Witness Name: Robert Nicholson
Statement No.: WITN7595001
Dated: 15 December 2022

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF ROBERT NICHOLSON

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 15 September 2022.

I, Robert Nicholson, will say as follows: -

I. Preliminary observations

i. I would like to make some preliminary comments that I think are relevant to my written answers. I left Baxter Healthcare Limited in 2001 and after that date I did no further work in the pharmaceutical industry. The questions raised by the Inquiry require me to try to recall events in detail, often involving complex medical and scientific matters, from around 40 years ago. I have had only a few weeks to consider the questions, review the documents provided by the Inquiry and try to recall information. I have done this to the best of my ability but have found this very difficult in the time available. In respect of many of the questions I either have no direct knowledge or no recollection. Where I think I can provide answers I have done so. My answers are the best that I can give at this time, but they may not be accurate as I may have forgotten or confused matters as a result of the passage of time.

ii. I have been asked to consider 40 questions, many with sub questions, and to consider 32 documents. I have read the documents provided to me by the Inquiry and considered the questions diligently and have done my best to answer them in the limited time the Inquiry has provided for my statement to be prepared. Where questions seem to me to be unclear I have tried to identify what I think is the point being raised and answered on that basis. Unfortunately a number of questions ask for information that, because of my role and the work undertaken by the companies I worked for, I have never had the knowledge to answer. There are also subjects and events about which I have no recollection.

iii. For ease of reference, the questions raised in the Rule 9 Request are included below in **bold** and *italics* before my responses.

Section 1: Introduction and professional history

1. ***Please set out your name, address, date of birth and professional qualifications.***

1.1 My full name is Robert Nicholson. I was born on GRO-C 1952 and my address is known to the Inquiry.

1.2 I attended Hull University from 1971 until 1974 and graduated with a BSc in Zoology. I then attended Strathclyde University from 1974 until 1975 and received an MSc in Forensic Science.

2. ***Please set out your employment history including the various roles and responsibilities that you have held throughout your career, as well as the dates. In particular, please set out the timeline of your work with Immuno Ltd. and Baxter Healthcare Ltd, including:***

a. The positions you held from time to time; and

b. The responsibilities that each of those positions entailed.

2.1 Between 1976 and 1979 I worked for Immuno Limited as a Medical Representative. In this role I would visit potential and existing customers, in the Yorkshire and Trent Regional Health Authorities, to promote Immuno Limited's pharmaceutical products and in-vitro diagnostic reagents.

2.2 Between 1979 and 1984 I became a Marketing Executive at Immuno Limited. This was a new role based at the UK Head Office in Sevenoaks. When I started this role, my job was to support the Marketing Manager, who was Peter Coombes, in the marketing function, for the promotion of the company's products. We also had a team of medical representatives working for us. My role largely encompassed writing letters to customers, sending samples or literature which may have been requested from the field staff. I also dealt with technical enquiries and took telephone orders from hospital staff including from staff working within a blood transfusion department or pathology laboratory. Immuno Limited also marketed diagnostic products. This involved creating a price list and printing related literature. I was also involved in the introduction of a new range of diagnostic products manufactured by Ismunit in Italy. This involved training the field staff, liaising with the Italian company and providing technical support.

2.3 At around 1984 I became Marketing Manager at Immuno Limited. This was shortly before Peter Coombes became Managing Director in 1985. I took on more responsibility over the course of my role as Marketing Manager. By 1985 I had begun to visit IMMUNO AG in Vienna, meeting with the Product Management and Registration staff and then reporting back to Immuno Limited on relevant developments and progress.

2.4 At some point during my role as Marketing Manager I also became responsible for the sales team, including providing training, but I cannot recall exactly when this was. Around this time the marketing function created promotional materials, though not for Immuno Limited's coagulation concentrates. This involved me briefing and liaising with advertising agencies. I also had a role recruiting, training and managing

field staff, and organising participation in trade shows, conferences and exhibitions. The Product Manager for the diagnostic range also reported to me for a period, although again I cannot recall the dates.

2.5 In 1987 I was invited to join the Immuno Limited board and my title became Marketing Director. I was Marketing Director from 1987 until Baxter Healthcare took over the company in 1996/1997.

2.6 Immuno Limited also had responsibility for the business in the Republic of Ireland from around 1976 and I took over responsibility for the marketing of products in Ireland when I became Marketing Director in 1987. I would have produced the promotional materials for products supplied in Ireland and had responsibility for the sales person there. I was not responsible for the sale and distribution of products in Ireland.

2.7 When Baxter Healthcare took over Immuno Limited in 1996/1997 I became a Marketing Manager at Baxter Healthcare Limited. My role was purely in relation to marketing and I no longer had any responsibility for sales. I recruited and managed a team of seven dedicated marketing staff.

2.8 At Baxter Healthcare Limited my marketing role covered both Baxter Healthcare products and the products formerly licensed to Immuno Limited. The marketing department was growing and we introduced a home delivery system for patients, who lived far away from the hospital, and patient booklets for children.

2.9 I was a Marketing Manager until 2001, when I left Baxter Healthcare Limited, and I have not worked in the pharmaceutical industry since.

3. Please set out your membership, past or present, of any committees, associations, parties, societies, organisations or groups relevant to the Inquiry's Terms of Reference, including the dates of your membership and the nature of your involvement.

3.1 I cannot recall exact dates but at some point I was a member of the Institute of Biology (now the Royal Society of Biology). During my time at Immuno Limited I was also a member of the British Institute of Regulatory Affairs – I think this was a corporate membership.

4. Please describe the relationship between Immuno Ltd and Immuno AG in Vienna, Austria (please note that the companies are referred to below generally as "Immuno" unless otherwise specifically stated).

4.1 Immuno Limited were the distributors in the UK of finished products which had been developed and produced by IMMUNO AG in Vienna Austria. Immuno Limited liaised with the UK regulatory authorities, obtaining UK licenses for IMMUNO AG produced products, and was a point of contact in the UK generally in relation to the products supplied by IMMUNO AG.

4.2 The relevant scientific knowledge and expertise in relation to the development and manufacture of blood products, as well as the regulatory team, was based at IMMUNO AG and Immuno Limited would consult them whenever detailed knowledge about specific products was required.

