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Department of Health and Social Security
Medicines Division Finsbury Square House
33-37a Finsbury Square London EC2A 1PP
Telex 883669
Telephone 01-638 6020 ext GRO-C

S G Brooks Esq
Armour Pharmaceutical Company Ltd
Hampden Park
Eastbourne
Sussex
BN22 9AQ

Your reference
SGB/JH

Our reference
PL/0231/0044

Date
13 June 1979

Dear Sirs

MEDICINES ACT 1968: PART II LICENSING

I refer to your application dated 20 November 1978 as amended by your letter(s) of 15 January 1979, 6 February 1979 and 14 May 1979.

Authority has now been given for the grant of a product licence for:

PRODUCT	LICENCE NUMBER
High Potency Factorate	0231/0044

The formal documents are enclosed. If you consider they contain information which is incorrect or is not in accordance with your application and amendment(s) please return them with brief details.

In relation to the above licence you will wish to note and consider the following:

1. The licence is subject to standard provisions which are contained in the schedule to the licence.

2. Your attention is drawn to the requirements concerning the reporting of suspected adverse reactions under Article 4 of Schedule I (Part 1) to the Medicines (Standard Provisions for Licences and Certificates) Regulations 1971 (SI 1971 No 972). Attached is a Standard Direction which sets out these requirements.

3. All products are subject to review by the Committee on Review of Medicines: currently anti-rheumatic, analgesic, biological and psychotropic categories are under review.

4. If any data sheets for the product(s) covered by this/~~these~~ licence(s) are to be issued, will you please arrange for copies to be sent to this office. The particulars to be included in such sheets are set out in the Medicines (Data Sheet) Regulations 1972 (SI 1972 No 2076).

5. Please let me know the date(s) on which the product(s) is/~~are~~ introduced on to the market. In this connection you are requested to complete item 3 of the attached letter and return it in the enclosed envelope as soon as possible.

6. This product is subject to batch release procedure as stated in the appropriate letter which is also enclosed.

Yours faithfully

GRO-C

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MEDICINES ACT 1968

PRODUCT LICENCE No. 0231 / 0044 has been granted under and subject to the provisions of the Medicines Act 1968 to

Armour Pharmaceutical Company Limited
Hampden Park
Eastbourne
East Sussex

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: 13th June, 1979

GRO-C

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

13th June 1979

Department of Health and Social Security
Finsbury Square House
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London EC2A 1PP

M E D I C I N E S A C T 1 9 6 8

Product Licence No. 0231 / 0044

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 (No 2) Regulations 1977 (SI 1977 No 1039) shall apply.

2. Leaflets issued with proprietary medicinal products shall comply with the requirements of the Medicines (Leaflets) Regulations 1977 (SI 1977 No 1058). Labels of medicinal products shall comply with the Medicines (Labelling) Regulations 1976 (SI 1976 No 1726) as amended by the Medicines (Labelling) Amendment Regulations 1977 (SI 1977 No 996).

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.

MEDICINES ACT 1968

Product Licence No.0231 / 0044

SCHEDULE

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

1.	Name of Product:	HIGH POTENCY FACTORATE
2.	Pharmaceutical form:	A white to pale yellow lyophilised cake in a vial with vacuum for intravenous administration to human beings after reconstitution.
3.	Active constituents:	Antihaemophilic Factor (Human). Each vial contains a minimum of 800 AHF units to be reconstituted with 30 ml of Water for Injections BP.
4.	Uses:	In therapy of classical haemophilia (Haemophilia A).
5.	Recommended dose and dosage schedule:	Dosage must be individualised according to the needs of the patients. Full recommended general dosages are given in the package insert leaflet.
6.	Contra-indications, Precautions and Warnings:	There are no known contraindications.
7.	Method of retail sale or supply:	PRESCRIPTION ONLY MEDICINE Supplied in single dose vials with the stated antihaemophilic factor activity on the label. Also supplied if required - a vial of diluent and sterile needles for reconstitution, withdrawal and injection. For hospital supply only.
8.	Manufacturer of dosage form:	Armour Pharmaceutical Company P.O. Box 511 Kankakee Illinois 60901 USA (Active constituent and dosage form)