WITNESS STATEMENT FROM DR R J PERRY

Issue in respect of which a statement is sought

Topic C3A

The use of blood product concentrates in Scotland in the period between the introduction of NHS heat treated products in 1984 and the supply of NHS products sufficiently treated to inactivate Hepatitis C.

Matters to be included in the statement

1. Heat treated NHS Factor VIII (8Y) , treated at 80 degrees for 72 hours, was introduced in England in September/October 1985 but it was not until May 1987 that NHS heat treated Factor VIII (Z8) treated with the same protocol became available for clinical use in Scotland. What is your recollection of events at this time? In particular what do you remember about the availability in Scotland prior to May 1987 of "hepatitis-safe" Factor VIII products supplied to England? From the copy correspondence attached it looks as though you obtained BPL's 8Y product for previously untreated patients in Edinburgh in the summer of 1986. Was this product available only for patients in Edinburgh or for patients elsewhere in Scotland?

Response:

The development and introduction of Factor VIII (Z8) in Scotland with reference to the development and introduction of 8Y in England and Wales is described in the SNBTS briefing paper (November 2010) and my witness statement on Topic C3 Hepatitis C – Viral Inactivation 1985-1987 (August 2011).

Although we now know that 8Y was a 'hepatitis safe' product its initial introduction in England and Wales was not accompanied by an expectation that the product would necessarily be 'hepatitis safe'. There was no clinical or laboratory evidence to support such a view. The first point at which it became to be regarded as possible or likely that 8Y was 'hepatitis safe' was October 1986 following the presentation of the preliminary 8Y clinical trial data to UK Haemophilia Directors. This may have been preceded around mid 1986 by a sense of increased optimism that 8Y had an increased margin of hepatitis safety compared with other available products. Thus the concept of a 'hepatitis safe' and available product did not exist prior to this time.

It was also widely recognised and understood during the period 1985-87 that the limited supplies of 8Y were only sufficient to meet a minority of the overall requirement for patients in England and Wales and that, given the separate arrangements for meeting the needs of patients in Scotland and Northern Ireland from PFC, the supply of 8Y to Scotland and Northern Ireland would further reduce its already limited availability in England and Wales and this could not be justified. Therefore there was no expectation of or rationale for a routine supply of 8Y to Scotland where a secure supply of 'HIV safe' product had been established and had all but eliminated the requirement for treatment with commercial products which were believed to carry a greater risk of both HIV and NANBH infectivity.

The circumstances surrounding my request to BPL for a small stock of 8Y for Scottish patients are described in the Preliminary Report (paragraphs 10.197 – 10.200). In June 1986 Dr Boulton from the Edinburgh and SE Scotland Transfusion Centre informed me of a report received from Dr Ludlam of a previously untreated (or minimally treated) patient who had developed laboratory evidence of NANBH transmission presumed to have been associated with his treatment with NYFVIII (68°C/24hrs). By this time there was preliminary evidence of at least a reduced risk of NANBH from 8Y and accordingly Dr Ludlam asked SNBTS (via Dr McClelland and Dr Boulton) if it would be possible to obtain from BPL a stock of 8Y (pending the introduction of PFC Z8) which could be used to treat any future patients who presented for treatment and who had no or little previous exposure to coagulation factor concentrates. This seemed to me to be a sensible precautionary measure to cover susceptible patients during the anticipated short period before introduction of the PFC Z8 FVIII product. I also judged that BPL/PFL would be able to support this request for a small stock.

As is clear from the Preliminary Report and the referenced correspondence BPL/PFL supplied 50 vials of 8Y on the understanding that any infectivity data from patients receiving the product could form part of the ongoing safety study. On this basis the product was supplied to PFC and subsequently delivered to the Edinburgh Transfusion Centre. I do not recollect further supplies from BPL being requested by PFC or whether the product supplied was used for this purpose in any patients.
The correspondence between myself and BPL indicates that my intention was to obtain this small working stock for any patient in Scotland and it would have been my view that the product could have been made available to any other Haemophilia Director making a similar request. However I am unable to recall whether such a

Scotland wide arrangement was formally established or whether I or Dr Ludlam advised other Scottish Haemophilia or SNBTS Director colleagues of this arrangement. I believe my view at that time would have been that the selection of products for individual patients was the responsibility of Haemophilia Directors reflecting the clear separation of roles and responsibilities between Manufacturer/Supplier and prescribing doctors although, as evidenced on this occasion, SNBTS would be ready to assist whenever possible and requested to do so. I do not know for certain if Scottish Haemophilia directors made any separate approaches to BPL for 8Y supplies for individual patients. They were clearly free to do so but I am not aware of any occasion on which this occurred except for the under noted occasion in 1988.

The Preliminary Report describes a further event in 1988 (paragraph 10.234) when supplies of 8Y were obtained from BPL to treat a specific Edinburgh patient who exhibited allergic reactions to Z8 and other commercially available products but tolerated 8Y. My recollection is that this arrangement was made directly between Dr Ludlam and BPL without SNBTS involvement. It appears that BPL discontinued supply for this patient in 1988 presumably because of supply pressures on 8Y for patients in England and Wales.

2. When the new products became available in Scotland (Factor IX in October 1985 and Factor VIII in May 1987) what steps, if any, were taken to recall existing stocks?

Response:

Details of the product recalls undertaken during this period and the rationales for the actions taken have been provided to the Inquiry in the attached paper submitted in June 2010 in response to a request from Mr Tullis:-

'Public Inquiry Request for Documentation concerning financial considerations in the "Recall of stocks" in the period 1985-1987'

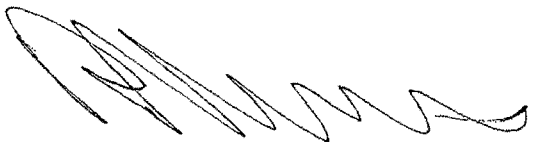
In summary:-

Small residual stocks of NYFVIII (68°C/24hrs) were not recalled following the introduction of Z8 in May 1987 using the established batch dedication system.

Local and PFC stocks of unheated FIX (DEFIX) were 'quarantined' in May 1985 (but not formally recalled). This arrangement was established to ensure the availability of emergency treatment for patients in the event that interim (pending the introduction of PFC heat treated FIX) supplies of heated commercial product could not be maintained or that clinical efficacy or safety issues emerged from the use of heated products in Haemophilia B or other patients. Unheated DEFIX was formally recalled on the 28th October 1985 following the successful clinical and safety evaluation of heat treated DEFIX (HTDEFIX), the establishment of stocks and its introduction into routine use in October 1985.

Statement of Truth

I believe the facts stated in this witness statement are true

Signed 

Dated 12 September 2011