MR R. G. Butchart

Armour Pharmaceutical Company Limited

Hampden Park, Eastbourne, East Sussex BN22 9AG Registered Office Registered No. 625224 England
Office: tel. Eastbourne (0323) 21422 telex 87141 Armlab Eastbourne
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Our Ref RGB/kj

20th August, 1979.

The Medical Assessor,
Committee on Safety of Medicines,
Finsbury Square House,
33/37A Finsbury Square,
London,
EC2A 1PP.

Dear Sir,

Re: Factorate

Please find enclosed three Yellow Forms each concerning reports of hepatitis following the use of several batches of Factorate.

All three patients developed HBsAg positive hepatitis. HBs antigen positive hepatitis has not previously been reported to any of these batches.

Batch S17405 is, however, a common denominator with respect to all three of these cases and arrangements have been made to re-test this batch for HBs antigen using Dr, David Dane's more sensitive RIA procedure.
Further details of each of the cases have been requested and these shall be forwarded as soon as we receive them.

Yours sincerely,

GRO-C

R. G. Butchart, B Pharm MPS
Clinical Research Officer

Enc.

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IN CONFIDENCE

CSM/AR/IND
B/M272/086

REPORT ON SUSPECTED TOXICITY OR SIDE-EFFECTS

For the information of THE COMMITTEE ON SAFETY OF MEDICINES

GRO-A

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.
3. 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)

GRO-A

From (Name and address):
Company doctor or other representative of product licence holder—

Dr. W. S. Munro,
Armour Pharmaceutical Co Ltd,
Hampden Park, Eastbourne, Sussex

Signed: GRO-C Date: 14th August

Sex	Age or Date of Birth	Weight if known
M		

Name of patient's own doctor (and address if known):
Dr. J. Keith Wood
Consultant Haematologist,
The Leicester Royal Infirmary,
Leicester.

DRUGS* (Brand name where appropriate)	ROUTE	DOSE	DATES From	DATES To	INDICATIONS
FACTORATE					
Batches S12303	iv				
S17405			17/11/78	1/5/79	HAEMOPHILIA A
S18406					
S20107					
(*For Vaccines give Batch No.)					

REACTIONS (List separately)	Started	Ended	OUTCOME (e.g. fatal: recovered)
HEPATITIS			
HBsAg negative on 10/1/79			
became HBsAg positive on 8/5/79			

Additional Notes

Received Factorate as home treatment

Dd 224127 5M 1/73 G. B & S. Ltd. Gp 3613

N CONFIDENCE

CSM/AR/IND
B/M272/086

REPORT ON SUSPECTED TOXICITY OR SIDE-EFFECTS

For the information of THE COMMITTEE ON SAFETY OF MEDICINES

NOTES FOR GUIDANCE

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2. Record, on the top line, the drug suspected of causing harmful effects to the patient at normal dosage.
3. Record all other drugs, including self-medication, taken in the previous 3 months. With congenital abnormalities, record all drug 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. W. S. Munro, Armour Pharmaceutical Co Ltd, Hampden Park, Eastbourne, Sussex. Signed: GRO-C Date: 15th August

Sex	Age or Date of Birth	Weight if known	Name of patient's own doctor (and address if known):
M	21		Dr. T. E. Blecher, Consultant Haematologist, General Hospital, Nottingham.

DRUGS* (Brand name where appropriate)	ROUTE	DOSE	DATES From	DATES To	INDICATIONS
FACTOR VIII					
FACTORATE Batch S15104	iv	8X243i.u.	15.1.79	7.2.79	HAEMOPHILIA A
FACTORATE Batch S17405	iv	7x504 iu	10.3.79	21.4.79	
FACTORATE Batch S16305	iv	4x271 iu	on 21.	3. 79	
FACTORATE Batch S23509	iv	8x235 iu	on 21.	4. 79	
LISTER INSTITUTE FACTOR VIII	iv		FEB AND	MARCH 1979	
(* Vaccines give Batch No.)					

REACTIONS (List separately)	Started	Ended	OUTCOME (e.g. fatal: recovered)
VIRAL HEPATITIS			

Additional Notes

"His serum was found to be strongly positive for HBsAg and Dane particles".

Dd 224427 5M 1/73 G. B & S. Ltd. Gp 3613

CONFIDENCE

CSM/AR/IND
B/M272/086

REPORT ON SUSPECTED TOXICITY OR SIDE-EFFECTS

For the information of THE COMMITTEE ON SAFETY OF MEDICINES

GRO-A

NOTES FOR GUIDANCE

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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. W. S. Munro
Armour Pharmaceutical Co Ltd,
Hampden Park, Eastbourne, Sussex.

Signed: GRO-C Date: *17th August*

Sex	Age or Date of Birth	Weight if known

Name of patient's own doctor (and address if known):
Dr. L. M. Swinburne,
St. James's University Hospital,
Beckett Street, LEEDS.

DRUGS* (Brand name where appropriate)	ROUTE	DOSE	DATES From	DATES To	INDICATIONS
FACTORATE					*HAEMOPHILIA A*
Batch S17405	*iv*		*March*	*1979*	
Batch S16005	*iv*		*January*	*1979*	
ANOTHER FACTOR VIII					
Preparation	*iv*		*January*	*1979*	
(*Vaccines give Batch No.)					

REACTIONS (List separately)	Started	Ended	OUTCOME (e.g. fatal: recovered)
HBsAg positive Hepatitis			

Additional Notes