

Our Ref: PEH/dm/letters2005/Foster240205



24th February 2005

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RECEIVED 28 FEB 2005

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Mr Keith Foster
Scheme Administrator
Skipton Fund
PO Box 50107
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Dear Mr Foster,

Re: Skipton Fund Ex Gratia Payment Scheme

Thank you for your letter of 16th February 2005 regarding requests for payment from applicants treated with anti-D immunoglobulin during the 1980s.

Anti-D immunoglobulin produced within the UK, either by the Bioproducts Laboratory (England and Wales) or the SNBTS (Scotland and Northern Ireland) has been used over many years and has an unparalleled safety record with regard to transmission of viruses. There are no established reports of infection transmission by the intramuscular product produced within the UK since treatment began.

On the other hand, there have been well documented transmission episodes from anti-D immunoglobulin preparations produced outside the UK. The most well known is the case of the anti-D immunoglobulin prepared by the Irish Blood Transfusion Board during the 1970s and early 1980s, which transmitted hepatitis C to a large number of female recipients treated after childbirth. Similarly, there was a well documented episode relating to anti-D immunoglobulin used in Germany at a similar time. These anti-D preparations involved a completely different method of manufacture from that used within the UK. Furthermore, the Irish anti-D immunoglobulin was an intravenous preparation, unlike the UK products. I am aware that some Irish anti-D immunoglobulin was imported into the UK and used, on a named patient basis, on a very small number of women who required a larger dose of anti-D immunoglobulin than that provided by the UK product. The vast majority of this imported product was traced when the Irish Blood Transfusion Board carried out a recall and notification exercise in the 1990s. I am not aware of any UK recipients, traced through this process, who were found to be infected with hepatitis C as a result of this exercise. It is possible, however, that there may be cases which have only subsequently come to light. I am not aware that the product used in Germany was ever imported into the UK.

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In general, therefore, women who have been treated with anti-D immunoglobulin within the UK will have received UK product which is considered safe from the point of view of viral transmission. There may be a few women who received product manufactured outside the UK, which might have presented a risk of hepatitis C infection. In order to totally exclude this scenario, it would be necessary to know whether there are any reasons to believe that non-UK product was used. This would only have been in exceptional circumstances and not for routine treatment during and after pregnancy.

I hope these comments are helpful. Please do not hesitate to contact me again if I can be of any help in relation to the four requests that are currently under consideration.

Yours sincerely,

GRO-C

Dr P E Hewitt
NBS National Claims Manager &
Lead Consultant in Transfusion Microbiology

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