



**Edited version for publication on NBA website**

The contract provided here has been edited, and is not in the form as executed. In addition, certain parts of the contract are not disclosed.

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

**Defined Blood Products Deed**

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

Baxter Healthcare Pty Limited

# Table of contents

Background.....	4
Parties.....	4
Operative provisions.....	4
Section A: Definitions and Term.....	4
1 Definitions .....	4
2 Term .....	8
Section B: Supply of Products and Services .....	9
3 Australian preferred customer status .....	9
4 Supply of Products and Services .....	9
5 Obligations under Therapeutic Goods Act.....	12
6 Performance Measures .....	13
7 Passing of Ownership and Risk.....	14
8 Warranties .....	14
Section C: Payment.....	16
9 Payments to be made by the NBA .....	16
10 Taxes.....	17
11 Invoicing obligations.....	17
12 Recovery of moneys by the NBA.....	17
13 Right of Set Off .....	18
Section D: Deed Management.....	19
14 Subcontracting .....	19
15 Personnel.....	19
16 Data security .....	20
17 Confidentiality.....	21
18 Privacy .....	22
19 Conflict of Interest.....	24
20 Intellectual Property .....	25
21 NBA Material .....	25
22 Records.....	25
23 Reports .....	26
24 Provision of information to the NBA .....	26
25 Access to information and premises and Audit.....	27
26 Public Affairs Management .....	29
27 Review processes.....	30
28 Variations to the Deed.....	30
29 Compliance with Laws .....	31
30 Offences under Crimes Act and Criminal Code 1995.....	31
31 Compliance with Commonwealth policies .....	32
32 Equal Employment Opportunity .....	32

33	Assignment .....	32
34	Further acts .....	32
35	Contacts and Notices .....	33
	<b>Section E: Treatment of Risks .....</b>	<b>34</b>
36	Principles in relation to the allocation of risk .....	34
37	Risk Management Plan .....	34
38	Indemnities .....	34
39	Undertakings .....	35
40	Insurance .....	35
41	Force Majeure .....	36
42	Dispute Resolution .....	36
	<b>Section F: Termination and Transition Management .....</b>	<b>37</b>
43	Termination for Default .....	37
44	Termination by the NBA .....	38
45	Transition Management .....	39
	<b>Section G: Interpretation and Operation of Deed .....</b>	<b>40</b>
46	Rules of Interpretation .....	40
47	Relationship of the Parties .....	41
48	Costs .....	41
49	Entire agreement .....	41
50	Execution of separate documents .....	42
51	Governing law and jurisdiction .....	42
52	Severability .....	42
53	Waiver .....	42
54	Time of the essence .....	42
	Schedule 1 (Deed details) .....	43
	Schedule 2 (Products and Services) .....	44
	Schedule 3 (Performance Measures) .....	53
	Schedule 4 (Payments and Invoicing) .....	54
	Schedule 5 (Records and Reports) .....	57
	Schedule 6 (Insurance) .....	59
	Schedule 7 (Financial Undertaking and Performance Guarantee) .....	60

## Parties

THE DEED OF AGREEMENT is made on the twenty seventh day of April 2006

## BETWEEN

**Commonwealth of Australia**, acting through and represented by the **National Blood Authority**, a Commonwealth agency established under the *National Blood Authority Act 2003 (NBA)*

**Baxter Healthcare Pty Limited ABN 43 000 392 781** a company having its registered office at 1 Baxter Drive, Old Toongabbie, New South Wales 2146 (**Supplier**)

## Background

- A The NBA requires the supply of certain Products and Services to implement 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.
- B The Supplier has participated in a competitive tender process conducted by the NBA in which it provided details to the NBA of its particular expertise, experience and its continuing capacity to supply Products and Services.
- C The Supplier 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: Definitions and Term

#### 1 Definitions

- 1.1 In the Deed, unless the contrary intention appears:

**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 2 (Products and Services)**.

**Business Day** in relation to a place, means a day that is not a Saturday, Sunday or a public holiday in that place, and where a place is not specified, means such a day in the Australian Capital Territory.

**Commencement Date** means the date set out in **item 1 of Schedule 1 (Deed Details)**.

**Commencement of Supply Date** means the date set out in **item 2 of Schedule 1 (Deed Details)**.

**Commonwealth** means the Commonwealth of Australia.

**Confidential Information** means information that is by its nature confidential, and is either:

- (a) specified in **item 5 of Schedule 1 (Deed Details)** as confidential; or
- (b) agreed in writing by the Parties to be confidential;

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 4 (Payments)**) are not Confidential Information.

