OCCASION

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

DISCLAIMER

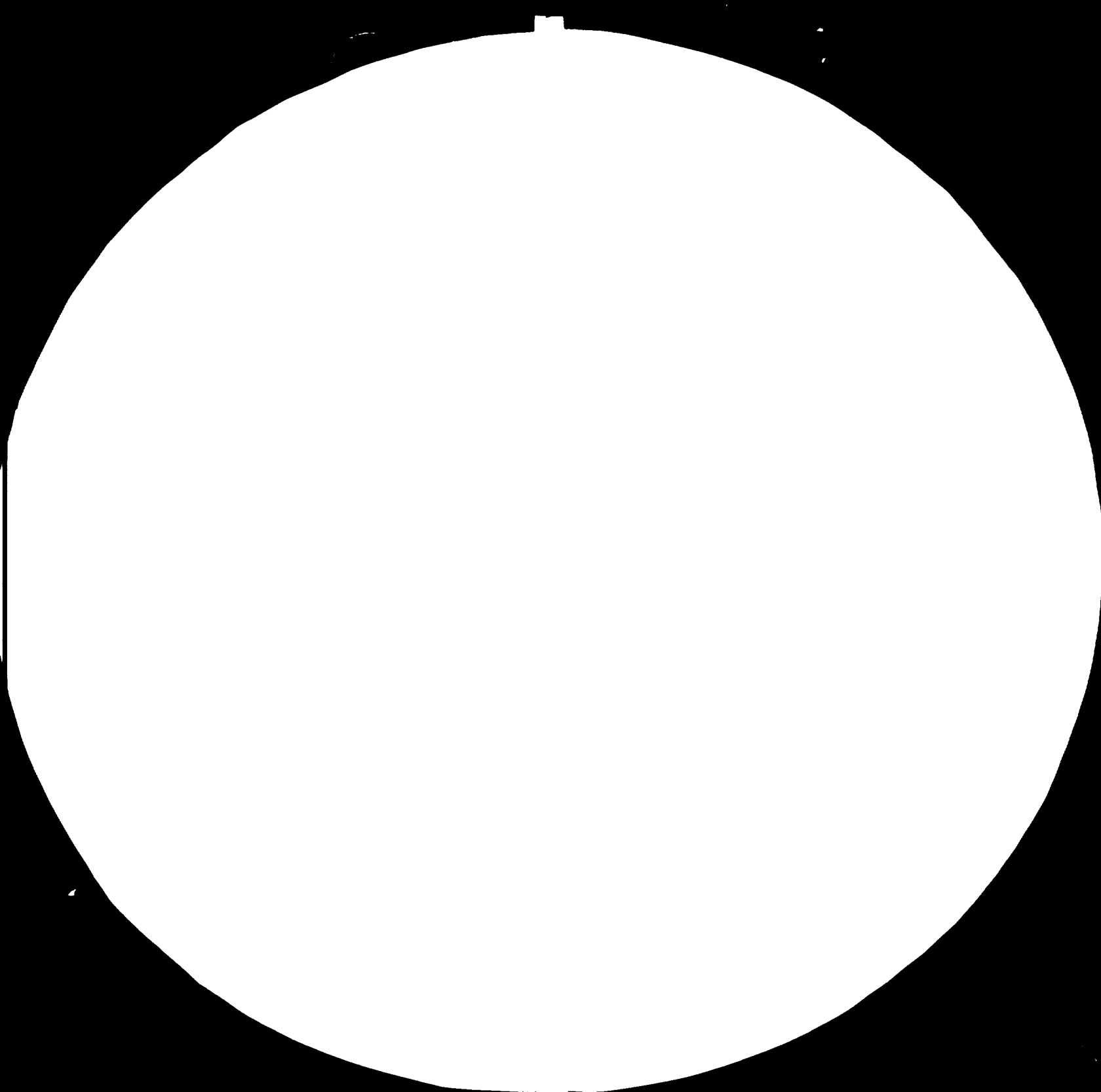
FAIR USE POLICY

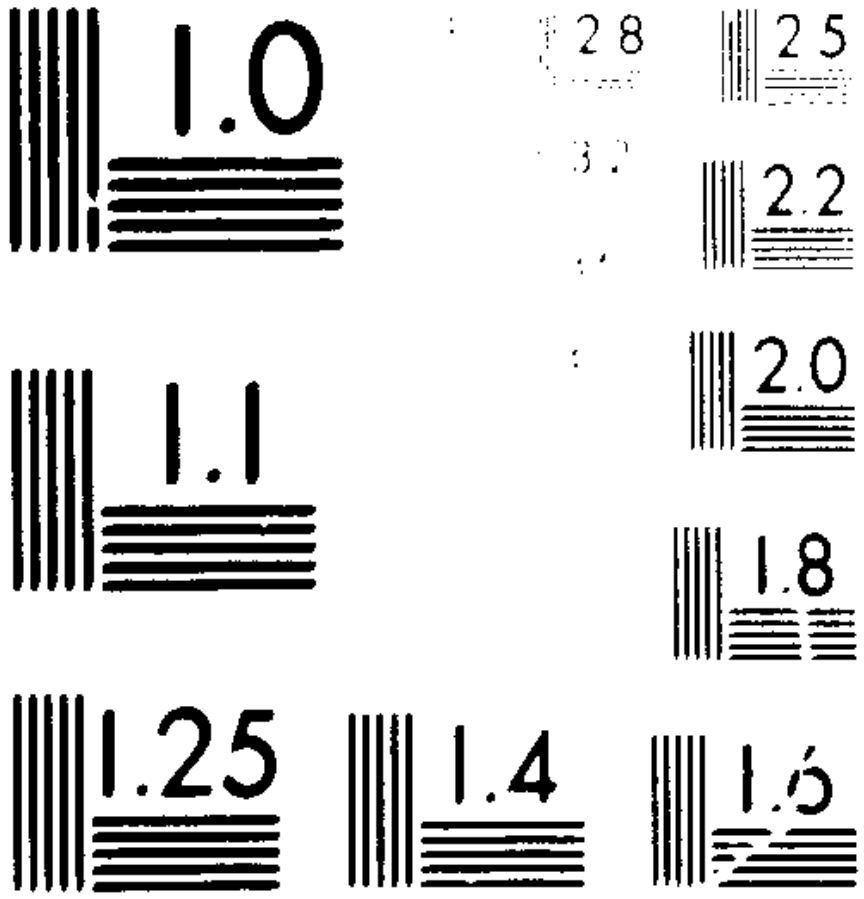
CONTACT

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

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

UNITED NATIONS INDUSTRIAL DEVELOPMENT ORGANIZATION
Vienna International Centre, P.O. Box 300, 1400 Vienna, Austria
Tel: (+43-1) 26026-0 · www.unido.org · unido@unido.org




1.0
2.8
2.5
2.2
1.1
2.0
1.8
1.25
1.4
1.6

12994

1130

DR. E. REIBEL

Guidelines for Contractual Arrangements.

July 1982

Background note

MEDICAL APPLICATIONS OF THE PRODUCT

(Note : "Medical applications of the product is one part of the Article" Définition of product (s) proposed in July 7. outline).

The provisions contained in this paragraph have the following objectives :

- it is a usual means to precisely define the product, which must be clarified long ago before registration is introduced. Many active principles have both human and veterinary applications and very little difference in specifications.
- this precise definition is necessary for registration purposes.
- a product may have several medical applications. Some of them may not be suitable at all in the licensee's country. Through the said provisions, the license is duly informed by the licensor, and under the licensor's responsability, of the limits to be observed in the use of the product.
- if the Contract on formulation of dosage forms which usually follows the production licence agreement is not established with the licensor, but with a third party, then the license will remain without documentation and data on the medical applications of the product developped and licensed by the licensor.

(The same apply for medical documentation) : These documentation and data, which include a high degree of responsability from the issuer and which are expensive to elaborate, are generally requested for Social Security, physicians and patients).
The licensee should not take the risk to specify, alone, the medical applications of the product, nor he should, alone, elaborate the corresponding documentation and data.

Specimen clause

MEDICAL APPLICATIONS OF THE PRODUCT(S)

1. The detailed applications of the product(s) which are object of the present Contract are the following (or detailed in Annex...)

.....

.....

2. The licensor shall provide, according to the schedule figuring in Annex....., the license with all the documentation and data related to the above stated medical applications of the product. Such documentation shall include appropriate information related to restrictions,if any.
The license shall assist the licensor to determinate what are in the licensee's country the usual requirements in that respect, in particular what information is to be released to professionals (Social Security and physicians) and to patients.
The licensor shall establish separate documentation specific to each one of the expected users (Social Security, physicians, and patients).
The cost of the elaboration and of the accurate translation of such documentation shall be at licensor's expense.
The said documentation shall be clearly identified as being issued by the licensor and shall include the appropriate references to official approvals granted in licensor's country, in other countries and by international organizations (whenever applicable).

.../...

