AUGLÝSING

um gildistöku nýrra alþjóðapóstsamninga.

Hinn 1. júlí 1971 ganga í gildi samningar, sem gerðir voru og undirritaðir fyrir Íslands hönd á póstþinginu í Tokyo hinn 14. nóvember 1969.

Samningarnir eru þessir:

1. Viðbótarlokabókun Stofnskrár Alþjóðapóstsambandsins.
2. Almenn reglugerð fyrir Alþjóðapóstsambandið.
3. Lokabókun almennu reglugerðarinnar fyrir Alþjóðapóstsambandið.
4. Alþjóðasamningurinn.
5. Lokabókun Alþjóðapóstsamningsins.
6. Starfsreglugerð Alþjóðapóstsamningsins.
7. Samningurinn um bréf og öskjur með tilgreindu verði.
8. Starfsreglugerð samningsins um bréf og öskjur með tilgreindu verði.
9. Samningurinn um póstböggla.
10. Lokabókun samningsins um póstböggla.
11. Starfsreglugerð samningsins um póstböggla.
12. Samningurinn um póstávísanir og ferðapóstávísanir.
13. Starfsreglugerð samningsins um póstávísanir og ferðapóstávísanir.
14. Samningurinn um póstfærslur.
15. Starfsreglugerð samningsins um póstfærslur.
16. Samningurinn um póstkröfusendingar.
17. Starfsreglugerð samningsins um póstkröfusendingar.

Fullgildingarskjal Íslands varðandi ofangreinda samninga var afhent utanríkisráðuneytinu í Bern hinn 29. marz 1971.

Þetta er hér með gert almenningi kunnugt.

Utanríkisráðuneytið, Reykjavík, 30. marz 1971.

Emil Jónsson.

Pétur Thorsteinsson.

Nr. 6. 5. apríl 1971.

AUGLÝSING

um samning um gagnkvæma viðurkenningu á eftirliti með framleiðslu lyfja.

Hinn 28. janúar 1971 var utanríkisráðuneyti Svíþjóðar afhent fullgildingarskjal Íslands varðandi samning um gagnkvæma viðurkenningu á eftirliti með framleiðslu lyfja, sem undirritaður var fyrir Íslands hönd í Genf hinn 8. október 1970. Samkvæmt 9. gr. samningsins mun hann taka gildi hinn 25. maí 1971.

Samningurinn er birtur sem fylgiskjal með auglýsingu þessari.

Þetta er hér með gert almenningi kunnugt.

Utanríkisráðuneytið, Reykjavík, 5. apríl 1971.

Emil Jónsson.

Pétur Thorsteinsson.

Fylgiskjal.

CONVENTION

for the mutual recognition of inspections in respect of the manufacture of Pharmaceutical products.

(and Explanatory Notes)

PREAMBLE

The Republic of Austria, the Kingdom of Denmark, the Republic of Finland, the Republic of Iceland, the Principality of Liechtenstein, the Kingdom of Norway, the Portuguese Republic, the Kingdom of Sweden, the Swiss Confederation and the United Kingdom of Great Britain and Northern Ireland:

Considering that in the interest of public health pharmaceutical products whether exported or not should be produced according to appropriate standards;

Considering that the rapid development of new drugs, especially complex synthetic substances of great pharmacological potency, necessitates strict quality control of their manufacture;

Considering that official inspection is necessary to ensure such manufacturing control;

Determined to have effective systems of national inspection and testing of pharmaceutical products operating in their countries;

Having regard to the work already undertaken between the Nordic countries and to the discussions in progress in other international organizations, especially the World Health Organization and the Council of Europe (Partial Agreement);

Considering that the present Convention would contribute towards the removal of obstacles in international trade on a wider scale through the recognition of inspections made by national health authorities;

Have agreed as follows:

PART I

Exchange of information.

Article 1

1. The Contracting States shall exchange, in accordance with the provisions of this Convention, such information as is necessary for the mutual recognition of inspections relating to pharmaceutical products manufactured within their territories and intended for import into other Contracting States.