**Conflict of Interest** means, in relation to the Supplier or its Personnel, any circumstances which:

- (a) constitute a conflict;
- (b) constitute a known risk of a conflict; or
- (c) may be perceived by others to constitute a conflict,

between the interests of the NBA and those of the Supplier or its Personnel (or between the duties of the Supplier 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.

**Contract Material** means all Material:

- (a) brought into existence for the purpose of providing the Products or performing the Services;
- (b) incorporated in, supplied or required to be supplied along with the Material referred to in paragraph (a); or
- (c) copied or derived from Material referred to in paragraphs (a) or (b).

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

**Deed** means this Deed, including the Schedules and any other attachments.

**Expiry Date** means the date set out in **item 3 of Schedule 1 (Deed Details)**.

**In- country Inventory** means the inventory of Product held by the Supplier in Australia in accordance with **item 12 of Schedule 2 (Products and Services)**.

**Insolvency Event**, in respect of the Supplier, means the occurrence of:

- (a) the appointment of a liquidator, provisional liquidator or administrator to the Supplier;
- (b) the appointment of a controller (as defined in section 9 of the Corporations Act) or analogous person appointed to the Supplier or any of its property;
- (c) the Supplier failing to comply, under paragraph 459F(1) of the Corporations Act, with a statutory demand;
- (d) the Supplier being unable to pay its debts as they fall due or otherwise becoming insolvent;
- (e) the Supplier ceasing to exist, for whatever reason, or otherwise becoming incapable of managing its own affairs for any reason;
- (f) the Supplier taking any step that could result in the Supplier 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 the Supplier; or
- (h) the Supplier 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 (Performance Measures)**.

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

**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.

**NBA Material** means any Material provided by, or on behalf of, the NBA to the Supplier for the purposes of the Deed, or which is copied or derived from Material so provided.

**Order** means an order for Products placed under the Deed in accordance with **clause 4**.

**Party** means the NBA or the Supplier, as the context requires.

**Payments** means those amounts which are to be paid by the NBA for the supply of the Products and the Services by the Supplier, or otherwise under the Deed, and which are set out or described in **Schedule 4 (Payments and Invoicing)**.

**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 officers, employees, agents, subcontractors, and their Personnel.

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

**Products** means those products which are specified in, or determined in accordance with the process set out in, **Schedule 2 (Products and Services)** (and includes any ancillary products which are specified as part of a Product in **Schedule 2 (Products and Services)**).

**Review** means a review referred to in **clause 27**.

**Services** means the services to be provided by the Supplier under the Deed which are specified in, or determined in accordance with the process set out in, **Schedule 2 (Products and Services)**.

**Subcontractor** means a person to whom the Supplier has subcontracted the performance of any part of the Deed. **Subcontract** has a corresponding meaning.

**Term** means the term of the Deed, calculated in accordance with **clause 2**.

**TG Act** means the *Therapeutic Goods Act 1998* (Cth) and all regulations and subordinate legislation or instruments made under the TG Act.

**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.

## **2 Term**

2.1 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).

2.2 The NBA may by notice in writing to the Supplier at least:

2.2.1 3 months prior to the Expiry Date, extend the Term for a period of one year from the Expiry Date; and

2.2.2 3 months prior to the expiry of the one year period referred to in **clause 2.2.1**, extend the Term for a further period of one year from the expiry of the first one year period.

2.3 If the Deed is extended in accordance with **clause 2.2**, the Parties will negotiate in good faith to agree on the price payable for each Product during the relevant period of the extension. If no agreement is reached within 3 months from the date of the notice given under clause 2.2, the default Price payable for each Product during the relevant period of extension will be 101.8% of the price payable immediately prior to the extension taking effect.

## Section B: Supply of Products and Services

### 3 Australian Valued customer status

3.1 The Supplier agrees to:

3.1.1 take specific measures to ensure the planned supply of Products to Australia;

3.1.2 take specific measures to supply Products to Australia in the event that forecast demand exceeds planned supply, either domestically or internationally; and

3.1.3 where practicable, take specific measures to supply reasonable alternative products at no additional cost in the event that the Supplier is unable to meet its obligations under this Deed to supply Products to Australia;

as set out in **Schedule 2 (Products and Services)**.

