

NATIONAL FRACTIONATION AGREEMENT FOR AUSTRALIA

Commonwealth of Australia
acting through and represented by the
National Blood Authority

CSL Behring (Australia) Pty Ltd

Edited version for publication on NBA website

The contract provided here has been edited, and is not in the form as executed.

In addition, certain parts of the contract are not disclosed.

The contract is provided for information only and should not be relied on by any person.
The NBA is not liable for any reliance upon the contract herein which results in loss or damage to any person.

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Chapter 1

About the Deed of Agreement

Chapter outline

This chapter specifies basic details about the Deed, including:

- identification of the parties to the Deed;
- the background to the Deed;
- the relationship principles the Parties intend to apply in managing their relationship under the Deed;
- the commencement and expiry dates of the Deed.

1 Parties

- 1.1 The Parties to this Deed of Agreement are:
- 1.1.1 **Commonwealth of Australia**, acting through and represented by the **National Blood Authority ABN 87 361 602 478**, a Commonwealth agency established under the *National Blood Authority Act 2003* (Cth) (NBA)
 - 1.1.2 **CSL Behring (Australia) Pty Ltd ABN 48 160 734 761**, with the registered address of 45 Poplar Road, Parkville, Victoria 3052 (CSL)

2 Background to the Deed

- 2.1 The NBA operates in accordance with functions and powers set out in the *National Blood Authority Act 2003* (Cth) and the National Blood Agreement referred to in that Act, and is a non-corporate Commonwealth entity for the purposes of the *Public Governance, Performance and Accountability Act 2013* (Cth).
- 2.2 The NBA requires the provision of certain fractionated human blood plasma products and associated services, in connection with the objectives of Australian Governments of ensuring an adequate, safe, secure and affordable supply of blood and blood related products in Australia, on a basis which represents an efficient and effective use of public money.
- 2.3 At the Commencement Date, Australian human blood plasma is obtained through donations collected through the services of the Australian Red Cross Blood Service.
- 2.4 CSL is bound by the provisions of the CSL Act.
- 2.5 CSL has particular expertise and experience in providing the Products and Services and at the Commencement Date is the sole domestic provider of such Products and Services.
- 2.6 CSL has agreed to provide the Products and Services, and the NBA has agreed to make the Payments for those Products and Services, in accordance with the terms and conditions of the Deed.
- 2.7 The Products are ordered by and delivered to Approved Health Providers through channels which are already established as at the Commencement Date. Adequacy and efficiency of the Product supply chain are important aspects of the Services provided under the Deed.
- 2.8 For certainty, this clause 2 does not override or limit the provisions of the Deed.

3 Objectives and principles guiding the relationship of the Parties

- 3.1 Through this Deed, the Parties seek to ensure a safe, secure, adequate and affordable supply of high-quality therapeutic products manufactured from Australian plasma, to the extent that Australian Governments determine from time to time that such products should be funded under the National Blood Arrangements, by achieving the following shared objectives:
- 3.1.1 ensuring that Australian patients continue to have access to care at the forefront of international clinical practice through provision of a broad range of high-quality plasma products manufactured in Australia;
 - 3.1.2 maintaining and developing appropriate and adequate capacity, capability and resources to supply Australia's needs for high-quality products manufactured from Australian plasma;
 - 3.1.3 ensuring value for money for Australian Governments; and
 - 3.1.4 promoting the effective and efficient use of the capacity, capability and resources dedicated to the Deed.
- 3.2 The Parties intend to act towards each other on the basis of the following principles:
- 3.2.1 recognising the importance of maintaining an open and communicative relationship, and achieving this through regular meetings and correspondence to enable optimisation of information flows;
 - 3.2.2 seeking to identify, manage and mitigate risks within their control;
 - 3.2.3 conducting themselves in a spirit of cooperation and good faith;
 - 3.2.4 recognising the financial, legal and accountability frameworks and constraints applying to each Party, in that:
 - (a) CSL is a company operating in accordance with the Corporations Act and applicable Australian Securities Exchange rules;
 - (b) CSL has adopted a Code of Responsible Business Practice; and
 - (c) the NBA is a Commonwealth public authority operating in accordance with the *National Blood Authority Act 2003* (Cth), the National Blood Agreement referred to in that Act, the *Public Governance, Performance and Accountability Act 2013* (Cth), and other applicable Laws and policies of the Commonwealth; and
 - 3.2.5 working together at all times to proactively resolve potential issues of dispute as far as possible and without unnecessary formal escalation process.
- 3.3 CSL and the NBA acknowledge that they will take all reasonable efforts consistent with the Deed to minimise the impact of activities under the Deed on the environment, and agree to:
- 3.3.1 inform the other Party of any applicable environmental Laws, regulations, codes or covenants that may impact materially on the activities under the Deed, and work together to ensure that each Party can, at a minimum,

comply with any mandatory binding environmental Laws, regulations, codes or covenants that apply; and

3.3.2 annually review operations and performance under the Deed to consider environmental issues, and to identify, consider, and where appropriate, take action in respect of any identified areas of potential improvement, through the Deed management process described in clause 7 and Schedule 3.

3.4 For certainty, this clause 3 does not override or limit the provisions of the Deed.

4 Period of operation of the Deed

Commencement

4.1 The Deed commences on the Commencement Date of **1 January 2018**.

Expiry

4.2 The Deed operates until the Expiry Date, which is:

4.2.1 **31 December 2026**;

4.2.2 if so determined by the Contract Term Review - **31 December 2022** or an alternative date as determined under clause 64.5.2(b); or

4.2.3 as otherwise extended by variation, or terminated, in accordance with the Deed.

Note – *Termination of the Deed, and the consequences of expiry or termination, are dealt with in Chapter 8.*

Chapter 2

Managing communications under the Deed

Chapter outline

This chapter sets out how the Parties have agreed to communicate on matters relating to the Deed, including:

- notification of significant Notifiable Events which may affect supply of Products or the operation of the Deed;
- a cycle of Deed management meetings; and
- processes for formal communications under the Deed.

Matters covered in this chapter are detailed more specifically in Schedules 1, 2 and 3 and Templates 1 and 2.

5 Contacts for communications under the Deed

- 5.1 Where a Party has specified a contact person in Schedules 1 or 2 for communications of a particular type under or in relation to the Deed, the Parties agree that communications of that type will be undertaken through that contact person.
- 5.2 Each Party agrees to specify a contact person in Schedule 1 or 2, as the case may be, for the giving and receipt of Formal Notices under the Deed.
- 5.3 Unless specified to the contrary in Schedule 1 or 2, as relevant, a contact person specified in Schedules 1 or 2 may, from time to time, notify the other Party by Formal Notice of their authorised delegates for the purpose of relevant communications under the Deed and of any limitations or conditions applying to the authorisation of the delegate.

6 Notifiable Events

- 6.1 CSL must provide a written report to the NBA in accordance with this clause 6 of the occurrence, or the likely occurrence, of:
- 6.1.1 any of the following events, where the occurrence of the event will or is likely to mean that CSL is not able to supply Products in accordance with the Deed at any time:
- (a) Orders received by CSL for a Product in a month are more than 10% above the level of demand estimated in the then current Annual Supply Estimate for that month;
 - (b) any other material increase in demand not previously foreseen; or
 - (c) material failures in production, Ordering, inventory holding or delivery processes;
- 6.1.2 any other actual or likely inability to supply an Ordered Product meeting the Product Specifications within the required timeframe under the Deed for any reason;
- 6.1.3 an act or omission of CSL, a Subcontractor or its or their Personnel, or any other circumstances, that will or will be likely to cause a material problem or delay in CSL's ability to provide the Products or Services in accordance with the Deed;
- 6.1.4 extraordinary circumstances, or material new or changed risks, that will or are likely to affect Product or Service supply or quality under the Deed;
- 6.1.5 insufficiency of suitable Starting Plasma or a material loss of Starting Plasma;
- 6.1.6 a meeting of CSL's creditors being held or called, where the meeting may be in connection with an Insolvency Event;
- 6.1.7 a change to requirements under, or an action taken by TGA or CSL under, the TG Act which in CSL's opinion will or is likely to have a material impact on CSL's ability to supply Products in accordance with the Deed;
- 6.1.8 any material change in fractionation carried out by CSL at the Broadmeadows facility for customers other than the NBA which in CSL's opinion will or is

- likely to have a material impact on CSL's ability to supply Products in accordance with the Deed; or
- 6.1.9 any other material event or circumstance relevant to this Deed within a class of events or circumstances reasonably nominated by the NBA from time to time.
- 6.2 On becoming aware that a report is required under clause 6.1, CSL must provide the report promptly and in any case within 2 working Days.
- 6.3 The NBA may exclude specified types of events from the operation of clause 6.1 by Formal Notice to CSL.
- 6.4 A written report under clause 6.1 must be prepared in the format specified at Template 1.

7 Deed management process

Scheduled Deed management meetings

- 7.1 The Parties agree to hold the following scheduled meetings in accordance with Schedule 3:
- 7.1.1 Risk Management Workshops;
- 7.1.2 CEO Update and Planning Meetings; and
- 7.1.3 Contract Management Meetings.

Continuous dialogue and additional meetings

- 7.2 In addition to other processes under this Deed, the Parties agree to maintain a continuous and open dialogue and exchange of information in relation to matters concerning this Deed, to the extent that it is practicable and appropriate to do so, in order to ensure that each Party is well informed about matters concerning this Deed, and to ensure that issues can be considered between the Parties when they arise without being limited to the scheduled Deed management meetings.
- 7.3 The Parties may agree to hold additional meetings, face to face or using remote meeting technology, on a regular or ad hoc basis, and at times and locations agreed between the Parties, where there are matters which could usefully be considered at such meetings.

Forward warning of possible supply issues

- 7.4 Each Party agrees to provide information to and liaise with the other Party at an early stage in relation to emerging circumstances or issues which have the potential to have a material impact on the supply of Products or Services under the Deed, through the Deed management processes set out in this clause 7 and Schedule 3.

Involvement of third parties

- 7.5 The Parties may agree to involve third parties, including the Starting Plasma Provider, in the Deed management processes under this clause 7 where and to the extent that this is necessary or appropriate for the efficient and effective operation of the Deed.

Note – Other clauses of the Deed may provide for matters to be formally agreed, decided or notified by one or both Parties. The meetings and other Deed management processes specified in clause 7 do not take the place of any formal agreement, decision or notification process specified in another clause, unless the other clause specifies that processes under clause 7 are, or are part of, the formal process.

8 New Developments

CSL to keep the NBA informed

- 8.1 CSL must use reasonable endeavours to keep the NBA up-to-date on industry trends and new developments, including in technology and methodology, that are, in CSL's reasonable opinion, directly relevant to the Deed or any aspect of the performance of the Deed, including through the scheduled Deed management meetings in Schedule 3.

Invitations to CSL briefings and presentations

- 8.2 CSL must invite representatives of the NBA to attend briefings or presentations held by CSL on matters relevant to the Deed (other than internal or private briefings). CSL may propose reasonable conditions or restrictions on NBA participation in any such briefings or presentations.

Specific requests by the NBA

- 8.3 CSL must actively participate, at no additional cost to the NBA, in activities related to the Deed or the subject matter of the Deed (including planning, policy development, blood sector process improvement, and public health investigation activities) as reasonably requested by the NBA, following consultation with CSL, including:
- 8.3.1 providing written information or assessment to the NBA of new technology, products or services relevant to the Deed within a reasonable period of time following the introduction of such technology, products or services or within a reasonable time requested by the NBA; and
 - 8.3.2 attendance at, and participation in, meetings with the NBA (provided that, where practicable, such meetings are conducted by telephone or similar means).
- 8.4 CSL must prepare and provide information or assessments to the NBA pursuant to clauses 8.1, 8.2 and 8.3 in good faith but:
- 8.4.1 makes no representation or warranty to the NBA or any other person as to the accuracy or completeness of; and
 - 8.4.2 accepts no duty, liability or responsibility to the NBA or any other person in connection with,
- such information or assessments.
- 8.5 Clause 8.4 does not apply to the extent that the information or assessments relate to Products or Services which are included in the Deed at any time during the Term, and does not limit CSL's warranties in clause 39.

Electronic business

- 8.6 The Parties agree to share information and maintain consultation through the Deed management process in clause 7 and Schedule 3 in relation to possibilities and opportunities for the use of electronic systems and processes in relation to the supply of Products and Services, or other aspects of the conduct of business between the Parties, under the Deed.
- 8.7 The NBA may, after reasonable consultation with CSL through the Deed management process in clause 7 and Schedule 3 (including consultation in relation to cost, benefit, practicality and timing for implementation) and by giving Formal Notice to CSL, give reasonable instructions to CSL about:

- 8.7.1 standards or requirements for the interface of NBA and CSL systems or data;
- 8.7.2 the use of electronic systems operated by or on behalf of the NBA and made available for use by CSL, Approved Health Providers or other relevant third parties;
- 8.7.3 standards for barcoding of Products; or
- 8.7.4 use of a system specified by the NBA to electronically receive order and order change messages and to electronically dispatch order responses and despatch devices.

in relation to the Ordering or receipting of Products or other aspects of the supply of Products or Services, or other aspects of the conduct of business between the Parties, under the Deed.

9 Public Affairs Management

[Not disclosed. This clause specifies that the parties agreed to consult on, and cooperate in, public affairs management where practicable and appropriate.]

10 Formal Notices under the Deed

Giving of Formal Notices

- 10.1 A clause of the Deed may provide for a Formal Notice to be given by one Party to the other Party for a specific purpose under the clause.
- 10.2 A Formal Notice that must or may be given to a Party under the Deed is only given if it is:
 - 10.2.1 in writing and delivered or posted to the relevant contact for that Party at the address specified in Schedule 1 or 2; and
 - 10.2.2 in the format set out in Template 2.

Process for giving Formal Notices

- 10.3 A Formal Notice given by a Party to the other Party is taken to be given if and when it is:
 - 10.3.1 delivered by hand, at the time it is left with an Employee of the other Party at the correct address;
 - 10.3.2 sent by post, at the time it is delivered to the relevant address for the other Party; or
 - 10.3.3 sent by electronic mail, at the time of receipt by the sender of an automatically generated electronic mail message confirming that the electronic mail message has been received by the recipient.
- 10.4 A Party giving Formal Notice by electronic mail must use reasonable endeavours (in addition to sending the Formal Notice) to alert the recipient of the sending of the Formal Notice.
- 10.5 A Party receiving a Formal Notice must give prompt notification of receipt (including the time of receipt) by one of the methods for the giving of a Formal Notice in clause 10.3.

Agreement by Formal Notice

- 10.6 A clause of the Deed may provide for a matter to be agreed by the Parties by Formal Notice for a specific purpose under the clause.
- 10.7 A Formal Notice that must or may be agreed under the Deed is only agreed if it is:
- 10.7.1 in writing and signed (in one copy or counterpart copies) by the relevant contacts for the Parties specified in Schedule 1 or 2; and
 - 10.7.2 in the format set out in Template 2.

Change of representatives for Formal Notices

- 10.8 If a Party gives the other Party a Formal Notice, with no less than 3 Working Days written notice of a change to the details specified in Schedule 1 or 2 for that Party, a Formal Notice is only given or agreed by that other Party if it is given or agreed in accordance with those changed details.

Other communications under or in connection with the Deed

- 10.9 The Parties may undertake other communications under or in connection with the Deed, but such a communication will not comprise a Formal Notice unless:
- 10.9.1 referable to and in accordance with a clause of the Deed which refers to a Formal Notice being given; and
 - 10.9.2 given in accordance with this clause 10.

Chapter 3

Production and supply of Products

Chapter outline

This chapter sets out the processes, rights and obligations agreed between the Parties for the production and supply of Products under the Deed, including:

- the specifications which the Products must comply with, including minimum Shelf Life requirements;
- the processes for receipt and management and use of Starting Plasma by CSL, including the holding of a minimum Starting Plasma inventory;
- the exchange of information about forecast levels of Starting Plasma to be provided for production, and forecast levels of demand for Products;
- the production of Products, the holding of Products including minimum inventory requirements, and the supply of Products to Approved Health Providers; and
- arrangements for alternative supply should the supply of Products under the Deed be significantly interrupted.

Matters covered in this chapter are detailed more specifically in Schedules 4, 5, 6, 7, 8 and 15.

11 Provision of Products and Services

11.1 CSL must:

- 11.1.1 produce, manage and supply the Products and Services in accordance with, and otherwise comply with, the requirements set out in, or determined in accordance with processes set out in, this Deed;
- 11.1.2 comply with any limitations, constraints, conditions or prohibitions in relation to the Products or Services set out in, or determined in accordance with processes set out in, this Deed; and
- 11.1.3 provide, deploy, monitor and maintain (as relevant) all facilities, arrangements, resources, equipment, procedures and Personnel, and do or refrain from doing all things (whether or not expressly provided in this Deed), necessary or appropriate to comply with its obligations and warranties under the Deed, including as necessary to ensure that:
 - (a) Starting Plasma provided by the Starting Plasma Provider is received, stored and used by CSL in accordance with the Deed;
 - (b) adequate quantities of Products complying with the Product Specifications are produced from suitable Starting Plasma available for production in accordance with this Deed;
 - (c) sufficient inventory of Products, including Minimum Product Inventory and National CSL Reserve, are held in accordance with the Deed; and
 - (d) Products are supplied to meet Orders in accordance with this Deed.

11.2 In providing the Products and Services CSL must:

- 11.2.1 liaise with Approved Health Providers, Approved Home Delivery Recipients in accordance with Schedule 15, and the NBA, if required;
- 11.2.2 comply with any reasonable request of a relevant Approved Health Provider or the NBA that is consistent with the Deed; and
- 11.2.3 respond promptly to any reasonable queries made by the NBA and provide any information that the NBA may reasonably require in relation to the Products and Services.

12 Products

Products to comply with Product Specifications

12.1 CSL must:

- 12.1.1 ensure that Products produced and supplied under this Deed meet the Product Specifications; and
- 12.1.2 produce and supply the range of Products, in the range of vial sizes and concentrations, specified in the Product Specifications.

Changes to Products in accordance with Product Specifications

- 12.2 CSL must use reasonable endeavours to develop and implement improvements to Products, and obtain all necessary TGA approvals for such improvements, as specified in the Product Specifications, and by the time specified in the Product Specifications or as soon as practicable thereafter.
- 12.3 A Party may, in accordance with a process specified in the Product Specifications for a particular Product, and the outcomes of the process, give Formal Notice to the other Party that:
- 12.3.1 the Product is no longer available to be Ordered and supplied under this Deed; or
 - 12.3.2 the Product has become available to be Ordered and supplied under this Deed;
- and such Formal Notice will have effect from the date specified in the Formal Notice without requiring any further variation of this Deed.
- 12.4 Despite clause 12.3, CSL acknowledges that a decision of Australian Governments (including a decision by the NBA or any other decision making body authorised by Australian Governments from time to time) may be required under the National Blood Arrangements before a change referred to in clause 12.3 will have effect, as set out in the Product Specifications or notified by Formal Notice from the NBA to CSL.

Product enhancement and development opportunities

- 12.5 The Parties agree to maintain a dialogue regarding product enhancement and development opportunities relevant to this Deed, through the Deed management process set out in clause 7 and Schedule 3.

Process Migration

- 12.6 The Parties agree to establish and participate in good faith in a Process Migration Governance Committee in accordance with this Deed, in order to ensure that the NBA, on behalf of Australian Governments, is able to:
- 12.6.1 be provided with information a timely manner;
 - 12.6.2 provide input and advice on matters of interest or concern;
 - 12.6.3 undertake any confirmatory checks or obtain any appropriate expert advice; and
 - 12.6.4 make any necessary or appropriate decisions, including to issue any Formal Notice in accordance with the relevant provisions of this Deed or to vary the Deed in accordance with clause 67;
- in relation to:
- 12.6.5 current and potential future products and services supplied by CSL under this Deed and funded by Australian Governments under the National Blood Agreement;
 - 12.6.6 matters otherwise arising from Process Migration relevant to:
 - (a) policies of Australian Governments stated in or determined under the National Blood Agreement; or

- (b) the functions and responsibilities of the NBA under the *National Blood Authority Act 2003* (Cth).
- 12.7 The Parties agree to establish the terms of reference for the Process Migration Governance Committee by Formal Notice agreed between them.
- 12.8 The Process Migration Governance Committee will:
 - 12.8.1 comprise the chief executives of each Party (or any deputy nominated by each chief executive) and any other representatives nominated by each Party;
 - 12.8.2 meet on a basis agreed between the Parties.

13 Starting Plasma and Plasma Material

Provision of Starting Plasma

- 13.1 CSL acknowledges that the Starting Plasma provided to it for the purposes of this Deed is funded by Australian Governments through the National Blood Arrangements.
- 13.2 The Parties acknowledge that:
 - 13.2.1 CSL has informed the NBA that the size and technology of CSL's Broadmeadows plasma fractionation facility means that CSL's ability to achieve economies of scale and to provide internationally competitive pricing for Australian plasma products is facilitated through a throughput of plasma for fractionation in the order of 500 tonnes per year;
 - 13.2.2 at the Commencement Date, Australia is the primary customer of CSL's Broadmeadows facility, while overseas customers also contribute to annual throughput; and
 - 13.2.3 [Not disclosed – this clause provides for the availability of a minimum volume of Starting Plasma for each financial year of the Agreement.]
- 13.3 Despite clause 13.2, the NBA does not warrant or guarantee the quality, fitness for purpose or suitability of the Starting Plasma, or the quantity of Starting Plasma to be provided to CSL at any time or over any period.
- 13.4 The NBA acknowledges that CSL relies on the Starting Plasma Provider holding a current TGA licence for blood collection, and having conducted such tests and procedures in relation to the Starting Plasma as are required to have been undertaken by that provider to meet TGA requirements, prior to delivery to CSL (subject to any requirements of CSL applying under the TG Act in relation to Starting Plasma).
- 13.5 CSL and the NBA may agree by Formal Notice on a specification to apply for Starting Plasma suitable for particular Products under this Deed.
- 13.6 CSL's obligations to produce and supply Products under this Deed are subject to:
 - 13.6.1 circumstances affecting the timely provision of adequate Starting Plasma, which is available for production, to CSL; and
 - 13.6.2 circumstances in relation to safety concerns, latent defects, contaminants or donor issues which prevent or limit the effective use of Starting Plasma;in accordance with clause 43, where these circumstances are beyond the reasonable control of CSL, and are not able to be reasonably mitigated by CSL.

- 13.7 CSL must:
- 13.7.1 comply with any required process for ordering Starting Plasma from the Starting Plasma Provider; and
 - 13.7.2 comply with any reasonable instructions given by the NBA about the amount or timing of Orders for Starting Plasma from CSL to the Starting Plasma Provider;
- notified by Formal Notice from the NBA from time to time after reasonable consultation with CSL through the Deed management process in clause 7 and Schedule 3.

Receipt of Starting Plasma

- 13.8 Following receipt of Starting Plasma, CSL must:
- 13.8.1 complete any delivery docket or other process for confirmation of receipt;
 - 13.8.2 check and weigh the Starting Plasma;
 - 13.8.3 test the Starting Plasma;
 - 13.8.4 ensure the safe storage and handling of the Starting Plasma;
 - 13.8.5 store the Starting Plasma securely and separately from other plasma;
 - 13.8.6 participate in any reconciliation process for the receipt of Starting Plasma provided to CSL against records of delivery held by the NBA or the Starting Plasma Provider; and
 - 13.8.7 maintain records of matters relating to the number of units, weight, receipt, testing, reconciliation, storage, use or disposal of Starting Plasma;
- as required by this Deed, the TG Act, or the TGA, and in accordance with reasonable instructions in relation to the matters in this clause notified by Formal Notice from the NBA from time to time after reasonable consultation with CSL through the Deed management process in clause 7 and Schedule 3, including consultation in relation to the cost, benefit, practicality and timing for implementation of such an instruction.

Note - CSL may choose to undertake any testing of Starting Plasma which CSL considers reasonably appropriate to ensure that the Products meet the requirements of the Deed, in addition to any requirements under clause 13.8.

- 13.9 The Parties may agree by Formal Notice on a standard methodology to be used to determine the weight of Starting Plasma at relevant times for relevant clauses of the Deed.

Note – For example, the Parties may agree a standard adjustment for bag weight, condensation or ice, to be applied in determining the net weight of Starting Plasma at relevant times.

Minimum Starting Plasma Inventory

- 13.10 Subject to this clause 13, CSL must hold an inventory of Starting Plasma which is no less at any time than the Minimum Starting Plasma Inventory.
- 13.11 [Not disclosed – the parties agreed to consult with each other regarding the Minimum Starting Plasma Inventory.]
- 13.12 CSL may not use Starting Plasma for production where this would at any time reduce the level of Starting Plasma inventory held by CSL below the Minimum Starting Plasma Inventory, except:

- 13.12.1 as authorised in advance by Formal Notice from the NBA, and strictly in accordance with any conditions specified in the Formal Notice; or
 - 13.12.2 where there is an unexpected delay or shortfall in the delivery of Starting Plasma (contrary to current advice of planned delivery provided by the Starting Plasma Provider), and CSL has a reasonable expectation that the level of Starting Plasma inventory will be able to be reinstated to the Minimum Starting Plasma Inventory within 10 Working Days, provided that CSL promptly gives the NBA Formal Notice of such use.
- 13.13 Where Starting Plasma has been used in accordance with clause 13.12 or otherwise falls below the Minimum Starting Plasma Inventory, or where the level of Minimum Starting Plasma Inventory has been increased under clause 13.11, CSL must:
- 13.13.1 propose for consideration and approval by the NBA a plan for establishment or reinstatement of the required level of Starting Plasma inventory as soon as reasonably practicable; and
 - 13.13.2 implement the plan as approved by the NBA.

Use of Plasma Material by CSL or third parties

- 13.14 CSL must:
- 13.14.1 ensure that Starting Plasma and Production Intermediates are used only for the production of Products in accordance with the Deed (including any necessary procedures and tests (including stability trials) as described in clause 13.15), or otherwise as approved by the NBA under clause 13.16; and
 - 13.14.2 provide reporting in relation to the use or disposal of all Plasma Material in accordance with clause 30 and Schedule 9.
- 13.15 The NBA acknowledges that certain procedures and tests (including stability trials) carried out by CSL using Plasma Material are a necessary part of the production of Products, in order to ensure that the Product Specifications, requirements under the TG Act, and other requirements of the Deed are met. These necessary procedures and tests do not require approval under clause 13.16.
- 13.16 CSL may seek the NBA's prior approval in writing for use of Plasma Material for the purposes of process or product development or other purposes which are not a necessary part of the production of Products, in which case:
- 13.16.1 the NBA may seek further information to assist in consideration of the request; and
 - 13.16.2 the NBA must not unreasonably delay consideration of CSL's request, and may give approval by Formal Notice to CSL subject to conditions reasonably determined by the NBA and specified in the Formal Notice.
- 13.17 The NBA may not unreasonably withhold or delay approval under clause 13.16 where:
- 13.17.1 the quantity of relevant Plasma Material requested is no more than 25% of the relevant Plasma Material that is expected to be surplus to the requirements of this Deed in any financial year;
 - 13.17.2 the proposed use is for the purpose of process or product development for products made in Australia from Australian plasma;

- 13.17.3 the Plasma Material can be used without affecting CSL's ability to meet Orders in accordance with clause 19; and
- 13.17.4 the Plasma Material would otherwise be discarded.
- 13.18 Despite clauses 13.16 and 13.17, CSL acknowledges that a decision of Australian Governments may be required under the National Blood Arrangements before the NBA gives approval under those clauses.
- 13.19 CSL must comply with any request from the NBA to provide Plasma Material to third party researchers nominated by the NBA, provided that:
 - 13.19.1 the third party researcher or the NBA has obtained all necessary legal approvals to allow the provision of Plasma Material to the third party researcher for the intended purpose;
 - 13.19.2 such a request does not unreasonably prevent CSL from meeting obligations under this Deed in relation to supply of Products or holding of Minimum Starting Plasma Inventory, Minimum Product Inventory or the National CSL Reserve;
 - 13.19.3 CSL's reasonable costs in doing so are met by the NBA or the third party researcher;
 - 13.19.4 CSL may require the third party researcher to agree to reasonable terms in relation to:
 - (a) protection of CSL from liability; and
 - (b) safeguarding of CSL's rights under this Deed in relation to confidentiality of, and Intellectual Property in respect of, Excluded Material; and
 - 13.19.5 CSL is not obliged to disclose any Excluded Material.