2. For the purpose of this Convention "pharmaceutical product" means:

(a) any medicine or similar product intended for human use which is subject to control by health legislation in the manufacturing Contracting State or in the importing Contracting State; and

(b) any ingredient which the manufacturer uses in the manufacture of a product referred to in subparagraph (a) above.

Article 2

1. Upon the request of the competent authority of a Contracting State into which a pharmaceutical product manufactured in another Contracting State is to be imported, the competent authority of the latter State shall, subject to the provisions of Article 4, provide information regarding:

(a) the general standards of manufacturing practice in a particular firm;

(b) the specific standards of manufacture and control of a given product in a particular firm;

(c) supplementary questions of the requesting competent authority which are relevant to the quality control of pharmaceutical products and based on the legal provisions of the importing Contracting State.

2. Information provided under this Convention shall not extend to data concerning financial and commercial matters or, in so far as they are not related to quality control of manufacture, to data concerning technical "know-how", research information and personal data other than those relating to the duties of the persons concerned.

Article 3

1. The information to be provided shall be based on inspections carried out by the competent authority. Such inspections shall normally be those made in the course of the enforcement of the system of compulsory control established in the manufacturing Contracting State.

2. If the product concerned does not fall within the system of compulsory control established by the manufacturing Contracting State or if the system of compulsory control of the manufacturing Contracting State, though applicable to the product concerned, does not extend to the particular aspects with regard to which the information is sought, the exporting manufacturer may apply to the competent authority of the manufacturing Contracting State for an inspection to be made on a voluntary basis.

Article 4

1. Before providing information about any particular firm or any product manufactured by it, the competent authority of the manufacturing Contracting State shall notify the manufacturer.

2. The manufacturer may at any time withhold his consent to information relating to his firm or to any product manufactured by him being disclosed to the competent authority of another Contracting State. In such a case the withholding of consent shall be notified to the competent authority of the Contracting State concerned, which may:

(a) where the information withheld relates to the general standards of manufacturing practice in the particular firm, regard any product of the manufacturer;

(b) where the information withheld relates to a specific product only, regard that specific product; as being a product in respect of which full information has not been provided in accordance with this Convention.

Article 5

If a competent authority discovers in the course of its inspection duties or otherwise particular circumstances which cause a pharmaceutical product to be of imminent and serious danger to the public, it shall immediately communicate its findings to the competent authorities of the other Contracting States.

PART II

Inspections.

Article 6

1. Inspection within the meaning of this Convention shall cover personnel, premises and facilities, equipment, hygiene and manufacturing and control procedures. The essential factors to be covered are product quality specifications and

production control. Product quality specifications may be found in official formularies or should be established by the manufacturer. Production control embodies:

(a) environmental control pertaining to suitability of premises, equipment and staff;

(b) manufacturing control with respect to process inherent factors which might adversely affect the execution of manufacturing procedures and with regard to adverse extraneous factors;

(c) final control of the finished products to ensure that they comply with the established specifications and have been manufactured and controlled according to prescribed procedures.

2. The Contracting States shall ensure:

(a) that their competent authority has the power to call for the submission of quality control records and, if appropriate, samples relating to any batch of any pharmaceutical product;

(b) that the inspectors in the service of their competent authorities have appropriate qualifications and experience for the task to be undertaken by them.

PART III

Mutual Recognition of Inspections.

Article 7

The Contracting States accept and recognize as equivalent to their own national inspections in respect of the manufacture of pharmaceutical products those carried out in conformity with the provisions of this Convention by the competent authority of the manufacturing Contracting State, provided that full information is supplied in respect of the requirements in force in the importing Contracting State.

PART IV

Consultation.