Since in most cases, such documentation shall be previously approved before it is released by the licensee's Health Authorities, the licensor shall fully cooperate with the licensee, to enable him to obtain such approval, particulary if modifications and/or additions are requested by the said Health Authorities. The same apply if, during the course of the present Contract, up-dating is requested.

3. The licensor shall not be any longer responsible for this documentation and data if the licensee modifies said documentation and data without the agreement of the licensor.

Background note

REGISTRATION OF THE DRUG(S)

1. Although the legislation may vary from one country to another, registration of intermediates and/or drug is an absolute must before their production and use among population is authorized by the Health Authorities.
Procedure is time consuming and costly, and although it is seldom, registration may not be granted at all. When a drug has not yet been used, procedure may take as long as 6 years. If the drug is already used (imported drug), the procedure is shorter, but will take at least 1 year or 2 .
Registration is thus a key point to be carefully studied long time ago before entering into a license agreement.
Documentation for registration concerns in most cases :

- analytical and technical data
- data related to experimentations on animals
- data related to experimentations on man.

It represents an expansive amount of documentation and references.

2. The major customers of the licensee are likely to be the Social Security and/or public health organizations.
These public bodies generally cannot purchase any drug (bulk or not) without a previous medical agreement with the licensee as far as efficiency is concerned and without a previous mid-term or long-term agreement with the licensee on prices.

.../...

To obtain these agreements, the license must submit detailed data related to the expected results of the drug and data related mainly to his production costs.
This second kind of registration is almost as important as the first one for the licensee.
Consequently, it is of major importance to determinate if these previous requirements should be, or should not be, included in the licence agreement and, the case beeing, how responsabilities and costs are to be shared between the licensor and the licensee.
Since registrations authorize production and use, and open access to the public share of the market, the registrations should be introduced by licensee under the licensee's name.
however, considering the responsabilities and costs, it is advisable that this be done in close association with the licensor.

If registration is not included in the licence agreement for the production of a drug, but stpulated under a separate contract, the licence agreement should be closely linked to the registration contract. Registration is not an industrial property right and, as such, registration obtained alone does not give any exclusivity to a potential licensee for production.

Specimen clause

REGISTRATION OF THE DRUG(S)

1. The licensor and the licensee hereby agree that in order to comply with the Health regulations in force in the licensee's country, they shall closely cooperate for the registration of the following drug(s) :

.....
.....

is obtained.

2. The registration shall be effectuated under the licensee's name.

3. The operation for the registration shall be undertaken by and the responsability of a joint registration team composed of representatives of both parties as follow :

.....	.....
.....	.....
.....	.....

