CONFIDENTIAL

PENROSE INQUIRY – PROFESSOR GORDON LOWE – REQUEST FOR WITNESS STATEMENT – 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*

As I have advised the Inquiry, between October 1985 and May 1987 I was Senior Lecturer in Medicine and Honorary Consultant Physician in the University Medical Unit, Glasgow Royal Infirmary.

From that time, in addition to my NHS duties in General Medicine, Vascular Medicine and Thrombosis, I shared Consultant responsibility for the care of haemophilia patients at Glasgow Royal Infirmary with Dr. Forbes. However, Dr. Forbes as Haemophilia Centre Co-Director was in charge of the Centre's administration and policy and attended the meetings of UK Haemophilia Reference Centre Directors and other Haemophilia administrative bodies, until he moved to Dundee in 1987. I succeeded Dr. Forbes as Haemophilia Centre Co-Director from late 1987, initially with Dr. G.A. MacDonald, Consultant Haematologist, then following his retiral in 1990 with Dr. I.D. Walker, Consultant Haematologist.

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. During this period, was there an awareness among treating haemophilia physicians that the Scottish NHS product was less effectively treated against non A non B hepatitis?*

1.1 I recall that from 1986 (I cannot recall which month) Dr. Forbes informed me that the current SNBTS factor VIII concentrate (heat treated at 68 degrees) might not be effective against non A non B

hepatitis. Hence he, Dr. MacDonald and Dr. Davidson had decided to continue their policy to treat moderately severe patients with haemophilia A or von Willebrand's disease with cryoprecipitate, which had a smaller blood donor pool than factor concentrates, to reduce the risk of non A non B hepatitis.

2. *What was the treatment policy for patients with haemophilia in Scotland in the period between the introduction of NHS heat treated products in 1984 until the supply of "hepatitis-safe" NHS concentrates? More specifically, what steps were taken to reduce the risk of patients acquiring NANBH from their treatment?*

2.1 I recall that in Glasgow Royal Infirmary the Haemophilia Co-Directors' policy was that patients with severe haemophilia A were treated with SNBTS factor VIII concentrates; patients with moderately severe haemophilia A or von Willebrand's disease were treated with cryoprecipitate (as noted above) to reduce the risk of non A non B hepatitis; and patients with mild haemophilia A or von Willebrand's disease were treated with desmopressin (if effective and tolerated) to reduce the risk of non A non B hepatitis.

2.2 The Inquiry produced evidence (letter from Dr. Davidson to Dr. Mitchell) at the oral hearings on June 30 that from April 1985 commercial heat-treated factor IX concentrate was used in Glasgow Royal Infirmary for patients with severe or moderately severe haemophilia B, instead of SNBTS factor IX concentrate, to reduce the risk of non-A non-B hepatitis. I recall that patients with mild haemophilia B were treated with fresh frozen plasma; which had a smaller blood donor pool than factor concentrates, to reduce the risk of non A non B hepatitis.

3. *Were any of the "hepatitis-safe" Factor VIII products supplied to England made available to Scotland prior to May 1987?*

3.1 I have perused the list of factor VIII products used at Glasgow Royal Infirmary in 1985-1987 in the Inquiry's Preliminary Report (Appendix 1).

3.2 I note that in each of these years cryoprecipitate and fresh frozen plasma (FFP) appear, as discussed above.

3.3 In 1985 commercial factor IX (Immuno) appears, as discussed above.

3.4 In each of these years, FEIBA (factor VIII inhibitor bypassing activity) and porcine FVIII appear: these were used for treatment of a small number of patients with factor VIII inhibitors. FEIBA was virally-inactivated, and porcine FVIII would not transmit non A non B hepatitis.

3.5 I cannot see in this table any use of other factor VIII products in 1985-1987; and I cannot recall any being used.

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

4.1 I was not involved in the practicalities of recall of stocks of products, which were arranged by Drs Forbes, MacDonald and Davidson.

Gordon Lowe — 9 September 2011

Signed — Date