

Submitted on behalf of Shire Pharmaceuticals Limited
Witness Name: S. O'Reilly
Statement No.: WITN2989001
Exhibits: WITN2989002, WITN2989003, WITN2989004, WITN2989005, WITN2989006,
WITN2989007
Dated: 4 September 2019

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF SUSAN O'REILLY

I, SUSAN O'REILLY of Shire Pharmaceuticals Ireland Limited, Block 2 Miesian Plaza, 50-58 Baggot Street Lower, Dublin 2, will say as follows:

1. I joined the Shire group of companies in September 2015 as International Counsel. I took on the role of Lead Counsel for UK and Ireland in May 2017. In that capacity, I have primary conduct of Shire Pharmaceuticals Limited's ("**SPL**") participation in the Infected Blood Inquiry (the "**Inquiry**"), and I make this statement on behalf of SPL. In this statement I refer to Shire Pharmaceuticals Limited as "SPL" rather than "Shire", as used in the Inquiry's letter, in order to avoid confusion with references to Shire plc or the Shire group of companies.
2. The purpose of this statement is to respond to the request for information made in the Inquiry's letter dated 30 November 2018 addressed to our legal representative for the purposes of the Inquiry, Hogan Lovells International LLP (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 counsel at SPL 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 SPL, set out in paragraphs 1 to 4 of the same. I provide below SPL's responses to each of the requests.

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

5. In this section, I provide SPL'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 SPL 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 SPL

6. SPL is a private company limited by shares that was incorporated as "Aimcane Limited" on 26 June 1986. The company name was changed to Shire Pharmaceuticals Limited on 30 January 1987. SPL's current registered address is 1 Kingdom Street, London, United Kingdom, W2 6BD. SPL's business is the registration, marketing and sale of prescription medicines in the UK. SPL does not manufacture biological products, including blood products. The relevant part of the current SPL corporate structure can be summarised as follows:

- 6.1 SPL is a wholly-owned subsidiary of Baxalta UK Limited ("**Baxalta UK**").
- 6.2 Shire Pharmaceutical Holdings Ireland Limited ("**SPHIL**") is the indirect owner of Baxalta Incorporated, which is in turn the indirect owner of Baxalta UK.
- 6.3 Shire plc was, until recently, the immediate parent of SPHIL. Shire plc was registered in Jersey (No. 99854) and its headquarters were in Ireland. Takeda Pharmaceutical Company Limited ("**TPCL**") acquired Shire plc on 8 January 2019 and in May 2019 Shire plc was converted into a limited company (becoming Shire Limited) and put into voluntary liquidation in July 2019. Prior to its liquidation, Shire Limited transferred its shareholding in SPHIL to TPCL.
- 6.4 SPL has three wholly owned subsidiaries:
- (a) NPS Pharma UK Limited;
 - (b) Shire Human Genetic Therapies UK Limited; and

(c) ViroPharma Limited.

7. The business of the three subsidiaries of SPL does not involve any products relevant to the Inquiry's Terms of Reference and all of these subsidiaries are in fact dormant companies. As far as I am aware, none of the subsidiaries hold any documents relevant to the Terms of Reference. This means that there are no entities that fall within the scope of "Relevant Entities" as defined at subparagraph (ii) of the Inquiry's Letter.
8. For the Inquiry's background, it may be helpful to know that, in June 2015, Baxter International Inc. spun off a portion of its BioScience business to Baxalta Incorporated. This BioScience business included haemophilia treatments and other products manufactured from human plasma. At the time of the spinoff, Baxter's haemophilia treatments comprised the products previously manufactured outside the UK and sold or distributed by Baxter Healthcare Limited, Travenol Laboratories Limited, Hyland Laboratories Limited and Immuno Limited. Shire plc acquired Baxalta Incorporated in June 2016, and Baxalta Incorporated became part of the Shire group of companies.

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

9. As noted above, there are no Relevant Entities within the definition provided in the Inquiry's Letter. As Shire only acquired Baxalta Incorporated in 2016, my understanding of the corporate history of the entities referred to by the Inquiry is very limited but, to the best of my knowledge and from the documents available to me, the table below sets out information relating to the UK entities that provided blood factor products manufactured from pooled plasma that were shipped to the UK between 1970 and 1993. Information responsive to sub-paragraph 1(a) of the Inquiry's Letter that relates to SPL is set out in the previous subsection.