In the licensee's country, all operations of the joint registration team shall be conducted by : ..... (representative of the licensee) assisted by : .....(chief representative officer of the licensor).
The licensor shall give his representatives full written powers and authorizations to represent him for the registration purposes.

.../...

4. The registration team shall gather all legal, technical, medical requirements necessary in the licensee's country to introduce the registration.

5. The licensee shall provide at his expense all the required data already available in his country. The licensor shall check and approve these data. Record of this approval shall be established.

6. The licensor shall provide at his expense all the remaining and required data, concerning, but not limited to, analytical and technical informations as well as clinical data.
The translation and the accuracy of the translation of these data shall be at licensor's expense and under licensor's responsability.
The corresponding documentaion shall be clearly identified as being issued by the licensor.

7. All the costs incurred by the registration procedure in the licensee's country, except those of the licensor's representatives during they stay in licensee's country for registration purpose, shall be at licensee's expense.
All similar costs incurred in the licensor's country shall be at licensor's expense.

8. Under the same above mentionned conditions and until the present Contract expires, the licensor shall supply the licensee with all required data necessary for the up-dating of the registration, if any.

9. If the registration is definitely rejected by the health Authorities, the present contract shall be terminates without prejudice for any of the parties.

.../...

.../...

10. If the registration has not been obtained..... years after the effective date of the present contract, the licensor or the licensee shall have the right, without prejudice, to terminate the said contract.
(Alternative : the obtention of the registration is one of the requirements stipulated in Article "Effective date of Contract").

11. The licensee shall have full rignt to registrate the drug(s) in third countries to which he may export.

Background note

COMPONENTS OF TECHNOLOGY TO BE TRANSFERRED

The technology to be transferred to any licensee is not an "Ordinary product" one may thoroughly examine and get acquainted with before ist acquisition.

consists

It* generally of one formula, somme manuals and other written documents, explantions and training, plus some complementary informations related to the environment of the production process, such as input, maintenance, storage and basic design.

The risks, if idequate precautions are not taken, the transferred data will not be sufficient to implement the technology are very important ; enormous if the future licensee is not experienced.

Although this Article is not very long, it is of crucial importance since it should clearly state :

- a precise definition of the process, eventually more detailed in an appropriate Annex, since one process generally have several variants the economics results and the yield of which may be very different.
- a clear identification of where the process developped by the licensor is being used and where the licensee's personnel should be trained and, through double command, experiment at least to some extent the said process at licensor's site.
- a detailed and exhaustive list of what the technology to be transferred is precisely composed of.

.../...

.../...

The list naturally depends on the drug and the process concerned.
It is highly probable that any point left aside from such list and later requested by the licensee shall either be refused or expansively proposed by the licensor.
It should be of great help for the to be licensee during the nego iation period anu shall enable him to compare different offers and to select the right licensor.
It should also be helpful for the price itemization stated in Article "Remuneration of the licensor".
It should permit "to stamp" "what is confidential and what is not, to be stated in Article "Confidentiality and Secrecy".

(Note : Point 7. Of july 9. Outline "definition of each component of the technology to be transferred" is the complement of this Article.)

Specimen clause

COMPONENTS OF TECHNOLOGY TO BE

TRANSFERRED

1. 1. 1. The technology to be transferred under the provisions of the present Contract concerns the manufacture of ..... (suggested : name and brief description of the drug as it is exactly written in the summarized first page of the the patent deposited by in licensor's country, whether said patent is already valid or not. If not applicable, name and description should be whenever possible taken from any other official document, national or international.

1. 2. The process concerning the manufacture of..... (drug name) is described as follows :.....(suggested : name and brief description of the process as suggested above).

1. 3. (When required) for identification purpose, the process is more specifially detailed and identified among its variants in Annex..... of the present Contract.

1. 4. The process refered to in point 1.2 and point 1.3 (if any) has been developped by the licensor and is presently being used by the licensor at licensor's facilities of ..... (town), plant .....(plant name or number), workshop..... (workshop name or number) which have already been visited by representatives of the licensee (whenever applicable) and/or where licensee's personnel shall be trained (whenever applicable)

.../...

2. The components of the technology to be transferred shall include (but not to be limited to, depending on drug and process)

- process described in points 1.2 and 1.3. (if any)
- specific knowhow developped by the licensor
- required raw materials, specifications and consumption of same
- equipement and materials and lay-out
- utilities and their specifications
- operations to be performed in the course of the process
- basic design and basic engineering
- storage of raw materials, semi-finished and finished products
- quality control techniques
- treatment of effluents (whenever applicable)
- recovery of solvents (whenever applicable)
- requirements of qualified personnel
- safety instructions ; protection of the personnel
- strain specifications (whenever applicable)
- drug medical documentation
- sampling ; keeping of samples (up to 10 years)

(Note : know-how should be understood as anything beyond the GMP and without which the expected results of the transferred technology cannot be reached. Know-how not only concerns all the steps of production process but also quality control, maintenance, raw materials etc, that is almost all of the composents of the technology)

Background note

METHOD OF TRANSFERRING THE TECHNOLOGY

The object of this article, which is the continuation of Article 7. in July 9. proposed outline (definition of each component to be transferred) is to fix clear rules to ensure the proper transfer of technology.

The technology is composed of documents and services. Because of their specific nature, they cannot be shipped and delivered like goods within the recognized frame of Incoterms.

In too many opportunities, this aspect of the transfert is unformal--ly treated alledgely not to "complicate" the Contract because the parties have so many opportunities to meet that these "details" shall be solved personnaly by both representatives on a ponctual basis. Experience has shown this lack of foresight may cause many problems. The transfer should be formalized precisely to avoid this kind of problems which are almost unsolvable afterwards.