14 Supply planning

CSL planning approach

- 14.1 CSL must apply a documented planning approach to the production and supply of Products, at least on a rolling 12 month basis, to ensure the performance of its obligations under the Deed.

Annual supply planning

- 14.2 The NBA must consult with CSL as part of the supply planning process of the NBA and Australian Governments under the National Blood Agreement, and in doing so in relation to a particular financial year must give CSL Formal Notice of:
 - 14.2.1 proposed levels of Starting Plasma to be collected and provided to CSL for production under this Deed for the relevant financial year, by plasma type and by month, and forecast levels of Starting Plasma for two forward financial years, by 30 November preceding the financial year;
 - 14.2.2 a draft Annual Supply Estimate, by 30 November preceding the financial year;
 - 14.2.3 a revised draft Annual Supply Estimate, if any, by 15 March preceding the financial year;

- 14.2.4 a final Annual Supply Estimate promptly following the approval by Australian Governments of the supply plan for the relevant financial year under the National Blood Agreement, which is expected to occur by 30 June preceding the financial year; and
- 14.2.5 any formal revision of the Annual Supply Estimate promptly following a decision of Australian Governments or of the NBA to formally update the supply plan for the financial year under the National Blood Agreement.
- 14.3 CSL must:
- 14.3.1 by no later than 10 Working Days after receipt of proposed and forecast levels of Starting Plasma from the NBA under clause 14.2.1, give the NBA Formal Notice either:
- (a) that CSL has the capacity to produce Products from the proposed level of Starting Plasma for the relevant financial year; or
 - (b) of any known or likely unavoidable constraints which will prevent CSL from producing Products from the proposed level of Starting Plasma for the relevant financial year; and
- 14.3.2 by no later than 10 Working Days after receipt of a draft, final or revised final version of the Annual Supply Estimate from the NBA under clauses 14.2.3 to 14.2.5, give the NBA Formal Notice of any known or likely unavoidable constraints which will prevent CSL from supplying the Products required by the Annual Supply Estimate for the relevant financial year.
- 14.4 The NBA may provide to CSL, or facilitate the provision to CSL of, other information which the NBA considers it practicable and appropriate to provide to facilitate supply planning by CSL for the purposes of the Deed.
- 14.5 The NBA must promptly give CSL Formal Notice (once the NBA can appropriately do so) of proposed implementation of policies or procedures by Australian Governments, if any, which may affect demand for Products.

Supply planning liaison

- 14.6 The NBA must give CSL Formal Notice promptly, and by no later than one month prior to commencement of the relevant production batch, if at any time the NBA forms the view that CSL commencing manufacture of a production batch pursuant to the Annual Production Plan will, in the NBA's opinion, likely to lead to expiry of Products and request that CSL alter the Annual Production Plan to avoid any potential expiry of Products.
- 14.7 CSL must:
- 14.7.1 provide to the NBA a report every 6 months on:
- (a) CSL's horizon scanning and analysis of emerging trends relevant to the Products and this Deed; and
 - (b) contacts with health professionals and other stakeholders, relevant to the demand for and supply of Products; and
- 14.7.2 provide to the NBA any other Documents or information reasonably requested by the NBA from time to time in relation to CSL production planning for Products under the Deed.

- 14.8 The Parties agree that the planning, forecasts or other information provided to the other Party referred to in this clause 14 does not give rise to any legal obligation in relation to any aspect of the information, including particular levels of production or supply of Starting Plasma or Products.

15 Production and yield

General

- 15.1 CSL must produce the Products from Starting Plasma at its plasma fractionation plant at Broadmeadows, Victoria, Australia, unless the NBA specifically approves otherwise (including in accordance with the Process Migration procedures set out in clauses 12.6 to 12.8).
- 15.2 CSL must use reasonable endeavours to manage the production of Products and the holding of inventory of Products in a way which will be most likely to:
- 15.2.1 ensure that Products are able to be supplied in accordance with Orders;
 - 15.2.2 maximise the remaining Shelf Life of Product Units on delivery to an Approved Health Provider; and
 - 15.2.3 minimise expiry of Product Units in CSL Inventory or National CSL Reserve;
- in accordance with the requirements of this Deed (including requirements in relation to maintenance of Minimum Starting Plasma Inventory, Minimum Product Inventory and National CSL Reserve).

Yield

- 15.3 CSL must, subject to the amount and characteristics of available Starting Plasma and the demand for Products from time to time:
- 15.3.1 use reasonable endeavours to maximise yield of each Product per kilogram of Starting Plasma; and
 - 15.3.2 meet the target yield for each Product specified in KPI 2 under clause 28 and Schedule 10.

16 Inventory management requirements

General

- 16.1 CSL must maintain warehouse facilities for the holding of CSL Inventory and National CSL Reserve which will allow CSL to meet its obligations under the Deed, and which must at least meet the following requirements:
- 16.1.1 licensing requirements under the TG Act;
 - 16.1.2 temperature control, alarms and monitoring;
 - 16.1.3 location in Melbourne, Sydney, Brisbane, Adelaide, Perth and other locations as may be agreed between CSL and the NBA; and
 - 16.1.4 capacity for CSL Inventory and National CSL Reserve to be held separately within each facility.

- 16.2 CSL must provide transport for Products between warehouse facilities that meets licence requirements under the TG Act.
- 16.3 CSL must:
- 16.3.1 maintain a Product control system which will allow accurate tracking of the specific location of individual Product Units, and checking and reconciliation of Products delivered and held in CSL Inventory and National CSL Reserve;
 - 16.3.2 undertake a continuous cycle of physical counts of all Products held in CSL Inventory and National CSL Reserve in accordance with CSL Standard Operating Procedures; and
 - 16.3.3 report to the NBA on Products held in CSL Inventory and National CSL Reserve in accordance with clause 30 and Schedule 9.
- 16.4 CSL must, after consultation with the NBA and taking into account priorities for Product location, if any, reasonably notified by the NBA from time to time, endeavour to locate CSL Inventory and National CSL Reserve between different warehouse facilities on a basis that will optimise the efficiency and effectiveness of:
- 16.4.1 Product rotation; and
 - 16.4.2 delivery in accordance with Orders under the Deed;
- and will minimise the risks of loss or damage to Products, and potential Product expiry.

Minimum Product Inventory

- 16.5 Subject to this clause 16, CSL must hold an amount of each Product in CSL Inventory that is no less at any time than the Minimum Product Inventory.
- 16.6 The Minimum Product Inventory specified in Schedule 7 may be revised by Formal Notice from the NBA to CSL, following consultation between the NBA and CSL through the Deed management process in clause 7 and Schedule 3, provided that Schedule 7 may not specify a Minimum Product Inventory level for a Product which is greater than 25% of the current Annual Supply Estimate for that Product.
- 16.7 CSL may not supply a Product Unit from CSL Inventory where this would at any time reduce the level of that Product held in CSL Inventory below the Minimum Product Inventory for the Product, except
- 16.7.1 as authorised in advance by notice in writing from the NBA, and strictly in accordance with any conditions specified in the notice; or
 - 16.7.2 where, in CSL's reasonable opinion, supply of the Product Unit is necessary to meet a particular Order in an emergency situation, and no other Product Units are reasonably available to be supplied or otherwise made available to meet that emergency, provided that CSL promptly gives the NBA notice in writing of such supply.
- 16.8 Where Product Units have been supplied in accordance with clause 16.7 or CSL Inventory otherwise falls below the Minimum Product Inventory, or where the level of Minimum Product Inventory has increased, CSL must:
- 16.8.1 propose for consideration and approval by the NBA a plan for establishment or reinstatement of the required level of Products as soon as reasonably practicable; and
 - 16.8.2 implement the plan as approved by the NBA.

Product rotation

- 16.9 Subject to any relevant Intensive Product Management arrangements, CSL must:
- 16.9.1 maintain rotation of Products held in CSL Inventory and National CSL Reserve on a first-expiry-first-out basis, subject to reasonable inventory location constraints;
 - 16.9.2 ensure that Product rotation does not at any time reduce the amount of Products held in CSL Inventory below the Minimum Product Inventory, or the amount of Products held in National CSL Reserve;
 - 16.9.3 endeavour to minimise levels of expiry of all Products held in CSL Inventory and National CSL Reserve; and
 - 16.9.4 give priority in inventory management and rotation between CSL Inventory and National CSL Reserve on a basis, if any, notified by Formal Notice from the NBA, following prior consultation with CSL

Note - Movement of Product Units into or from National CSL Reserve for the purposes of Product rotation in accordance with clause 16.9 does not comprise the placement of the Product into National CSL Reserve, for which a Payment is required in accordance with this Deed.

17 National CSL Reserve

- 17.1 CSL must establish and hold the National CSL Reserve as a separately identified and managed inventory of Products, in accordance with this clause 17 and otherwise in accordance with this Deed.
- 17.2 The National CSL Reserve must, subject to this clause 17, contain the amount of each Product specified in Schedule 8.
- 17.3 Schedule 8 may be revised by Formal Notice from the NBA to CSL, following consultation between the NBA and CSL through the Deed management process in clause 7 and Schedule 3.
- 17.4 CSL may only supply Products from the National CSL Reserve as authorised in advance by Formal Notice from the NBA, and strictly in accordance with any conditions specified in the notice.
- 17.5 Where Products have been supplied from the National CSL Reserve or the National CSL Reserve otherwise falls below the level required under this clause 17, CSL must:
- 17.5.1 propose for consideration and approval by the NBA a plan for reinstatement of the required level of Products as soon as reasonably practicable;
 - 17.5.2 implement the plan as approved by the NBA;
 - 17.5.3 issue the NBA with a credit note for an amount equal to the price of the Products withdrawn from National CSL Reserve; and
 - 17.5.4 issue the NBA with an invoice for an amount equal to the price of the Products reinstated in the National CSL Reserve.
- 17.6 Where the level of Products to be held in the National CSL Reserve has increased, CSL must:
- 17.6.1 propose for consideration and approval by the NBA a plan for establishment of the required level of Products as soon as reasonably practicable; and

- 17.6.2 implement the plan as approved by the NBA.
- 17.7 The NBA must make Payments to CSL in accordance with clause 33 in respect of:
 - 17.7.1 Products placed into the National CSL Reserve in accordance with this clause 17 (other than for Product rotation purposes under clause 16.9); and
 - 17.7.2 the management of the National CSL Reserve by CSL.
- 17.8 CSL must ensure that, unless otherwise agreed by the NBA, the remaining shelf life of Products held in the National CSL Reserve is in accordance with Schedule 8 of the Deed.

18 Ordering by Approved Health Providers

Approved Health Providers and Distributors

- 18.1 CSL must seek the NBA's approval for a person seeking the supply of a Product to be an Approved Health Provider under the Deed.
- 18.2 The NBA may give Formal Notice to CSL of the withdrawal of approval of a person as an Approved Health Provider.
- 18.3 CSL must allocate a unique identifying number to each Approved Health Provider for each location for that Approved Health Provider (and must report the number to the NBA in accordance with clause 30 and Schedule 9) in accordance with any Formal Notice given by the NBA under clause 18.5 from time to time.
- 18.4 CSL must only accept an Order under the Deed from:
 - 18.4.1 an Approved Health Provider; or
 - 18.4.2 a person that CSL considers is likely to be approved as an Approved Health Provider, where the person has Ordered the supply of a Product in urgent circumstances.
- 18.5 The NBA must give Formal Notice to CSL of:
 - 18.5.1 the categories of people who may be approved as Approved Health Providers;
 - 18.5.2 the form and process to be used for seeking approval of an Approved Health Provider by the NBA; and
 - 18.5.3 the criteria for distinguishing locations to be separately approved for an Approved Health Provider.
- 18.6 The NBA may, after reasonable consultation with CSL through the Deed management process in clause 7 and Schedule 3 (including consultation in relation to cost, benefit, practicality and timing for implementation), give Formal Notice to CSL designating an Approved Health Provider to be a Distributor.
- 18.7 The NBA may give Formal Notice to CSL from time to time of instructions in relation to the quantity of particular Products which CSL may supply in response to future Orders from a Distributor for a particular period of time.

Approved Home Delivery

- 18.8 If the NBA gives CSL Formal Notice that certain Products may be supplied by Home Delivery, CSL must comply with Schedule 15 in relation to Home Delivery supply of those Products.

Requirements in relation to Orders

- 18.9 CSL must be able to receive Orders 24 hours a day, 7 days a week, each day of the year, with customer service Personnel on 24 hour on call availability outside normal CSL working hours.
- 18.10 Subject to clauses 18.12 and 18.13, CSL must not accept an Order unless the form of the Order allows CSL to make a record of:
- 18.10.1 the date and time specified in the Order;
 - 18.10.2 the name and position of the person placing the Order;
 - 18.10.3 the name of the Product to be delivered by CSL;
 - 18.10.4 the Item Number of the Product to be delivered by CSL;
 - 18.10.5 the quantity of Product to be delivered by CSL;
 - 18.10.6 the Product strength required by the Approved Health Provider;
 - 18.10.7 the name and authorisation number of the Approved Health Provider (or other basis of the supply);
 - 18.10.8 the shipping address details; and
 - 18.10.9 in the case of Home Delivery Orders, any additional matters described in Schedule 15,
- and CSL must make such a record.
- 18.11 Schedule 6 may specify quantities to be used as the normal basis for Ordering by a Distributor.

Exception Orders

- 18.12 Despite anything in this clause 18, CSL must accept an Order as an exception Order where:
- 18.12.1 the Order does not, at the time the Order is placed, allow CSL to make a record of all of the matters required by clause 18.10;
 - 18.12.2 the Order requires delivery in less than the Required Delivery Time; or
 - 18.12.3 the Order is made by a Distributor and is not based on quantities specified in Schedule 6.
- 18.13 In relation to exception Orders, CSL must:
- 18.13.1 meet the Order in accordance with the Deed;
 - 18.13.2 as soon as practicable, use all reasonable endeavours to obtain all of the information required by clause 18.10, and make a record of the Order as required by that clause; and
 - 18.13.3 use all reasonable endeavours to meet the Order in the delivery time specified in the Order to the extent that this is less than the Required Delivery Time.

No warranty as to Orders

- 18.14 CSL acknowledges and agrees that:
- 18.14.1 the NBA may at any time enter into arrangements for the provision of Products or Services, or products and services similar to the Products or Services, from one or more third parties;
 - 18.14.2 the arrangements under clause 18.14.1 may affect the NBA's requirements for the provision of Products or Services under the Deed; and
 - 18.14.3 the NBA does not give any representation or warranty in any way as to the actual quantity of Products or Services for which Orders will be placed in any year during the Term.

19 Supply of Products

General

- 19.1 Subject to this Deed, CSL must supply, and must only supply, Products to Approved Health Providers and Approved Home Delivery Recipients in accordance with Orders, and in accordance with this Deed.
- 19.2 Subject to any relevant Intensive Product Management arrangements under clause 21 or guidelines given by the NBA from time to time in accordance with clause 19.3, CSL must:
- 19.2.1 supply Products from CSL Inventory to meet Orders; or
 - 19.2.2 where the NBA has given approval under clause 17.4 for the supply of Products from National CSL Reserve - supply Products from the National CSL Reserve to meet Orders, and must do so before supplying product from CSL Inventory if required as part of the conditions of that approval.
- 19.3 In meeting Orders under the Deed, CSL must follow any applicable guidelines, which are consistent with the Deed, notified by the NBA by Formal Notice to CSL from time to time for the purpose of the Deed.

Substantial demand fluctuations

- 19.4 [Not disclosed. This clause establishes arrangements which apply if substantial fluctuations in demand occur.]

Delivery requirements

- 19.5 Products must be delivered to the shipping address (or alternative shipping address for Home Delivery Orders in accordance with Schedule 15) specified in an Order.
- 19.6 Subject to clause 18.13.3, after receipt of an Order Products must be delivered within:
- 19.6.1 the date and time specified in the Order, if any; or
 - 19.6.2 if no time is specified in the Order, the Required Delivery Time as determined in accordance with Schedule 6; and
 - 19.6.3 for a Home Delivery Order, within the timeframe specified in accordance with Schedule 15.

Acknowledgment and verification of delivery

- 19.7 CSL must:

- 19.7.1 establish and maintain procedures to ensure that acknowledgment of receipt in accordance with the relevant Order is obtained from all Approved Health Providers and Approved Home Delivery Recipients in respect of all deliveries of Products under the Deed;
- 19.7.2 establish and maintain procedures to track and record all instances where Products are not able to be delivered in accordance with Orders under the Deed;
- 19.7.3 establish and maintain internal process controls, checks and audits to ensure that the requirements of clause 19.7.1 are met in respect of all deliveries of Products under the Deed; and
- 19.7.4 give the NBA all reports and assistance required under the Deed or by the NBA from time to time in relation to the verification of Product deliveries in accordance with Orders and the requirements of the Deed;

and CSL must comply with any reasonable instructions issued in writing by the NBA from time to time about the matters specified in this clause 19.7.

20 Shelf Life and expiry of Products

Shelf Life on delivery

- 20.1 CSL must use reasonable endeavours to:
 - 20.1.1 maximise the remaining Shelf Life of Products on delivery to an Approved Health Provider; and
 - 20.1.2 without limitation to clause 20.1.1, ensure that Products are supplied with no less than the Target Minimum Shelf Life at the time of delivery.
- 20.2 CSL must report on all Products held in CSL Inventory or National CSL Reserve which have less than the Target Minimum Shelf Life remaining, in accordance with clause 30 and Schedule 9.
- 20.3 Subject to the requirements of this Deed, CSL must use reasonable endeavours (including but not limited to any relevant Intensive Product Management arrangements in place under clause 21), to ensure that all Products held in CSL Inventory or National CSL Reserve which have less than the Target Minimum Shelf Life remaining are supplied to Approved Health Providers in accordance with this Deed before the remaining Shelf Life reduces to three months.
- 20.4 CSL must not supply a Product with less than three months remaining Shelf Life at the time of delivery, unless:
 - 20.4.1 prior to supply the remaining Shelf Life was brought to the attention of the NBA and the Approved Health Provider and the Approved Health Provider specifically agreed to receive the Product; and
 - 20.4.2 CSL notifies the Approved Health Provider that, if the Product expires after delivery but before it is used by the Approved Health Provider, then CSL will supply the Approved Health Provider with a replacement Product on request and return of the expired Product, and at no additional charge to the NBA or the Approved Health Provider.

Payment consequences of Product expiry

- 20.5 Where a Product Unit expires in CSL Inventory or National CSL Reserve:
- 20.5.1 a KPI rebate may apply for loss of Starting Plasma, as determined in accordance with KPI 1, clause 28 and Schedule 10, if the relevant Product is specified in KPI 1 as potentially being subject to such a rebate and:
 - (a) CSL is determined not to have complied with obligations under this clause 20 to ensure the supply of the Product Unit before expiry; or
 - (b) the NBA has relevantly given Formal Notice to CSL under clause 14.6;
 - 20.5.2 if the Product Unit expired in National CSL Reserve, and the NBA was entitled to apply a KPI rebate as referred to in clause 20.5.1 (whether or not the NBA chose to apply that rebate), the NBA will be entitled to a refund of any Payment made in respect of the Product Unit, in accordance with clause 33.3.4;
 - 20.5.3 if the Product Unit is an Expiry Risk Product which expired in CSL Inventory, and the NBA was not entitled to apply a KPI rebate as referred to in clause 20.5.1, then the NBA will be required to make a Payment to CSL in accordance with clause 33; or
 - 20.5.4 in any other case, there is no Payment consequence.

21 Intensive Product management

- 21.1 The NBA may, following consultation with CSL, nominate Products to be subject to Intensive Product Management from time to time.
- 21.2 Intensive Product Management may include any special arrangements for a nominated Product in relation to supply planning, production, inventory management, ordering, delivery, reporting or invoicing as may reasonably be notified by Formal Notice from the NBA, following reasonable consultation with CSL. Such special arrangements may operate in addition to or in place of any other provision of the Deed, as notified by the NBA.
- 21.3 CSL must comply with any reasonable Intensive Product Management arrangements nominated by the NBA from time to time, provided that where the Intensive Product Management is not necessitated by any failure of CSL to perform its obligations under this Deed, the NBA may not impose any greater obligations on CSL under the Intensive Product Management unless CSL has agreed to such obligations, such agreement not to be unreasonably withheld.

22 Alternative supply arrangements

[Not disclosed. This clause establishes alternative supply arrangements which may apply if supply is unable to occur under the Deed.]

23 Possession of Products

- 23.1 CSL and the NBA acknowledge that, as between CSL and the NBA, and subject to any express provisions of the Deed to the contrary, CSL:
- 23.1.1 has and will retain rights of possession, custody or control of the Products as required for the purpose of the Deed; and
 - 23.1.2 bears all risks associated with such possession, custody or control of the Products;
- until possession of the Products passes from CSL to an Approved Health Provider, upon physical delivery of that Product to the Approved Health Provider in accordance with an Order under the Deed.
- 23.2 CSL does not warrant that it owns the Products.
- 23.3 Any third party ownership, or any passing of ownership, of a Product does not affect CSL's obligations to supply Products in accordance with the Deed and to ensure the Products comply in full with the Deed, including in respect of any recall or other obligations under clause 24.

24 Obligations under Therapeutic Goods Act

Definitions

- 24.1 In this clause:
- 24.1.1 the terms **Licence**, **Listed Goods**, **manufacturer**, **manufacturing principles**, **sponsor** and **therapeutic goods** have the same meanings as in the TG Act;
 - 24.1.2 **Listed** means included as a listed good in the Register. **Listing** has a corresponding meaning;
 - 24.1.3 **Special Access Scheme** means the scheme of that name, administered by the TGA in accordance with the TG Act, under which unapproved therapeutic goods may be supplied in Australia to individual named patients in certain circumstances;
 - 24.1.4 **Sponsored Products** means Products supplied by CSL under the Deed for which CSL has obligations as a sponsor under the TG Act; and

CSL's legislative obligations

- 24.2 In addition to CSL's general obligations under clause 61, CSL must at all times during the Term comply with its obligations under the CSL Act, the TG Act and any other applicable Law.

CSL's obligations as a sponsor

- 24.3 CSL must, for all Sponsored Products:
- 24.3.1 do all things necessary to ensure that each of the Sponsored Products is and remains included in the Register during the Term, unless:
 - (a) a Sponsored Product is exempt from the requirement to be included in the Register under the TG Act; or

- (b) the TGA grants approval in writing in respect of a Sponsored Product which is, or will become, available under the Special Access Scheme. For the purposes of this clause 24.3.1;
 - (i) CSL must, before seeking TGA approval, seek NBA approval for the supply of a Special Access Scheme Product under the Deed; and
 - (ii) CSL acknowledges that the NBA's approval will only be granted in exceptional circumstances, as reasonably determined by the NBA; and
- 24.3.2 comply with all of CSL's obligations under the TG Act, including (without limitation):
 - (a) holding and making available all information in relation to the Sponsored Products which is required to meet CSL's obligations under the TG Act; and
 - (b) observing any and all conditions of the registration or listing of the Sponsored Products.

CSL's obligations where CSL is not the sponsor

- 24.4 If CSL is not the sponsor for one or more Products supplied under the Deed, CSL must:
 - 24.4.1 ensure that CSL obtains those Products (or part or parts of those Products) under contractual arrangements that oblige the suppliers to CSL to meet any obligations those suppliers have as a sponsor under the TG Act in respect of the Product (or part or parts of those Products); and
 - 24.4.2 promptly, following a request by the NBA, provide the NBA with copies of any contractual arrangements referred to in clause 24.4.1.

General obligations

- 24.5 CSL must for all Products:
 - 24.5.1 ensure that the Products comply with all relevant requirements under the TG Act for labelling, packaging and advertising; and
 - 24.5.2 not make any statements about the Products which are inaccurate, misleading or deceptive.

CSL's Obligations as a Licensed manufacturer

- 24.6 If CSL is the manufacturer of part or all of a Product supplied under the Deed, CSL must:
 - 24.6.1 do all things necessary to ensure that a Licence for the manufacture of each Product supplied by CSL under the Deed is obtained and remains in force during the Term, unless that Product is one for which a Licence is not required by the TG Act;
 - 24.6.2 in relation to any revocation or suspension, or proposed revocation or suspension of the Licence, take any action that the NBA, following prior consultation with CSL, considers reasonably necessary or desirable to ensure that the purposes of the Deed are fulfilled; and
 - 24.6.3 comply with all of CSL's obligations under the TG Act, including (without limitation):

- (a) ensuring that the manufacturing processes for Products supplied under the Deed comply with the applicable manufacturing principles determined under the TG Act;
- (b) observing any and all conditions imposed on CSL by or under the TG Act from time to time;
- (c) holding all information and records in relation to the Product manufactured under the Licence as required by the TG Act;
- (d) in addition to the NBA's access rights under the Deed, allowing 'authorised persons' under the TG Act to enter and inspect the premises the subject of the Licence at any reasonable time;
- (e) publicly displaying a current copy of the Licence and schedule of conditions applicable to the Licence at the premises specified in the Licence; and
- (f) ensuring that the manufacture of the Products is performed in accordance with the TG Act and that any quality control measures required under the TG Act are maintained in accordance with the Licence.

CSL's Obligations where CSL is not the manufacturer

- 24.7 If CSL is not the manufacturer of part or all of a Product supplied under the Deed, CSL must ensure that it obtains that Product (or the relevant part or parts of that Product):
- 24.7.1 from a supplier that holds a Licence under the TG Act, except in the case of Products for which a Licence is not required by the TG Act or which have otherwise satisfied the requirements of the TG Act for the import and supply of the Products in Australia; and
 - 24.7.2 under contractual arrangements that oblige the supplier (and, if the supplier is not the manufacturer, which require the supplier to require the manufacturer) to meet its obligations under the TG Act in respect of that Product (or the relevant part or parts of that Product).

Product compliance and return

- 24.8 CSL must not supply a Product Unit under the Deed if CSL is aware that the Product Unit does not meet the requirements of its Registration or Listing, or that there are reasonable grounds to believe that the Product Unit may not meet the requirements of its Registration or Listing.
- 24.9 If a Product Unit is supplied in accordance with the Deed and, before the use of the Product Unit, it is shown that the Product Unit as supplied by CSL does not meet the requirements of its Registration or Listing, or that there are reasonable grounds to believe that the Product Unit as supplied by CSL may not have met the requirements of its Registration or Listing, CSL must:
- 24.9.1 accept the return of the Product Unit; and
 - 24.9.2 except where the failure to meet the requirements of Listing or Registration was not within the reasonable control of CSL, as substantiated by CSL to the reasonable satisfaction of the NBA, either:

- (a) supply a replacement Product Unit at no additional cost to meet the requirements of the relevant Approved Health Provider or Approved Home Delivery Recipient for the unit of Product; or
 - (b) if no replacement Product Unit can be supplied to meet the requirements of the Approved Health Provider or Approved Home Delivery Recipient, credit the amount paid or payable under the Deed for the Product Unit against Tax Invoices for future Orders under the Deed.
- 24.10 If a Product Unit is supplied in accordance with the Deed and, after the use of the Product Unit, it is shown that the Product Unit did not meet the requirements of its Registration or Listing (where the failure was within the reasonable control of CSL), CSL agrees to credit the amount paid or payable under the Deed for the Product Unit against Tax Invoices for future Orders under the Deed.
- 24.11 If the NBA or an Approved Health Provider or Approved Home Delivery Recipient considers on reasonable grounds that the Products do or may not meet the safety, quality, efficacy or any other requirements of Registration or Listing, CSL must:
 - 24.11.1 liaise with the NBA or Approved Health Provider or, in accordance with Schedule 15, the Approved Home Delivery Recipient, in relation to the grounds on which the person considers that the Products may not meet the safety, quality, efficacy or any other requirements of registration or listing;
 - 24.11.2 accept return of Product Units in accordance with clause 24.9.1; and
 - 24.11.3 promptly conduct such investigation as is necessary to determine whether or not the Products comply with applicable safety, quality and efficacy or other requirements, and notify the NBA of the outcomes of that investigation.

