Purchaser and the work to be done thereon, shall constitute the basis for the Contractor's contract. This provision, however, shall not apply to contracts or part of contracts which are awarded on the basis of an outright price.

Illustrative clauses 2/

Accounting and audit

The Contractor shall maintain suitable accounting and other relevant records pertaining to the payments received by him from the Purchaser and the quantum of work done against which such payments were made, and shall preserve these records for a period of at least two years after Final Acceptance of the Works or the Termination of the Contract.

The Purchaser shall provide facilities to the Purchaser to have access to the Contractor's accounts and records, which shall be for the purpose of any work undertaken by the Contractor.

Pursuant to any audit or examination by the Purchaser, shall have the right to audit all payments made on behalf of the Purchaser by the Contractor under the Contract, and the Contractor shall be obliged to provide any other financial data and information required at the option of the Purchaser in regard to the transactions between the Purchaser and the Contractor, pursuant to this Contract.

The Purchaser shall bear all expenses of any such audit.

4. Notices

In order to avoid misunderstandings and difficulties among the parties, clear and efficient procedures for notices should be established.

Though in general it is advisable to convey notices by registered airmail post, they may be anticipated through telex or cable means.

Illustrative clauses 3/

4. Notices

4.1 Any notice to be given to or served upon either party under this Contract shall be deemed to have been properly served in the following circumstances:

4.1.1 Provided that:

4.1.1.1 Any notice to be given to the Contractor is to be conveyed by registered airmail post, or left at the address stated below, followed thereafter by the transmission of the same notice by cable or telex with a copy to be delivered to the Contractor's office at the Site.

3/ For reflection in document where appropriate.

In the case of a notice to be served on the Purchaser it is to be sent by registered mail to the care of the address stated above, returned to the Commission of the same office by cable or telegraph.

When any such notice is received and it shall be found to be in accordance with the provisions of the contract, it shall be deemed to have been received by the Purchaser on the date of its receipt by the Commission.