

No. 5022

**AUSTRIA, BELGIUM, FRANCE,
FEDERAL REPUBLIC OF GERMANY, GREECE, etc.**

European Agreement on the exchange of therapeutic substances of human origin (with Protocol and annexes to the Protocol). Done at Paris, on 15 December 1958

Official texts: English and French.

Registered on 29 February 1960 by the Council of Europe acting on behalf of the Contracting Parties, in accordance with Resolution 54 (6) of the Committee of Ministers of the Council of Europe adopted on 3 April 1954.

**AUTRICHE, BELGIQUE, FRANCE,
RÉPUBLIQUE FÉDÉRALE D'ALLEMAGNE, GRÈCE, etc.**

Accord européen relatif à l'échange de substances thérapeutiques d'origine humaine (avec Protocole et annexes au Protocole). Fait à Paris, le 15 décembre 1958

Textes officiels anglais et français.

Enregistré le 29 février 1960 par le Conseil de l'Europe agissant au nom des Parties contractantes, conformément à la résolution 54 (6) du Comité des Ministres du Conseil de l'Europe adoptée le 3 avril 1954.

No. 5022. EUROPEAN AGREEMENT¹ ON THE EXCHANGE
OF THERAPEUTIC SUBSTANCES OF HUMAN ORIGIN.
DONE AT PARIS, ON 15 DECEMBER 1958

The Governments signatory hereto, being Members of the Council of Europe,

Considering that therapeutic substances of human origin are by their very nature the result of an act of the human donor and therefore not available in unlimited quantities;

Considering that it is most desirable that member countries, in a spirit of European solidarity, should assist one another in the supply of these therapeutic substances, should the need arise;

Considering that such mutual assistance is only possible if the character and use of such therapeutic substances are subject to rules laid down jointly by the member countries and if the necessary import facilities and exemptions are granted,

Have agreed as follows :

Article 1

For the purposes of this Agreement, the expression “ therapeutic substances of human origin ” refers to human blood and its derivatives.

The provisions of this Agreement may be extended to cover other therapeutic substances of human origin by exchange of letters between two or more of the Contracting Parties.

Article 2

The Contracting Parties undertake, provided that they have sufficient stocks for their own needs, to make therapeutic substances of human origin available to other Parties who are in urgent need of them and to charge only those costs involved in the collection, processing and carriage of such substances.

Article 3

Therapeutic substances of human origin shall be made available to the other Contracting Parties subject to the express condition that no profit is made on them, that they shall be used solely for medical purposes and shall be delivered only to bodies designated by the Governments concerned.

¹ In accordance with article 8, the Agreement came into force on 1 January 1959 for the following States which had signed the Agreement, without reservation in respect of ratification, on 15 December 1958 : Belgium, Ireland, Norway, Sweden.

Article 4

The Contracting Parties shall certify that the minimum requirements with regard to the properties of the therapeutic substances, and the regulations on labelling, packing and dispatch, as laid down in the Protocol¹ to this Agreement, have been observed.

They shall also comply with any rules to which they have subscribed with regard to international standardisation in this field.

All consignments of therapeutic substances of human origin shall be accompanied by a certificate to the effect that they were prepared in accordance with the specifications in the Protocol. This certificate shall be based on the model to be found in Annex 1² to the Protocol.

The Protocol and its Annexes may be amended or supplemented by the Governments of the Parties to this Agreement.

Article 5

The Contracting Parties shall take all necessary measures to exempt from all import duties the therapeutic substances of human origin placed at their disposal by the other Parties.

They shall also take all necessary measures to provide for the speedy delivery of these substances, by the most direct route, to the consignees referred to in Article 3 of this Agreement.

Article 6

The Contracting Parties shall forward to one another, through the Secretary-General of the Council of Europe, a list of the bodies empowered to issue certificates as provided in Article 4 of this Agreement.

They shall also forward a list of bodies empowered to distribute imported therapeutic substances of human origin.

