WITNESS STATEMENT FROM DR R J PERRY

PENROSE INQUIRY - DR ROBERT PERRY
EVIDENCE ABOUT PACKAGE INSERTS USED WITH PFC AND PFL/BPL CONCENTRATES AND THEIR REFERENCE TO NANBH

Issue in respect of which a statement is sought

1. **Why, prior to March 1987 when Z8 was introduced, did package inserts for SNBTS Factor VIII (and presumably also Factor IX) make no reference to NANBH?**

Response:

The specific wording used in warning statements in product leaflets, product labels and outer packaging was that prescribed by the British Pharmacopoeia and approved by the UK licensing authority following the PFC licence application in March 1978.

Between (at least) 1978 and 1985 the following wording was used in leaflets provided with PFC unheated FVIII and FIX products [1]:-

> ***Description – "Nevertheless none of these tests are of sufficient sensitivity to eliminate the possibility of transmitting hepatitis"***
>
> ***Side Effects – "Complications in the use of FVIII (or FIX) concentrate are rare. Apart from the general complications of hepatitis……..."***

Similarly the following warnings were used on product labels and product packaging respectively:-

> ***Vial Label – "This preparation is of human origin and cannot be assumed to be free of hepatitis virus"***
>
> ***Packaging – "This preparation is of human origin and despite careful screening of donations cannot be assumed to be free of hepatitis virus"***

Following the introduction of FVIII and FIX heat treatment in 1985 the product labels and leaflets were revised as follows:-

> ***FVIII (NY 68°/24hr)***
>
> ***Vial label – "The freeze dried product has been heat treated but cannot be assumed to be non-infective"***
>
> ***Leaflet – "This product has been heat treated at 68°C for twenty four hours in the dried state but it cannot be assumed that the product is non-infective"***
>
> ***FIX (DEFIX HT 80°C/72hrs)***
>
> ***Vial label – not available***

SNBTS DOCUMENT REQUEST No:

2011/00143

Leaflet

Description

"The product has been heat treated at 80°C for seventy two hours in the freeze dried state. This treatment is expected to inactivate viruses associated with the Acquired Immune Deficiency Syndrome (HTLVIII, LAV, ARV). The effect of this heat-treatment on Hepatitis B, and Hepatitis, nonA-nonB has still to be elucidated and therefore, this product cannot be assumed to be non-infective with regard to the hepatitis viruses".

Side Effects

"Apart from the general complications of virus transmission……."

The above statements were designed to comply with regulatory and pharmacopoeial standards and to provide a warning to expert and experienced prescribers of the product (ie Haemophilia doctors) of the generally recognised and understood infectivity risks associated with the use of these products. It was reasonable to assume that these expert users would understand that these risks included NANBH. Explanation of such risks to patients was exclusively the responsibility of Haemophilia doctors.

Notwithstanding that some patients (eg patients on home treatment) would have sight of the information provided by the manufacturer this was not the target audience for the technical information which was required to be included. The requirement for pharmaceutical manufacturers to provide information specifically designed for the patient (patient information leaflets, PILs) did not emerge until 1994[2].

Examples of leaflets held by SNBTS from other manufacturers [1] suggest that the statements included with PFC products were typical of products at that time.

2. When did package inserts for PFL/BPL Factor VIII and Factor IX products first make reference to NANBH?

Response:

I have no information concerning package inserts included with PFL/BPL products.

References

(1) Information provided to Lord Archer by Dr P Foster, September 2007. Document supplied to the Inquiry 16.02.2011 (SNBTS 2010-00011).

(2) The Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994. SI 1994/3144

Statement of Truth:

I believe that the facts stated in this witness statement are true

Signed: GRO-C

Dated: 5/12/2011