Treaty Series No. 110 (1973)

Revised Text

of the Protocol to the European Agreement on the Exchange of Therapeutic Substances of Human Origin

(with Annexes 7, 8, 9 and 10)

adopted by the Committee of Ministers of the Council of Europe on 30 April 1973

Presented to Parliament
by the Secretary of State for Foreign and Commonwealth Affairs
by Command of Her Majesty
November 1973

LONDON
HER MAJESTY'S STATIONERY OFFICE
13p net

Cmnd. 5463

REVISED TEXT OF THE PROTOCOL TO THE EUROPEAN AGREEMENT ON THE EXCHANGE OF THERAPEUTIC SUBSTANCES OF HUMAN ORIGIN AND ANNEXES 7, 8, 9 AND 10 TO THE SAID PROTOCOL

CERTIFICATE OF THE SECRETARY GENERAL

Whereas it is stated in the fourth paragraph of Article 4 of the European Agreement on the Exchange of Therapeutic Substances of Human Origin(1) that the Protocol(2) and its Annexes(3) may be amended or supplemented by the Governments of the Contracting Parties to the said Agreement;

Whereas, at the 218th meeting of the Ministers' Deputies held in Strasbourg from 12th to 16th February 1973, the representatives to the Committee of Ministers of the Council of Europe of the Governments of Belgium, Cyprus, Denmark, France, the Federal Republic of Germany, Ireland, Italy, Luxembourg, Malta, the Netherlands, Norway, Sweden, Switzerland, Turkey and the United Kingdom, Contracting Parties to the said Agreement, approved the provisions concerning human coagulation factors VIII and IX for insertion in the Protocol to the European Agreement on the Exchange of Therapeutic Substances of Human Origin, and two new Annexes to that Protocol, for insertion after Annex 6, as well as certain modifications to the text of the Protocol and of its Annexes resulting from the insertion of the said provisions and Annexes;

Whereas at the same meeting, the representatives of the above-mentioned Governments, further agreed that the Governments of the Contracting Parties to the Agreement, which are not represented on the Committee of Ministers, should be invited to make known, by a specific date, their agreement to the said insertions and modifications and that, after the expiry of this time-limit, any Government so invited which had not replied to the invitation would be deemed to have given its tacit approval to these insertions and modifications;

Whereas by letters of the Secretary General dated 26th March 1973, the Governments of Greece and of the Principality of Liechtenstein, Contracting Parties to the Agreement, but not represented on the Committee of Ministers, were invited to make known their agreement to the said insertions and modifications before 30th April 1973, date on which insertions and modifications would be considered as definitively adopted in the absence of any objection on the part of a Government of a Contracting Party;

Whereas by letter of 10th May 1973, the Government of Greece made known to the Secretary General its agreement to the said insertions and modifications and the Government of the Principality of Liechtenstein has not replied to the invitation addressed to it on 26th March 1973,

The Secretary General hereby certifies as follows:

I. The following text constitutes the Protocol to the European Agreement on the Exchange of Therapeutic Substances of Human Origin.

---

(1) Treaty Series No. 27 (1965), Cmnd. 2591.

(2) Treaty Series No. 110 (1968), Cmnd. 3822 (revised text).

(3) Treaty Series No. 107 (1970), Cmnd. 4549 (revised text of Annex 9).

PROTOCOL TO THE EUROPEAN AGREEMENT ON THE EXCHANGE OF THERAPEUTIC SUBSTANCES OF HUMAN ORIGIN

PART I

GENERAL PROVISIONS

A. Labelling

A label printed in English and French, based on the appropriate model to be found in Annexes 2 to 10 to the Protocol, shall be affixed to each container or giving-set.

B. Packing and dispatch

Whole human blood shall be dispatched in containers in which a temperature of 4° to 6° C. is maintained throughout the period of transport.

This condition is not required for the derivatives mentioned in the Protocol.