Once the complete list of the components to be transferred has been established and once each component has been in turn defined, including the identification of the support (manuals, drawing, charts, computerized documents, tapes, training sessions, demonstration sessions, etc,...) which shall "Contain" said component of the technology, then one should clearly state for each component and support :

.../...

- when, how to whom it is to be delivered by the licensor, including penalties in case of delay,
- how the licensee shall adknowledge reception and good reception ; how long after reception date to enable the licensee to valiidly check the content or the service,
- when it becomes definitive property of the licensee,
- if applicable, number of copies, unit system and language (very often, computerized technical data are in english which might not be the language of the Contract)
- when related payments, if any, shall take place (the itemization per support or group of supports enables the licensee to know exactly how much he is paying and for what)
- what is confidential and what is not.

(Note : The strict definition of components and supports and corresponding way of transfer should prevent the licensee from receiving unadapted documentation. In too many instances, documentation is mostly composed of internal manuals for the licensor's personnel use only. The documentation as well as training sessions should be a "product" specific for exportation, adapted whenever necessary to the requirements of the licensee).

Specimen clause

METHOD OF TRANSFERRING THE TECHNOLOGY

The components of the technology describe in Article(s).....
Shall be provided under the following provisions agreed
by both parties :

1. The components shall be provided by the licensor to the licensee according to the schedule(s) and delivery dates indicated in annex : .....
2. The licensor's representative in charge of transferring all documentation is : .....
   The licensee's representative in charge of receiving all the documentation is : .....
3. List of documentation to sent by.....to.... .. (adress), attention : .....
4. List of documentation to be handed over to ..... ensee representative) at licensor's facilities :
5. List of documentation to be handed over to .....(licensee representative) at licensee's facilities :
6. Delivery date shall mean the .....(week or month) the documentation is to be received and/or service is to be performed by the licensee. The licensor shall confirm by telex to the licensee the expedition date of each lot of documentation expedited (if applicable)
7. Upon reception, the licensee shall issue a "reception certificate" according to the format contained in Annex ....., stating that the requested quantity of documentation has been received, indicating eventually the missing quantity.

8. After performance by the licensor of the scheduled training sessions and or demonstration sessions, the licensee shall issue a "performance certificate" according to the format contained in Annex.....

9. The licensee shall dispose of (X) days after the date of issuance of reception/performance certificates to claim additions, modifications and complements related to the provisions contained in the contract, and the licensor shall provide said omissions and/or corrections.

10. If, (X) days after the issuance date of reception/performance certificates, the licensor has not received any claim from the licensee, he shall be reputed as having fulfilled satisfactorily his obligations.

11. Payments specifically related to documentation and performance of services of the licensor (whenever applicable) shall be paid by the licensee (X) days after the issuance date of reception/performance certificates or when the licensor shall have provided to the licensee the said omissions and/or corrections.

12. Documentation not received and/or services not performed .....days after the scheduled delivery date shall be subject, each of them, to a penalty of ..... (amount and currency) up to a cumulated maximum of .....(amount and currency)

13. The property of the documentation transferred shall become the one of the licensee(X) days after the issuance date of reception certificate ans shall remain the property of the licensee even if the contract is terminated before expiration date, whatever the cause is.

14. All the documentation shall be provided by the licensor to the licensee in .....copies, ... (language), using.....(unit system), with the following exceptions, if any :

Background note

QUALITY CONTROL WITHIN THE PLANT

In the pharmaceutical industry, a production unit cannot validly operate without a quality Control Dept. which must check and approve any input, any output and any step of the production process.

The Q.C. Dept. should be independant from the production unit and should only report to the general manager of the licensee.

It should also be free to exchange information without restriction with the licensor's Q.C. Dept. Thus both Q.C. Dept. should be able to speak the same technical language.

The function of the Q.C. Dept. is very important since its approval is required for the implementation of the transfered technology, including licensee's payments in some cases.

Although it is an obvious security for both parties and patients that the licensee's Q.C. Dept. exists, operates correctly and is able to control the required specifications, and the technology implementation, there is a tendancy in some developping countries to underestimate its importance and goals (it is an expansive and trouble-maker function).

To some extent, it also exists a temptation among certain licensors to put aside the key role of the licensee's Q.C. Dept. in order to possibly minimize the vigilance of such Dept.

In the interest of all parties involved, a license agreement for the manufacture of medical products shoud contain specific provisions for the creation or adaptation of an efficient Q.C. Dept.

.../...

The methods used and the operations performed by the licensee's Q.C. Dept., as long as records and samples are kept, are the only way to eventually detect the responsability of the licensor in case of production problem.
Thus, the importance in case of possible conflict and arbitration, of what has been previously recommanded by the licensor.

Specimen clause

QUALITY CONTROL WITHIN THE PLANT

1. Both parties do hereby recognize that the successful transfer of the technology concerned by the present Contract cannot be achieved without the existence at the licensee's facilities of an efficiently operating Quality Control Dept.
   The licensor shall fully assist the licensee to constitute such a Q.C. Dept. or, if already existing, to adapt and check the efficiency of said Dept. to meet the specific requirements of the transferred technology and to achieve the expected results.
   The licensee do hereby agree to implement the recommandations of the licensor in that respect.
   These recommandations shall take into account the financial, technical and human ressources of the licensee as well as the specific conditions prevailing in the licensee' country.

2. To implement point 1. above, the licensor and the licensee shall constitute within.....days after the effective date of Contract a "joint commitee for Q.C.". The representatives of the licensor belonging to that commitee shall belong to the licensor's Q.C. Dept. in charge of controling at licensor's facilities the production technology being transferred under the licence agreement.

3. Both parties recognize that due to their specific function and responsabilities, each Q.C. Dept. shall have the largest possible autonomy
   Consequently, Q.C. Dept. shall only reports to the topest managerial level and not to the production management.

.../...

