C8C27

Ref: F8

Dr S Wood (MB3B)

From: Dr H Pickles
Med ISD/3

Date: 6 February 1990

Copy: Dr Rejman ISD/3 ✓
Mr Canavan EHF1B
Mr Rennison MB2B

FACTOR VIII PROMOTION

We are entering an unusual period in promotion of Factor VIII. Up to now, most of the use in this country has been of unlicensed product, and in addition there has been a world shortage. Hence "promotion" has been very restrained.

The situation is now changing. The Elstree factory is on stream so BPL can now supply virtually all the domestic market. Hence the market in the UK for the commercial sector is shrinking. Add to this now an adequacy of world supply and products now receiving licenses from the MCA, and we could be in a cut-throat situation.

We hope we can reply on the MCA to keep a good eye on this promotion. A particular concern is that because the commercial companies cannot compete on price (since BPL product can undercut them) nor on efficacy (since all products are identical), there will be an attempt to base product identities on safety profiles. But there is a danger if this gets out of hand and leads to "knocking copy", there could be a loss in patient confidence which for example may reflect badly on the HIV litigation now before the courts. So we hope you will keep a particularly close eye on promotional suggestions relating to safety that go outside those approved by the CSM.

A case in point is the new promotion from Armour. The attached letter reads as if significantly improved viral safety is a therapeutic advantage. I believe this goes beyond the claims approved by CSM/MCA. There is no evidence existing products on the market are virally unsafe. Monoclate-P's claimed advantage here is theoretical, but not one they should describe in the therapeutic terms they have. The data sheet is more suitably cautious.

I would be interested to have your views.

GRO-C

Hilary Pickles
Room 414
Eileen House Ext: GRO-C

07 FEB 1990
5/30