

Our Ref: NR/cds

Brampton Road Hampden Park Eastbourne East Sussex BN22 9AG Telephone (0323) 501111 Telex 877411

c.c. C G Blatchford

File: Recalls Factorate Reader

Dr D Thomas,
National Institute for Biological
Standards and Control,
Holly Hill,
Hampstead,
London. NW3 6RB

7th October, 1986

Dear Dr Thomas,

I refer to our telephone conversation today, in which I informed you of the withdrawal of FACTORATE from the UK market.

I enclose, for your files, a copy of the recall letter and the press release.

Yours sincerely, RORER HEALTH CARE LIMITED

GRO-C

N Randall, PhD., CChem., FRSC., FIQA Quality Control Manager

Encs.

To: R Goodsman

From: Lynette Field

Date: October 7th, 1986

Subject: OUTSTANDING FACTORATE ORDERS

Ref: LF/cen

Copies to:

J Michelmore J T A Moore C J Bloor Please cancel all outstanding Factorate orders - details

to follow.

Regards,

Lynette Field

Inter-office memorandum

ARMOUR003116



Armour Pharmaceutical Company Limited

St. Leonards House, St. Leonards Road, Eastbourne, Sussex BN21 3YG Telephone: Eastbourne (0323) 21422 Telex: 87141

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