

# AIDS

As a result of the meeting held on 3 June '83, HSIB circulated the questions listed in Dr Walford's minute of 14 June (copy attached) to suppliers and possible suppliers of coagulation factor concentrates. A copy of the questionnaire was sent to ten companies, nine have replied five of which are suppliers in the UK. Attached is a summary of the replies from these firms. You may also wish to note the following points:-

- a. Merck, Sharpe & Dohme Ltd and Amersham International Ltd do not supply blood products in the UK.
- b. Hoechst Ltd have applied for product licences which are still being considered by CSM.
- c. Speywood Labs Ltd do not manufacture human coagulents.
- d. The following firms are suppliers of blood products in the UK:-

Alpha Therapeutic Ltd  
Armour Pharmaceuticals Ltd  
Travenol Laboratories Ltd  
Immuno Ltd  
Miles Laboratories Ltd

- e. Annual imports of FVIII by the above firms total about 42 - 50m units.
- f. With the exception of Immuno the firms state they do not or have ceased to collect in 'Epidemic' areas. All state that their collection centres are FDA licensed.
- g. The plasma in each case is pooled prior to processing. In the case of Immuno products, European plasma and USA plasma are pooled separately.
- h. The origin of all plasma is identifiable.
- i. Each has given the assurance that future sales will comply with FDA guidelines. However, Miles Labs state that FVIII manufactured from plasma collected since March '83 will not be available until August, and Immuno in September '83.

The tenth company, Cutter International Ltd, have not yet replied. The product previously sold in the UK by this company is now being marketed by Miles Labs Ltd who have applied for a licence on assuming responsibility for the product.

GRO-C

28 June 1983

HSIB  
R309  
RSQ

To: Mr Parker HS1  
Dr Oliver MEDSEB  
Dr Walford "  
Mr Sloggem STB  
Miss Spencer MB

Mr. W. W. W. W.  
Have you a copy  
of the  
29/6.

AIDS - The following companies import coagulation factor concentrates into the UK from the USA:-

Company	Product	Annual UK Sales	FDA Licensed Centres	Centres in 'Epidemic' Areas	Remarks
Armour Pharmaceuticals	Factorate <sup>Factor VIII</sup> High Potency Factorate	15-20m i/u 1-1.5m i/u	Yes	No	Origin of plasma identifiable. Plasma pooled. Precautions instituted in Feb '83. Future sales in UK will have been processed under new procedures.
Alpha Therapeutic	Profilate (FVIII)	5m i/u	Yes	No	Origin of plasma identifiable. Plasma pooled. Precautions instituted Dec '82. All sales have been processed under new procedures
Travenol Labs (Hyland)	Hemofil* (FVIII)	8-9m i/u	Yes	**	* Full name is 'Hemofil' Antihemophilic Factor (Human) Method Four **Collection in 'Epidemic' centres ceased in March '83. Origin of plasma identifiable. Plasma pooled. Precautions instituted in Feb '83. Future sales will comply with FDA March '83 guidelines.
Immuno Ltd	Kryobulin Red " Blue - Prothromplex - Feiba	0.9m i/u 4.1m i/u 0.8m i/u 1.5m i/u	Yes	Miami New York	FVIII - ex German/Austrian plasma FVIII - ex USA plasma FIX - ex European or USA plasma For patients with FVIII inhibitor - ex European or USA plasma. Origin of plasma identifiable. Plasma pooled. Lots processed from pre-March '83 plasma are held in quarantine. Products complying with new procedures will be available September '83.
Miles Labs	Koate (FVIII)	8m i/u	Yes	No	Origin of plasma identifiable. Plasma pooled. FDA Directive implemented Mar '83. Product produced from plasma collected since Mar '83 available Aug '83. Has screened for AIDS for some years. X