



Armour Pharmaceutical Company Limited

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18th May, 1977

The Medical Assessor,
Committee on Safety of Medicines,
Finsbury Square House,
33/37a Finsbury Square,
LONDON.

Dear Sir,

We wish to inform you that we have received reports from three centres of clinical jaundice occurring in haemophilia patients who have received amongst their various treatments our drug Factorate (batch P80006). The three centres concerned are:-

Derbyshire Royal Infirmary (3),
St. James Hospital, Leeds (6) and
Nottingham General Hospital (1).

In all cases the hepatitis has been mild and the patients have all recovered.

At present we are pursuing these reports to acquire full details of the cases and will, of course, send you completed Yellow Forms as soon as possible.

All the other centres which have received this batch have been contacted to determine whether any further cases have occurred which have not been reported to us. This has brought to light three further cases of biochemical, but not clinical, hepatitis.

We believe that all of this batch has already been used so there is nothing we can do in this respect.

You will see from the reports when you receive them that these cases do not follow a clearly defined pattern. Most of them have been negative for HB antigen and the incubation period has been very variable ranging from thirteen days to seventeen weeks. Although we routinely test for HB antigen before a batch is distributed, we have arranged for a sample of this batch to be re-tested for HB antigen but the results are not yet available. However, the batch has already been tested at one centre with negative results.

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Directors
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In addition, we believe that all the patients have also received a number of donations of Cryoprecipitate and most have received other freeze-dried concentrates.

Although this batch of Facotrate cannot necessarily be implicated in these cases of hepatitis, in accordance with the terms of our Product Licence we are informing you of the present situation and will keep you up-to-date with further details as they become available.

Yours faithfully,
ARMOUR PHARMACEUTICAL COMPANY LTD.

Elizabeth Stockman, B.Sc. (Mrs.)
Registration Officer

cc: Mr. A. J. Fildes
Mr. G. J. Fildes
Mr. P. J. Fildes
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