5. Please confirm whether you have provided written or oral evidence to, or have been involved in, any other inquiries, investigations, criminal or civil litigation in relation to human immunodeficiency virus ("HIV") and/or hepatitis B virus ("HBV") and/or hepatitis C virus ("HCV") infections and/or variant Creutzfeldt-Jakob disease ("vCJD") in blood and/or blood products. Please provide details of your involvement and copies of any statements or reports that you provided.

5.1 I have not been involved, or provided written or oral evidence, in the circumstances stated.

Section 2: Product warnings and labelling

6. ***Please describe the mechanism by which users of Immuno blood products in the United Kingdom would be provided with information about those products, including warnings about the potential risks associated with them. In particular, was this information limited to the data sheet, leaflet and packaging provided with the product, or was other literature also supplied? (Please answer with particular reference to variants of Kryobulin, Prothromplex and FEIBA.)***

6.1 Immuno Limited's direct contacts were with their customers which were the hospitals and medical professionals who were knowledgeable about the conditions they were treating. The blood products Immuno Limited were supplying were prescribed and Immuno Limited did not communicate directly with the end "users" (if by "users" the Inquiry means the patients). The information provided with the products was strictly controlled by the UK Licensing Authority and there were restrictions on what that information could include.

6.2 I do not recall any information being provided with Kryobulin and Prothomplex other than a Data Sheet and packing information. I have a recollection that some supporting literature for FEIBA was produced for clinicians when it was licensed in the mid-1980s, but I have not been able to verify this. Even this kind of material had to comply with strict criteria and only include information that was supported by evidence and consistent with the Data Sheet for the product. I recall that there was an internal control process before any additional material could be used to ensure that it was also fully compliant with the APBI Code of Practice for the Pharmaceutical Industry ("the ABPI Code of Practice").

7. ***Please explain the process by which the wording of the data sheet, leaflet and packaging, and any other relevant literature, was determined. In particular, please explain:***

a. Your personal role in that process;

7.1 Creating the text of the Data Sheet, leaflet and packaging was not my responsibility at any time during my employment with Immuno Limited. As I recall, the original English text was prepared by IMMUNO AG in Vienna. Having looked at the documents provided to me by the Inquiry I am reminded that Immuno Limited would review the Data Sheet and leaflet and make observations and suggestions on the text. Sometime after I became Marketing Executive I began to have more contact with the regulatory team in Vienna which included liaising with them regarding licensing matters.

b. The role of any other officers or employees of Immuno Ltd;

7.2 My recollection is that Norman Berry and Peter Coombes may have had communications with IMMUNO AG in respect of the wording of Data Sheets and product information.

c. The respective roles of Immuno Ltd and the role of Immuno AG.

7.3 I cannot recall exactly how the process of finalising the text, which accompanied the various products, operated across the period of my employment with Immuno Limited. However, products were licensed and sold in a number of English speaking countries by IMMUNO AG. My recollection is that an English text version of the product information sheet would be prepared by IMMUNO AG for the UK company to review and then submit to the UK Licensing Authority. Immuno Limited might suggest changes in language and also relay comments from the UK Licensing Authority suggesting changes to wording.

8. To whom was the information in the data sheet, leaflet and packaging (and any other relevant literature) directed? In particular, did Immuno intend or expect it to be read by (i) clinicians, (ii) patients (or parents of patients), and/or (iii) both clinicians and patients (or parents of patients).

8.1 I do not recall discussions about to whom the information was directed, the focus was what the regulators determined could be said in the accompanying product information. I think the scope of what could be said was very limited. Immuno Limited's products were supplied to healthcare professionals who could read the Data Sheet and packing leaflet and they were knowledgeable about the treatments they were prescribing.

Warnings about AIDS (Kryobulin)

Please consider the following documents and answer the questions that follow:

- ***HSOC0023097: Letter from Peter Coombes to David Watters of the Haemophilia Society, 10 February 1987;***
- ***PARA0000038: Letter from Mr Coombes to Dr Parapia, Bradford Royal Infirmary, 10 June 1983;***
- ***ABPI0000016, p.3: Entry re. Kryobulin from the Association of the British Pharmaceutical Industry Data Sheet Compendium, 1978;***
- ***ABPI0000035, p.7-8: Entry re. Kryobulin from the Association of the British Pharmaceutical Industry Data Sheet Compendium, 1979-1980;***
- ***ABPI0000036, p.5-6: Entry re. Kryobulin from the Association of the British Pharmaceutical Industry Data Sheet Compendium, 1981-1982;***
- ***ABPI0000037, p.6-7: Entry re. Kryobulin from the Association of the British Pharmaceutical Industry Data Sheet Compendium, 1984-1985;***
- ***ABPI0000022, p.22-23: Entry re. Kryobulin from the Association of the British Pharmaceutical Industry Data Sheet Compendium, 1985-1986;***
- ***ABPI0000024, p.20-21: Entry re. Kryobulin Heat Treated from the Association of the British Pharmaceutical Industry Data Sheet Compendium, 1986-1987;***

- ***ABPI0000030, p.20-21: Entry re. Kryobulin Heat Treated from the Association of the British Pharmaceutical Industry Data Sheet Compendium, 1988-1989;***
- ***ABPI0000031, p.21: Entry re. Kryobulin Heat Treated from the Association of the British Pharmaceutical Industry Data Sheet Compendium, 1989-1990;***
- ***SHPL0000066_001: Letter dated 20 December 1989 from Dipl.Dolm. I. Diernhofer to Mr Coombes attaching copies of various Kryobulin and Prothromplex texts. (Please see Transcript, 24 September 2021, p.23-25 for an explanation of this document and the relevant abbreviations.)***
- ***See also the Transcript of 24 September 2021, p.16-28 and p.36-42. [INQY1000147]***

9. In his letter of 10 February 1987, Mr Coombes told Mr Watters that the only warning regarding viral inactivation on the data sheet and insert leaflet for unheated Kryobulin concerned hepatitis, "as at that time this was thought to be the only problem that could be associated with blood products." He also stated that the statement was changed when dry heated products were introduced in March 1985.

a. Were Mr Coombes' statements on these points correct, to the best of your knowledge and belief?