They shall be free to mutually exchange scientific and technical informations related to the drug(s) production controls refering to the present Contract. The conclusions they shall jointly reach shall bind both parties.

4. The informations to be transmitted and the verifications to be operated by the licensor shall concern, but not be limited to :

4.1. Internal organization, qualification, and responsabilities of licensee's personnel (for example : those in charge of sampling should be distinct from those in charge of the analisis)

4.2. Space availability and location at the disposal and under the sole responsability of the Q.C. Dept. (quarantine)

4.3. Identification (labeling) of the raw materials, semi-finished products and finished products according to their respective step in the production process,

4.4. equipment, materials, chemicals and reactive agents as well as their respective maintenance,

4.5. the sequence according to which Q.C. operations shall be performed and said operations,

4.6. records of controls performed and samples to be kept

4.7. conformity of the licensor's assistance with the Q.C. regulations in force in licensee's country.

5. During the course of the Contract, the licensor shall fully assist the licensee to allow (whenever aplicable) the integration of local products instead of imported products and/or to allow modifications incurring cost reductions proposed by the licensee's Q.C. Dept.

6. It shall be the responsability of the licensor to certify that the licensee's Q.C. Dept. is operational after the provisions contained in point 4. have been performed as well as it shall be the responsability of the licensee to keep records and samples (whenever applicable) of all operations undertaken by the licensee's Q.C. Dept. , as stated in point 4.6.

7. The licensor shall have free access to these records and samples as well as, whenever applicable, to the RM/1 supplied by the licensor and rejected by the licensee's Q.C. Dept.

8. Considering the free exchange of scientific informations is profitable to both parties and to the users of their products, the licensor and the licensee hereby agree not to limit to the duration of the present licence agreement the relations between their respective Q.C. Dept.

Background note

SUPPLY OF RAW MATERIALS/INTERMEDIATES (RM/i)

The object of this Article is to determine the conditions under which the RM/i shall be delivered and paid in an exclusivity situation.

In this case, the licensee must not be treated like any customer, but as a partner of the licensor.

Against the advantage of exclusive supply, the licensor shall bear almost all responsabilities of the operation.

The payment is due when the RM/i is delivered and when it is approved by the Control Dept.

Since a monopolistic situation is always disadvantageous, the door must always be left open if there is a change in the initial situation : possibility to switch to another supplier (if he exists) offering prices really lower than those of the licensor, or when a new supplier appears on the market after the signing of the Contract (mostly to occur each time demand expands anywhere in the world).

Specimen clause

SUPPLY OF RAW MATERIALS/INTERMEDIATES (RM/i)

1. Considering that by entering into the present license agreement, the licensee becomes a partner of the licensor in the worldwide development of his business, image and repartition ; considering the licensee will require for his production the following RM/i :

RM/i (A).....
RM/i (B).....
....

Considering the licensee accepts, under the conditions stated in the present article, to exclusively purchase from the licensor the said RM/i, the licensor agrees to supply the licensee during a minimum period of .....years, starting on ....., under the following preferential conditions he usually grants to his licensees and subsidiaries.

2. 2.1. The minimum yearly quantities of RM/i to be delivered by the licensor to the licensee are :

	RM/i (A)	Quantity
Year 1		
Year 2		
...		

2.2. The above mentioned quantities being the result of forecasts established jointly by the licensor and the licensee at the time of signing the present license agreement, it is agreed upon by both parties that .....month(s) before the beginning of each calendar year, said forecasts may be revised in order to adjust them, without prejudice for the licensee, to the real requirements of the licensee.

2.3. The licensor guarantees the licensee he shall take all necessary measures so that the forecasted, eventually revised, and agreed upon quantities of RM/i will be timely available for delivery to the licensee.

3. 3.1. The licensor recommands the licensee maintain, for each RM/i considered, a minimum security stock and the licensee accepts.

The quantities involved are :

RM/i (A) : .....

....

3.2. The licensor guarantees the licensee he shall take all necessary measures in order to be able to immediatly replace the eventual loss of the licensee's security stock(s) ; as well as the eventual loss of any delivery, whatever the cause of the loss.

4. 4.1. Within each year and per each RM/i, the split quantities to be delivered by the licensor are stated in Annex.....

4.2. However, upon.....month(s) written notive given to the licensor, the licensee may request, and obtain, without prejudice, modifications in quatities to be periodically delivered within a year, as long as the yearly total agreed upon for that year in Annex..... is not changed.

5. 5.1. In the case the licensor would not be able to comply with one (or more) delivery, as stated and agreed upon in Annex....., the licensor binds himself to immediatly inform by telex the licensee, indicating the :

- reasons of the interruption
- duration, or estimated duration,of the interruption
- alternative sources of supply he recommands

5.2. During the interruption, the licensee shall have the right to purchase the missing RM/i from any alternative source of supply recommended or not by the licensor. The eventual price increase, under same purchasing conditions, paid by the licensee to an alternative supplier will be reimbursed up to a maximum of .....% per KG for RM/i (A), ...% per KG for RM/i (B), by the licensor upon presentation by the licensee to the licensor of the corresponding paid invoice and debit note.

5.3. In the case, there is no possible alternative supplier, the licensor will pay to the licensee a penalty amounting to.....% of the ex factory value of the interrupted delivery.

5.4. The payment of this penalty will take place, the case being, at the date the delivery, as stated in Annex..... should have taken place.

5.5. The maximum accumulated amount of these penalties to be paid by the licensor to the licensee is fixed at ..... (amount and currency). Once this amount reached, the licensee shall have the right, giving written notice to the licensor, to terminate without prejudice the present contract.

5.6. Furthermore and at his sole judgement, the licensee may take all appropriate steps for obtaining indemnities due to the impossibility to carry out his activities.

5.7. The above mentioned penalties and indemnities do not apply in case of force majeure, duly and timely notified to the licensee by the licensor.

