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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.

PLASMA PRODUCTS AGREEMENT

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

CSL Limited

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Parties

THE DEED OF AGREEMENT is made on the 23rd day of December 2004

BETWEEN

Commonwealth of Australia, acting through and represented by the **National Blood Authority** ABN 83 361 602 478, a Commonwealth agency established under the *National Blood Authority Act 2003 (Cth)* (**NBA**)

CSL Limited ABN 99 051 588 348, of 45 Poplar Road, Parkville, Victoria 3052 (**CSL**)

Background

- A 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 prescribed agency for the purposes of the *Financial Management and Accountability Act 1997 (Cth)*.
- B 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.
- C CSL is bound by the provisions of the CSL Act.
- D CSL has particular expertise and experience in providing the Products and Services.
- E 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.

Operative provisions

Section A: Interpretation and Term

1 Definitions

- 1.1 In the Deed, unless the contrary intention is stated or applies by necessary implication:

Action Plan means the plan for supply continuity referred to in **clause 41**.

Annual Supply Estimates means the estimates prepared and given to CSL by the NBA in accordance with **Schedule 3 Business Processes Part B Supply Planning and Monitoring**.

Approved Recipient means those persons approved by the NBA to receive Products and Services who are specified in, or determined in accordance with the procedures set out in, **Schedule 3 Business Processes Part D Ordering and Delivery**.

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.

Confirmed Quarterly Requirements means the estimates prepared and given to CSL by the NBA in accordance with **Schedule 3 Business Processes Part B Supply Planning and Monitoring**.

Commencement Date means the date set out in Item 1 of **Schedule 1 Deed Details**.

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 6 Disclosure and Use of Information** 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. The Parties agree that the terms and conditions of the Deed (including the Payment amounts in **Schedule 3 Business Processes Part G Price, Invoicing and Payment**) 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 the interests of the NBA and those of CSL or its Personnel (or between 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 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.

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

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

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

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.

Emergency Supply Plan means the plan described in **clause 33.5**.

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:

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- (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.

Expiry Date means the date set out in Item 2 of **Schedule 1 Deed Details**.

Financial Undertaking means the financial undertaking referred to in **clause 36**.

Force Majeure Event has the meaning set out in **clause 38.1**.

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.

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 3 Business Processes Part E Reporting and Performance Measurement**.

Key Subcontract means a subcontract that the Parties have agreed is a Key Subcontract for the purposes of **clause 10.2**.

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.

Loss means:

- (a) all losses, liabilities, damages, fines, costs, interest, fees and expenses (including legal costs and expenses on a solicitor/own client basis and disbursements and costs of investigation, litigation, settlement, judgment interest and penalties and the value of internal management and staff time) and includes in respect of that loss:
 - (i) the cost of taking reasonable, preventative, protective remedial or mitigatory action; and
 - (ii) the cost of obtaining any replacement products or services to rectify, remedy or mitigate the damage caused by the relevant event; and
- (b) [Not disclosed.]

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

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 any reserve of Products of that name held by CSL under a contract with the NBA other than the Deed.

Notifiable Events means the events set out in **clause 16.2**.

Order means an order for Products or Services placed under the Deed as set out in **Schedule 3 Business Processes Part D Ordering and Delivery** and **Ordered** and **Ordering** have corresponding meanings.

Other Subcontract means a Subcontract other than a Key Subcontract.

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 **Schedule 3 Business Processes Part G Price, Invoicing and Payment**.

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.

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

Post-Payment Inventory means the inventory of Products (other than the National CSL Reserve) held by CSL in accordance with the Deed after the Products have been paid for by the NBA under the Deed, in accordance with **Schedule 3 Business Processes Part C Production and Inventory Management**.

Pre-existing Material has the meaning set out in **clause 27.4**.

Pre-Payment Inventory means any inventory of Products held by CSL in accordance with the Deed prior to the Products being paid for by the NBA under the Deed.

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

Product means a Product specified in, or determined in accordance with the process set out in, **Schedule 3 Business Processes Part A Product Specifications**, and any other product which may be provided by CSL under **clause 13**.

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.

Registered Goods has the same meaning as in the TG Act and **Registered** means included as a registered good in the Register. **Registration** has a corresponding meaning.

Review means a review referred to in **clause 6**.

Risk Management Plan means the plan referred to in **clause 33**.

Service means any service which may be provided by CSL to the NBA or another person in accordance with the Deed and in particular any service specified in, or determined in accordance with a process specified in, **Schedule 3 Business Processes**.

Specifications for the Products means the specifications set out in, or determined in accordance with the process set out in, **Schedule 3 Business Processes Part A Product Specifications**.

Starting Plasma means human blood plasma collected in Australia and supplied to CSL for the purpose of the Deed, and any substance other than Products produced or derived from such Plasma (including, without limitation, any intermediate substance or by-product produced in the manufacture of Products).

Step-In Notice has the meaning set out in **clause 40.1**.

Step-In Rights means the rights which the NBA may exercise in accordance with **clause 40.3**.

Subcontractor means a person:

- (a) to whom CSL has subcontracted the performance of any part of the Deed; or
- (b) whom CSL has engaged to provide goods or services required by CSL for the performance of any part of the Deed;

whether by contract, agreement, deed or arrangement, but does not include:

- (c) an Employee of CSL; or
- (d) a party to a Toll Fractionation Contract.

Subcontract has a corresponding meaning.

Term means the term of the Deed, calculated in accordance with **clause 3**.

TG Act means the *Therapeutic Goods Act 1998* (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 in Australia, other than the Deed.

Transition Out Plan means the plan of that name referred to in **clause 50**.

Trigger Event has the meaning set out in **clause 40.2**.

Working Days means Monday to Friday inclusive, but excludes any public holiday or bank holiday in the Australian Capital Territory or Victoria and, except in relation to CSL's obligations under **clause 13**, excludes the days 25 to 31 December, inclusive.

2 Rules of Interpretation

- 2.1 The rules set out in **Schedule 2 Interpretation** apply to the interpretation of the Deed.

3 Term and Transition In

- 3.1 The Deed commences on the Commencement Date, and continues until the Expiry Date or until terminated in accordance with the Deed (whichever is the earlier).

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- 3.2 The NBA must, by notice in writing to CSL no later than 24 months prior to the Expiry Date, give CSL notice of the NBA's intention as at that date, including such details and explanation of that intention as the NBA is reasonably able to give, in relation to any prospects of the procurement of the Products and Services from CSL following the Expiry Date.
- 3.3 CSL must:
- 3.3.1 if required by the NBA at any time prior to the NBA giving notice under **clause 3.2**, give the NBA notice of CSL's intentions, including such details and explanation of that intention as CSL is reasonably able to give, in relation to its plasma fractionation facility in Australia following the Expiry Date; and
- 3.3.2 notify the NBA if at any time CSL makes a decision to close its plasma fractionation facility in Australia, or to substantially modify that facility or the use of that facility.
- 3.4 The operation of this Deed is subject to and contingent upon the Parties executing a separate agreement with regard to the transition to arrangements under this Deed from arrangements operating prior to the Commencement Date.

Section B: Relationship Management

4 Relationship of the Parties

Principles guiding the relationship of the Parties

- 4.1 The Parties intend to act towards each other on the basis of the following principles:
- 4.1.1 recognising the importance of maintaining an open and communicative relationship;
 - 4.1.2 seeking to identify, manage and mitigate risks within their control;
 - 4.1.3 conducting themselves in a spirit of cooperation and good faith; and
 - 4.1.4 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 Stock Exchange rules; and
 - (b) 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 *Financial Management and Accountability Act 1997* (Cth), and other applicable laws and policies of the Commonwealth.
- 4.2 For the avoidance of doubt, the principles expressed in **clause 4.1** do not override or limit the provisions of the Deed.

No agency, partnership or other relationship

- 4.3 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.

No authority to act

- 4.4 Neither Party has any power or authority to:
- 4.4.1 act for, or to assume any obligation or responsibility on behalf of, the other Party;
 - 4.4.2 bind the other Party to any agreement;
 - 4.4.3 negotiate or enter into any binding relationship for, or on behalf of, the other Party; or
 - 4.4.4 pledge the credit of the other Party,

except as specifically provided in the Deed or by express written agreement between the Parties.

5 Contacts and Notices

Contacts

- 5.1 The relevant contact persons within each Party for specified categories of communications under or in relation to the Deed are specified in **Schedule 1 Deed Details**.

Giving notices

- 5.2 A notice, consent, information, application or request that must or may be given or made to a Party under the Deed is only given or made if it is in writing and:
- 5.2.1 delivered or posted to the relevant contact for that Party at the address specified in **Schedule 1 Deed Details**; or
 - 5.2.2 faxed to the relevant contact for that Party at the fax number specified in **Schedule 1 Deed Details**; or
 - 5.2.3 sent by electronic mail to the relevant contact for that Party at the address for electronic mail notices specified in **Schedule 1 Deed Details**.
- 5.3 If a Party gives the other Party no less than 3 Working Days written notice of a change to the details specified in **Schedule 1 Deed Details** for that Party, a notice, consent, information, application or request is only given or made by that other Party if it is given or made in accordance with those changed details.

Time notice is given

- 5.4 A notice, consent, information, application or request is taken to be received if it is:
- 5.4.1 delivered by hand, when it is left with an Employee of the other Party at the relevant address;
 - 5.4.2 sent by post, when it is actually received by the other Party;
 - 5.4.3 sent by fax, and an 'OK' transmission report is received by the sender, on the day of transmission if that is before 5.00pm on a Working Day, otherwise on the next Working Day; or
 - 5.4.4 sent by electronic mail, on receipt by the sender of an electronic mail message written by the recipient (and not automatically generated) confirming that the recipient has received and opened the electronic mail message and any electronic attachments to the electronic mail message.
- 5.5 A Party must not rely on a notice, consent, information, application or request having been received under **clause 5.4.2** unless that Party has received confirmation of receipt using registered mail or directly from the recipient Party.

6 Management Meetings and Reviews

Deed Management Meetings

- 6.1 The NBA may convene meetings to review performance of the Deed and undertake other strategic and operational management actions in relation to the Deed, and may do so on the following basis:

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- 6.1.1 meetings are to be conducted by teleconference or, where a teleconference is impracticable, at the NBA's premises or another venue reasonably nominated by the NBA;
 - 6.1.2 meetings are to be conducted at a date and time nominated by the NBA after consultation with CSL.
- 6.2 CSL must, at its own expense, participate in each meeting as reasonably requested by the NBA.

The NBA may conduct Reviews

- 6.3 The NBA may conduct Reviews in relation to the operation of 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.
- 6.4 The NBA must use reasonable endeavours to ensure that any Review performed in accordance with this **clause 6** does not unreasonably delay or disrupt CSL's operations in any material respect.

CSL to participate in Reviews

- 6.5 CSL must, at its own expense:
- 6.5.1 participate in each Review as is reasonably requested by the NBA; and
 - 6.5.2 for the purpose of any Review, within 5 Working Days of a request by the NBA, and in addition to other obligations under the Deed, provide any information, access to records, and advice reasonably requested by the NBA which are relevant to the Review.

Results of the Review

- 6.6 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 8**, propose one or more changes to the Deed to implement the results of the Review.
- 6.7 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 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.

7 Public Affairs Management

[Not disclosed. The parties agreed to consult on, and cooperate in, public affairs management where practicable and appropriate.]

8 Variations to the Deed

General

- 8.1 Subject to any express provision of the Deed which permits the contrary in particular circumstances, no change may be made to the Deed without:
- 8.1.1 prior consultation between the Parties;
 - 8.1.2 the Parties complying with the change control procedures included in this **clause 8**; and
 - 8.1.3 the Parties executing a variation in writing.

Change Control

- 8.2 Either Party may propose a change to any part of the Deed.
- 8.3 A Party proposing a change to the Deed must provide detailed written information to the other Party about:
- 8.3.1 the detailed amendments proposed to the Deed (including the Schedules);
 - 8.3.2 any timing implications arising from the proposal;
 - 8.3.3 a risk analysis and management strategy for the proposal;
 - 8.3.4 any specific matters required to be addressed in relation to that change by any other provision of the Deed; and
 - 8.3.5 any other matters reasonably requested by the other Party in relation to the proposed change.
- 8.4 A Party must:
- 8.4.1 take into account a proposal provided under **clause 8.3**; and
 - 8.4.2 respond to that proposal with reasons within 15 Working Days.
- 8.5 Subject to **clause 8.6**, the Parties must decide whether they agree on the proposal under **clause 8.2** within 30 Working Days of the provision of the proposal under **clause 8.3**.
- 8.6 Despite **clause 8.5**, 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.
- 8.7 Despite any other provision of this **clause 8**, where (at any time, whether before or after a proposal is made under **clause 8.2**) the NBA notifies CSL that a particular change to the Deed requires, or is required by, a decision of Commonwealth, State and/or Territory governments in accordance with the National Blood Arrangements, and notifies CSL of any:
- 8.7.1 additional processes;

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- 8.7.2 increased or decreased timeframes;
 - 8.7.3 deadlines; or
 - 8.7.4 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 8** will be modified in accordance with the changed arrangements notified by the NBA.

8.8 [Not disclosed.]

8.9 Without limitation to this **clause 8**, if CSL makes a proposal under **clause 8.8**, CSL must provide to the NBA:

- 8.9.1 written information about the specific circumstances giving rise to CSL's proposal;
- 8.9.2 evidence to the effect that the change was or will be beyond the reasonable control of CSL, and that CSL is unable to reasonably modify its operations or costs in relation to the change (at no material cost to CSL) to the extent necessary to obviate the need for any such proposal;
- 8.9.3 a written explanation of why the particular proposed change has been proposed; and
- 8.9.4 the necessary financial analysis demonstrating the relevant net increase in costs or net reduction in revenue which gave rise to CSL's proposal.

8.10 If the NBA receives a proposed change from CSL under **clause 8.8**, the NBA will consider and negotiate that proposal in good faith on a reasonable basis, and will not unreasonably delay any such consideration or negotiation. Subject to the preceding sentence and **clause 8.8.4**, any proposal under **clause 8.8** must be dealt with by the Parties in accordance with **clauses 8.3 to 8.7**.

8.11 [Not disclosed.]

8.12 For certainty, **clauses 8.10 and 8.11** do not limit a Party's rights or obligations under **clauses 8.3 to 8.7**.

9 New Developments

9.1 CSL agrees to 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.

9.2 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:

- 9.2.1 providing written information or assessment to the NBA of new technology, products or services relevant to the Deed within a reasonable period of time

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- following the introduction of such technology, products or services or within a reasonable time requested by the NBA; and
- 9.2.2 attendance at, and participation in, meetings with the NBA (provided that, where practicable, such meetings are conducted by telephone or similar means).
- 9.3 CSL agrees to prepare and provide information or assessments to the NBA pursuant to **clauses 9.1** and **9.2** in good faith but:
- 9.3.1 makes no representation or warranty to the NBA or any other person as to the accuracy or completeness of; and
- 9.3.2 accepts no duty, liability or responsibility to the NBA or any other person in connection with,
- such information or assessments.
- 9.4 **Clause 9.3** 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 34.1.1**.

10 Subcontracting

- 10.1 CSL must not Subcontract the performance of any material part of the Deed without complying with this **clause 10**, in addition to meeting the requirements of **clause 11**.

Key Subcontracts

- 10.2 From time to time, the Parties may agree that an individual Subcontract (or a class of Subcontracts) is a Key Subcontract where:
- 10.2.1 the Subcontract is for the supply of goods or services that are available from one Subcontractor only;
- 10.2.2 the Subcontract is for the supply of goods or Services which CSL is directly obliged to provide to the NBA or an Approved Recipient as part of the Products or Services under the Deed;
- 10.2.3 the Subcontract is for the supply of goods or services which are critical to the provision of Products or Services under the Deed; or
- 10.2.4 disruption to the supply of the goods or services under the Subcontract has the potential to result in significant disruption to supply of Products or Services under the Deed,

and CSL must not unreasonably withhold agreement to any proposal from the NBA that a Subcontract (or class of Subcontracts) is a Key Subcontract.

