

Submitted on behalf of Baxter Healthcare Limited

Witness Name: **Bo A. C. Tarras-Wahlberg**

Statement No.: WITN3805001

Exhibits: WITN3805002, WITN3805003, WITN3805004 WITN3805005

Dated: 27 January 2020

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF BO TARRAS-WAHLBERG

I, Bo Tarras-Wahlberg of Baxter Healthcare Limited, Wallingford Road, Compton, Newbury, Berkshire, UK will say as follows:

1. I joined the Baxter group of companies in 2013 as Senior Legal Counsel Nordics. I took the role of Senior Counsel UK, Ireland and Nordics in 2015. In that capacity I have primary conduct of Baxter Healthcare Limited's participation in the Infected Blood Inquiry (the "Inquiry"). This statement is made on behalf of Baxter Healthcare Limited, corporate registration number 00461365, with its registered office address at Caxton Way, Thetford, Norfolk, IP24 3SE. It is noted that in previous correspondence received from the Inquiry, Baxter Healthcare Limited. has been referred to as "Baxter". To distinguish between Baxter Healthcare Limited, UK and the wider Baxter organisation, it will be referred to as "BHL" throughout this statement. As BHL did not own or control any entity that produced blood products manufactured from pooled plasma that were used by the National Health Service in the United Kingdom between 1970 and 1993, it is considered that there are no other "Relevant Entities" as defined in the Inquiry letter dated 7th March 2019.
2. The purpose of this statement is to respond to the request for a written statement in the Inquiry's letter dated 7th March (and restated 11th October 2019) addressed to Ms. Donna Vinnels. These letters are together referred to as the "Inquiry's Letter".
3. Save where otherwise appears, I make this written statement to the best of my knowledge and belief, based upon the information available to me in my role as Senior Counsel UK, Ireland and Nordics and from facts within my own knowledge. Where the facts stated are not within my own knowledge I believe them to be true.

4. The Inquiry's Letter makes four requests for information from BHL. I provide below responses to each of the requests.

THE FIRST REQUEST OF THE INQUIRY'S LETTER: THE CORPORATE ORGANISATION, OWNERSHIP AND STRUCTURE OF BHL FROM 1965 TO DATE

5. In this section, I provide BHL's responses to the Inquiry's first request, set out in paragraph 1 of the Inquiry's Letter. First, I provide a brief overview of the BHL corporate structure and history in relation to the Inquiry's Terms of Reference. I then provide responses to each of the four sub-paragraphs of the first request in turn.

Overview of BHL

BHL is a private limited company limited by shares and was incorporated under the laws of England and Wales under the name "Wallerstein Co. Ltd" on 18th November 1948. The company name was changed from Baxter Laboratories Limited to Travenol Laboratories Limited on the 14th February 1972. Since 1st February 1988, BHL has operated under its current name Baxter Healthcare Limited. BHL's current registered address is Caxton Way, Thetford, Norfolk, IP24 3SE. BHL's business is the manufacture, registration, marketing and sale of prescription medicines and medical devices in the UK.

Details of the BHL corporate structure is not provided here as no entities in said structure are "Relevant Entities" as defined in the Inquiry letter dated 7th March 2019.

As BHL did not manufacture, or own or control any entity that produced blood products manufactured from pooled plasma that were used by the National Health Service in the United Kingdom between 1970 and 1993, it is considered that there are no other "Relevant Entities" as defined in the Inquiry letter dated 7th March 2019.

In June 2015, Baxter International Inc. spun off its Bioscience business to Baxalta Incorporated. At this time, Baxalta UK Limited was formed and the supply of blood products manufactured from pooled plasma in scope of the Inquiry transferred from BHL to Baxalta UK Limited, along with any historic liability.

Response to sub-paragraph 1(a) of the Inquiry's Letter

6. As noted above, there are no Relevant Entities within the definition provided in the Inquiry's Letter. In June 2015, Baxter International Inc. spun off a portion of its business, including its haemophilia treatments, to Baxalta Incorporated. At the time of the spinoff, Baxter's blood factor products manufactured from pooled plasma comprised the products previously sold by Travenol Laboratories Limited and manufactured by Hyland Laboratories and Immuno International AG. Based upon information in the public domain I understand that Shire plc acquired Baxalta Incorporated in June 2016, and Baxalta Incorporated became part of the Shire group of companies, which in its turn became part of Takeda Pharmaceutical Co., Ltd (TPCL) in January 2019.
7. Based upon the information available to me , Table 1. below provides information relating to the Baxter Group entities that produced blood factor products manufactured from pooled plasma that were shipped to the UK between 1970 and 1993, and entities which supplied blood factor products manufactured from pooled plasma in the UK during the same period.