9.1 I have not looked at documents which track the history of the licensing and supply of Kryobulin and so my answer is given to the best of my recollection and on that basis, yes, I think Peter Coombes' statements were correct. The Kryobulin 'unheated' product to which Peter was referring had been licensed in the UK for a number of years, the initial license dating back to the late 1970s. The information in the Data Sheet for non-heat treated Kryobulin was governed by the relevant license requirements for that product. What I understand Peter was saying was that at the time that non-heat treated products had been licensed, the

focus of attention of the regulator, and the medical community and the industry, was transmission of hepatitis, because knowledge about the virus which was subsequently identified as HTLV-III/HIV was limited and so it had not been identified as a 'problem'.

b. What role, if any, did you play in drafting the letter to Mr Watters?

9.2 I do not recall being involved.

10. It was announced in April 1984 that the virus causing AIDS, then known as HTLV-III, had been identified and that a blood test would be developed. The Inquiry has heard extensive evidence that there had been growing acceptance of the proposition that AIDS was caused by a blood-borne virus from at least late 1982. In March 1983 the FDA had made recommendations about donor selection in an effort to reduce risk. A letter from Mr Coombes to Dr Parapia of Bradford Royal Infirmary confirmed that Immuno were aware of those recommendations and complied with them [PARA0000038].

a. Why was it that Immuno did not include any warning concerning a possible or probable risk of AIDS from the use of its unheated blood products at any time before March 1985?

10.1 I think I had become Marketing Manager by this time. Decisions regarding licensing applications and variations were not my responsibility but as I recall there would need to be an application to change the wording, a company could not do this unilaterally. I cannot recall what was known in 1983 and 1984 about the risk of transmission of the virus and how well those risks were understood within the scientific community.

b. Did you have any concerns at the time that there should have been such a warning? If so, please explain those concerns and any actions that you took about them.

10.2 I do not recall having concerns.

c. Do you have any concerns now that such a warning should have been included?

10.3 I do not think so because that would be based on what we all know about HIV today, rather than reflecting on what was known at the time.

11. What steps would Immuno have need to take had it wished to add a warning about AIDS to the blood products that it sold in the United Kingdom in the period between 1982 and March 1985? In particular:

a. Would it have been necessary to obtain the approval of the Licensing Authority?

11.1 As noted already I was not a regulatory expert. As far as I recall any changes to warning information would have required an application to vary the product licence. Any application would have needed to include data supporting the reason for the change. The UK Licensing Authority would have needed to approve any changes in the warning information.

b. ***Would you have expected the Licensing Authority to agree to such a proposal? Please identify any difficulties that may have arisen.***

11.2. I do not recall that I would have anticipated how the UK Licensing Authority reacted to proposals for changes at this time.

12. The data sheet that accompanied the first (dry) heat-treated Kryobulin product made no express reference to AIDS or to HTLV-III/HIV [HSOC0023098; ABPI0000024, p.20-21; ABPI000030, p.20-21; ABPI0000031, p.21]. What was that? Did you have any concerns, at the time, about the absence of such an explicit warning (and if so, what steps did you take in respect of those concerns)?

12.1 I refer to my answers to questions 10 and 11 in respect of my recollection about how licensing worked and what information accompanied the products. I do not recall having concerns. It is worth restating that the

supply of Immuno Limited products was to healthcare professionals with expertise in this field and with their own knowledge of the developing science.

13. It appears that later information sheets for steam/vapour heat treated Kryobulin contained a more technical description of the effect of heat treatment on samples of the product spiked with HTLV-III [see the examples cited in the Transcript of 24 September 2021, p.40-42]. Is this an accurate assessment, and if so, do you know the reasons for this change of approach?

13.1 I have no personal recollection of these events or the background to the information contained in the later Data Sheets described. However based upon the excerpt of the transcript referenced, Counsel to the Inquiry's suggestion is that Immuno Limited's application was referring to pre-clinical studies which had been carried out with the HTLV-III virus and so there was new data. That seems to me to be a reason for the change but I do not have any independent direct knowledge or recollection of these events.

<u>Warnings concerning hepatitis</u>

Please consider the following documents and answer the questions that follow:

- ***SHPL0000067_056: Fax from you to Mrs Henninger, 19 December 1984;***
- ***SHPL0000067_055: Fax from Mrs Diernhofer to you, 20 December 1984;***
- ***SHPL0000067_053: Fax from you to Mrs Diernhofer, 21 December 1984;***
- ***SHPL0000067_052: Fax from Mrs Diernhofer to Mr Nicholson, 17 January 1985***
- ***SHPL0000114_012: Data sheet for FEIBA Heat Treated, stated date of preparation January 1986;***

- ***ABPI0000024, p.18-19: Entry re. FEIBA Heat Treated from the Association of the British Pharmaceutical Industry Data Sheet Compendium, 1986-1987;***
- ***ABPI0000031, p.20: Entry re. FEIBA Heat Treated from the Association of the British Pharmaceutical Industry Data Sheet Compendium, 1989-1990;***
- ***SHPL0000067_051: Letter from Mrs Diernhofer dated 22 January 1985, including inserts for Kryobulin TIM2;***
- ***See also the Transcript for 24 September 2021, p.59-65. [INQY1000147]***

14. The documents listed above show a discussion between you and Mrs Diernhofer about the appropriate wording concerning steps taken to reduce viral risk in heat treated FEIBA. Counsel to the Inquiry's analysis of the effect of that discussion is set out at p.64-65 of the Transcript of 24 September 2021.

a. Please state whether you agree or disagree with the analysis of Counsel to the Inquiry as set out at p.64-54 of the Transcript of 24 September 2021.

b. Please explain the reasons for holding the views that you expressed in this exchange.

c. Were you concerned with the position that was reached following your exchange with Mrs Diernhofer? Please explain your answer.

d. What, if anything, further could or did you do in response to reaching that position?

e. Please provide any further evidence that you wish to give relating to the exchange with Mrs Diernhofer.

14.1 I had no recollection of this correspondence but having looked at the correspondence selected by the Inquiry, the discussion which is recorded relates to a number of IMMUNO AG products and not just FEIBA. The correspondence also suggests that there were other discussions on this subject which I have not seen. The correspondence provided by the

Inquiry reflects a principle I recognise, which was that if claims were made in respect of products then IMMUNO AG, as the manufacturer, and Immuno Limited, as the licence holder or applicant for the licence, needed to have data and evidence to support the claims made. This is the point that I was making as part of this correspondence in my telex to Mrs Diernhofer dated 21 December 1984 [SHPL0000067_053]. The correspondence reflected a discussion about the technical requirements relevant to each product supplied.