Other remedies

- 24.12 The rights, obligations and remedies in this clause 24 do not limit or affect in any way, and are not a waiver or release of, a Party's other rights, obligations or remedies under or in relation to the Deed or at Law.

25 Standard Operating Procedures

- 25.1 CSL must maintain a planned, systematic and documented approach, in accordance with good commercial practice, to the performance of its obligations under the Deed.
- 25.2 In relation to CSL's Standard Operating Procedures (other than for Standard Operating Procedures for the manufacture of Products), CSL must:
 - 25.2.1 provide a copy of any specified Standard Operating Procedures to the NBA at the reasonable request of the NBA;
 - 25.2.2 consider any reasonable suggestion made by the NBA for the development or revision of any specified Standard Operating Procedures; and
 - 25.2.3 engage in consultation with the NBA or any other relevant person in respect of any Standard Operating Procedures, at the reasonable request of the NBA.

26 Product promotion and support activities

- 26.1 CSL must provide Services to support the management and use of the Products by healthcare professionals and administrators, patients and carers, including:
- 26.1.1 medical and technical advisory and education services in relation to Product use, handling and storage, including:
 - (a) educational materials (detailing basic Product information including storage and use) for reference;
 - (b) communicating changes to Product Information or government policy impacting the use of Products;
 - (c) organising conferences and training workshops to communicate educational material and demonstrate Product use; and
 - (d) providing clinical literature upon request;
 - 26.1.2 customer service, communication and education services, including:
 - (a) CSL monitoring of production and inventory, and working with Approved Health Providers to minimise potential wastage;
 - (b) providing dedicated Personnel for prompt and up-to-date responses to queries, including through a 24 hour telephone assistance service; and
 - (c) arranging urgent transportation, or meeting other special requirements; and
 - 26.1.3 providing a pharmacovigilance service in relation to the Products, including:
 - (a) collecting and investigating adverse event reports;
 - (b) periodically reviewing incoming adverse event reports for detection of new safety signals;
 - (c) conducting regular safety surveillance of clinical literature; and
 - (d) investigating clinical safety issues.
- 26.2 In relation to medical support provided for, or promotion undertaken of, the Products by CSL during the Term, CSL agrees that:
- 26.2.1 any form of medical advice, whether oral or written, provided to any person during the course of, or in any way associated with, the performance of any of CSL's obligations under the Deed, must be given by a person (or, to the extent permitted by Law, given under the direction of a person) who is qualified, competent and legally permitted to give that advice;
 - 26.2.2 any advertising or promotion of the Products to Approved Health Providers must comply with the Medicines Australia Code of Conduct (or equivalent industry guidelines agreed by the NBA) for the ethical marketing and promotion of prescription pharmaceutical products in Australia, as in force from time to time, as if the Products were products covered by that Code of Conduct; and

- 26.2.3 any advertising or promotion of the Products to patients must comply with a code of conduct, if any, developed or nominated by the NBA after reasonable consultation with CSL and which is applicable to all commercial suppliers of plasma derived or recombinant products under contracts entered into by the NBA.

27 Utilisation of surplus Products or Plasma Material

- 27.1 If Australian Governments decide a policy which allows the utilisation of surplus Products or Plasma Material rather than such material being discarded, the Parties agree:
- 27.1.1 to implement arrangements for such utilisation under the Deed if and to the extent this is consistent with the government policy decision; and
- 27.1.2 to do so based on agreed clauses, which may include, but are not limited to, the following matters:
- (a) identification of Plasma Material or Products that may be considered surplus, without affecting supply under the Deed;
 - (b) rights and obligations of CSL in relation to the manufacture of Products from surplus Plasma Material and in relation to utilisation of surplus Products;
 - (c) passage of title and risk in surplus Plasma Material or Products;
 - (d) conduct of commercial functions in relation to surplus Products, potentially including sales, transport, warehousing and distribution;
 - (e) specification of payments, and allocation and treatment of commercial returns, in respect of surplus Plasma Material or Products; and
 - (f) allocation and treatment of risks.

Chapter 4

Reporting and performance assessment

Chapter outline

This chapter describes:

- the basis on which the Parties have agreed that CSL's performance of obligations under the Deed will be assessed, and the consequences arising from different performance outcomes;
- the way in which information concerning the performance of the Deed will be recorded and reported by CSL; and
- the way in which the NBA may obtain information to verify CSL performance and reporting.

Matters covered in this chapter are detailed more specifically in Schedules 9 and 10, and Template 6.

28 Performance Requirements

Performance requirements for Products and Services

- 28.1 CSL must provide the Products and Services to meet in full, or exceed, the targets and requirements specified in the Key Performance Indicators specified in Schedule 10.
- 28.2 The Parties must comply with those parts of Schedule 10 which set out:
- 28.2.1 which Party is responsible for measuring CSL's performance against the Key Performance Indicators;
 - 28.2.2 when CSL's performance against the Key Performance Indicators is to be measured; and
 - 28.2.3 the reporting obligations in respect of CSL's performance against the Key Performance Indicators.

Consequences of outcomes against the Key Performance Indicators

- 28.3 If CSL does not meet, or exceeds, a target or requirement in the Key Performance Indicators, then the consequences set out in Schedule 10 may apply.
- 28.4 The Parties acknowledge and agree that the consequences set out in Schedule 10, as applied under the Deed:
- 28.4.1 are reasonable and appropriate for managing adherence to the Key Performance Indicators and for providing reward for good performance or rebate for poor performance, if applicable; and
 - 28.4.2 do not limit the Commonwealth's rights or remedies arising from any defective performance under the Deed, but will be taken into account in determining the extent of any loss suffered by the NBA.

29 Records

- 29.1 CSL must keep, and must require its Subcontractors to keep, comprehensive written records and accounts of all matters related to its performance of the Deed.
- 29.2 CSL must ensure that in all material respects all such records and accounts:
- 29.2.1 are true and accurate;
 - 29.2.2 are complete and maintained so as to be up-to-date;
 - 29.2.3 are kept in a manner that permits them to be conveniently and properly audited;
 - 29.2.4 enable the extraction of all information relevant to the performance of the Deed; and
 - 29.2.5 where the records are financial accounts - are drawn in accordance with any applicable Australian accounting standards.

30 Reports

- 30.1 CSL must provide the NBA with the reports set out in, or determined in accordance with the process set out in, Schedule 9:
- 30.1.1 which contain the information required by Schedule 9; and
 - 30.1.2 at the frequency, and by the due dates, specified in, or determined in accordance with the procedures set out in, Schedule 9.
- 30.2 CSL must comply with any reasonable instructions issued in writing by the NBA from time to time, following consultation with CSL through the Deed management process in clause 7 and Schedule 3, in relation to the timing, format, content, or means of provision of, reports under the Deed.

31 General obligation for CSL to provide information and assistance

- 31.1 CSL must, at its own expense:
- 31.1.1 respond promptly to any reasonable queries made by the NBA, and provide any information that the NBA may reasonably require, in the manner and form reasonably required by the NBA;
 - 31.1.2 promptly comply with any reasonable request from the NBA for CSL to provide copies of Documents or records (in a format and storage medium reasonably acceptable to the NBA) held by CSL, its Employees, agents or Subcontractors; or
 - 31.1.3 promptly comply with any reasonable request by the NBA for assistance in respect of any inquiry into or concerning the Products or Services or the Deed (for this purpose an inquiry includes any administrative or statutory review, audit or inquiry, whether within or external to the NBA, any request for information directed to CSL by any Commonwealth agency, and any inquiry conducted by Parliament or any Parliamentary committee);
- in relation to:
- 31.1.4 the Products or Services; or
 - 31.1.5 the performance of, or compliance with, the Deed by CSL or its Subcontractors.

32 Access to information and premises

General

- 32.1 CSL must grant the NBA, the Auditor-General, the Privacy Commissioner or their nominees, reasonable access, as they may require, to CSL's premises and data, records, accounts and other financial Material or other Material relevant to the purposes for which records and accounts are kept as specified in clause 29, however and wherever stored or located, under CSL's custody, possession or control for inspection and/or copying.

- 32.2 In the case of Documents or records stored on a medium other than in writing, CSL must make available on request and at no additional cost to the NBA such reasonable facilities as may be necessary to enable a legible reproduction to be created.
- 32.3 Without limiting any other provision of the Deed, the Auditor-General or a delegate of the Auditor-General or the Privacy Commissioner or a delegate of the Privacy Commissioner, for the purpose of performing the Auditor-General's or Privacy Commissioner's respective functions, may, at reasonable times on reasonable notice:
- 32.3.1 access the premises of CSL;
 - 32.3.2 require the provision by CSL of records and other information related to the Deed; and
 - 32.3.3 access, inspect and copy documentation and records or any other matter relevant to CSL's obligations under, or performance of, the Deed, however stored, in the custody or under the control of CSL.
- 32.4 CSL must use reasonable endeavours to ensure that any Subcontract entered into for the purpose of the Deed contains an equivalent clause granting the rights specified in this clause 32 with respect to the Subcontractors' premises, data, records, accounts, financial Material and information and those of its Personnel to the extent relevant to the goods and services provided to CSL to enable CSL to perform its obligations under the Deed.
- 32.5 This clause 32 applies for the Term and for a period of 7 years from the date of expiration or termination of the Deed.
- 32.6 Nothing in the Deed reduces, limits or restricts in any way any function, power, right or entitlement of the NBA, the Auditor-General or a delegate of the Auditor-General or the Privacy Commissioner or a delegate of the Privacy Commissioner.
- 32.7 The rights of the NBA under the Deed are in addition to any other power, right or entitlement of the NBA, the Auditor-General or a delegate of the Auditor-General or the Privacy Commissioner or a delegate of the Privacy Commissioner.
- 32.8 The NBA must, in having access to CSL's premises under this clause 32, comply with CSL's reasonable directions and procedures relating to health and safety, and security, when such directions and procedures are brought to their attention.
- 32.9 CSL's obligations to comply with this clause in relation to the Auditor-General and the Privacy Commissioner:
- 32.9.1 are subject to and do not limit applicable statutory rights and obligations; and
 - 32.9.2 do not limit CSL from seeking confidentiality undertakings from the Auditor-General and/or the Privacy Commissioner or their nominees but only on terms that are consistent with the NBA's confidentiality obligations under the Deed, and only in relation to information which is Confidential Information under the Deed.

Right to conduct audits

- 32.10 The NBA may, from time to time during normal business hours, conduct audits of:
- 32.10.1 CSL's practices and procedures as they relate to CSL's performance of the Deed; and
 - 32.10.2 CSL's performance of, and compliance with, the Deed.

- 32.11 The NBA may appoint an independent person to assist in audits under this clause 32. The NBA:
- 32.11.1 must ensure that any independent person so appointed complies with this clause; and
 - 32.11.2 agrees that CSL may seek confidentiality undertakings from the independent person but only on terms that are consistent with the NBA's confidentiality obligations under the Deed and only in relation to information which is Confidential Information under the Deed.

Process for conducting audits

- 32.12 The NBA will, from time to time, provide CSL with a schedule indicating the frequency with which it intends to conduct planned audits under this clause 32.
- 32.13 CSL acknowledges that the schedule provided under clause 32.12 is indicative only, and does not limit the NBA's rights to conduct audits under this clause 32.
- 32.14 Except for those circumstances in which notice is not practicable or appropriate, and without limiting any other right, recourse or remedy of the NBA, the NBA must give CSL Formal Notice containing reasonable prior notice of an audit and where reasonably practicable an indication of which Documents and/or class of Documents the auditor may require.
- 32.15 Without limiting its rights under the Deed, the NBA must:
- 32.15.1 use reasonable endeavours to ensure that audits performed pursuant to this clause 32 do not unreasonably delay or disrupt in any material respect CSL's operations; and
 - 32.15.2 in conducting an audit, comply with all reasonable directions and procedures of CSL in relation to occupational health and safety and security matters which have been notified in writing to the NBA by CSL.

CSL to participate in audits

- 32.16 CSL must participate promptly and cooperatively in any audits conducted by the NBA or its nominee.
- 32.17 The requirement for, and participation in, audits does not in any way reduce CSL's responsibility to perform its obligations in accordance with the Deed.

Costs and results of audits

- 32.18 Subject to this clause, each Party must bear its own costs of any audit conducted under the Deed, but where:
- 32.18.1 an audit reveals material errors, non-compliance or inaccuracies; or
 - 32.18.2 an audit is a follow-up audit after a previous audit, in relation to material errors, non-compliance or inaccuracies;
- CSL must, on request, reimburse the NBA an amount that represents 50% of the total cost incurred by the NBA in respect of the audit.
- 32.19 The NBA must provide copies of the findings of an audit to CSL promptly following the completion of the audit.

- 32.20 CSL must promptly take, at no additional cost to the NBA, corrective action reasonably necessary to rectify any material error, non-compliance or inaccuracy identified in any audit, including in the way CSL has under the Deed:
- 32.20.1 supplied any Products or Services;
 - 32.20.2 maintained any accounts or records; or
 - 32.20.3 calculated Payments, or any other amounts or charges billed to or claimed from the NBA.
- 32.21 The NBA must use reasonable endeavours to ensure that audits performed pursuant to this clause 32 do not unreasonably delay or disrupt in any material respect CSL's performance of its obligations under the Deed or any other contract between CSL and the NBA.
- 32.22 The operation of this clause 32 does not limit the operation of clause 51.

Chapter 5

Payment

Chapter outline

This chapter specifies the Payments to be made by the NBA to CSL for Products and Services under the Deed, and associated processes.

Matters covered in this chapter are detailed more specifically in Schedules 11 and 12.

33 Payments for Products and Services

- 33.1 Subject to the Deed, the NBA agrees to make Payments to CSL of the amounts specified in, or calculated in accordance with:
- 33.1.1 Schedule 11 for:
- (a) Products delivered by CSL to Approved Health Providers or Approved Home Delivery Recipient in accordance with the Deed (including Payments for Alternative Products under and in accordance with clause 22, and additional payments under Item 5 of Schedule 11, if applicable) for which acknowledgment of delivery has been obtained in accordance with the Deed;
 - (b) Monthly Block Fee payments for Ig Products;
 - (c) Products placed by CSL into the National CSL Reserve in accordance with clause 17 (other than for Product rotation purposes under clause 16.9);
 - (d) management of the National CSL Reserve by CSL pursuant to clause 17;
 - (e) Products which expire in CSL Inventory in circumstances where clause 20.5.3 applies; and
 - (f) Products in accordance with clause 69.4.2;
- 33.1.2 Schedule 12 for Payments under clause 34 or clause 69; and
- 33.1.3 Schedule 10 for any bonus payment under KPI 2.
- 33.2 Subject to the Deed, the NBA agrees to make Payments to CSL of the amounts calculated in accordance with clause 22.13 for Alternative Products supplied by CSL in accordance with clause 22.
- 33.3 CSL agrees that the Payments referred to in clause 33.1 and 33.2 may be subject to adjustment (whether or not any amount has already been paid by the NBA) in respect of:
- 33.3.1 Products which are identified as not having been supplied to an Approved Health Provider or Approved Home Delivery Recipient or placed in the National CSL Reserve in accordance with the Deed;
 - 33.3.2 Services included in the Tax Invoice which are identified as not having been provided by CSL in accordance with the Deed;
 - 33.3.3 payment consequences applying under clause 28 and Schedule 10 based on the extent to which the Products and Services meet the Key Performance Indicators;
 - 33.3.4 the refund of Payments previously made by the NBA for Products which expire in National CSL Reserve, in circumstances where clause 20.5.2 applies; and
 - 33.3.5 other adjustments provided for in the Deed (including those under clauses 24.9, 24.10 and 32.20.3).

- 33.4 No separate fees or charges are payable by the NBA for Services under this Deed, except as provided in clause 33.1.1(d).

34 Plasma Volume Payments

[Not disclosed. This clause establishes a Plasma Volume Payment if Annual Starting Plasma falls below a certain volume.]

35 Invoicing and payment

- 35.1 CSL may submit a Tax Invoice for Payments under this Deed monthly in arrears.
- 35.2 All Payments for Products must be invoiced based on the volume of Products which have been delivered in a particular month, and for which acknowledgment of delivery has been obtained, in accordance with the Deed.
- 35.3 CSL must submit a Tax Invoice in respect of a particular month by no later than 10 Working Days after the end of the month.
- 35.4 CSL must give a separate annual tax invoice or adjustment note in respect of KPIs if required in accordance with Schedule 10.
- 35.5 A Tax invoice under the Deed must include the information, specified in Template 6. The NBA may specify reasonable changes to the information required for a Tax Invoice under Template 6 by Formal Notice to CSL after reasonable consultation with CSL. In addition, CSL must comply with any reasonable instructions issued in writing by the NBA from time to time, following consultation with CSL, in relation to the timing, format, content, or means of provision of, invoices under the Deed.
- 35.6 Any Tax Invoice, credit note or adjustment note given under the Deed must comply with the requirements of the GST Legislation.
- 35.7 Subject to the Deed, the NBA agrees to make payments to CSL no later than 30 days after receipt of a correctly rendered Tax Invoice.
- 35.8 Unless otherwise specified in the Deed and without limitation to any other preconditions to Payment contained in the Deed, Payments under this Deed are subject to:
- 35.8.1 supply of the Products to Approved Health Providers or Approved Home Delivery Recipient in accordance with the requirements of the Deed, as reasonably determined by the NBA;
 - 35.8.2 performance of the Services by CSL in accordance with the Deed, as reasonably determined by the NBA; and
 - 35.8.3 the receipt by the NBA from CSL of a correctly rendered Tax Invoice in accordance with the Deed, as reasonably determined by the NBA;
- provided that the NBA must not unreasonably withhold payment for any part of a Tax Invoice which is not in dispute.
- 35.9 Subject to clause 35.10, where the Supplier makes a Taxable Supply under or in connection with the Deed or in connection with any matter or thing occurring under the Deed to the Recipient and the consideration otherwise payable for the Taxable Supply does not include GST, the Supplier is entitled, in addition to any other consideration

- recoverable in respect of the Taxable Supply, to recover from the Recipient the amount of any GST on the Taxable Supply.
- 35.10 If the amount paid by the Recipient:
- 35.10.1 to the Supplier in respect of GST differs from the GST on the Taxable Supply (taking into account any Adjustment Events that occur in relation to the Taxable Supply), an adjustment must be made, such that if the Payment:
- (a) exceeds the GST on the Taxable Supply, the Supplier must refund the excess to the Recipient; and
 - (b) is less than the GST on the Taxable Supply, the Recipient must pay the deficiency to the Supplier.
- 35.11 Where a Party to the Deed is entitled, under or in connection with the Deed or in connection with any matter or thing occurring under the Deed, to recover all or a proportion of its costs or is entitled to be compensated for all or a proportion of its costs, the amount of the recovery or compensation must be reduced by the amount of (or the same proportion of the amount of) any Input Tax Credits available in respect of those costs.
- 35.12 The Parties agree that any amount recoverable by a Party under any indemnity under the Deed includes any GST payable on a cost or liability incurred by the Party which is the subject of the claim under the indemnity.
- 35.13 Where at any time the NBA reasonably considers that a Tax Invoice issued by CSL is incorrect or otherwise requires adjustment in accordance with the Deed (whether or not any amount has been paid by the NBA in respect of the Tax Invoice), CSL must give to the NBA as reasonably required by the NBA:
- 35.13.1 a credit note and replacement invoice; or
 - 35.13.2 an adjustment note;
- as required to correct or adjust the Tax Invoice.
- 35.14 CSL must comply with any reasonable instructions issued in writing by the NBA (following consultation with CSL) from time to time in relation to reconciliation of Tax Invoices and the processes for resolving any matter of clarification in respect of Tax Invoices under the Deed.
- 35.15 CSL acknowledges that the making of any Payments by the NBA will not constitute an admission on the part of the NBA that the Products have been properly provided or the Services properly performed, or a waiver or release of CSL's obligations under the Deed.
- 35.16 If the rate of GST varies, the Parties must, by amendment in writing to the Deed in accordance with clause 67:
- 35.16.1 make a corresponding variation to any amount payable under the Deed; and
 - 35.16.2 provide that the date on which any payment under the Deed will vary as a result of the variation in the rate of GST will be the effective date of the variation in the rate of GST.
- 35.17 In this clause 35 and elsewhere in the Deed:
- 35.17.1 the expression **GST Legislation** means the *A New Tax System (Goods and Services Tax) Act 1999* (Cth);

- 35.17.2 the expressions **Adjustment Event**, **Input Tax Credit**, **Taxable Supply** and **Tax Invoice** have the meanings provided in the GST Legislation;
- 35.17.3 **Supplier** means a Party which makes a Taxable Supply under or in connection with the Deed or in connection with any matter or thing occurring under the Deed to another Party; and
- 35.17.4 **Recipient** means a Party which receives a Taxable Supply under or in connection with the Deed or in connection with any matter or thing occurring under the Deed from the Supplier.
- 35.18 For certainty, and without limiting the other provisions of this Deed, the obligations of the NBA to make Payments to CSL under the Deed in respect of the Term and any period specified under clause 70.1.1 survive the expiration or earlier termination of the Deed.

36 Recovery of moneys by the NBA

- 36.1 If, at any time during the Term or after the expiry or earlier termination of the Deed, as a result of the NBA's invoice reconciliation or otherwise, any Payments cannot be shown to the reasonable satisfaction of the NBA to represent Products or Services which were provided in accordance with the Deed or otherwise to have been made in accordance with the Deed, the NBA may give CSL a Formal Notice (**Repayment Notice**) requiring CSL to repay that part of the Payments set out in the notice, and CSL must pay that amount within 30 days of receipt of a Repayment Notice given validly in accordance with this clause 36.1.
- 36.2 If CSL fails to repay the amount specified in the Repayment Notice in accordance with clause 36.1:
- 36.2.1 CSL must pay the NBA interest on the amount set out in the Repayment Notice from the date that it was due, for the period it remains unpaid, calculated at an interest rate equal to the weighted average yield of the 13 week Treasury notes allotted in the latest tender of those notes prior to the date on which the amount was payable, plus 1%;
- 36.2.2 the amount set out in the Repayment Notice, and interest owed under clause 36, will be recoverable by the NBA as a debt due to the NBA by CSL; and
- 36.2.3 subject to clauses 36.3 and 36.4, the NBA may recover, by recourse to the Financial Undertaking, any amount that the NBA reasonably determines is the amount owing by CSL to the NBA, as a refund of any Payments for which Products and Services have not been provided, or which were not otherwise properly payable, in accordance with the Deed, plus interest determined by the NBA in accordance with the procedure set out in clause 36.2.1.
- 36.3 CSL may not give the NBA a Dispute Notice under clause 45.2 in relation to a Repayment Notice unless it does so within 10 Working Days or longer period agreed by the NBA of the receipt of the Repayment Notice.
- 36.4 Despite clause 36.3, if CSL gives the NBA a Dispute Notice under clause 45.2 in relation to a Repayment Notice, the NBA may not recover any amount under the Financial Undertaking in respect of the Repayment Notice unless the dispute is not resolved in accordance with clause 45 within 30 days of the Dispute Notice being given

by CSL. However, despite clause 45.5, the NBA is not obliged to commence legal proceedings prior to recovering any amount under the Financial Undertaking.

36.5 CSL acknowledges that interest calculated in accordance with clause 36.2.1 represents a reasonable pre-estimate of the loss incurred by the NBA as a result of the loss of investment opportunity for, or the reasonable cost of borrowing other money in place of, the amount which should have been repaid.

36.6 This clause 36 survives the expiration or earlier termination of the Deed.

37 Right of Set Off

37.1 Without limitation to the NBA's rights under the Deed or at Law, if CSL owes any amounts to the NBA in respect of the Deed or any subject matter of the Deed, the NBA may exercise a right of set-off in respect of those amounts against any moneys owed by the NBA to CSL under the Deed.

37.2 This clause 37 survives the expiration or earlier termination of the Deed.

Chapter 6

Treatment of risks

Chapter outline

This chapter deals with various aspects of the risks arising in relation to the supply of Products, and otherwise relating to the Deed:

- CSL's risk management and insurance approach;
- warranties and indemnity for the Products and Services provided by CSL under the Deed;
- Force Majeure events; and
- undertakings, guarantees and powers of direction which may be called on if serious risks occur.

Matters covered in this chapter are detailed more specifically in Schedule 13 and Templates 4 and 5.

38 CSL risk management

- 38.1 CSL must maintain a planned, systematic and documented approach, in accordance with recognised international best practice standards, to risk management in relation to foreseeable and material risks which may affect the supply of Products and performance of other obligations under the Deed.
- 38.2 In relation to CSL's documented risk management approach, CSL must:
- 38.2.1 provide any information or documentation in relation to CSL's risk management to the NBA at the reasonable request of the NBA; and
 - 38.2.2 consider any reasonable suggestion made by the NBA for the development or revision of any aspect of the CSL risk management approach.
- 38.3 The Parties agree to engage in consultation on issues concerning risk management relating to the supply of Products under the Deed through the annual Risk Management Workshop as part of the Deed management process under clause 7 and Schedule 3.
- 38.4 As part of a documented best practice risk management approach, CSL must:
- 38.4.1 in relation to continuity of CSL operations:
 - (a) maintain a business continuity plan relating to business operations connected with the supply of Products and performance of other obligations under the Deed;
 - (b) review and update the business continuity plan at least annually; and
 - (c) provide a copy of each update of the business continuity plan to the NBA;
 - 38.4.2 maintain physical security and other relevant risk planning and management in relation to national security risks such as terrorism; and
 - 38.4.3 in relation to national blood supply contingency planning coordinated by the NBA:
 - (a) provide any information, prepare any documentation, or comply with any process, reasonably required by the NBA for the purpose of national blood supply contingency planning;
 - (b) participate in any simulation or review of national blood supply contingency planning as reasonably required by the NBA; and
 - (c) comply with the requirements of CSL under national blood supply contingency planning documentation issued by the NBA and with the reasonable directions of the NBA, in the event of activation of the national blood supply contingency plan.

39 Warranties

Product Warranties

- 39.1 CSL warrants that:
- 39.1.1 all Products provided under the Deed:

- (a) have been manufactured, produced, processed, prepared and packaged, labelled, presented and described as required by Law and otherwise comply with all applicable Laws;
- (b) comply with all representations made to the NBA by CSL in writing in relation to those Products or any samples of those Products, including any representations as to the standard, quality, value, grade, composition, style, model, capacity, history and previous use of the Products;
- (c) meet the Product Specifications including any applicable requirements under the TG Act;
- (d) are free from defects; and
- (e) are fit for the purpose for which those Products are commonly supplied;

provided that all of the warranties in this clause 39.1.1 apply only to the extent to which they relate to CSL's obligations under the Deed in relation to the Products (including any warranties or indemnities given under the Deed except under this clause 39.1);

39.1.2 throughout the Term, the Products and the Starting Plasma will not be subject to any charge or Encumbrance given by CSL in favour of any third party, except with the prior agreement of the NBA in accordance with clause 62, other than any Encumbrance which is unavoidably imposed or implied by Law; and

39.1.3 to the best of CSL's knowledge after making reasonable enquiry, the manufacture and sale of Products does not infringe the rights of any other person.

Services Warranties

39.2 CSL warrants that all Services performed under the Deed:

- 39.2.1 comply with all representations made to the NBA by CSL in relation to the standard, quality and timing of the Service;
- 39.2.2 will be provided with due care and skill;
- 39.2.3 along with any Materials supplied under the Deed in connection with the Services, are fit for purpose; and
- 39.2.4 comply with any applicable requirements under the TG Act and satisfy all other applicable quality, performance and regulatory compliance requirements and other Laws.

General

39.3 CSL warrants that it has the capacity, capability and power to enter into and perform the Deed.

39.4 The warranties in this clause 39 survive the expiration or termination of the Deed in relation to Products or Services supplied under the Deed.

40 Indemnity

[Not disclosed. This clause deals with CSL's obligations indemnify the NBA in certain circumstances.]