- 10.3 All Key Subcontracts must be in writing.
- 10.4 Prior to CSL entering into any Key Subcontract, CSL must:

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- 10.4.1 provide the NBA with a draft copy of the proposed Subcontract (with the pricing details only removed) no less than 20 Working Days (or, if that is not practicable, as soon as possible) prior to the date that CSL proposes to enter into the Subcontract;
 - 10.4.2 allow the NBA no less than 5 Working Days for the NBA to provide any comments that the NBA may have on the proposed Subcontract;
 - 10.4.3 provide any additional information on the Key Subcontract (excluding pricing details) reasonably requested by the NBA; and
 - 10.4.4 consider any comments provided by the NBA, except that CSL is only obliged to take into account any comments that relate to a concern held by the NBA in relation to the proposed Key Subcontract, arising from the NBA's statutory functions, or in relation to the National Blood Arrangements, or that CSL will not be able to comply with its obligations under the Deed if CSL was to enter into the proposed Key Subcontract in the form provided by the NBA.
- 10.5 CSL must promptly provide the NBA with a copy of any Key Subcontract (with the pricing details only removed) upon the written request of the NBA.

Other Subcontracts

- 10.6 In accordance with the requirements of **Schedule 3 Business Processes Part E Reporting and Performance Measurement**, CSL will provide a list of Other Subcontracts that will set out the name of the Subcontractor, a general description of the nature of the Subcontract and the expiry date of the Subcontract.
- 10.7 CSL will promptly provide the NBA with a copy of any Other Subcontract (with the pricing details only removed) upon the written request of the NBA.

Subcontracts generally

- 10.8 CSL remains fully responsible for the performance of the Deed and any acts and omissions or other failures of any Subcontractors and 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.
- 10.9 If at any time the NBA is concerned that the performance of a Subcontractor of CSL may not be satisfactory, then (without limitation to any other rights of the NBA under the Deed or at Law):
- 10.9.1 the NBA may notify CSL of the concern and the reasons for the concern; and
 - 10.9.2 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.

11 CSL contracts with other National Blood Suppliers

- 11.1 In this clause:

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- 11.1.1 **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;
- 11.1.2 **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 the NBA to CSL from time to time;
- 11.1.3 **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 the NBA to CSL from time to time; and
- 11.1.4 **Starting Plasma Supplier** means the Australian Red Cross Blood Service or any other supplier of Starting Plasma to CSL from time to time.
- 11.2 CSL:
- 11.2.1 acknowledges that the requirements of NBA approval of arrangements between CSL and a Starting Plasma Supplier under this clause is consistent with the NBA's functions and powers;
- 11.2.2 must provide the NBA with a copy of any contract, arrangement or understanding between CSL and a Starting Plasma Supplier 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 11.2.3**; and
- 11.2.3 agrees not to enter into or vary a contract, arrangement or understanding between CSL and a Starting Plasma Supplier for or in relation to the supply of Starting Plasma without the prior written approval of the NBA.
- 11.3 The NBA agrees:
- 11.3.1 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 11.2.2**, or of receipt of further information from CSL under **clause 11.3.1(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;
- 11.3.2 to use reasonable endeavours to comply with any reasonable requests for urgent consideration; and
- 11.3.3 to not unreasonably withhold or delay approval.
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- 11.4 For contracts, arrangements, understandings or variations with National Blood Suppliers which CSL proposes to enter into, CSL agrees to:
- 11.4.1 notify the NBA as early as possible, within the constraints of the continuous disclosure obligations of CSL under the Australian Stock 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 11.4**), and prior to finalisation of the proposed contract, arrangement, understanding or variation;
 - 11.4.2 advise the NBA of any confidentiality requirements that, in addition to those in **clause 29**, 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;
 - 11.4.3 if the NBA agrees to the requirements referred to in **clause 11.4.2**, 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;
 - 11.4.4 provide any further information reasonably requested by the NBA and within the constraints of the requirements referred to in **clauses 11.4.1, 11.4.2 and 11.4.3**; and
 - 11.4.5 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
 - 11.4.6 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.
- 11.5 **Clause 10.8** 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.
- 11.6 This **clause 11** does not apply to a Toll Fractionation Contract.

12 Personnel

Employer obligations

- 12.1 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.
- 12.2 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 Losses 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

- 12.3 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.
- 12.4 If at any time the NBA is concerned that the warranties in **clause 12.3** may not be met, then (without limitation to any other rights of the NBA under the Deed or at Law):
- 12.4.1 the NBA may notify CSL of the concern and the reasons for the concern;
and
- 12.4.2 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.

Section C: Products/Services obligations

13 Provision of Products and Services

General

- 13.1 CSL must, on the terms and conditions of the Deed:
- 13.1.1 produce, manage and provide 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, **Schedule 3 Business Processes**;
 - 13.1.2 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, **Schedule 3 Business Processes**; and
 - 13.1.3 provide all facilities, arrangements and resources, and do or refrain from doing all things (whether or not expressly provided in the Deed), necessary or appropriate to ensure that it is able to comply with this **clause 13.1**.

Provision of Products and Services

- 13.2 CSL must provide the Products and Services:
- 13.2.1 only to the NBA or Approved Recipients in accordance with Orders under the Deed;
 - 13.2.2 at the times and in the manner provided in, or determined in accordance with the procedures set out in, **Schedule 3 Business Processes**;
 - 13.2.3 exercising professional standards of skill, care and diligence;
 - 13.2.4 subject to **clause 13.5**, in a manner that ensures the Products meet the Specifications; and
 - 13.2.5 in a manner that ensures that all targets or requirements for the Products and Services specified in the KPIs are met.
- 13.3 In providing the Products and Services CSL must:
- 13.3.1 liaise with the relevant Approved Recipient, and the NBA if required;
 - 13.3.2 comply with any reasonable direction of the NBA that is consistent with the Deed; and
 - 13.3.3 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.
- 13.4 CSL must not, and must ensure that its Personnel do not, at any time during the Term:
- 13.4.1 provide any form of medical advice, whether oral or written, to any person during the course of, or in any way associated with, the performance of any

of CSL's obligations under the Deed, unless that advice is given by a person (or, to the extent permitted by law, under the direction of a person) who is qualified, competent and legally permitted to give that advice;

- 13.4.2 undertake any direct advertising of a Product or provide material inducements for the Ordering of a Product, supplied under the Deed, where:
- (a) the advertising or inducement is targeted at Approved Recipients or a class of persons which includes Approved Recipients; and
 - (b) the advertising or inducement is not part of a Service provided in accordance with **Schedule 3 Business Processes Part F Included Services**,

without prior approval in writing from NBA; or
- 13.4.3 undertake any advertising or promotion for the Products to Approved Recipients which does not 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.

No warranty as to quantity of Orders

- 13.5 CSL acknowledges and agrees that:
- 13.5.1 subject to **clause 14.1**, at any time, the NBA may 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;
 - 13.5.2 the arrangements under **clause 13.5.1** may affect the NBA's requirements for the provision of Products or Services under the Deed; and
 - 13.5.3 subject to **Schedule 3 Business Processes Part B Supply Planning and Monitoring, Schedule 3 Business Processes Part D Ordering and Delivery and Schedule 3 Business Processes Part G Price, Invoicing and Payment**, 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.

Standard Operating Procedures

- 13.6 CSL must maintain a planned, systematic and documented approach, in accordance with good commercial practice, to the performance of obligations under the Deed.
- 13.7 In relation to CSL's Standard Operating Procedures, CSL must:
- 13.7.1 provide a copy of any specified Standard Operating Procedures to the NBA at the reasonable request of the NBA;
 - 13.7.2 consider any reasonable suggestion made by the NBA for the development or revision of any specified Standard Operating Procedures; and

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- 13.7.3 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.

Notice Obligations

- 13.8 CSL must promptly notify the NBA if, for any reason:
- 13.8.1 CSL is unable to supply a Product meeting the Specifications in accordance with an Order (including, without limitation, where this arises due to an insufficiency of adequate Starting Plasma received by CSL, or because CSL has received Orders in excess of 105% of the Confirmed Quarterly requirements under **Schedule 3 Business Processes Part B Supply Planning and Monitoring**); or
- 13.8.2 an act or omission of CSL, a Subcontractor or its or their Personnel, or any other circumstances, will or is likely to cause a problem or delay that will or is likely to have an impact on CSL's ability to provide the Products or Services in accordance with the Deed.

Inability to supply in accordance with Specifications

- 13.9 Where a situation which must be notified by CSL to the NBA under **clause 13.8** arises due to CSL's failure to comply with its obligations under the Deed, but not including a situation which is a Force Majeure Event under **clause 38.1**, the following process will apply:
- 13.9.1 CSL must provide detailed information to the NBA on one or more options offered by CSL to supply alternative Products that meet the requirements of the Deed, which are comparable on a value for money basis, and at a price that is no greater than the price of the original Product as specified in the Deed;
- 13.9.2 the NBA will determine whether an alternative Product is comparable on a value for money basis having regard to any factors the NBA considers relevant, including:
- (a) the level of clinical equivalence of the alternative Product to the original Product, which will be determined on the basis of TGA specifications and substantial common indicators; and
- (b) the price of the alternative Product compared with the price of the original Product as specified in the Deed;
- 13.9.3 the NBA will promptly provide a response to CSL on whether or not any option is acceptable to NBA or on whether the NBA requires further information on any option or consultation with CSL; and
- 13.9.4 the NBA may accept or reject any or all options offered by CSL, and if the NBA accepts any option, the Parties agree to promptly implement it under **clause 8**.
- 13.10 Where a situation which must be notified by CSL to the NBA under **clause 13.8** arises due to:

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- 13.10.1 a Force Majeure Event – the NBA may require CSL; or
 - 13.10.2 an insufficiency of adequate Starting Plasma received by CSL, or because CSL has received Orders in excess of 105% of the Confirmed Quarterly requirements under **Schedule 3 Business Processes Part B Supply Planning and Monitoring** – the Parties may agree,

to follow the process in **clause 13.9**, except that the Parties are then obliged to comply with **clause 13.9** only to the extent reasonably practicable.

- 13.11 **Clauses 13.8, 13.9 and 13.10** do not limit a Party's:
 - 13.11.1 obligations under **clauses 33 and 38**; or
 - 13.11.2 other rights of the NBA under the Deed or at Law.

14 Starting Plasma

Exclusive right to fractionate Australian plasma

- 14.1 Subject to **clause 14.2**, the NBA agrees until 30 June 2008 not to enter, or to consent to, approve or endorse, a contract with any other person for the production or supply of products equivalent to the Products specified in **Schedule 3 Business Processes Part A Product Specifications** from human blood plasma collected in Australia.
- 14.2 **Clause 14.1** does not apply:
 - 14.2.1 where the supply of the Products occurs after 30 June 2008; or
 - 14.2.2 in the period from the Commencement Date until 30 June 2008, where in the reasonable opinion of the NBA from time to time CSL does not have the capacity or capability to produce the products referred to in **clause 14.1** from the human blood plasma referred to in that clause, in accordance with the Deed.

Use of Starting Plasma

- 14.3 Unless otherwise agreed by the NBA, the Products produced and supplied by CSL under the Deed must be manufactured using only Starting Plasma provided to CSL at the direction of the NBA for the purposes of the Deed.
- 14.4 CSL acknowledges that the Starting Plasma provided to it for the purposes of the Deed is funded by the governments of the Commonwealth, States and Territories of Australia, through National Blood Arrangements administered by the NBA.
- 14.5 Despite **clauses 14.1 and 14.4**:
 - 14.5.1 the NBA does not warrant or guarantee the quality, fitness for purpose or suitability of the Starting Plasma; and
 - 14.5.2 CSL must:
 - (a) test any Starting Plasma in compliance with any TGA requirements applicable to CSL; and

- (b) do such other testing as CSL considers reasonably appropriate to ensure that the Products meet the requirements of the Deed.

14.6 Without limiting **clause 14.5**, the NBA acknowledges that CSL relies on any approved provider of Starting Plasma 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).

14.7 CSL must:

14.7.1 ensure that the Starting Plasma is used only for the purposes of the Deed;

14.7.2 ensure the safe storage and handling of the Starting Plasma; and

14.7.3 use the Starting Plasma strictly in accordance with any conditions or restrictions set out in the Deed, or notified from time to time in writing by the NBA.

Prohibitions on use

14.8 CSL must not supply or use the Starting Plasma or Products other than in accordance with the Deed, without obtaining the NBA's prior approval in writing, which approval may be given on conditions reasonably determined by the NBA.

14.9 CSL acknowledges that an approval or determination of conditions by the NBA under **clause 14.8** may require a prior decision of Australian governments under the National Blood Arrangements.

15 Surplus Products and Starting Plasma

15.1 The Parties acknowledge that if circumstances arise which make it reasonably necessary or desirable to sell or otherwise dispose of surplus Products or Starting Plasma to third parties, they will consider and negotiate any appropriate changes to the Deed in accordance with **clause 8**.

16 Reports

General

16.1 CSL must provide the NBA with the reports set out in, or determined in accordance with the process set out in, **Schedule 3 Business Processes Part E Reporting and Performance Measurement**:

16.1.1 which contain the information required by **Schedule 3 Business Processes Part E Reporting and Performance Measurement**; and

16.1.2 at the frequency, and by the due dates, specified in, or determined in accordance with the procedures set out in, **Schedule 3 Business Processes Part E Reporting and Performance Measurement**.

Notifiable Events

- 16.2 In addition to the reports required by **clause 16.1**, CSL must provide a written report to the NBA promptly upon becoming aware of the occurrence, or the likely occurrence, of any of the following events:
- 16.2.1 inability to supply an Ordered Product within the required timeframe;
 - 16.2.2 extraordinary circumstances that may affect Product or Service supply or quality under the Deed;
 - 16.2.3 a possible or actual insufficiency of adequate Starting Plasma;
 - 16.2.4 difficulties with Ordering or delivery processes that were unable to be resolved;
 - 16.2.5 a meeting of CSL's creditors being held or called, where the meeting may be in connection with an Insolvency Event; and
 - 16.2.6 any other significant matter reasonably notified by the NBA from time to time.

General obligation for CSL to provide information

- 16.3 CSL must, at its own expense, 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, in relation to:
- 16.3.1 the Products or Services; or
 - 16.3.2 CSL's performance of, or compliance with, the Deed.
- 16.4 CSL must ensure that, in all material respects, all reports, notifications and proposals under **clauses 8** and **16.1** or responses to queries or requests under **clause 16.3** are accurate, complete and not misleading.

17 Compliance with Laws

- 17.1 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.

18 Obligations under Therapeutic Goods Act**Definitions**

- 18.1 In this clause:
- 18.1.1 **Licence** means a licence issued under Part 4 of the TG Act;
 - 18.1.2 **Listed Goods** has the same meaning as in the TG Act and **Listed** means included as a listed good in the Register. **Listing** has a corresponding meaning;

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- 18.1.3 **manufacturer** means a person engaged in the manufacture (as that term is defined in the TG Act) of therapeutic goods;
- 18.1.4 **manufacturing principles** has the same meaning as in the TG Act;
- 18.1.5 **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;
- 18.1.6 **sponsor** has the same meaning as in the TG Act;
- 18.1.7 **Sponsored Products** means Products supplied by CSL under the Deed for which CSL has obligations as a sponsor under the TG Act; and
- 18.1.8 **therapeutic goods** has the same meaning as in the TG Act.

CSL's legislative obligations

- 18.2 In addition to CSL's general obligations under **clause 17**, 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

- 18.3 CSL must, for all Sponsored Products:
- 18.3.1 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:
 - (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;
- 18.3.2 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

- 18.4 If CSL is not the sponsor for one or more Products supplied under the Deed, CSL must:
- 18.4.1 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
 - 18.4.2 promptly, following a request by the NBA, provide the NBA with copies of any contractual arrangements referred to in **clause 18.4.1**.

General obligations

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

CSL's Obligations as a Licensed manufacturer

- 18.6 If CSL is the manufacturer of part or all of a Product supplied under the Deed, CSL must:
- 18.6.1 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;
 - 18.6.2 in relation to any revocation or suspension, or proposed revocation or suspension of the Licence, take any action, following prior consultation with CSL, that the NBA considers reasonably necessary or desirable to ensure that the purposes of the Deed are fulfilled; and
 - 18.6.3 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;

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- (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

- 18.7 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):
- 18.7.1 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
 - 18.7.2 under contractual arrangements that oblige the supplier to meet its obligations under the TG Act in respect of that Product (or the relevant part or parts of that Product).