C. Products and apparatus

The products and apparatus referred to in Part II of this Protocol shall be sterile, non-pyrogenic and non-toxic.

It is recommended that the giving-set, as well as the solvents required for the dried products, be sent with each consignment.

D. Freedom from toxicity of plastic blood transfusion equipment

Equipment shall comply with the provisions set out in Annex 11 to this Protocol.

PART II

SPECIFIC PROVISIONS

1. Whole Human Blood

Whole Human Blood is blood which has been mixed with a suitable anti-coagulant, after collection from a human subject in normal health.

The blood shall not be obtained from a human subject:

(*a*) who is known to be suffering from or to have suffered from syphilis or hepatitis,

(*b*) whose blood has not been tested with negative results for evidence of syphilitic infection, or

(*c*) who is not, as far as can be ascertained after medical examination and the study of his antecedents, free from disease transmissible by blood transfusion.

The blood shall be withdrawn aseptically through a closed system of sterile tubing into a sterile container in which the anticoagulant solution has been placed before the container is sterilised. The equipment used must be pyrogen-free. When withdrawal is complete the container shall be immediately sealed and cooled to 4° to 6°C. and not opened thereafter until immediately before the blood is to be used.

The blood will be collected into a citrate solution of acid reaction containing dextrose. No antiseptic or bacteriostatic substance shall be added. The volume of the anticoagulant solution must not exceed 22% of the Whole Human Blood, and the haemoglobin content must not be less than 9·7 g. per 100 ml.

Blood Group. The blood group under the ABO system shall have been determined by examination of both corpuscles and serum and that under the Rh system by examination of the corpuscles, using a separate sample of the donor's blood. When there is a national standard, or nationally recommended technique of blood grouping, that technique shall be used.

The term Rh negative is only to be used when specific tests have shown the absence of the antigens C, D, D^u and E. All other blood must be labelled Rh positive.

Blood exchange under this agreement should only be used for recipients of the corresponding ABO group.

Storage. Whole human blood shall be kept in a sterile container sealed so as to exclude micro-organisms and stored at a temperature of 4° to 6° C. until required for use, except during any period necessary for examination and transport at higher temperatures, any such period not to exceed thirty minutes after which the blood must immediately be cooled again to 4° to 6° C.

Labelling. The label on the container shall give all the information shown on the model label (Annex 2). The Rhesus group shall be written as " Positive " or " Negative " or, in abbreviated form, " POS " or " NEG ".

2. Dried Human Plasma

Dried Human Plasma is prepared by drying the supernatant fluids which are separated by centrifuging or by sedimentation from quantities of Whole Human Blood.

During preparation no antiseptic or bacteriostatic or other substance shall be added. Dried Human Plasma shall be obtained by freeze-drying or by any other method which will avoid denaturation of proteins. The dried product shall be readily soluble in a quantity of water equal to the volume of the liquid from which the substance was prepared. The solution thus obtained must not contain less than 4·5% w/v of protein and must not show visible evidence of the products of haemolysis. The haemaglutinin titre shall not be greater than 1 : 32.

Dried human plasma prepared from one or two donations of blood

Donations shown to contain dangerous levels of iso-haemolysins (determined using a sample of fresh serum) or any immune haemaglutinins shall be excluded. Unless the plasma is pooled and frozen within 48 hours of collecting the blood, the sterility of each unit shall be tested by culturing not less than 10 ml.

Dried human plasma prepared from pools of more than two donations

Pools shown to contain dangerous levels of immune haemaglutinins or of iso-haemolysins shall be excluded. To avoid untoward effects due to the products of bacterial growth in the plasma no individual donation shall be used if there is any evidence of bacterial contamination, and the sterility of each pool shall be tested by culturing not less than 10 ml. To minimize the risk of transmitting serum hepatitis, plasma should be prepared from pools which should contain not more than twelve donations, or by any other method that has been shown to diminish the risk in comparable manner.