41 Undertakings

Financial Undertaking

- 41.1 CSL must, at its expense, provide to the NBA, within 45 Working Days of the Commencement Date, security in the form of an unconditional and irrevocable financial undertaking (the **Financial Undertaking**) which must be:
- 41.1.1 executed by a financial institution approved by the NBA (the **Financial Institution**) and (if necessary) stamped;
 - 41.1.2 substantially in the form of the undertaking appearing in Template 4; and
 - 41.1.3 for the sum of specified in Schedule 13.
- 41.2 The Financial Undertaking is for the purpose of ensuring the due and proper performance of the Deed by CSL and the NBA may demand any sum under the Financial Undertaking from the Financial Institution in respect of:
- 41.2.1 amounts owed to the NBA by CSL;
 - 41.2.2 damages suffered by the NBA, the NBA's Personnel, Approved Health Providers or their Personnel as a result of a breach of the Deed by CSL; or
 - 41.2.3 any loss, damage (whether direct or indirect), liability, cost or expense including legal expenses on a solicitor and own client basis suffered by the NBA or the Approved Health Providers or their Personnel that is the subject of an indemnity under the Deed.
- 41.3 For the purposes of clause 41.2, the NBA is deemed to be acting as agent or trustee for and on behalf of its Personnel or Approved Health Providers and their Personnel from time to time and may exercise the rights in clause 41 for its Personnel and Approved Health Providers and their Personnel on their behalf.
- 41.4 The NBA will release the Financial Undertaking when the NBA is reasonably satisfied that CSL has fulfilled its obligations under the Deed, including, to the extent reasonable, those that survive expiry or termination of the Deed and for which the payment of money or damages would be a remedy.

Performance Guarantee

- 41.5 CSL must, at its expense, provide to the NBA, within 60 Working Days of the Commencement Date, a performance guarantee executed by a guarantor specified in Schedule 13 or alternative guarantor acceptable to the NBA, guaranteeing the performance by CSL of its obligations under the Deed in respect of relevant Products specified in Schedule 13, which must be substantially in the form of the performance guarantee appearing in Template 4.
- 41.6 CSL may at any time propose a change to the guarantor referred to in clause 41.5 and, subject to this clause, the NBA will not unreasonably refuse such a request. The NBA will release the guarantee provided under clause 41.5 but not until it has received:

- 41.6.1 a performance guarantee executed by an alternative guarantor reasonably acceptable to the NBA in the manner set out in clause 41.5; or
 - 41.6.2 an alternative security arrangement that, in the NBA's reasonable opinion, provides equivalent or adequate protection for the NBA's risks if, using reasonable endeavours, CSL is unable to comply with clause 41.6.1.
- 41.7 Without limiting clause 41.6, the NBA will release a performance guarantee when the NBA is reasonably satisfied that CSL has fulfilled its relevant obligations under the Deed, including, to the extent reasonable, those that survive expiry or termination of the Deed.

42 Insurance

- 42.1 CSL must:
- 42.1.1 maintain a comprehensive portfolio of insurance or self-insurance in relation to risks arising from or in connection with CSL's obligations under this Deed in relation to Starting Plasma, production and supply of Products , and provision of Services, and risks otherwise arising from or in connection with this Deed;
 - 42.1.2 provide information annually on CSL's insurance and self-insurance arrangements through the Deed management process in clause 7 and Schedule 3; and
 - 42.1.3 at the reasonable request of the NBA, provide to the NBA reasonable details of the scope and terms of the insurances or self-insurance arrangements held under clause 42.1.1, and evidence of the currency of such insurances or arrangements, including:
 - (a) the nature and scope of cover;
 - (b) the claims basis of the policy;
 - (c) the level of cover (per claim and aggregate);
 - (d) the period of the cover;
 - (e) the identity of the insured; and
 - (f) the exclusions from cover.
- 42.2 If at any time the NBA has a concern in relation to the scope or adequacy of the insurances held by CSL under clause 42.1.1, then (without limitation to any other rights of the NBA under the Deed or at Law):
- 42.2.1 the NBA may notify CSL of the concern and the reasons for the concern; and
 - 42.2.2 CSL must, as soon as practicable after notification, investigate and consider the concern, and notify the NBA of its finding and conclusions and any appropriate remedial action in relation to the concern.

43 Force Majeure Event

Force Majeure Event

- 43.1 If a Party is prevented in whole or in part from carrying out its obligations under the Deed (other than an obligation to pay money) as a result of an act or event beyond the reasonable control of that Party or its Personnel (**Force Majeure Event**), including without limitation an insufficiency of adequate or suitable Starting Plasma referred to in clause 13.6, it must promptly give a Formal Notice to the other Party that complies with clause 43.3.

[Remainder of clause 43 not disclosed – this clause deals with the obligations of the parties under exceptional circumstances.]

44 Directions

[Not disclosed – this clause deals with the obligations of the parties under exceptional circumstances.]

45 Dispute Resolution

- 45.1 The Parties undertake to use all reasonable efforts in good faith to resolve any disputes which arise between them in connection with the Deed.
- 45.2 A Party may give the other Party a notice of dispute (**Dispute Notice**) in connection with the Deed.
- 45.3 Following the giving of a dispute notice under clause 45.2, the dispute must initially be referred to the contact persons specified in Schedules 1 and 2 who must use reasonable efforts to resolve the dispute within 20 Working Days of the giving of the dispute notice, provided that a Party must not refuse a reasonable extension to this period to allow the matters in dispute to be considered by the executive management or Board of a Party, or, in the case of the NBA, by Australian Governments (or any decision making body on behalf of Australian Governments).
- 45.4 If the Parties have not been able to resolve the dispute in accordance with clause 45.3, then the Parties may agree on a process for resolving the dispute through means other than litigation or arbitration, including by mediation or conciliation or by an appropriately qualified independent expert.
- 45.5 In the event that the dispute, controversy or claim has not been resolved, or referred to a process for resolution under clause 45.4, within 30 Working Days (or such other period as agreed between the Parties in writing) after the Parties have commenced action to resolve the dispute under clause 45.3, then either Party may, if it wishes, commence legal proceedings.
- 45.6 Nothing in clauses 45.1 to 45.5 inclusive prevents either Party from seeking urgent injunctive relief.

Chapter 7

General provisions

Chapter outline

This chapter covers a range of general matters relating to the accountability requirements of the NBA as a Commonwealth government procurement body, and otherwise supporting the contract relationship between the Parties.

Matters covered in this chapter are detailed more specifically in Schedule 14.

46 Subcontracting

- 46.1 CSL remains fully responsible for the performance of the Deed and any acts and omissions or other failures of any Subcontractors or their Personnel in connection with the Products or Services, even if CSL has subcontracted any part of the provision of Products or performance of any part of Services.
- 46.2 CSL must, at the reasonable request of the NBA, promptly provide to the NBA a list of all material Subcontracts including:
- 46.2.1 the name of the Subcontractor;
 - 46.2.2 the period of the Subcontract; and
 - 46.2.3 the nature of the subcontracted services.
- 46.3 CSL must ensure that all Subcontractors:
- 46.3.1 are aware of the obligation of CSL under clause 46.2; and
 - 46.3.2 are aware that the information provided by CSL under clause 46.2 may be publicly disclosed by the NBA.
- 46.4 If at any time the NBA is concerned that the performance of a Subcontractor engaged by CSL may not be satisfactory, then (without limitation to any other rights of the NBA under the Deed or at Law):
- 46.4.1 the NBA may notify CSL of the concern and the reasons for the concern; and
 - 46.4.2 CSL must, as soon as practicable after notification, investigate and consider the concern, and notify the NBA of its finding and conclusions and any appropriate remedial action in relation to the concern.
- 46.5 The Parties may agree by Formal Notice that a contract or a class of contracts will not be regarded as a Subcontract for the purposes of this Deed.

47 CSL contracts with other National Blood Suppliers

- 47.1 In this clause:
- 47.1.1 **blood products and services** has the meaning defined in the *National Blood Authority Act 2003* (Cth), and includes, without limitation, Products and Services within the meaning of the Deed;
 - 47.1.2 **National Blood Supplier** means any person who is or might reasonably be expected to become a party to a contract, agreement or other arrangement with the Commonwealth for the supply of blood products and services in accordance with the *National Blood Authority Act 2003* (Cth) and notified (by name or by class) by Formal Notice from the NBA to CSL from time to time; and
 - 47.1.3 **Relevant Products and Services** means those blood products and services that the Commonwealth currently contracts for, or may reasonably be expected to be seeking to contract for, as notified by Formal Notice from the NBA to CSL from time to time.
- 47.2 CSL:

- 47.2.1 acknowledges that the requirement of NBA approval of arrangements between CSL and a Starting Plasma Provider under this clause is consistent with the NBA's functions and powers;
 - 47.2.2 must promptly provide the NBA with a copy of any contract, arrangement or understanding between CSL and a Starting Plasma Provider for or in relation to the supply of Starting Plasma, or a variation of such a contract, arrangement or understanding, to obtain the NBA's approval under clause 47.2.3; and
 - 47.2.3 agrees not to enter into or vary a contract, arrangement or understanding between CSL and a Starting Plasma Provider for or in relation to the supply of Starting Plasma without the prior written approval of the NBA.
- 47.3 The NBA agrees:
- 47.3.1 to inform CSL as soon as practicable within 20 Working Days of notification by CSL of a proposal to enter into or vary a contract, arrangement or understanding referred to in clause 47.2.2, or of receipt of further information from CSL under clause 47.3.1(b):
 - (a) that the contract, arrangement or understanding, or any variation, is approved or not approved (and, if not approved provide reasons); or
 - (b) of any further information reasonably required by the NBA in order to make a decision under this clause, which request CSL must comply with within 10 Working Days;
 - 47.3.2 to use reasonable endeavours to comply with any reasonable requests for urgent consideration; and
 - 47.3.3 to not unreasonably withhold or delay approval.
- 47.4 For contracts, arrangements, understandings or variations with National Blood Suppliers which CSL proposes to enter into, CSL must:
- 47.4.1 notify the NBA as early as possible, within the constraints of the continuous disclosure obligations of CSL under the Australian Securities Exchange Listing Rules and any confidentiality restrictions imposed on CSL by the relevant third party (which CSL must use reasonable endeavours to avoid, to the extent to which those confidentiality restrictions relate to disclosure under this clause 47.4), and prior to finalisation of the proposed contract, arrangement, understanding or variation;
 - 47.4.2 advise the NBA of any confidentiality requirements that, in addition to those in clause 51, will need to be complied with by the NBA in order for the NBA to gain access to information about the proposed contract, arrangement, understanding or variation;
 - 47.4.3 if the NBA agrees to the requirements referred to in clause 47.4.2, or to the extent to which the NBA's agreement to those requirements would enable any of the following disclosures, inform the NBA of:
 - (a) who the other party is;
 - (b) the scope and nature of the arrangement (excluding the pricing details); and

- (c) the potential impact on the Australian blood sector including the supply of blood products;
 - 47.4.4 provide any further information reasonably requested by the NBA and within the constraints of the requirements referred to in clauses 47.4.1, 47.4.2 and 47.4.3;
 - 47.4.5 consider and take into account any comments provided by the NBA, which comments will be provided in a timely manner and must be relevant to the NBA's statutory functions; and
 - 47.4.6 when the contract, arrangement, understanding or variation is finalised, promptly provide to the NBA a summary of that finalised contract, arrangement, understanding or variation including whether and the extent to which the NBA's comments have been taken into account.
- 47.5 Clause 47 applies to any contracts, arrangements, understandings, or variations referred to in this clause to the extent to which they relate to the performance of CSL's obligations under the Deed, and CSL must to that extent, during the term of those contracts, arrangements or understandings, provide information on them as reasonably requested by the NBA for purposes of administration of this Deed.
- 47.6 This clause 47 does not apply to a Toll Fractionation Contract.

48 CSL Personnel

Employer obligations

- 48.1 Any Personnel of CSL providing Products or performing Services on behalf of CSL under the Deed is and remains at all times an officer, Employee, independent contractor or agent of CSL.
- 48.2 CSL indemnifies the NBA in respect of any payment which the NBA is required to make (including but not limited to payments under the *Superannuation Guarantee (Administration) Act 1992* (Cth), payroll tax, other taxes, and any penalties and legal costs on an indemnity basis) and any loss or liability incurred by the NBA (including, but not limited to, the tax effect of the loss of any tax deductions) which results from the NBA being held at any time, despite the provisions of the Deed, to be the employer or principal of any of CSL's Personnel or becomes liable to pay any amounts in respect of such person.

Warranty as to qualifications of CSL's Personnel

- 48.3 CSL warrants to the NBA that CSL and its Personnel have the necessary qualifications, skills, competence, experience and ability to provide Products and perform Services required under the Deed.
- 48.4 If at any time the NBA is concerned that the warranties in clause 48.3 may not be met, then (without limitation to any other rights of the NBA under the Deed or at Law):
- 48.4.1 the NBA may notify CSL of the concern and the reasons for the concern; and
 - 48.4.2 CSL must, as soon as practicable after notification, investigate and consider the concern, and notify the NBA of its finding and conclusions and any appropriate remedial action in relation to the concern.

49 Intellectual Property

[Not disclosed. These clauses relate to pertinent intellectual property rights.]

Moral Rights

- 49.7 CSL must, if at any time reasonably requested by the NBA, obtain from all of its Personnel who are involved in the delivery of the Products or Services, a Moral Rights consent and waiver, in the form reasonably required by the NBA from time to time.

IP warranty

- 49.8 CSL warrants that, to the best of its knowledge and belief after having made reasonable enquiries, it is entitled, or will be entitled or will ensure that it is entitled at the relevant time, to deal with the Intellectual Property in respect of any Pre-existing Material (other than Pre-existing Material owned by a third party), Contract Material and other Material so as to perform its obligations under the Deed, including, without limitation to comply with clause 44.

50 Commonwealth Material

- 50.1 CSL acknowledges the NBA's ownership or control by licence of the Commonwealth Material and all Intellectual Property rights in respect of the Commonwealth Material.
- 50.2 Subject to this clause 50, the NBA grants a non-exclusive, non-transferable, royalty-free licence to CSL for the Term to use the Commonwealth Material solely for the purpose of providing the Products and performing the Services, and beyond the Term to the extent required to comply with mandatory legal requirements in relation to tax or accounting records.
- 50.3 The NBA will inform CSL of any Commonwealth Material provided to CSL under the Deed in respect of which third parties hold the Intellectual Property rights, and of any conditions attaching to the use of that Commonwealth Material because of such Intellectual Property rights.
- 50.4 CSL must:
- 50.4.1 ensure that Commonwealth Material is used, copied, supplied or reproduced only for the purposes of the Deed;
 - 50.4.2 ensure the safe keeping and maintenance of Commonwealth Material; and
 - 50.4.3 use Commonwealth Material strictly in accordance with any conditions or restrictions set out in the Deed, or as detailed or informed by the NBA to CSL from time to time.
- 50.5 On expiration or earlier termination of the Deed, CSL must promptly deliver the Commonwealth Material, and any copies of the Commonwealth Material, to the NBA or as the NBA directs, except that CSL may retain one copy in compliance with mandatory legal requirements in relation to tax and accounting.

51 Confidentiality

- 51.1 Each Party agrees not to disclose to any person, other than the other Party, any Confidential Information without prior written consent from the other Party (which consent will not be unreasonably withheld or delayed).
- 51.2 Despite clause 51.1, a Party may disclose Confidential Information of the other Party if the Confidential Information is:
- 51.2.1 disclosed to its advisers or Personnel solely in order to comply with obligations, or to exercise rights, under the Deed;
 - 51.2.2 disclosed to internal management Personnel, solely to enable effective management or auditing of Deed-related activities;
 - 51.2.3 disclosed to external auditors where required for mandatory auditing or reporting requirements under the *National Blood Authority Act 2003* (Cth), *Public Governance, Performance and Accountability Act 2013* (Cth), *Auditor-General Act 1997* (Cth), the Corporations Act or the rules of a the Australian Securities Exchange;
 - 51.2.4 in the case of the NBA, disclosed by the NBA to the responsible Minister (or his or her staff) or to the Parliamentary Cabinet for the purposes set out in clauses 49.5.1 to 49.5.3 or for the purposes of the National Blood Arrangements;
 - 51.2.5 in the case of the NBA, disclosed by the NBA in response to a request by a House or a Committee of the Parliament of the Commonwealth of Australia;
 - 51.2.6 in the case of the NBA, shared by the NBA within the NBA, or with another Commonwealth, State or Territory government agency in Australia, for the purposes set out in clauses 49.5.1 to 49.5.3 or for the purposes of the National Blood Arrangements;
 - 51.2.7 in the case of the NBA, provided by the NBA to the States and Territories or a State or Territory agency for purposes related to the NBA's functions under the National Blood Arrangements;
 - 51.2.8 disclosed by CSL as part of its mandatory or obligatory reporting requirements as a public company or under the rules of a stock exchange; or
 - 51.2.9 authorised or required by Law, or under the Deed, under a licence or otherwise, to be disclosed.
- 51.3 Where a Party determines that it is necessary to or is obliged to disclose Confidential Information under clause 51.2, the Party must limit the disclosure to the extent which the Party considers is reasonably necessary, and must inform the recipient of the other Party's claim that the information disclosed is confidential.
- 51.4 Nothing in this clause 51 derogates from any obligation which either Party may have either under the Privacy Act, or under the Deed, in relation to the protection of Personal Information.
- 51.5 Nothing in this clause limits or affects a Party's Intellectual Property rights set out or referred to in this Deed.
- 51.6 This clause 51 survives the expiration or earlier termination of the Deed.

52 Data Security

- 52.1 In this clause 52:
- 52.1.1 **Official Information** means any information developed, received or collected in connection with this Deed and by or on behalf of the Commonwealth, whether through the NBA or any other agency or any other Commonwealth contracted service provider.
- 52.2 Without limiting its obligations under the Deed, CSL must comply with the security requirements for the protection of Official Information detailed in the Commonwealth's Protective Security Manual, as amended from time to time. The NBA must give Formal Notice to CSL of Protective Security Manual requirements and CSL's obligation to comply with those requirements commences promptly after the date of notification.
- 52.3 CSL agrees that the NBA has a unilateral right, in its absolute discretion, to vary in any way the security requirements as specified in the Deed.
- 52.4 CSL must comply with any variation under clause 52.3 within 20 Working Days after notification of any such variation, or as otherwise agreed by the Parties.
- 52.5 CSL must participate in security reviews of the procedures implemented in performance of the Deed at least annually, if requested by the NBA. To the extent reasonably practicable, if the NBA requests such a review it will form part of a Review.
- 52.6 CSL must not permit any of its Personnel to have any access to information which has a security classification under the Protective Security Manual other than 'unprotected' (**Security Classified Information**) unless:
- 52.6.1 that person has been cleared, to a security level adequate for that access and in accordance with applicable processes for clearance advised by the NBA;
- 52.6.2 the NBA has given approval in writing for that person to have access to the specific items of security classified information; and
- 52.6.3 that person has undergone the training required by the NBA relating to the access to and use of security classified information.
- 52.7 CSL must notify the NBA promptly upon becoming aware that any unauthorised person has had access to Security Classified Information.
- 52.8 If an incident set out in clause 52.7 occurs, CSL must promptly comply with any reasonable directions of the NBA in order to rectify the security problem.
- 52.9 In granting approval under clause 52.6.2 the NBA may impose any conditions it considers necessary.
- 52.10 The rights and obligations arising in connection with this clause 52 will survive the expiry or earlier termination of the Deed.

53 Privacy

Interpretation

- 53.1 In this clause 53, **APP code**, **Australian Privacy Principle** and **CR code** have the same meaning as in the Privacy Act.

Application of the clause

53.2 This clause applies only where CSL deals with Personal Information when, and for the purpose of, providing the Products and Services under this Deed.

Obligations

53.3 CSL must:

53.3.1 comply with its obligations under the Privacy Act, including all applicable regulations and registered APP codes or CR codes; and

53.3.2 not engage in an act or practice in connection with the provision of the Products or Services that would:

(a) breach an Australian Privacy Principle;

(b) be an interference with the privacy of an individual under the Privacy Act;

unless that act or practice is permitted under the Privacy Act;

53.3.3 not do any act, or engage in any practice, in connection with the provision of the Products or Services or this Deed, that would breach an Australian Privacy Principle if it were done or engaged in by the NBA;

53.3.4 collect, use, disclose, store, retain and dispose of any Personal Information obtained in the course of performing its obligations under this Deed only for the purposes of, and as required by, this Deed.

53.3.5 without limiting clause 53.3.4, not use any Personal Information obtained in the course of performing its obligations under this Deed for the purposes of direct marketing (as that term is used in the Privacy Act);

53.3.6 comply with the security obligations in the Deed in relation to the collection, storage, use or disclosure of any Personal Information obtained in the course of performing its obligations under this Deed;

53.3.7 not transfer outside of Australia any Personal Information obtained as a result of or in connection with performing its obligations under this Deed, or allow access to such Personal Information from a location outside of Australia without the prior approval of the NBA;

53.3.8 comply with any Notice given to CSL by the NBA which is necessary to enable the NBA to comply with any data breach notification requirement under the Privacy Act;

53.3.9 ensure that all of its Personnel who collect, use, disclose or retain Personal information obtained in the course of performing CSL's obligations under the Deed are made aware of CSL's obligations under this clause 53; and

53.3.10 immediately notify the NBA if CSL becomes aware of any breach, or possible breach, of any obligations under this clause, including by its Personnel or subcontractors.

Subcontracts

53.4 CSL must ensure that any subcontract entered into for the purpose of fulfilling its obligations under this Agreement contains provisions to ensure that the subcontractor has the same awareness and obligations as CSL has under this clause 53, including the requirement in relation to subcontracts.

Indemnity

- 53.5 CSL indemnifies the NBA in respect of any loss suffered or incurred by the NBA which arises directly or indirectly from a breach of any of the obligations of CSL under this clause 53, or a subcontractor under the subcontract provisions referred to in clause 53.4.

54 Conflict of Interest

- 54.1 CSL warrants that, except as notified to the NBA at the date of signing the Deed, no Conflict of Interest exists or is likely to arise for it or its Personnel.
- 54.2 CSL must use its reasonable endeavours (including making all appropriate enquiries) to:
- 54.2.1 ensure that a situation does not arise that may result in a Conflict of Interest; and
 - 54.2.2 ensure that none of its Personnel, during the Term, engages in any activity or obtains any interests that may reasonably be considered to conflict with, or restrict CSL in, performing its obligations under the Deed fairly and independently.
- 54.3 CSL must not during the Term, engage in any activity, transaction or arrangement that would be likely to result in a Conflict of Interest arising or continuing (including any activity, transaction or arrangement which the NBA may reasonably view as a Conflict of Interest), unless CSL has complied with clause 54.4 and the NBA has given its written approval for CSL to engage in that activity.
- 54.4 Where a Conflict of Interest arises or may arise in the performance of CSL's obligations under the Deed, CSL must notify the NBA promptly of the situation, provide any information reasonably requested by the NBA and follow all reasonable directions by the NBA about the method for handling the Conflict of Interest.

55 Offences under Crimes Act and Criminal Code Act 1995

- 55.1 CSL acknowledges that:
- 55.1.1 any unauthorised access, alteration, removal, addition, possession, control, supply or impediment to the access, reliability, security or operation of data held in any computer (or, in some cases, any storage device) in the course of performing a Deed for the NBA may be an offence under Part 10.7 of the *Criminal Code Act 1995* (Cth) for which there are a range of penalties, including a maximum of ten years' imprisonment;
 - 55.1.2 the giving of false and misleading information to the NBA or its Personnel is a serious offence under Division 137 of the *Criminal Code Act 1995* (Cth); and
 - 55.1.3 the publication or communication of any fact or document by a person which has come to their knowledge or into their possession or custody by virtue of the performance of the Deed (other than to a person to whom CSL is authorised to publish or disclose the fact or document) may be an offence

under sections 70 and 79 of the *Crimes Act 1914* (Cth), the maximum penalty for which is seven years' imprisonment.

56 Compliance with Commonwealth policies

- 56.1 CSL must, when using the NBA's premises or facilities, comply with:
- 56.1.1 all reasonable directions and Commonwealth procedures relating to occupational health (including the NBA's smoke free work place policy), safety and security in effect at those premises or in regard to those facilities, when such procedures are brought to their attention; and
 - 56.1.2 all other reasonable Commonwealth, State or Territory policies which are notified to it from time to time.

57 Indigenous Procurement Policy

Interpretation

- 57.1 In this clause 57, **Indigenous Enterprise** means an organisation that is 50 per cent or more Indigenous owned that is operating a business.

Requirement to increase purchasing from Indigenous Enterprises and employment of Indigenous Australians

- 57.2 CSL acknowledges that it is the Commonwealth's policy to stimulate Indigenous entrepreneurship and business development, and to provide Indigenous Australians with more opportunities to participate in the economy. The Commonwealth's Indigenous Procurement Policy as amended from time to time is available at the Commencement Date at <http://www.dpmc.gov.au/indigenous-affairs/publication/commonwealth-indigenous-procurement-policy>.
- 57.3 CSL must use reasonable endeavours to increase its:
- 57.3.1 purchasing from Indigenous Enterprises; and
 - 57.3.2 employment of Indigenous Australians,
- in its performance of its obligations under the Deed.
- 57.4 For the purposes of clause 57.3, purchases from Indigenous Enterprises may be in the form of engagement of an Indigenous Enterprise as a subcontractor, and use of Indigenous suppliers in CSL's supply chain.

Reporting

- 57.5 CSL must provide a written report and evidence of its compliance with this clause 57 every year during the term of the Deed, promptly following each anniversary of the Commencement Date.

58 Illegal Workers

- 58.1 For the purposes of this clause 58, **Illegal Worker** means a person who:
- 58.1.1 has unlawfully entered and remains in Australia;

- 58.1.2 has unlawfully entered Australia, but remains in Australia after his or her visa has expired; or
- 58.1.3 is working in breach of his or her visa conditions.
- 58.2 CSL must ensure that none of its Personnel, including those engaged by any subcontractors (in each case, after the Commencement Date), are Illegal Workers.
- 58.3 CSL must include requirements similar to clause 58.2 in any subcontract.
- 58.4 CSL must remove, or cause to be removed, any Illegal Worker from any involvement in the performance of its obligations under this Deed and arrange for their replacement at no cost to the NBA and immediately upon becoming aware of the involvement of the Illegal Worker.
- 58.5 If requested by the NBA, CSL must provide evidence within 10 Working Days that it has taken all reasonable steps to ensure that it has complied and is complying with its obligations under this clause 58.
- 58.6 CSL may check each of its Personnel's entitlement to work in Australia at <http://www.border.gov.au/Busi/Visa>.

59 Workplace Gender Equality

- 59.1 This clause 57 applies only to the extent that CSL is a relevant employer for the purposes of the *Workplace Gender Equality Act 2012 (Cth)* (**WGE Act**).
- 59.2 CSL must comply with its obligations, if any, under the WGE Act.
- 59.3 If CSL becomes non-compliant with the WGE Act during the term of the Deed, CSL must notify the NBA.
- 59.4 CSL must provide a current letter of compliance within 18 months from the Commencement Date and following this, annually, to the NBA.
- 59.5 Compliance with the WGE Act does not relieve CSL from its responsibility to comply with its other obligations under the Deed.

60 Work Health and Safety

- 60.1 In this clause 60:
- 60.1.1 corresponding WHS Law has the meaning given in section 4 of the WHS Act;
- 60.1.2 Regulator means an authority referred to in a WHS Law as the relevant authority for occupational health and safety complaints, queries or investigations;
- 60.1.3 WHS Act means the *Work Health and Safety Act 2011 (Cth)*;
- 60.1.4 WHS Law means the WHS Act and any corresponding WHS Law;
- 60.1.5 WHS entry permit holder has the meaning given in the WHS Act; and
- 60.1.6 WHS Regulations means the regulations made under the WHS Act.
- 60.2 CSL must, in carrying out its obligations under this Deed, comply, and use reasonable endeavours to ensure that its subcontractors comply, with the provisions of all relevant statutes, regulations, by-laws and requirements of any Commonwealth, State, Territory

or local authority including those arising under a WHS Law in respect of occupational health and safety.