14.2 I note the discussion in respect of this correspondence in the transcript of 24 September 2021 [pages 64 and 65]. This does not accord with my recollections of Immuno Limited's approach or the correspondence which I have been asked to consider. This discussion was about the importance of having relevant data to support claims made. As noted in the telex, dated 21 December 1984, Immuno Limited took the same approach regarding supporting data in respect of licenced and unlicensed products.

14.3 Please note also that I was not expressing a personal opinion to IMMUNO AG in this correspondence; I was simply stating what Immuno Limited's position on this matter was. As regards the remarks in the transcript at [pages 64 and 65] regarding FEIBA's unlicensed supply and Counsel to the Inquiry's analysis, that the language used in leaflets for FEIBA was in opposition to Immuno Limited's comments, this does not accord with my reading of this correspondence, which as noted appears to me to be incomplete. I do not recall and would not consider that the approach of IMMUNO AG to the text of the leaflet was in opposition to, or 'despite', Immuno Limited's advice.

14.4 Mrs Diernhofer and Dr Schwarz recognised the point being made by Immuno Limited regarding the need to respect the 'licensing position' in respect of all the products supplied as is clear from her telex in response dated 17 January 1985. I think in fact we were agreed.

14.5 The suggestion by the Chair of the Inquiry [see page 61] that Immuno was free to say 'as it liked' in the accompanying Data Sheet and pack insert for unlicenced products supplied on a named patient basis does

not accord with my recollection either. The telex of 21 December 1984 reflects Immuno Limited's approach about evidence based claims for all supplied products and my recollection is that Immuno Limited acted within the spirit of the ABPI Code of Practice and was subject to the Medicines Act in respect of unlicensed products.

Section 3: Licensing

15. ***Please describe, in broad terms, your experience of applying for and obtaining product licences for blood products in the UK in the 1980s. Please include an account, in broad terms, of how Immuno Ltd would go about applying for a licence (including any meetings that may be held), and your role in that process. In your view and experience, how stringent, how effective, and how efficient was the licensing process in the UK, and did this change over time?***

15.1 When I was appointed as a Marketing Executive in 1979 I relocated to Immuno Limited's Head Office in Sevenoaks. At that time Norman Berry was the Managing Director and he was communicating with the UK Licensing Authority. Whilst I was a Marketing Executive I began to liaise with IMMUNO AG about issues including licensing, however Norman Berry continued to communicate with the UK Licensing Authority.

15.2 At some time around 1984 I was appointed Marketing Manager. Norman Berry or Peter Coombes would have been Immuno Limited's primary point of contact with the UK Licensing Authority, but at some point in this new role I did begin to liaise with some of the personnel at the UK Licensing Authority, though not on a regular basis.

15.3 In 1987 I was appointed as the Marketing Director. Peter Coombes continued to be the primary point of contact with the UK Licensing Authority. However if something needed clarifying then I might have picked up the

telephone to someone at the UK Licensing Authority, but I do not recall having detailed conversations on the content of product licence applications.

15.4 Immuno Limited was a small company and therefore I had a general idea by talking with Norman Berry and Peter Coombes what the UK Licensing Authority were saying about our product licence applications.

15.5 IMMUNO AG's regulatory function was based in Vienna. In very general terms Immuno Limited acted as a link between IMMUNO AG's regulatory function and the UK Licensing Authority. Immuno Limited submitted product licence application files, which were prepared by IMMUNO AG, to the UK Licensing Authority. We would refer any questions or issues raised by the UK Licensing Authority to IMMUNO AG.

15.6 IMMUNO AG would provide the licence application and determine the content of the submission. If Immuno Limited had observations to make about how the information was presented then we would raise those matters with IMMUNO AG.

15.7 I do not consider that I have the knowledge or expertise to answer how stringent, how effective, and how efficient the licensing process in the UK was, and whether it changed over time.

16. Please describe the division of responsibilities and labour between Immuno Ltd and Immuno AG in applying for UK licences. How effective was the relationship between Immuno Ltd and Immuno AG when it came to licensing matters? Please describe and explain any difficulties or tensions that arose.

16.1 See my answers related to the roles of Immuno Limited and IMMUNO AG above.

16.2 From time to time there may have been differences of opinion between those at Immuno Limited and IMMUNO AG. Looking at the documents provided to me by the Inquiry I note the language describing 'tensions' but that is not how I recall the general working relationship.

17.In a memorandum dated 26 September 1986, you recorded that [SHPL0000075_020]:

> ***"The perception of the UK as a difficult registration area does not help although the prestige of a UK product licence is acknowledged and helps registration in other countries. In addition the UK authorities are seen by some as arrogant, inflexible and unhelpful which I pointed out is not our experience and if information of clarification is needed DHSS are very willing to provide this."***

a. Please explain who held the perception of the UK as being a "difficult registration area" and who considered the UK authorities as arrogant, inflexible and unhelpful? What were your views on these points?

17.1 Document SHPL0000075_020 is a summary of my impressions of conversations I had with members of IMMUNO AG between 22 to 24 September 1986. I do not recall now who at IMMUNO AG may have said they perceived the UK as a 'difficult' registration area. However from paragraph 4 of the memorandum I recorded that the person responsible for UK regulatory matters also dealt with the USA and Japan which I noted in this memorandum as 'difficult' markets. I think it is correct to say that at that time the UK was considered by at least some in the pharmaceutical industry as a difficult market in which to obtain a product licence. The note of a meeting between Immuno Limited and Beecham Pharmaceuticals, document SHPL0000008_108 as referred to at question 18 below includes the observation, "The DHSS is now regarded as one of the most stringent licensing authorities for blood products."

17.2 Document SHPL0000075_020 notes, "In addition the U.K. authorities are seen by some as arrogant, inflexible and unhelpful." This may have been my interpretation of a discussion, or my general perception of a discussion, rather than a direct quote from an individual. My own view at the time on the UK authorities is also noted in document SHPL0000075_020 and counters this perception: that it was, "not our

experience and if information or clarification is needed DHSS are very willing to provide this."

b. What were the wider "registration problems" that are referred to in the memorandum?