Article 8

1. Officials of the competent authorities shall meet whenever necessary but at least once a year in order to:

(a) make recommendations and proposals for standards of good manufacturing practice;

(b) exchange experience on means and methods for achieving appropriate and effective inspections;

(c) promote co-operation between the competent authorities to facilitate the application of the Convention;

(d) promote the mutual training of inspectors; and

(e) make recommendations on any question relating to the implementation of this Convention or to make proposals for its amendment; such recommendations or proposals shall be transmitted to the depositary Government of this Convention.

2. In the exercise of these functions account shall be taken, where appropriate, of current developments and work in other international organizations.

PART V
General.

Article 9

1. This Convention shall be ratified by the signatory States. The instruments of ratification shall be deposited with the Government of Sweden which shall notify all other signatory States.

2. This Convention shall enter into force ninety days after deposit of the fifth instrument of ratification. In relation to any other signatory depositing subsequently this Convention shall enter into force thirty days after the date of deposit of the instrument of ratification but not before the expiry of the period of ninety days.

3. Any arrangements in relation to the inspection system of a Contracting State which are necessary in order to comply with the provisions of this Convention shall be completed not later than eighteen months after deposit of the instrument of ratification of that Contracting State. Such arrangements shall be communicated to the depositary Government which shall notify all other Contracting States.

4. Each Contracting State shall communicate to the depositary Government, which shall notify all other Contracting States, the name and address of its principal national authority which will be its competent authority within the meaning of this Convention.

Article 10

1. The depositary Government shall notify to all other Contracting States any recommendation relating to the implementation of this Convention received in accordance with paragraph 1 (e) of Article 8.

2. The depositary Government shall submit to all other Contracting States for acceptance any proposal for amendment of this Convention received in accordance with paragraph 1 (e) of Article 8 or from any Contracting State.

3. If, within sixty days from the date of the submission of a proposal for amendment, a Contracting State requests that negotiations be opened on the proposal, the depositary Government shall arrange for such negotiations to be held.

4. Provided it is accepted by all Contracting States, an amendment of this Convention shall enter into force thirty days after deposit of the last instrument of acceptance unless another date is provided for in the amendment. Instruments of acceptance shall be deposited with the depositary Government which shall notify all other Contracting States.

Article 11

1. Any State being a Member of the United Nations or of any of the specialized agencies or of the International Atomic Energy Agency or a party to the Statute of the International Court of Justice and having the national arrangements necessary to apply an inspection system comparable to that referred to in this Convention may, upon invitation of the Contracting States to be transmitted by the depositary Government, accede to this Convention.

2. The date of the entry into force of this Convention in relation to an acceding State shall be agreed between that State and the Contracting States.

3. Instruments of accession shall be deposited with the depositary Government which shall notify all other Contracting States.

Article 12

Any Contracting State may withdraw from this Convention provided that it gives twelve months' notice in writing to the depositary Government which shall notify all other Contracting States.

Article 13

The Explanatory Notes annexed to this Convention shall form an integral part of it and serve for the interpretation and explanation of its provisions.

In witness whereof the undersigned, duly authorized thereto, have signed the present Convention.

Done at Geneva this 8th day of October 1970,

in a single copy in the English and French languages, both texts being equally authentic, which shall be deposited with the Government of Sweden by which certified copies shall be transmitted to all other signatory and acceding States.

EXPLANATORY NOTES

Title and scope of the Convention.

1. This Convention deals with the mutual recognition of inspections in respect of the manufacture of pharmaceutical products and with the measures necessary to achieve such recognition. It is therefore concerned with quality control irrespective of whether information on such control is required in the course of the registration procedure or later. The Convention is not intended to interfere with the normal registration procedure nor with the providing of information by the manufacturer or his representative directly to the registration authority.

2. The Convention is divided into five parts. The first part deals with the exchange of information, the second with the inspections necessary to provide this information and the third part with the mutual recognition of inspections. The fourth part deals with the consultations which shall take place in order to improve the practical application and operation of the Convention. General clauses are contained in part five.

Exchange of Information.