- 60.3 CSL must, in carrying out its obligations under this Deed, comply, and use reasonable endeavours to ensure that its subcontractors comply, with any of the Commonwealth's work, health and safety policies as notified, referred to, or made available, by the Commonwealth to CSL in writing.
- 60.4 If CSL is required by a WHS Law to report to a Regulator an incident arising out of the provision of the Products and Services:
- 60.4.1 at the same time, or as soon as is possible in the circumstances, CSL must give notice of such incident, and a copy of any written provided to a Regulator, to the NBA; and
- 60.4.2 CSL must provide to the NBA, within such time as is specified by the NBA, a report detailing the circumstances of the incident, the results of investigations into its cause, and any recommendations or strategies for prevention in the future.
- 60.5 CSL must inform the NBA of the full details of:
- 60.5.1 any suspected contravention of a WHS Law relating to the provision of the Products and Services, within 24 hours of becoming aware of any such suspected contravention;
- 60.5.2 any cessation or direction to cease work relating to the provision of the Products and Services, due to unsafe work, immediately upon CSL being informed of any such cessation or direction;
- 60.5.3 any workplace entry by a WHS entry permit holder, or an inspector, to any place where CSL's obligations under the Deed are being performed or undertaken, within 24 hours of becoming aware of any such workplace entry; and
- 60.5.4 any proceedings against CSL or its officers, or any decision or request by the Regulator given to CSL or its Personnel, under a WHS Law, within 24 hours of becoming aware of any such proceedings, decision or request.

61 Compliance with Laws

- 61.1 Without limiting any other clause in the Deed, CSL must supply Products and perform Services and otherwise comply with the Deed so as to comply with all applicable Laws.

62 Encumbrances

- 62.1 CSL must not Encumber any Asset, without the prior written approval of the NBA (provided that this clause does not apply to encumbrances which are unavoidably imposed or implied by Law).

Chapter 8

Review, variation, termination and transition

Chapter outline

This chapter provides for:

- transition processes at the commencement of the Deed;
- a Contract Term Review to determine the duration of the Deed;
- other processes for review and variation of the Deed;
- the grounds and processes for termination of the Deed and handover to a new arrangement.

Matters covered in this chapter are detailed more specifically in Schedules 11 and 12 and Template 3.

63 Transition in

- 63.1 The provisions of this Deed operate subject to any separate agreement entered into by the Parties for the purpose of this clause 63 with regard to the transition to arrangements under this Deed from arrangements operating prior to the Commencement Date.

64 Contract Term Review

General

- 64.1 The NBA agrees to conduct a review of this Deed (**Contract Term Review**), in accordance with this clause 64 to determine the Expiry Date of the Deed under clause 4.2.
- 64.2 The NBA must give CSL Formal Notice of the commencement of the Contract Term Review, and must use reasonable endeavours to complete the Contract Term Review by 30 June 2022 or as soon as practicable after that date.

Note – Clause 4.2 provides that the Expiry Date of the Deed will be 31 December 2026 unless the Contract Term Review determines that it is 31 December 2022 or an alternative date as determined under clause 64.5.2(b).

Key parameters

- 64.3 In the Contract Term Review the NBA must determine whether the NBA is reasonably satisfied that:
- 64.3.1 CSL has satisfactorily performed its obligations under this Deed up to and as at the date of the Contract Term Review, based on consideration of:
 - (a) the level of achievement of KPIs by CSL; and
 - (b) whether CSL has been or remains materially in default of obligations under this Deed in a way which has not been or is unable to be satisfactorily remedied by CSL;
 - 64.3.2 the supply of Products under this Deed continues to satisfactorily meet clinical needs of patients in Australia for the purposes determined by Australian Governments under the National Blood Agreement and represents the proper use of public resources in accordance with the *Public Governance, Performance and Accountability Act 2013* (Cth);
 - 64.3.3 Process Migration has been satisfactorily implemented in accordance with any decisions made, or guidance issued, by the Process Migration Governance Committee in accordance with its terms of reference established pursuant to clause 12.7; and
 - 64.3.4 there are no material policy changes by Australian Governments that would affect the production or supply of Products under this Deed.
- 64.4 For the purposes of clause 64.3.2, the NBA must provide CSL with an opportunity to offer revised prices to the NBA which provide equivalent or better value for money for Products and Services under this Deed before the NBA makes a final determination that it is not reasonably satisfied of the matters referred to in clause 64.3.
- 64.5 The outcome of the Contract Term Review will be as follows:

- 64.5.1 if the NBA determines that it is reasonably satisfied of each of the matters in clause 64.3, then the Expiry Date of the Deed will be 31 December 2026 in accordance with clause 4.2.1;
- 64.5.2 if the NBA determines that it is not reasonably satisfied of one or more of the matters in clause 64.3, then:
 - (a) the Expiry Date of the Deed will be 31 December 2022 in accordance with clause 4.2.2; or
 - (b) the Parties may agree to an alternative Expiry Date (including provision to further amend the Expiry Date on one or more occasions) provided that any alternative Expiry Date is not later than 31 December 2026, and to any other variation to the Deed, in accordance with clause 67.

Review process

- 64.6 The NBA may take into account any relevant information available to it in relation to the Contract Term Review.
- 64.7 The NBA must:
 - 64.7.1 provide CSL with a reasonable opportunity to provide information to the NBA in relation to the matters to be considered in the Contract Term Review;
 - 64.7.2 provide CSL with a reasonable opportunity to respond to information not known to CSL which may materially affect the NBA's considerations in the Contract Term Review, to the extent that the NBA can appropriately do so; and
 - 64.7.3 take information and responses provided by CSL into account in good faith for the purposes of the Contract Term Review.
- 64.8 If CSL considers that the NBA may not have taken into account in good faith, information or a response provided by CSL under clause 64.8, CSL may give a Dispute Notice of that matter under clause 45.
- 64.9 The NBA must give CSL Formal Notice of:
 - 64.9.1 the NBA's findings in relation to the matters required to be determined in the Contract Term Review; and
 - 64.9.2 the outcomes of the Contract Term Review, including, if applicable, a revised Schedule 11 to apply during the Additional Period.

65 Other Reviews

The NBA may conduct Reviews

- 65.1 The NBA may conduct Reviews in relation to the Deed at a date and time nominated by the NBA in consultation with CSL. The NBA anticipates that, subject to unforeseen circumstances, it will conduct no more than one review of the Deed in any calendar year.
- 65.2 Without limitation to clause 65.1, the NBA may conduct a review with particular reference to any of the following matters:
 - 65.2.1 a material change in requirements under the TG Act;

- 65.2.2 CSL's level of performance of its obligations under this Deed;
 - 65.2.3 a material change or intended change to the clinical demand, the Product Specifications, or the funding policy of Australian Governments, in relation to a Product under this Deed;
 - 65.2.4 a material change to the relative demand for Products which may affect the pricing basis under this Deed;
 - 65.2.5 the outcomes of a review by the NBA or Australian Governments of policy or implementation under the National Blood Agreement;
 - 65.2.6 the value for money of prices for Products under this Deed; and
 - 65.2.7 any matter referred to in clause 64.3.
- 65.3 The NBA must use reasonable endeavours to ensure that any Review performed in accordance with this clause 65 does not unreasonably delay or disrupt CSL's operations in any material respect.

Results of the Review

- 65.4 If, in the NBA's opinion, the results of a Review indicate that any changes should be made to the Deed, the NBA may, in accordance with clause 67, propose one or more changes to the Deed to implement the results of the Review.
- 65.5 Unless otherwise agreed in writing by the NBA, if a Review identifies that CSL has failed to comply with any of its obligations under the Deed, upon receiving Formal Notice from the NBA of that failure, CSL must, following consultation between CSL and the NBA, promptly undertake any actions needed to rectify the failure at the NBA's reasonable direction and CSL's cost. This clause does not limit any of the NBA's rights under the Deed or otherwise in respect of any failure by CSL to comply with any obligation under the Deed.

66 CSL to participate in Reviews

- 66.1 CSL must, at its own expense:
- 66.1.1 participate in each Review under clause 64 or 65 as is reasonably requested by the NBA; and
 - 66.1.2 for the purpose of any such Review, use all reasonable endeavours to provide, within 10 Working Days of a request by the NBA, and in addition to other obligations under the Deed, any information, access to records, and advice reasonably requested by the NBA which are relevant to the review.

67 Variations to the Deed

General

- 67.1 Subject to any express provision of the Deed which permits the contrary in particular circumstances, no change may be made to the Deed without:
- 67.1.1 prior consultation between the Parties;
 - 67.1.2 the Parties complying with the change control procedures included in this clause 67; and

67.1.3 the Parties executing a variation in writing.

Change Control

67.2 Either Party may propose a change to any part of the Deed.

67.3 A Party proposing a change to the Deed must provide detailed written information to the other Party about:

67.3.1 the reason and purpose for the proposed change;

67.3.2 the detailed amendments proposed to the Deed (including the Schedules);

67.3.3 any timing or transitional implications arising from the proposal;

67.3.4 any specific matters required to be addressed in relation to that change by any other provision of the Deed; and

67.3.5 any other matters reasonably requested by the other Party in relation to the proposed change;

in accordance with Template 3.

67.4 A Party must:

67.4.1 take into account a proposal provided under clause 67.2; and

67.4.2 respond to that proposal with reasons within 15 Working Days.

67.5 Subject to clause 67.7, the Parties must decide whether they agree on the proposal provided under clause 67.2 within 30 Working Days of the provision of the proposal.

67.6 Despite clause 67.5, a Party is not obliged to agree to any proposal made by the other Party and, in particular, the NBA is not liable for any additional work undertaken or expenditure incurred by CSL unless the change has been made in accordance with the Deed.

67.7 Despite any other provision of this clause 67.1, where (at any time, whether before or after a proposal is made under clause 67.2) the NBA gives CSL Formal Notice that a particular change to the Deed requires, or is required by, a decision of Australian Governments in accordance with the National Blood Arrangements, and notifies CSL of any:

67.7.1 additional processes;

67.7.2 increased or decreased timeframes;

67.7.3 deadlines; or

67.7.4 other changed requirements for the process of considering the change;

which are necessary or appropriate to be followed as a consequence of the National Blood Arrangements, the operation of this clause 67 will be modified in accordance with the changed arrangements notified by the NBA.

67.8 Without limiting the rights of a Party under this clause 67, CSL may at any time propose a change to the Deed (including, without limitation, increases to the Payments) if:

67.8.1 after the Commencement Date there is a change to requirements under or action taken by the TGA that affects the manufacture of the Products and has or will result in a material increase in costs of CSL or has or will adversely impact the yield for one or more Products; or

- 67.8.2 there is a direction given by the NBA under the Deed that CSL is obliged to follow and that direction will result in a material increase in costs of CSL or has or will adversely impact the yield for one or more Products.

Limitation on variations

- 67.9 CSL must not propose a change under this clause 67 to the price or fees applying to a Product under Schedule 11, where and to the extent that the reason for the proposed change is a reduction in the level of Orders received or anticipated to be received by CSL for the Product.

68 Termination for Cause

- 68.1 Without prejudice to its rights at common law or under any statute, the NBA may, by Formal Notice in writing to CSL, immediately:
- 68.1.1 terminate the Deed in whole; or
 - 68.1.2 terminate the Deed with respect to particular Products or Services (to reduce the scope of the Deed), which termination is a partial termination;
 - 68.1.3 if:
 - 68.1.4 an Insolvency Event occurs in respect of CSL;
 - 68.1.5 CSL commits a material breach of the Deed which is not capable of remedy; or
 - 68.1.6 CSL fails to take action to remedy a breach of another obligation under the Deed and does not commence to remedy the breach within 5 Working Days after being given Formal Notice by the NBA requiring CSL to remedy the breach or fails to remedy the breach within 20 Working Days (or such longer period as consented to by the NBA) after being given that Formal Notice.
- 68.2 A Party may terminate the Deed as expressly permitted under clauses 34.8, 43.7.2, 43.8 or 44.8.
- 68.3 Nothing in this Deed affects any right CSL may have at common law or under any statute to terminate the Deed.
- 68.4 If the Deed is terminated under this clause 68, clause 69 or any other provision of this Deed, subject to the Deed:
- 68.4.1 the Parties are relieved from future performance (to the extent of the termination if a partial termination occurs), without prejudice to any right of action that has accrued at the date of termination;
 - 68.4.2 the NBA's rights to recover damages are not affected, provided that termination as permitted under clause 44 does not, of itself, give rise to a right to recover damages;
 - 68.4.3 CSL must take all reasonable steps to protect, and otherwise must comply with all obligations in the Deed relating to, Commonwealth Material and Contract Material, Personal Information, Confidential Information and Intellectual Property;
 - 68.4.4 CSL must at its cost deliver any Commonwealth Material, Contract Material or other NBA Confidential Information held by it to the NBA, except that CSL

may retain a copy of Contract Material for the purpose of compliance with Laws, maintaining a record of its performance of the Deed or, where Contract Material is of general application, its ongoing business activities; and

- 68.4.5 CSL must continue to provide Products and Services in accordance with this Deed until the effective date of the notice of termination.

69 Termination for Change in Policy

Notice of termination

- 69.1 The NBA may, at any time by Formal Notice to CSL, terminate the Deed following any change in government policy where the NBA is requested by Australian Governments under the National Blood Arrangements to terminate the Deed, or which, in the NBA's reasonable opinion, makes continuation of the Deed inconsistent with that changed policy. The NBA will provide:

- 69.1.1 not less than 24 months' notice of an exercise of the NBA's rights under this clause, but may provide less notice where the remaining period of the Term is less than 24 months; or

Note – Clause 4.2 provides that the Expiry Date of the Deed will be 31 December 2026 unless the Contract Term Review determines that it is 31 December 2022 or as otherwise determined in accordance with clause 64.5.2(b).

- 69.1.2 such lesser period of notice as is practicable in the context of the change in government policy.

- 69.2 Termination under clause 69.1 takes effect on and from the time specified in the notice.
- 69.3 For the avoidance of doubt, and subject to clause 69.1, the NBA has an unfettered discretion to terminate the Deed in accordance with this clause 69.

Termination payments

- 69.4 If the Deed is terminated under clause 69.1, the NBA will be liable only for:
- 69.4.1 Payments which would otherwise be properly payable in accordance with the Deed for the Products or Services provided in accordance with the Deed and any Payment required under clause 34 before the effective date of termination, or after that date in accordance with clause 69; and
- 69.4.2 [Not disclosed – this clause provides a framework for calculating payment for plasma volume.]
- 69.5 [Not disclosed – this clause provides the formula to calculate payments for plasma volume.]

70 Handover obligations

- 70.1 CSL must:
- 70.1.1 as requested by Formal Notice from the NBA, continue the provision of the Products and Services for a period specified in the Formal Notice of up to one year after the termination or expiry of the Deed or such other period as is agreed by Formal Notice by the Parties, so as to ensure an orderly handover of the Products and Services;

- 70.1.2 allow where reasonably required by the NBA, any new service provider(s) to access CSL's Personnel so as to assist in the orderly handover of provision of the Products and Services;
- 70.1.3 undertake all reasonable measures to ensure that all CSL Personnel are aware of their obligations under the Deed which relate to confidentiality, security and privacy and that continue after the expiry or earlier termination of the Deed; and
- 70.1.4 allow the NBA to audit compliance with this clause 70.
- 70.2 In respect of expiry of the Deed or termination for any reason:
- 70.2.1 the NBA may, after reasonable consultation with CSL, determine a Transition Out Plan which, without limitation, may provide for the following matters:
- (a) delivery by CSL to the NBA of Commonwealth Material and Contract Material (not including Excluded Material, and irrespective of whether such Contract Material is Confidential Information) which may be reasonably required by the NBA for the purposes of this clause 69;
 - (b) provision of information by CSL on all Subcontracts, whether or not they have previously been disclosed to the NBA, relating to the provision of the Products and Services;
 - (c) delivery by CSL to the NBA or any other person in accordance with the NBA's direction, of any Starting Plasma held by CSL, of Products held in CSL Inventory or National CSL Reserve, at the date of cessation of CSL's obligations under clause 70.1.1;
 - (d) the obligations to be performed by each Party in connection with the orderly handover of delivery of the Products and Services from CSL to the NBA or its nominee within the handover period; and
 - (e) training to be provided by CSL including the period and nature of the training;
- 70.2.2 CSL must assist the NBA in developing, and must implement and comply with the Transition Out Plan and provide all reasonable assistance and cooperation, whether or not on matters specifically dealt with in the Transition Out Plan, necessary for the orderly handover of the provision of the Products and Services from CSL to the NBA or its nominee at the expiration or termination of the Deed;
- 70.2.3 the Parties agree that the terms and conditions of the Deed including in relation to Payments (including any applicable indexation) apply to the provision of any Products and/or Services by CSL during the handover period under this clause 70; and
- 70.2.4 CSL must not hinder in any way, the handover of the provision of services similar to the Services and/or the provision of products similar to the Products to a new service provider upon termination or expiration of the Deed or part of the Deed.
- 70.3 For greater certainty, but without limiting the NBA's rights under the Deed, nothing in this clause 70 or the Transition Out Plan:

- 70.3.1 will oblige CSL to disclose or permit the NBA to disclose any of CSL's Confidential Information or Intellectual Property to any other person, without the prior written consent of CSL;
- 70.3.2 is an assignment of CSL's Intellectual Property rights;
- 70.3.3 obliges CSL to grant Intellectual Property licences that are not already granted under this Deed; or
- 70.3.4 obliges CSL to provide assistance in relation to the handover of the provision of the Products and Services to the NBA or any third party that would require providing Materials to NBA or any third party other than the Materials set out in clause 70.2.

Costs

- 70.4 The NBA agrees to make Payments to CSL for:
 - 70.4.1 any Products and/or Services that CSL provides in accordance with the Deed in complying with its obligations under this clause 70; and
 - 70.4.2 the lesser of:
 - (a) the Minimum Product Inventory; or
 - (b) CSL Inventoryas at the later of:
 - (c) the termination or expiry of the Deed; or
 - (d) the end of the handover period specified under clause 70.1.1;(the **End Date**)
as though those amounts of Products had been supplied by CSL to Approved Health Providers in accordance with the Deed on the End Date.
- 70.5 In addition to this clause, the NBA agrees to pay CSL's reasonable costs of complying with the Transition Out Plan except where the handover referred to in clause 70.1 arises from a termination by the NBA under clauses 68.1 or 44.8.

Chapter 9

Definitions, interpretation and legal operation of the Deed

Chapter outline

This chapter includes:

- definitions and rules of interpretation which apply throughout the Deed; and
- certain clauses describing the basic legal operation of the Deed.

71 Definitions

71.1 In the Deed, the following definitions apply unless the contrary intention is stated or applies by necessary implication:

Definition

Action Plan means the plan for supply continuity referred to in clause 44

Additional Period means a period from 1 January 2023 to 31 December 2026 which forms part of the Term of the Deed, or as otherwise determined by the Contract Term Review in accordance with clauses 4.2 and 64

Alternative Product means a product which may be supplied by CSL in place of a comparable Product under the Deed, through alternative supply arrangements under clause 22

Annual Supply Estimate means the draft, final or revised estimate of the requirement for supply of Products under the Deed for a financial year (including two forward years), specified by Product on a monthly basis, which is based on the supply plan approved by Australian Governments under the National Blood Agreement so far as it relates to Starting Plasma and Products under this Deed, as prepared and given to CSL by the NBA in accordance with clause 14.2

Approved Health Provider means those persons approved by the NBA to receive Products under the Deed who are specified in, or determined in accordance with the procedures set out in clause 18

Approved Home Delivery Recipient means an individual who is approved to receive Products approved for Home Delivery under this Deed

Asset means any:

- (a) plant or equipment; or
- (b) premises or facilities;

owned by CSL and used for the purposes of performing the Deed; and

- (c) Starting Plasma;
- (d) Products; and
- (e) incomplete Products

in the possession, custody or control of CSL at any time on or after the Commencement Date

Australian Governments means the Australian Commonwealth, State and Territory governments that are parties to the National Blood Arrangements

Commencement Date means the date specified in clause 4.1

Commonwealth means the Commonwealth of Australia

Commonwealth Material means any Material provided by, or on behalf of, the NBA to CSL for the purposes of the Deed

Confidential Information means information that is by its nature confidential and which is:

- (a) specified in Schedule 14 to be confidential; or
- (b) agreed in writing by the Parties to be confidential, prior to the information being disclosed by one Party to the other;

but does not include information which is or becomes public knowledge other than by breach of the Deed or any other confidentiality obligation. Except as specified in Schedule 14, the Parties agree that the terms and conditions of the Deed (including the Payment amounts in Schedules 11 and 12) are not Confidential Information

Conflict of Interest means, in relation to CSL or its Personnel, any circumstances which:

- (a) constitute a material conflict;
- (b) constitute a known and material risk of conflict; or
- (c) may reasonably be perceived by others to constitute a material conflict, between
- (d) the interests of the NBA and those of CSL or its Personnel; or
- (e) the duties of CSL or its Personnel to the NBA and their duties to another person;

in relation to the provision of the Products or the performance of the Services, whether through corporate, professional or personal relationships or otherwise, but does not include performance of obligations under the Deed or a dispute under the Deed

Contract Material means all Material:

- (a) provided or required to be provided by CSL to the NBA under the Deed;
- (b) used for the purpose of providing the Products or performing the Services or otherwise complying with the Deed;
- (c) used or created for the purpose of business processes relevant to the Deed, whether or not that Material is supplied to the NBA;
- (d) incorporated in, supplied or required to be supplied along with the Material in paragraph (a); and
- (e) copied or derived from Material referred to in paragraphs (a) to (d),

but does not include Excluded Material or Commonwealth Material

Contract Term Review means the review of the Deed undertaken by the NBA in accordance with clause 64

Corporations Act means the *Corporations Act 2001* (Cth)

CSL Act means the *Commonwealth Serum Laboratories Act 1961* (Cth)

CSL Inventory means the inventory of Products held by CSL, including Minimum Product Inventory but excluding National CSL Reserve

Deed means this Deed, including its Schedules and any documents incorporated into the Deed by reference

Delivered Annual Starting Plasma for a financial year means the amount of Starting Plasma determined as such in accordance with Schedule 12

Direction Notice means a notice given by the NBA under clause 44

Distributor means an Approved Health Provider designated by the NBA as a Distributor under clause 18.6

Document means:

- (a) any paper or other Material on which there is writing, marks, figures or symbols having a meaning for persons qualified to interpret them; or
 - (b) any article or Material from which sounds, images or writings are capable of being reproduced with or without the aid of any other article or device
-

Employee means a person:

- (a) engaged under a contract of service, whether express or implied, oral or in writing; or
 - (b) engaged under statute as an employee
-

Encumber in relation to property, means to grant any interest, including without limitation a contingent interest, or an interest in or a power over the property which secures payment of a debt or any other obligation, in relation to that property. **Encumbrance** has a corresponding meaning

Excluded Material means Material that relates solely to:

- (a) Intellectual Property rights in respect of the composition or manufacture of the Products; and
 - (b) Material referred to in paragraph (c) of the definition of 'Contract Material' to the extent that it is unrelated to the supply of Products and Services under the Deed
-

Expired Product Unit means a Product Unit which has passed the expiry date specified for the Product Unit in accordance with the requirements of the TG Act

Expiry Date means the date until which the Deed operates, as specified in clause 4.2

Expiry Risk Product means a Product which is identified as such in Schedule 5

Note – Products have been identified as Expiry Risk Products where the Parties consider that the Product may at risk of expiry based on normal patterns of production, management and supply in relation to the Product.

Financial Undertaking means the financial undertaking referred to in clause 41 and Template 4

Force Majeure Event has the meaning set out in clause 43

Formal Notice means a notice given by a Party under a clause of the Deed referring to a Formal Notice, in accordance with clause 10 and Template 2

General Manager means the contact person for a Party specified in Schedules 1 or 2 as that Party's General Manager for the purpose of the Deed

Home Delivery means arrangements for supply of a Product where CSL delivers the Product to a patient or a parent or guardian of a patient under the supervision of an AHP, in accordance with clause 18.8 and Schedule 15.

Home Delivery Order means an Order made in accordance with Schedule 15

Hyperimmune Product means any of the following types of Products:

- (a) CMV Immunoglobulin;
 - (b) Hepatitis B Immunoglobulin;
 - (c) Normal Immunoglobulin;
 - (d) Rh (D) Immunoglobulin;
 - (e) Tetanus Immunoglobulin; and
 - (f) Zoster Immunoglobulin
-

Ig Products means IVIg and SCIg

Insolvency Event, in respect of CSL, means the occurrence of:

- (a) the appointment of a liquidator, provisional liquidator or administrator to CSL;
- (b) the appointment of a controller (as defined in section 9 of the Corporations Act) or analogous

- person appointed to CSL or any of its property;
- (c) CSL failing to comply, under paragraph 459F(1) of the Corporations Act, with a statutory demand;
 - (d) CSL being unable to pay its debts as they fall due or otherwise becoming insolvent;
 - (e) CSL ceasing to exist, for whatever reason, or otherwise becoming incapable of managing its own affairs for any reason
 - (f) CSL taking any step that could result in CSL becoming insolvent under administration (as defined in section 9 of the Corporations Act);
 - (g) any action being commenced to bankrupt or wind-up the affairs of CSL; or
 - (h) CSL entering into a compromise or arrangement with, or assignment for the benefit of, any of its members or creditors, or any analogous event
-

Intellectual Property means:

- (a) any copyright, trade mark, trade secret, service mark, design, drawing, patent, know-how, secret process and other similar proprietary rights and the rights to the registration of those rights; and
 - (b) any application or right to apply for registration of any of the rights in paragraph (a), whether created, formed or arising before or after the date of the Deed in Australia or elsewhere
-

Intensive Product Management means arrangements for the management of the supply of Products established by the NBA under clause 21 from time to time

IVIg means polyvalent intravenous immunoglobulin

Key Performance Indicators (or **KPIs**) means the Key Performance Indicators for the Products and Services which are set out in, or established in accordance with the process set out in, Schedule 10

Law means the common law, and any Commonwealth, State, Territory or local government statute, regulation, by-law, ordinance, proclamation or other or subordinate legislation, as applicable and in force from time to time

Material includes documents, equipment, software, goods, information and data stored by any means (but not including Products).

Minimum Annual Starting Plasma Volume for a financial year means the amount of Starting Plasma specified as such in Schedule 12

Minimum Product Inventory means, for each Product, the minimum amount of the Product that CSL is required to hold in CSL Inventory in accordance with clause 16 and Schedule 7

Minimum Starting Plasma Inventory means the minimum amount of Starting Plasma that CSL is required to hold in accordance with clause 13 and Schedule 7

Moral Rights means rights of integrity of authorship, rights of attribution of authorship, rights not to have authorship falsely attributed, and rights of a similar nature conferred by statute that exist, or may come to exist, anywhere in the world

National Blood Arrangements means the policy, administrative and financial arrangements established between Commonwealth, State and Territory governments in the National Blood Agreement and the *National Blood Authority Act 2003* (Cth)

National CSL Reserve means the reserve of Products required to be held under clause 17

Notifiable Events means the events set out in clause 6.1

Order means an order at a particular time for a particular quantity of one or more particular Products under the Deed as set out in clause 18, and **Ordered** and **Ordering** have corresponding meanings

Party means the NBA or CSL, as the context requires. **Parties** means both the NBA and CSL

Payments means those amounts which are to be paid by the NBA for the provision of the Products or Services by CSL, or otherwise under the Deed, and which are set out or described in clauses 33 to 35

Personal Information means information or an opinion (including information or an opinion forming part of a database), whether true or not, and whether recorded in a material form or not, about a natural person whose identity is apparent, or can reasonably be ascertained, from the information or opinion or as otherwise provided from time to time in the Privacy Act

Personnel of a Party means its directors, officers, employees, agents, subcontractors and their Personnel

Plasma Material means:

- (a) Starting Plasma;
 - (b) Production Intermediates;
 - (c) Product Units;
 - (d) Expired Product Units; and
 - (e) any other substance containing or derived from Starting Plasma
-

Plasma Volume Payment means a Payment required under clause 34

Pre-existing Material has the meaning set out in clause 49.4.