17.3 I think this question is referring to the "registration problems" referenced at the sixth paragraph on the second page of this memorandum. Having reviewed this memorandum I believe the "registration problems" I was referring to were delays Immuno Limited had experienced in obtaining documentation, data, or other information for provision to the UK Licensing Authority.

c. At paragraph 6, you noted that "a certain amount of data [has been] produced which for various reasons has not been presented to the UK authorities." Do you recall what these data were, and why they were not presented to the UK authorities?

17.4 I do not recall what data is being referred to or in relation to what products that data had been produced.

18. In the minutes of a meeting between Immuno and Beecham that you attended on 13 October 1987 it is recorded that "The DHSS is now regarded as one of the most stringent licensing authorities for blood products" [SHPL0000008_108].

a. Was this a view that you shared at that time?

18.1 I note that the minutes of this meeting were prepared by Beecham. As I have commented I was not an expert on the approach of the UK Licensing Authority, or other licensing authorities in other markets, so I do not think I can comment further beyond the answers I have already given.

b. To the best of your knowledge, and from your experience, did the stringency of the DHSS as a licensing authority increase, decrease or remain relatively constant during the course of the 1970s and 1980s?

18.2 I think that it was only at some point after 1984, when I became Marketing Manager, that I began to have direct communications with some personnel at the UK Licensing Authority. Due to my limited direct knowledge and experience of the UK Licensing Authority, across the period mentioned, I have no real opinion on whether the "stringency" of the DHSS as a licensing authority changed over this period.

c. How did the UK Licensing Authority compare with international equivalents?

18.3 See my answers to questions 17(a) and 18(a) above.

19. Were there any specific individuals that Immuno had relationships with at the DHSS, and how would this impact Immuno's applications?

19.1 Norman Berry, and then Peter Coombes, were Immuno Limited's primary point of contact with the DHSS. However, if either of them were not available, I liaised with the UK Licensing Authority regarding the licensing of Immuno Limited's products to answer a query or if clarification was needed.

19.2 I would not say that there were individuals at the DHSS with whom I had a relationship. I recall having occasional telephone conversations with the Assessors on the Biological Sub-Committee of the DHSS's Committee on Safety of Medicines ("CSM") relating to the licensing of Immuno Limited's blood products. Particular individuals I recall dealing with included: Frances Rotblat, John Sloggem and Glenda Sylvester. In terms of 'impact' I am not clear what is meant. Individuals at the DHSS would clarify any specific issues regarding Immuno Limited's product licence applications, provide feedback on those applications and, if asked, advise on licensing issues.

20. You wrote a "Dear Doctor" letter dated 11 March 1985 concerning heat treated Kryobulin, which had obtained a UK product licence, and heat treated Prothromplex TIM 4, which at that time did not have a UK product licence [PRSE0002530]. On the latter, you informed doctors that until a licence was obtained, "we can only supply this on a doctor/named patient basis."

a. What was your intention in including the information on Prothromplex TIM 4 in the letter?

20.1 This letter informed clinicians of changes to the product licences for Immuno Limited's Factor VIII and Factor IX coagulation concentrates following the introduction of heat treatment. The status of both of these Immuno products were included in this communication.

20.2 We were communicating with a relatively small number of specialist clinicians and I believe they would have expected to be kept informed of developments around this time relating to the introduction of viral inactivation steps in the manufacture of coagulation concentrates.

b. ***Was it common to include information of this kind about unlicensed blood products in letters to clinicians in this period?***

20.3 Looking back on this correspondence now, my recollection is that it was unusual to include this kind of information about an unlicensed product, but the circumstances at this time were unusual because of the introduction of heat treated products .

20.4 I consider the relatively small number of specialist clinicians receiving this letter would have expected to be told that Prothromplex was no longer available within the UK and, had we not mentioned Prothromplex TIM 4, many of those who had been using Prothromplex would almost certainly have contacted Immuno Limited to ask what product was available.

c. ***The Medicines (Exemption from Licences) (Importation) Order 1984 required those importing medicines without a licence to give an undertaking that they would not "at any time issue or cause another***

person to issue any advertisement or make any representation in respect of that medicinal product and that [they] will sell or supply that medicinal product only in response to a bona fide unsolicited order" [PRSE0000177, article 4(b)(iii)].

i. Did this prohibition apply to the supply of Prothromplex TIM 4 to the UK market in March 1985?

ii. In your view, did your letter of 11 March 1985 comply with article 4(b)(iii) of the 1984 Order? Please explain your answer.

20.5 As already indicated above, at the time the letter was written, we considered it was an appropriate communication. I think the letter would have been reviewed by others at Immuno Limited before it was sent. I have done my best to give my view but I am not a lawyer and so I am not in a position to answer this question regarding the applicability of the legislation.

21. Were you or (to your knowledge) Immuno Ltd ever criticised for advertising or promoting the use of unlicensed medical products, contrary to article 4(b)(iii) of the 1984 Order or any other relevant legal or professional standards?

21.1 I do not recall that I was ever criticised for advertising or promoting unlicensed medical products and I am not aware of Immuno Limited being criticised.

22. The Inquiry has heard evidence about the efforts made to licence FEIBA in the United Kingdom [Transcript of 23 September 2021, p.150-166 INQY1000146]. Counsel to the Inquiry analysed that evidence in the following way [p.166]:

"From our analysis of that chronology, it follows that between the introduction of FEIBA I the mid-1970s to the UK market and the

granting of the variation licence in June 1993, the only time at which variants of FEIBA were provided for use in the UK under a contemporary licence was a 10-month period between October 1985, the date of the first licence, and July 1986, the point at which dry heated FEIBA ceased to be provided. For the rest of this period, approximately 18 years, FEIBA variants were supplied on a named patient basis.

We do note, however, that the licences were granted in 1985 and 1993 for products which had been previously supplied on a named patient basis."

a. Do you agree with Counsel to the Inquiry's analysis of the position in respect of licensing for FEIBA in the UK? If not, please explain the correct position.

If that analysis is correct:

22.1 I have not looked at documents which track the history of the licensing and supply of FEIBA and so I am unable to comment on Counsel to the Inquiry's analysis of events. Whilst I was at Immuno Limited FEIBA was both supplied on a licensed and an unlicensed basis. I do recall that there was a continued dialogue with the UK Licensing Authority regarding efforts by Immuno Limited to get FEIBA licensed in the UK.

b. From your experience, and to the best of your knowledge, why was FEIBA unlicensed for so long?

