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Department of Health and Social Security

Medicines Division Finsbury Square House
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Travenol Laboratories Ltd
Caxton Way
Thetford
Norfolk

Your reference

Our reference B/T8/34B

Date 12 October 1972

For the attention of B L Steer Esq

Dear Sirs

1. I am writing with regard to your application for a licence under Part I of the Therapeutic Substances Act 1956 to enable you to import HEMOFIL (Factor VIII) and the visit by inspectors of the licensing authority to your premises at Bowles House on 29 July. As you are aware the visit was made as a result of promotional literature relating to hemofil (a copy of which is enclosed) coming into the possession of the licensing authority which implied that the product was available in this country.
2. The inspectors on the occasion of their visit ascertained that a consignment of hemofil had been imported recently, that stocks of hemofil were in your possession and that quantities had been sold and supplied to a number of doctors.
3. You should know that:-
 - (a) under section 3 of the Therapeutic Substances Act 1956 the importation of a substance controlled under Part I of the Act is prohibited unless the substance is consigned to a person licensed by the licensing authority to import it;
 - (b) under section 6 of the T.S. Act it is an offence for a person (i) to sell or have in his possession for sale a controlled substance knowing it to have been manufactured or imported in contravention of Part I of the Act or the regulations made thereunder; (ii) to fail to comply with the provisions of any regulation made under Part I of the Act;
 - (c) under section 45(1) of the Medicines Act it is an offence for any person to import any medicinal product except in accordance with a product licence as also is the possession of that product for the purpose of selling or supplying;
 - (d) under section 96(5) of the Medicines Act it is an offence for a commercially interested party to send or deliver to a doctor advertising material relating to a medicinal product without an accompanying data sheet or in advance of such a data sheet being sent or delivered to doctors;

- (e) under section 124(1) of the Medicines Act where an offence under the Act which is committed by a body corporate is proved to have been committed with the consent and connivance of, or to be attributable to any neglect on the part of, any director, manager, secretary or similar officer of the body corporate, or any person who was purporting to act in any such capacity, he, as well as the body corporate, shall be guilty of that offence and shall be liable to be proceeded against and punished accordingly.

The Department takes a most serious view of this matter but have noted the undertaking given by Mr Steer on behalf of the company that there would be no further distribution of hemofil without authority.

4. I understand you are in the process of preparing an application for a product licence under the Medicines Act for hemofil and I should like to be advised as to when you expect to be in a position to submit the application to the licensing authority. Your application for an import licence under the Therapeutic Substances Act has been received and is under consideration.

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