Privacy Act means the *Privacy Act 1988* (Cth)

Process Migration means a suite of changes to the production and supply of Products under this Deed, arising from changes to CSL's manufacturing plant and underlying fractionation processes, which have been proposed by CSL as at the Commencement Date and which are dealt with in clauses 12.6 - 12.8 and Schedule 4

Product means a Product specified in, or determined in accordance with the process set out in, clauses 11 and 12 and the Product Specifications

Product Specifications means the specifications set out in, or determined in accordance with the process set out in, Schedule 4

Product Unit means an individual vial of a Product, including packaging and any ancillary kit or other items supplied with the Product, as specified in the Product Specifications, but does not include Expired Product Units

Production Intermediate means any substance wholly or partly derived from or including Starting Plasma which arises from the process of production of Products by CSL, including:

- (a) intermediate stage substances used for later stages of the production process; and
 - (b) substances which are discarded from the production process
-

Public Announcement means an announcement that is intended for distribution to the general public or to a specific class of the public that relates to the subject matter of the Deed

Register means the Australian Register of Therapeutic Goods maintained under the TG Act

Required Delivery Time means the maximum time for the fulfilment of Orders by CSL, specified in Schedule 6

Review means a review referred to in clauses 64 or 65

SCIg means polyvalent subcutaneous immunoglobulin

Service means any service which may be provided by CSL to the NBA or an Approved Health Provider in accordance with this Deed

Shelf Life means the shelf life specified under or in accordance with the TG Act in respect of a Product Unit

Standard Operating Procedures means documented procedures maintained by CSL in relation to the fulfilment of CSL's obligations under the Deed

Starting Plasma means human blood plasma collected in Australia and supplied to CSL for the purpose of the Deed

Starting Plasma Provider means the provider of Starting Plasma determined by Australian Governments under the National Blood Arrangements

Subcontractor means a person to whom CSL has subcontracted the performance of any part of the Deed

Subcontract means any contract with a Subcontractor to the extent that it relates to the performance of any part of this Deed

Target Minimum Shelf Life means the minimum shelf life a Product should have on delivery to an Approved Health Provider, as set out in Schedule 5

Term means the term of the Deed, determined in accordance with clause 4.2 and 64, subject to earlier termination in accordance with the Deed

TG Act means the *Therapeutic Goods Act 1989* (Cth) and all regulations and subordinate legislation or instruments made under that Act (or, if that Act is repealed in whole or part, any other Act or Acts nominated by the NBA which is a substitute for or which replaces that Act in whole or in part

TGA means that part of the Commonwealth Department of Health and Ageing known as the Therapeutic Goods Administration, or any other part of the Commonwealth responsible for administering the provisions of the TG Act

Toll Fractionation Contract means a contract, arrangement or understanding under which CSL provides plasma fractionation services using CSL's plasma fractionation facility at Broadmeadows, Victoria, Australia, other than the Deed

Transition Out Plan means the plan of that name referred to in clause 70.2

Trigger Event has the meaning set out in clause 44.1.

Working Days means Monday to Friday inclusive, but excludes any public holiday or bank holiday in the Australian Capital Territory or Victoria and excludes the days 25 to 31 December, inclusive

72 Rules of Interpretation

72.1 In the Deed, unless the contrary intention is expressly stated, the following rules of interpretation apply:

72.1.1 a reference to a matter or information being taken into account by a Party means that the Party must give due consideration to that matter, but does not require the Party to follow, give effect to, implement or otherwise act on the matter or information;

72.1.2 in respect of a period of time:

- (a) a month means a calendar month;
- (b) a quarter means the period of three months from July to September, October to December, January to March, and April to June; and
- (c) a financial year means the period of twelve months from July to June,

- or any part of such a period occurring at the beginning or end of the Term;
- 72.1.3 a reference to a matter being material means that the matter is not trivial;
- 72.1.4 a reference to something being done promptly is a reference to it being done as soon as is reasonably practicable, using all reasonable endeavours;
- 72.1.5 a reference to any Law or legislation or legislative provision includes any statutory modification, amendment or re-enactment, and any subordinate legislation or regulations issued under that legislation or legislative provision;
- 72.1.6 a reference to any agreement or document is to that agreement or document as amended, novated, supplemented or replaced from time to time;
- 72.1.7 a reference to a clause, part, schedule or attachment is a reference to a clause, part, schedule or attachment of or to the Deed unless otherwise stated;
- 72.1.8 an expression importing a natural person includes any company, trust, partnership, joint venture, association, corporation, body corporate or governmental agency;
- 72.1.9 if the day on which any act, matter or thing is to be done under the Deed is not a Working Day in the place in which it must be done, that act, matter or thing may be done on the next Working Day in that place;
- 72.1.10 a covenant or agreement on the part of two or more persons binds them jointly and severally;
- 72.1.11 where the context permits, words suggesting the singular number should be read as including the plural and vice versa;
- 72.1.12 the Schedules and any attachments or annexures form part of the Deed;
- 72.1.13 all references to 'dollars' or '\$' are to Australian dollars;
- 72.1.14 to the extent that there is any inconsistency between anything in:
- (a) the clauses of the Deed;
 - (b) the Schedules; or
 - (c) any attachments or annexures,
- then the document ranked higher in the list above will prevail; and
- 72.1.15 unless otherwise required by the context, the word 'includes' is to be read as 'includes, but is not limited to' and 'including' is to be read as 'including, but not limited to'.

73 Assignment

Assignment or novation by CSL

- 73.1 CSL must not assign or novate any of its rights under the Deed, or enter into consultations or negotiations for the assignment of its rights under, or the novation of, the Deed, without the prior written consent of the NBA (which may be withheld in the NBA's absolute discretion).

Assignment by the NBA

- 73.2 Despite any other provision of the Deed, the Deed may be administered on behalf of the Commonwealth by any department or agency of the Commonwealth that from time to time has responsibility for the administration of the Deed, as notified to CSL by Formal Notice from the Commonwealth from time to time.

74 Costs

- 74.1 Except as otherwise agreed by the Parties in writing, each Party must pay its own costs in relation to preparing, negotiating and executing the Deed and any document related to the Deed.

75 Entire agreement

- 75.1 The Deed sets out the entire agreement between the Parties in relation to the Parties' rights and obligations during the Term, in respect of the subject matter of the Deed, and where provided for in the Deed, after expiry or termination of the Deed.
- 75.2 No Party can rely on an earlier document, or anything said or done by another Party, or by any Personnel of that Party, in relation to the subject matter of the Deed, before the Deed was executed, save as permitted by Law.

76 Execution of separate documents

- 76.1 The Deed is properly executed if each Party executes either this document or an identical document and in the latter case, the Deed takes effect when the separately executed documents are exchanged between the Parties.

77 Further acts

- 77.1 The Parties must promptly do and perform all acts and things and execute all documents as may from time to time be required, and at all times must act in good faith, for the purposes of or to give effect to the Deed.

78 Governing law and jurisdiction

- 78.1 The Deed is governed by the law of the Australian Capital Territory.
- 78.2 The Parties submit to the non-exclusive jurisdiction of the courts of the Australian Capital Territory.

79 Severability

- 79.1 If a clause or part of a clause of the Deed can be read in a way that makes it illegal, unenforceable or invalid, but can also be read in a way that makes it legal, enforceable and valid, it must be read in the latter way.

- 79.2 If any clause, or part of a clause is illegal, unenforceable or invalid, that clause or part is to be treated as removed from the Deed, but the rest of the Deed is not affected.

80 Waiver

- 80.1 The fact that a Party fails to do, or delays in doing, something the Party is entitled to do under the Deed, does not amount to a waiver of any obligation of, or breach of obligation by, another Party.
- 80.2 A waiver by a Party is only effective if it is in writing.
- 80.3 A written waiver by a Party is only effective in relation to the particular obligation or breach in respect of which it is given and it is not to be taken as an implied waiver of any other obligation or breach or as an implied waiver of that obligation or breach in relation to any other occasion.

81 No agency, partnership, authority or other relationship

- 81.1 Except as expressly provided in the Deed, neither Party is an agent, representative, trustee, Employee or partner of the other Party by virtue of the Deed and neither Party may represent itself as such in any circumstances.
- 81.2 Neither Party has any power or authority to:
- 81.2.1 act for, or to assume any obligation or responsibility on behalf of, the other Party;
 - 81.2.2 bind the other Party to any agreement;
 - 81.2.3 negotiate or enter into any binding relationship for, or on behalf of, the other Party; or
 - 81.2.4 pledge the credit of the other Party,
- except as specifically provided in the Deed or by express written agreement between the Parties.

82 Certification of government decisions

- 82.1 Where this Deed refers to a decision made by Australian Governments under the National Blood Arrangements, and the NBA has notified CSL that such a decision has been made:
- 82.1.1 CSL may request a formal written statement of the decision from the General Manager of the NBA or another representative of Australian Governments; and
 - 82.1.2 the NBA must use reasonable endeavours to provide or seek such a statement, to the extent it can appropriately be given.

Schedules

List of Schedules

- Schedule 1 – NBA contacts
- Schedule 2 – CSL contacts
- Schedule 3 – Deed management meetings
- Schedule 4 - Product Specifications
- Schedule 5 – Shelf Life and expiry of Products
- Schedule 6 – Ordering and delivery requirements
- Schedule 7 - Minimum Inventory Requirements
- Schedule 8 – National CSL Reserve
- Schedule 9 – Required Reports
- Schedule 10 – Key Performance Indicators
- Schedule 11 – Prices and fees
- Schedule 12 – Plasma Volume Payments
- Schedule 13 – Required guarantees and undertakings
- Schedule 14 – Confidential Information of CSL
- Schedule 15 – Home Delivery

Schedule 1

NBA contacts

Process for updates of schedule	Formal Notice from NBA to CSL
Version number	1
Version issue date	Commencement Date
Version date of effect	Commencement Date

NBA General Manager

[not disclosed – contact details]

NBA contact person for Formal Notices under the Deed:

[not disclosed – contact details]

NBA contact person for formal resolution of disputes under clause 45 of the Deed:

[not disclosed – contact details]

Note – Clause 5.3 of the Deed provides that a contact person specified in this Schedule may from time to time notify the other Party of their authorised delegates for the purpose of relevant communications under the Deed.

Schedule 2

CSL contacts

Process for updates of schedule	Formal Notice from CSL to NBA
Version number	1
Version issue date	Commencement Date
Version date of effect	Commencement Date

CSL General Manager for the purposes of the Deed

[not disclosed – contact details]

CSL contact person for receipt of Formal Notices under the Deed:

[not disclosed – contact details]

CSL contact person for issue of Formal Notices under the Deed:

[not disclosed – contact details]

CSL contact person for formal resolution of disputes under clause 45 of the Deed:

[not disclosed – contact details]

***Note** – Clause 5.3 of the Deed provides that a contact person specified in this Schedule may from time to time notify the other Party of their authorised delegates for the purpose of relevant communications under the Deed.*

Schedule 3

Deed Management Meetings

Process for updates of schedule	Deed variation under clause 67
Version number	1
Version issue date	Commencement Date
Version date of effect	Commencement Date

1 General

1.1 Unless otherwise agreed between the Parties:

- 1.1.1 meetings will be held between the Parties as specified in this Schedule;
- 1.1.2 scheduled meetings must be held as face to face meetings, unless the Parties have agreed to alternative means of holding a meeting;
- 1.1.3 the specified host of a scheduled meeting must:
 - (a) arrange the date, time and venue of a meeting on a basis acceptable to both Parties;
 - (b) chair the meeting;
 - (c) prepare and/or distribute relevant agendas, papers, meeting outcomes and records; and
 - (d) otherwise support the operation of the relevant meetings;
- 1.1.4 each Party must make reasonable endeavours to ensure the attendance of the intended representatives of the Party specified in this Schedule, or a reasonable alternate representative agreed by the other Party;
- 1.1.5 meetings may be attended by additional representatives of the Parties as agreed by the Parties; and
- 1.1.6 each presentation by a representative of a Party to an agenda item at a scheduled meeting must be accompanied by a written outline or copy of the presentation provided to the other Party (which may comprise a report otherwise required under this Deed).

2 Risk Management Workshop

Frequency - Annual, in conjunction with a CEO Meeting and Planning Forum

Host and location - CSL, Melbourne

Expected duration - One day

<i>Purpose -</i>	High level review and planning of risk management in relation to the Deed
<i>Potential topics -</i>	<p>Overview of CSL's world-wide approach to insurance and self-insurance, including any implications and risks for CSL's Australian operations, and a description of insurance or self-insurance to be maintained by CSL in relation to risks relating to this Deed and the supply of Products and CSL's other obligations under this Deed</p> <p>Overview / update on CSL's Risk Management Plan for the Broadmeadows facility</p> <p>Overview / update on NBA's Risk Management Plan for supply issues under this Deed</p> <p>Overview / update on NBA's national blood supply risk and contingency planning, particularly as relevant to this Deed</p> <p>Other topics as agreed by the Parties</p>
<i>CSL representatives -</i>	<p>General Manager, CSL Behring Australia and New Zealand</p> <p>Director, Global Risk and Insurance Management</p> <p>Head of Risk Management (Broadmeadows site)</p> <p>Director Contract Fractionation Australia and New Zealand</p> <p>Senior Manager Supply Chain and Logistics</p> <p>Contract Manager</p>
<i>NBA representatives -</i>	<p>Chief Executive</p> <p>Deputy General Manager</p> <p>Executive Director, Supply Management, Plasma & Recombinants</p> <p>Contract Manager, Supply Management, Plasma & Recombinants</p> <p>Supply Manager, Supply Management, Plasma & Recombinants (if required)</p> <p>NBA National Blood Supply Contingency Plan Manager (if required)</p>

3 CEO Update and Planning Meeting

<i>Frequency -</i>	Six monthly. One meeting each year to be held in conjunction with the Risk Management Workshop.
<i>Host and location -</i>	Alternately CSL, Melbourne and NBA, Canberra

<i>Expected duration -</i>	One day.
<i>Purpose -</i>	Update on strategic developments; key forum for discussion of supply trends and forecasts and business planning to support the Deed.
<i>Potential topics -</i>	<p>Updates from each Party on trends and forecasts for plasma collection and plasma products, in Australia and worldwide</p> <p>Review and discuss Annual Supply Estimate or any revised Annual Supply Estimate update</p> <p>Update on CSL supply capability and capacity including developments in relation to facilities, technology, customer base and business strategy</p> <p>Update on research and development within CSL including worldwide CSL group</p> <p>Update and consultation on Product enhancement and development opportunities relevant to the Deed</p> <p>Consultation on CSL business planning to support service delivery under the Deed</p> <p>Annual update on the fractionation activities conducted for customers other than the NBA at CSL's Broadmeadows facility in the previous and forthcoming years</p> <p>Other topics as agreed by the Parties</p>
<i>CSL representatives -</i>	<p>General Manager, CSL Behring Australia and New Zealand</p> <p>Director Contract Fractionation Australia and New Zealand</p> <p>Senior Manager Supply Chain and Logistics</p> <p>Contract Manager</p>
<i>NBA representatives -</i>	<p>Chief Executive</p> <p>Deputy General Manager</p> <p>Executive Director, Supply Management, Plasma & Recombinants</p>

4 Contract Management Meeting

<i>Frequency -</i>	Quarterly. Scheduled to coincide with CEO Update and Planning Meeting in relevant quarters.
<i>Host and location -</i>	Alternately CSL, Melbourne and NBA, Canberra.
<i>Expected duration -</i>	One day.

<i>Purpose -</i>	Liaison, consultation and agreement on key contract management elements under the Deed.
<i>Potential topics -</i>	<p>KPI results and CSL performance</p> <p>Review of key reporting including monthly CSL Inventory Report, monthly Production Report, and others as necessary</p> <p>Discussion of Minimum Product Inventory and Minimum Starting Plasma Inventory</p> <p>Discussion on management of National CSL Reserve, and any expected changes to volumes held in the Reserve</p> <p>Product location and rotation</p> <p>Adverse events; Notifiable Events</p> <p>Demand and supply planning updates, where necessary</p> <p>Other topics as agreed by the Parties</p>
<i>CSL representatives -</i>	<p>Director Contract Fractionation Australia and New Zealand</p> <p>Senior Manager Supply Chain and Logistics</p> <p>Contract Manager</p>
<i>NBA representatives -</i>	<p>Deputy General Manager</p> <p>Executive Director, Supply Management, Plasma & Recombinants</p> <p>Contract Manager, Supply Management, Plasma & Recombinants</p> <p>Supply Manager, Supply Management, Plasma & Recombinants (if required)</p>

Schedule 4

Product Specifications

Process for updates of schedule	Formal Notice from CSL to NBA for routine changes, as specified in this Schedule Otherwise, Deed variation under clause 67
Version number	1
Version issue date	Commencement Date
Version date of effect	Commencement Date

1 Specifications applying for all Products

- 1.1 Each Product must meet all requirements in relation to the Product applying under the TG Act, including, without limitation, complying with the specifications and conditions for the registration of the Product under the TG Act.
- 1.2 Each Product must be supplied with any kit items specified in this Schedule.

2 Individual Product Specifications

- 2.1 The Product Specifications for each Product are as set out in the Product Specifications Table attached to this Schedule.

3 CSL notification of routine changes to Product Specifications

- 3.1 CSL may give Formal Notice to the NBA of routine changes to the Product Specifications in respect of the following matters or in the following circumstances:
- 3.1.1 a change to the CSL Product number;
 - 3.1.2 a change to the Product name;
 - 3.1.3 a change in ARTG number;
 - 3.1.4 an increase in the Shelf Life on manufacture; or
 - 3.1.5 an improvement in storage conditions;
- not associated with any other change to the Product Specifications.

4 Specifications relating to Packaging

- 4.1 The NBA may by Formal Notice to CSL specify requirements in relation to details to be published on the packaging of a Product.

National Fractionation Agreement for Australia

CSL Product Number	34700110
Product Name	ALBUMEX 20 10mL
Product Description	Human albumin 20%, solution for intravenous infusion
Product Concentration	Each vial nominally contains 2g of human albumin in 10mL of electrolyte solution
Kit Items (if applicable)	-
ARTG Number	AUST R 31820
Approved Indications	Hypoproteinaemia in the acutely ill patient, shock, extensive burns, respiratory distress syndrome, haemodialysis and plasma exchange.
Shelf Life (months)	48
Storage Conditions	2° - 8°C (Refrigerate. Do not freeze). Protect from light.
Planned Product Changes	[Not disclosed – specifies planned product changes]
Ability for a Party to remove the Product from supply under the Deed	[Not disclosed – specifies when products may be removed from supply under the Deed]
Ability for a Party to add the Product to supply under the Deed	[Not disclosed – specifies when products may be added to supply under the Deed]

National Fractionation Agreement for Australia

CSL Product Number	34700155
Product Name	ALBUMEX 20 100mL
Product Description	Human albumin 20%, solution for intravenous infusion
Product Concentration	Each vial nominally contains 20g of human albumin in 100mL of electrolyte solution
Kit Items (if applicable)	-
ARTG Number	AUST R 46283
Approved Indications	Hypoproteinaemia in the acutely ill patient, shock, extensive burns, respiratory distress syndrome, haemodialysis and plasma exchange.
Shelf Life (months)	48
Storage Conditions	Store below 30°C. (Do not freeze) Protect from light.
Planned Product Changes	[Not disclosed – specifies planned product changes]
Ability for a Party to remove the Product from supply under the Deed	[Not disclosed – specifies when products may be removed from supply under the Deed]
Ability for a Party to add the Product to supply under the Deed	[Not disclosed – specifies when products may be added to supply under the Deed]

National Fractionation Agreement for Australia

CSL Product Number	34500150
Product Name	ALBUMEX 4 50mL
Product Description	Human Albumin 4%, solution for intravenous infusion
Product Concentration	Each vial nominally contains 2g of human albumin in 50mL of electrolyte solution
Kit Items (if applicable)	-
ARTG Number	AUST R 59154
Approved Indications	Hypovolaemia/shock, priming the cardiopulmonary bypass pump and plasma exchange.
Shelf Life (months)	48
Storage Conditions	Store below 30°C. (Do not freeze) Protect from light.
Planned Product Changes	[Not disclosed – specifies planned product changes]
Ability for a Party to remove the Product from supply under the Deed	[Not disclosed – specifies when products may be removed from supply under the Deed]
Ability for a Party to add the Product to supply under the Deed	[Not disclosed – specifies when products may be added to supply under the Deed]

CSL Product Number	34500170
Product Name	ALBUMEX 4 500mL
Product Description	Human Albumin 4%, solution for intravenous infusion
Product Concentration	Each vial nominally contains 20g of human albumin in 500mL of electrolyte solution
Kit Items (if applicable)	-
ARTG Number	AUST R 59155
Approved Indications	Hypovolaemia/shock, priming the cardiopulmonary bypass pump and plasma exchange.
Shelf Life (months)	48
Storage Conditions	Store below 30°C. (Do not freeze.) Protect from light.
Planned Product Changes	[Not disclosed – specifies planned product changes]
Ability for a Party to remove the Product from supply under the Deed	[Not disclosed – specifies when products may be removed from supply under the Deed]
Ability for a Party to add the Product to supply under the Deed	[Not disclosed – specifies when products may be added to supply under the Deed]

CSL Product Number	37900125
Product Name	INTRAGAM 10 25mL
Product Description	Human Normal Immunoglobulin solution for intravenous injection
Product Concentration	Each vial nominally contains 2.5g of IgG
Kit Items (if applicable)	-
ARTG Number	AUST R 162486
Approved Indications	<p>INTRAGAM 10 is indicated for replacement IgG therapy in:</p> <ul style="list-style-type: none"> • Primary Immunodeficiency Diseases (PID) • Symptomatic hypogammaglobulinaemia secondary to underlying disease or treatment. <p>INTRAGAM 10 is indicated for immunomodulatory therapy in:</p> <ul style="list-style-type: none"> • Idiopathic Thrombocytopenic Purpura (ITP), in adults or children at high risk of bleeding or prior to surgery to correct the platelet count • Kawasaki disease • Guillain-Barré Syndrome (GBS) • Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) • Multifocal Motor Neuropathy (MMN) • Myasthenia Gravis (MG) in acute exacerbation (myasthenic crisis) or prior to surgery and/or thymectomy; as maintenance therapy for moderate to severe MG when other treatments have been ineffective or caused intolerable side effects • Short-term therapy for severely affected nonparaneoplastic • Lambert-Eaton Myasthenic Syndrome (LEMS) patients • Treatment of significant functional impairment in patients who have a verified diagnosis of stiff person syndrome.
Shelf Life (months)	24
Storage Conditions	Store at 2° - 8°C (Refrigerate. Do not freeze). Once removed from refrigeration, store below 25°C and use within 3 months. Protect from light.
Planned Product Changes	[Not disclosed – specifies planned product changes]
Ability for a Party to remove the Product from supply	[Not disclosed – specifies when products may be removed from supply under the Deed]

under the Deed	
Ability for a Party to add the Product to supply under the Deed	[Not disclosed – specifies when products may be added to supply under the Deed]

CSL Product Number	37900155
Product Name	INTRAGAM 10 100ml
Product Description	Human Normal Immunoglobulin solution for intravenous injection
Product Concentration	Each vial nominally contains 10g of IgG
Kit Items (if applicable)	-
ARTG Number	AUST R 162488
Approved Indications	<p>INTRAGAM 10 is indicated for replacement IgG therapy in:</p> <ul style="list-style-type: none"> • Primary Immunodeficiency Diseases (PID) • Symptomatic hypogammaglobulinaemia secondary to underlying disease or treatment. <p>INTRAGAM 10 is indicated for immunomodulatory therapy in:</p> <ul style="list-style-type: none"> • Idiopathic Thrombocytopenic Purpura (ITP), in adults or children at high risk of bleeding or prior to surgery to correct the platelet count • Kawasaki disease • Guillain-Barré Syndrome (GBS) • Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) • Multifocal Motor Neuropathy (MMN) • Myasthenia Gravis (MG) in acute exacerbation (myasthenic crisis) or prior to surgery and/or thymectomy; as maintenance therapy for moderate to severe MG when other treatments have been ineffective or caused intolerable side effects • Short-term therapy for severely affected nonparaneoplastic • Lambert-Eaton Myasthenic Syndrome (LEMS) patients • Treatment of significant functional impairment in patients who have a verified diagnosis of stiff person syndrome.
Shelf Life (months)	24
Storage Conditions	Store at 2° - 8°C (Refrigerate. Do not freeze). Once removed from refrigeration, store below 25°C and use within 3 months. Protect from light.
Planned Product Changes	[Not disclosed – specifies planned product changes]

Ability for a Party to remove the Product from supply under the Deed	[Not disclosed – specifies when products may be removed from supply under the Deed]
Ability for a Party to add the Product to supply under the Deed	[Not disclosed – specifies when products may be added to supply under the Deed]

CSL Product Number	37900160
Product Name	INTRAGAM 10 200ml
Product Description	Human Normal Immunoglobulin solution for intravenous injection
Product Concentration	Each vial nominally contains 20g of IgG
Kit Items (if applicable)	-
ARTG Number	AUST R 162489
Approved Indications	<p>INTRAGAM 10 is indicated for replacement IgG therapy in:</p> <ul style="list-style-type: none"> • Primary Immunodeficiency Diseases (PID) • Symptomatic hypogammaglobulinaemia secondary to underlying disease or treatment. <p>INTRAGAM 10 is indicated for immunomodulatory therapy in:</p> <ul style="list-style-type: none"> • Idiopathic Thrombocytopenic Purpura (ITP), in adults or children at high risk of bleeding or prior to surgery to correct the platelet count • Kawasaki disease • Guillain-Barré Syndrome (GBS) • Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) • Multifocal Motor Neuropathy (MMN) • Myasthenia Gravis (MG) in acute exacerbation (myasthenic crisis) or prior to surgery and/or thymectomy; as maintenance therapy for moderate to severe MG when other treatments have been ineffective or caused intolerable side effects • Short-term therapy for severely affected nonparaneoplastic • Lambert-Eaton Myasthenic Syndrome (LEMS) patients • Treatment of significant functional impairment in patients who have a verified diagnosis of stiff person syndrome.
Shelf Life (months)	24
Storage Conditions	Store at 2° - 8°C (Refrigerate. Do not freeze). Once removed from refrigeration, store below 25°C and use within 3 months. Protect from light.
Planned Product Changes	[Not disclosed – specifies planned product changes]
Ability for a Party to remove the Product from supply	[Not disclosed – specifies when products may be removed from supply under the Deed]

under the Deed	
Ability for a Party to add the Product to supply under the Deed	[Not disclosed – specifies when products may be added to supply under the Deed]

CSL Product Number	37400150
Product Name	INTRAGAM P 50mL
Product Description	Normal Immunoglobulin (Human) solution for intravenous injection
Product Concentration	Each vial nominally contains 3g of IgG and 5g of maltose
Kit Items (if applicable)	-
ARTG Number	AUST R 68632
Approved Indications	Replacement IgG therapy in primary immunodeficiency diseases (PID); symptomatic hypogammaglobulinaemia secondary to underlying disease or treatment. Immunomodulatory therapy in: Idiopathic Thrombocytopenic Purpura (ITP), in adults or children at high risk of bleeding or prior to surgery to correct the platelet count; Kawasaki disease; and Guillain-Barre Syndrome (GBS).
Shelf Life (months)	24
Storage Conditions	Store at 2°C to 8°C (Refrigerate. Do not freeze). Once removed from refrigeration, store below 25°C and use within 3 months. Protect from light.
Planned Product Changes	[Not disclosed – specifies planned product changes]
Ability for a Party to remove the Product from supply under the Deed	[Not disclosed – specifies when products may be removed from supply under the Deed]
Ability for a Party to add the Product to supply under the Deed	[Not disclosed – specifies when products may be added to supply under the Deed]

CSL Product Number	38100105
Product Name	EVOGAM 5mL
Product Description	Human Normal Immunoglobulin solution for subcutaneous injection
Product Concentration	Each vial nominally contains 0.8g of IgG
Kit Items (if applicable)	One Mix2Vial filter transfer set.
ARTG Number	AUST R 173315
Approved Indications	<p>Replacement IgG therapy in primary immunodeficiency diseases (PID); symptomatic hypogammaglobulinaemia secondary to underlying disease or treatment.</p> <p>Immunomodulatory therapy in: Idiopathic Thrombocytopenic Purpura (ITP), in adults or children at high risk of bleeding or prior to surgery to correct the platelet count; Kawasaki disease; and Guillain-Barre Syndrome (GBS).</p>
Shelf Life (months)	24
Storage Conditions	Store at 2° - 8°C (Refrigerate. Do not freeze). Once removed from refrigeration, store below 25°C and use within 2 weeks. Protect from light.
Planned Product Changes	[Not disclosed – specifies planned product changes]
Ability for a Party to remove the Product from supply under the Deed	[Not disclosed – specifies when products may be removed from supply under the Deed]
Ability for a Party to add the Product to supply under the Deed	[Not disclosed – specifies when products may be added to supply under the Deed]

