1.Mr C Wilson MCA
2.Dr K Jones MCA

From: J C Booth MB6B
Date: 13 November 1989
Copies: Mr Franks
Mr Turner
Mr Sloggem
Mr Canavan HS1A
Mrs Richter
} Minute only

MANUFACTURER: ALPHA THERAPUETIC CORPORATION
5555 VALLEY BOULEVARD
LOS ANGELES
CALIFORNIA
USA

PRODUCT LICENCE NUMBER: 4447/0005 PROFILATE (FACTOR VIII)

1. The IAG, at their meeting this morning proposed:

)a) to suspend the above product licence with immediate effect for 3 months.

b) to recall all stocks from the UK market; and

c) to suspend the PL for 6 months (to enable the company to appeal).

2. The Medicines Inspectorate inspected the site 22-24 February 1985 and produced a list of serious deficiencies. The company made assurances that the situation would be examined with a view to rectifying it. A re-inspection on 6-10 October 1989 revealed that the company had failed to carry out agreed upgradings in order to ensure safe production ie (viral)-free Factor VIII ("Profilate"). No effort had been made to rectify the major deficiency whereby air from the albumin-handling area was drawn and blown over the Factor VIII Bulk Product after treatment. In addition, the situation has deteriorated since 1986 and is now considered critical. A copy of the Inspector's report is enclosed. (Relevant Sections are highlighted).

3. They will not upgrade the "Profilate" for the UK market for financial reasons and they wish to switch to a process which is believed to be similar, but not identical to the product supplied in the US. The company have submitted an application to vary the UK Product Licence. The anti-(vivol) detergent step in their PL variation application is likely to be acceptable, but it is new technology in which a Committee view is likely to be sought. The company themselves admit that their current UK product is inferior to that provided for the US. The Group agreed that there was a risk to patient safety and that immediate suspension of the licence and withdrawal of existing UK stocks was justified.

SUPPLIES

4. Bulk supply of UK Factor VIII is from BPL, Elstree, (70%+). Alpha maintain they supply some 80% of the balance. Advice from Supply Branch and HS1 is that BPL could meet the gap created by suspension of Alpha's PL. There are also other suppliers, existing or shortly to be approved.

RECALL

5. "Profilate" is hospital use only. But haemophiliac patients are likely to have stocks in home refrigerators. They may be identified by registration. HSI are concerned about the publicity which a Drug Alert letter will attract. They ask for time to consult with their legal advisers before action. You will also be aware of this evening's Adjournment Debate on the plight of haemophiliacs who have contracted AIDS.

ACTION

6. The proposal is:

a) Immediate suspension of Alpha Therapeutics PL4447/0005 for Profilate (under paras 3, 10 and 11 of Schedule 2 to the ~~Directive~~ Medicines Act).

b) Recall of all stocks from hospitals and patients.

c) Proposed suspension of PL4447/0005 for six months (Section 28 of the Medicines Act).

7. Subject to your agreement we shall proceed accordingly.

GRO-C

J G BOOTH
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