MEDICINES ACT 1968

PRODUCT LICENCE No. 0116 /0011 has been granted under and subject to the provisions of the Medicines Act 1968 to

Travenol Laboratories Limited
Caxton Way
Thetford
Norfolk

in respect of the products, particulars of which are set out in Part 1 of the attached Schedule. The Licence is subject to the further provisions set out or referred to in Part 2 of the said Schedule.

This Licence, unless previously suspended, revoked or varied as to the period of its validity, shall continue in force until the end of a period of five years from the date on which it was granted.

Date granted : 19 February 1973

GRO-C

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

10 September 19 73

Department of Health and Social Security,
Finsbury Square House,
33/37A, Finsbury Square,
London, E.C.2.

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: GRO-C On Prescription through hospitals and Haemophilia centres only.

7. Manufacturer: Hyland Laboratories, Division of Travenol Laboratories International
P O Box 2214
3300 Hyland Avenue
Costa Mesa
California 92626
USA.

MEDICINES ACT 1968

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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 (S.I. 1971 No. 972) 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 provisions as set out in Regulation 4(g), (h) and (i) of the Therapeutic Substances (Manufacture and Importation) General Regulations 1963 (SI 1963 No 1450) shall apply and for this purpose any reference in those provisions to 'substance' shall be taken as referring to the medicinal product specified in Part 1 of the Schedule to this licence, any reference to 'licensee' shall be taken as referring to the holder of this licence and any reference to the 'licensing authority' shall be taken as referring to the licensing authority within the meaning of Section 6(3) of the Medicines Act 1968.

4. 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.