19 Product compliance and return

- 19.1 CSL must not supply a unit of Product under the Deed if CSL is aware that the unit of Product does not meet the requirements of its Registration or Listing, or that there are reasonable grounds to believe that the unit of Product may not meet the requirements of its Registration or Listing.
- 19.2 If a unit of Product is supplied in accordance with the Deed and, before the use of the unit of Product, it is shown that the unit of Product as supplied by CSL does not meet the requirements of its Registration or Listing, or that there are reasonable grounds to believe that the unit of Product as supplied by CSL may not have met the requirements of its Registration or Listing, CSL must:
- 19.2.1 accept the return of the unit of Product; and
 - 19.2.2 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 unit of Product at no additional cost to meet the requirements of the relevant Approved Recipient for the unit of Product; or
 - (b) if no replacement unit of Product can be supplied to meet the requirements of the Approved Recipient, credit the amount paid or payable under the Deed for the unit of Product against invoices for future Orders under the Deed.
- 19.3 If a unit of Product is supplied in accordance with the Deed and, after the use of the unit of Product, it is shown that the unit of Product 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 unit of Product against invoices for future Orders under the Deed.

- 19.4 If the NBA or an Approved 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:
- 19.4.1 liaise with the NBA or Approved 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;
 - 19.4.2 accept return of units of Product in accordance with **clause 19.2.1**; and
 - 19.4.3 promptly conduct such testing, or arrange for such testing to be conducted, as is necessary to determine whether or not the Products comply with applicable safety, quality and efficacy or other requirements, and notify the NBA and the TGA of the results of that testing.

Other remedies

- 19.5 The rights, obligations and remedies in this **clause 19** 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.

20 Performance Requirements

Performance requirements for Products and Services

- 20.1 CSL must:
- 20.1.1 provide each of the Products so as to meet in full any targets or requirements in the Key Performance Indicators, if any, specified in **Schedule 3 Business Processes Part E Reporting and Performance Measurement** in respect of that Product;
 - 20.1.2 provide each of the Services so as to meet in full any targets or requirements in the Key Performance Indicators, if any, specified in **Schedule 3 Business Processes Part E Reporting and Performance Measurement** in respect of that Service.
- 20.2 The Parties must comply with those parts of **Schedule 3 Business Processes Part E Reporting and Performance Measurement** which set out:
- 20.2.1 which Party is responsible for measuring CSL's performance against the Key Performance Indicators;
 - 20.2.2 when CSL's performance against the Key Performance Indicators is to be measured; and
 - 20.2.3 the reporting obligations in respect of CSL's performance against the Key Performance Indicators.

Consequences of failure to meet performance requirements

- 20.3 If CSL does not meet a target or requirement in the Key Performance Indicators set out in:
- 20.3.1 **Schedule 3 Business Processes Part E Reporting and Performance Measurement** for a particular Product, then the consequences set out in **Schedule 3 Business Processes Part E Reporting and Performance Measurement** in relation to that Product apply; and
 - 20.3.2 **Schedule 3 Business Processes Part E Reporting and Performance Measurement** for a particular Service, then the consequences set out in **Schedule 3 Business Processes Part E Reporting and Performance Measurement** in relation to that Service apply.
- 20.4 A Schedule may indicate that more than one consequence applies in respect of any particular failure to meet one or more Key Performance Indicators for a Product or Service.
- 20.5 If more than one consequence applies in respect of any particular failure to meet a target or requirement in a Key Performance Indicator, the NBA may elect (in its absolute discretion) that one or more of the listed consequences applies.
- 20.6 CSL acknowledges and agrees that the listed consequences in **Schedule 3 Business Processes Part E Reporting and Performance Measurement**, as applied under the Deed:
- 20.6.1 are reasonable and appropriate for managing adherence to the Key Performance Indicators and for providing compensation for Loss, if applicable; and
 - 20.6.2 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.

Section D: Payment obligations

21 Payments to be made by the NBA

Payments

- 21.1 Subject to **clauses 21.2, 21.3 and 21.5**, the NBA agrees to make Payments to CSL monthly in arrears for Products and Services provided under this Deed, in accordance with **Schedule 3 Business Processes Part G Price, Invoicing and Payment**.
- 21.2 Unless otherwise specified in the Deed, Payments under this Deed are subject to:
- 21.2.1 satisfactory provision of the Products and performance of the Services by CSL in accordance with the Deed, as reasonably determined by the NBA; and
- 21.2.2 the receipt by the NBA from CSL of a correctly rendered Tax Invoice which complies with **clause 23** and **Schedule 3 Business Processes Part G Price, Invoicing and Payment**,
- provided that the NBA must not unreasonably withhold payment for any part of an invoice which is not in dispute.
- 21.3 CSL acknowledges and agrees that:
- 21.3.1 the amount of the Payments that may be payable under the Deed may be affected by the extent to which the Products and Services meet the Key Performance Indicators; and
- 21.3.2 the value of the Products and Services to the NBA will be affected by the achievement or otherwise of the Key Performance Indicators and meeting or failing to meet the Specifications.
- 21.4 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.

Changes to the Payments

- 21.5 Subject to **clause 8**, the Payments may only be altered during the Term on the basis, if any, set out in **Schedule 3 Business Processes Part G Price, Invoicing and Payment**.

22 Taxes

- 22.1 In this **clause 22** and elsewhere in the Deed:
- 22.1.1 the expression **GST Legislation** means the *A New Tax System (Goods and Services Tax) Act 1999* (Cth);
- 22.1.2 the expressions **Adjustment Event, Input Tax Credit, Taxable Supply** and **Tax Invoice** have the meanings provided in the GST Legislation;

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- 22.1.3 **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
- 22.1.4 **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.
- 22.2 If the Payments are expressed to be inclusive of GST, the Payments are inclusive of GST and the NBA has no obligation to reimburse (except by payment of the Payments) CSL for any GST imposed on any Taxable Supply made by CSL pursuant to the Deed, to the extent that such Taxable Supply relates to the part of the Payments that are expressed to be inclusive of GST.
- 22.3 Subject to **clause 22.5**, 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.
- 22.4 If the amount paid by the Recipient:
- 22.4.1 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;
- 22.4.2 exceeds the GST on the Taxable Supply, the Supplier must refund the excess to the Recipient; and
- 22.4.3 is less than the GST on the Taxable Supply, the Recipient must pay the deficiency to the Supplier.
- 22.5 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.
- 22.6 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.
- 22.7 The Payments are inclusive of all taxes, duties and government charges (other than GST except where they are expressed to be inclusive of GST) imposed or levied on CSL in Australia or overseas in connection with the Deed.
- 22.8 If the rate of GST varies, the Parties must, by amendment in writing to the Deed in accordance with **clause 8**:
- 22.8.1 make a corresponding variation to any amount payable under the Deed; and
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- 22.8.2 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.

23 Invoicing Obligations

- 23.1 CSL must:
- 23.1.1 comply with all invoicing obligations set out in **Schedule 3 Business Processes Part G Price, Invoicing and Payment**; and
- 23.1.2 ensure that each invoice given by CSL to the NBA complies with the requirements of a Tax Invoice under the GST Legislation.

24 Recovery of moneys by the NBA

- 24.1 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 written 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 24.1**.
- 24.2 If CSL fails to repay the amount specified in the Repayment Notice in accordance with **clause 24.1**:
- 24.2.1 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%;
- 24.2.2 the amount set out in the Repayment Notice, and interest owed under this **clause 24**, will be recoverable by the NBA as a debt due to the NBA by CSL; and
- 24.2.3 subject to **clauses 24.3** and **24.4**, the NBA may recover any amount under the Financial Undertaking 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 24.2.1**.
- 24.3 CSL may not give the NBA a dispute notice under **clause 51.2** 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.

- 24.4 Despite **clause 24.2.3**, if CSL gives the NBA a dispute notice under **clause 51.2** 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 51** within 30 days of the dispute notice being given by CSL. However, despite **clause 51.5**, the NBA is not obliged to commence legal proceedings prior to recovering any amount under the Financial Undertaking.
- 24.5 CSL acknowledges that interest calculated in accordance with **clause 24.2.1** 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.
- 24.6 This **clause 24** survives the expiration or earlier termination of the Deed.

25 Right of Set Off

- 25.1 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.
- 25.2 This **clause 25** survives the expiration or earlier termination of the Deed.

Section E: Ownership Issues

26 Possession of Products

26.1 CSL acknowledges that, as between CSL and the NBA, and subject to any express provisions of the Deed to the contrary, CSL:

26.1.1 has and will retain rights of possession, custody or control of the Products as required for the purpose of the Deed; and

26.1.2 bears all risks associated with such possession, custody or control of the Products,

until possession of the Products passes from CSL to an Approved Recipient, upon physical delivery of that Product to the Approved Recipient in accordance with an Order under the Deed.

26.2 CSL does not warrant that it owns the Products.

26.3 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 19**.

27 Intellectual Property

Intellectual Property rights in Contract Material

[Clauses 27.1 to 27.7 not disclosed. The provisions relate to pertinent Intellectual Property rights, including IP rights in the Contract Material and Pre-existing material.]

Moral Rights

27.8 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

27.9 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 **clauses 40 and 41**.

28 Commonwealth Material

28.1 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.

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- 28.2 Subject to this **clause 28**, 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.
- 28.3 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.
- 28.4 CSL must:
- 28.4.1 ensure that Commonwealth Material is used, copied, supplied or reproduced only for the purposes of the Deed;
 - 28.4.2 ensure the safe keeping and maintenance of Commonwealth Material; and
 - 28.4.3 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.
- 28.5 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.

Section F: Protection of Information

29 Confidentiality

- 29.1 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).
- 29.2 Despite **clause 29.1**, a Party may disclose Confidential Information of the other Party if the Confidential Information is:
- 29.2.1 disclosed to its advisers or Employees solely in order to comply with obligations, or to exercise rights, under the Deed;
 - 29.2.2 disclosed to internal management personnel, solely to enable effective management or auditing of Deed-related activities;
 - 29.2.3 disclosed to external auditors where required for mandatory auditing or reporting requirements under the Corporations Act or the rules of a the Australian Stock Exchange;
 - 29.2.4 in the case of the NBA, disclosed by the NBA to the responsible Minister or to the Parliamentary Cabinet for the purposes set out in **clauses 27.5.1 to 27.5.3** or for the purposes of the National Blood Arrangements;
 - 29.2.5 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;
 - 29.2.6 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 27.5.1 to 27.5.3** or for the purposes of the National Blood Arrangements;
 - 29.2.7 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;
 - 29.2.8 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
 - 29.2.9 authorised or required by Law, or under the Deed, under a licence or otherwise, to be disclosed.
- 29.3 Where a Party determines that it is necessary to or is obliged to disclose Confidential Information under **clause 29.2**, 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.
- 29.4 Nothing in this **clause 29** 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.
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29.5 Nothing in this clause limits or affects a Party's Intellectual Property rights set out or referred to in this Deed.

29.6 This **clause 29** survives the expiration or earlier termination of the Deed.

30 Data Security

30.1 In this **clause 30**:

30.1.1 **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.

30.2 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 notify CSL of Protective Security Manual requirements and CSL's obligation to comply with those requirements commences promptly after the date of notification.

30.3 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.

30.4 CSL must comply with any variation under **clause 30.3** within 20 Working Days after notification of any such variation, or as otherwise agreed by the Parties.

30.5 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.

30.6 CSL must not permit any of its Personnel to have any access to security classified information unless:

30.6.1 that person has been cleared, to a security level considered appropriate by the NBA and in accordance with applicable processes for clearance advised by the NBA;

30.6.2 the NBA has given approval in writing for that person to have access to the specific items of security classified information; and

30.6.3 that person has undergone the training required by the NBA relating to the access to and use of security classified information.

30.7 CSL must notify the NBA promptly upon becoming aware that any unauthorised person has had access to security classified information.

30.8 If an incident set out in **clause 30.7** occurs, CSL must comply with any reasonable directions of the NBA in order to rectify the security problem.

30.9 In granting approval under **clause 30.6.2** the NBA may impose any conditions it considers necessary.

- 30.10 The rights and obligations arising in connection with this **clause 30** will survive the expiry or earlier termination of the Deed.

31 Privacy

- 31.1 CSL must, with respect to all Personal Information relating to or concerning the provision of the Products or Services under the Deed:
- 31.1.1 comply with the provisions of the Privacy Act both in relation to its own obligations as an organisation and also as if it were an agency (as those terms are defined by the Privacy Act) bound by that Act concerning the security, use and disclosure of information to which the NBA is subject in respect of that information and which affects the Products or Services;
 - 31.1.2 only use such information for the purposes of fulfilling its obligations under the Deed or as required by Law;
 - 31.1.3 not disclose any Personal Information obtained in connection with the Deed unless such disclosure is:
 - (a) required for the purposes of fulfilling its obligations under the Deed or as required by Law; and
 - (b) made in accordance with the Privacy Act;
 - 31.1.4 co-operate with any reasonable demands or inquiries made by the Privacy Commissioner;
 - 31.1.5 ensure that any person who has an access level which would enable that person to obtain access to any information in respect of which the NBA has obligations under the Privacy Act is made aware of the provisions of this **clause 31**;
 - 31.1.6 take all reasonable measures to ensure that such information is protected against loss and against unauthorised access, use, modification, disclosure or other misuse and that only authorised Personnel of CSL have access to it. For the avoidance of doubt, the Personal Information must not be used for, or in any way relating to, any direct marketing purpose unless all requirements of the Privacy Act have been complied with;
 - 31.1.7 give to any person, on his or her request, and on payment of a reasonable charge and having taken reasonable steps to satisfy itself of that person's identity, access to that person's Personal Information held by CSL, except to the extent that CSL is required or authorised by Law to refuse to provide the person with access to that information;
 - 31.1.8 if requested to do so by a person to whom the Personal Information relates, take reasonable steps to correct or update the Personal Information, unless otherwise required by Law;
 - 31.1.9 inform any person, on his or her request, in writing of the content of any provision of the Deed that is inconsistent with an approved privacy code binding CSL or a National Privacy Principle as set out in the Privacy Act;

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- 31.1.10 not transfer Personal Information outside Australia, or allow parties outside Australia to have access to it, without the prior written approval of the NBA;
 - 31.1.11 promptly notify the NBA if CSL becomes aware of a breach of any obligation concerning security, use and/or disclosure of Personal Information;
 - 31.1.12 subject to prior consultation with the NBA, destroy or permanently de-identify any Personal Information as soon as practicable after it is no longer required for the purpose for which it was originally collected by CSL;
 - 31.1.13 promptly notify the NBA of, and co-operate with the NBA in the resolution of, any complaint alleging an interference with privacy; and
 - 31.1.14 [Not disclosed.]
- 31.2 CSL must ensure that all Subcontractors who may use or collect Personal Information relating to or concerning the Products or Services are obliged under their Subcontracts to meet privacy obligations that are equivalent to those of CSL under the Deed, including the requirement in relation to Subcontracts.
- 31.3 CSL's obligations in this **clause 31** are in addition to, and do not restrict, any obligations it may have under:
- 31.3.1 the Privacy Act; or
 - 31.3.2 any:
 - (a) privacy codes; or
 - (b) privacy principles contained in, authorised by or registered under any Law,
- including any such privacy codes or principles that would apply to CSL but for the application of the other provisions of this **clause 31**.
- 31.4 CSL must, in respect of Personal Information relating to or created or accessed by CSL in connection with the Deed:
- 31.4.1 only disclose Personal Information if required for the purposes of fulfilling the Deed; and
 - 31.4.2 must make any disclosures of Personal Information in accordance with the Privacy Act and all other Laws.
- 31.5 This **clause 31** survives the expiration or earlier termination of the Deed.

32 Conflict of Interest

- 32.1 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.
- 32.2 CSL must use its best endeavours (including making all appropriate enquiries) to:

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- 32.2.1 ensure that a situation does not arise that may result in a Conflict of Interest; and
- 32.2.2 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.
- 32.3 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 32.4** and the NBA has given its written approval for CSL to engage in that activity.
- 32.4 Where a Conflict of Interest arises 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.

