

REVLON HEALTH CARE (UK) LIMITED

 **Armour Pharmaceutical
Company Limited**
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INTER OFFICE MEMORANDUM


BERK
Pharmaceuticals Ltd.

TO : Mr M Rodell, Tarrytown

DATE: 15 July 1985

FROM : Mr C J Collins

REF: CJC/tb

SUBJECT : FACTORATE - CONTAMINATION WITH HTLV III VIRUS

COPIES TO :

Mr K W Fitch
Dr C J Swartz
Dr P A Harris
R B Christie
Mr C R Bishop
R85/
Day

The current status of the batches received in the UK related to their contamination through plasma donations made by [REDACTED] at Louisville, Kentucky between 25 August 1983 and 22 May 1984 is as follows:

Details of Batches Involved in UK

Two batches of intermediate purity Factorate only are implicated in the UK. Batch details are:

Batch No	Potency	Date of Manufacture	Expiry Date	No of Vials Available for Distribution
Y69402	540 iu	February 1984	February 1986	578
Y77304	565 iu	May 1984	May 1984	628

Both batches had been heat-treated. Batch Y69402 was imported from the USA and had been heat-treated using the conditions and processing now approved under the PL details for PL 0231/0038. Batch Y77304 had been received into the UK non-heat-treated but had been shipped to Germany for heat-treatment using the conditions as for the US product. Since the heat-treatment process was not formally approved at the time these batches were in-house, supply was under named patient conditions. You will recall that around the end of 1984/early 1985 no heat-treated products were PL approved in the UK, but the 'AIDS scare' was at its height and Haemophilia Centre Directors would only accept heat-treated product.

Fate of Each Batch

Batch No Y77304 is currently held in quarantine at Revlon Health Care (UK) Limited, Hampden Park, Eastbourne, pending disposal. No vials were released for sale.

Batch No Y69402. This batch was released for sale on a named patient basis. We did send samples to NIBS & C* in the way normally adopted for batches released under our Product Licence even though there was no need to under 'named patient sale conditions'. The batch was released for sale and sold between 14 December 1984 and 11 January 1985. The batch was supplied to the centres listed below. We requested the return of any material still available and returns to date are given in the right hand column.

* National Institute of Biological Standards and Control, Holly Hill, Hampstead, London.

Centre	No of Vials	No of Vials Returned to 15.7.85
University Hospital Nottingham Dr T E Bletcher	30	11
Royal Victoria Hospital Newcastle Dr P Jones	150	29
Thanet District Hospital Margate Dr M Winter	30	
Southampton General Hospital Dr P Bell	50	
Royal Victoria Hospital Belfast Dr E Mayne	154	
Morrison Hospital Swansea Dr Ishmael	60	2
Lewisham Hospital London Dr D N Whitmore	54	
Royal Hallamshire Hospital Sheffield Dr F E Preston	50	33
TOTAL	578	75

On-going Surveillance Programme

We have agreed with our DHSS that we will endeavour, through the Haemophilia Centre Directors, to follow up the patients who have received batch Y69402 and will check their HTLV III virus antibody status both prior to receipt of the batch concerned (if this is possible) and at intervals over the next two years or so.

I trust this provides you with the information requested in Dr C J Swartz's memo to me of 20 June 1985. If you need clarification of any point, please let me know.

Regards.

GRO-C

Clive J Collins
Regulatory Affairs Manager