

2638

Mr K Egerton
Room 315 RSQ

AIDS - ENQUIRY TO MANUFACTURERS

I have seen Mr Wrigglesworth's minute to Miss Spencer and Dr Oliver.
Dr Oliver has asked me to reply.

The following is a list of questions which rather expands on the draft provided by Mr Wrigglesworth:

1. Does your company manufacture coagulation factor concentrates for use in the UK? If yes, name the products and state how much of each is supplied annually.
2. From which country or countries is the source plasma obtained?
3. If from the USA, is all plasma collected at FDA-licensed plasma collection centres? Please give the names of the centres and their locations.
4. If non-USA plasma is used, name the countries involved and state whether the plasma collection centres in these countries are licensed by the national regulatory authorities.
5. Are you able to identify the origin of the plasma included in each batch of final product and the date on which it was collected?
6. Is the plasma from each collection centre fractionated separately or is plasma from several collection centres pooled prior to processing?
7. If the plasma is of USA origin, are you able to supply final products which do not contain plasma from the major "epidemic" areas for AIDS eg New York, San Francisco, Los Angeles, Miami?
8. Can you confirm that all plasma of USA origin in your products is being collected in conformity with the FDA directive of 23 March 1983?
9. Did your company institute, in advance of the FDA requirements, any special precautions to be taken by plasma collection centres in respect of AIDS? If so, what were these precautions and when were they introduced?
10. If USA plasma is used, are you able to confirm that all future supplies of coagulation factor concentrates to be sold in the UK will be manufactured from plasma collected in accordance with the FDA directive of 23 March 1983 (or in accordance with the special precautions, if any, instituted by your company at an earlier date)?
11. If the answer to (10) is No, from what date can you meet this requirement?

GRO-C

cc Dr Oliver
Miss Spencer Med Div
Mr Sloggen
Mr Wrigglesworth o/r

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