Section H: Treatment of Risks

33 Risk Management Plan

- 33.1 CSL must:
- 33.1.1 within 120 days of the Commencement Date provide to the NBA a Risk Management Plan that complies with the requirements of this **clause 33**;
 - 33.1.2 update the Risk Management Plan no less than annually; and
 - 33.1.3 implement the Risk Management Plan throughout the Term.
- 33.2 The Risk Management Plan must address actual or potential risks arising:
- 33.2.1 in respect of CSL's operations generally as they are relevant to the Deed; and
 - 33.2.2 in connection with the Deed,
- and must include all identified risks in relation to Products and Services, such as regulatory risks, quality risks, resource risks, loss, damage, unauthorised access or use or theft of a Product, and any risks notified to CSL by the NBA from time to time.
- 33.3 The Risk Management Plan must include avoidance or mitigation strategies for all identified risks, including for:
- 33.3.1 options for supply of alternative Products as contemplated under **clause 13.9**; and
 - 33.3.2 any foreseeable Force Majeure Event as described in **clause 38.1**.
- 33.4 The Risk Management Plan must incorporate a contingency plan. CSL must cooperate to assist NBA in contingency planning on a national and/or State or Territory basis during the Term and participate in simulations for contingency planning purposes.
- 33.5 The Risk Management Plan must also incorporate a CSL-specific Emergency Supply Plan, which sets out:
- 33.5.1 the steps which the Parties will take in the event of a disaster or national emergency occurring, as notified by the NBA;
 - 33.5.2 the responsibilities of each Party, and particularly CSL, and the tasks to be performed; and
 - 33.5.3 a procedure for, with the written approval of the NBA, introducing new or revising existing risk management strategies to take account of new or changed risks.
- 33.6 CSL must promptly notify the NBA if it becomes aware of any circumstance that could affect adversely CSL's ability to provide any Product, including:

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- 33.6.1 any new risks which arise during the Term which, in the reasonable opinion of CSL, are not appropriately or adequately dealt with in the Risk Management Plan;
- 33.6.2 any changes to existing risks in the Risk Management Plan; and
- 33.6.3 CSL's proposed method for dealing with the new risks or changes to existing risks which have arisen.
- 33.7 The Parties must negotiate in good faith to update the Risk Management Plan to implement processes to manage new or changed risks which arise during the Term (including any risks which are identified by the NBA and notified to CSL from time to time).
- 33.8 CSL must participate in simulations or evaluations of the Risk Management Plan (or any part of it) as reasonably required by the NBA.

34 Warranties

Product Warranties

- 34.1 CSL warrants that:
- 34.1.1 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 Specifications including any applicable requirements under the TG Act;
 - (d) are of merchantable quality, and free from defects (provided that the term 'free from defects' has the same meaning as under Part VA of the *Trade Practices Act 1975* (Cth) and that the same defences apply to that term as would apply under that Act); and
 - (e) are fit for the purpose for which Products are commonly supplied,
- provided that all of the warranties in this **clause 34.1.1** 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 34.1**);
- 34.1.2 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
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clause 61, other than any Encumbrance which is unavoidably imposed or implied by law; and

- 34.1.3 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

34.2 CSL warrants that all Services performed under the Deed:

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

General

- 34.3 CSL warrants that it has the capacity, capability and power to enter into and perform the Deed.
- 34.4 The warranties in this **clause 34** survive the expiration or termination of the Deed in relation to Products or Services supplied under the Deed.

35 Indemnities

Indemnity by CSL

[Not disclosed.]

36 Undertakings

Financial Undertaking

- 36.1 CSL must, at its expense, provide to the NBA, within 30 Working Days of the Commencement Date, security in the form of an unconditional and irrevocable financial undertaking (the **Financial Undertaking**) which must be:
- 36.1.1 executed by a financial institution approved by the NBA (the **Financial Institution**) and stamped;
- 36.1.2 substantially in the form of the undertaking appearing at **Schedule 5 Undertakings**; and
- 36.1.3 for the sum of specified in **Schedule 5 Undertakings**.

- 36.2 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:
- 36.2.1 amounts owed to the NBA by CSL;
 - 36.2.2 damages suffered by the NBA, the NBA's Personnel, Approved Recipients or their Personnel as a result of a breach of the Deed by CSL; or
 - 36.2.3 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 Recipients or their Personnel that is the subject of an indemnity under the Deed.
- 36.3 For the purposes of **clause 36.2**, the NBA is deemed to be acting as agent or trustee for and on behalf of its Personnel or Approved Recipients and their Personnel from time to time and may exercise the rights in **clause 36** for its Personnel and Approved Recipients and their Personnel on their behalf.
- 36.4 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

- 36.5 CSL must, at its expense, provide to the NBA, within 45 Working Days of the Commencement Date, a performance guarantee executed by a guarantor specified in **Schedule 5 Undertakings** or alternative guarantor acceptable to the NBA, guaranteeing the performance by CSL of its obligations under the Deed, which must be substantially in the form of the performance guarantee appearing at **Schedule 5 Undertakings**.
- 36.6 CSL may at any time propose a change to the guarantor referred to in **clause 36.5** and, subject to this clause, the NBA will not unreasonably refuse such a request. The NBA will release the guarantee provided under **clause 36.5** but not until it has received:
- 36.6.1 a performance guarantee executed by an alternative guarantor reasonably acceptable to the NBA in the manner set out in **clause 36.5**; or
 - 36.6.2 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 36.6.1**.
- 36.7 Without limiting **clause 36.6**, the NBA will release the performance guarantee 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.

37 Insurance

- 37.1 CSL must comply with all obligations regarding insurance set out in **Schedule 4 Insurance**.

38 Force Majeure Event

Event of Force Majeure Event

- 38.1 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), it must promptly give a notice to the other Party that complies with **clause 38.3**.

[Remainder of Clause 38 not disclosed – this clause deals with the obligations of the parties under extreme circumstances.]

39 Supply Continuity Options

- 39.1 The Parties acknowledge and agree that:
- 39.1.1 continuity of supply of the Products and Services is essential for proper performance of the NBA's functions;
 - 39.1.2 in addition to the Risk Management Plan and CSL's obligations under the Deed to identify, avoid or mitigate risks, it is reasonable that the NBA have specific remedies which can be implemented in certain circumstances to ensure supply continuity;
 - 39.1.3 the circumstances in which such remedies can be implemented must be clearly stated in the Deed; and
 - 39.1.4 it is reasonable for the NBA to take into account circumstances which create a risk to CSL's compliance with the terms of its external debt financier arrangements.
- 39.2 [Not disclosed.]
- 39.3 [Not disclosed.]
- 39.4 This **clause 39** does not require CSL to incur substantial additional costs (not including legal fees or out-of-pocket expenses) under or in connection with the external debt financier arrangements referred to in **clause 39.1.4**, but if a substantial cost is likely in connection with obtaining the approvals, the Parties will, without limiting the NBA's rights under the Deed, discuss the matter.

40 Step-In Rights with consents

[Not disclosed.]

41 Supply Continuity

Issue of Action Plan

- 41.1 Without prejudice to any other right or remedy which the NBA may have under the Deed or at Law, if a Trigger Event described in **clause 40.2** occurs, and whether or

not the conditions precedent in **clause 39.2** have been met, the NBA may, at its discretion, provide an Action Plan to CSL.

- 41.2 The Action Plan, without limitation, may provide for the following actions:
- 41.2.1 directions to CSL for priority of fulfilment of existing or future Orders;
 - 41.2.2 establishment of a management committee incorporating representatives of the NBA and CSL to assist CSL in managing the circumstances giving rise to the Trigger Event;
 - 41.2.3 directions on the functions of and tasks to be performed by the management committee referred to in **clause 41.2.2**; and
 - 41.2.4 detailed specifications for provision of the Products and Services.
- 41.3 The NBA may, but is not obliged to:
- 41.3.1 consult with CSL in preparation of the Action Plan, but must take into account CSL's comments on the Action Plan; and
 - 41.3.2 incorporate strategies set out or referred to in the Risk Management Plan in the Action Plan.
- 41.4 Upon the issue of an Action Plan to CSL, CSL must take all reasonable steps to implement the Action Plan including by:
- (a) performing the tasks specified in the Action Plan;
 - (b) ensuring the NBA or its nominee(s) is able to exercise the NBA's Intellectual Property rights;
 - (c) allowing the NBA or its nominee(s) to access the relevant part of CSL's facilities and use CSL's equipment, furnishings and fittings, including Assets;
 - (d) providing the NBA or its nominee(s) with access to relevant Personnel of CSL for no additional charge; and
 - (e) ensuring that the NBA is able to assist CSL to continue to meet CSL's ongoing contractual or other obligations (other than obligations arising under the Deed) that relate to CSL's activities affected by the Action Plan.
- 41.5 The steps which the NBA, acting on its own behalf or through a nominee, will be entitled to take in ensuring the Action Plan is complied with do not include taking possession or control of Assets or other property or directing CSL in the conduct of CSL's business, unless otherwise permitted under the Deed, but include all other steps as are, in the reasonable opinion of the NBA, necessary to safeguard the provision of the Products and/or Services as required by the Deed, or to remedy or resolve the Trigger Event.

Cessation of Action Plan

- 41.6 The Action Plan will cease to have effect on written notice from the NBA that, in the NBA's reasonable opinion:
- 41.6.1 the Trigger Event is remedied or resolved; and
 - 41.6.2 the NBA is reasonably satisfied that there is no longer a material risk to the provision of the Products and Services.

Termination by NBA

- 41.7 If the event giving rise to the Action Plan has not been remedied or resolved within a period of 30 days from the date that the Action Plan was issued, or such later date which has been agreed to by the NBA and CSL, the NBA may terminate the Deed in accordance with **clause 48.1.4**.
- 41.8 For the avoidance of doubt and without prejudice to the NBA's right to terminate the Deed under **clause 48.1**, for events which do not constitute Trigger Events which are the subject of the Action Plan, the NBA's rights to terminate this Deed in accordance with **clause 48.1** are suspended until the end of the period set out in **clause 41.7** or until the cessation of the Action Plan, whichever occurs first.
- 41.9 If the Deed is terminated in the circumstances referred to in **clause 41.7**, CSL is not entitled to any termination compensation or payment whatsoever, including any payment in relation to the remaining period of the Deed.

Indemnity

- 41.10 Subject to **clause 41.12**, CSL indemnifies the NBA against any Loss that the NBA incurs or suffers as a result of CSL's compliance with the Action Plan in accordance with this **clause 41**.

Other matters

- 41.11 No action of the NBA under this **clause 41** limits or otherwise affects CSL's liability to the NBA with respect to any default or non-performance by, or other liability of, CSL under the Deed.
- 41.12 CSL's liability under this **clause 41** will be reduced proportionately to the extent that any tortious (including negligent), unlawful act or omission or wilful misconduct of the NBA or its nominee caused or contributed to the Loss.

Section I: Other requirements of CSL

42 Records

- 42.1 CSL must keep comprehensive written records and accounts of all matters related to its performance of the Deed, including the provision of the Products and Services, Orders, the receipt of Payments, compliance with obligations under the TG Act, the creation of Contract Material and the creation or management of Intellectual Property rights in connection with the Deed.
- 42.2 CSL must ensure that in all material respects all such records and accounts:
- 42.2.1 are true and accurate;
 - 42.2.2 are complete and maintained so as to be up-to-date;
 - 42.2.3 are kept in a manner that permits them to be conveniently and properly audited; and
 - 42.2.4 enable the extraction of all information relevant to the performance of the Deed.
- 42.3 In addition to the obligations under **clause 42.2**, CSL must ensure that all accounts are drawn in accordance with any applicable Australian accounting standards.

43 Access to information and premises

- 43.1 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 42.1**, however and wherever stored or located, under CSL's custody, possession or control for inspection and/or copying.
- 43.2 In the case of documents or records stored on a medium other than in writing, CSL must make available on request at no additional cost to the NBA such reasonable facilities as may be necessary to enable a legible reproduction to be created.
- 43.3 Without limiting any other provision of the Deed, the NBA, 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 statutory functions and/or powers respectively, may, at reasonable times on reasonable notice:
- 43.3.1 access the premises of CSL;
 - 43.3.2 require the provision by CSL of records and other information related to the Deed; and

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- 43.3.3 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.
- 43.4 CSL must ensure that any Key Subcontract, and use reasonable endeavours to ensure that any other Subcontract, entered into for the purpose of the Deed contains an equivalent clause granting the rights specified in this **clause 43** 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.
- 43.5 This **clause 43** applies for the Term and for a period of 7 years from the date of expiration or termination of the Deed.
- 43.6 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.
- 43.7 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.
- 43.8 The NBA must, in having access to the CSL's premises under this clause, or **clause 44**, comply with the CSL's reasonable directions and procedures relating to health and safety, and security, when such directions and procedures are brought to their attention.
- 43.9 CSL's obligations to comply with this clause in relation to the Auditor-General and the Privacy Commissioner:
- 43.9.1 are subject to and do not limit applicable statutory rights and obligations; and
- 43.9.2 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.

44 Audit

Right to conduct audits

- 44.1 The NBA may, from time to time during normal business hours, conduct audits of:
- 44.1.1 CSL's practices and procedures as they relate to CSL's performance of the Deed, including security procedures;
- 44.1.2 the manner in which CSL performs its obligations under the Deed;
- 44.1.3 the compliance of CSL's invoices and reports with its obligations under the Deed;

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- 44.1.4 CSL's compliance with its obligations under the Deed;
 - 44.1.5 CSL's compliance with its confidentiality, privacy, security and Commonwealth policy obligations under the Deed; and
 - 44.1.6 any other matters reasonably determined by the NBA to be relevant to the performance of CSL's obligations under the Deed.
- 44.2 Audits under this **clause 44** may consider all aspects of CSL's performance including but not limited to any Key Performance Indicators, benchmarks or targets.
- 44.3 The NBA may appoint an independent person to assist in audits under this **clause 44**. The NBA:
- 44.3.1 must ensure that any independent person so appointed complies with this clause; and
 - 44.3.2 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

- 44.4 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 44**.
- 44.5 CSL acknowledges that the schedule provided under **clause 44.4** is indicative only, and does not limit the NBA's rights to conduct audits under this **clause 44**.
- 44.6 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 reasonable notice of an audit and where reasonably practicable an indication of which documents and/or class of documents the auditor may require.
- 44.7 Without limiting its rights under the Deed, the NBA must:
- 44.7.1 use reasonable endeavours to ensure that audits performed pursuant to this **clause 44** do not unreasonably delay or disrupt in any material respect CSL's operations; and
 - 44.7.2 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

- 44.8 CSL must participate promptly and cooperatively in any audits conducted by the NBA or its nominee.
- 44.9 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

- 44.10 Subject to this clause, each Party must bear its own costs of any audit conducted under the Deed, but where:
- 44.10.1 an audit reveals substantial errors, non-compliance or inaccuracies; or
 - 44.10.2 an audit is a follow-up audit after any audit referred to in **clause 44.10.1** in relation to the 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.
- 44.11 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:
- 44.11.1 supplied any Products or Services;
 - 44.11.2 maintained any accounts or records; or
 - 44.11.3 calculated Payments, or any other amounts or charges billed to or claimed from the NBA.
- 44.12 The NBA must use reasonable endeavours to ensure that audits performed pursuant to this **clause 44** 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.
- 44.13 This **clause 44** applies for the Term and for a period of 7 years from the date of expiration or termination of the Deed.
- 44.14 The operation of this **clause 44** does not limit the operation of **clause 29**.

45 Offences under Crimes Act and Criminal Code 1995

- 45.1 CSL acknowledges that:
- 45.1.1 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* (Cth) for which there are a range of penalties, including a maximum of ten years' imprisonment;
 - 45.1.2 the giving of false and misleading information to the NBA or its Personnel is a serious offence under Division 137 of the *Criminal Code* (Cth); and
 - 45.1.3 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.

46 Compliance with Commonwealth policies

46.1 CSL must, when using the NBA's premises or facilities, comply with:

46.1.1 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

46.1.2 all other reasonable Commonwealth, State or Territory policies which are notified to it from time to time.

47 Equal Employment Opportunity

47.1 CSL must comply with its obligations, if any, under the *Equal Employment Opportunity for Women in the Workplace Act 1999* (Cth) (the **Act**).