Table 1

Entity	Nature of company and location of registration	Current ownership	Previous ownership and control
Travenol Laboratories Limited (now Baxter Healthcare Limited)	Based on information obtained from Companies House, the company is now named Baxter Healthcare Limited and has its registered office at Caxton Way, Thetford, Norfolk, IP24 3SE.	<p>The company changed its name to Baxter Healthcare Limited in 1988 and remains, to this day, part of the Baxter group of companies.</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 Baxter Healthcare Limited's BioScience business, including the legacy Travenol Laboratories Limited business.</p>	<p>The Baxter group of companies acquired Travenol in or around 1948. Travenol Laboratories Limited changed its name to Baxter Healthcare Limited in 1988.</p> <p>Further information regarding the historical ownership and control of this entity is not known to SPL.</p>
Hyland Laboratories	This information is	With the spin-off of Baxter International	The Baxter group of companies acquired

Limited	not known to SPL.	Inc.'s BioScience business to Baxalta Incorporated in June 2015, the latter became successor in rights and obligations to Baxter Healthcare Limited's BioScience business, including the legacy Hyland Laboratories Limited business.	Hyland in 1952. Further information regarding the historical ownership and control of this entity is not known by SPL.
Immuno Limited	This information is not known to SPL.	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 Baxter Healthcare Limited's BioScience business, including the legacy Immuno Limited business.	Baxter Healthcare Limited purchased all Immuno Limited shares effective 30 November 1997 and thus Immuno Limited merged with Baxter Healthcare Limited. Immuno International AG was renamed Baxter AG in 1999. Immuno International AG was founded in 1960 with its principal place of business in Vienna. Immuno International AG was a parent company for Immuno

			<p>Limited but further details are not known to SPL.</p> <p>Further information regarding the historical ownership and control of this entity is not known by SPL.</p>
Baxalta UK Limited	Private limited company with registered address at 1 Kingdom Street, London, United Kingdom, W2 6BD.	See paragraph 6.2 above.	<p>Incorporated on 3 October 2014 as a private limited company and wholly owned subsidiary of Baxalta UK Holdco Limited.</p> <p>The current owner of Baxalta UK Limited is Baxalta Holding BV which is ultimately owned by TPCL.</p>

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

10. As noted above, SPL does not have control of any of the entities mentioned in the Inquiry's Letter and there are no Relevant Entities as defined in the Inquiry's Letter.
11. The extent of the legal and corporate relationship between SPL and Baxalta UK is set out above in paragraph 6. There is no legal or corporate relationship between SPL and Hyland Laboratories Limited, Travenol Laboratories Limited or Immuno Limited.

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

12. **SPL:** SPL did not manufacture any blood products during the period of 1970 and 1993. As noted above, none of SPL's direct subsidiaries manufactured blood products during the period of 1970 and 1993 either.
13. **Immuno Limited:** I understand that Immuno Limited did not manufacture factor concentrates from pooled plasma but it marketed factor concentrates in the UK that were manufactured from pooled plasma by its affiliate, Immuno AG, Vienna (which was renamed Baxter AG in 1999). From the documents available to me, I believe that the specific factor concentrates manufactured from pooled plasma by Immuno AG and distributed in the UK to various NHS entities between 1970 and 1993 were:
- Bebulin 200 and 500 (Factor IX)
 - Bebulin TIM 2
 - Bebulin TIM 3
 - Bebulin TIM 3 (amended virus inactivation)
 - Bebulin TIM 4
 - Bebulin S-TIM 4
 - Factor IX S-TIM 4
 - Factor IX
 - Feiba (supplied in the UK between 1983-1988)
 - Feiba VH
 - Feiba TIM 3
 - Feiba TIM 4
 - Feiba S-TIM 3
 - Feiba S-TIM 4

- Kryobulin (small pool preparation)
- Kryobulin (Factor concentrate)
- Kryobulin S
- Kryobulin S-TIM 2
- Kryobulin S-TIM 3
- Kryobulin TIM 2
- Kryobulin TIM 3
- Kryobulin TIM 4
- Prothromplex (Factor II, IX, X)
- Prothromplex (steam treated)
- Prothromplex P
- Prothromplex TIM 3
- Prothromplex TIM 4
- Prothromplex T (FII, FVII, IX, X)

14. **Travenol Laboratories Limited and Hyland Laboratories:** From the documents available to me I believe that the specific factor concentrates manufactured by Travenol, Hyland and Baxter Healthcare Corporation (US) and distributed in the UK to various NHS entities between 1970 and 1993 were:

- Antihemophilic Factor
- AHF (ARC source)
- AHF CT
- AHF-M (ARC Source)

- AHF-T (ARC Source)
 - AHF HT Ultrafiltered (ARC Source)
 - Autoplex
 - Autoplex T
 - Factor IX Complex
 - Factor IX Complex Heat Treated (ARC Source)
 - Hemophil
 - Hemofil (supplied in the UK between 1978-1984)
 - Hemofil C
 - Hemofil CT (Antihemophilic Factor, Heat Treated)
 - Hemofil T (supplied in the UK between 1983-1988) (Antihemophilic Factor, Heat Treated)
 - Hemofil M (supplied in the UK between 1988-1990) (Antihemophilic Factor, Monoclonal Purified)
 - Proplex (supplied in the UK between 1978-1985)
 - Proplex SX
 - Proplex SX-T (supplied in the UK between 1983-1988)
 - Proplex T
15. At some point prior to 1993, Baxter Healthcare Limited became Marketing Authorisation Holder (MAH) of the Travenol and Hyland factor concentrates listed above.