22.2 FEIBA was licensed in other countries including the USA. It was used in the treatment for that small group of patients who had an inhibitor to Factor VIII which meant that it was a challenge to find an effective treatment for them. Because it was a small percentage of haemophilia patients there was limited data on efficacy; but I recall that there was helpful anecdotal information.

22.3 I believe initially there were concerns on the part of the UK Licensing Authority over the absence of sufficient data to support the efficacy of

FEIBA. I recall the publication of a paper about a trial by Sjamsoedin in 1981 which provided support on the efficacy of FEIBA, other published papers followed and a product licence was granted in the UK. Following the introduction of the S-TIM 4 process (I cannot recall the dates precisely) there was a further delay before that version of FEIBA was licensed as FEIBA Vapour Heated.

c. What were the practical consequences for Immuno Ltd of the product being unlicensed for such a period of time?

22.4 Immuno Limited could not promote the product and in my view that probably affected sales.

d. How was Immuno able to sell substantial quantities of FEIBA while the product was unlicensed?

22.5 FEIBA was being supplied on request and Immuno Limited were meeting a demand. As noted above therapeutic options for patients who developed Factor VIII inhibitors were limited and the response to particular therapies varied from patient to patient. The haemophilia community in Europe and elsewhere communicated about treatments and were aware of developments in therapy options. On that basis clinicians in the UK approached Immuno Limited about supplies of FEIBA, which was licensed in other countries, to treat their patients in the UK. The demand for FEIBA came from the clinicians who wanted to use the product.

22.6 The amount of FEIBA used per patient was unpredictable and could be very high. It would not be unusual for tens of thousands of units to be given to one patient. Whilst a large number of units of FEIBA may have been supplied that does not mean there were a large number of patients receiving the product. My recollection is that only a relatively small number of patients in the UK were being prescribed this product, they were in the tens of patients and not hundreds.

e. In your view, did the sale of significant quantities of FEIBA without a product licence in this period undermine the effectiveness of the product licensing regime in the UK?

22.7 I do not consider myself to be qualified or have had the relevant knowledge to answer this question which is about functioning of the regulatory regime.

f. In your view what effect, if any, did the sale of FEIBA without a product licence in this period have on patient safety in the UK?

22.8 As already stated, my recollection is that the product was considered by some clinicians in the UK to be helpful in treating a challenging condition in specific patients and FEIBA was licensed in other countries. I am not sure I understand the question regarding the effect on patient safety and refer to my answers above.

g. Please provide any further evidence that you wish to provide in respect of the licensing of FEIBA in this period.

22.9 Please see my comments above.

23. Please consider the enclosed documents concerning incidents of unlicensed products being incorrectly labelled as licensed [SHPL0000067_054 and SHPL0000048_015].

a. To the best of your ability and recollection, please explain why blood products were erroneously labelled as licensed.

23.1 I do not recall this specific incident but it would appear to be the result of an error made at IMMUNO AG. It would appear that the PL and PA numbers from previously licensed versions of Kryobulin and Prothromplex were incorrectly included.

23.2 Document SHPL0000067_054 indicates Immuno Limited noted these errors.

b. Were such incidents regular occurrences?

23.3 No, I do not recall any other similar incidents.

c. What, if any, steps were taken to prevent such errors reoccurring?

23.4 I recall that all licensed pharmaceutical products were inspected under the supervision of a "Qualified Person" on arrival at the UK offices. Samples were checked against batch protocols, NIBSC release certificates, and representative packs were checked to ensure the correct labelling had been used. Products would be held in quarantine until such checks had been completed and the batch signed off and released for sale.

23.5 Document SHPL0000067_054 indicates Immuno Limited had checked these unlicensed products and noted the errors made.

23.6 I do not know what steps were taken by IMMUNO AG to try and prevent such errors reoccurring. Immuno Limited continued to check products as described above.

d. Do you recall if the mislabelled products were distributed and used in ignorance of the fact that they were not licensed?

23.7 I do not recall what actually happened with these mislabelled products.

24. The Inquiry has heard evidence that in the second half of the 1980s, Immuno retained some licences for non-heat treated blood products, and dry-heat treated blood products even though these products were apparently not being sold at that time [Transcript of 23 September 2021, p.123-129, p.142-146 INQY1000146].

a. Is that a correct analysis of the situation? In particular, is it correct that the non-heat treated products were not being sold in the UK in the second half of the 1980s.

24.1 Other than the documents provided by the Inquiry in relation to this request I have not looked at documents which track the history of the licensing of blood products. My recollection is that once heat treated products became available non-heat treated products were withdrawn from sale.

b. If that analysis is correct, why did Immuno seek to retain and renew those licences? What was the advantage to the company?

24.2 I note Counsel to the Inquiry's submission on page 124 of the transcript of 23 September 2021, "even though they're not selling that product in the UK they want to maintain the licence so that they can then apply to vary it to produce the steam-treated product rather than starting from scratch and putting in a new licence application. It should be noted that the Licensing Authority were made fully aware of the fact that this is the approach they were seeking to take." As I recall varying the licence rather than applying for a new licence was an advantage to Immuno Limited because the existing license information was retained and did not need to be resubmitted so less documentation needed to be provided for a variation.

c. Did you and, to the best of your knowledge, expect those licences to be renewed by the Licensing Authority? What did you understand to be the advantage to the Licensing Authority of renewing those licences?
(You may wish to comment on the exchange between Counsel to the Inquiry and the Chair at p.143-145 of the Transcript of 23 September 2021.)

24.3 I note pages 144 and 145 of the transcript of 23 September 2021, and Counsel to the Inquiry's submission, citing the Cunliffe Report, that "it's easier for the Licensing Authority to consider an abridged product licence when the licence is already there, and then you look at the steam-treating method or the dry-heat treating method and see if it is sufficient to allow the licence to be granted."

24.4 I was not a regulatory expert so I cannot comment on how the UK Licensing Authority operated and how it viewed license variations. I do not consider myself to be qualified or have had the relevant experience to answer this question further.

