NQH 23/1/73

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Dr Keel

Copy: Miss Teale
Mrs Towers
Mr Troup
Mrs Falconer
Mr Bell

OUTSTANDING QUESTIONS ON ASPECTS OF HEPATITIS C

1. As agreed when we met on Friday 14 January, I am writing to consult you on the questions which it seems to me have still to be answered in relation to SNBTS's submission, plus the clinical information I think we need. I would be grateful if you could advise me on the pertinence of these questions, and whether there are any you think I may have missed. I would intend to approach SNBTS for further information, and look to you and/or the haemophilia directors for answers to the "clinical" questions.

Questions Arising From SNBTS Submission

Para.	Question
2.6	What does "co-purify" mean (more info on "purification" of Factor VIII)?
3.2	Ref 16 (published 1985 though submitted 1983) points to abstract in *Hepatology* 2:687, 1982 which suggested insidious progression of NANBH. No mention in SNBTS submission. Can they comment?
4.7	Re reports at a meeting in Hungary about heating to 80° C - were SNBTS up to speed with these developments at the time?
4.10	Was ICTH protocol followed in UK? Did patients in the studies actually know they were being studied; were they told about test results and about their condition ?
5.1	What does "purified" mean in this context? When did SNBTS make the findings about the behaviour of NY under heat treatment?
5.4, 5.5, 5.6	(work on pasteurisation) - when did all this happen?
8.7	When did SNBTS buy these ovens?
9.1	What were the precise timings involved in the clinical evaluation?
10.6	[for DH] comments on SNBTS assertion that commercial imports (predominantly heated at 60-68°C) accounted for about 70% of Factor VIII used in E&W? More precise timings on relative usage of 8Y and commercial imported products in England over the period in question?

General Did SNBTS and their English opposite numbers keep each other posted (and if so, formally or informally) on developments? Did they take each other's work into account when planning R&D?

[well-aware of work going on + picked up expeditiously?]
State of relationships

Clinical Questions

What are:

- The numbers of haemophiliacs infected during the period in question?
- What has happened to them?
- What was haemophilia directors' understanding of the risks involved with Factor VIII at the time in question?
- What was their policy on informing patients of any risks?
- Was it their policy to make any practical distinction between treatment for life-threatening and non-life-threatening incidents?
- What was the policy on the information given to Hepatitis C-infected patients at this time?
- What are the general clinical and statistical expectations of the progression of hepatitis C (i.e. what percentage of people infected with the virus go on to develop liver disease, and what happens to them?) – does it differ in haemophiliacs from the rest of the population?
- What is the prevalence of hepatitis C in the general population?
- What is the availability of treatment, counselling or support for people with the virus, and how has this changed over the years since the mid-eighties?

2. Your comments and advice on both sets of questions would be greatly appreciated.

3. There are also as you know a number of questions set out in the Haemophilia Society's submission and in individual letters, not all of which are germane to the scope of this exercise. Perhaps if we can set aside an hour or two to go through them together with Mrs Falconer (and any other copy recipients who wished to join us) it would enable us to identify answers to the questions asked, or at least to identify ways of finding out the answers. If you agree, can your secretary ring me to arrange a time?

CCD

CHRISTINE DORA
21 January 2000

SEHD: Health Care Policy
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Et GRO-C