WITNESS STATEMENT FROM DR R J PERRY

Issue in respect of which a statement is sought

Topic C2

Matters to be included in the statement

In the footnote to his C2 supplementary statement Professor Cash refers to documents in 1994 which discuss whether donor plasma sent to BPL for fractionation should be ALT tested with a view to enabling any excess plasma products produced by BPL (in particular, albumin and immunoglobulin) to be exported.

We are unsure whether or not ALT testing of plasma sent to BPL for fractionation was actually introduced in England and Wales and, if it was, when it was introduced and for how long such testing lasted.

Response

The documents referred to by Professor Cash describe discussions between 1989 and 1994 concerning the desirability or otherwise of introducing ALT testing of plasma to be sent to BPL for the manufacture of Intravenous Immunoglobulin. As evidenced by these documents the rationale for this development was primarily based on marketing and commercial considerations for both UK supply and export. There was no suggestion at the time that such a requirement could be justified by scientific or product safety argument.

My understanding of the BPL proposal was that selected centres in England and Wales would be 'contracted' to supply plasmapheresis donations to BPL for on site ALT testing prior to manufacture into intravenous immunoglobulin and other potential export products. It was not intended that whole blood donations should be similarly ALT tested.

My recollection is that, despite the arguments put forward by BPL, their proposals were rejected and the strategy abandoned. It is possible that small scale trials were conducted by one or more of the selected centres prior to this decision but I have (and do not recall having at the time) no information on this. I have contacted current senior staff from BPL who share my recollections but cannot be certain that this was the case.

I have been unable to find any evidence to support my recollections other than a hand written annotation from the SNBTS General Manager (Mr D McIntosh) on Professor Cash's letter to Dr Gunson dated 18th April 1994 in which he states *'OK. Not to be done – Thank Heavens'*.

My understanding also is that, following the abandonment of BPL's original IVIG process as a result of NANBH transmissions to patients during clinical trials, the process subsequently selected in the early 1990's by BPL for the manufacture of their Intravenous Immunoglobulin product (Vigam) was licensed from a commercial fractionation company. The terms of this licence precluded the licensee from supplying the product outside the UK. Thus the key BPL rationale for ALT testing to support export activity became irrelevant.

Irrespective of whether my recollections are accurate, by 1995 (the earliest date by which BPL may have introduced their strategy) the US FDA had concluded that ALT

testing of volunteer blood donors was no longer scientifically valid and could be discontinued. This position was also adopted by the European Commission in 1996. Also by 1995 plasma products were subjected to effective and validated virus inactivation processes and the plasma used in their manufacture was screened for HCV. The introduction of ALT testing in 1995 would therefore have offered no increase in product safety underlining the marketing and commercial motivation for the proposed strategy.
I regret that I am unable to provide an authoritative response to this question. It may be that a formal approach to BPL from the Inquiry could provide further clarification.

Statement of Truth

I believe the facts stated in this witness statement are true

Signed

Dated 18 November 2011