5.8. In the case, the licensee is not able to purchase any quantity of RM/i from the licensor, the above mentioned stipulations concerning the licensor shall apply to the licensee

6. 6.1. The specification of the RM/i to be delivered are stipulated in Annex..... The licensor guarantees the licensee that the specifications of all RM/i delivered by him to the licensee will, at least, meet the minimum specifications stipulated in that Annex.

6.2. The licensor will replace, free of charge, the RM/i which will not meet these minimum specifications and thus rejected by the Quality Control Dept. of the licensee.

6.3. The licensor shall forward to the licensee, together with the shipping documents, one certificate of analisis per batch, or fraction of batch, composing each delivery.
The analisis corresponding to such certificates shall be performed by the licensor according to the methods and operational modes stated in the present Contract.

6.4. The storage conditions concerning the RM/i, recommended by the licensor are stipulated in Annex.....
They take into account the specific conditions prevailing at the licensee's facilities and in the licensee's country.

6.5. Within.....days after reception of the RM/i, at licensee's facilities, the licensor will perform analisis of these RM/i according to the methods and operational modes stated in Article "Quality Control of the present Contract".

6.6. The date of the conformity certificate issued by the licensee's Quality Control Dept. will be the date of final acceptance of the received RM/i by the licensee and shall determine the corresponding payments which are detailled in Article "Payment Conditions".

6.7. A copy of all analisis performed by the licensor shall be transmitted to the licensor.

6.8. In case of rejection by the licensee's Quality Control Dept., a sample of the rejectid RM/i shall be sent to the licensor together with the analisis certificate.

6.9. Any disagreement concerning the results of licensee's analisis shall not stop the future deliveries by the licensor

6.10. If such a disagreement is not settled within.....days/ months, both parties agree they shall accept the final decision of the expert (company or individual) mutually designated below :

.....

.....

.....

.....

committed to that effect by the most diligent party. The cost of the expertise will be paid by the faultly party according to the final decision of this expert.

7. All costs, charges, taxes, occuring before the deli very point shall be at licensor s expense.
All costs, charges, taxes, occuring after the delivery point shall be at licensee's expense
However, when such costs, charges, taxes occur because of a proven fault of the other party, then the latter shall be responsible for the payment or reimbursement to the former.

8. 8.1. The conditions under which the licensee orders required RM/i and the conditions under which the licensor confirms, ships and invoices are detailed in Annex.....

8.2. They shall refer to, but not be limited to :
- delivery point, CIF, FOB, means of shipping
- packaging and containerization, adapted to licensee's country
- Indentification of RM/i, batch, fraction of batch

.../...

- purchase order format with reference to the present Contract and import licence
- list of all required shipping documents
- export licence, if any, from licensor's country
- confirmation order format, invoices format mentioning as a minimum ex-factory value, insurance, freight up to the delivery point
- customs, sanitary, transportation regulations and data

8.3. All related data necessary to the importation of the RM/i in the licensee's country shall be transmitted to the licensor by the licensee before .....(date)

8.4. All related data necessary to the exportation of the RM/i from the licensor's country shall be transmitted to the licensee by the licensor before .....(date)

8.5. Both parties shall reply to each other, at least ..... days, before the first delivery is to take place.

9. 9.1. Prices and terms of payment are detailed in Annex.....

9.2. As far as payments and credit terms are concerned, it must be clearly stated in that Annex, whatever other provisions might be, that payments and credit terms are linked to the date of the conformity certificate issued by the licensee's Quality Control Dept., and not to the date the RM/i reach the delivery point.

9.3. As far as prices are concerned, it must be clearly stated in that Annexe that :

- prices are fixed and unrevisable for a minimum period (12 months suggested)
- once revised, prices are again unrevisable for the same minimum period
- when applicable the indexation clause if any, does not apply if the resulting increase of price is below.....%
- the indexation clause, if any, must be linked to, at least, one official or governmental index.

9.4. Above .....% of resulting price increase, the licensee is not any longer obligated to exclusively purchase from the licensor.

9.5. If the licensee receives a quotation, under similar purchasing conditions, from an alternative supplier, which is at least.....% below the licensor's price, the licensor must then adjust his price to the level of this quotation, otherwise and for the time of this quotation, the licensee may purchase without prejudice from the alternative supplier.

9.6. In case there is one supplier, and only one, for a long period of time, a special provision (strongly recommended) should carefully stipulate the maximum.....% price increase per year during the purchasing period allowed to the licensor. If no agreement can be reached on that point and if no other firm guarantees are given to the licensee, then it would be advisable not to enter into such a risky license and purchase agreement.

10. All the clauses, whenever applicable, of the present Contract, particularly those concerning "improvements, arbitration, force majeure, are applicable to this Article even if the duration of the purchasing period exceeds the duration of the present Contract (it is advisable that both duration be the same), the mutual agreement represented by this Article being a condition of the signing of the present Contract.

11. The licensor shall not prevent exchange of information between the licence and the licensor"s licensees.

12. The licensor shall adjust the above detailed supply conditions when he grants more favorable conditions to a new licensee under similar conditions.

Background note

IMPACT OF CHANGES IN NATIONAL HEALTH AND SANITARY REGULATIONS

It is becoming more and more frequent that side effects, unexpected consequences or otherwise unexplainable accidents before, are discovered and attributed to a pharmaceutical product (either drug or component of drug).
The use of such product generally is suspended or prohibited by the Health Authorities.
Due to the increasing power of modern means of investigation and to the greater concern of global effects of pharmaceutical products on Man, it is probable that this type of situation will occur even more frequently in the coming years.
The changes, under such circumstances, of health regulations may have dramatic consequences on the implementation of the Contract. Consequently, it is advisable that a specific provision be included in the Contract to settle the conflicting interests of both parties when this kind of problem arises.
Modified health regulations may implicate the following consequences :

- compulsory but minor changes in this composition ot the product,
- important changes which no one knows in advance if they will be possible, after how long and under which cost,
- total and definitive ban of the product totally preventing this implementation of the Contract.