Solubility in water. Add a quantity of water equal to the volume of the liquid from which the sample was prepared; the substance dissolves completely within 10 minutes at 15° to 20° C.

Identification. Dissolve a known quantity of the product in a volume of water equal to the volume of the liquid from which it was prepared; the solution passes the following tests:

(i) by precipitation tests with specific antisera, it must be shown to contain only human plasma proteins;

(ii) to 1 ml. add a suitable amount of thrombin or calcium chloride; coagulation occurs, which can be accelerated by incubation at 37° C.

Loss of weight on drying. When dried over phosphorus pentoxide at a pressure not exceeding 0·02 mm. of mercury for 24 hours, Dried Human Plasma must not lose more than 0·5% of its weight.

Sterility. The final product, after reconstitution, shall be sterile when examined by a suitable bacteriological method.

Storage. Dried Human Plasma must be kept in an atmosphere of nitrogen or in a vacuum in a sterile container sealed so as to exclude micro-organisms and, as far as possible, moisture, protected from light and stored at a temperature below 20° C.

Labelling. The label on the container shall give all the information shown on the model label (Annex 3).

3. Human Albumin and Human Plasma Protein Fraction

Human Albumin and Human Plasma Protein Fraction are preparations of that protein component which forms about 60% of the total protein content of the plasma of Whole Human Blood.

The method of preparation used shall be one which produces a material meeting the requirements herein described. Regardless of whether the final product is liquid or dried, the preparation, after the addition of a suitable stabilising agent or agents, must have been heated in the liquid state in the final container at 60° C. $\pm$ 0·5° C. for 10 hours, in order to inactivate the agent causing serum hepatitis. During preparation no antiseptic or bacteriostatic substance shall be added.

In preparations of Human Albumin, not less than 95% of the proteins present shall be albumin. In preparations of Human Plasma Protein Fraction not less than 85% of the protein shall be albumin. In both preparations, not more than 1% immunoglobulin G shall be present.

When the final product is freeze-dried it must contain not less than 95% of protein.

When Human Plasma Protein Fraction is prepared as a solution it shall have a total protein concentration between 4·5 and 5% w/v. When Human Albumin is prepared as a solution it shall have a total protein concentration not less than 4·5% w/v.

Solubility of the dried product. Add water to the recommended volume; the dried preparation must be completely soluble.

Stability. By comparison of the solutions before and after heat treatment no evidence of significant denaturation of the proteins in solution shall have been detected as estimated by viscosity and turbidity measurements, ultracentrifugation and electrophoresis. The solution shall be substantially free from visible particles after heating at 57°C. and after agitation in a mechanical shaker for 6 hours at this temperature.

Identification:

(i) By precipitation tests with specific antisera, both preparations must be shown to contain only human plasma proteins.

(ii) By electrophoresis, using the moving boundary technique under acceptable and appropriate conditions, it must be shown that the percentage of proteins having the mobility of the albumin component of normal human plasma, is not less than 95% in preparations of Human Albumin, or not less than 85% in preparations of Human Plasma Protein Fraction.

Sodium content. The sodium content of salt-poor Human Albumin must not exceed 0·014 g per gramme of albumin. In other preparations of Human Albumin and in Human Plasma Protein Fraction the sodium content must not exceed 0·352 g per 100 ml. of solution or reconstituted dried product.

Potassium content. The potassium content of Human Albumin and Human Plasma Protein Fraction must not exceed 2 mEq per litre of solution or reconstituted dried product.

Acidity. The pH of either preparation shall be 6·8 $\pm$ 0·2 when measured at a temperature of 15° to 25°C. in a solution diluted to 1% w/v of protein with 0·15M sodium chloride.

Loss of weight on drying. Dried preparations, when dried over phosphorus pentoxide at a pressure not exceeding 0·02 mm. of mercury for 24 hours, must not lose more than 0·5% of their weight.

Sterility. The final product shall be sterile when examined by a suitable bacteriological method.