Article 1

3. This Article sets out the basic principle of this Convention according to which Contracting States are prepared to exchange such information as is necessary for the mutual recognition of inspections relating to pharmaceutical products manufactured within their territories and intended for import into other Contracting States. The Convention does not extend to the control of products which are used purely for domestic purposes although it presupposes a domestic control system.

4. The definition in paragraph 2 is not intended to affect the very different definitions contained in the various national legislations. In order to bridge such differences the definition of the Convention extends to all products which are subject to control imposed by the health legislation of the manufacturing Contracting State, and also covers products which while not falling under this control in the country of manufacture do so in the importing Contracting State.

Due to the differences in national legislation in the Contracting States, terms have been used deliberately which are rather broad. "Any medicine or similar

product" has been used in order to cover all sorts of medicine (médicament, Arzneimittel, laegemiddel, lääkeaine, lyf, legemiddel, medicamentos, läkemedel, medicinali or equivalent terms) which in any one of the Contracting States are subject to the control of health legislation. The definition does not cover veterinary products.

5. As far as ingredients are concerned it is for the manufacturer to satisfy himself as to the quality of the ingredients purchased from other firms before using them in the manufacture of his pharmaceutical product. The inspections by the competent authorities and the information to be provided would have to ascertain whether the manufacturer does in fact do so.

6. In this connection it should be noted that the terms "manufacturer" and "manufacturing" are used in this Convention as intending to cover not only firms and processes for the complete production of a finished product, but also separate operations in the production of a pharmaceutical product, such as processing, compounding, formulating, filling, packing, labelling, etc., irrespective of whether these operations are carried out by one or more firms.

Article 2

7. Information is to be provided upon the request of the competent authority of an importing Contracting State. The request can relate either to the general standards of manufacturing practice, or to specific standards of manufacture and quality control in respect of particular products, or to both. Furthermore, supplementary questions can be asked by the requesting competent authority. These supplementary questions must be relevant to the quality control of pharmaceutical products which are to be imported into the territory of the requesting authority and must be based on the provisions of the health legislation of the importing Contracting State, that is to say, that supplementary questions can be asked but only those in respect of which a requesting authority needs an answer in order to comply with the provisions of its national legislation. In providing the information the provisions of Article 4, giving protection to the manufacturer, have to be applied (cf. notes on Article 4).

8. The information to be supplied under Article 2 and requests for such information shall be in writing if so required by either of the interested competent authorities; information can be exchanged orally between the competent authorities of Contracting States which desire to proceed in this way. In addition to the official channel information can also be transmitted to the competent authority of the importing Contracting State, if this is acceptable to the latter, through the exporter's representative in that State.

9. On account of its confidential nature, information provided under the Convention shall not be disclosed to persons outside the public health service of a Contracting State. This provision does not exclude the transmission of information to persons outside the government service of a Contracting State in connection with the exercise by those persons of functions related to the medicines or pharmaceutical legislation of that State.

10. Information of the type described in Article 2, paragraph 2, is, however, in any event excluded from the provisions of the Convention. Therefore, the omission of such information does not imply that full information has not been given in accordance with this Convention. The expression "technical 'know-how' " is meant to comprise any technical process in the course of production, which is not generally known. "Personal data relating to the duties of the persons concerned" are data such as the relevant education, practical experience, functions and duties within

the enterprise and whether the personnel of the enterprise is medically checked from time to time.

11. It is the understanding of the Contracting States that in exceptional circumstances where the exchange of information has not satisfied fully the importing country's requirements, the competent authorities of that country and of the exporting country should seek practical means of overcoming the importing country's doubts. Such practical means may include informal discussions about the particular outstanding points of doubt between officials of the importing country and of the exporting country with suitable participation of representatives of the manufacturer concerned at a place mutually agreed by them having regard to the nature of those points. The ensuing written report of the exporting country's inspector would constitute the information required to be provided under Article 2 of the Convention.

