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cc Alan Harvey

Can you keep in touch i charter over this — so we keep "joined up"

Thanks. GRO-C

Charles Lister
04/01/2001 14:21

Sent by: Charles Lister/HSD2

To: Nick Raisen/PH-DCMO/DOH/GB@ GRO-C

cc: Alex Berland/HSD2/DOH/GB@ GRO-C
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Subject: SYNTHETIC BLOOD PRODUCTS

Nick

You asked me to write up the briefing I gave orally to Pat. She may like to know that this issue was raised in an Adjournment Debate on 9 November (Robert Syms MP) and by Lord Morris in an oral PQ on 14 December. I am attaching an extract from John Denham's response to Robert Syms.

The key points I provided for Pat were:

- The Government required NHS Trusts to provide synthetic Factor 8 for all new haemophilia patients and children under 16 from April 1998, and Factor 9 from April 1999 as soon as it became available. [This policy was worked out with the Haemophilia Society and the UK Haemophilia Centres Doctors Organisation. There was a limited supply of synthetic clotting factors and children were seen as the priority group.]

- From April 1999, all plasma derived clotting factors (along with other blood products) were made from imported plasma to reduce the theoretical risk of vCJD.

- Ministers have recently received representations from the Haemophilia Society arguing the case for provision of synthetic clotting factors for haemophilia patients in England. Lord Hunt is meeting the Society and the UK Haemophilia Doctors Organisation on 24 January to discuss this issue.

Synthetic clotting factors offer no therapeutic benefit over plasma-derived products. The issue is one of safety. Plasma derived clotting factors have had an excellent safety record since the introduction of viral inactivation in the mid 1980s, and we have taken steps to minismise the risk from vCJD. However, the Haemophilia Society and UKHCDO argue that, as long as we continue to use the plasma-dervied product, haemophilia patients are at risk from new or undected viruses and still, potentially, vCJD - and there are products available now that could eliminate that risk Scotland, Wales and Northern Ireland have all moved towards universal provision of synthetic clotting factors (Scotland aims to complete the process by April 2001) which puts us under additional pressure to do likewise.

A shift towards provision of synthetic clotting facors for all haemophilia patients in England would have to be phased in over a period of perhaps 2-3 years. There is still insufficient product on the market to supply the whole of the needs of the NHS immediately. There would also be substantial cost implications for the NHS which we are currently calculating (I should have figures by the middle of next week showing numbers of haemophilia patients in England currently recieving snythetic and plasma derived products). We would want to involve PASA in negotiating central contracts to get best value for money. I will be putting

this information in a submission to Lord Hunt, hopefully by 12 Janaury.

This is not an issue that has ever been put to an Advisory Committee. The only group that could perhaps look at it is NICE and they have declined to do so on the grounds that it's primarily a safety issue and therefore outside their remit. In Scotland they have devolved decision making on funding for synthetic clotting factors to Health Boards and decisions on phasing in were given to a Recombinant Factor 8 Consortium Group made up of Health Board representatives and others. Wales and Northern Ireland have similarly devolved decision making on this issue.

I hope this is helpful. Please let me know if you need anything further.

Charles

Extract from John Denham's Speech. 9 No