Storage. Dried Human Albumin must be kept in an atmosphere of nitrogen or in a vacuum in a sterile container, sealed so as to exclude micro-organisms and, as far as possible, moisture, protected from light and stored at a temperature below 20°C.

Solutions of Human Albumin and Human Plasma Protein Fraction must be kept in sterile containers, sealed so as to exclude micro-organisms, protected from light and stored at a temperature of 4° to 6°C.

Labelling. The label on the container shall give all the information shown on the appropriate model label (Annex 4). For solutions, the date of preparation is the date of heat treatment in the final container.

4. Human Normal Immunoglobulin

Human Normal Immunoglobulin is a preparation of the plasma proteins prepared from Whole Human Blood, containing the antibodies of normal adults. It is obtained from pooled liquid human plasma from not less than 1,000 donors.

The method of preparation used should be one which produces a material meeting the requirements herein prescribed and which prevents the transmission of serum hepatitis by the final product. In addition the method of preparation shall be such that the antibodies contained in the starting material shall be concentrated in an adequate amount in the final product. The procedure shall be shown, for each final preparation, to be satisfactory in this respect by titrating in the starting material and in the final product antibodies to at least one virus and one bacterial toxin. The antibodies chosen shall be those for which there are recognised methods of titration.

During preparation no antiseptic or bacteriostatic substance shall be added; a suitable preservative and a stabilising agent may be added to the final preparation to maintain bacterial sterility and stability of the final product.

The final product is issued as a solution the immunoglobulin concentration of which shall be between 10 and 17 g. per 100 ml.

Identification:

(i) By precipitation tests with specific antisera, it must be shown to contain only human plasma proteins.

(ii) By electrophoresis, using the moving boundary technique under acceptable and appropriate conditions, not less than 90 % of the proteins have the mobility of the gamma component of the globulins of normal human plasma.

Stability. Both before and after heating the final solution at 37°C. for 7 days there should be no visible evidence of precipitation or turbidity. It is advisable also to carry out tests using an ultracentrifugation method to determine the extent of degradation of the product to smaller molecular weight components. The method used should be one approved by the national control authority.

Acidity. The pH of the final solution shall be $6{\cdot}8 \pm 0{\cdot}4$ when measured at a temperature of 15° to 25°C. in a solution diluted to 1 % w/v of protein with 0·15M sodium chloride.

Sterility. The final product shall be sterile when examined by a suitable bacteriological method.

Storage. Human Immunoglobulin solution must be kept in a sterile container, sealed so as to exclude micro-organisms, protected from light and stored at a temperature of 4° to 6°C.

Labelling. The label on the container shall give all the information shown on the model label (Annex 5). The date of preparation is the date of filling the final container.

5. Human Specific Immunoglobulins

Human Specific Immunoglobulins contain antibodies against designated viral or bacterial agents. Therefore they may be prepared from pools of a limited number of donations.

The following human specific immunoglobulins are included in these requirements:

Human Immunoglobulin Anti-Tetanus
Human Immunoglobulin Anti-Vaccinia.

Other specific immunoglobulins may be developed and when the appropriate international standard is in existence, they should be assayed in relation to that standard and their potency expressed in international units.

Human Immunoglobulin Anti-Vaccinia shall contain not less than 500 IU per ml. of vaccinia antibody as determined by a neutralisation test on chorio-allantoic membranes or in tissue culture. Human Immunoglobulin Anti-Tetanus shall contain not less than 50 IU per ml. of tetanus antitoxin as determined by a neutralisation test in animals.

Human Specific Immunoglobulins must further meet the requirements as described in section 4, Human Normal Immunoglobulin.

Depending on the antibody content, the immunoglobulin concentration of the final solution may vary between 10 and 17 g. per 100 ml.

Labelling. The label on the container shall give all the information shown on the model label (Annex 5). In addition the label shall state the potency in international units in terms of the appropriate International Standard or International Reference Preparation.

