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CJC/tb/731/85

cc Mr R B Christie

R85/224
DHSS
Day

3 October 1985

Dr M Duncan
Department of Health and Social Security
Market Towers
1 Nine Elms Lane
Vauxhall
LONDON
SW8 5NQ

Dear Dr Duncan

PL 0231/0038 - FACTORATE HEAT-TREATED
(ANTI-HAEMOPHILIC FACTOR) - BATCH NUMBER Y69402

During my recent absence from the office, I understand that your administrative colleagues have been requesting a letter from me in respect of the long term follow-up of patients who received the above batch of material prior to its withdrawal from the UK market. As I recall the situation in June, we did indeed discuss the follow-up of these patients and, as a result, my clinical colleagues wrote, in June, to all the physicians who had had patients exposed to this particular batch. The information requested was:

(i) To provide the number of patients who received Factorate batch Y69402, the dose and the number of separate occasions that the product was administered to individual patients.

(ii) If known, the HTLV-III antibody status of these patients prior to receiving Y69402.

(iii) The patient's clinical condition and immunological status prior to receiving Y69402.

(iv) The patient's current HTLV-III antibody status, and clinical condition, T4 T8 lymphocyte ratio, etc, and then a follow-up at approximately six month intervals for two years.

While we believe that just about every centre is following up its patients with HTLV-III antibody determinations, we have, unfortunately, not received written replies from all despite follow-up. However, we are monitoring the situation to the best of our ability in the hope that some meaningful information can be gleaned from what appeared to be a unique situation that arose earlier this year. This information was conveyed in our letter of 5 June 1985. I recall that we subsequently spoke about the follow-up for a period of time in excess of the two years stated and my clinical colleagues agreed to attempt to obtain this information.

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However, we are entirely dependent on the co-operation of Haemophilia Centre Directors, which is normally very good and helpful. There may be some cases, however, over a long period of time where patients move, are temporarily lost to follow-up, etc, and the agreed testing or clinical observation is missed.

It is hoped that, with the collaboration of the clinicians concerned, we will be able to obtain complete data covering histories over a period of several years on the majority of patients who received batch Y69402.

Apologies for the delay in response and hope that the above answers the query, if you have any additional comment, please let me know.

Yours sincerely

GRO-C

C J Collins
Regulatory Affairs Manager