Article 7

The present Agreement shall be open to the signature of Members of the Council of Europe, who may become Parties to it either by :

- (a) signature without reservation in respect of ratification, or
- (b) signature with reservation in respect of ratification followed by ratification.

Instruments of ratification shall be deposited with the Secretary-General of the Council of Europe.

¹ See p. 168 of this volume.

² See p. 182 of this volume.

Article 8

The present Agreement shall enter into force on the first day of the month following the date on which three Members of the Council shall, in accordance with Article 7, have signed the Agreement without reservation in respect of ratification or shall have ratified it.

In the case of any Member of the Council who shall subsequently sign the Agreement without reservation in respect of ratification, or who shall ratify it, the Agreement shall enter into force on the first day of the month following such signature or deposit of the instrument of ratification.

Article 9

The Committee of Ministers of the Council of Europe may invite any non-Member State to accede to the present Agreement. Such accession shall take effect on the first day of the month following the deposit of the instrument of accession with the Secretary-General of the Council of Europe.

Article 10

The Secretary-General of the Council of Europe shall notify Members of the Council and acceding States :

(a) of the date of entry into force of this Agreement and of the names of any Members who have signed without reservation in respect of ratification or who have ratified it;

(b) of the deposit of any instrument of accession in accordance with Article 9;

(c) of any notification received in accordance with Article 11 and its effective date;

(d) of any amendment to the Protocol or its Annexes¹ under Article 4, paragraph 4.

Article 11

The present Agreement shall remain in force indefinitely.

Any Contracting Party may terminate its own application of the Agreement by giving one year's notice to that effect to the Secretary-General of the Council of Europe.

IN WITNESS WHEREOF the undersigned, duly authorised thereto by their respective Governments, have signed the present Agreement.

DONE at Paris, this 15th day of December 1958, in the English and French languages, both texts being equally authoritative, in a single copy which shall remain deposited in the archives of the Council of Europe. The Secretary-General shall transmit certified copies to each of the signatory and acceding Governments.

¹ See pp. 182 to 196 of this volume.

For the Government
of the Republic of Austria :

*sous réserve de ratification*¹

Léopold FIGL

Pour le Gouvernement
de la République d'Autriche :

For the Government
of the Kingdom of Belgium :

P. WIGNY

Pour le Gouvernement
du Royaume de Belgique :

For the Government
of the Kingdom of Denmark :

Pour le Gouvernement
du Royaume de Danemark :

For the Government
of the French Republic :

*with reservation in respect
of ratification*

M. COUVE DE MURVILLE

Pour le Gouvernement
de la République française :

sous réserve de ratification

For the Government of the
Federal Republic of Germany :

*with reservation in respect
of ratification*

V. BRENTANO

Pour le Gouvernement de la
République Fédérale d'Allemagne :

sous réserve de ratification

For the Government
of the Kingdom of Greece :

*with reservation in respect
of ratification*

CAMBALOURIS

Pour le Gouvernement
du Royaume de Grèce :

sous réserve de ratification

For the Government
of the Icelandic Republic :

For the Government
of Ireland :

Pròinsias MAC AOGAIN

Pour le Gouvernement
de la République islandaise :

Pour le Gouvernement
d'Irlande :

For the Government
of the Italian Republic :

*with reservation in respect
of ratification*

C. A. STRANEO

Pour le Gouvernement
de la République italienne :

sous réserve de ratification

¹ With reservation in respect of ratification.

For the Government of the Grand
Duchy of Luxembourg :
*with reservation in respect
of ratification*

Pour le Gouvernement du Grand
Duché de Luxembourg :
sous réserve de ratification

BECH

For the Government of the
Kingdom of the Netherlands :

Pour le Gouvernement
du Royaume des Pays-Bas :

*Signé à Strasbourg, le 26 février 1959
sous réserve de ratification¹*

M. Z. N. WITTEVEEN

For the Government
of the Kingdom of Norway :

Pour le Gouvernement
du Royaume de Norvège :

Hans ENGEN

For the Government
of the Kingdom of Sweden :

Pour le Gouvernement
du Royaume de Suède :

[TRADUCTION² — TRANSLATION³]

At the time of signing the present
Agreement the Swedish Government de-
clares that it accepts the provisions of the
Agreement and of the Protocol only so far
as they apply to human blood.

