YG530

To: Mr C Wilson

From: E H W Luxton PD

Date: 14 November 1989

cc: Dr K Jones
Dr Roblat
Mr J Turner
Mr J Canavan HS1
Mr Franks MB6
Mr Booth MB6B
Dr Pickles
Mr Dobson HS1
Mr Nilsson SOLC5
Miss Duncan
Mr Bray
Mr Burton
Mr Sutherland

Profilate Factor VIII

1. I am replying for PD to some of the issues raised in para 6 of your minute of 14 November to Mr Franks on the above.

2. We accept BPL's own estimates that they meet some 70 per cent of NHS requirements for Factor VIII. Alpha Therapeutics, the manufacturer of Profilate, reckon to have 80 per cent of the rest of the UK market, ie roughly a quarter of the UK market share. Other manufacturers with a current UK product licence - all from overseas - are as follows:-

Miles Cutter (a subsidiary of Bayer)
Baxter (also selling an improved, but unlicenced product variant whose application is awaiting approval)
Immuno (also selling an improved, but unlicenced product variant whose application is awaiting approval)
Hoechst (not currently marketing in the UK, but they have a UK licence)
Speywood (a porcine-based Factor VIII)

3. BPL have had supply problems in the recent past, while they converted production to a new factory. Their GMP problems now seem resolved but some parts of the NHS refrain from using them in part because of their "public sector" status and past history, but more importantly because of their strange and selective pricing structures. BPL themselves are pressing for implementation of "a policy of self-sufficiency in supply of blood products". As the sole UK manufacturer they are a far from disinterested party and actually by pass product licence requirements through Crown Immunity - a point that may interest the media. We believe it to be reasonable that they should have the opportunity to increase their market share - eg as a result of the problems with Profilate - but competition from the commercial sector should remain available for say 10 to 20 per cent of the market to keep them on their toes and to avoid too many eggs in one basket that might go wrong one day. It is, however, essential that all suppliers are kept up to the safety, efficacy and quality control mark. Failure to tackle the Profilate difficulties firmly now will store up problems with all our suppliers at some future stage.

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4. We are satisfied that BPL and other supplies have sufficient short-term reserve stocks on hand to cope with the recommended action of suspending Profilate. However we have not approached them directly while the issue remains "sub judice" and delicate. We would like to see a Drug Alert recall issued and if the manufacturers refuses to co-operate with that we would wish to issue a Hazard Notice recommending that current hospital stocks of Profilate be taken out of use. The statistical risk of contamination or recontamination, though smaller than in the Armour cases, is too great to risk with any haemophiliac patients.

E LUXTON
PD
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