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Armour Pharmaceutical Company Limited

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Our Ref. PAG/SY

12th September 1979

The Medical Assessor Committee on Safety of Medicines Finsbury Square House 33-37a Finsbury Square London EC2 1PP

Dear Sir

FACTORATE BATCH T30902

Please find enclosed two Yellow Forms on two patients in the Haemophilia Unit, St Thomas' Hospital, London, who have received Factorate Batch T30902.

Both patients are suffering from hepatitis, they were HbsAg negative before and after treatment, but their liver function tests are abnormal.

We have received no other adverse reactions to this batch of Factorate.

Yours faithfully

GRO-C

Pauline A Goldsmith, B Sc, Dip Inf Sci Medical Services Manager

c.c. Mr R G Butchart

REPORT ON SUSPECTED TOXICITY OR SIDE-EFFECTS

For the information of THE COMMITTEE ON SAFETY OF MEDICINES

NOTES FOR GUIDANCE

- 1. For all drugs, please record serious or unusual reactions. For new drugs record all reactions.
- 2. Record, on the top line, the drug suspected of causing harmful effects to the patient at normal dosage.
- Record all other drugs, including self-medication, taken in the previous 3 months. With congenital abnormalities, record all drugs taken during pregnancy.
- 4. Please do not be deterred from reporting because some details are not known.

Name of Patient: (Required in confidence to allow linkage with other reports for same patient)				From (Name and address): Company doctor or other representative of product licence holder— DR WM SIM MUNRO ARMOUR PHARMACEUTICAL CO LTD HAMPDEN PARK I FASTBOURNE FAST SUSSEX Signed: GRO-C Date: (2 / 9) 39				
Sex M	Age or Date of Birth	Weight if know 85 k	a	DR G HAEMO ST TH LONDO	Name of patient's own doctor (and address if known): DR G C INGRAM HAEMOPHILIA UNIT ST THOMAS' HOSPITAL LONDON			
DRUGS* (Brand name where appropriate)		ROUTE	DOSE	DATES		INDICATIONS		
				From	То			
FACTORATE								
BATCH T30902		īv	5,,700	11/7/79	12/7/79	DENTAL EXTRACTION		
			units					
		X 01140 042						
			0.2164					
						Aga ang h		
(*For Vaccines give Batch No.)			- "2" A - (1877)		in the			
REACTIONS (List separately)			Started	Ended	OUTCOM	E (e.g. fatal: recovered)		
Generally unwell for a few days prior to				21/8/79	The state of the s	Jaundice	still present	
development of jaundice					•	but feels generally well.		
				151124				
						*		
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Additional Notes

HbsAg negative before and after treatment. Liver function tests abnormal.