Au moment de signer le présent Accord,
le Gouvernement suédois déclare qu'il
n'accepte les dispositions de l'Accord et du
Protocole que pour autant qu'elles s'appli-
quent au sang humain.

Leif BELFRAGE

For the Government
of the Turkish Republic :
*with reservation in respect
of ratification*

Pour le Gouvernement
de la République turque :
sous réserve de ratification

Fatin R. ZORLU

For the Government
of the United Kingdom of Great
Britain and Northern Ireland :

Pour le Gouvernement
du Royaume-Uni de Grande-
Bretagne et d'Irlande du Nord :

¹ Signed at Strasbourg on 26 February 1959, with reservation in respect of ratification.

² Traduction du Secrétariat général du Conseil de l'Europe.

³ Translation by the Secretariat General of the Council of Europe.

PROTOCOL TO THE AGREEMENT

PART I

GENERAL PROVISIONS

A. *Labelling*

A label printed in two languages, based on the appropriate model to be found in Annexes 2 to 6¹ 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.

PART II

SPECIFIC PROVISIONS

1. *Whole Human Blood*

Whole human blood is blood which has been mixed with a suitable anticoagulant, 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,
- (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 inspection or simple examination and consideration of his medical history, 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 before dispatch to one of the Member States.

¹ See pp. 183 to 195 of this volume.

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 gr/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 shall be used.

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 state :

1. the ABO group;
2. the Rh group, either Rh positive or Rh negative. The term Rh negative is only to be used when specific tests have shown the absence of the antigens C, D and E. All other bloods must be labelled Rh positive;
3. the total volume of blood, the volume and the composition of the anti-coagulant solution;
4. the dates of collection and expiry;
5. the conditions under which it should be stored;
6. that the contents should not be used if there is any visible evidence of deterioration.

2. *Dried Human Plasma*

Dried human plasma is prepared by drying the supernatant fluids which are separated by centrifuging or by standing from quantities of whole human blood. The *titre* of anti-A and anti-B, both naturally occurring and immune, should not exceed 32.

To avoid untoward effect due to the products of bacterial growth in the plasma, no individual contribution shall be used if there is any evidence of bacterial contamination, and the bacterial sterility of each pool shall be tested by culturing not less than 10 ml.

During preparation no antiseptic or bacteriostatic substance shall be added.

To minimise the risk of transmitting homologous serum jaundice, plasma should be prepared from pools not containing more than twelve separate donations or by any other method that has been shown to diminish this risk in a comparable manner.

The plasma shall be dried by freeze-drying or by any other method which will avoid denaturation of the proteins and will yield a product readily soluble in a quantity of water equal to the volume of the liquid from which the substance was prepared. When dissolved in a quantity of water equal to the volume of the liquid from which the substance was prepared, the solution must not contain less than 4.5 per cent w/v of protein and must show no visible evidence of the products of haemolysis.

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 ten minutes at 15° to 20° C.

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

1. by precipitation tests with specific antisera, it must be shown to contain only human serum proteins;
2. to 1 ml. add a suitable amount of thrombin or calcium chloride, and 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 it must not lose more than 0.5 per cent of its weight.

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

Storage.—Dried human plasma must be kept in 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 state :

1. the nature and percentage of anticoagulant and of any other material introduced;
2. the quantity of solvent necessary to reconstitute the original volume of liquid human plasma;
3. the minimum protein content of the reconstituted liquid human plasma;
4. the dates of preparation and expiry;
5. the conditions under which it should be stored;
6. that the reconstituted liquid human plasma must be used immediately after reconstitution.

