

~~RINE~~
UK Reg
General

PJC/BSH

19th July 1990.

Mr. L.R. Whitbread,
Assistant Secretary,
Committee on Safety of
Medicines,
Market Towers,
1 Nine Elms Lane,
London SW6 5NQ.

Dear Mr. Whitbread,

I refer to your letter dated 21st June 1990 concerning HIV 2 testing of blood donors. I have discussed this with Immuno A.G. and I am detailing below their comments on this matter.

1. At the present time plasma donors are not tested for HIV 2 antibodies. So far the health authorities of other countries have not requested such a test. Our in-house pre-clinical tests indicate that for the Immuno inactivation method HIV 2 shows the same inactivation kinetic characteristics as HIV 1.

2. The German health authority "Bundesgesundheitsamp (BGA)" has indicated in their administration procedure plan "Stufenplanverfahren" that beginning with January 1, 1993, all plasma products intended for the German market must be manufactured from plasma which has been tested HIV 2 antibody negative.

In the U.S. authorities so far have not requested HIV 2 testing and it is to be expected that within a short time a recommendation will be issued stating that anti-HIV 2 tests are not bindingly required.

In the whole of the U.S.A. there are at present only 17 individuals known to be anti-HIV 2 positive..

I would point out that plasma donations in the U.S.A. collected at FDA licensed plasmaphoresis stations cannot be tested for HIV 2 antibody until the FDA have given authority for this test to be carried out.

We would point out that we test all plasma pools in Austria for HIV 1 and HIV 2 antibody where we are currently using the Abbott recombinant test kit. When a decision is made to start HIV 2 antibody testing it will take some time for the plasma to work through the production procedure so that products are produced which are from HIV 2 antibody screened donors. Our current estimate is that this may take 9-12 months from the date when donors are first tested.

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In your letter you have not given a date by which HIV 2 antibody testing should be implemented, nor when HIV 2 antibody tested products should be available. We would appreciate further information on this matter as soon as possible.

We are very concerned at the sudden request for HIV 2 antibody testing and we look forward to a reply from you on our comments as soon as possible.

Yours sincerely,
for IMMUNO LIMITED

GRO-C

P.J. Coombes,
Managing Director.

c.c. Mr. Gordon Hellyer
Smith Kline Beechams,
Registration Department.