Since the lifetime of such Contract is rather short (a few months), it is advisable to extend after the expiration date the necessary cooperation between the licensor and the licensee, under such circumstances or , to establish the duration of the Contract taking into account that specific aspect.

Specimen clause

IMPACT OF CHANGES IN NATIONAL HEALTH AND SANITARY REGULATIONS

1. In order to minimize the consequences of possible changes in Health and Sanitary regulations which may affect the present Contract, the licensor and the licensee shall carefully follow the evolution of said regulations in their respective country ans shall immediatly inform the other party as soon as a risk for the correct implementation of the present Contract shall appear.
The information transmitted to the other party shall be as detailed and appropriate as possible so that the other party may immediatly undertake the required actions.

2. The licensor binds himself, under such circunstances, to fully cooperate with the licensee to determine the impact of the modified regulations on the implementation of the Contract, the solutions that are to be contemplated, including related time and expenses for implementation, and to select with licensee's agreement the adequate solution required in licensee's country.
The licensor shall consequently adjust all the components of of the technology affected by the enforcement of that solution.
Whenever applicable, the licensor shall transmit without delay to the licensee any additional data required by the Health Authorities of the licensee's country.

Whenever applicable, the licensor shall cooperate with the licensee for complementary registration required in the licensee' country under the same conditions as stipulated in Article : "Registration of the product".

3. Whatever the problem is, if the licensor is not able to provide the licensee with the required solution within..... ..... weeks after modifications have been imposed by the Health Authorities, the Contract shall be suspended for a maximum period of ..... .months (or for the maximum period of time agreed upon by both parties).
During the suspension time of the Contract, any payment due by the licensee to thy licensor shall be suspended without prejudice for the same period as well as any other obligation stipulated herein, unless it is otherwise convened by both parties.

4. At the end of said maximum period, if the licensor fails to provide the licensee with the required solution , the licensee shall have the right without prejudice, according to the magnitude of the impact, either to select a third party to have the specific problem incurred by the modified regulations be solved at licensee's expense the rest of the Contract remaining valid, either to terminated thu contract under the provisions of Article "Force majeure". If said third fails to provide the required solution within....., the licensor shall have the right to terminate the Contract under the provisions of Article "Force majeure".

5. 5.1.In case a substitue is required to comply with the new regulations, the licensor binds himself to undertake all possible efforts to supply the licensee with that susbtitute under the same delivery conditions previously agreed between both parties except price, if applicable.

5.2. If both parties do not reach an agreement on price of substitute after the substitute has been proposed to the licensee by the licensor, the licensee shall be free to purchase it from any alternative supplier.

6. The costs of changes incurred by the modified regulations shall be paid by the party located in the country where the Health Authorities have imposed such modifications. They shall be shared on a 50% basis when said modifications are imposed in both countries.
The licensor shall timely provide the licensee with an appropriate estimation of the expenses he is contemplating and the licensee shall give his written agreement for these expenses (whenever applicable).

7. In case the modified regulations prevent definitly the use of the drug or where no substitute or alternative is available, the consequences of that situation are treated according to the provisions of Article "Force Majeure".

8. Both parties agree that the specific cooperation stipulated under the present Article be extended for.....years after the expiration date of the Contract (whenever applicable).

Background note

VARIETY OF THE PRODUCT

The molecule of one active principle is composed of a certain number of atoms displaid according to a specific structure. Generally a part only of this structure is at the origine of the action of the active principle. The remaining atoms have no medicamental effect ; they may be replaced and/or other atoms may be added without changing the medical applications of the active principle.

The results of modifying the "secondary" part of the molecule reside in the side effects of the active principle.

Considerable investigation is being presently undertaken to minimize side effects of drugs which sometimes also prevent the use of said drugs in association with other drugs.

The modified active principle is more attractive that the initial one.

Consequently, it is important this licensee be protected against the granting by the licensor of licence agreements related to said modified active principles. Otherwise this licensee would soon have acquired are absolete product.

Specimen clause

VARIETY OF THE PRODUCT

1. In case the licensor shall have the intention, in the licensee's country, to grant a licence for the manufacture of a variety of.....(product name), that is a product with the same basic molecule and the same medical applications but with different side effects, then the licensee shall be given a first refusal right by the licensor.

2. The validity of the present Article is extended for a period of .....years after the expiration date of the Contract.

EXAMPLES

1. Medical application : Acetylsalicylic acid coated and not coated do not have the same medical applications although both products are chemically identical.

2. Registration of product ; Concerns all pharmaceutical products except a few countries where no health regulations exist.

3. Components of technology : Applies to all pharmaceutical products.
   Without specification of the "Culture" where the strain is to be kept, the transfer of technology streptomycine is uncomplete and unseful.

4. Method of transfer : Applies particularly to pharmaceutical products since transfers of technology in this field are complex without permiting the omission of one single element.

5. Anality Control : Cyanocobalamine which is sold per gram is extremely sensible to humidity. Apart from the importance to control pharmacopea specifications, humidity above 2% shall affect production of formulated drugs as well as commercial transactions.

6. Supply of raw mateirals : Concerns all phamaceutical products

7. Impact of changes in health regulations : It is unlikely that a product among UNIDO's list be prohibited in the future ; but coating agents, anti-motting agents, colouring agents,

.../...

stability agents, etc... which come with the active principle as per licensor' specifications are more and more frequently banned since it appears they have been unsufficiently tested.
As an exemple, a basic active principle such as bismuth and its salts have been totally banned a few years ago. The same happened to di-hydro-streptomicine.

