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Mr Wi... GRO-C 29/7 File

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RECOMBINANT FACTOR VIII - ANNOUNCEMENT IN SCOTLAND

1. This is to alert Ministers to an imminent announcement by SofS Scotland on about the central funding of recombinant Factor VIII which may have implications for other Health Departments.

Background

2. Factor VIII is the clotting factor concentrate used in the treatment of haemophilia. Traditionally it has been manufactured within the NHS from the plasma provided as a by-product of blood donation. In recent years a genetically engineered (recombinant) alternative has been developed commercially.

3. Around 160 million (1994 figures) international units (i.u.) of Factor VIII are used in the UK of which currently some 10% is thought to be recombinant. The trend is for recombinant to increasingly replace plasma-based as the preferred treatment. In England the price differential may be currently inhibiting this development (24p per i.u. for plasma-based compared with 50p for recombinant - the additional cost of recombinant per average haemophiliac treated is around £16,500 p.a.).

4. The relative benefits of recombinant have not been precisely established. Haemophilia Centre Directors are preparing Guidelines for recommended clinical use. Its efficacy as a clotting agent appears to be no better than plasma-based but it is generally accepted that some patients may benefit and some clinicians have strongly argued that because it is not plasma derived it is less likely to transmit viruses. The manufacturers have not been able to claim that it is safer as it contains human albumin. But given the history of infection through blood products any prospect (even theoretical) of a safer product is highly attractive to clinicians who feel vulnerable and in England there has been some lobbying for recombinant to be supported by central funding. PS(H) will recall that "funding for the widespread introduction of recombinant products" is one of the proposals contained in the Haemophilia Society's letter to him of 18 June 1996. He will also be aware of the recent Parliamentary pressure to exempt recombinant from VAT.

5. The introduction of recombinant in Scotland has been relatively slower. This is because the Scottish National Blood Service supplies plasma derived blood products (including Factor VIII) without charge. Thus the additional cost to the health board of haemophilia centres using recombinant is very much greater than in England where cross-charging means that centres are already paying for plasma-based products. Scotland have been under pressure from haemophilia centres to address this disincentive. As a result, we understand that Scottish Ministers will shortly be announcing a central injection of £1m to meet the costs of recombinant usage in haemophilia centres. The announcement is to be made by way of an inspired PQ the terms of which are as follows :-

PQ Mr ..... ( ) : To ask the Secretary of State for Scotland, what consideration has been given to the use of synthetic Factor VIII for the treatment of haemophilia and if he will make a statement.

A: Synthetic, or recombinant, Factor VIII is a new treatment considered appropriate for some patients with haemophilia. The treatment is an alternative to the plasma derived Factor VIII currently in use and supplied free of charge to the NHS by the Scottish National Blood Transfusion Service. To assist with the costs involved in the acquisition of the new product, which is only available from commercial sources, I have agreed to make available funding of £1 million in the current year. Future arrangements will depend on the speed and extent of the transition from plasma derived Factor VIII to recombinant. This will be kept under review.

The Problem

6. The fact that Scotland is introducing central funding to support recombinant may be exploited by those lobbying for a similar development in England (notably the Haemophilia Society). Whilst questions about the reasons for central funding in Scotland will be for Scottish Ministers it is likely that Ministers in England will be faced with comparisons and there may be some press interest.

Argument

7. Scotland have been careful to present this development as a reflection of their funding mechanism for blood products, rather than a policy priority eg based on patient safety. They have stressed that it is an interim measure to address the immediate need for recombinant which is only available from commercial sources. Arguments about unequal treatment will only hold water if it can be shown that Scottish haemophiliacs will be in a more advantageous position. In fact, even with the central injection, the pro rata provision of recombinant in the two countries will be very similar and it can be reasonably argued that the Scottish decision is in fact ensuring rather than threatening equal treatment.

Conclusion

8. This is to inform Ministers and no action is sought. We understand that the announcement is likely to be made next week and further briefing will be provided in the light of new information. The proposed line to take in the event of questions on the position in England is as follows :-

FUNDING

"Like other treatments, recombinant Factor VIII is available to NHS patients if their doctor decides that they should receive it, taking account of the patient's individual needs, the alternative treatments available and the availability of resources.".

SAFETY

"Products derived solely from human plasma continue to be used for the majority of patients, and have a good safety record. The safety of blood products depends on a number of factors which, taken together, reduce as far as possible the risk of viral infection. These include the screening of donors, the testing of donations, plasma pool testing and the ability of the manufacturing process to remove or inactivate viruses, and viral marker tests that can be undertaken on certain finished products. The absolute safety of blood products cannot be guaranteed and this applies to currently licensed recombinant Factor VIII which contains human serum as a stabiliser. ".

COMPARISON WITH SCOTLAND

"Patients in England are in no different a position from those in Scotland. Decision on what treatment should be given are for clinical judgement of the doctors concerned, in the light of available resources and the needs of the individual patients. ".

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