### 4 Supply of Products and Services

4.1 The Supplier must, from the Commencement of Supply Date, on the terms and conditions of this Deed, supply the Products and Services, and must do so in accordance with the procedures, including procedures for the Ordering of Products, set out in this Deed including in particular **Schedule 2 (Products and Services)**.

#### *Placement of Orders*

4.2 Orders for Products may be placed with the Supplier in the manner set out in **Schedule 2 (Products and Services)**.

#### *Supply of Products and Services*

4.3 Upon receiving an Order which is made in the manner set out in **Schedule 2 (Products and Services)**, the Supplier must supply the Products and Services:

4.3.1 to the Approved Recipient in accordance with the Order;

4.3.2 to meet any specifications or other requirements with regard to Products set out in **Schedule 2 (Products and Services)**;

4.3.3 at the times and in the manner specified in the Order or, if no such requirements are specified in the Order, in accordance with the requirements specified in **Schedule 2 (Products and Services)**; and

4.3.4 so as to ensure that the Key Performance Indicators and other requirements of the Deed for the Products and Services are fully met.

4.4 In supplying the Products and Services the Supplier must:

4.4.1 liaise with the Approved Recipient, and the NBA if required;

- 4.4.2 comply with any reasonable direction of the NBA that is consistent with the Deed; and
  - 4.4.3 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.
- 4.5 The Supplier acknowledges and agrees that:
- 4.5.1 the NBA has, and may at any time in the future, enter into arrangements for the supply of products or services similar to the Products and Services, from one or more third parties;
  - 4.5.2 the arrangements under **clause 4.5.1** may affect the NBA's requirements for the provision of Products and Services under the Deed; and
  - 4.5.3 there is no obligation for any or a minimum volume of Orders for Products to be placed under the Deed.

### ***Management of Products***

- 4.6 The Supplier must at all times comply with all obligations and responsibilities in relation to the management of the Products set out in **Schedule 2 (Products and Services)**.

### ***Standard Operating Procedures***

- 4.7 The Supplier must maintain a planned, systematic and documented approach, in accordance with good commercial practice, to the performance of obligations under the Deed.
- 4.8 In relation to the Supplier's standard operating procedures, the Supplier must:
- 4.8.1 provide a copy of any specified standard operating procedures relevant to the supply of the Products and Services or compliance with the Deed by the Supplier to the NBA at the reasonable request of the NBA;
  - 4.8.2 consider any reasonable suggestion made by the NBA for the development or revision of any specified standard operating procedures relevant to the supply of the Products and Services or compliance with the Deed by the Supplier; and
  - 4.8.3 engage in consultation with the NBA or any other relevant person in respect of any standard operating procedures relevant to the supply of the Products and Services or compliance with the Deed by the Supplier, at the reasonable request of the NBA.

### ***Inability to supply in accordance with Specifications***

- 4.9 Where a situation which must be notified by the Supplier to the NBA under **clause 24.5** arises due to the Supplier's failure to comply with its obligations under the Deed, but not including a situation which is a Force Majeure Event under **clause 41.1**, the following process will apply:
- 4.9.1 the Supplier must provide detailed information to the NBA on one or more options offered by the Supplier 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;

- 4.9.2 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;
- 4.9.3 the NBA will promptly provide a response to the Supplier on whether or not any option is acceptable to NBA or on whether the NBA requires further information on any option or consultation with the Supplier; and
- 4.9.4 the NBA may accept or reject any or all options offered by the Supplier, and if the NBA accepts any option, the Parties agree to promptly implement it under **clause 28**.
- 4.10 Where a situation which must be notified by the Supplier to the NBA under **clause 24.5** arises due to a Force Majeure Event, the NBA may require the Supplier to follow the process in **clause 4.9**, except that the Parties are then obliged to comply with **clause 4.9** only to the extent reasonably practicable.
- 4.11 **Clauses 4.9 and 4.10** do not limit a Party's:
- 4.11.1 obligations under **clauses 37 and 41**; or
  - 4.11.2 other rights of the NBA under the Deed or at Law.

### ***Intensive Product Management***

- 4.12 The NBA may, following consultation with the Supplier, nominate Products to be subject to Intensive Product Management from time to time.
- 4.13 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 the Supplier. Such special arrangements may operate in addition to or in place of any other provision of this **Schedule 2 (Products and Services)**, as notified by the NBA.
- 4.14 The Supplier must comply with any reasonable Intensive Product Management arrangements nominated by the NBA from time to time.