6. Dried Human Fibrinogen

Dried Human Fibrinogen is a dried preparation which contains the soluble constitutent of liquid human plasma which, on the addition of thrombin, is transformed to fibrin. The method of preparation used should be one which produces a material meeting the requirements herein prescribed and which minimises the risk of transmitting serum hepatitis. Plasma pools used in the preparation of fibrinogen should contain as few donations as possible.

During preparation no antiseptic or bacteriostatic substance shall be added. The final product shall be freeze-dried.

Solubility. Add water to the recommended volume; the dried preparation must be completely soluble. No precipitation shall occur within 60 minutes of reconstitution.

Identification:

(i) By precipitation tests with specific antisera, it must be shown to contain only human plasma proteins.

(ii) The freshly reconstituted product has the property of clotting on the addition of thrombin. When thrombin is added to a solution of Human Fibrinogen of the same concentration as that in fresh normal plasma, clotting shall occur in not more than twice the time taken for clotting to occur in fresh normal plasma after the addition of thrombin.

(iii) Clottable protein. Not less than 50% of the total protein shall be clottable by thrombin.

Loss of weight on drying. Preparations, when dried over phosphorus pentoxide at a pressure not exceeding 0·02 mm. of mercury for 24 hours, must not lose more than 0·5% of their weight.

Sterility. The final product after reconstitution shall be sterile when examined by a suitable bacteriological method.

Storage. Human Fibrinogen shall be kept in an atmosphere of nitrogen or in a vacuum in a sterile container, sealed so as to exclude micro-organisms and, as far as possible, moisture, protected from light and stored at the temperature recommended.

Labelling. The label on the container shall give all the information shown on the model label (Annex 6). The date of preparation is the date of placing into final solution before freeze-drying.

7. Dried or frozen human coagulation factor VIII

I. *Requirements applying to donors*

Donors must be in good health and, in particular, free of any communicable disease, in accordance with the criteria adopted for dried human plasma.

II. *Requirements applying to preparations*

Sterility and atoxicity. The final product must be sterile and pyrogen-free. Where cryoprecipitation is performed in plastic bags, the product must not contain organic solvent or other foreign substances present in the freezing mixture. The passage of such products through the walls of the plastic bag can be prevented by placing the bag in a second impermeable bag during the whole period of immersion. The risk of the plastic bag tearing during storage in the frozen state can be reduced by keeping each bag in a protective box.

Erythrocytes, leukocytes and platelets. Centrifuging should be such as to eliminate the formed elements of the blood as soon and as completely as possible after its collection.

Solubility. The addition of the indicated quantity of appropriate solvent must result in the complete solution of the dry product in less than 30 minutes at 37°C. Small and easily separable aggregates of fibrinogen may persist.

Stability. The preparation conserved at 20°C., must not show any sign of precipitation within three hours after it has been dissolved.

Potency. The reconstituted preparation should contain the indicated minimum quantity of factor VIII, one unit corresponding to the potency of 1 ml. of average normal fresh plasma, the potency being determined by a method approved by the competent national authority.

Absence of irregular antibodies and, if the preparation is intended for patients of any ABO group, a titre of anti-A and anti-B antibodies not exceeding 32.

Identification. Precipitation tests with specific antisera shall show that the product contains only human plasma proteins.

Loss of weight on drying. Freeze-dried preparations, when dried over phosphorus pentoxide at a pressure not exceeding 0·02 mm. of mercury for 24 hours must not lose more than 1·5% of their weight.

Storage. Human factor VIII shall be stored in the deep frozen state at a temperature under −30°C., and in the freeze-dried state below 5°C., and protected from light. The dried preparation shall be kept in an atmosphere of nitrogen or in vacuo, in a sterile vial, stoppered so as to exclude all micro-organisms and, as far as possible, all humidity. Storage in the frozen state shall not exceed six months, in the dried state one year, unless the preparation has been retested for minimum required potency.