Article 3

12. Paragraph 1 of Article 3 states the rules that the information to be given must have been acquired in the course of inspections. It is therefore not permissible to give information in respect of the manufacture of a product without the firm in question having been inspected. The question whether in the case of a request a new inspection has to be made will depend on whether the information acquired in previous inspections is up to date and sufficient in order to reply to the request. The inspections contemplated under this paragraph will be those which are made normally in the course of the enforcement of the system of compulsory control which prevails in the manufacturing Contracting State.

13. Paragraph 2 of this Article provides for the case where the product or certain aspects of its production are not subject to the compulsory control prevailing in the manufacturing Contracting State. In such a case the manufacturer who wishes to export has the right to ask for an inspection on a voluntary basis. Such a request must be complied with by his competent authority. Voluntary inspections must be at least of the same standard as compulsory inspections and carried out by persons competent in the field concerned. This request may be repeated whenever fresh inspections or follow-up inspections are necessary in order to meet the requirements of the requesting competent authority.

Article 4

14. This Article is included for the protection of the manufacturer. The manufacturer shall be notified by his own competent authority before information is given in reply to a request of a competent authority. It will depend on national legislation how detailed the notification will be. The manufacturer has the right to request that information should be withheld and not be transmitted to the requesting competent authority. The withholding of consent is to be notified to the requesting competent authority.

15. Paragraph 2 of this Article deals with the rights of the requesting competent authority in such cases. The action which the latter may take varies according to whether the refusal concerns information about the general standards of manufacturing practice of the firm or concerns a specific product only. The Article has been drafted on the assumption that the rights conferred upon the requesting competent authority will not be used where this concerns information which is of minor importance only. Genuine health considerations, however, are always paramount.

Article 5

16. It can happen for example that in the course of the manufacture of a pharmaceutical product or of a particular batch, an error occurs which causes an immediate and serious danger to persons using the product in question. In such a case, the competent authority discovering this, whether in the course of its inspections or otherwise, shall immediately notify the competent authorities of the other Contracting States in order that the dangerous product or batch can be removed from the market. It is evident that in such a case, no prior consent of the manufacturer is required, but he should be informed of it.

Inspections.

Article 6

17. Paragraph 1 states the extent of the inspections. It describes the essential facts, circumstances and data to be covered in the course of inspections. At the same time, the paragraph represents the basic elements of good manufacturing practice.

18. In order that the Contracting States shall be able to fulfil the provisions of the Convention and, in particular, of paragraph 1 of this Article, paragraph 2 obliges them to ensure that they have the necessary minimum of legal powers. In this connection the provisions of Article 9, paragraph 3, are relevant, which provide a maximum time-limit within which the Contracting States are to make the necessary arrangements in their inspection systems in order to comply with the provisions of this Convention.

19. The provision in Article 6, paragraph 2 (b) is of vital importance. If the inspectors have not appropriate qualifications and experience, the value of the information supplied may be much reduced and insufficient to meet the requirements of the importing State. Where necessary, lists of names of inspectors, including their qualifications and professional experience should be exchanged. The provisions of Article 8, paragraph 1 (d), relating to the mutual training of inspectors will ensure that the competence of inspectors and the quality of their inspections will be based on a common standard. The reports shall be signed by the inspector whose inspection yielded the information supplied.

Mutual recognition of inspections.

Article 7

20. Provided that full information is given in respect of the requirements of the importing Contracting State, the recognition stipulated under this Article has the effect that inspections made by the competent authority of the manufacturing Contracting State will be regarded as though they had been made by the inspectors of the competent authority of the importing Contracting State. The proviso regarding full information allows the importing Contracting State to refuse an import licence if information is incomplete or if the information supplied does not fulfil the requirements in force in its territory. The decision in each case rests with the competent authority of the importing Contracting State.

Consultation.