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

16. In relation to the queries raised under subparagraph "i" and "ii", I have provided the products, the entities which distributed the products and the

periods during which the relevant products were supplied (where this information was available) in paragraphs 13 and 14 above.

17. In relation to the queries raised in subparagraphs "iii" and "iv", I refer the Inquiry to Table 1 above where I provide this information in relation to the entities that distributed the products.

THE SECOND AND THIRD REQUESTS OF THE INQUIRY'S LETTER: DOCUMENT REPOSITORIES AND ARCHIVING SYSTEM

18. As described above, the Shire group of companies only became involved in the blood products business when Shire plc acquired Baxalta Incorporated in June 2016. Following the acquisition, SPL acquired some documents from the Baxalta group of companies and these are currently stored in the following repositories (with relevant details as to how they are archived):
 - (a) Historic Immuno documents stored in hard copy at an Iron Mountain facility in Vienna, Austria. The documents held here are historic regulatory documents, such as regulatory filings and licence applications. At some point following the acquisition of Baxalta Incorporated, these paper records were scanned and uploaded into an Electronic Document Management System which was integrated into the current regulatory records repository, BaxEdge. In addition, some data created post-scanning is stored on an Archiving File Share location (and will be transferred into BaxEdge).
 - (b) Historic Baxter documents stored in hard copy at SPL's office in Paddington, London (One Kingdom Street, 9th Floor, Paddington, London, W2 6BD). These documents are UK regulatory documents which are stored across a total of 4 boxes and a filing cabinet, with each box and the filing cabinet containing a varying number of files. In addition, there are some historic Baxter regulatory documents stored on a Regulatory Team local drive at SPL's Paddington office.
 - (c) Historic Baxter documents stored in hard copy at an external Iron Mountain document storage facility in the United Kingdom. This

repository contains a total of 258 boxes. There is an index providing a list of the 258 boxes as well as details of 61 boxes (in addition to the 258 boxes) that were destroyed before Shire plc acquired Baxalta Incorporated. It is possible to run searches across this index but SPL does not have a comprehensive index listing the detailed contents of each box.

19. Various other Shire entities in the US and Belgium hold a voluminous amount of legacy Baxter/Baxalta documents which were transferred to Shire upon the acquisition of Baxalta Incorporated in 2016. These repositories of documents may include documents relevant to the Inquiry's Terms of Reference.
20. Historic Baxter/Baxalta documents are stored in hard copy at an external Merak document storage facility in Belgium. This repository contains 9,900 boxes. There is an index which lists the 9,900 boxes. It is possible to run searches across this index but SPL does not have a comprehensive list of the detailed contents of each box.
21. Furthermore, Baxter's former US Counsel, Dechert LLP, and Hogan Lovells International LLP, Baxter's prior legal representative in various European jurisdictions, also hold documents which may contain documents relevant to the Inquiry's Terms of Reference. From initial inquiries, there are tens of thousands of boxes held across these various repositories. The documents held by Dechert LLP are archived litigation files held on behalf of their client Baxter Healthcare Corporation that relate to the Factor Concentrate litigation in the United States and elsewhere, including the United Kingdom. There are very few documents relating to the United Kingdom and I am informed by Dechert that those that do relate to the UK comprise i. individual case materials such as medical records, ii. privileged documents, and iii. documents relating to Baxter Healthcare Corporation's forum non conveniens motion and subsequent dismissal of the UK plaintiffs' claims in the US.

THE FOURTH REQUEST OF THE INQUIRY'S LETTER: DOCUMENT RETENTION AND DESTRUCTION POLICIES

22. We do not hold copies of historic document retention or document destruction policies for Hyland Laboratories, Travenol Laboratories Limited or Immuno Limited. We do have the current records retention policy for the Shire group of companies, including SPL.
23. We also have some limited document management and retention policies from Baxter and Baxalta that were effective from 2014-2017, as follows:
- (a) Baxalta Quality Record Retention effective from 24 September 2014 **[Exhibit WITN2989002]**;
 - (b) Baxalta Inc Global Information Management Policy effective from 1 July 2015 **[Exhibit WITN2989003]**;
 - (c) Baxter Document and record management requirements effective from 15 October 2015 **[Exhibit WITN2989004]**;
 - (d) Baxalta Record Retention Schedule dated 29 April 2016 **[Exhibit WITN2989005]**;
 - (e) Baxter US supply chain record retention effective from 10 February 2017 **[Exhibit WITN2989006]**; and
 - (f) Baxter records retention schedules 2017 **[Exhibit WITN2989007]**.
24. The exhibited policies are, as far as I am aware, the only document management and retention policies that were transferred to the Shire group following Shire plc's acquisition of Baxalta Incorporated.

Statement of Truth

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

Signed:

GRO-C

Dated:

4th September 2019