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For the attention of Dr. Eli Greene

Your ref

Our ref

Direct dialling

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Date

NE/AC/005

GRO-C

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21 December 1992

Dear Eli

Re: Source Plasma-viral screening tests

Further to our recent conversation on the above issue we can now confirm that the stance of the UK authorities is as follows:

1. From 1 January 1993 all source plasma must be screened for absence of HCV Ab.
2. Product which is released for sale/supply to the market prior to 1 January 1993 and which has not been screened for HCV Ab may continue to be available for sale/supply until 31 December 1995.

The interpretation of "release for sale/supply to the market" may differ in different EC countries. In the UK our authorities stance is that "release" refers to NIBSc testing, not internal company testing. Hence from 1 January 1993 all batches of product submitted to NIBSc for release testing must be manufactured from HCV Ab -ve plasma.

3. As you are aware the stance of the UK authorities has been for a considerable period of time that screening must be performed for both HIV-1 and HIV-2 Ab. We cannot comment on the stance of other EC countries and suggest that you consult with the individual local regulatory departments. However, all products made available to the UK market must be manufactured from HIV-1 and HIV-2 Ab -ve source plasma.

We understand from our authorities that the CPMP stance on the above issue is confusing and is not clearly worded. Interpretation in the different EC countries may differ greatly, e.g. some countries may consider "release for sale/supply" to refer to manufacturer release testing. We strongly advise you that the only way to clarify the stance adopted by individual EC countries is to consult with the relevant local regulatory departments. It would also seem that non HCV Ab screened plasma stored on site and not yet processed cannot be used in manufacture post - 1 January 1993, the above discussion relates to finished product release.

We trust that these points clarify the position in the UK with regards to source plasma screening. If you have any further questions on this issue please do not hesitate to contact us.

Kind regards  
Yours sincerely

GRO-C

Craig Simpson  
Registration Manager

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