3. Human Albumin

Human albumin is a preparation of that protein component which forms about 60% of the total protein content of the plasma of whole human blood.

The processing method used shall be one which produces a material meeting the requirements herein prescribed. Regardless of whether the final product is liquid or dried, the albumin, after the addition of a suitable stabilizing agent or agents, must be heated in the liquid state during processing at $60^{\circ}\text{C} \pm 0.5^{\circ}\text{C}$. for 10 hours, in order to inactivate the agent causing homologous serum jaundice. During preparation no antiseptic or bacteriostatic substance shall be added. When the final product is freeze-dried it must contain not less than 95% of protein. When the final product is prepared as a solution, the solution shall contain not less than 20% of protein and must not show any visible turbidity during the period for which the solution is approved for use.

Solubility of the dried product.—Add water to give a 20% solution; the albumin must be completely soluble.

Stability.—The viscosity relative to water, determined at 37°C . of a 6.25% solution of human albumin must not increase by more than 5% during the heating process at 60°C . for 10 hours.

Identification

1. By precipitation tests with specific antisera, it must be shown to contain only human plasma proteins.
2. By electrophoresis, using the moving boundary technique under acceptable and appropriate conditions, it must be shown to contain not less than 95% of the protein having the mobility of the albumin component of normal human plasma.

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

Sodium content.—The sodium content must not exceed 750 mg. per 100 ml. 25% albumin solution. In the case of salt-poor albumin the sodium content must not exceed 325 mg. per 100 ml. 25% solution.

Acidity.—After dilution of the albumin solution to a protein concentration of 1%, the pH should be 6.9 ± 0.4 .

Loss of weight on drying.—When dried over phosphorus pentoxide at a pressure not exceeding 0.02 mm. of mercury for 24 hours it must not lose more than 0.5 per cent of its weight.

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 .

Liquid human albumin 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 must state :

1. the amount of human albumin contained in it and the nature and percentage of any other material introduced;
2. the amount of sodium;
3. the dates of preparation and expiry;
4. the conditions under which it should be stored;
5. in the case of the liquid product, that it should not be used unless it is clear and free from deposits;
6. in the case of the dried product, that it should be used immediately after reconstitution.

4. *Human Gamma Globulin*

(This schedule does not apply to gamma globulin, derived from human placentae)

Human gamma globulin 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 processing method used should be one which produces a material meeting the requirements herein prescribed. It should be such as to prevent the transmission of homologous serum jaundice by the final product. During preparation no antiseptic or bacteriostatic substance shall be added.

When the final product is issued in the freeze-dried form it shall not contain less than 95% of protein. When the final product is issued as a solution, it shall not contain less than 10% of protein.

Solubility of the dried product.—Add water to give a 10% solution; the gamma globulin must be completely soluble.

Identification

1. By precipitation tests with specific antisera, it must be shown to contain only human plasma proteins;
2. by electrophoresis, using the moving boundary technique under acceptable and appropriate conditions, it must be shown to contain not less than 90% of the proteins having the mobility of the gamma components of the globulins of normal human plasma.

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

Stability test.—Both before and after heating the final liquid product or reconstituted dried product at 37° C. for 7 days there should be no visible evidence of precipitation or turbidity. Moreover, after heating at 57° C. for 4 hours there should be no visible evidence of gelation.

Loss of weight on drying.—When dried over phosphorus pentoxide at a pressure not exceeding 0.02 mm. of mercury for 24 hours it must not lose more than 0.5 per cent of its weight.

Storage.—The dried human gamma globulin 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.

Liquid human gamma globulin 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 state :

1. the amount of human gamma globulin contained in it and the nature and percentage of any other material introduced;
2. in the case of the dried product, the volume and composition of the solvent;
3. the dates of preparation and expiry;
4. the conditions under which it should be stored;
5. “ not for intravenous injection ”;
6. in the case of the dried product, that it should be used immediately after reconstitution.

