THE PENROSE INQUIRY
STATEMENT OF DUNCAN MACNIVEN
C3: COMPENSATION AND INDEMNITY ARRANGEMENTS FOR Z8

i. My name is Duncan Macniven. I am a retired civil servant. My date of birth is [redacted]. I have been asked to provide this statement because, from May 1986 to July 1989, I was Head of the Division in the Scottish Home and Health Department which was responsible for SNBTS.

ii. I have been asked to comment on the observation that, although Z8 was available for clinical evaluation in December 1986, clinical trials did not begin until March/April 1987 because compensation and indemnity arrangements for patients participating in the trials were not put in place until February 1987 despite the lack of such arrangements having been raised by Dr Ludlam (Consultant Haematologist at the Royal Infirmary of Edinburgh) in 1983.

iii. I recall the subject but can no longer remember, nearly 25 years later, the detailed sequence of events. So this statement is based on consulting the papers provided to me by the Inquiry and also my Division's file (NQL 5/1, Part 1) on the subject.

iv. As I made clear orally at a meeting with Dr Ludlam and others on 9 February 1987, we fully recognised why he was reluctant to trial new blood products without being able to give patients reassurance about compensation in the unlikely event that harm befell them in the trials (SGF.001.2261). SHHD did not have delegated authority to agree a "contingent liability" by offering to compensate patients as Dr Ludlam advocated. We required the approval of the Treasury, which was concerned to ensure that the compensation was a proper use of taxpayers' money.

v. My Division's file suggests that my involvement with the subject began in December 1986, prompted by Dr Ludlam's letter of 5 January 1987 to Dr Cash (SGH.003.1911), of which I had had forewarning from my colleagues Dr McIntyre and Dr Forrester on 29 December 1986 (NQL 5/1, Part 1, page 198). I took steps to seek the urgent approval of Treasury to a compensation scheme (the letter of 14 January 1987 from Mr Kernohan in my Finance Division to Miss Everest-Phillips at

Treasury, NQL 5/1, Part 1, pages 159-160). DHSS made a parallel request, because the same issue had arisen in England. After an exchange of letters with Treasury seeking clarification of the need for a scheme, Treasury approval was given on 5 February (NQL 5/1, Part 1, page 149). This was communicated to Dr Cash by Mr Murray's letter of 6 February (NQL 5/1, Part 1, page 148) and to the Haemophilia Directors (including Dr Ludlam) at the meeting which I attended on 9 February 1987 (SGF.001.2261). As Dr Ludlam's letter of 9 January 1987 shows, we had in the meantime kept him informed of the action we were taking and he was then aware that we expected to be able to give in the near future the reassurance he sought.

vi. There is an important factual point on which I am unclear from the papers I have seen: did the delay in obtaining Treasury authority delay clinical trials? The papers include a letter of 5 December 1986 from Dr Boulton of SNBTS (SNB.007.6274) which makes clear both that the Z8 product was not at that stage ready for trials, and that Dr Mayne (another Consultant Haematologist) was willing to participate in trials of Z8. Dr Cash's letter of 13 January 1987 to Dr Ludlam (SNF.001.3022) shows that the Z8 product (heated to 80°C for 72 hours) was not then ready to trial and that another Consultant Haematologist was willing to trial a different product (heated to 75°C for 72 hours). Dr Forrester's note of 26 February to Mr Murray (NQL 5/1, Part 1, p131) records that Dr Perry of PFC had informed him that trials had by then begun. The briefing for Mr Morison's attendance at the BTS sub-committee meeting on 25 February (NQL 5/1, Part 1, page 133-134) says that "We were in fact able to get Treasury approval for such a compensation scheme in time (though it was a close-run thing)". These documents suggest to me that the observation on which I have been asked to comment is incorrect in respect of the date at which Z8 was ready to trial and it is not clear to me that the lack of formal reassurance on compensation prevented clinical trials going ahead whenever the product was ready.

Statement of Truth

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

Signed .....

Dated ..... 16 September 2011