

# Armour Pharmaceutical Company Limited

Pancedon Park, Eastbourne, Suston, Elish's State in expression of elegations to estate engines. Officer tel, Eastbourne, 21422 (SYD-6343) telek 87141 Armiab Eastbourne. Plant: tel, Eastbourne 51111, telex 877411 Labarm, telegrams and cables: Armolab Eastbourne.

> c.e. Mr. K. W. Fitch Dr. W. S. Munro

Our ref: SES/DA

22nd June, 1978

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

Dear Sir,

## Factorate Batches R8112 and R7411

I enclose a Yellow Form reporting a case of clinical jaundice suspected of being associated with the administration of Factorate batches R8112 and R7411. Seven vials of these batches were administered on the 4th May and the jaundice developed on the 14th May. This is the only report we have received with these batches.

We have written to Dr. Oscier requesting further details of this case but have received nothing to date. We plan to follow this up and will let you have further details as soon as possible.

Yours faithfully,

# GRO-C

Mrs. S. E. Stockman B.Sc., Clinical Officer

Enc.

S. B. Postschier (USA) 1. J. C. van Schelvan (USA) 1. A. Dome, 1984)

## 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

300329

#### 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 Company Ltd., Hampdan Park, Eastbourne, Sussex. Signed: Date: 21/6/75.		
Sex M	Age or Date of Birth	Weight if known	1	Name of patient's own doctor (and address if known): Dr. D. Oscier, Blood Transfusion Centre, Hammersmith Hospital, London. W12 OHS		
Γ 'GS* (Brand name where appropriate)		ROUTE	DOSE	DATES		INDICATIONS
				From	То	
FACTORATE		i/v	7	4.5.78		
Batches R8112 & R7411			vials		********************	
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*						
£ 20						· ·
(*For Vaccines giv	e Batch No.)					
k_sCTIONS (List separately)				Started	Ended	OUTCOME (e.g. fatal: recovered)
Clinical Jaundice				14.5.78	van factoria	
***************************************	15 (8)				•	
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Additional Notes

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