## 5 Obligations under Therapeutic Goods Act

5.1 In addition to Supplier's general obligations under **clause 29**, the Supplier agrees at all times during the Term to comply with obligations applying under the TG Act in relation to Products and Services provided under the Deed.

5.2 The Supplier agrees, for all Products:

5.2.1 to the extent that the Supplier is the sponsor of any of the Products:

- (a) to do all things necessary to obtain and maintain TG Registration or TG Listing for the Products during the Term; and
- (b) to notify the NBA in writing immediately upon the Supplier becoming aware that the TG Registration and TG Listing has ceased, or that the Supplier has reasonable grounds to consider that the TG Registration or TG Listing may cease, and to take any consequential action reasonably required by the NBA to ensure that the obligations of the Supplier under this Deed are met following the cessation of the TG Registration or TG Listing;

5.2.2 to the extent that the Supplier is the licensed manufacturer of any of the Products:

- (a) to obtain and maintain such licensing during the Term; and
- (b) to notify the NBA in writing immediately upon the Supplier becoming aware that a licence has been suspended or has ceased, or that the Supplier has reasonable grounds to consider that a licence may be suspended or cease, and to take any consequential action reasonably required by the NBA to ensure that the obligations of the Supplier under this Deed are met following the suspension or cessation of such a licence; and

5.2.3 to the extent that the Supplier supplies a Product under the SAS Scheme:

- (a) to do all things necessary under the TGA Act to ensure that the Product is able to be supplied under the SAS Scheme; and
- (b) to notify the NBA in writing immediately upon the Supplier becoming aware of changes in Product status which may affect supply under the SAS Scheme.

### ***Adverse reaction or event reporting***

5.3 The Supplier must promptly advise the NBA in writing in relation to any adverse reactions or events reported from use of the Product specified in, or determined in accordance with the process set out in **Schedule 5 (Records and Reports)**.

### ***Product compliance and return***

5.4 The Supplier must not supply a unit of Product under the Deed if the Supplier is aware that the unit of Product does not meet the applicable TGA requirements, or that there are

reasonable grounds to believe that the unit of Products may not meet the requirements of its registration or listing.

5.5 If the NBA or an Approved Recipient notifies the Supplier that it considers on reasonable grounds that a Product does or may not meet the applicable requirements of the TG Act, the Supplier agrees to:

5.5.1 liaise with the NBA or Approved Recipient, as appropriate, in relation to the grounds on which the person considers that the Product may not meet the applicable requirements of the TG Act;

5.5.2 accept return of the relevant units of Product, where reasonably practicable;

5.5.3 promptly conduct any necessary investigations to determine whether or not the Product met the requirements of the TG Act; and

where the non compliance with the applicable requirements of the TG Act involves a potential risk of harm to persons, notify the NBA and the TGA of the results of that investigation.

#### ***Other Remedies***

5.6 The rights, obligations and remedies in this **clause 5** 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.

## **6 Performance Measures**

6.1 The Parties must comply with those parts of **Schedule 3 (Performance Measures)** which set out:

6.1.1 which Party is responsible for measuring the Supplier's performance against the Key Performance Indicators;

6.1.2 when the Supplier's performance against the Key Performance Indicators is to be measured; and

6.1.3 the reporting obligations in respect of the Supplier's performance against the Key Performance Indicators.

#### ***Consequences of failure to meet Key Performance Indicators***

6.2 If the Supplier does not meet a Performance Indicator set out in **Schedule 3 (Performance Measures)**, then the consequence set out in **Schedule 3 (Performance Measures)** applies.

6.3 **Schedule 3 (Performance Measures)** may indicate that more than one consequence applies in respect of any particular failure to meet one or more Performance Indicators. If more than one consequence applies in respect of any particular failure to meet a Performance Indicator, the NBA may elect (in its absolute discretion) that one or more of the listed consequences applies.

- 6.4 The Supplier acknowledges and agrees that the listed consequences in **Schedule 3 (Performance Measures)**, as applied under the Deed:
- 6.4.1 are reasonable and appropriate for managing adherence to the Performance Indicators and for providing compensation for Loss, if applicable; and
  - 6.4.2 do not limit the Commonwealth's rights or remedies arising from any defective performance under the Deed.

