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TELECOPY MESSAGE - TRANSMITTED 18.2.86

Fertile But Tired

REVION HEALTH CARE (UK) LIMITED



Armour Pharmaceutical
Company Limited
B0000072

INTER OFFICE MEMORANDUM

R. B. C.
19 FEB 1986



TO : Dr C Swartz

DATE: 17.2.86

FROM : Dr P Harris

REF: PAH/LEW

SUBJECT : FACTORATE CONCENTRATE - ALERT CONDITION

COPIES TO :

Dr Tretter
Mr Christie
Mr C Bishop
Mr P Lloyd

Dear Charles

Please find attached a copy of my memo on the above. You will note that our Department of Health wish to receive details of our viral inactivation studies of this product, including those involved with spiking using HTLV-III virus.

I would be most grateful if you would have these data sent to me by courier at your earliest convenience.

Thank you for your help in this regard.

GRO-C: L Wilson

pp Dr Peter Harris

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REVION HEALTH CARE (UK) LIMITED



INTER OFFICE MEMORANDUM **R. B. C.**

19 FEB 1986

TO : Mr K W Fitch

DATE: 17.2.86

FROM : Dr P A Harris

REF: PAH/LEW

SUBJECT : **ALERT CONDITION - FACTORATE**

CONFIDENTIAL

COPIES TO :

Dr J Tretter
Mr P Edgworth
Mr Galvan
Mr P Lloyd
Mr J Moore
Mr J Michelmore
Mr A Sheppard
Mr S Tomlin
Mr R Christie
Mr C Bishop
Dr G Freischutz
Dr C Swartz

On 13th February I received a telephone call from Dr Rotblatt of the DHSS Medicines Division concerning a Dutch patient who was alleged to have contracted AIDS after receiving heat-treated Factorate. This revelation, along with information on three cases said to have occurred in the USA, was made by Dr Peter Jones of the Royal Victoria Infirmary, Newcastle at an AIDS meeting in Newcastle on 12th February 1986. Dr Rotblatt wanted confirmation that all our Factorate now being supplied is collected from individually AIDS tested donors; I gave her this confirmation and after discussing this with both Chris Bishop and Peter Lloyd it has been agreed that, although we still hold stocks of product from untested donors, this will no longer be supplied by us.

Dr Rotblatt also requested further information on the Dutch case. I spoke with both Mr Henk Beunk and Mr Jan Vanhalle in Holland and Mr Vanhalle agreed to relay to me by courier a preliminary report obtained from Dr Ten Cate from Amsterdam on the Dutch case.

PAH, RBC and CB on 14th February met and agreed an outline communication to send to our plasma field force. RBC and PAH finalised this on Monday morning for immediate transmission to the field force via Chris Bishop's office.

PAH confirmed with Dr Rotblatt that further data were being sent from Holland and that the company would be in touch with her early the following week. I discussed matters with Dr Freischutz in Woelm and asked him to confirm that batch X57610-6 was heat-treated and this he subsequently confirmed. The importance of this particular batch is that we were notified last year by Tuckahoe that one of the donors of this batch subsequently developed clinical AIDS. Mr Vanhalle had indicated that the alleged patient in Holland had received, inter alia, one or more treatments with this batch number.

Monday lunchtime I received a communication from Holland. In the communication it is stated that two sero-conversions occurred among 15 recipients of intermediate purity Factorate concentrate (Armour USA). One of these patients was discounted as having also received non heat-treated Factorate products. The other patient received exclusively dry heat-treated Factorate concentrate. This was a 27 year old male, sero-negative to HTLV-III, with severe haemophilia, who since 1983 was maintained on heat-treated Factorate, home treatment and prophylaxis. He presented in January 1985 with fatigue and fever. On examination,

he had a persistent, unexplained lymphadenopathy with splenomegaly. He had no history of other recent illness, no history of drug abuse nor homosexuality. Serological testing by direct binding assay detected HTLV-III antibodies which was confirmed by immunoblotting. Antibody titre was 226 which subsequently rose to 7140. Viral cultures from patient's plasma were negative.

The batch numbers received by the patient since January 1984 were as follows:-

7060315, 7640418, 1950116, AX19501/6, 51108/12, AX28304/5, X57610/6, X24003, Y6630115, 4180619, AY92609, Y663011, AY87308, Y98611-3

Confirmation will be sought from Germany that all of these batches, which were supplied from Germany to Tramedico and thence to this patient, were all heat-treated.

This afternoon, in my absence, Dr Rotblatt from the DHSS called again. Dr Jones had further informed her that there were two cases in Holland (as above). Dr Rotblatt asked for our heat-treatment process which Mr Christie gave to her as 60°C for 30 hours. She further asked for us to submit to her full documentation of our vial inactivation studies. She stated that she was looking for confirmation of a lethal process for spiked plasma samples. Finally, she stated that Dr Jones had told her that someone in the US (? a Dr Levi) is alleged to have cultured HTLV-III virus from Armour's heat-treated concentrate. She has naturally asked for our formal comment on this observation.

Both RBC and PAH had unsuccessfully tried to contact the Dutch clinicians today and further attempts will be made in the morning, subsequent to a probable visit by one or both to further discuss this particular case.

GRO-C: L Wilson

PP Dr Peter Harris