5. Human Fibrinogen

Human fibrinogen is a dried preparation of the soluble constituent of liquid human plasma which, on the addition of thrombin, is transformed to fibrin. The processing method used should be one which produces a material meeting the requirements herein prescribed and which minimises the risk of transmitting homologous serum jaundice.

During preparation no antiseptic or bacteriostatic substance shall be added. The final product shall be freeze-dried. No less than 60% of the total protein present shall be contained in the clot formed by the addition of thrombin.

Solubility.—When the appropriate volume of the recommended solvent is added, the fibrinogen must be soluble, and form a colourless solution.

Identification:

1. By precipitation test with specific antisera, it must be shown to contain only human plasma proteins;
2. the freshly reconstituted product has the property of clotting on the addition of thrombin.

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

Loss of weight on drying.—When dried over phosphorus pentoxide at a pressure not exceeding 0.02 mm. of mercury for 24 hours it must not lose more than 0.5 per cent of its weight.

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 state :

1. the amount of fibrinogen contained in it and the nature and percentage of any other material introduced;
2. the volume and composition of the solvent;
3. the dates of preparation and expiry;
4. the conditions under which it should be stored;
5. that it should be used immediately after reconstitution.

ANNEXES

ANNEXE I AU PROTOCOLE
ANNEX 1 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

CERTIFICAT

(article 4)

CERTIFICATE

À NE PAS DÉTACHER DE L'ENVOI

NOT TO BE SEPARATED FROM THE SHIPMENT

. 19 .

(lieu) (date)
(place)

Nombre de colis	Le soussigné déclare que l'envoi spécifié en marge
Number of packages	The undersigned certifies that the shipment specified in the
.....	margin
.....
.....	préparé sous la responsabilité de
.....	prepared under the responsibility of
Désignation
Marked
.....	organisme visé à l'article 6 de l'Accord, est conforme aux
.....	one of the bodies referred to in Article 6 of the Agreement, is
N° des lots	spécifications du Protocole à l'Accord et qu'il peut être
Batch No.	in conformity with the specifications of the Protocol to the
.....	délivré immédiatement au destinataire (nom et lieu).....
.....	Agreement and can be delivered immediately to the
.....
.....	consignee (name and place)

(cachet)	(signature)	(titre)
(stamp)	(signature)	(title)

ANNEXE 2 AU PROTOCOLE
ANNEX 2 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 du producteur :
Name of the producer :

2. SANG HUMAIN TOTAL
WHOLE HUMAN BLOOD

3. Numéro de référence :
Reference number :

4. Groupe sanguin :
Blood-group :

5. Groupe Rh $\frac{\text{positif}}{\text{négatif}}$

Rh-group $\frac{\text{positive}}{\text{negative}}$

6. ... ml. $\left\{ \begin{array}{l} \text{solution anticoagulante} \\ \text{anti-coagulant solution} \end{array} \right.$

... % glucose

... % $\left\{ \begin{array}{l} \text{citrate disodique} \\ \text{di-sodiumcitrate} \end{array} \right.$

... ml. $\left\{ \begin{array}{l} \text{de sang} \\ \text{blood} \end{array} \right.$

7. Date de prélèvement :
Date of collection :

Date de péremption :
Date of expiry :

8. Conserver de + 4° C à + 6° C.
Store at + 4° C to + 6° C.

9. Ne pas utiliser en cas de signe visible quelconque d'altération (hémolyse).
Not to be used if there is any visible evidence of deterioration (haemolysis).

ANNEXE 2 (*suite*)
ANNEX 2 (*continued*)

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 du producteur :
Name of the producer :

2. DISPOSITIF À INJECTION
GIVING-SET

Dispositif pour l'utilisation du SANG HUMAIN TOTAL.
Giving-set for the administration of WHOLE HUMAN BLOOD.