National Fractionation Agreement for Australia

CSL Product Number	38100120
Product Name	EVOGAM 20mL
Product Description	Human Normal Immunoglobulin solution for subcutaneous injection
Product Concentration	Each vial nominally contains 3.2g of IgG
Kit Items (if applicable)	One Mix2Vial filter transfer set.
ARTG Number	AUST R 173324
Approved Indications	Replacement IgG therapy in primary immunodeficiency diseases (PID); symptomatic hypogammaglobulinaemia secondary to underlying disease or treatment. Immunomodulatory therapy in: Idiopathic Thrombocytopenic Purpura (ITP), in adults or children at high risk of bleeding or prior to surgery to correct the platelet count; Kawasaki disease; and Guillain-Barre Syndrome (GBS).
Shelf Life (months)	24
Storage Conditions	Store at 2° - 8°C (Refrigerate. Do not freeze). Once removed from refrigeration, store below 25°C and use within 2 weeks. Protect from light.
Planned Product Changes	[Not disclosed – specifies planned product changes]
Ability for a Party to remove the Product from supply under the Deed	[Not disclosed – specifies when products may be removed from supply under the Deed]
Ability for a Party to add the Product to supply under the Deed	[Not disclosed – specifies when products may be added to supply under the Deed]

National Fractionation Agreement for Australia

CSL Product Number	33000185
Product Name	BIOSTATE 250IU
Product Description	Human coagulation factor VIII and human von Willebrand factor complex, powder for injection
Product Concentration	Each vial nominally contains 50 IU/mL FVIII:C, 100 IU/mL VWF
Kit Items (if applicable)	One 5mL vial of Water for Injections and one Mix2Vial filter transfer set
ARTG Number	AUST R 73032
Approved Indications	The prophylaxis and treatment of non-surgical and surgical bleeding in patients with von Willebrand disease when desmopressin (DDAVP) treatment is ineffective or contraindicated. Treatment and prophylaxis of non-surgical and surgical bleeding associated with FVIII deficiency due to haemophilia A.
Shelf Life (months)	36
Storage Conditions	Store at 2°C to 8°C (Refrigerate. Do not freeze). BIOSTATE can be stored below 25°C for a single period of 6 months. The product must not be returned to refrigeration after storage below 25°C. Protect from light.
Planned Product Changes	[Not disclosed – specifies planned product changes]
Ability for a Party to remove the Product from supply under the Deed	[Not disclosed – specifies when products may be removed from supply under the Deed]
Ability for a Party to add the Product to supply under the Deed	[Not disclosed – specifies when products may be added to supply under the Deed]

National Fractionation Agreement for Australia

CSL Product Number	33000192
Product Name	BIOSTATE 500IU
Product Description	Human coagulation factor VIII and human von Willebrand factor complex, powder for injection
Product Concentration	Each vial nominally contains 50 IU/mL FVIII:C, 100 IU/mL VWF
Kit Items (if applicable)	One 10mL vial of Water for Injections and one Mix2Vial filter transfer set
ARTG Number	AUST R 79993
Approved Indications	The prophylaxis and treatment of non-surgical and surgical bleeding in patients with von Willebrand disease when desmopressin (DDAVP) treatment is ineffective or contraindicated. Treatment and prophylaxis of non-surgical and surgical bleeding associated with FVIII deficiency due to haemophilia A.
Shelf Life (months)	36
Storage Conditions	Store at 2°C to 8°C (Refrigerate. Do not freeze). BIOSTATE can be stored below 25°C for a single period of 6 months. The product must not be returned to refrigeration after storage below 25°C. Protect from light.
Planned Product Changes	[Not disclosed – specifies planned product changes]
Ability for a Party to remove the Product from supply under the Deed	[Not disclosed – specifies when products may be removed from supply under the Deed]
Ability for a Party to add the Product to supply under the Deed	[Not disclosed – specifies when products may be added to supply under the Deed]

CSL Product Number	33100194
Product Name	BIOSTATE 1000IU
Product Description	Human coagulation factor VIII and human von Willebrand factor complex, powder for injection
Product Concentration	Each vial nominally contains 100 IU/mL FVIII:C, 200 IU/mL VWF
Kit Items (if applicable)	One 10 mL vial of Water for Injections and one Mix2Vial filter transfer set
ARTG Number	AUST R 150657
Approved Indications	The prophylaxis and treatment of non-surgical and surgical bleeding in patients with von Willebrand disease when desmopressin (DDAVP) treatment is ineffective or contraindicated. Treatment and prophylaxis of non-surgical and surgical bleeding associated with FVIII deficiency due to haemophilia A.
Shelf Life (months)	36
Storage Conditions	Store at 2°C to 8°C (Refrigerate. Do not freeze). BIOSTATE can be stored below 25°C for a single period of 6 months. The product must not be returned to refrigeration after storage below 25°C. Protect from light.
Planned Product Changes	[Not disclosed – specifies planned product changes]
Ability for a Party to remove the Product from supply under the Deed	[Not disclosed – specifies when products may be removed from supply under the Deed]
Ability for a Party to add the Product to supply under the Deed	[Not disclosed – specifies when products may be added to supply under the Deed]

National Fractionation Agreement for Australia

CSL Product Number	32600194
Product Name	MonoFIX-VF 1000IU
Product Description	Human coagulation factor IX, powder for injection
Product Concentration	Each vial nominally contains 100 IU/mL factor IX
Kit Items (if applicable)	One 10mL vial of Water for Injections and one Mix2Vial filter transfer set
ARTG Number	AUST R 101711
Approved Indications	Treatment of haemorrhages, use in surgery, and as prophylaxis in patients with haemophilia B.
Shelf Life (months)	24
Storage Conditions	Store at 2°C to 8°C (Refrigerate. Do not freeze). Protect from light
Planned Product Changes	[Not disclosed – specifies planned product changes]
Ability for a Party to remove the Product from supply under the Deed	[Not disclosed – specifies when products may be removed from supply under the Deed]
Ability for a Party to add the Product to supply under the Deed	[Not disclosed – specifies when products may be added to supply under the Deed]

National Fractionation Agreement for Australia

CSL Product Number	32800192
Product Name	PROTHROMBINEX-VF 500IU
Product Description	Human Prothrombin Complex, powder for injection
Product Concentration	Each vial nominally contains approx. 500IU of Factor IX, approx. 500IU of Factor II and approx. 500IU of Factor X
Kit Items (if applicable)	One 20mL vial of Water for Injections and one Mix2Vial filter transfer set
ARTG Number	AUST R 124381
Approved Indications	Treatment and perioperative prophylaxis of bleeding in acquired deficiency of prothrombin complex factors, such as deficiency caused by treatment with vitamin K antagonists, or in case of overdose of vitamin K antagonists, when rapid correction of the deficiency is required. Treatment and prophylaxis of bleeding in patients with single or multiple congenital deficiency of factor IX, II or X when purified specific coagulation factor product is not available.
Shelf Life (months)	24
Storage Conditions	Store at 2° - 8°C (Refrigerate. Do not freeze). Prothrombinex-VF can be stored below 25°C for a single period of 6 months. The product must not be returned to refrigeration after storage below 25°C . Protect from light.
Planned Product Changes	[Not disclosed – specifies planned product changes]
Ability for a Party to remove the Product from supply under the Deed	[Not disclosed – specifies when products may be removed from supply under the Deed]
Ability for a Party to add the Product to supply under the Deed	[Not disclosed – specifies when products may be added to supply under the Deed]

National Fractionation Agreement for Australia

CSL Product Number	32200194
Product Name	THROMBOTROL-VF 1000IU
Product Description	Human Antithrombin III Concentrate (ATIII), for intravenous administration
Product Concentration	Each vial nominally contains 1000IU of ATIII
Kit Items (if applicable)	One 20mL vial of Water for Injections and one Mix2Vial filter transfer set
ARTG Number	AUST R 66736
Approved Indications	In patients with hereditary deficiency of ATIII under the following circumstances: Prophylactic administration for the prevention of thrombosis and pulmonary embolism in surgery, pregnancy and childbirth; and therapeutic administration in thrombosis or pulmonary embolism.
Shelf Life (months)	24
Storage Conditions	Store at 2° - 8°C (Refrigerate. Do not freeze). Protect from light.
Planned Product Changes	[Not disclosed – specifies planned product changes]
Ability for a Party to remove the Product from supply under the Deed	[Not disclosed – specifies when products may be removed from supply under the Deed]
Ability for a Party to add the Product to supply under the Deed	[Not disclosed – specifies when products may be added to supply under the Deed]

CSL Product Number	36100130
Product Name	CMV Immunoglobulin-VF 1.5MILL U
Product Description	Human Cytomegalovirus Immunoglobulin, solution for intravenous injection
Product Concentration	Each vial nominally contains 1.5 million units of CMV immunoglobulin activity
Kit Items (if applicable)	-
ARTG Number	AUST R 31810
Approved Indications	Prevention of CMV infection following bone marrow and renal transplants. Specifically, the product is indicated when the recipient is seronegative for CMV and receives a graft from a CMV positive donor. CMV Immunoglobulin-VF may also be a helpful adjunct to therapy in patients with established CMV infection, e.g. CMV pneumonitis.
Shelf Life (months)	24
Storage Conditions	Store at 2° - 8°C (Refrigerate. Do not freeze). Protect from light.
Planned Product Changes	[Not disclosed – specifies planned product changes]
Ability for a Party to remove the Product from supply under the Deed	[Not disclosed – specifies when products may be removed from supply under the Deed]
Ability for a Party to add the Product to supply under the Deed	[Not disclosed – specifies when products may be added to supply under the Deed]

CSL Product Number	36400180
Product Name	Hepatitis B Immunoglobulin-VF 100IU
Product Description	Human Hepatitis B Immunoglobulin, solution for intramuscular injection
Product Concentration	Each vial nominally contains 100IU hepatitis B antibody
Kit Items (if applicable)	-
ARTG Number	AUST R 61213
Approved Indications	<p>Post-exposure prophylaxis in persons who did not receive prior vaccination, or whose prior vaccination regimen is incomplete, or when the hepatitis B antibody level is inadequate (<10 IU/L). Also for prophylaxis in infants born to HBsAg-positive mothers.</p> <p>Post-exposure prophylaxis should be considered following percutaneous or permucosal exposure to HBsAg-positive or suspected HBsAg-positive material, for example, by needle stick, oral ingestion or sexual exposure.</p> <p>Hepatitis B Immunoglobulin-VF is also indicated for prophylaxis in infants born to HBsAg-positive mothers.</p>
Shelf Life (months)	36
Storage Conditions	Store at 2° - 8°C (Refrigerate. Do not freeze). Protect from light.
Planned Product Changes	[Not disclosed – specifies planned product changes]
Ability for a Party to remove the Product from supply under the Deed	[Not disclosed – specifies when products may be removed from supply under the Deed]
Ability for a Party to add the Product to supply under the Deed	[Not disclosed – specifies when products may be added to supply under the Deed]

CSL Product Number	36400190
Product Name	Hepatitis B Immunoglobulin-VF 400IU
Product Description	Human Hepatitis B Immunoglobulin, solution for intramuscular injection
Product Concentration	Each vial nominally contains 400IU hepatitis B antibody
Kit Items (if applicable)	-
ARTG Number	AUST R 61214
Approved Indications	<p>Post-exposure prophylaxis in persons who did not receive prior vaccination, or whose prior vaccination regimen is incomplete, or when the hepatitis B antibody level is inadequate (<10 IU/L). Also for prophylaxis in infants born to HBsAg-positive mothers.</p> <p>Post-exposure prophylaxis should be considered following percutaneous or permucosal exposure to HBsAg-positive or suspected HBsAg-positive material, for example, by needle stick, oral ingestion or sexual exposure.</p> <p>Hepatitis B Immunoglobulin-VF is also indicated for prophylaxis in infants born to HBsAg-positive mothers.</p>
Shelf Life (months)	36
Storage Conditions	Store at 2° - 8°C (Refrigerate. Do not freeze). Protect from light.
Planned Product Changes	[Not disclosed – specifies planned product changes]
Ability for a Party to remove the Product from supply under the Deed	[Not disclosed – specifies when products may be removed from supply under the Deed]
Ability for a Party to add the Product to supply under the Deed	[Not disclosed – specifies when products may be added to supply under the Deed]

CSL Product Number	36200102
Product Name	Normal Immunoglobulin-VF 2mL
Product Description	Human Normal Immunoglobulin, solution for intramuscular injection
Product Concentration	Vial nominally contains 2mL Normal Ig solution, containing 160mg/mL human plasma proteins and 22.5 mg/mL glycine
Kit Items (if applicable)	-
ARTG Number	AUST R 61215
Approved Indications	Management of congenital and acquired forms of primary hypogammaglobulinaemia, in treating secondary forms of this disorder, and in susceptible contacts of hepatitis A, measles and poliomyelitis.
Shelf Life (months)	36
Storage Conditions	Store at 2° - 8°C (Refrigerate. Do not freeze). Protect from light.
Planned Product Changes	[Not disclosed – specifies planned product changes]
Ability for a Party to remove the Product from supply under the Deed	[Not disclosed – specifies when products may be removed from supply under the Deed]
Ability for a Party to add the Product to supply under the Deed	[Not disclosed – specifies when products may be added to supply under the Deed]

CSL Product Number	36200105
Product Name	Normal Immunoglobulin-VF 5mL
Product Description	Human Normal Immunoglobulin
Product Concentration	Vial nominally contains 5mL Normal Ig solution, containing 160mg/mL human plasma proteins and 22.5 mg/mL glycine
Kit Items (if applicable)	-
ARTG Number	AUST R 61216
Approved Indications	Management of congenital and acquired forms of primary hypogammaglobulinaemia, in treating secondary forms of this disorder, and in susceptible contacts of hepatitis A, measles and poliomyelitis.
Shelf Life (months)	36
Storage Conditions	Store at 2° - 8°C (Refrigerate. Do not freeze). Protect from light.
Planned Product Changes	[Not disclosed – specifies planned product changes]
Ability for a Party to remove the Product from supply under the Deed	[Not disclosed – specifies when products may be removed from supply under the Deed]
Ability for a Party to add the Product to supply under the Deed	[Not disclosed – specifies when products may be added to supply under the Deed]

CSL Product Number	36900185
Product Name	Rh (D) Immunoglobulin-VF 250IU
Product Description	Human Anti-D Rho Immunoglobulin, solution for intramuscular injection
Product Concentration	Vial nominally contains 250IU Rh (D) antibody
Kit Items (if applicable)	-
ARTG Number	AUST R 76643
Planned Indications	Prevention of Rh sensitisation in Rh (D) negative females at or below child bearing age.
Anticipated Shelf Life (months)	24
Anticipated Storage Conditions	Store at 2° - 8°C (Refrigerate. Do not freeze). Protect from light.
Planned Product Changes	[Not disclosed – specifies planned product changes]
Ability for a Party to remove the Product from supply under the Deed	[Not disclosed – specifies when products may be removed from supply under the Deed]
Ability for a Party to add the Product to supply under the Deed	[Not disclosed – specifies when products may be added to supply under the Deed]

CSL Product Number	36800101
Product Name	Rh (D) Immunoglobulin-VF 625IU
Product Description	Human Anti-D Rho Immunoglobulin, solution for intramuscular injection
Product Concentration	Vial nominally contains 625IU Rh (D) antibody
Kit Items (if applicable)	-
ARTG Number	AUSTR 61217
Planned Indications	Prevention of Rh sensitisation in Rh (D) negative females at or below child bearing age.
Anticipated Shelf Life (months)	24
Anticipated Storage Conditions	Store at 2° - 8°C (Refrigerate. Do not freeze). Protect from light.
Planned Product Changes	[Not disclosed – specifies planned product changes]
Ability for a Party to remove the Product from supply under the Deed	[Not disclosed – specifies when products may be removed from supply under the Deed]
Ability for a Party to add the Product to supply under the Deed	[Not disclosed – specifies when products may be added to supply under the Deed]

CSL Product Number	36300185
Product Name	Tetanus Immunoglobulin-VF 250IU
Product Description	Human Tetanus Immunoglobulin, solution for intramuscular injection
Product Concentration	Vial nominally contains 250IU human tetanus antitoxin
Kit Items (if applicable)	-
ARTG Number	AUST R 61218
Approved Indications	Passive protection of individuals who have sustained a tetanus-prone wound and who have either not been actively immunised against tetanus or whose immunisation history is doubtful.
Shelf Life (months)	24
Storage Conditions	Store at 2° - 8°C (Refrigerate. Do not freeze). Protect from light.
Planned Product Changes	[Not disclosed – specifies planned product changes]
Ability for a Party to remove the Product from supply under the Deed	[Not disclosed – specifies when products may be removed from supply under the Deed]
Ability for a Party to add the Product to supply under the Deed	[Not disclosed – specifies when products may be added to supply under the Deed]

CSL Product Number	36000195
Product Name	Tetanus Immunoglobulin-VF 4000IU
Product Description	Human Tetanus Immunoglobulin, solution for intravenous injection
Product Concentration	Vial nominally contains 4000IU human tetanus antitoxin
Kit Items (if applicable)	-
ARTG Number	AUST R 31829
Approved Indications	Management of clinical tetanus.
Shelf Life (months)	24
Storage Conditions	Store at 2° - 8°C (Refrigerate. Do not freeze). Protect from light.
Planned Product Changes	[Not disclosed – specifies planned product changes]
Ability for a Party to remove the Product from supply under the Deed	[Not disclosed – specifies when products may be removed from supply under the Deed]
Ability for a Party to add the Product to supply under the Deed	[Not disclosed – specifies when products may be added to supply under the Deed]

CSL Product Number	36500183
Product Name	Zoster Immunoglobulin-VF 200IU
Product Description	Human Zoster Immunoglobulin, solution for intramuscular injection
Product Concentration	Vial nominally contains 200IU varicella-zoster antibody
Kit Items (if applicable)	-
ARTG Number	AUST R 61219
Approved Indications	<p>For prophylaxis against varicella in patients who meet all four of the criteria listed below:</p> <ol style="list-style-type: none"> 1. One of the following underlying illnesses or conditions: <ol style="list-style-type: none"> a. Neoplastic disease (leukaemia or lymphoma) b. Congenital or acquired immunodeficiency c. Immunosuppressive therapy with steroids or antimetabolites. 2. One of the following types of exposure to chickenpox or shingles patients: <ol style="list-style-type: none"> a. Household contact b. Playmate contact (> 1 hour play indoors) c. Hospital contact (in same 2 to 4 bedroom or adjacent beds in a large ward) d. Newborn contact (newborn of mother who had onset of chickenpox < 5 days before delivery or within 48 hours after delivery) e. Premature infant (\geq 28 weeks gestation) whose mother lacks a prior history of chickenpox f. Premature infant (< 28 weeks gestation or \leq 1000g) regardless of maternal history. 3. Negative or unknown prior history of chickenpox. 4. If Zoster Immunoglobulin-VF can be administered within 96 hours after exposure.
Shelf Life (months)	36
Storage Conditions	Store at 2° - 8°C (Refrigerate. Do not freeze). Protect from light.
Planned Product Changes	[Not disclosed – specifies planned product changes]
Ability for a Party to remove the Product from supply	[Not disclosed – specifies when products may be removed from supply under the Deed]

under the Deed	
Ability for a Party to add the Product to supply under the Deed	[Not disclosed – specifies when products may be added to supply under the Deed]

5 Products following Process Migration

5.1 As at the Commencement Date, CSL has proposed the following changes in relation to Process Migration.

[Not disclosed – changes to Products following Process Migration are subject to the approvals and decisions of the Process Migration Governance Committee.]

5.2 Process Migration as set out in Item 5.1 above will take effect subject to the approvals and decisions of the Process Migration Governance Committee made in accordance with the process set out in clauses 12.6 to 12.8.

5.3 The Parties agree to use best endeavours to ensure that the Process Migration Governance Committee considers the relevant approvals and makes any necessary decisions in relation to the proposed process for manufacturing prothrombin complex concentrate following Process Migration within 6 months of the Commencement Date.

Schedule 5

Shelf Life and expiry of Products

Process for updates of schedule	Formal Notice from NBA to CSL
Version number	1
Version issue date	Commencement Date
Version date of effect	Commencement Date

Product	Target Minimum Shelf Life on delivery (months)	Is the Product an Expiry Risk Product?
ALBUMEX 20 10mL	12	No
ALBUMEX 20 100mL	12	No
ALBUMEX 4 50mL	12	No
ALBUMEX 4 500mL	12	No
INTRAGAM P 50mL	6	No
INTRAGAM 10 200mL	6	No
INTRAGAM 10 25mL	6	No
INTRAGAM 10 100mL	6	No
EVOGAM 5mL	6	No
EVOGAM 20mL	6	No
BIOSTATE 250IU	12	No
BIOSTATE 500IU	12	No
BIOSTATE 1000IU	12	No
MonoFIX-VF 1000IU	9	Yes
PROTHROMBINEX-VF 500IU	9	No
THROMBOTROL-VF 1000IU	6	No
CMV Immunoglobulin-VF 1.5MILL U	6	Yes
Hepatitis B Immunoglobulin-VF 100IU	6	Yes
Hepatitis B Immunoglobulin-VF 400IU	6	Yes
Normal Immunoglobulin-VF 2mL	6	Yes
Normal Immunoglobulin-VF 5mL	6	Yes
Rh (D) Immunoglobulin-VF 250IU	6	Yes

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Product	Target Minimum Shelf Life on delivery (months)	Is the Product an Expiry Risk Product?
Rh (D) Immunoglobulin-VF 625IU	6	Yes
Tetanus Immunoglobulin-VF 250IU	6	Yes
Tetanus Immunoglobulin-VF 4000IU	6	Yes
Zoster Immunoglobulin-VF 200IU	6	Yes

Schedule 6

Ordering and delivery requirements

Process for updates of schedule	Formal Notice from NBA to CSL
Version number	1
Version issue date	Commencement Date
Version date of effect	Commencement Date

1 Delivery quantities for normal Orders from Distributors

Product	Vials per shipper	Delivery Quantity Increments (vials)
ALBUMEX 20 10mL	200	10
ALBUMEX 20 100mL	30	30
ALBUMEX 4 50mL	60	60
ALBUMEX 4 500mL	10	10
INTRAGAM P 50mL	60	60
INTRAGAM 10 25mL	60	60
INTRAGAM 10 100mL	30	30
INTRAGAM 10 250mL	20	20
EVOGAM 5mL	100	100
EVOGAM 20mL	100	100
BIOSTATE 250IU	50	10
BIOSTATE 500IU	50	10
BIOSTATE 1000IU	50	10
MonoFIX-VF 1000IU	50	10
PROTHROMBINEX-VF 500IU	50	50
THROMBOTROL-VF 1000IU	50	10
CMV Immunoglobulin-VF 1.5MILL U	30	10
Hepatitis B Immunoglobulin-VF 100IU	200	10
Hepatitis B Immunoglobulin-VF 400IU	200	10

Product	Vials per shipper	Delivery Quantity Increments (vials)
Normal Immunoglobulin-VF 2mL	200	10
Normal Immunoglobulin-VF 5mL	200	10
Rh (D) Immunoglobulin-VF 250IU	200	10
Rh (D) Immunoglobulin-VF 625IU	200	10
Tetanus Immunoglobulin-VF 250IU	30	10
Tetanus Immunoglobulin-VF 4000IU	200	1
Zoster Immunoglobulin-VF 200IU	200	5

2 Required Delivery Time for Orders from Distributors

State / Territory	Required Delivery Time (Working Days)
Victoria	2
South Australia	3
New South Wales	3
ACT	3
Tasmania	5
Queensland	5
Western Australia	7
Northern Territory	7

3 Required Delivery Time for Orders from other Approved Health Providers

- 3.1 The Required Delivery Time for an Order from an Approved Health Provider other than a Distributor is 2 Working Days in any State or Territory.

4 Required Delivery Time for Home Delivery Orders

- 4.1 The Required Delivery Time for a Home Delivery Order is as specified in accordance with Schedule 15.

Schedule 7

Minimum inventory requirements

Process for updates of schedule	Formal Notice from NBA to CSL in accordance with clause 13.11 (Minimum Starting Plasma Inventory) or clause 16.6 (Minimum Product Inventory)
Version number	1
Version issue date	Commencement Date
Version date of effect	Commencement Date

1 Minimum Starting Plasma Inventory

Type of Starting Plasma	Minimum Starting Plasma Inventory (kilograms)
[Not disclosed – specifies the type of Starting Plasma]	[Not disclosed – specifies the minimum Starting Plasma Inventory volume in kilograms]

2 Minimum Product Inventory

Product	Minimum Product Inventory (Product Units)
[Not disclosed – specifies products supplied under the Deed that have a Minimum Product Inventory (MPI)]	[Not disclosed – specifies MPI volumes in product units]

Schedule 8

National CSL Reserve

Process for updates of schedule	Formal Notice from NBA to CSL in accordance with clause 17.3
Version number	1
Version issue date	Commencement Date
Version date of effect	Commencement Date

Product	Amount required in National CSL Reserve (Product Units)	Minimum shelf life in National CSL Reserve (months)
[Not disclosed – specifies products supplied under the Deed that have a National Reserve (NR)]	[Not disclosed - specifies NR volumes in product units]	[Not disclosed - specifies minimum shelf life of products in NR in months]

Schedule 9

Required Reports

Process for updates of schedule	As agreed by Formal Notice
Version number	1
Version issue date	Commencement Date
Version date of effect	Commencement Date

[Not disclosed – specifies the reports that CSL is required to submit to the NBA]

Schedule 10

Key Performance Indicators

Process for updates of schedule	Deed variation under clause 66
Version number	1
Version issue date	Commencement Date
Version date of effect	Commencement Date

1 General

- 1.1 CSL's performance against the KPIs will be measured, and the consequences determined, on the basis set out in this Schedule.
- 1.2 The measurement and application of KPIs based on reports provided by CSL in accordance with Schedule 9 is subject to later adjustment as reasonably required by the NBA if a CSL Report is identified as being materially incomplete or incorrect based on any verification or audit process under the Deed or on other available information.
- 1.3 Where the measurement of performance or determination of consequences in relation to a KPI is affected by a Force Majeure Event (including, without limitation, circumstances affecting Starting Plasma referred to in clause 13.6), the effects of the Force Majeure Event will as far as practicable be ignored and excluded in the measurement or determination of consequences for the KPI.
- 1.4 For the purposes of this Schedule:
- 1.4.1 production of Products from Starting Plasma will be taken to have commenced at commencement of thawing of the Starting Plasma;
 - 1.4.2 a production batch is taken to have been completed when batch release in accordance with the TG Act is obtained for the batch;
 - 1.4.3 an IVIg Product production batch is a production batch which produces IVIg Products, whether or not other Products are also produced;
 - 1.4.4 a SCIg Product production batch is a production batch which produces SCIg Products, whether or not other Products are also produced; and
 - 1.4.5 non-monetary variables used for the purposes of calculations must be rounded to three decimal places in accordance with the Standard Operating Procedure.
- 1.5 All monetary amounts specified in this Schedule are specified on a GST exclusive basis.
- 1.6 The Parties may agree by Formal Notice to establish:
- 1.6.1 a Standard Operating Procedure for the calculation of KPIs: and
 - 1.6.2 a process for joint monthly reconciliation of KPI outcomes.

2 Yield

Interpretation

- 2.1 In this Schedule 10:
- 2.1.1 **Adjusted Ig Yield Target** means an Ig Yield Target determined in accordance with Item 2.2;
 - 2.1.2 **Average Annual IgG Concentration** means the figure for a relevant year specified in Item 2.2, or reported by CSL under Item 2.6;
 - 2.1.3 **Ig Yield Target** means a target level for Ig yield for the purposes of KPI1 or KPI2, as specified in this Item 2;
 - 2.1.4 **Initial Ig Yield Target** is an Ig Yield Target applicable from the Commencement Date as specified in Item 2.3.

