W'drawal of FACTOR VIII

COMMERCIAL - IN CONFIDENCE

Mr O'Connor

FACTOR VIII and AIDS

1 This is to inform Minister of action already taken, or planned for next week, in connection with reports to Medicines Division by the pharmaceutical company Armour of two further cases of seroconversion (ie developing the HIV (AIDS antibody)) associated with their heat-treated product, "Factorate". This blood product is used to treat haemophiliacs.

2 Similar reports in February 1986 were considered by the Committee on Safety of Medicines who concluded that there was insufficient evidence for action to be taken but that they should continue to keep the matter under review.

3 We now have 2 cases of children in which Factorate is strongly implicated as causing sero-conversion, although neither patient has clinical AIDS. A further patient treated with the Armour product in Holland has developed AIDS related complex. Two other cases are associated with the Armour product but the evidence is not conclusive.

4 After careful consideration of the evidence, senior doctors in Medicines Division decided to discuss the implications urgently with the Company and talked to senior representatives from the UK today. Arrangements have been made to meet senior officials from the US parent company on Monday 6 October when it is proposed to seek the Company's voluntary agreement immediately to cease production and distribution of the product, and to arrange for immediate voluntary recall of the material already distributed. If the Company refuses to co-operate, it is proposed to issue a formal notice to the Company on 6 October under Section 28(3) of the Act, suspending their licence on grounds of safety.

5 Discussions will be held with the Company to agree upon the most satisfactory arrangements for recalling products already distributed either to Haemophliac Centres or patients. Preliminary enquiries suggest that there will not be a major problem of supply if this product is immediately withdrawn and that other products will be available to fill the gap.

6 There is no evidence at present to suggest that Factor VIII products produced by other companies are unsafe.

7 A further submission, together with a draft press notice, will be made on 6 October in the light of what arises during the meeting with the Company.

GRO-C

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3 October 1986

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