25. In general terms, how, if at all, did the unlicensed status of a blood product affect demand for blood products?

25.1 I am not sure whether I understand this question. As noted in my answer to question 22(c), Immuno Limited was unable to promote unlicensed products. I consider the unlicensed status of a blood product would limit the demand for that product. If there was an equivalent therapeutic product then I believe most clinicians might prefer to use a licensed product rather than an unlicensed product.

26. To the best of your knowledge, did NIBSC test unlicensed blood products that were imported into the UK? If so, how did Immuno engage in this process?

26.1 To the best of my recollection NIBSC did not routinely test unlicensed products manufactured by IMMUNO AG.

Section 4: Miscellaneous

Please consider the following documents and answer the questions that follow:

- ***INQY1000147: Transcript of 24 September 2021, p.29-36***
- ***SHPL0000066_001, p.16-21: data sheets for Kryobulin "rot" and "blau"'***
- ***SHPL0000071_130: packaging for Kryobulin red;***
- ***MHRA0033321_022: packaging for Kryobulin blue;***
- ***SHPL0000071_066: fax from Mr Berry to Immuno AG, 9 November 1978;***
- ***SHPL0000071_061: fax from Mrs Diernhofer for Dr Schwarz to Mr Berry (date illegible).***

27. The Inquiry has heard that packaging of Immuno's blood product Kryobulin was made distinguishable by colour (red or blue) depending on the source of the plasma (European or American), but that the geographical source of the plasma was not explained on the packaging, data sheet or insert.

a. Please state whether, to the best of your knowledge, the position summarised by Counsel to the Inquiry at p.29-36 of the Transcript of 24 September 2021 is correct.

27.1 I do not have any detailed knowledge regarding the manufacture of Kryobulin and the sourcing of plasma for the "Red" or "Blue" Kryobulin. However I was aware that the original product with the "Red" label was from European sourced plasma and for some clinicians this product was preferred; which is why it was continued to be supplied after the "Blue" Kryobulin was introduced.

b. Please explain what role, if any, you played <u>at any time</u> in decisions concerning whether or not the geographical origins of the plasma used to produce Kryobulin should be included on the packaging, data sheets or leaflets accompanying the products.

27.2 As noted above I was not involved in such decisions or discussions.

c. To the best of your knowledge, why was the decision made, and maintained, not to include reference to the geographical origins of the plasma used to produce Kryobulin on the packaging, data sheets or leaflets accompanying the products?

27.3 As noted above I was not involved in such decisions or discussions.

d. Did you have any concerns at the time about the lack of reference to the geographical origins of the plasma used to produce Kryobulin on the packaging, data sheets or leaflets accompanying the products? Please explain your answer.

27.4 I was not involved in the decisions regarding packaging and whether to include information about plasma source but I do not recall having concerns about it.

28. Please consider this correspondence sent from you to Mrs Henninger [SHPL0000162_067] and [SHPL0000162_065] both dated May 1989 regarding whether the removal of the lyophilisation step in Albumin would affect product safety regarding Non-A Non-B Hepatitis.

a. To the best of your recollection, were you satisfied with the answer that you were given to your query? Please explain your answer.

28.1 Yes I believe so because, as noted in the answer received, this was supported by expert evidence.

b. Did you take any further steps to obtain information on this point?

28.2 I do not recall doing so.

c. Are you aware of any further research carried out by Immuno AG in respect of the removal of the lyophilisation step?

28.3 I cannot recall what research was undertaken.

d. To the best of your knowledge, were there any subsequent concerns about the safety of the product following the removal of the lyophilisation step?

28.4 No, to the best of my knowledge and recollection.

29. Do you know of any instances of research relevant to the risks of HCV, HIV and other infections posed by Immuno products, or knowledge of risk more generally, being withheld from publication or dissemination?

29.1 I have no knowledge or recollection of relevant research being withheld.

Section 5: Interactions with External Bodies; the DHSS, Haemophilia Centres, UKHCDO and the Haemophilia Society

30. ***Please describe, in broad terms, Immuno's relationship with the Department of Health and Social Security ("DHSS") during the period in which you were employed by Immuno and how, if at all, it changed over time. (Please note it is not necessary to repeat evidence already given about Immuno's relationship with those working on licensing matters.)***

30.1 Please see my comments above.

30.2 I do not think the relationship with the DHSS changed over the period I was employed by Immuno Limited.

30.3 I am not sure whether IMMUNO AG had any direct contact with the DHSS. Some IMMUNO AG scientists may have attended presentations in respect of licence applications.

30.4 Whilst I was employed at Baxter Healthcare Limited, and after a short transition period following the acquisition of Immuno Limited in around 1997, I had no involvement with the DHSS. Baxter Healthcare Limited had its own regulatory department which liaised with the DHSS and I was a Marketing Manager.

31. Please describe, in broad terms, Immuno's relationship with the Blood Products Laboratory in Elstree and the Protein Fractionation Centre in Liberton during the period in which you were employed by Immuno and how, if at all, it changed over time.

a. How did the work of domestic, state fractionators in the UK affect Immuno's approach to the UK market for blood products?

31.1 I had no contact with Blood Products Laboratory ("'BPL") or Protein Fractionation Centre ("PFC"') management, research and development,

or production staff. I did have some limited contact with BPL and PFC sales and marketing staff, for example, we might meet at conferences.

31.2 My recollection is that when BPL and PFC were unable to supply enough factor concentrates, Immuno Limited, amongst the other commercial fractionators, would provide the shortfall. Hospitals would buy the products directly from Immuno Limited. I think all haemophilia treatment centres would buy at least some factor concentrates from the commercial fractionators.

31.3 BPL and PFC products were perhaps the hospitals' first choice but there was often a shortfall in supply. At some point, perhaps in the late 1970s, Immuno Limited had a government contract with NHS Supplies.

31.4 I think whilst I was employed at Immuno Limited the demand for factor concentrates was growing and BPL and PFC could not meet the demand.

31.5 Immuno Limited would try and generate sales ahead of other commercial competitors and offer a competitive price but found it increasingly difficult to compete with the US-based fractionators.

32. Please describe, in broad terms, Immuno's relationship with other Pharmaceutical Companies during the period in which you were employed by Immuno and how, if at all, it changed over time.

32.1 As I recall the other pharmaceutical companies supplying blood products in the UK were Alpha, Armour, Travenol and, to a lesser degree, Speywood. I am not sure if Cutter and Miles were supplying in the UK during the time I was employed by Immuno Limited.