Initial Ig Yield Targets

[Items 2.2 – 2.4 not disclosed – these items set out the methodology for calculating performance targets.]

Adjusted Ig Yield Targets

- 2.5 If the Average Annual Ig Concentration for a financial year is different from 7.07 grams per kilogram, the Parties agree to adjust the Ig Yield Targets to apply in respect of that financial year in accordance with the following formula:

$$\text{Adjusted Ig Yield Target} = \text{Initial Ig Yield Target} \times \frac{\text{Average Annual IgG Concentration}}{7.07}$$

Measurement and reporting of Average Annual IgG Concentration

- 2.6 During the Term, CSL will:
- 2.6.1 conduct an assay on each first homogenous starting plasma pool to determine the concentration of IgG in that plasma pool;
 - 2.6.2 following the end of each quarter, calculate on a rolling quarterly basis the average IgG concentration of all starting plasma pooled for manufacture of Ig Products during the previous 12 month period (Average Annual IgG Concentration); and
 - 2.6.3 report the quarterly rolling Average Annual IgG Concentration to the NBA in accordance with Schedule 9 (Required Reports).
- 2.7 The NBA may, in accordance with clause 32, conduct, or engage an independent person to conduct, an audit of the Average Annual IgG Concentration reported by CSL.

3 Process for determining KPI outcomes and invoicing

- 3.1 By no later than 30 days after the end of a financial year, or as soon as practicable thereafter, CSL must:
- 3.1.1 finalise the outcomes of the measurement of CSL's performance and determination of consequences for all applications of each of the KPIs for the financial year;

- 3.1.2 provide the NBA with a single annual Tax Invoice or credit note (as the case may be), in accordance with clause 35, in respect of and itemising all rebate and bonus amounts arising from all applications of each of the KPIs in respect of the financial year;
- 3.1.3 provide the NBA with documentation demonstrating and substantiating the outcomes of the measurement of CSL's performance and determination of consequences against the KPIs for the financial year, in support of the Tax Invoice or credit note; and
- 3.1.4 if a credit note is given but no subsequent Tax Invoice from CSL will be available against which the credit note can operate, provide the NBA with a refund of Payments under clause 36 in respect of the amount indicated by the credit note.
- 3.2 The NBA's obligation to make a Payment under an annual KPI Tax Invoice is, in addition to the matters specified in clause 35.7, subject to the NBA being reasonably satisfied of the outcomes of the measurement of CSL's performance and determination of consequences against the KPIs for the relevant financial year, on which the Tax Invoice is based, provided that the NBA must not unreasonably withhold Payment for any part of a Tax Invoice which is not in dispute.

4 KPI 1 – Plasma stewardship

- 4.1 [Not disclosed - this clause sets out information used for calculating performance targets]

General	[Not disclosed - this information is used for calculating performance targets]
Purpose	<p>3. CSL is a custodian of Starting Plasma, and of all Products and other Plasma Material derived from Starting Plasma, which is a valuable and scarce resource funded by Australian Governments. CSL is required to have adequate control mechanisms in place to safeguard this resource at all stages of custodianship.</p> <p>4. KPI 1 imposes a reasonable rebate, based on the cost to governments of funding the collection of Starting Plasma, where CSL is responsible for loss of Plasma Material outside agreed normal tolerances.</p>
Period	[Not disclosed - this information is used for calculating performance targets]
Measurement	[Not disclosed - this information is used for calculating performance targets]
Consequences	[Not disclosed - this information outlines how the consequences of the KPI are to be applied]

5 KPI 2 – Production Yield

- 5.1 [Not disclosed - this clause sets out information used for calculating performance target].

General	[Not disclosed - this information is used for calculating performance targets]
Purpose	<ol style="list-style-type: none"> 3. The yield achieved by CSL in production of the Products from Starting Plasma is an important element in making the best possible use of the valuable and scarce resource of Starting Plasma, and in maximising the cost efficiency of funding provided by Australian Governments for Starting Plasma and Products. 4. KPI 2 provides for CSL to be paid a bonus if it achieves annual average production yields above a specified Applicable Yield Target (Bonus) for IVIg Products and SCIg Products 5. KPI 2 also provides for a reduction in the Monthly Block Fee payable under Schedule 11 if the average annual yield of IVIg Products or SCIg Products is below a specified Applicable Yield Target (Block Fee Reduction).
Period	[Not disclosed - this information is used for calculating performance targets]
Measurement	[Not disclosed - this information is used for calculating performance targets]
Consequences	[Not disclosed - this information outlines how the consequences of the KPI are to be applied]

6 KPI 3 – Management of Minimum Inventory and National CSL Reserve levels

Purpose	<ol style="list-style-type: none"> 1. The maintenance of adequate minimum inventory levels and of the National CSL Reserve, as required by the Deed, is an important means of ensuring continuity of supply of Products in all situations. Further, the National CSL Reserve is an inventory of Products which has been paid for by Australian Governments through the NBA. 2. KPI 3 imposes a reasonable rebate where CSL fails to maintain inventory of Starting Plasma or Products, or the National CSL Reserve, at the required level.
Period	[Not disclosed - this information is used for calculating performance targets]
Measurement	[Not disclosed - this information is used for calculating performance targets]
Consequences	[Not disclosed - this information outlines how the consequences of the KPI are to be applied]

7 KPI 4 – Fulfilment of Orders

General	[Not disclosed - this information is used for calculating performance targets]
Purpose	<ol style="list-style-type: none"> 2. Fulfilment of Orders by CSL on time, as Ordered and in accordance with the requirements of the Deed is an important indicator of the efficient and effective supply of Products under the Deed. 3. KPI 4 imposes a reasonable rebate for each instance where CSL fails to meet the requirements of the Deed in relation to fulfilment of Orders.
Period	[Not disclosed - this information is used for calculating performance targets]

Measurement	[Not disclosed - this information is used for calculating performance targets]
Consequences	[Not disclosed - this information outlines how the consequences of the KPI are to be applied]

8 KPI 5 – Shelf Life of Products in National CSL Reserve

General	[Not disclosed - this information is used for calculating performance targets]
Purpose	<ol style="list-style-type: none"> 2. The maintenance the National CSL Reserve with Product Units having satisfactory remaining Shelf Life is an important means of ensuring that the National CSL Reserve will be effective to address the severe situations of supply or demand risk for which it is intended. 3. KPI 5 imposes a reasonable rebate where CSL fails to maintain inventory of Products with satisfactory remaining Shelf Life in the National CSL Reserve.
Period	[Not disclosed - this information is used for calculating performance targets]
Measurement	[Not disclosed - this information is used for calculating performance targets]
Consequences	[Not disclosed - this information outlines how the consequences of the KPI are to be applied]

Schedule 11

Prices and fees

Process for updates of schedule	Deed variation under clause 66
Version number	1
Version issue date	Commencement Date
Version date of effect	Commencement Date

1 Prices for Products

1.1 The price payable by the NBA per Product Unit supplied under the Deed from the Commencement Date, and which applies (unless otherwise specified) for Product Units placed into National CSL Reserve and payments or credits under the Deed for Expired Products, is as follows:

Product	Price per Unit (\$, ex GST)	Indexation basis
ALBUMEX 20 10 mL	15.50	CPI
ALBUMEX 20 100mL	67.62	CPI
ALBUMEX 4 50mL	15.50	CPI
ALBUMEX 4 500mL	67.62	CPI
INTRAGAM P 50mL	144.00	CPI – 1%
INTRAGAM 10 25mL	120.00	CPI – 1%
INTRAGAM 10 100mL	480.00	CPI – 1%
INTRAGAM 10 200mL	960.00	CPI – 1%
EVOGAM 5mL	38.40	CPI – 1%
EVOGAM 20mL	153.60	CPI – 1%
BIOSTATE 250IU	218.14	CPI
BIOSTATE 500IU	436.29	CPI
BIOSTATE 1000IU	872.57	CPI
MonoFIX-VF 1000IU	872.57	CPI
PROTHROMBINEX-VF 500IU	278.14	CPI
THROMBOTROL-VF 1000IU	1407.02	CPI
CMV Immunoglobulin-VF 1.5MILL U	1203.13	CPI
Hepatitis B Immunoglobulin-VF 100IU	43.98	CPI
Hepatitis B Immunoglobulin-VF 400IU	100.69	CPI

National Fractionation Agreement for Australia

Product	Price per Unit (\$, ex GST)	Indexation basis
Normal Immunoglobulin-VF 2mL	31.65	CPI
Normal Immunoglobulin-VF 5mL	51.89	CPI
Rh (D) Immunoglobulin-VF 250IU	29.79	CPI
Rh (D) Immunoglobulin-VF 625IU	74.44	CPI
Tetanus Immunoglobulin-VF 250IU	43.47	CPI
Tetanus Immunoglobulin-VF 4000IU	695.48	CPI
Zoster Immunoglobulin-VF 200IU	275.75	CPI
Monthly Block Fee	2,666,666.67	CPI – 1%

- 1.2 The price payable by the NBA per Product Unit supplied under the Deed from 1 September 2021, and which applies (unless otherwise specified) for Product Units placed into National CSL Reserve and payments or credits under the Deed for Expired Products, is as follows:

Product	Price per Unit (\$, ex GST)	Indexation basis
Albumex 20 100mL	64.00	CPI
Albumex 4 500mL	64.00	CPI
Intragam 10 25mL	116.25	CPI – 1%
Intragam 10 100mL	465.00	CPI – 1%
Intragam 10 200mL	930.00	CPI – 1%
Monthly Block Fee	2,583,333.33	CPI – 1%

2 Monthly Block Fee

- 2.1 The Monthly Block Fee specified in Item 1 of this Schedule 11 is payable by the NBA each month in respect of the production and supply of Ig Products under the Deed.
- 2.2 The Monthly Block Fee payable by the NBA may be reduced by the application of KPI 2 under clause 28 and Schedule 10.

3 Fee for management of the National CSL Reserve

- 3.1 The NBA must pay an amount of \$22,723.27 (GST exclusive) per month during the Term in arrears in respect of CSL's management of the National CSL Reserve in accordance with this Deed.
- 3.2 The amount payable under item 3.1 of this Schedule 11 may be reduced in accordance with the Deed.

4 Indexation

- 4.1 The prices specified in Item 1 (including the Monthly Block Fee), and the amounts specified in Item 3.1 of this Schedule 11 or in any other provision of the Deed referring to

this Item 4 of Schedule 11 ('other amounts'), will be subject to indexation taking effect as follows:

- 4.1.1 on 1 July 2019, 1 July 2020 and 1 July 2021 for prices and amounts covered in Item 1.1;
 - 4.1.2 on 1 July 2022 and on the first day of each financial year thereafter for prices and amounts covered in Item 1.2; and
 - 4.1.3 on 1 July 2019 and on the first day of each financial year thereafter for prices and amounts not covered by Items 1.1 or 1.2.
- 4.2 Prices and other amounts will be indexed on the basis identified in Item 1, or otherwise at CPI, taking into account the percentage change in the Australian Consumer Price Index (ABS Cat No. 6401.0, All Groups, Weighted Average of the eight capital cities) (the **All Groups CPI Index**) since the last date from which indexation under Item 4.1 took effect, based on the most recent data published by the Australian Bureau of Statistics at the time the indexation is to be applied. If the indexation amount is less than zero, indexation of prices and other amounts for the relevant period will take effect at a rate of 0%.
- 4.3 If the All Groups CPI Index is suspended or discontinued, or the basis of calculating the All Groups CPI Index is changed substantially, the All Groups CPI Index will be replaced for the purposes of Item 4.3 with the index published by the Australian Bureau of Statistics at the time the indexation is to be applied which reflects changes in the cost of living for metropolitan households on a weighted average basis across the eight capital cities in Australia, which will be:
- 4.3.1 as agreed by the Parties; or
 - 4.3.2 if the Parties are unable to agree within 10 Working Days after one of the Parties proposes a replacement index, as determined in accordance with the dispute resolution process in clause 45.

5 Additional payment

- 5.1 Subject to Item 5.2, if, in relation to any financial year within the Term where the prices for Ig Products and Block Fee in that year were indexed on the basis of CPI – 1% to apply from 1 July in that financial year, and:
- 5.1.1 the volume (kilograms) of Starting Plasma provided to CSL in that year is less than 5% greater than the volume (kilograms) of Starting Plasma provided in the previous financial year; or
 - 5.1.2 the total volume (grams) of all Ig Products ordered from CSL for supply in that year is less than 5% greater than the total volume (grams) ordered for supply in the previous financial year
- CSL may give a Tax Invoice to the NBA under clause 35 requiring an additional payment in accordance with this Item 5.
- 5.2 An additional payment will not be payable by the NBA under this Item 5 if the shortfall in Starting Plasma arises because:
- 5.2.1 CSL does not, or is judged by Australian Governments not to, have the capacity or capability in the relevant financial year to accept the Minimum Annual Starting Plasma Volume or to produce a sufficient amount of Products from the Minimum Annual Plasma Volume to meet Orders in accordance with clause 19; or

- 5.2.2 CSL is in breach or anticipatory breach, or is judged by Australian Governments to be or to be likely to be in breach, of obligations under this Deed in the relevant financial year which materially relate to CSL's acceptance of the Minimum Annual Starting Plasma Volume or production of a sufficient amount of Products from the Minimum Annual Plasma Volume to meet Orders in accordance with clause 19.
- 5.3 An additional payment under this Item 5 will be calculated as the difference between the total sum of the amounts paid by the NBA to CSL for Ig Products and Block Fee supplied under the Deed in that financial year, and the total sum of the amounts that would have been paid by the NBA to CSL for the Block Fee and IVIg Products and SCIg Products supplied in that financial year had the Block Fee and prices for IVIg Products and SCIg Products been indexed on the basis of CPI.

Schedule 12

Plasma Volume Payments

Process for updates of schedule	Deed variation under clause 66
Version number	1
Version issue date	Commencement Date
Version date of effect	Commencement Date

[Not disclosed – this Schedule provides a framework for calculating payment for plasma volume]

Schedule 13

Required guarantees and undertakings

Process for updates of schedule	Deed variation under clause 67
Version number	1
Version issue date	Commencement Date
Version date of effect	Commencement Date

1. **Required financial undertaking amount:** [Not disclosed – this item identifies the value of the undertaking]

2. **Required performance guarantor(s):**

Guarantor	Guaranteed products
CSL Behring AG	Albumin Ig Products Rh (D) Immunoglobulin CMV Immunoglobulin
CSL Behring GmbH	Plasma derived Factor VIII Plasma derived Factor IX Prothrombin Complex Concentrate Antithrombin III Hepatitis B Immunoglobulin Tetanus Immunoglobulin IM Zoster Immunoglobulin Normal Immunoglobulin

Schedule 14

Confidential Information

Process for updates of schedule	Deed variation under clause 66
Version number	1
Version issue date	Commencement Date
Version date of effect	Commencement Date

[Not disclosed – this Schedule outlines Confidential Information of CSL under the Deed]

Schedule 15

Home Delivery

Process for updates of schedule	Formal Notice issued by the NBA
Version number	1
Version issue date	Commencement Date
Version date of effect	Commencement Date

1 Interpretation

- 1.1 In this Schedule 15, **Supervising AHP** means an Approved Health Provider responsible for the treatment of an Approved Home Delivery Recipient in respect of the administration of Products supplied to the Approved Home Delivery Recipient in accordance with this Deed.

2 Home Delivery System

- 2.1 CSL must have an effective Home Delivery System which records and tracks all Home Delivery supply.

3 Approval

- 3.1 CSL may provide Products supplied under this Deed to an Approved Home Delivery Recipient if:
- 3.1.1 the NBA has notified CSL that the NBA has approved Home Delivery in relation to a Product supplied under this Deed;
 - 3.1.2 the Supervising AHP has notified CSL of the relevant supervisory arrangements in place in relation to the treatment of the Approved Home Delivery Recipient;
 - 3.1.3 CSL has established an accessible feedback mechanism for Approved Home Delivery Recipients and Supervising AHPs to provide their feedback to CSL; and
 - 3.1.4 CSL has implemented a Home Delivery System that is approved by the NBA and the Supervising AHP.
- 3.2 CSL must obtain written authorisation from the Supervising AHP to supply the Approved Home Delivery Recipient with additional product above the authorised dose.

4 Ordering and Delivery

Ordering by Supervising AHPs

- 4.1 When an Approved Home Delivery Recipient requires a Product available under Home Delivery under the Deed, the Approved Home Delivery Recipient's Supervising AHP will

initiate the Ordering process with CSL and notify CSL of any reasonable protocols or procedures in relation to notify and contacting Approved Delivery Recipients and the Supervising AHP, with which CSL must comply.

4.2 CSL must:

- 4.2.1 confirm the ordering arrangements process with the Supervising AHP;
- 4.2.2 provide the Approved Home Delivery Recipient with information on CSL ordering processes including stock count, stock rotation and cold chain integrity; and
- 4.2.3 inform the Approved Home Delivery Recipient of the collection process if the Approved Home Delivery Recipient is not available to receive the Product.

Requirements in relation to Home Delivery Orders

- 4.3 CSL must deliver Products to the Approved Home Delivery Recipient's nominated address specified in the Home Delivery Order.
- 4.4 After receipt of a Home Delivery Order, CSL must deliver the Ordered Products on the date specified in the Order (which must be a Working Day or a Saturday).
- 4.5 When delivering Products to Approved Home Delivery Recipients, CSL must offer the Approved Home Delivery Recipient a minimum of two, four hour delivery windows per day. The delivery window must be confirmed by the Approved Home Delivery Recipient or the supervising AHP, as required by the supervising AHP, at a minimum 48 hours in advance where practicable.
- 4.6 For the purposes of this Schedule 15, the Required Delivery Time is:
 - 4.6.1 the date specified in the Order, which must be no less than two Working Days after the day on which the Order is received; and
 - 4.6.2 a time within the delivery windows offered by CSL in accordance with Item 4.5; provided that if the Order is received less than two Working Days before the requested time of delivery, CSL Behring must use reasonable endeavours to fulfil the Order within the requested delivery time.
- 4.7 Should the delivery date fall on a public holiday, CSL must arrange delivery in consultation with the Approved Home Delivery Recipient and Supervising AHP prior to the public holiday.
- 4.8 CSL must ensure that the Approved Home Delivery Recipient signs for or otherwise gives written acknowledgement of the receipt of Products at the time of delivery.
- 4.9 CSL must inform the Approved Home Delivery Recipient as soon as possible of any reason delivery cannot be made.
- 4.10 If delivery cannot be made for any reason other than the Approved Home Delivery Recipient or approved receiver not being available to receive the delivery within the requested delivery day and time window, CSL must then arrange a delivery time which is convenient to the Approved Home Delivery Recipient.
- 4.11 If delivery cannot be made as a result of the Approved Home Delivery Recipient or approved receiver not being available to receive the delivery within the requested delivery day and time window, CSL must ensure that, as soon as possible after it discovers that a delivery cannot be made that it:
 - 4.11.1 promptly delivers the Home Delivery Order to the alternative address (if any) specified in the Approved Home Delivery Recipient's registration form; or

- 4.11.2 if no alternative address is specified in the Approved Home Delivery Recipient's registration form, or delivery is not possible to the specified alternative address, obtains instructions from the Supervising AHP on where to redirect the Home Delivery Order.
- 4.12 If an event described in Item 4.11 or 4.11 occurs, CSL must notify the NBA and the Supervising AHP in writing of the following matters within 10 Working Days of the event occurring:
 - 4.12.1 the reason why CSL was unable to make the delivery;
 - 4.12.2 the impact of the event on CSL's ability to deliver the Product within the Required Delivery Time;
 - 4.12.3 the impact of the event on CSL's ability to comply with any other obligations under the Deed; and
 - 4.12.4 the instructions given by the Supervising AHP in relation to redirection of the delivery and the steps taken by CSL to comply with those instructions.
- 4.13 CSL must accept return of Products identified as out of date by the Approved Home Delivery Recipient for disposal.
- 4.14 In the event of a Product recall, CSL must arrange for the recovery of recalled Product from the Approved Home Delivery Recipient.

5 Privacy

- 5.1 CSL must not collect Sensitive Information (as that term is defined in the Privacy Act) about an Approved Home Delivery Recipient unless:
 - 5.1.1 the collection is necessary to perform CSL's obligations under the Deed; and
 - 5.1.2 the Approved Home Delivery Recipient provides written consent to the collection.
- 5.2 Before obtaining the written consent of the Approved Home Delivery Recipient, CSL must ensure that the Approved Health Delivery Recipient is provided with a notice in writing:
 - 5.2.1 that the Approved Health Delivery Recipient's Sensitive Information may be disclosed to the NBA and the purpose for that disclosure;
 - 5.2.2 that includes a link to the NBA's Privacy Policy at www.blood.gov.au/privacy;
 - 5.2.3 of the main consequence for the individual if they choose not to consent; and
 - 5.2.4 of all matters required to be notified in accordance with Australian Privacy Principle 5.
- 5.3 CSL must take reasonable steps to maintain and store records containing the Sensitive Information of Approved Home Delivery Recipients to protect the information from misuse, interference, unauthorised access, modification and disclosure in accordance with Australian Privacy Principle 11.

6 Product Support

- 6.1 CSL must provide Services to support the management and use of the Products delivered to Approved Home Delivery Recipients by healthcare professionals and administrators, patients and carers, which may include the following, as determined by

CSL acting reasonably and having regard to the nature of the Product and any applicable requirements set out in the Medicines Australia Code of Conduct:

- 6.1.1 clinical educational materials, copies of published studies and papers, demonstration and practice kits, dosage calculators, pocket guides, infusion guides, troubleshooting guides, pictorial guides or other informational materials in relation to the Products and the use of the Products, suitable for doctors, nurses, counsellors, laboratory staff and other health care professionals;
 - 6.1.2 similar information, clinical, educational and troubleshooting materials and practice kits suitable to be given by health care professionals to patients and their carers;
 - 6.1.3 in-service and other training for health care professionals;
 - 6.1.4 validated software tools to assist in the determination of optimal dosing regimens or other clinical purposes;
 - 6.1.5 paper-based systems, or electronic data capture systems and devices able to be offered by health care professionals to suitable patients, to assist in monitoring treatment and Product stock levels (and which will provide the ability to easily export electronic data into any national system for recording such data that may be established or nominated by the NBA); and
 - 6.1.6 an expert medical or scientific contact point for Product enquiries from health care professionals, available by telephone on a 24 hour basis 7 days a week.
- 6.2 CSL must, within 30 Working Days of the Commencement Date, provide to the NBA a Product Support Plan in relation to Products supplied to Approved Home Delivery Recipients describing the Product support which CSL and all Product support materials provided under this Deed to the NBA in conjunction with the Product Support Plan or otherwise as requested by the NBA.
- 6.3 In relation to Product support provided for Products supplied to Approved Home Delivery Recipients:
- 6.3.1 any form of medical advice, whether oral or written, provided to any person during the course of, or in any way associated with, the performance of any of CSL's obligations under the Deed, must be given by a person (or, to the extent permitted by Law, given under the direction of a person) who is qualified, competent and legally permitted to give that advice;
 - 6.3.2 Product support information, materials and services must be provided to health care professionals on a basis which is consistent with the Medicines Australia Code of Conduct;
 - 6.3.3 any Product support provided to patients must comply with the Medicines Australia Code of Conduct, and must also comply with a code of conduct, if any, developed or nominated by the NBA after reasonable consultation with CSL and which is applicable to all commercial suppliers of products under contracts entered into by the NBA; and
 - 6.3.4 Product support information, materials and services intended for patients and their carers must, except where required in unusual circumstances, be provided through or under the supervision of the health care professionals caring for the patient, rather than being provided directly by the supplier to the patient.

- 6.4 Unless covered by Product support activities under item 6.3 above, or undertaken in relation to the delivery and receipt of Products, or otherwise specifically authorised by the NBA, CSL is prohibited from initiating contact with individual patients.
- 6.5 Following registration or all other necessary TGA approvals for a Product improvement, or other Product improvement or alternative, the Parties may agree in writing that the improved Product will be available for supply under this Deed from a specified date, subject to:
- 6.5.1 any decision by the NBA, or any other decision making body authorised by Australian Governments from time to time, which may be required in accordance with arrangements established under the National Blood Agreement in order for the Product improvement to be able to be supplied under arrangements funded by the NBA; and
- 6.5.2 the Parties agreeing an implementation plan for the introduction of the Product improvement.

7 Packaging and Labelling

- 7.1 All components required for the reconstitution and administration of Products delivered to Approved Home Delivery Recipients must be provided at the time of supply of the Product under this Deed.
- 7.2 Alternative or additional components, including but not limited to a suitable syringe for pooling of doses, must be supplied free of charge with the Product.

8 Reporting

[Not disclosed – this clause outlines reporting by CSL for home delivery purposes under the Deed.]

Templates

List of Templates

Template 1 – Notification of Notifiable Event

Template 2 – Formal Notice

Template 3 - Variation proposal

Template 4 – Financial Undertaking

Template 5 – Performance Guarantee

Template 6 – Reports

Template 1

Notification of Notifiable Event

Process for updates of template	Formal Notice from NBA to CSL
Version number	1
Version issue date	Commencement Date
Version date of effect	Commencement Date

National Fractionation Agreement for Australia

Notification of Notifiable Event

(clause 6)

Date of Notifiable Event:

Description of Notifiable Event:

Possible Product supply consequences of Notifiable Event:

Other consequences of Notifiable Event:

Responses to Notifiable Event by CSL or other persons:

Notification given by the following CSL representative:

Signature -

Name -

Title -

Date -

CSL reference -

Template 2

Formal Notice

Process for updates of template	Formal Notice from NBA to CSL
Version number	1
Version issue date	Commencement Date
Version date of effect	Commencement Date

National Fractionation Agreement for Australia

Formal Notice

(clause 10)

Date of Formal Notice:

Purpose of Formal Notice:

Deed clause(s) under which the Formal Notice is given:

Content of Formal Notice:

Formal Notice given by the following representative of [Party]:

Signature -

Name -

Title -

Date -

[Party] reference -

Where the Formal Notice is given to obtain agreement of the Parties by Formal Notice

Formal Notice agreed by the following representative of [other Party]:

Signature -

Name -

Title -

Date -

[other Party] reference -

Template 3

Variation proposal

Process for updates of template	Formal Notice from NBA to CSL
Version number	1
Version issue date	Commencement Date
Version date of effect	Commencement Date

National Fractionation Agreement for Australia

Proposal for Variation

(clause 67)

Reason and purpose for proposed change:

Detailed amendments proposed to the Deed:

Timing or transitional implications of the proposed change:

Specific matters required to be addressed by other Deed clauses in relation to the proposed change:

Proposal given by the following representative of [Party]:

Signature -

Name -

Title -

Date -

[Party] reference -

Template 4

Financial Undertaking

Process for updates of template	Formal Notice from NBA to CSL
Version number	1
Version issue date	Commencement Date
Version date of effect	Commencement Date

[Not disclosed – this Schedule specifies the terms of a Financial Undertaking by CSL to the NBA for the purpose of ensuring the due and proper performance of the Deed]

Template 5

Performance Guarantee

Process for updates of template	Formal Notice from NBA to CSL
Version number	1
Version issue date	Commencement Date
Version date of effect	Commencement Date

[Not disclosed - this Schedule specifies the terms of a Performance Guarantee by CSL to the NBA for the supply of products under the Deed on conditions set out in the Guarantee]

Template 6

Reports

Process for updates of template	Formal Notice from NBA to CSL
Version number	1
Version issue date	Commencement Date
Version date of effect	Commencement Date

[Not disclosed – this Schedule specifies the content and format of reports to be provided to the NBA]

Execution

Executed as a deed

Date:

Signed as a deed for and on behalf of the
Commonwealth of Australia, acting through
and represented by the National Blood
Authority, in the presence of:

.....
Signature of witness

.....
Signature of authorised person

.....
Name of witness (print)

.....
Name of authorised person (print)

Signed as a deed for and on behalf of
CSL Behring (Australia) Pty Ltd by its duly authorised
representatives:

.....
Signature of authorised person

.....
Signature of authorised person

.....
Name of authorised person (print)

.....
Name of authorised person (print)