Article 8

21. For the effective functioning of the Convention and its uniform application frequent consultations and co-operation are essential. This Article therefore provides for officials of the competent authorities to meet whenever necessary, but at least

once a year. The words "officials of the competent authorities" have been used in order to allow the Heads of the competent authorities or any of the officials or inspectors in their service to attend meetings, depending on the nature of the items to be discussed. Several tasks are entrusted to those meetings. In fulfilling them account must be taken, whenever relevant, of current developments and the work done in other international organizations.

22. One of the first tasks will be to study, taking into account the work done by WHO, by the Council of Europe, (Partial Agreement) and by industrial organizations, the details of general standards of good manufacturing practice as currently proposed and to make recommendations to this end.

23. Up to now, except in the Nordic area, there exists no wider international co-operation between national inspectors. In some countries systems have been developed to control particular products or particular aspects of their manufacture. These are not always known to the inspectors in other countries. The Convention therefore provides that information and experience on the best means and methods for achieving these inspections shall be currently exchanged so that each Contracting State may profit from the experience of the others.

24. Furthermore, the meetings may provide for the mutual training of inspectors in order that they may be made familiar with methods and systems in use or attend symposia where certain questions are discussed in a methodical manner. In this way inspectors would, in the course of time, gain equivalent knowledge and experience. This could greatly facilitate the application of the Convention by building up mutual confidence in the standards of inspection of the Contracting States.

25. Another task of the meetings is to further co-operation between the competent authorities. This entails all details of the operation of the Convention rules, in particular all questions relating to the exchange of information, and its simplification. One of the first questions to be discussed under this heading will be that of written reports.

26. In the course of time it may arise that the participants in the meetings come to the conclusion that one or the other provisions of the Convention should be amended; in such a case, they should be free to make a proposal to this end.

General.

Article 9

27. This Article deals with the ratification of the Convention, the deposit of the instruments of ratification and the entry into force of the Convention.

28. In order to facilitate the adjustments in national legislation or in national inspection systems to be made in order to comply with this Convention, a time-limit has been stated in the course of which these arrangements have to be made. Such arrangements must be notified to all Contracting States through the depositary Government.

29. The Contracting States are obliged to communicate in the same way the name and address of their principal national authority which is to be considered as the competent authority within the meaning of the Convention. This communication is due not only when ratifying or acceding to the Convention but also when a Contracting State assigns the responsibilities conferred upon the competent authority by this Convention to another national authority.

Article 10

30. Recommendations emanating from the meetings referred to in Article 8 and any proposal for amending the Convention shall be channelled through the depositary Government to the other Contracting States. Amendments to the Convention require acceptance by all Contracting States.

Article 11

31. The Convention is open to accession by such other States referred to in Article 11 as have the national arrangements necessary to apply an inspection system comparable to that referred to in this Convention. Accession by invitation has been chosen on account of the technical character of this Convention and is intended to facilitate the widest participation of States on that basis. An invitation to accede may be extended not only to a State which has expressed interest in accession, but also to a State which, in the opinion of the Contracting States, may be expected to be so interested. Such an invitation shall normally be preceded by an invitation to its competent authority to arrange for its inspectors to take part in activities organized under the provisions of Article 8 and by a reciprocal invitation by that State to participate in similar activities organized on its territory. Since the question of a transitional period may arise, the entry into force of the Convention in relation to the acceding State shall be agreed between that State and the Contracting States.

Article 12

32. This Article provides for withdrawal from the Convention which is effected by giving twelve months' notice in writing to the depositary Government.

Nr. 7. 5. apríl 1971.

AUGLÝSING

um samþykktir fyrir Kjarnfræðistofnun Norðurlanda (NORDITA).

Hinn 28. janúar 1971 staðfesti menntamálaráðherra samþykktir fyrir kjarnfræðistofnun Norðurlanda (NORDITA).

Samþykktirnar eru birtar sem fylgiskjal með auglýsingu þessari.

Þetta er hér með gert almenningi kunnugt.

Utanríkisráðuneytið, Reykjavík, 5. apríl 1971.

Emil Jónsson.

Pétur Thorsteinsson.