Table 1

Entity	Nature of company and location of registration	Current Ownership	Previous ownership and control
Travenol Laboratories Limited (now Baxter Healthcare Limited)	<p>The name of BHL UK from 1st March 1972 to 1st February 1988. The company is now named Baxter Healthcare Limited and has its registered office at Caxton Way, Thetford, Norfolk, IP24 3SE.</p> <p>Travenol Laboratories Limited's business was the manufacture, registration, marketing and sale of prescription medicines and medical devices in the UK.</p>	BHL remains part of the Baxter group of companies.	The Baxter group of companies acquired Travenol in or around 1948.

	<p>Travenol Laboratories Limited supplied, but did not manufacture, blood products manufactured from pooled plasma in the UK.</p>		
Hyland Laboratories	<p>Hyland Laboratories was a division of the Baxter group of companies based in Glendale, CA, USA with a manufacturing plant in Thousand Oaks CA USA.</p> <p>Blood products manufactured by Hyland Laboratories from pooled plasma were supplied by BHL to the NHS during the relevant period.</p>	<p>With the spin-off of Baxter International Inc.'s BioScience business to Baxalta Incorporated in June 2015, the latter became successor in rights and obligations to BHL's Bioscience business, including the legacy Hyland Laboratories Limited business.</p>	<p>The Baxter group of companies acquired Hyland in 1952.</p> <p>Following the acquisition of Immuno International by Baxter International in 1996, this became known as Hyland Immuno, a division of Baxter International.</p> <p>Since the spin-off of Baxalta, , these facilities are no longer part of the Baxter group of companies.</p>
Immuno Limited	<p>Immuno Limited, Arctic House, Rye Lane, Dunton Green, Sevenoaks, Kent, TN14 5HB, United Kingdom.</p> <p>Following the acquisition of Immuno International AG by Baxter International in 1996, Immuno Ltd</p>	<p>With the spin-off of Baxter International Inc.'s BioScience business to Baxalta Incorporated in June 2015, the latter became successor in rights and obligations to BHL's Bioscience</p>	<p>Immuno International AG was acquired by Baxter International in 1996 and was renamed Baxter AG in 1999.</p> <p>Immuno International AG was founded in 1960 with its principal place of business in</p>

	<p>became part of BHL and its national marketing authorisations were transferred to BHL.</p> <p>Prior to 1996 blood products manufactured from pooled plasma were supplied by Immuno Limited during the relevant period. Immuno Limited did not manufacture blood products manufactured from pooled plasma.</p>	<p>business, including the legacy Immuno Limited business.</p>	<p>Vienna.</p> <p>Immuno International AG was a parent company for Immuno Ltd.</p> <p>Further information regarding the historical ownership and control of this entity is not known by BHL.</p>
Baxalta UK Limited	<p>Private limited company with registered address at 1 Kingdom Street, London, United Kingdom, W2 6BD.</p>	<p>It is understood that Shire Pharmaceutical Holdings Ireland Limited is the indirect owner of Baxalta Incorporated, which is in turn the indirect owner of Baxalta UK Limited.</p>	<p>Incorporated on 3 October 2014 as a private limited company and wholly owned subsidiary of Baxalta UK Holdco Limited.</p>

Response to sub-paragraph 1(b) of the Inquiry's Letter

8. As noted above, there are no other "Relevant Entities" as defined in the Inquiry letter dated 7th March 2019. The extent of the legal and corporate relationship between BHL and those entities listed in Table 1 is detailed therein.

Response to sub-paragraph 1(c) of the Inquiry's Letter

9. As stated, BHL did not manufacture any blood products from pooled plasma during the period of 1970 and 1993.

BHL did however supply blood products manufactured by Hyland Laboratories in the UK to NHS entities between 1970 and 1993.

In July 2015, BHL transferred any records existing and concerning the distribution of blood products to Baxalta UK Limited as part of the spin-off. I have had sight of the written statement provided by Shire and am aware that this included information regarding the products supplied.

Where products held Marketing Authorisations, the Marketing Authorisation Holder was BHL (previously named Travenol Laboratories Limited) between 1970 and 1993.

Immuno Limited: It is understood that Immuno Limited did not manufacture blood products, but it sold blood products in the UK that were manufactured by its affiliate, Immuno AG, Vienna (which was renamed Baxter AG in 1999). BHL transferred any existing records concerning the distribution of blood products to Baxalta UK Limited in July 2015. I have had sight of the written statement provided by Shire and am aware that this included information regarding the products distributed in the UK to various NHS entities between 1970 and 1993.

Response to sub-paragraph 1(d) of the Inquiry's Letter

10. In relation to the queries raised under subparagraph "i" and "ii", BHL no longer holds information with which to respond. However, I have had sight of the written statement provided by Shire and am aware that this included information regarding the products supplied in the UK between 1970 and 1993, the entities which distributed the products, along with the periods during which each product was supplied. In relation to the queries raised in subparagraphs "iii" and "iv", I refer the Inquiry to Table 1 above where I provide what information I can in relation to the entities that distributed the products.

