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Your ref

Our ref  
NQL/5/1

Date  
10 June 1987

Dear Mr Donald

CLINICAL TRIALS OF FACTOR VIII: ARRANGEMENTS FOR COMPENSATION

1. The Department has sought Treasury approval to appropriate arrangements for compensation in the event of injury during clinical trials of Factor VIII. We sought cover for those haemophilia patients participating in clinical trials to ascertain the quality and efficacy of new batches of Factor VIII which have been subjected to the improved heat-treatment process.

2. Treasury approval has now been received to a compensation scheme adhering to the guidelines recommended by the Association of the British Pharmaceutical Industries.

3. Claims from a patient or his family which cannot appropriately be resolved by CSA (see paragraph 5) will be considered by a panel of assessors comprising:-

- a. the Legal Adviser, Central Legal Office, CSA (or his deputy)
- b. a Regional Transfusion Director, and
- c. a Chief Administrative Medical Officer or his nominee.

4. Patients participating in the clinical testing of new batches of such Factor VIII may be advised of the existence of the above arrangements.

5. These arrangements do not affect the CSA's delegated powers to make ex-gratia payments of up to £5,000 in certain circumstances (NHS Circulars No 1980(GEN)II and 1985(GEN)17 refer).

I am copying this letter to Professor Cash and to RTDs.

Yours sincerely

*A J Murray*

PP A J MURRAY