47.2 CSL must not enter into a Subcontract in respect of the Deed with a Subcontractor named by the Director of Equal Opportunity for Women in the Workplace as an employer currently not complying with the Act.

47.3 Any Subcontract must include a provision which requires the Subcontractor to notify the Equal Opportunity for Women in the Workplace Agency of any failure to comply with the Act.

Section J: Termination and Disputes

48 Termination for Default

- 48.1 Without prejudice to its rights at common law or under any statute, the NBA may, by notice in writing to CSL, terminate the Deed immediately in whole or immediately terminate part of the Products or Services (to reduce the scope of the Deed), which termination is a partial termination, if:
- 48.1.1 an Insolvency Event occurs in respect of CSL;
 - 48.1.2 CSL commits a material breach of the Deed which is not capable of remedy;
 - 48.1.3 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 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 notice; or
 - 48.1.4 as expressly permitted under any other provision of the Deed.
- 48.2 Nothing in this Deed affects any right CSL may have at common law or under any statute to terminate the Deed.
- 48.3 If the Deed is terminated under this **clause 48**:
- 48.3.1 subject to the Deed, 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;
 - 48.3.2 the NBA's rights to recover damages are not affected, provided that termination as permitted under **clauses 40 and 41** does not, of itself, give rise to a right to recover damages;
 - 48.3.3 subject to the Deed, 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
 - 48.3.4 CSL must comply with all obligations in the Deed relating to Commonwealth Material, Contract Material and other Material referred to in the Deed.

49 Termination for Change in Policy

Notice of termination

- 49.1 The NBA may, at any time, 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:

49.1.1 not less than 24 months prior written 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

49.1.2 whatever lesser notice is practicable in the context of the change in government policy.

49.2 Termination under **clause 49.1** takes effect on and from the time specified in the notice.

Termination payments

49.3 If the Deed is terminated under **clause 49.1**, the NBA will be liable only for:

49.3.1 Payments which would otherwise be properly payable in accordance with the Deed for the Products or Services provided in accordance with the Deed before the effective date of termination, or after that date in accordance with **clause 50**; and

49.3.2 the amount calculated on the basis set out in **clause 49.4**, which will be payable in accordance with **clause 49.9**.

49.4 [Not disclosed.]:

49.5 [Not disclosed.].

49.6 [Not disclosed.].

49.7 [Not disclosed.].

49.8 [Not disclosed.].

49.9 [Not disclosed.].

Refund of pre-payments

49.10 Where the NBA has made any Payment in advance to CSL and all or part of that Payment does not relate to Products or Services which have been provided by CSL in accordance with the Deed, the portion of that Payment that does not relate to Products or Services so provided must be repaid by CSL to the NBA and, if not repaid by the due date, is recoverable by the NBA from CSL as a debt. Any such repayment must be made by CSL within 30 days after CSL's obligations to supply Products or Services under this Deed cease (including, without limitation, any obligations pursuant to **clause 49.11.4** and **50.3.1**).

Other

49.11 Upon receipt of a notice of termination, and in addition to **clause 49.5**, CSL must:

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- 49.11.1 stop work as specified in the notice and comply with any other directions or requests included in the notice;
 - 49.11.2 comply with all obligations in the Deed relating to Commonwealth Material and Contract Material;
 - 49.11.3 take all reasonable steps to protect Commonwealth Material and Contract Material; and
 - 49.11.4 subject to this **clause 49.11** and **clause 50.3.1**, continue to provide Products and Services in accordance with this Deed until the effective date of the notice of termination.
- 49.12 For the avoidance of doubt, and subject to **clause 49.1**, the NBA has an unfettered discretion to terminate the Deed under this **clause 49**.

50 Handover obligations

- 50.1 CSL must assist the NBA in developing and maintaining a Transition Out Plan that will provide 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, or part of the Deed, for any reason. For greater certainty, assistance provided by CSL may, as requested by the NBA, include drafting sections of the Transition Out Plan and attending and providing information, documents and access to Personnel or subcontractors' meetings at the NBA's premises to assist in preparation of the Transition Out Plan.
- 50.2 The Transition Out Plan must provide for transition within 6 months and, without limitation, for the following matters:
- 50.2.1 delivery 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 50**;
 - 50.2.2 at the NBA's request, and subject to any limits on CSL's disclosure obligations in **clause 10**, providing information on all Subcontracts, whether or not they have previously been disclosed to the NBA, relating to the provision of the Products and/or Services;
 - 50.2.3 delivery to the NBA or any other person in accordance with the NBA's direction, of any Products held in the Post-Payment Inventory and National CSL Reserve at the date of expiration or termination of the Deed and at the date of cessation of Services under **clause 50.3.1**;
 - 50.2.4 delivery to the NBA or a person nominated by the NBA, or otherwise dealing with in accordance with the directions of the NBA, the stock of Products in the possession or control of CSL at the expiration or termination of the Deed and the date of cessation of Services under **clause 50.3.1**;
 - 50.2.5 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 transition period; and

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- 50.2.6 training to be provided by CSL including the period and nature of the training.
- 50.3 CSL must:
- 50.3.1 continue the provision of the Products and/or Services, for up to 6 months after the termination or expiry of the Deed or such other date as is agreed by the Parties, so as to ensure an orderly handover of the Products and Services as requested by the NBA;
- 50.3.2 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;
- 50.3.3 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
- 50.3.4 allow the NBA to audit compliance with this **clause 50**.
- 50.4 Upon expiry of the Deed or termination for any reason, CSL 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.
- 50.5 The NBA may review the Transition Out Plan in any Review and not less than 12 months before the expiration of the Term to ensure that the Transition Out Plan remains appropriate to the circumstances of the NBA and CSL must, on request, assist the NBA in ensuring the Transition Out Plan is at all times up-to-date.
- 50.6 The Parties agree that the terms and conditions of the Deed including in relation to Payments apply to the provision of any Products and/or Services by CSL during the handover period under this **clause 50**.
- 50.7 CSL agrees that it will 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.
- 50.8 For greater certainty, but without limiting the NBA's rights under the Deed, nothing in this **clause 50** or the Transition Out Plan:
- 50.8.1 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;
- 50.8.2 is an assignment of CSL's Intellectual Property rights;
- 50.8.3 obliges CSL to grant Intellectual Property licences that are not already granted under this Deed; or
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- 50.8.4 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 50.2**.

Costs

- 50.9 The NBA agrees to make Payments to CSL for any Products and/or Services that CSL provides in accordance with the Deed in complying with its obligations under this **clause 50**.
- 50.10 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 50.1** arises from a termination by the NBA under **clause 48**.

51 Dispute Resolution

- 51.1 The Parties undertake to use all reasonable efforts in good faith to resolve any disputes which arise between them in connection with the Deed.
- 51.2 A Party may give the other Party a notice of dispute (**dispute notice**) in connection with the Deed.
- 51.3 Following the giving of a dispute notice under **clause 51.2**, the dispute must initially be referred to the contact officers in **Schedule 1 Deed Details** who must use reasonable efforts to resolve the dispute within 10 Working Days of the giving of the dispute notice.
- 51.4 If the Parties have not been able to resolve the dispute in accordance with **clause 51.3**, 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.
- 51.5 In the event that the dispute, controversy or claim has not been resolved 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 51.3**, then either Party may, if it wishes, commence legal proceedings.
- 51.6 Nothing in **clauses 51.1 to 51.5** inclusive prevents either Party from seeking urgent injunctive relief.

Section K: Miscellaneous

52 Assignment

Assignment by CSL

- 52.1 CSL must not assign 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

- 52.2 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 the Commonwealth from time to time.

53 Costs

- 53.1 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.

54 Entire agreement

- 54.1 Subject to **clause 3.4**, 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.
- 54.2 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.

55 Execution of separate documents

- 55.1 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.

56 Further acts

- 56.1 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.

57 Governing law and jurisdiction

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

58 Severability

- 58.1 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.
- 58.2 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.

59 Waiver

- 59.1 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.
- 59.2 A waiver by a Party is only effective if it is in writing.
- 59.3 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.

60 Time of the essence

- 60.1 Time is of the essence in relation to any timing obligations in the Deed associated with the delivery of, or meeting other material obligations relating to, Products and Services.

61 Encumbrances

- 61.1 CSL agrees not to 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).

Schedule 1 Deed Details

Item 1

(Commencement Date): **1 January 2005**

Item 2

(Expiry Date): **31 December 2009**

Item 3

(Contacts)

Contacts for delivery of formal notices under the Deed:

NBA:

[Not published]

CSL:

[Not published]

The contacts specified for the delivery of formal notices for each of the NBA and CSL may, from time to time, notify the other Party of their authorised delegates for the purpose of delivery of specified categories of notices under the Deed.

Contacts for resolution of disputes under the Deed:

NBA:

[Not published]

CSL:

[Not published]

Schedule 2 Interpretation

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

62 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;

63 in respect of a period of time:

63.1.1 a month means a calendar month;

63.1.2 a quarter means the period of three months from July to September, October to December, January to March, and April to June; and

63.1.3 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;

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- 64 a reference to a matter being material means that the matter is not trivial;
- 65 a reference to something being done promptly is a reference to it being done as soon as is reasonably practicable, using all reasonable endeavours;
- 66 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;
- 67 a reference to any agreement or document is to that agreement or document as amended, novated, supplemented or replaced from time to time;
- 68 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;
- 69 an expression importing a natural person includes any company, trust, partnership, joint venture, association, corporation, body corporate or governmental agency;
- 70 subject to clause 60, if the day on which any act, matter or thing is to be done under the Deed is not a Working Day, that act, matter or thing may be done on the next Working Day;
- 71 a covenant or agreement on the part of two or more persons binds them jointly and severally;
- 72 where the context permits, words suggesting the singular number should be read as including the plural and vice versa;
- 73 headings are included merely to assist the reader and should not be used to assist with the interpretation of any other part of the Deed;
- 74 the Schedules and any attachments or annexures form part of the Deed;
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- 75** all references to ‘dollars’ or ‘\$’ are to Australian dollars;
- 76** to the extent that there is any inconsistency between anything in:
- 76.1.1 the clauses of the Deed;
 - 76.1.2 the Schedules; or
 - 76.1.3 any attachments or annexures,
- then the document ranked higher in the list above will prevail; and
- 77** unless otherwise required by the context, the word **includes** is to be read as **includes**, but not limited to **and including** is to be read as **“including, but not limited to”**.

Schedule 3 Business Processes

Part A – Product Specifications

A1.1 List of Products and unit sizes

A1.1.1 CSL must produce and supply the following range of Products in the following range of unit sizes:

Product	Unit Size	TG Act Registration number
Group 1		
Albumex® 20	10mL	AUST R 31820
Albumex® 20	100mL	AUST R 46283
Albumex® 4	50mL	AUST R 59154
Albumex® 4	500mL	AUST R 59155
Intragam® P	50mL	AUST R 68632
Intragam® P	200mL	AUST R 68633
Biostate®	250IU	AUST R 73032
MonoFIX® - VF	500IU	AUST R 66066
Prothrombinex™ – HT	500IU	AUST R 64012
Thrombotrol® - VF	1000IU	AUST R 66736
Group 2		
CMV Immunoglobulin	30mL	AUST R 31810
Hepatitis B Immunoglobulin	100IU	AUST R 61213
Hepatitis B Immunoglobulin	400IU	AUST R 61214
Normal Immunoglobulin	2mL	AUST R 61215
Normal Immunoglobulin	5mL	AUST R 61216
Rh (D) Immunoglobulin	250IU	AUST R 76643
Rh (D) Immunoglobulin	625IU	AUST R 61217
Tetanus Immunoglobulin	250IU	AUST R 61218
Tetanus Immunoglobulin	4000IU	AUST R 31829
Zoster Immunoglobulin	200IU	AUST R 61219

A1.2 TG Act specifications

A1.2.1 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.

A1.3 Program to develop 2VI Products

A1.3.1 CSL agrees to use all reasonable endeavours to submit, or warrants that at the Commencement Date it has submitted (as the case may be), an application to the TGA for any regulatory approval required under the TG Act for the introduction of a second viral inactivation step for the following Products, in accordance with the following timetable, or as soon practicable thereafter:

Product	Application submission
Normal Immunoglobulin - VF	December 2004
Hepatitis B Immunoglobulin - VF	December 2004
Rh (D) Immunoglobulin - VF	December 2004
Zoster Immunoglobulin - VF	December 2004
Tetanus Immunoglobulin - VF (250iu)	December 2004
CMV Immunoglobulin - VF	February 2005
Tetanus Immunoglobulin - VF (4000iu)	February 2005
Prothrombinex - VF	July 2005

If CSL does not submit any application within 30 Working Days of the specified date, CSL will advise the NBA of the reasons for the delay and that action that CSL is taking to submit the application, and of a revised date for submission for the purpose of this clause.

- A1.3.2 CSL agrees to use all reasonable endeavours, at its own cost, to obtain all regulatory approvals required under the TG Act for the introduction of a second viral inactivation step for the Products referred to in A1.3.1.
- A1.3.3 CSL must, within 30 Working Days of receiving all approvals required under the TG Act for the introduction of a second viral inactivation step for a Product referred to in A1.3.1, propose a change to the Deed under **clause 8** to add that product to the Products as soon as reasonably practicable, and must ensure that any such proposal is made in accordance with Part G Price, Invoicing and Payment.

Part B – Supply Planning and Monitoring

B1. Summary process and timetable for supply planning and monitoring

Timetable	Action	Reference
1. During September and/or October	NBA must consult with CSL and consider CSL input to the development of Annual Supply Estimates for the subsequent financial year	B2.2
2. By 30 November	NBA must give CSL Annual Supply Estimates for the subsequent financial year	B2.3
3. At any time, as appropriate	NBA may give CSL revised Annual Supply Estimates for a particular financial year	B2.4
4. During September, December, March and June	NBA must consult with CSL on the development of Confirmed Quarterly Requirements to be given to CSL at the beginning of the next month	B3.2
5. By the first day of each quarter	NBA must give CSL Confirmed Quarterly Requirements for the quarter commencing six months after that date	B3.4
6. At any time, as necessary	NBA may give CSL variations of Confirmed Quarterly Requirements previously given by NBA which are required as a direct result of: <ul style="list-style-type: none"> • a variation of the Deed under clause 8; • a force majeure event under clause 38; • a partial termination under clause 48; or • an agreed resolution of a dispute under clause 51. 	B3.5
7. Monthly	CSL may convene a Monthly Operations Review Meeting	B4
8. Quarterly	NBA may convene a Quarterly Supply Plan Review Meeting	B4

B2. Annual Supply Estimates***B2.1 Scope and status of Annual Supply Estimates***

B2.1.1 Annual Supply Estimates prepared by the NBA must include an estimate by the NBA of the amount of each Product which may be required to be supplied by CSL under this Deed in a particular financial year, and subject to Part C Production and Inventory Management may include forecasts for:

- (a) Pre-Payment Inventory;
- (b) Post-Payment Inventory;
- (c) inventory of Starting Plasma to be held by CSL; and
- (d) the National CSL Reserve.

B2.1.2 CSL acknowledges and agrees that:

- (a) the NBA must prepare Annual Supply Estimates in accordance with the National Blood Arrangements based on forecast requirements in Australian States and Territories, where those forecast requirements are determined in conjunction with the Commonwealth, State and Territory governments;
- (b) Annual Supply Estimates are prepared and given by the NBA as forecasts for planning purposes only, and are subject to change due to a range of factors, including in particular:
 - (i) finalisation of governments' health budgets;
 - (ii) government policy changes;
 - (iii) safety or regulatory changes;
 - (iv) inventory levels; and
 - (v) significant changes in clinical demand or practice;
- (c) the NBA is under no obligation, gives no warranty, and bears no liability, in relation to the amount of Products estimated to be required in Annual Supply Estimates;
- (d) the giving of Annual Supply Estimates by the NBA does not impose any obligation or liability on the NBA in relation to Confirmed Quarterly Requirements or Orders;
- (e) the giving of Annual Supply Estimates by the NBA does not limit any obligation or liability of CSL under the Deed in relation to Confirmed Quarterly Requirements or Orders; and
- (f) despite any other provision of the Deed:
 - (i) the NBA is under no obligation to give Annual Supply Estimates for any period occurring after the Expiry Date; and

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- (ii) Annual Supply Estimates have no status or effect between the Parties in relation to any period after the Term.