ANNEXE 3 AU PROTOCOLE
ANNEX 3 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 du producteur :
Name of the producer :
 2. PLASMA HUMAIN DESSÉCHÉ
DRIED HUMAN PLASMA
 3. Numéro de référence :
Reference number :
 4. Le plasma reconstitué contient :
The reconstituted plasma contains :
... % glucose
... % { citrate disodique
 di-sodiumcitrate
 5. Reconstituer avec ... ml. d'eau distillée, stérile et apyrogène.
To reconstitute with ... ml. sterile, pyrogen-free, distilled water.
 6. Taux de protéines { ... %
Protein content
 7. Date de préparation :
Date of preparation :
Date de péremption :
Date of expiry :
8. *Protéger de la lumière et conserver à une température inférieure à 20° C.*
Store, protected from light, below 20° C.
 9. *À utiliser immédiatement après la reconstitution.*
To be used immediately after reconstitution.

ANNEXE 3 (*suite 1*)
ANNEX 3 (*continued 1*)

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 du producteur :
Name of the producer :
2. DISPOSITIF À INJECTION
GIVING-SET

Dispositif pour l'utilisation du PLASMA HUMAIN.
Giving-set for the administration of HUMAN PLASMA.

ANNEXE 3 (*suite* 2)
ANNEX 3 (*continued* 2)

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 du producteur :
Name of the producer :
2. EAU DISTILLÉE, STÉRILE ET APYROGÈNE
STERILE, PYROGEN-FREE DISTILLED WATER
Pour la reconstitution du PLASMA HUMAIN DESSÉCHÉ.
For the reconstitution of DRIED HUMAN PLASMA.
3. Quantité {
Quantity } ... ml.

ANNEXE 4 AU PROTOCOLE
ANNEX 4 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 du producteur :
Name of the producer :
2. ALBUMINE HUMAINE DESSÉCHÉE
DRIED HUMAN ALBUMIN
3. Numéro du lot :
Batch number :
4. Albumine : ... grammes
Albumin : ... grams
Stabilisateur,
Stabilizer,
nature :, ...%
Sodium { ... grammes
 { ... grams
5. Date de préparation :
Date of preparation :
Date de péremption :
Date of expiry :
6. Reconstituer avec ... ml. d'eau distillée, stérile et apyrogène.
To reconstitute with ... ml. sterile, pyrogen-free, distilled water.

7. *Protéger de la lumière et conserver à une température inférieure à 20° C.*
Store, protected from light, below 20° C.
 8. *À injecter immédiatement après reconstitution.*
To be used immediately after reconstitution.

ANNEXE 4 (*suite 1*)
ANNEX 4 (*continued 1*)

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 du producteur :
Name of the producer :

2. ALBUMINE HUMAINE LIQUIDE
LIQUID HUMAN ALBUMIN

3. Numéro du lot :
Batch number :

4. Albumine : ... grammes
Albumin : ... grams

Stabilisateur,
Stabilizer,

nature :, ... %

Sodium : { ... grammes
 { ... grams

5. Date de préparation :
Date of preparation :

Date de péremption :
Date of expiry :

6. *Protéger de la lumière et conserver de + 4° C à + 6° C.*
Store, protected from light, at + 4° C to 6° C.

7. *À injecter seulement si le liquide est clair et sans dépôt.*
Not to be used unless clear and free from deposits.

ANNEXE 4 (*suite 2*)
ANNEX 4 (*continued 2*)

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 du producteur :
Name of the producer :
2. DISPOSITIF A INJECTION
GIVING-SET

Dispositif pour l'utilisation de l'ALBUMINE HUMAINE.
Giving-set for the administration of HUMAN ALBUMIN.

ANNEXE 4 (suite 3)
ANNEX 4 (continued 3)

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 du producteur :
Name of the producer :
2. EAU DISTILLÉE STÉRILE ET APYROGÈNE
STERILE, PYROGEN-FREE, DISTILLED WATER
Pour la reconstitution de l'ALBUMINE HUMAINE DESSÉCHÉE.
For the reconstitution of DRIED HUMAN ALBUMIN.
3. Quantité :
Quantity : ... ml.

