MEDICINES ACT 1968

RENEWAL OF PRODUCT LICENCE

PRODUCT LICENCE No 0116 / 0011

Granted to: Travenol Laboratories Limited
Caxton Way
Thetford
Norfolk

Date of grant 19 February 1973

The Licence granted under the above reference number in respect of the product, particulars of which are set out in Part 1 of the attached Schedule, is hereby renewed, subject to the further provisions set out or referred to in Part 2 of the said Schedule.

The Licence, as now renewed, will, unless previously suspended, revoked or varied as to the period of its validity, continue in force until the end of a period of five years from the date of renewal given below.

Date of renewal: 19 February 1978

GRO-C

A person authorised to sign on behalf of the Secretary of State for Social Services

22 May 1978

Department of Health and Social Security
Finsbury Square House
33/37A Finsbury Square
London EC2A 1PP

MEDICINES ACT 1968

Product Licence No. 0116/0011

SCHEDULE

Part 1 - PARTICULARS OF THE PRODUCTS TO WHICH THE LICENCE RELATES

1.	Name of Product:	HEMOFIL (Antihaemophilic Factor (Human) Method Four).
2.	Pharmaceutical form:	The product is a sterile, lyophilised preparation of purified Antihaemophilic Factor (Human) in a single-dose glass container, packaged with a suitable volume of water for injection USP for reconstitution into a form for intravenous administration. Antihaemophilic Factor (Human) is identical to Blood Coagulation Factor VIII.
3.	Composition:	The active constituent is a fraction of fresh human Plasma. The specification of the constituents and of the finished product shall be in accordance with the information contained in the application for this product licence. To be manufactured only in accordance with the method given in the application for this product licence.
4.	Uses:	The product is intended for use in the therapy of classical haemophilia (Haemophilia A) and correction of partial AHF deficiencies. It has also proved valuable in patients with acquired Factor VIII inhibitors.
5.	Recommended dose and dosage schedule:	The amount of AHF which a haemophiliac requires for normal haemostasis varies with circumstances and with the patient. The amount to be supplied depends on the degree of deficiency and on the AHF level desired.
6.	Method of retail sale and supply:	Prescription Only Medicine
7.	Manufacturer:	Hyland Laboratories, Division of Travenol Laboratories International P O Box 2214 3300 Hyland Avenue Costa Mesa California 92626 USA.
8.	Dates of variation to the original licence:	17 July 1974 16 May 1975 13 June 1975 12 May 1976 4 November 1976 20 December 1977

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Product Licence No: /

SCHEDULE

Part 2 - FURTHER PROVISIONS SUBJECT TO WHICH THE LICENCE HAS BEEN GRANTED

1. All the provisions of Part I of Schedule 1 of the Medicines (Standard Provisions for Licences and Certificates) REGULATIONS 1971 (SI 1971 No 972) as amended by the Medicines (Standard Provisions for Licences and Certificates) Amendment Regulations 1972 (SI 1972 No 1226), the Medicines (Standard Provisions for Licences and Certificates) Amendment Regulations 1974 (SI 1974 No 1523), the Medicines (Standard Provisions for Licences and Certificates) Amendment Regulations 1977 (SI 1977 No 675) and the Medicines (Standard Provisions for Licences and Certificates) Amendment Regulations 1977 (SI 1977 No 1039) shall apply.

2. The number of the Licence shall appear on all containers or packages in which the product(s) is/are packed, on any package inserts or accompanying literature and on any data sheets issued in connection with the product(s).

3. The product(s) shall not be recommended to be used for any purposes other than those specified in Part 1 of this Schedule as Uses.

4. The specification of the constituent and of the finished product shall be in accordance with the information contained in the application for this product licence.

5. The product shall be manufactured only in accordance with the method given in the application for this product licence.