B2.2 Preparation of Annual Supply Estimates

- B2.2.1 The NBA must consult with CSL during September and/or October on the preparation of Annual Supply Estimates for the subsequent financial year.
- B2.2.2 CSL must, without limitation to any other obligation of CSL under this Deed:
- (a) give the NBA such information and cooperation as the NBA may reasonably request to assist the NBA in the preparation of Annual Supply Estimates, within 5 Working Days of any request from the NBA (or as otherwise agreed by the Parties); and
 - (b) in the course of consultation on Annual Supply Estimates, notify the NBA of any matter of which CSL is aware that will or may arise in the relevant financial year, that would significantly impede CSL's ability to supply Products in the relevant financial year.
- B2.2.3 The NBA must prepare the Annual Supply Estimates taking into account any matters raised by CSL in relation to the Annual Supply Estimates, and may take into account any other matters the NBA considers relevant, including without limitation:
- (a) past supply and production data from CSL and other relevant sources;
 - (b) past collection and supply data, and planned and forecast collection and supply levels, of Starting Plasma;
 - (c) average and target yields as advised by CSL in the Yield Report in E1.1.2; and
 - (d) the matters referred to in B2.1.2(b).

B2.3 Giving and receipt of Annual Supply Estimates

- B2.3.1 The NBA must give CSL the Annual Supply Estimates for a particular financial year by no later than the preceding 30 November.
- B2.3.2 CSL must, by no later than 10 Working Days after receipt of Annual Supply Estimates from the NBA, notify the NBA either:
- (a) that the revised Annual Supply Estimates are within the capacity of CSL to achieve for the relevant financial year; or
 - (b) of any known or likely unavoidable constraints which will prevent CSL from achieving the Annual Supply Estimates for the relevant financial year.

B2.4 Revision of Annual Supply Estimates

- B2.4.1 Subject to Confirmed Quarterly Requirements, the NBA may at any time give CSL revised Annual Supply Estimates to take into account:
- (a) any response from CSL under B2.3.2(b);

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- (b) a material change in government policy or budgets, a material safety or regulatory change, or a material change in clinical practice;
 - (c) a variation, force majeure event, partial termination or agreed resolution of a dispute under the Deed; or
 - (d) any other matter affecting the Annual Supply Estimates.
- B2.4.2 CSL must, by no later than 10 Working Days after receipt of revised Annual Supply Estimates from the NBA, notify the NBA either:
- (a) that the revised Annual Supply Estimates are within the capacity of CSL to achieve for, or for the remainder of, the relevant financial year; or
 - (b) of any known or likely unavoidable constraints which will prevent CSL from achieving the revised Annual Supply Estimates for, or for the remainder of, the relevant financial year.
- B2.4.3 CSL acknowledges and agrees that the NBA is under no obligation, gives no warranty, and bears no liability, in relation to giving or not giving or to the content of revised Annual Supply Estimates or any actions or omissions of CSL based on Annual Supply Estimates given by the NBA.
- B3. Confirmed Quarterly Requirements
- B3.1 Scope and status of Confirmed Quarterly Requirements***
- B3.1.1 Confirmed Quarterly Requirements prepared by the NBA must state the NBA's reasonable expectation of quantities of Products that may be the subject of Orders under Part D Ordering and Delivery for the relevant quarter, and may include:
- (a) forecasts for inventories;
 - (b) minimum or maximum target levels for Pre-Payment Inventory of Group 1 Products; and
 - (c) Orders for Post-Payment Inventory and National CSL Reserve,
- for that quarter.
- B3.1.2 CSL and the NBA acknowledge and agree that:
- (a) the NBA must prepare Confirmed Quarterly Requirements in accordance with the National Blood Arrangements based on forecast requirements in Australian States and Territories, where those forecast requirements are determined in conjunction with the Commonwealth, State and Territory governments;
 - (b) the Confirmed Quarterly Requirements prepared by the NBA for a quarter may be materially different from any Annual Supply Estimate previously given by the NBA so far as it applied in respect of that quarter;
 - (c) the NBA's obligations and liabilities in relation to Confirmed Quarterly Requirements are as set out in Part B Supply Planning and Monitoring, Part D Ordering and Delivery and Part G Price, Invoicing and Payment, and
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except to the extent expressly provided in Part B Supply Planning and Monitoring, Part D Ordering and Delivery and Part G Price, Invoicing and Payment:

- (i) the NBA is under no obligation, gives no warranty, and bears no liability, in relation to the amount of Products estimated to be required in Confirmed Quarterly Requirements;
 - (ii) the giving of Confirmed Quarterly Requirements by the NBA does not impose any obligation or liability on the NBA in relation to Orders;
 - (iii) the giving of Confirmed Quarterly Requirements by the NBA does not limit any obligation or liability of CSL under the Deed in relation to Orders; and
- (d) despite any other provision of the Deed:
- (i) the NBA is under no obligation to give Confirmed Quarterly Requirements for any period occurring after the Expiry Date; and
 - (ii) Confirmed Quarterly Requirements have no status or effect, and impose no obligation or liability, between the Parties in relation to any period after the Term.

B3.1.3 The Parties will monitor production output, ordering and delivery against Confirmed Quarterly Requirements in accordance with Part E Reporting and Performance Management.

B3.1.4 The parties acknowledge that the Confirmed Quarterly Requirements (subject to the Deed) affect:

- (a) the extent of CSL's obligations to supply Products, in accordance with Part D Ordering and Delivery;
- (b) the Products ordered into Post-Payment Inventory by the NBA, in accordance with Part C Production and Inventory Management; and
- (c) the extent of the NBA's obligations to make Payments, in accordance with Part G Price, Invoicing and Payment.

B3.2 Preparation of Confirmed Quarterly Requirements

B3.2.1 The NBA must consult with CSL during September, December, March and June on the preparation of the proposed Confirmed Quarterly Requirements required to be given by the NBA by the first day of the following quarter.

B3.2.2 CSL must, without limitation to any other obligation of CSL under this Deed:

- (a) give the NBA such information and cooperation as the NBA may reasonably request to assist the NBA in the preparation of proposed Confirmed Quarterly Requirements, within 5 Working Days of any request from the NBA (or as otherwise agreed between the Parties); and

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- (b) in the course of consultation on proposed Confirmed Quarterly Requirements given by the NBA, notify the NBA of any matter of which CSL is aware that will or may arise in the relevant quarter, that would significantly impede CSL's ability to supply Products in accordance with the proposed Confirmed Quarterly Requirements in the relevant quarter.
- B3.2.3 The NBA must prepare the proposed Confirmed Quarterly Requirements taking into account any matters raised by CSL in relation to the proposed Confirmed Quarterly Requirements, and may take into account any other matters the NBA considers relevant, including without limitation:
- (a) past supply and production data from CSL and other relevant sources;
 - (b) past collection and supply data, and planned and forecast collection and supply levels, of Starting Plasma;
 - (c) average and target yields as advised by CSL in the Yield Report in E1.1.2;
 - (d) inventory levels; and
 - (e) batch sizes in which CSL can manufacture Products, as advised by CSL from time to time.
- B3.2.4 For Group 2 Products, the NBA must prepare the Confirmed Quarterly Requirements based on multiples of the batch sizes agreed between the Parties (taking into account CSL's recommended production batch sizes and average yields as advised to the NBA from time to time). The Parties will negotiate in good faith to agree, prior to the commencement of each financial year during the Term, the batch sizes for that financial year for the purpose of this clause.
- B3.2.5 For the purposes of this Deed, in the event of an inconsistency or conflict between Confirmed Quarterly Requirements and Annual Supply Estimates, the Confirmed Quarterly Requirements prevail.

B3.3 Minimum target levels for Pre-Payment Inventory

- B3.3.1 The minimum target level for Pre-Payment Inventory of any Group 1 Product specified by the NBA in the Confirmed Quarterly Requirements may be no greater than two months supply of that Product in accordance with Orders under the Deed, at an average monthly supply level calculated over the previous twelve month period.
- B3.3.2 The NBA may, prior to 1 January 2006 and thereafter prior to giving CSL the Confirmed Quarterly Requirements for the first quarter of any subsequent financial year:
- (a) consult with CSL on the minimum target levels of Pre-Payment Inventory of Group 1 Products which the NBA may specify in the Confirmed Quarterly Requirements in that financial year; and
 - (b) taking into account any matters raised by CSL and any other relevant matters, and subject to B3.3.1, notify CSL of the greatest minimum target levels of Pre-Payment Inventory of Products which the NBA may specify in the Confirmed Quarterly Requirements for that financial year.

B3.4 Agreement of Confirmed Quarterly Requirements

- B3.4.1 The NBA must by the first day of each quarter, give CSL the NBA's proposed Confirmed Quarterly Requirements for the quarter commencing six months from that date.
- B3.4.2 CSL must, by no later than 5 Working Days after receipt of the NBA's proposed Confirmed Quarterly Requirements, notify the NBA either:
- (a) that the proposed Confirmed Quarterly Requirements are agreed by CSL – in which case they become the Confirmed Quarterly Requirements applying for the relevant quarter; or
 - (b) that the proposed Confirmed Quarterly Requirements are not agreed by CSL due to known or likely unavoidable constraints which will prevent CSL from achieving the Confirmed Quarterly Requirements for the relevant quarter – in which case CSL must notify the NBA of the specific reasons why the proposed Confirmed Quarterly Requirements are not agreed, and substantiate those reasons in accordance with any reasonable request by the NBA.
- B3.4.3 Where CSL does not agree to the NBA's proposed Confirmed Quarterly Requirements under B3.4.2(b):
- (a) if requested by the NBA, CSL must, within 2 Working Days of CSL's notice under B3.4.2, cooperate in good faith with the NBA to develop and agree on alternative options for the Confirmed Quarterly Requirements which, as far as possible given the known or likely unavoidable constraints of CSL, will meet the NBA's requirements; and
 - (b) the NBA may give CSL further proposed Confirmed Quarterly Requirements under B3.4.1.

B3.5 Revision of Confirmed Quarterly Requirements

- B3.5.1 The NBA may, at any relevant time, give CSL variations of Confirmed Quarterly Requirements previously given by NBA, which are required as a direct result of:
- (a) a variation of the Deed under **clause 8**;
 - (b) a Force Majeure event under **clause 38**;
 - (c) a partial termination under **clause 48**; or
 - (d) an agreed resolution of a dispute under **clause 51**.
- B3.5.2 CSL must, by no later than 5 Working Days after receipt of revised Confirmed Quarterly Requirements from the NBA, notify the NBA either:
- (a) that the revised Confirmed Quarterly Requirements are agreed by CSL – in which case they become the Confirmed Quarterly Requirements applying for, or for the remainder of, the relevant quarter; or

- (b) that the revised Confirmed Quarterly Requirements are not agreed by CSL due to known or likely unavoidable constraints which will prevent CSL from achieving the Confirmed Quarterly Requirements for the remainder of the relevant quarter – in which case CSL must notify the NBA of the specific reasons why the proposed Confirmed Quarterly Requirements are not agreed, and substantiate those reasons in accordance with any reasonable request by the NBA.

B3.5.3 Where CSL does not agree to the NBA's proposed Confirmed Quarterly Requirements under B3.5.2(b):

- (a) if requested by the NBA, CSL must, within 5 Working Days of CSL's notice under B3.5.2, cooperate in good faith with the NBA to develop alternative options for the Confirmed Quarterly Requirements which, as far as possible given the known or likely unavoidable constraints of CSL, will meet the NBA's requirements; and
- (b) the NBA may give CSL further revised Confirmed Quarterly Requirements under B3.5.1.

B3.5.4 Where revised Confirmed Quarterly Requirements are agreed under B3.5.2(a), the Confirmed Quarterly Requirements for the relevant quarter for the purposes of G5 will, unless otherwise agreed by the Parties, be the Confirmed Quarterly Requirements first agreed for the relevant quarter under B3.4.2(a)

B4. Supply Planning and Monitoring Meetings

B4.1 Description and scope

B4.1.1 The Parties will establish and participate in the following supply planning and monitoring meetings on the following basis:

Title	Period	Convenor	Scope
Monthly Operations Review Meeting	Monthly	CSL	<p>Meeting may be convened by CSL as part of its operational management. The timing of the meeting may be proposed by CSL but must be notified to the NBA with at least 5 Working Days prior notice. The NBA may choose to participate or not as it considers appropriate.</p> <p>The matters to be addressed at the Monthly Operations Review Meeting include:</p> <ul style="list-style-type: none"> - review and resolution of demand and supply issues; - intensive management of supply (when required); - high level overview of the CSL Sales & Operations Plan.
Quarterly Supply Plan Review Meeting	Quarterly	NBA	<p>The NBA may choose whether or not to convene the meeting in respect of a particular quarter. CSL must participate in the meeting if convened by the NBA. Meetings to be held by teleconference or, where a teleconference is impracticable, at the NBA's premises or another venue reasonably nominated by the NBA. Timing of the meeting each quarter to be proposed by the NBA but must be notified</p>

Title	Period	Convenor	Scope
			<p>to CSL with at least 10 Working Days prior notice. The meeting may be held in conjunction with a Deed Management Meeting under clause 6. CSL to make relevant personnel available to participate in the meeting, as reasonably requested by the NBA.</p> <p>The matters to be addressed at the Quarterly Supply Plan Review Meeting include:</p> <ul style="list-style-type: none"> - review and resolution of demand, production and supply and issues; - high level overview of the Annual Supply Planning Process; - high level overview of the Confirmed Quarterly Requirements; - monitoring the accuracy of the Annual Supply Estimates and Confirmed Quarterly Requirements; - recommendations on alterations to the Confirmed Quarterly Requirements (taking into account demand, inventory levels & supply), provided that any revision of Confirmed Quarterly Requirements is dealt with in accordance with B3.5; - intensive management of supply (when required); or - high level overview of the CSL Sales & Operations Plan.

B4.2 Administration

B4.2.1 Subject to B4.1.1, and unless otherwise agreed between the Parties, the convenor of a meeting referred to in B4.1.1 must:

- (a) subject to intensive product management arrangements in accordance with Part F Included Services, convene the relevant meetings as specified in B4.1.1;
- (b) arrange the time, place and format (face-to-face or teleconference) of a meeting on a basis acceptable to both Parties;
- (c) use reasonable endeavours to ensure that all papers or reports required for a meeting are prepared and distributed by the relevant person in sufficient time for the meeting;
- (d) chair the meeting;
- (e) prepare and/or distribute relevant agendas, papers, meeting outcomes and records, and out of session items; and
- (f) otherwise support the operation of the relevant meetings.

- B4.2.2 Each Party must bear its own costs of (where applicable) convening and participating in a meeting referred to in B4.1.1.
- B4.2.3 The Parties may agree that other persons, including, without limitation, any supplier of Starting Plasma or distributor of Products, may attend or participate in a meeting referred to in B4.1.1.
- B4.2.4 Except as expressly provided in this Deed, a meeting referred to in B4.1.1 does not have any authority to make any decision or determination, or give any notice or other document, under the Deed.

Part C – Production and Inventory Management

C1. Production planning

C1.1.1 CSL must apply a documented planning approach to the production of Products, at least on a rolling 12 month basis, to ensure the performance of its obligations under the Deed.

C1.1.2 CSL must (in addition to the Sales & Operations Plan required under Part E Reporting and Performance Measurement) provide the NBA with all documents or information reasonably requested by the NBA from time to time in relation to CSL production planning for Products under the Deed.

C2. Production requirements

C2.1 General

C2.1.1 CSL's obligations to produce and provide Products under this Deed are subject to:

- (a) circumstances affecting the timely provision of adequate Starting Plasma to CSL; and
- (b) circumstances in relation to safety concerns, latent defects, contaminants or donor issues which prevent or limit the effective use of Starting Plasma,

where these circumstances are beyond the reasonable control of CSL, and not able to be reasonably mitigated by CSL.

C2.1.2 CSL must produce the Products:

- (a) from Starting Plasma;
- (b) to comply with the Specifications and all relevant requirements of the Deed; and
- (c) on a production cycle which will (together with available inventories) be likely to maximise the remaining shelf life of Products on delivery to an Approved Recipient, taking into account any target levels for shelf life of Products on delivery to Approved Recipients notified by the NBA from time to time after consultation with CSL.

