DEPARTMENT OF HEALTH

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Your reference
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Barrow194

Phil - any comments?

Dr T W Barrowcliffe
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20 April 1993

Dear Trevor

BATCH RELEASE OF BLOOD PRODUCTS

I promised to drop you a note summarising our views following the meeting on 7 April.

We would prefer to have a system which is universally accepted across the EC rather than having individual states determining their own positions regarding batch release. In addition we would hope that there would be agreement across Europe of how batch release should be conducted and which laboratories fulfil the criteria to perform batch release.

In respect of phase 1 of batch release that is testing all batches of blood products, we would be prepared to consider this but only for virological screening of plasma pools. We could see no advantage at all for testing the final product, since this is impossible for some products anyway.

We would hope that phase 2 would be the main detailed system of batch release. This would be applied to new products before release onto the market and for a specified number of batches after the product was on the market. The number of batches would be determined by the particular product concerned and each of this number of batches would have to consistently satisfy the criteria before routine batch release was terminated for that product. Additional detailed batch release would be applied as part of spot testing by the Licensing Authority in respect of post market surveillance.

All the other special circumstances detailed under para 2.2 such as change in production process, change in sight of

manufacture, adverse drug reactions etc would all determine that a phase 2 approach should be applied. Following each change then the same number of consistently satisfactory batch release tests would need to be achieved before reverting to the normal scenario of only occasional batch release. We would hope that with this system batch release could be targetted and could be done in a more cost effective method with better value for money.

Ultimately there is no absolute guarantee with any blood product. If the manufacturer does not individually test donations, then there may be a low level of seropositivity which is missed by testing plasma pools. The manufacturer has responsibilities under Product Liability not only in respect of safety but also in respect of potency etc.

Dr Minor agreed to provide details of the number of positive donations which need to be present in a plasma pool in order for the plasma pool test to show positive for HIV, hepatitis B or hepatitis C. Despite your views and those of Dr Minor, we think this information is crucial in any presentation of our case to Ministers. As you recall I pointed out that the current release certificates which are issued by NIBSC are of dubious value since they absolve NIBSC from any responsibility by stating that permission to release the batch is on the understanding that each individual donation was negative for HIV. If the batch release system is agreed across Europe, then the batch release certificates which are sent to DH will obviously have to be amended.

With best wishes.

Yours sincerely

GRO-C

pp Dr A Rejman MD MRCP MRCPath
Senior Medical Officer

cc Dr J Purves MCA
Mr J Canavan CA-OPU2