8. Variety of product : "Modified" penicillin, chloro-tetracydine and oxy-tetracycline respectively are "varieties" of penicillin and tetracycline. Their basic molecules are identical as well as medical applications but side effects are different .

OUTLINES OF PROPOSED STUDIES

TO BE PREPARED

1. To prepare long-term contract of supply specific to the supply either of raw materials, or intermediates or bulk drugs or combination of same in the pharmaceutical industry : the document to be elaborated will take into account UNIDO'S objectives to increase the availability at reasonable prices of pharmaceutical drugs in developping countries and will integrate all the appropriate aspects which may permit to control the financial condition of such supply. The control will not only contain the usual clause (1) in this type of agreement such as purpose, scope, definitions, obligations of the supplier, obligations of the purchaser, specifications, quality control, delivery conditions, apllicable law, settlement of disputes, etc... But will concentrate on financial aspects and mechanisms (2) able to regulate and minimize the purchasing prices such as, indexation clauses, escalated prices, international price references, years of price references; variable terms of payement, places of price references (FOB, CIF,EX-Works), currency of payments, currency for price calculation, methods of price calculation, patented or not patented supplies, non less favourable clause, minimum duration of agreed upon prices, limits of the price increase enforcement, prices schemes related to drugs selected from UNIDO's list, interferences of world market conditions, availability of govermental and/or international reference index, interferences of guarantes offered by the suppliers, minimum quantities, purchasing conditions etc... Plus any other factor to be determined after a thorough investigation of price fixing and price control in the pharmaceutical industry.
   The finality of such contract will be to propose an extended list of possibilities/alternatives to determine bench work prices and the control of their evolution during the lifetime of the agreement.
   The document to be prepared will be composed of specimen clauses and background notes as well as commentaries on works already undertaken or proposed by the UNIDO and coutained in documentation given to the consultant to study. Whenever possible the document will include examples related to UNIDO's list of 26 essential drugs and to the 3 main production processes : fermentation, synthetis, extraction.

2. To prepare a report related only to part (2) of point 1. above, that is the economic and financial factors to be negociated and included in a long time supply contract in pharmaceutical industry in order to fix references prices and to control their evolution. According to types of drugs to be selected from UNIDO'S essential drugs' list, the work to be done shall concentrate on bench mark price fixing, indixation clauses and other possible mechanisms

.../...

to be convened between purchaser and vendor in order to acceptably regulate the price increases.
The document to be prepared will be composed of specimen clauses and background notes as well as comments and alternatives on pricing system already proposed by UNIDO. Whenever possible the report will include examples of what is being done in France in that respect. France, in the pharmaceutical field, is not as advanced as the U. S. A., GERMANY or SWITZERLAND and is facing price and availability problems related to the importation of patented (or not patented) raw materials/ intermediates.
The french pharmaceutical industry is rather well organized ; a certain number of "tools" have been developped to solve some of these problems which represent valuable data to be utilisated to complement UNIDO's INVESTIGATIONS ON THE SAME MATTER.

3. To prepare a report based on part or on totality of attached outline named "outline on price Control mechanisms at National level" included in UNIDO's document : "Summary of the deliberations of the experts informal meeting on the issues for the second Consultation on the phamaceutical industry. Vienna 22-24 March 1982" The report to be prepared will concern the present situation in France.(See attached Annex I (b))

4. To prepare "Contractual arrangements for setting up of a plant for the production of bulk drugs intermediates" and/or "Contractual arrangements for the formulation of dosage forms" as detailed in Mr CORREA's document, "Future work" dated July 6,1982.
If the Consultant is to contribute to any of these contractual arrangements, it would be easier for integration purpose he prepares his own version of said arrangements rather than conplementing afterwards the documents to be prepared by the other consultants (during one session only, the various versions would be compared, discussed and integrated). In that case, as stipulated in Mr CORREA's document, the consultant will prepare specimen clauses and background notes on each item, plus additional items the consultant would feel complementary.

ANNEX I (b)

OUTLINE OF PAPER ON PRICE CONTROL MECHANISMS AT NATIONAL LEVEL

As further developed after the meeting

I. BACKGROUND

1. Motivation for price control
2. Voluntary or compulsory
3. History of price control legislation and why changes were introduced
4. The customers for drugs, hospital, pharmacies, doctors
5. The pattern of drug distribution and sales

II. THE NATIONAL PRICE CONTROL MECHANISM

- What price is controlled - retail price and/or other prices.
- Basis for control - unit manufacturing cost or return on investment profits or a combination.
- Whether and how the price of new drugs are controlled.
- How is controlling authority organized and what tasks do they perform.
- Method of calculating the cost of imported materials.
  (a) finished and packaged product
  (b) bulk drugs
  (c) intermediates used in drug synthesis
  (d) how is the level of the above prices calculated for the purpose of (i) calculating customs tariff and other duties (ii) transfer prices for inter-company transactions.
- Method of calculating other available costs
  (a) R and D
  (b) License costs
  (c) Sales promotion costs
  (d) Other allowable costs
- Where the controlled prices are published and how frequently they are revised.

III. COMPARISON OF NATIONAL PRICES WITH THOSE OF OTHER COUNTRIES

To what extent does the controlling authority:
(a) collect information on prices in other countries for formulations, bulk drugs, intermediates
(b) share this information with other countries
(c) have the willingness to share this information with UNIDO and/or developing countries

IV. THE IMPACT OF PRICE CONTROLS

Provide information over a period of 10/20 years covering

(a) the cost of drugs to the consumer
(b) the cost of drugs to the National Health Service
(c) the cost of drugs to hospitals
(d) the cost of imported bulk drugs and intermediates
(e) the expenditure on drug promotion
(f) return on investment of companies

ANNEXES

Texts of Price Control Legislation
The controlled price of 20 selected drugs over the last 10/20 years.