THE SECOND REQUEST OF THE INQUIRY'S LETTER: AN ACCOUNT OF THE ARCHIVING SYSTEM OF BAXTER AND THE RELEVANT ENTITIES,

12. BHL falls under the scope of the Baxter Global Quality Requirements GQR-04 document, of which (i) the Global Policy Process GQP-04-01 (which describes requirements for archiving records), and (ii) Documentation and Records Retention Process GQP-04-03, both form a part. As noted above, there are no "Relevant Entities" as defined in the Inquiry letter dated 7th March 2019.

The aforementioned corporate procedures have been in place since 2007. Prior to this date record management was governed by local procedures.

Note that as a general rule and in line with the Baxter internal quality system, any new policy or procedure, including any archiving and retention policy, supersedes previous versions, which consequently become obsolete. Therefore, any archiving or retention policy or procedures in place during the period of 1970 – 1993 are no longer applicable, including any policy prescribing longer retention periods than the current applicable retention policy. For the current retention periods, please see response to question 4. In any event, policies and procedures prior to 2007 are no longer available.

The above-mentioned policies and procedures are provided as follows:

Exhibit WITN3805002 - GQR-04 - Baxter Global Quality Requirements

Exhibit WITN3805003 -, GQP-04-01 - Baxter Global Policy Process

Exhibit WITN3805004 - GQP-04-03 - Baxter Documentation and Records Retention Process

THE THIRD REQUEST OF THE INQUIRY'S LETTER: AN ACCOUNT AND LIST OF ALL REPOSITORIES HOLDING MATERIALS CREATED, OWNED OR CONTROLLED BY BHL AND THE RELEVANT ENTITIES

13. With the spinoff of Baxalta UK Limited, a review of the existing UK hard copy and electronic archives was completed by individuals who subsequently became employees of Baxalta UK Limited. These records were removed from the BHL archive.

Baxter International Inc. also went through a comprehensive process and searched all relevant data systems (including file share sites) and then transferred this data to Baxalta Incorporated. Once Baxalta Incorporated confirmed receipt of this data Baxter

International Inc. purged any copies of this data. Baxter also went through our paper records and gave Baxalta all those records.

On receipt of the letter from Deirdre Domingo dated 20th September 2018, BHL performed an extensive investigation of our records, including those held at offsite locations and electronically. I am not aware of any other repositories holding materials created, owned or controlled by BHL which are relevant to the Inquiry's Terms of Reference.

Searches were performed using key terms relevant to the Inquiry's Terms of Reference (including product and location names) to cover the timeframe shortly prior to and after the period 1970 to 1993. A small number of documents were identified as a result of this search (as listed in Schedule I attached to our letter dated 25th October 2018 and re submitted here as Exhibit WITN3805005) and these have been provided to the Inquiry. Based upon completion of this search I am confident that all other documents still active under the requirements of our document and records management policies, were removed from BHL systems as part of the Baxalta spin off in 2015.

THE FOURTH REQUEST OF THE INQUIRY'S LETTER: AN ACCOUNT OF THE RETENTION AND DESTRUCTION POLICIES AND PROCESSES OPERATED BY BHL AND THE RELEVANT ENTITIES.

14. As stated above in paragraph 12, BHL falls under the conditions of the Global Quality Requirements GQR-04 document, of which the Global Policy Process and Documentation and Records Retention Process both form a part. These corporate procedures have been in place since 2007. Prior to this date record management was governed by local procedures.

GQP-04-03 provides full details of the documentation and records retention process. This procedure requires all employees to follow retention requirements and retain documents for the longest retention period stated. Please refer to section 6.5 of Exhibit WITN3805004 (GQP-04-03 – Table 1: Global Retention Table).

For medicinal products, such as those covered by the Inquiry's Terms of Reference, GQP-04-03 requires that Product Distribution Records be maintained from the date of distribution plus 5 years, or from the date of product expiration plus 2 years, whichever is longer. On this basis, any such records relating to product distributed between 1970 and 1993 will have been destroyed.

Archiving Records Procedure GQP-04-01, section 6.2.2 describes the requirements for End of Retention Destruction and requires that a record inventory must be updated with the status of records. Today, as and when records are identified for destruction this process will apply.

Any historical destruction records for materials created, owned or controlled by Baxter which are relevant to the Inquiry's Terms of Reference will have been removed from Baxter systems as part of the Baxalta spin off in 2015, to the extent they existed at the time of the spin-off.

Statement of Truth

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

Signed:

GRO-C

Dated:

27 Jan 2020