III. *Labelling*

The label on the preparation shall give all the information shown on the model label (Annex 7).

8. Dried human coagulation factor IX

I. *Requirements applying to donors*

Donors must be in good health and, in particular, free from any communicable disease in accordance with the criteria adopted for dried human plasma.

II. *Requirements applying to the concentrate*

Sterility and atoxicity. The final product, tested by appropriate methods must be sterile, pyrogen-free and free from undesirable vaso-depressor or or respiratory effects. The test for absence of vaso-depressor effects, should be performed on a dog or cat.

Solubility. The addition of the indicated quantity of the solvent must result in complete solution in 10 minutes at 37°C.

Thromboplastin activity and absence of free thrombin. The recalcification time of a normal plasma measured at 37°C. in the presence of an equal volume of various dilutions of the reconstituted product, must not be less than 40 seconds. The reconstituted product, with an equal volume (300 mg./100 ml.) of fibrinogen added to it, must not coagulate within six hours at 37°C.

Potency. The reconstituted preparation must contain the indicated minimum quantity of factor IX, 1 unit corresponding to the potency of 1 ml. of average normal fresh plasma, the potency being determined by a method approved by the competent national authority.

Yield and stability in vivo. The method of preparation must be such that the injection of a dose of 50 units/kg. body weight, rapidly administered intravenously, using several batches of material given to several patients, shall cause, in 15 minutes, in the absence of a specific inhibitor and in basal conditions, an average rise of not less than 30 units/100 ml. plasma and the persistence, after 24 hours, of an average rise of not less than 6 units/100 ml.

Identification. Precipitation tests with specific antisera shall show that the product contains solely human plasma proteins.

Loss of weight on drying. When dried over phosphorus pentoxide at a pressure not exceeding 0·02 mm. of mercury for 24 hours, the product must lose more than 1·5% of its weight.

Storage. The preparations must be stored dry at a temperature below 5°C. The period of storage must not exceed two years, unless the potency of the preparation has been re-tested.

III. *Labelling*

The label on the preparation shall give all the information shown on the model label (Annex 8).

II. The following texts constitute Annexes 7, 8, 9 and 10 to the Protocol to the European Agreement on the Exchange of Therapeutic Substances of Human Origin.

ANNEXE 7 AU PROTOCOLE

ANNEX 7 TO THE PROTOCOL

CONSEIL DE L'EUROPE
COUNCIL OF EUROPE

Accord européen relatif à l'échange de substances thérapeutiques d'origine humaine

European Agreement on the exchange of therapeutic substances of human origin

1. Nom et adresse du producteur / Name and address of the producer :
2. Facteur VIII de coagulation humain congelé / Facteur VIII de coagulation humain desséché ou : / Frozen human coagulation factor VIII / Dried human coagulation factor VIII or :
   Méthode de préparation / Method of preparation :
3. Numéro du lot / Batch number :
4. Quantité minimale de facteur VIII, quantité de protéines totales, nature et quantité de toute substance ajoutée
   Minimum quantity of factor VIII, quantity of total proteins, nature and quantity of any added substance
5. Nature et volume du solvant / Nature and volume of solvent :
6. Nombre de donneurs par lot / Number of donors per batch :
7. *Titre des hémagglutinines non supérieur à I : 32* ou / *Groupe sanguin ABO*
   Haemaglutinin titre not greater than I : 32 or / *ABO blood group*
8. Date de préparation / Date of preparation :
9. Date de péremption / Date of expiry :
10. *Protéger de la lumière et conserver congelé à une température inférieure à —30° C ou desséché à une température inférieure à 5° C.*
    Store, protected from light and frozen at a temperature below —30° C or in the dry state at a temperature below 5° C.
11. *Après reconstitution du produit, injecter immédiatement par voie intraveineuse ou au plus tard après 3 heures de conservation à 20° C.*
    After reconstitution of the product, inject intravenously, immediately or at the latest after 3 hours of storage at 20° C.