## **7 Passing of Ownership and Risk**

### ***Ownership of Products to pass to the Approved Recipient***

- 7.1 The Supplier acknowledges that:
- 7.1.1 as between the Parties it retains ownership of the Products; and
  - 7.1.2 it bears all risks of loss or damage to Products in its care, custody or control;
- until possession of the Products passes from the Supplier to an Approved Recipient in accordance with this Deed.

### ***Passing of ownership not to affect recall obligations***

- 7.2 Any passing of ownership of a Product does not affect the Supplier's obligations to ensure the Products comply in full with the Deed or in respect of any recall or other obligations under **clause 5**.

## **8 Warranties**

### ***Products***

- 8.1 The Supplier warrants that:
- 8.1.1 all Products provided under the Deed:
    - (a) have been manufactured, produced, processed, prepared and packaged, labelled, presented and described as required by, and otherwise comply with, any applicable laws within or outside Australia;
    - (b) comply with all representations made to the NBA and Approved Recipients by the Supplier in relation to those Products, including representations as to the standard, quality, value, grade, composition, style, model, capacity, history and previous use of the Products;
    - (c) are of merchantable quality, made of good material and workmanship, and free from defects; and

- (d) are fit for the purpose for which goods of the same kind are commonly supplied, if goods of the same kind exist, and any other purpose made known to the Supplier;
- 8.1.2 it has all rights and title necessary to enable it to supply Products under the Deed including the right to sell the Products at the time when title to those Products is to pass in accordance with **clause 7.1**;
- 8.1.3 on delivery, the Products will be free from any charge or encumbrance in favour of any third party that is not known by, or notified to, and agreed by the NBA before the contract is made;
- 8.1.4 the manufacture and sale of Products does not infringe the rights of any other person, including Moral Rights and rights in relation to patents, trademarks, designs and copyright;
- 8.1.5 on delivery, the Approved Recipient, or other person to whom the Products are to be supplied in accordance with an Order will enjoy quiet possession of the Products;
- 8.1.6 the Products will be delivered in the correct quantity and at the required times; and
- 8.1.7 it has the capacity and power to enter into and perform the Deed.

### ***Services Warranties***

- 8.2 The Supplier warrants that all Services performed under the Deed:
  - 8.2.1 comply with all representations made to the NBA by the Supplier in relation to the standard, quality and timing of the Service;
  - 8.2.2 will be rendered with due care and skill;
  - 8.2.3 along with any materials supplied under the Deed in connection with the Services, are fit for purpose or are of such a nature and quality that they might reasonably be expected to achieve or satisfy the Supplier's obligations under the Deed.
- 8.3 The warranties in this **clause 8** survive the expiration or termination of the Deed.

## Section C: Payment

### 9 Payments to be made by the NBA

#### *Payments*

- 9.1 Subject to **clauses 9.2 and 9.3**, the NBA agrees to make the Payments to the Supplier for Products and Services provided in the manner set out in **Schedule 4 (Payments and Invoicing)**, and in the amounts set out in, or determined in accordance with the procedures described in, **Schedule 4 (Payments and Invoicing)**.
- 9.2 All Payments under the Deed are subject to:
- 9.2.1 compliance by the Supplier with the Deed;
  - 9.2.2 satisfactory supply of Products and performance of the Services by the Supplier (including in meeting any Performance Indicators for those Products and Services), as determined by the NBA; and
  - 9.2.3 the receipt by the NBA from the Supplier of a correctly rendered Tax Invoice which complies with **clause 10** and **Schedule 4 (Payments and Invoicing)**.
- 9.3 The Supplier acknowledges and agrees that:
- 9.3.1 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 Performance Indicators; and
  - 9.3.2 the value of the Products and Services to the NBA is affected by the achievement or otherwise of the Performance Indicators.
- 9.4 The Supplier acknowledges that the making of any Payments by the NBA will not constitute an admission on the part of the NBA that Products have been properly provided or the Services properly performed, or a waiver or release of the Supplier's obligations under the Deed.
- 9.5 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:
- 9.5.1 the unit of Product as supplied by the Supplier does not meet the requirements of its registration or listing; or
  - 9.5.2 that there are reasonable grounds to believe that the unit of Product as supplied by the Supplier may not have met the requirements of its registration or listing;

the Supplier must, 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 as

specified in, or determined in accordance with the process set out in **Schedule 4 (Payments and Invoicing)**

## **10 Taxes**

10.1 In this **clause 10**:

10.1.1 the expression „GST Law means the *A New Tax System (Goods and Services Tax) Act 1999 (Cth)*;

10.1.2 words or expressions which are defined in the GST Law have that defined meaning;

10.1.3 the meaning of „Supplier is limited to a Party who makes a taxable supply to the other Party;

10.1.4 the meaning of „taxable supply is limited to a taxable supply made by one Party to the other Party under or in connection with this Deed; and

10.1.5 the meaning of „Recipient is limited to a Party who receives a taxable supply from the other Party.