32.2 We would talk to competitor companies when we met at conferences, for example those arranged by the British Blood Transfusion Society and the World Federation of Haemophilia, or at Haemophilia Society meetings and at the annual meetings of the UKHCDO.

32.3 I do not recall that the relationship with other pharmaceutical companies changed during the time I was employed by Immuno Limited.

33. Please describe, in broad terms, Immuno's relationship with clinicians and hospitals during the period in which you were employed by Immuno and how, if at all, it changed over time.

33.1 As noted above, Immuno Limited was a supplier to clinicians and hospitals. Immuno Limited's field staff would visit clinicians, hospital pharmacists and blood bank staff with the aim of maintaining and expanding Immuno Limited's business. Immuno Limited's field staff would make an appointment or see if relevant staff happened to be available when they were visiting the hospital. On occasions a clinician or other member of hospital staff might request an appointment. Meetings with hospital staff would relate to the products used by the clinician or hospital, including how much of a particular product the hospital wanted to order.

33.2 On occasion, if a clinician wanted to discuss a product then a member of the management team might visit them.

33.3 I do not recall the details of meetings I may have attended with specific clinicians or about specific issues. In terms of changes over time I do remember, that when concerns regarding HIV infection grew, there were more discussions regarding donor selection, donor screening and virus inactivation.

34. Please describe, in broad terms, Immuno's relationship with the Haemophilia Society in the UK during the period in which you were employed by Immuno and how, if at all, it changed over time. Please include any specific interactions or meetings with the Haemophilia Society in which you were involved during the 1970's and 1980's.

34.1 The Haemophilia Society would organise meetings for patients to discuss matters affecting the haemophilia community. Immuno Limited might be invited to attend some of the meetings and, when I was working in Head Office, I recall attending such meetings on behalf of Immuno Limited.

34.2 I believe that Immuno Limited would make an annual donation to the Haemophilia Society to support their work. I think that the other pharmaceutical companies supplying blood products may also have done so.

34.3 I cannot recall when or how often but I think that Norman Berry or Peter Coombes may have met with David Watters or other members of the Haemophilia Society's management.

35. Please:

a. Describe, in broad terms, Immuno's relationship with the UK Haemophilia Centre Directors Organisation ("UKHCDO") including Immuno's sales/marketing policies or strategies with regard to UK haemophilia centres/directors during the 1980's. Please include a description of any arrangements which Immuno had for visiting centres/directors and any financial or non-financial assistance or incentives provided to centres and directors.

35.1 Immuno Limited's staff would liaise with UKHCDO members in the same way as with any other clinicians. Please see my answer to question 33 above.

35.2 In addition, Immuno Limited would attend the UKHCDO's annual meeting at which it would have an exhibition stand. We did not attend the closed business meeting sessions that took place at these annual meetings. Immuno Limited would pay a fee to the UKHCDO to cover the costs of the exhibition stand. We may also have provided folders, pens and pads for use at the annual meetings. These items were provided in accordance with the ABPI Code of Practice.

35.3 Immuno Limited might also on occasion have agreed to fund a clinician or nurse to attend one of the big conferences such as those organised by the World Federation of Haemophilia, which was held every couple of years, or the International Society of Thrombosis and Haemostasis, or the British Society for Haematology.

b. Identify any particular haemophilia centre directors in the UK with whom Immuno had a close relationship, sought advice, provided consultancy advice to Immuno or who undertook research for or with Immuno in the 1980's. Please provide details.

35.4 The haemophilia centre directors with which we dealt were the same clinicians we dealt with regularly at hospitals. I recall Professor Eric Preston at the Sheffield Hallamshire Hospital provided advice on a consultancy basis.

36. How would Immuno Ltd seek to persuade clinicians, hospitals and haemophilia centres to use Immuno products? In particular:

a. Who would be the main points of contact (e.g. clinicians or administrators, individual hospitals/haemophilia centres or Regional Health Authorities)?

b. What methods did Immuno Ltd employ to achieve sales, and how did this vary depending on whether the product was licensed or unlicensed?

c. What rules or codes of conduct applied? Were they followed?

36.1 In answer to (a) and (b), as explained in my answer to question 31 above, in relation to the sale of licensed products, Immuno Limited had a contract with NHS Supplies for a period.

36.2 In addition, as noted in my answer to question 33, Immuno Limited's staff would visit the clinicians, hospital pharmacists and blood bank staff to discuss Immuno Limited's products. Field staff would try to identify features of Immuno Limited's products that the clinicians and other hospital staff were interested in and we would try and provide products in a form they wanted. For example by providing the products with lower reconstitution volumes, home treatment packs, storage at room temperature, and alternative pricing based on actual assay values rather than a price based on nominal pack size.

36.3 It was made very clear to Immuno Limited's field staff that discussions in relation to unlicensed products were not to be initiated. A clinician may have heard about an unlicensed product from a colleague in the UK or abroad and therefore might enquire about it. As clinicians were aware that the plasma fractionation process produces a range of products; Immuno Limited might be asked if another blood product was manufactured by IMMUNO AG.

36.4 In answer to part (c) my recollection is that all Immuno Limited activities were carried out in accordance with the ABPI Code of Practice and the relevant sections of the Medicines Act 1968. All field staff were required to pass the ABPI Medical Representatives exam; I think within the first year of employment.

37. Are you aware of any differences in approach adopted by other pharmaceutical companies? Were you aware of any practices that were employed that you considered to be unethical or contrary to contemporaneous legal or professional standards?

37.1 No.

38. Are you aware of any incidents in which Immuno Ltd or Immuno AG offered financial or other inducements to clinicians, hospitals or haemophilia centres with the intention of increasing sales of Immuno products? Please provide as many details as you are able to provide.

38.1 No.

39. Are you aware of any incidents in which other pharmaceutical companies offered financial or other inducements to clinicians, hospitals or haemophilia centres with the intention of increasing sales of Immuno products? Please provide as many details as you are able to provide.

39.1 No.

Section 6: General

40. ***Please provide any further evidence that you wish to provide that is of relevance to the Infected Blood Inquiry, having regard to its Terms of Reference and to the current List of Issues.***

40.1 I have nothing further to add.

Statement of Truth

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

Signed: GRO-C

Dated: 15/12/2022