ANNEXE 8 AU PROTOCOLE

ANNEX 8 TO THE PROTOCOL

CONSEIL DE L'EUROPE

COUNCIL OF EUROPE

Accord européen relatif à l'échange de substances thérapeutiques d'origine humaine

European Agreement on the exchange of therapeutic substances of human origin

1. Nom et adresse du producteur / Name and address of the producer :
2. Fatceur IX de coagulation humain desséché:
   Autres facteurs de coagulation présents :
   Dried human coagulation factor IX :
   Other blood coagulation factors present :
   Méthode de préparation / Method of preparation :
3. Numéro du lot / Batch number :
4. Quantité minimale de facteur IX, quantité de protéines totales, nature et quantité de toute substance ajoutée:
   Minimum quantity of factor IX, quantity of total proteins, nature and quantity of any added substance:
5. Nature et volume du solvant / Nature and volume of solvent :
6. Nombre de donneurs par lot / Number of donors per batch :
7. Date de préparation / Date of preparation :
8. Date de péremption / Date of expiry :

9. *Protéger de la lumière et conserver à une température inférieure á 5°C.*
   Store, protected from light at a temperature below 5° C.
10. *Après reconstitution du produit, injecter immédiatement par voie intraveineuse*
    After reconstitution of the product, inject immediately by the intravenous route.

ANNEXE 9 AU PROTOCOLE

ANNEX 9 TO THE PROTOCOL

CONSEIL DE L'EUROPE

COUNCIL OF EUROPE

Accord européen relatif à l'échange de substances thérapeutiques d'origine humaine

European Agreement on the exchange of therapeutic substances of human origin

1. Nom et adresse du producteur
   Name and address of the producer :

2. Eau distillée, stérile et apyrogène
   Sterile, pyrogen-free distilled water

   Pour la reconstitution du Plasma Humain Desséché
   de l'Albumine Humaine Desséchée
   du Fibrinogène Humain Desséché
   ou des Facteurs VIII et IX humains de coagulation desséchés

   For the reconstitution of Dried Human Plasma
   Dried Human Albumin
   Dried Human Fibrinogen
   or Dried Human coagulation Factors VIII and IX.

3. Quantité
   Quantity .....ml.

ANNEXE 10 AU PROTOCOLE

ANNEX 10 TO THE PROTOCOL

CONSEIL DE L'EUROPE
COUNCIL OF EUROPE

Accord européen relatif à l'échange de substances thérapeutiques d'origine humaine

European Agreement on the exchange of therapeutic substances of human origin

1. Nom et adresse du producteur
   Name and address of the producer :

2. Dispositif à Injection
   Giving-set

   Dispositif pour l'administration du Sang Humain Total, du Plasma Humain Desséché Reconstitué, de l'Albumine Humaine, des Solutions Stables de Protéines Plasmatiques Humaines, du Fibrinogène Humain ou du Facteur VIII de coagulation humain congelé ou desséché ou du Facteur IX de coagulation humain desséché.

   Giving-set for the administration of Whole Human Blood, Reconstituted Dried Human Plasma, Human Albumin, Human Plasma Protein Fraction, Human Fibrinogen or of Dried or Frozen Human coagulation Factor VIII or Dried Human coagulation Factor IX.

III. The text which constituted Annex 9 to the Protocol to the European Agreement on the Exchange of Therapeutic Substances of Human Origin, in the version certified in the certificate of the Secretary General dated 21 September 1970,(3) constitutes Annex 11 to the said Protocol.

Done at Strasbourg, this 27th day of July 1973.

LUJO TONCIC-SORINJ

Secretary General

---

(3) Treaty Series No. 107 (1970), Cmnd. 4549.

Printed in England by Her Majesty's Stationery Office

20902—138 3143375 Dd. 253227 K12 11/73

ISBN 0 10 154630 0