C2.2 Place of manufacture

C2.2.1 CSL must manufacture all Products at its plasma fractionation plant in Australia, unless the NBA specifically approves otherwise.

C2.3 Yield

C2.3.1 CSL must:

- (a) use reasonable endeavours to produce all Products to maximise yield of Product per kilogram of Starting Plasma, including to meet any target yield given by CSL in the Yield Report given under Part E Reporting and Performance Measurement, given the requirements for Products under the

Deed from time to time, and subject to the amount and characteristics of available Starting Plasma from time to time; and

- (b) for each Product:
- (i) meet or exceed any target yield in respect of that Product specified in the KPIs under Part E Reporting and Performance Measurement; or
 - (ii) use reasonable endeavours to meet or exceed any target yield agreed as part of any intensive product management arrangements under Part F Included Services.

C3 Starting plasma

C3.1.1 Following receipt of Starting Plasma, CSL must:

- (a) complete any delivery docket or other process for confirmation of receipt;
- (b) check and weigh the Starting Plasma;
- (c) test the Starting Plasma;
- (d) store Starting Plasma securely and separately from other plasma;
- (e) participate in any reconciliation process for the receipt of Starting Plasma provided to CSL against records of delivery held by the NBA or another person;
- (f) maintain records of matters relating to the number of units, weight, receipt, testing, reconciliation, storage, use or disposal of Starting Plasma;

as required by the Deed, the TG Act, or the TGA, and in accordance with reasonable instructions given to CSL from time to time by the NBA in relation to the matters in paragraphs (a), (b), (e) and (f).

C4. Holding of inventory

C4.1 Classes of inventory

C4.1.1 The classes of inventory relevant to the Deed are:

Inventory	Description
Pre-Payment Inventory	<ul style="list-style-type: none"> • Products produced by CSL under the Deed • Not supplied to Approved Recipients • Not paid for by the NBA
Post-Payment Inventory	<ul style="list-style-type: none"> • Products produced by CSL under the Deed • Ordered and placed into Post-Payment Inventory in accordance with Part D Ordering and Delivery • Not yet supplied to Approved Recipients

	<ul style="list-style-type: none"> • Paid for by the NBA • Held in accordance with Part F Included Services
Starting Plasma	<ul style="list-style-type: none"> • Starting Plasma supplied to CSL and not yet used by CSL for production, or in the process of production but not yet transformed into finished Products
National CSL Reserve	<ul style="list-style-type: none"> • Inventory held in accordance with a separate contract between CSL and the NBA, if any, where that contract is specified by the NBA from time to time for the purpose of the Deed as being a National CSL Reserve contract • Ordered and placed into National CSL Reserve in accordance with Part D Ordering and Delivery • Not yet supplied to Approved Recipients • Paid for by the NBA

C4.2 Post-Payment Inventory

- C4.2.1 CSL must only place Products into Post-Payment Inventory where Products are, or are taken to be, ordered into Post-Payment Inventory by the NBA in accordance with Part D Delivery and Ordering.
- C4.2.2 CSL must supply Products held in Post-Payment Inventory in accordance with conditions specified by the NBA from time to time in relation to the supply of Post-Payment Inventory.
- C4.2.3 For certainty, rotation of Post-Payment Inventory in accordance with C5 is not supply of Products as referred to in C4.2.2.

C4.3 National CSL Reserve

- C4.3.1 CSL must only place Products into National CSL Reserve where Products are, or are taken to be, ordered into National CSL Reserve by the NBA in accordance with Part D Delivery and Ordering.
- C4.3.2 CSL may only supply Products held in National CSL Reserve with the prior written approval of the NBA (which may be given on a standing basis), and then may only supply such Products in accordance with any conditions specified by the NBA in relation to that approval.
- C4.3.3 For certainty:
- (a) rotation of National CSL Reserve in accordance with C5 is not supply of Products as referred to in C4.3.2; and
 - (b) the operation of the Deed in relation to National CSL Reserve is subject to the provisions of any contract referred to in C4.1.1 under which the National CSL Reserve is held.

C4.4 Inventory levels and targets

- C4.4.1 CSL must report inventory levels in accordance with Part E Reporting and Performance Measures.
- C4.4.2 Where the Confirmed Quarterly Requirements include a minimum target for Pre-Payment Inventory of a Product, CSL must endeavour to achieve and maintain that target level, subject to:
- (a) availability of adequate and suitable Starting Plasma;
 - (b) requirements for supply of the Product in accordance with Orders under the Deed;
 - (c) competing Orders and targets for different classes of inventory;
 - (d) variations between Confirmed Quarterly Requirements and Orders met by CSL in accordance with the Deed; and
 - (e) variations between planned and actual production,
- and must endeavour to meet or replenish any such inventory target:
- (f) at an incremental rate approved by the NBA; and
 - (g) giving priority between different classes of inventory on a basis approved by the NBA.
- C4.4.3 Where the Confirmed Quarterly Requirements include a maximum target for Pre-Payment Inventory of a Product CSL must endeavour not to exceed that target, subject to:
- (a) constraints and requirements of CSL production of Products, including optimising production batch size and seeking to maximise yield;
 - (b) requirements for supply of the Product in accordance with Orders under the Deed;
 - (c) variations between Confirmed Quarterly Requirements and Orders met in accordance with the Deed; and
 - (d) variations between planned and actual production.
- C5. Inventory management requirements
- C5.1.1 CSL must maintain warehouse facilities for the holding of inventories which will allow CSL to meet its obligations under the Deed, and which must at least meet the following requirements:
- (a) licensing requirements under the TG Act;
 - (b) temperature control, alarms and monitoring;
 - (c) location in Melbourne, Sydney, Brisbane, Adelaide, Perth and other such locations as may be agreed between CSL and the NBA; and

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- (d) capacity for different classes of inventory to be held separately within each facility.
- C5.1.2 CSL must provide transport for Products between warehouse facilities that meets licence requirements under the TG Act.
- C5.1.3 CSL must:
- (a) 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 inventory;
 - (b) undertake a continuous cycle of physical counts of all finished Product inventories in accordance with CSL Standard Operating Procedures; and
 - (c) undertake any specific checking or counting of inventories reasonably required by the NBA.
- C5.1.4 Subject to any relevant Intensive Product Management arrangements under Part F Included Services, CSL must:
- (a) maintain rotation of Products held in inventories on a first-expiry-first-out basis, subject to reasonable inventory location constraints;
 - (b) endeavour to minimise levels of Product expiry in inventory; and
 - (c) give priority in inventory management and rotation between different classes of inventory on a basis, if any, notified by the NBA, following prior consultation with CSL
- C5.1.5 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 inventories of Product between different warehouse facilities on a basis that will optimise the efficiency and effectiveness of:
- (a) Product rotation; and
 - (b) delivery in accordance with Orders under the Deed,
- and will minimise the risks of loss or damage to Products, and potential Product expiry.

Part D – Ordering and Delivery

D1. Categories of Orders

D1.1.1 There are two categories of Orders:

- (a) Inventory Orders for Products to be placed into Post-Payment Inventory or National CSL Reserve, in accordance with D3.2; and
- (b) Delivery Orders for Products to be delivered to Approved Recipients, in accordance with D3.3.

D2. Approved Recipients

D2.1.1 CSL must comply with instructions issued in writing by the NBA from time to time, after consultation with CSL, about:

- (a) the persons (specified individually or by classes) who are Approved Recipients for the purposes of this Deed;
- (b) processes for the issue or withdrawal of authorisation numbers to Approved Recipients by the NBA (which number may also be a customer number issued to an Approved Recipient by CSL); and
- (c) the circumstances in which Products may be supplied to persons who are Approved Recipients but who have not been issued with an authorisation number by the NBA.

D3. Ordering Products and Services

D3.1 Requirements for Delivery Orders

D3.1.1 CSL must only accept a Delivery Order:

- (a) where the Approved Recipient has a current authorisation number issued by the NBA; or
- (b) in accordance with instructions issued in writing by the NBA from time to time about supply of Product to Approved Recipients who do not have an authorisation number in certain circumstances.

D3.1.2 CSL must be able to receive Delivery Orders 24 hours, 7 days a week, each day of the year, with customer service personnel on 24 hour on call availability outside normal CSL working hours.

D3.1.3 Subject to D3.4.1, CSL must not accept a Delivery Order unless the form of the Order allows CSL to make a written record of:

- (a) date of order;
- (b) name and position of person placing order;
- (c) the name of the Product to be delivered by CSL;
- (d) the Item Number of the Product to be delivered by CSL;

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- (e) the quantity of Product to be delivered by CSL;
 - (f) the Product strength required by the Approved Recipient;
 - (g) the name and authorisation number of the Approved Recipient; and
 - (h) the shipping address details,

and CSL must make such a written record.

D3.1.4 All Delivery Orders must be made in multiples of the minimum Order quantities agreed between the Parties from time to time. The Parties will negotiate in good faith to agree, prior to the commencement of each financial year during the Term, the minimum Order quantities for that financial year for the purpose of this clause.

D3.2 Inventory Orders

D3.2.1 The NBA will be taken to have made an Order for placement of Products into Post-Payment Inventory or National CSL Reserve where and from the time that:

- (a) the NBA gives CSL a written order for an amount of Products to be placed into Post-Payment Inventory or National CSL Reserve, as part of the Confirmed Quarterly Requirements or otherwise; or
- (c) an amount of Product is to be placed in Post-Payment Inventory in accordance with G5.1.4.

D3.2.2 Where the Confirmed Quarterly Requirements given by the NBA under Part B Supply Planning and Monitoring include a requirement for a Group 2 Product in the relevant quarter, the NBA is taken to have made an Inventory Order for placement of an amount of that Group 2 Product into Post-Payment Inventory equal to 95% (or as otherwise agreed by the Parties) of the amount of that Product specified in B3.2.4.

D3.2.3 The NBA agrees to consult with CSL on the operation of D3.2.2 prior to 30 June 2005 and 30 June 2006.

D3.3 Obligations to meet Orders

D3.3.1 Subject to:

- (a) this Deed;
- (b) any relevant Intensive Product Management arrangements under Part F Included Services;
- (c) guidelines given by the NBA from time to time in accordance with D3.3.3;

CSL must:

- (d) meet Orders for Products up to 105% of the Confirmed Quarterly Requirement for the quarter in which Products under the Order must be delivered under the Deed;

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- (e) use best endeavours to meet Orders for Products above 105% of the Confirmed Quarterly Requirement for the quarter in which Products under the Order must be delivered under the Deed;
 - (f) subject to any conditions to the contrary specified by the NBA under C4.2.2, meet Delivery Orders from Post-Payment Inventory before meeting Orders from Pre-Payment Inventory; and
 - (g) where the NBA has given approval under C4.3.2 in relation to the supply of Products from National CSL Reserve, meet Delivery Orders from National CSL Reserve before meeting Orders from Post-Payment Inventory, Pre-Payment Inventory, or both, if required as part of the conditions of that approval.
- D3.3.2 Despite D3.3.1, CSL's supply obligation to meet Orders for a Group 2 Product in a quarter will be limited to 100% of CSL's production in response to the relevant Confirmed Quarterly Requirement for the Product, plus any further product CSL may hold in its Pre-Payment Inventory in the quarter.
- D3.3.3 In meeting Orders under the Deed, CSL must follow any applicable guidelines, which are consistent with the Deed, notified by the NBA to CSL from time to time for the purpose of the Deed.
- D3.3.4 CSL will place Products in Post-Payment Inventory or National CSL Reserve in accordance with Inventory Orders under this Part D Ordering and Delivery.

D3.4 Exception Orders

- D3.4.1 Despite anything in this Part D Ordering and Delivery, CSL must accept a Delivery Order as an exception Order where:
- (a) the Order does not, at the time the Order is placed, allow CSL to make a record of all of the matters in D3.1.3;
 - (b) the Order is for less than the minimum order quantities in D3.1.4; or
 - (c) the Order requires delivery in less than the maximum delivery time in D4.2.2.
- D3.4.2 In relation to exception Orders, CSL must:
- (a) meet the Order in accordance with the Deed;
 - (b) as soon as practicable, use all reasonable endeavours to obtain all of the matters in D3.1.3, and make a record of the Order as required under D3.1.3; and
 - (c) use all reasonable endeavours to meet the Order in the delivery time specified in the Order to the extent that this is different from the maximum delivery time in D4.2.2.

D4. Delivery

D4.1 CSL delivery facilities and arrangements

D4.1.1 CSL must establish and maintain all facilities, resources and arrangements which are necessary and appropriate to ensure the delivery of Products in accordance with the Deed, and which must meet the following requirements, where appropriate:

- (a) licence requirements under the TG Act; and
- (b) temperature control, alarms and monitoring.

D4.2 Delivery requirements

D4.2.1 Products must be delivered to the shipping address specified in an Order.

D4.2.2 Products must be delivered in accordance with the maximum delivery times agreed between the Parties, applying from the time of receipt of a Delivery Order by CSL (where a metropolitan delivery address is any address within 30km of the GPO in the capital city of each State and Territory). The Parties will negotiate in good faith to agree, prior to the commencement of each financial year during the Term, the maximum delivery times for that financial year for the purpose of this clause.

D4.3 Acknowledgment and verification of delivery

D4.3.1 Subject to D4.3.2, CSL must

- (a) establish and maintain procedures to ensure that acknowledgment of receipt in accordance with the relevant Order is obtained from all Approved Recipients in respect of all deliveries of Products under the Deed;
- (b) 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;
- (c) establish and maintain internal process controls, checks and audits to ensure that the requirements of paragraph (a) are met in respect of all deliveries of Products under the Deed; and
- (d) 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.

D4.3.2 CSL must comply with any reasonable instructions issued in writing by the NBA from time to time about the matters specified in D4.3.1.

Part E – Reporting and Performance Measurement

E1. Reporting

E1.1.1 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, reports under the Deed.