ANNEXE 5 AU PROTOCOLE
ANNEX 5 TO THE PROTOCOL

CONSEIL DE L'EUROPE
COUNCIL OF EUROPE

Accord européen relatif à l'échange de substances thérapeutiques d'origine humaine
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1. Nom du producteur :
Name of the producer :
2. GAMMA GLOBULINE HUMAINE DESSÉCHÉE
DRIED HUMAN GAMMA GLOBULIN
3. Numéro du lot :
Batch number :
4. Gamma globuline : ... grammes
Gamma globulin : ... grams
Autres substances ajoutées,
Other material introduced,
nature :, ... %
5. Date de préparation :
Date of preparation :
Date de péremption :
Date of expiry :
6. Reconstituer avec ... ml. d'eau distillée, stérile et apyrogène.
To reconstitute with ... ml. sterile, pyrogen-free, distilled water.

7. *Protéger de la lumière et conserver à une température inférieure à 20° C.*
Store, protected from light, below 20° C.
 8. *À injecter immédiatement après la reconstitution.*
To be used immediately after reconstitution.
 9. *Ne pas injecter par voie intraveineuse.*
Not for intravenous injection.

ANNEXE 5 (suite 1)
ANNEX 5 (continued 1)

CONSEIL DE L'EUROPE
COUNCIL OF EUROPE

Accord européen relatif à l'échange de substances thérapeutiques d'origine humaine
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1. Nom du producteur :
Name of the producer :
 2. GAMMA GLOBULINE HUMAINE LIQUIDE
LIQUID HUMAN GAMMA GLOBULIN
 3. Numéro du lot :
Batch number :
 4. Gamma globuline : ... grammes
Gamma globulin : ... grams
Autres substances ajoutées,
Other material introduced,
nature :, ... %
 5. Date de préparation :
Date of preparation :
Date de péremption :
Date of expiry :
6. *Protéger de la lumière et conserver de + 4° C à + 6° C.*
Store, protected from light, at + 4° C to + 6° C.
 7. *Ne pas injecter par voie intraveineuse.*
Not for intravenous injection.

ANNEXE 5 (*suite 2*)
ANNEX 5 (*continued 2*)

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 du producteur :
Name of the producer :

2. EAU DISTILLÉE, STÉRILE ET APYROGÈNE
STERILE, PYROGEN-FREE, DISTILLED WATER

Pour la reconstitution de la GAMMA GLOBULINE HUMAINE DESSÉCHÉE.
For the reconstitution of DRIED HUMAN GAMMA GLOBULIN.

3. Quantité :
Quantity : ... ml.

ANNEXE 6 AU PROTOCOLE
ANNEX 6 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 du producteur :
Name of the producer :
2. FIBRINOGENÈ HUMAIN
HUMAN FIBRINOGEN
3. Numéro du lot :
Batch number :
4. Fibrinogène : ... grammes
Fibrinogen : ... grams
Autres substances ajoutées,
Other material introduced,
nature :, ... %
5. Date de préparation :
Date of preparation :
Date de péremption :
Date of expiry :
6. Reconstituer avec ... ml. d'eau distillée, stérile et apyrogène.
To reconstitute with ... ml. sterile, pyrogen-free, distilled water.

7. *Protéger de la lumière et conserver à une température inférieure à 20° C.*
Store, protected from light, below 20° C.
 8. *À injecter immédiatement après la reconstitution.*
To be used immediately after reconstitution.

ANNEXE 6 (*suite*)
ANNEX 6 (*continued*)

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 du producteur :
Name of the producer :
 2. EAU DISTILLÉE, STÉRILE ET APYROGÈNE
STERILE, PYROGEN-FREE, DISTILLED WATER

Pour la reconstitution du FIBRINOGENÈ HUMAIN.
For the reconstitution of HUMAN FIBRINOGEN.
 3. Quantité :
Quantity : ... ml.
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