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REVLON HEALTH CARE (U.K.) LIMITED

TO: Plasma Team

FROM: Mr. R. B. Christie

DATE: February 17, 1986

THIS MEDICAL BULLETIN IS NOT FOR DISTRIBUTION TO THE MEDICAL PROFESSION AND IS FOR YOUR ATTENTION ONLY

SUBJECT: HEAT TREATED FACTOR VIII AND AIDS RISK

As you are aware, Dr. Peter Jones has made observations at a recent AIDS Conference in Newcastle that cast doubt on the efficacy of heat treatment of Factor VIII products as a means of killing the HTLV-III virus.

You can rest assured that we have already contacted the specialist in Holland and that we are in the process of obtaining all details of the Dutch case cited by Dr. Jones. Having regard to the views expressed by Dr. Tedder, that the HTLV-III virus may have a much longer incubation period (up to 4 years) than originally believed, any patients previously treated with an unheated blood product within the last four years could theoretically have acquired an infection from this source.

We therefore take the view that the statement by Dr. Jones was speculative and premature, and the criticism from Professor Donald Acheson of the DHSS as reported in the Guardian is worthy of note **"It was an error of judgment for him to go public on scanty and slender evidence". The thousands of haemophiliacs who needed the life-saving treatment could be confident that they were receiving safe supplies.**

GRO-C

R. B. CHRISTIE,
DIRECTOR, CLINICAL SCIENCES

REVLON HEALTH CARE (UK) LIMITED

Armour Pharmaceutical Company Limited
B0000084/2

BERK Pharmaceuticals Ltd.

INTER OFFICE MEMORANDUM

TO : See Distribution

DATE: 3rd March 1986.

FROM : C.R. Bishop

REF: CRB/BAK

SUBJECT : STATUS REPORT ON FACTORATE AND HTLV-III/LAV SERO-CONVERSION

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Background

12.2.86 - Dr. P. Jones expressed doubt regarding efficacy of HTLV-III inactivation by heat treatment and cited 3 U.S. and 1 Dutch case of sero-conversion.

13.2.86 - Dr. Rotblatt (D.H.S.S.) requested confirmation that all FACTORATE being supplied is HTLV-III donor tested and further information on the Dutch case treated with Armour product.

- All U.K. unscreened product quarantined and U.S. asked for viral inactivation data.

- D.H.S.S. (Professor Acheson) refuted Dr. Jones' comments and confirmed safety of heat treated Factor VIII.

17.2.86 - A Technical Bulletin was issued to the Plasma Team based on Professor Acheson's comments.

18.2.86 - Dr. P. Harris and R.B. Christie visited Dr. Ten Cate in Holland to elicit full facts and a copy of the proposed letter to New England Journal of Medicine outlining the case was obtained, which confirms sero-conversion on Armour's I.P. or H.P. heat-treated products.

19.2.86 - Dr. P. Jones was asked (P. Harris) for further details of the U.S. cases cited 12.2.86.

24.2.86 - U.K. Meeting discussed U.S. PEC decisions to:-

(a) Investigate new heat treatment methods (Dr.'s Rodell/Terry)
(b) Embargo on all shipments of non-tested products.
(c) Meet with F.D.A. on 25th February (Dr. Rodell).

(d) Delay any action with Customers.

and confirmed:-

(i) Embargo on all U.K batches from untested donors (13.2).
(ii) Quarantine of all stock in foreign distributors (pended awaiting J. Michelmore release of telex).
(iii) Imminent meeting with D.H.S.S. (3.3.) with U.S. representative to discuss data.

25.2.86 - Report on sero-conversion on U.K. patient (Dr. Whitemore) who received Factorate material from an 'AIDS' donor.

28.2.86 - Senior Executive Meeting - Fort Washington - confirmed the policy:-

(a) Only heat treated Factorate from HTLV III tested donors to be supplied.
(b) No requirement for a full product recall.
(c) Unscreened product could be supplied if, e.g. potency requirements and the clinician deemed it necessary.
(d) A replacement batch of HP/HT screened product to go to Sweden via packing in Eschwege to fulfil promise to Professor Nilsson.

3.3.86 - Report on visit to D.H.S.S. today awaited.

Outstanding issues

(i) Voluntary replacement of customer's stock.
(ii) Continued Marketing of Factorate IP and HP in its current form.
(iii) Disposal of existing unscreened product:-

(a) Mechanics.
(b) Financial issues.

(iv) Revision of D & S in the light of:-

(a) Current market forces/competitor activity.
(b) Existing stocks.
(c) Run down and switch to Monoclate.
(d) U.K. self-sufficiency (Dr. Lane - Haemophilia Society Meeting - 1-2.3.86).

(v) Marketing position statement/strategy relative to:-

(a) Existing product IP/HT.
(b) Possible switch to HP/HT.
(c) Competitor (including NHS) claims.
(d) Our own viral inactivation data.
(e) Monoclate activities.
(f) Circular to all Haemophilia Centre Directors.