

Ref: PJ/MB

CONFIDENTIAL

17 March 1986

The Medical Assessor
The Committee on Safety of Medicines
Market Towers
1 Nine Elms Lane
LONDON
SW8 5NQ

Dear Sir

AIDS, heat treatment of clotting factor concentrates and haemophilia

I have now received a confidential reply from Dr Harris, the Medical and Technical Director of Revlon Health Care (UK) Ltd, to my letter of the 25th February. It would appear from Dr Harris' letter that, contrary to an earlier statement made by a representative of the company, factor VIII concentrate which has not been individually donor tested for anti-HTLV III is still in circulation in the United Kingdom.

Dr Harris has kindly given details of the heat inactivation process and its efficiency in-vitro, but the fact that he is now looking to recall material that has not been individually donor tested implies that he too is aware that there may still be in-vivo risk of seroconversion. We are still seeing fluctuations in liver function tests of the type associated with non A non B hepatitis (which may indicate retroviral infection) in our patients despite the use of heat treated material.

I understand fully the difficulty of taking action in this "grey" area but given this further piece of information, and despite the obvious worry it may give to some patients, urge that any material which has not been a) collected in low risk areas, b) individually donor tested and c) heat treated in a manner approved by the Committee on the Safety of Medicines, be withheld, at the very least, from seronegative people.

Yours sincerely

PETER JONES MD FRCP DCH
Director

| | |
|---------------|-------------------|
| cc Dr J Smith | Dr Evatt |
| Dr A Smithies | Professor Rawlins |

Ref: W/28

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17 March 1986

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The Medical Assessor
The Committee on Safety of Medicines
Market Towers
1 Nine Elms Lane
LONDON
SW8 5ND

Dear Sir

AIDS, heat treatment of clotting factor concentrates and Kaposi's

I have now received a confidential reply from Dr Harris, the Medical and Technical Director of Revlon Health Care (UK) Ltd, to my letter of the 5th February. It would appear from Dr Harris' letter that, contrary to an earlier statement made by a representative of the company, factor VIII concentrates which have not been individually donor tested for anti-HIV III is still in circulation in the United Kingdom.

Dr Harris has kindly given details of the heat inactivation process and the efficiency involved, but the fact that he is now looking to recall material that has not been individually donor tested implies that he now is aware that there may still be the risk of seroconversion. We are still seeing "inclusions in liver function tests of the type associated with non A non B hepatitis (which may indicate retroviral infection) in our patients despite the use of heat treated material.

I understand fully the difficulty of taking action in this "grey" area but given this further piece of information, and despite the obvious worry it may give to some patients, urge that any material which has not been (a) collected in low risk areas, (b) individually donor tested and (c) heat treated in a manner approved by the Committee on the Safety of Medicines, be withheld at the very least, from seronegative people.

Yours sincerely

PETER JONES MD FRCP DCH
Director

cc Dr J Smith
Dr A Smith
Dr Evans
Professor Rawlings