Reference .....

2603

Dr Walford

FVII (Sic) AND AIDS

In reply to your first minute on the above subject dated 16 May 1983, the manufacturers are certainly able to identify those batches of plasma collected after 24 March 1983 and are therefore able to identify batches of concentrate made from such plasma. Whether or not they would be prepared to release this information is another matter.

All FVIII concentrates are subject to full "Stop Orders", which require the manufacturers to submit protocols and samples from every batch they propose to sell in the UK, to Dr Duncan Thomas's department at NIBSC. The content of an individual manufacturer's protocol is very much a matter for agreement between Dr Thomas and the company. I do not think that date of plasma collection is a requirement at present, but I see no reason why it should not become so if it were thought desirable. The Licensing Authority would then, on the advice of Dr Thomas, be able to reject those batches which did not comply.

The practical and legal aspects of this suggestion would, of course, have to be checked beforehand, but even the threat of such action might be sufficient to persuade the manufacturers to comply voluntarily.

GRO-C

DR L K FOWLER
MB4
Rm 1619 MP
Ext GRO-C

23 May 1983

CODE 18-77

12/9

Copies: Dr Parker
Dr Oliver
Dr Sibellas
Mr Gregory
Dr Sharpe
Mr Wrigglesworth
Mr Hugson
Miss Spencer (Med. Div)
Mr Green
Dr Harris
Mr Lister

Reference 2603

Dr Walford

FVIII AND AIDS

I refer to your second minute on the above subject dated 16 May 1983.

Your suggestion that US manufacturers may try to "dump" pre 24 March 1983 material on the UK market has to be taken seriously. If you will refer to my other minute which accompanies this one, you will see that we may be able to exercise some control through the "stop orders" administered by NIBSC. If this proves to be a non-runner, we shall be wholly dependant on the manufacturers as we would have no other means of checking the source of materials we import.

With regard to your specific questions, I shall take them in order using your numbering.

1. As to whether we could obtain concentrates made from plasma which does not come from the "epidemic" centres, the short answer is that I do not know. The source of all plasma is known to the manufacturers but unless they take a specific decision to segregate the plasma on geographical grounds, my best guess is that the huge pools employed would contain everything available. As we both know, Travenol have closed down their downtown New York City Plasmapheresis Centre and I would guess that they and the other three companies are giving thought to doing the same thing to centres in San Francisco, Florida, etc. In a word, no, unless the companies choose to make this distinction.

2. My accompanying minute refers. As to an adequacy of post 24 March 1983 supplies, I do not know. I think we should bear in mind that the companies have probably got large supplies of Factor VIII in store waiting for batch clearance by NIBSC and it is very unlikely that material was made solely from post 24 March 1983 plasma.

3. My accompanying minute refers.

4. My best information is that neither Immuno nor the other European manufacturers could have any chance at all of producing a fraction of the 30 million units you refer to, from European plasma, for sale in the United Kingdom. The Swiss are said to have a small surplus of "home grown" concentrate but the amounts involved are minuscule by comparison with the amount you mention.

Thank you for the copies of letters from Harold Gunson and Alan Barrell. I have confirmed that the latter was sent to Directors of Haemophiliac Centres and Regional Transfusion Centres, and thus in my view, constitutes promotion of a product for which Travenol do not yet have an appropriate licence. The implied claims made in the latter for heat treated Factor VIII make it mandatory

for the expected application to be referred to the Committee on Safety of Medicines, rather than dealt with "LA only" which will, of course, significantly delay its consideration.

GRO-C

DR L K FOWLER
MB4
Rm 1619 MT
Ext GRO-C

23 May 1983

CODE 18-77