E1.1.2 CSL must provide reports to the NBA in accordance with the following table:

Name of Report	Details	Period covered	Date Due
Sales & Operations plan	<p>Extract of CSL's Sales & Operations Plan covering CSL's operations for the purposes of the Deed, detailing:</p> <ul style="list-style-type: none"> • forecast demand; • forecast production; • batch sizes; • inventory levels; • scheduling of commencement of production batches; and • interim yield results for production batches completed in the preceding month. <p>Each Sales & Operations Plan CSL must be annotated to indicate any significant changes from the previous Supply & Operations Plan given to the NBA.</p>	Rolling annual in advance, at least by month	<p>(a) Prior to any meeting of the Monthly Operations Review or Quarterly Supply Plan Review under B4.1;</p> <p>(b) after any significant change to CSL's Supply & Operations Plan; and</p> <p>(c) as required in accordance with Intensive Product Management arrangements under Part F Included Services.</p>
Sales & Operations exception report	CSL to notify the NBA from time to time of exceptional circumstances which require a significant departure from the latest Sales & Operations Plan notified to the NBA, which will, or is likely to, impact CSL's ability to supply in accordance with the Deed.	Ad hoc	n/a

Name of Report	Details	Period covered	Date Due
Invoices	In accordance with Part G Price, Invoicing and Payment.	Month, in arrears	10 Working Days after the end of each month
Monthly Orders	Report of Orders under the Deed, detailing: <ul style="list-style-type: none"> • Orders placed; • Orders fulfilled; • Exception Orders under D3.4; • Orders which are not able to be fulfilled, including an explanation, and steps taken by CSL to fill the Order; • Products (of which CSL is aware) which have been incorrectly supplied, recalled, lost, damaged or destroyed. 	Month, in arrears	20 Working Days after the end of each month
Inventory report	Inventory (all classes) held by CSL, detailing: <ul style="list-style-type: none"> • Product; • batch numbers; • remaining shelf life; • storage location. 	Month, in arrears	20 Working Days after the end of the period
Starting Plasma & finished Product report	Report on starting plasma received during the relevant period: <ul style="list-style-type: none"> • date and delivery details of receipt or Starting Plasma; • type, number and weight of units of Starting Plasma received; • net Starting Plasma position; • Percentage of plasma loss for each normal plasma and each hyperimmune plasma; • percentage of finished Product loss. 	Quarter, in arrears	20 Working Days after the end of each quarter

Name of Report	Details	Period covered	Date Due
Yield report	Production yield report, detailing: <ul style="list-style-type: none"> • Production yield (by individual batches and average) of each Product per kg of Starting Plasma for the preceding six month period; • material factors affecting yield in the relevant period; • average and any target yields recommended by CSL for supply planning purposes. 	Six months, in arrears	KPI timetable
TG Act compliance report	Copy of CSL internal management report of levels and trends of compliance with TGA and cGMP requirements.	Quarter, in arrears	20 Working Days after the end of each quarter
Risk Management Plan	Copy of CSL's Risk Management Plan required under clause 32.	Annual, in advance	Initially 120 days from Commencement Date, then as updated annually
Risk Management Report	Report against CSL's Risk Management Plan, detailing: <ul style="list-style-type: none"> • implementation of Risk Management Plan; • risks arising, and mitigation strategies; • systemic issues and recommendations for solutions; • emerging risks or risk areas. 	Annual, in arrears	With Risk Management Plan
Key Subcontracts	CSL to provide NBA with a copy of any Key Subcontracts under clause 10.	Ad Hoc	n/a
Other subcontractors	Listing of other subcontractors under clause 10.	Annual	60 days after end of calendar year
New Product Development	Under clause 9	Ad Hoc	n/a

Name of Report	Details	Period covered	Date Due
Industry & technological developments	Under clause 9	Ad Hoc	n/a
Notifiable Events	Reports to NBA on the happening of Notifiable Events under clause 16.2.	Ad Hoc	n/a
Intensive product management Strategies	Reports required under Intensive Product Management arrangements under Part F Included Services.	Ad Hoc	n/a
Storage facilities maintained by CSL	Information on actual storage locations as required by NBA.	Ad Hoc	n/a
Included Services Business Plan	Annual business plan for Included Services - refer Part F Included Services.	Annual, in advance	In accordance with F2
Included Services report	Report on progress and achievements against annual business plan for Included Services.	Annual, in arrears	With Included Services Business Plan
Pharmacovigilance report	Copy of any summary or compilation pharmacovigilance report given by CSL to TGA.	Ad hoc	n/a

E2. Key Performance Indicators Regime

E2.1 General

E2.1.1 The Parties agree to apply the following [not disclosed] Key Performance Indicators regime in accordance with the Deed:

2.1.2 The Parties must before each financial year, review and agree on the matters to be agreed between the Parties in E2.1.1 to apply in that financial year.

Part F – Included Services

F1. Included Services

F1.1 Description and scope

F1.1.1 CSL must provide the following Included Services:

Included Service	Description of CSL obligations
1. Management of Post-Payment Inventory	<ul style="list-style-type: none"> • Post-Payment Inventory ordered by the NBA under Part D Ordering and Delivery must be managed by CSL in accordance with Part C Production and Inventory Management.
2. Intensive Product Management	<ul style="list-style-type: none"> • The NBA may, following consultation with CSL, nominate Products to be subject to Intensive Product Management from time to time. • Intensive Product Management may include any special arrangements for a nominated Product in relation to supply planning, production, inventory management, ordering, delivery, reporting, invoicing or payment as may reasonably be notified by the NBA, following reasonable consultation with CSL. Such special arrangements may operate in addition to or in place of any other provision of this Schedule 3 Business Operations, as notified by the NBA. • 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.
3. Advice to and participation in national supply and security planning undertaken	<ul style="list-style-type: none"> • CSL participation in supply planning in accordance with Part B Supply Planning and Monitoring. • CSL to advise NBA of emerging trends. • CSL to give advice to NBA based on CSL procedures and statistical models for determining appropriate target reserve levels. • CSL contact with clinicians through visits, focus groups, workshops, etc.
4. Contingency and emergency management	<ul style="list-style-type: none"> • CSL participation in contingency and emergency management planning and activities in accordance with the Deed.

5. Joint CSL-NBA projects, and sector improvement strategies and activities	<ul style="list-style-type: none"> • CSL involvement as reasonably required by the NBA from time to time.
6. Data collection and reporting on behalf of the NBA or other entities in the sector	<ul style="list-style-type: none"> • As reasonably required by the NBA after consultation with CSL, CSL data collection and provision of reports to the NBA or other persons nominated by the NBA in respect of receipt of Starting Plasma or inventories, movements or deliveries of Products, where the data relates to the activities of persons other than CSL but is able to be collected and reported by CSL.
7. Other customer service, communication and education services	<ul style="list-style-type: none"> • CSL monitoring of production and inventory, and work with Approved Recipients to minimise potential wastage. • CSL arrange urgent transportation, or meeting other special requirements.
8. Medical and technical advisory and education services in relation to Product use, handling and storage	<ul style="list-style-type: none"> • Developing educational materials (detailing basic Product information including storage and use) for reference by healthcare professionals and consumers. • Communicating changes to Product Information or Government policy impacting the use of Products to relevant hospital staff (medical, pharmacy, blood bank and administrative). • Providing dedicated personnel for prompt and up-to-date responses to medical queries from Approved Recipients, consumers and healthcare professionals. • Organising conferences and workshops to communicate educational material and demonstrate Product use. • Providing clinical literature to external customers upon request.
9. Providing a pharmacovigilance service in relation to the Products	<ul style="list-style-type: none"> • Collecting and investigating adverse event reports received from Approved Recipients, consumers and health professionals. • Periodically reviewing incoming adverse event reports for detection of new safety signals. • Conducting regular safety surveillance of clinical literature. • Investigating clinical safety issues.
10. CSL updates and new developments	<ul style="list-style-type: none"> • Report by CSL on new developments under clause 9.1, no less than annually. • Ad hoc requirements under clause 9.2. • Twice yearly briefing by CSL senior management team to NBA senior management team. • Invitation to the NBA to attend briefings or presentations held by CSL on operations under or 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.
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F1.2 Business planning process for Included Services

- F1.2.1 The Included Services described in F1.1.1 must be carried out by CSL in accordance with an annual business plan for the Included Services in each Financial Year, which must be approved by the NBA.
- F1.2.2 The NBA must provide CSL with its requirements and priorities for the Included Services in the relevant financial year:
- (a) for the first financial year – within 30 days of the Commencement Date; and
 - (b) for each subsequent financial year – in the last quarter of the preceding financial year.
- F1.2.3 CSL must, within 45 days from the receipt of the NBA's requirements and priorities for the Included Services in the relevant financial year, submit a business plan for the Included Services to the NBA for approval.
- F1.2.4 A business plan for the Included Services must at least specify:
- (a) staff and other resources allocated by CSL to each Included Service for the financial year;
 - (b) key priorities, major activities and specific projects for each Included Service for the financial year; and
 - (c) objective measures of performance and success for each Included Service for the financial year.
- F1.2.5 The NBA must approve any material change to a business plan for Included Services previously approved by the NBA.
- F1.2.6 For the purpose of business planning in relation to the Included Services, and any variation of the Deed in relation to those Services, the Parties agree that an amount of 4% of the prices (GST exclusive) for each Product specified in Part G Prices, Invoicing and Payment will be taken to be paid to CSL in respect of the Included Services.

Part G – Price, Invoicing and Payment
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G1. Price for Products

G1.1 Prices

G1.1.1 The prices for the Products are as follows:

Product	Unit Size	Final price (\$, ex GST)	Final price (\$, incl 10% GST)*
Group 1			
Albumex® 20	10mL	12.17	13.39
Albumex® 20	100mL	44.30	48.73
Albumex® 4	50mL	12.17	13.39
Albumex® 4	500mL	44.30	48.73
Intragam® P	50mL	171.60	188.76
Intragam® P	200mL	686.40	755.04
Biostate®	250IU	137.80	151.58
MonoFIX® - VF	500IU	353.60	388.96
Prothrombinex™ – HT	500IU	404.04	444.44
Thrombotrol® - VF	1000IU	1154.40	1269.84
Group 2			
CMV Immunoglobulin	30mL	1029.11	1132.02
Hepatitis B Immunoglobulin	100IU	37.61	41.37
Hepatitis B Immunoglobulin	400IU	86.11	94.72
Normal Immunoglobulin	2mL	27.09	29.80
Normal Immunoglobulin	5mL	44.40	48.84
Rh (D) Immunoglobulin	250IU	25.48	28.03
Rh (D) Immunoglobulin	625IU	63.70	70.07
Tetanus Immunoglobulin	250IU	37.18	40.90
Tetanus Immunoglobulin	4000IU	594.88	654.37
Zoster Immunoglobulin	200IU	235.87	259.46

* The GST component is subject to change as set out in **clause 22.8**.

G1.2 Prices for certain Product change proposals

G1.2.1 The prices for Products to be introduced with a second viral inactivation step, in accordance with A1.3, are as follows:

Product	Unit Size	Final price (\$, ex GST)	Final price (\$, incl 10% GST)*
CMV Immunoglobulin - VF	30mL	1029.11	1132.02
Hepatitis B Immunoglobulin - VF	100IU	37.61	41.37
Hepatitis B Immunoglobulin - VF	400IU	86.11	94.72
Normal Immunoglobulin - VF	2mL	27.09	29.80
Normal Immunoglobulin - VF	5mL	44.40	48.84
Rh (D) Immunoglobulin - VF	250IU	25.48	28.03
Rh (D) Immunoglobulin - VF	625IU	63.70	70.07
Tetanus Immunoglobulin - VF	250IU	37.18	40.90
Tetanus Immunoglobulin - VF	4000IU	594.88	654.37
Zoster Immunoglobulin - VF	200IU	235.87	259.46
Prothrombinex™ - VF	500IU	404.04	444.44

* The GST component is subject to change as set out in **clause 22.8**.

G1.2.2 Where the Parties agree to the production and supply of an alternative unit size or additional unit size or concentration of a product already supplied under the Deed, CSL agrees that the price per gram or international unit for the additional unit size or concentration will be no greater than the cheapest price per gram or international unit of any unit size of the product already supplied under the Deed in the table in G1.1.1, subject to any reasonable additional cost in relation to the cost of the vials, stoppers, labels, dispensing and packaging processes in relation to the new vial size or concentration. For certainty, this does not apply to a change that is not limited to a change in unit size or concentration.

G1.3 Price indexation

G1.3.1 Prices specified in G1.1.1 will be subject to annual indexation in accordance with the following rates, to take effect on 1 July 2006 and on the first day of each financial year thereafter:

Financial year	Indexation rate
1 July 2005 to 30 June 2006	0%
1 July 2006 to 30 June 2007	1.75%
1 July 2007 to 30 June 2008	1.75%
1 July 2008 to 30 June 2009	1.75%
1 July 2009 to 30 June 2010 (indexed prices applicable only to period 1 July 2009 to 31 December 2009)	1.75%

G2. Invoicing

G2.1.1 CSL may submit tax invoices monthly in arrears based on:

- (a) Products supplied from Pre-Payment Inventory in accordance with Delivery Orders; and
- (b) Products placed into Post-Payment Inventory or National CSL Reserve in accordance with Inventory Orders,

during the relevant month.

G2.1.2 CSL must provide a tax invoice within 10 Working Days of the end of a calendar month. This invoice will be in the form agreed between the Parties and must include a schedule to the tax invoice (in excel format), in accordance with this Schedule.

G2.1.3 The tax invoice must summarise the data on the spread sheet tagged BILEP020 (below) and contain the following:

- (a) CSL's Name, Address and Australian Business Number;
- (b) Tax Invoice date and number;
- (d) bank account details (name BSB and account Number) for electronic funds transfer;
- (e) for the Products:
 - (i) unique Product Identifier;
 - (ii) Product name and volume;
 - (iii) Price of Product excluding GST;
 - (iv) Quantity of Product summarised from spread sheet BILEP020 (below);
 - (v) Value of Product (ie Quantity multiplied by Product price);
 - (vi) GST applicable; and

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- (vii) Line total;
 - (f) total value, total GST and tax invoice total; and
 - (i) any other requirement for a valid tax invoice under the GST law.
- G2.1.4 The work sheet schedule to the tax invoice is to be tagged [not disclosed] and contain the following:
- [Not disclosed – this worksheet contains information formats for electronic records.]
- G2.1.5 CSL must comply with any further 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.
- G3. Payment of invoices
- G3.1.1 Subject to the Deed, the NBA agrees to make payments within 30 days from the date of a correctly rendered tax invoice.
- G4. Reconciliation and adjustment of invoices
- G4.1.1 CSL must comply with any reasonable instructions issued in writing by the NBA (following consultation with CSL) from time to time in relation to the processes for resolving any matter of clarification in respect of an invoice, or for undertaking any process of reconciliation of an invoice, when required by the NBA.
- G4.1.2 Where at any time the NBA reasonably considers that an invoice issued by CSL is incorrect (whether or not any amount has been paid by the NBA in respect of the invoice), CSL must give to the NBA as reasonably required by the NBA:
- (a) a credit note and replacement invoice; or
 - (b) an adjustment note;
- as required to correct the invoice, and in compliance with any requirements of the GST legislation as defined in **clause 22.1**.
- G5. Adjustment payments by the NBA based on 95% of Confirmed Quarterly Requirements
- G5.1.1 CSL must, in respect of Group 1 Products:
- (a) maintain a record, for each Product, of the extent to which Inventory Orders (excluding National CSL Reserve Orders) and Delivery Orders filled from Pre-Payment Inventory made for that Product in each quarter exceed, or fall short of, 95% of the amount of that Product specified by the NBA in the Confirmed Quarterly Requirements for that quarter; and
 - (b) report the amount of excess or shortfall referred to in (a) to the NBA no more than 10 Working Days after the end of each quarter, and provide any information reasonably requested by the NBA from time to time to substantiate the amount reported.
- G5.1.2 If over any of the following periods:
- (a) 1 January 2006 to 30 June 2007;
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- (c) 1 July 2007 to 30 June 2008;
 - (d) 1 July 2008 to 30 June 2009; or
 - (e) 1 July 2009 to 31 December 2009,

the sum of the amounts of the quarterly excess or shortfall, as defined in G5.1.1 for any Product for all quarters in the period is an amount which is less than zero, CSL may invoice the NBA for an additional Payment in respect of that the absolute value of that amount of additional units of the Product, calculated at the average price for the Product applying over all quarters of the relevant period.

G5.1.3 Where the NBA is reasonably satisfied that an invoice submitted by CSL under G5.1.2 is correct, the NBA must pay the relevant amount within 30 days from the date of a correctly rendered tax invoice.

G5.1.4 If CSL invoices the NBA under G5.1.2 and the NBA makes payment in accordance with the invoice, CSL must place the invoiced amounts of the relevant Products into Post-Payment Inventory.

G6 [Not disclosed.]

Schedule 4 Insurance

1. Risks to be insured

[Not disclosed. However CSL is required to maintain insurance in the following categories:

Public liability;

Professional indemnity;

Product liability;

Occupational health & safety; and

Workers compensation.]

2. Reporting and review

2.1 CSL must, at the reasonable request of the NBA, provide to the NBA details of the terms of the insurances held to cover the risk areas in 1.1 above, and evidence of the currency of such insurances, including:

- (a) the nature and scope of cover;
- (b) the claims basis of the policy;
- (c) the level of insurance (per claim and aggregate);
- (d) the period of the cover;
- (e) the identity of the insured; and
- (f) the exclusions from the cover.

2.2 CSL must, prior to each Financial Year, provide to the NBA a list of the insurances proposed to be held by CSL in or in respect of that Financial Year to cover the risk areas in 1.1 above.

2.3 CSL must:

- (a) take into account any matters raised by the NBA from time to time in relation to the adequacy of the insurances held by CSL to cover the risk areas in 1.1 above; and
- (b) not unreasonably withhold agreement to any proposal made by the NBA from time to time in relation to a change to the risk areas in 1.1 above.

Schedule 5 Undertakings

Part A - Financial Undertaking

[Not disclosed.]

Part B - Performance Guarantee

[Not disclosed.]

Schedule 6 Disclosure and Use of Information

[Not disclosed.]

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)

Executed as a deed by CSL Limited pursuant to section 127(1) of the *Corporations Act* 2001 by:

.....
Signature of Director

.....
Signature of Director/Secretary