Armour Pharmaceutical Company Limited

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URGENT

PAH/LEW

October 7, 1986

FACTORATE IP PL NUMBER 0231/0038 &
FACTORATE HP PL NUMBER 0231/0044

Dear

With immediate effect, Armour Pharmaceutical Company Limited is withdrawing from the UK market the Factorate products detailed above. The Company has relinquished the relevant product licences. This action follows consultation with the DHSS after notification by a UK physician of two cases of HIV antibody sero-conversion associated with the use of Factorate.

Armour is not yet in possession of the complete clinical profile concerning these two sero-conversions. However, the decision to withdraw Factorate was made even though the material used in these two cases is not that currently on the market. In view of the decision taken yesterday we advise that no further administration of Factorate should be given. You should return all Armour Factorate in inventory to Armour Pharmaceutical Company Limited, 2 Whittle Drive, Eastbourne, East Sussex, BN23 6QT marked for the attention of Mr C G Blatchford.

Yours sincerely

Dr P A Harris
Medical & Technical Director

FACTORATE - PRESS RELEASE

With immediate effect, ARMOUR PHARMACEUTICAL COMPANY LIMITED is withdrawing its Factorate products from the U.K. market. The company has relinquished the relevant product licences. This action follows consultation with the DHSS after notification, by a U.K. physician, of two cases of sero-conversion associated with the use of Factorate. Factor VIII is a blood-clotting factor which is deficient in haemophiliac patients.

On September 29th, ARMOUR received a telephoned report that two haemophiliac patients in the U.K. had sero-converted - that is, blood tests showed that these two patients may have been exposed to the AIDS virus. The physician reports that the patients remain well. On the same day, Armour notified the DHSS, and is rigorously pursuing all data concerning these patients.

Both patients had, for some months, been treated with Armour's heat-treated Factorate, which was manufactured from plasma collected before the general availability of the AIDS antibody screening test for donors. It was the product manufactured from plasma from screened donors which was withdrawn today. This decision was made even though the material used in these two cases is not that currently on the market.

Contact:

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