10.2 Subject to **clause 10.3**, unless the consideration is expressed in this Deed to be inclusive of GST, for each taxable supply the Recipient agrees to make a payment to the Supplier equal to the GST liability of the Supplier in respect of the taxable supply.

10.3 The Parties agree to comply with all applicable requirements of the GST Law (including without limitation in relation to tax invoices and adjustment events) in respect of all taxable supplies.

10.4 Except as provided in this clause, each Party is responsible for complying with all taxes, duties and government charges imposed or levied on that Party in Australia or overseas in connection with this Deed, without requiring any additional payment from the other Party.

## **11 Invoicing obligations**

11.1 The Supplier agrees to:

11.1.1 comply with all invoicing obligations set out in **Schedule 4 (Payments and Invoicing)**; and

11.1.2 ensure that each invoice given by the Supplier to the NBA complies with the requirements of a Tax Invoice under the GST Legislation.

## **12 Recovery of moneys by the NBA**

12.1 If, at any time during the Term or after the expiry or earlier termination of the Deed, 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, the NBA may (without limitation to any other rights of the NBA under the Deed or at law) give the Supplier a written notice (Repayment Notice) requiring the Supplier to repay that part of the Payments set out in the notice, and the Supplier must pay that amount within 21 days of receipt of the Repayment Notice.

12.2 If the Supplier fails to repay the amount specified in the Repayment Notice under **clause 12.1**:

12.2.1 the Supplier 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%; and

12.2.2 the amount set out in the Repayment Notice, and interest owed under this **clause 12**, will be recoverable by the NBA as a debt due to the NBA by the Supplier.

12.3 The Supplier acknowledges that interest calculated in accordance with **clause 12.2.1** 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.

12.4 This **clause 12** survives the expiration or earlier termination of the Deed.

### **13 Right of Set Off**

13.1 Without limitation to the NBA's rights under the Deed or at Law, if the Supplier 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 the Supplier under the Deed.

13.2 This **clause 13** survives the expiration or earlier termination of the Deed.

## Section D: Deed Management

### 14 Subcontracting

- 14.1 The Supplier must not Subcontract the performance of any part of the Deed without prior approval from the NBA.
- 14.2 The Supplier must notify the NBA of all Subcontractors in accordance with **Schedule 5 (Records and Reports)**.
- 14.3 The Supplier 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 the Supplier has Subcontracted any part of the provision of Products or performance of any part of Services.
- 14.4 The Supplier must ensure each Subcontractor complies with the provisions of this Deed, and in particular, those relating to Intellectual Property, rights and ownership and dealing with Contract Material, confidentiality of information, and rights of access and audit by the NBA, the Auditor General and Privacy Commissioner or their nominees.
- 14.5 If at any time the NBA is concerned that the performance of a Subcontractor of the Supplier may not be satisfactory, then (without limitation to any other rights of the NBA under the Deed or at Law):
- 14.5.1 the NBA may notify the Supplier of the concern and the reasons for the concern; and
  - 14.5.2 the Supplier 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.

### 15 Personnel

#### ***Employer obligations***

- 15.1 Any Personnel of the Supplier providing Products or performing Services on behalf of the Supplier under the Deed is and remains at all times an employee, independent contractor or agent of the Supplier.
- 15.2 The Supplier must at all times and at its own expense comply with the provisions of any relevant Law and industrial instruments (as that term is defined in the *Corporations Act*) in respect of its Personnel.
- 15.3 If requested by the NBA, the Supplier must provide proof to the NBA of compliance with any Law or industrial instrument referred to in **clause 15.2**.

- 15.4 The Supplier indemnifies the NBA in respect of:
- 15.4.1 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) if, despite the provisions of the Deed, the NBA is held at any time to be the employer or principal of any of the Supplier's Personnel or becomes liable to pay any amounts in respect of such person; and
  - 15.4.2 for any failure of the Supplier to comply with **clause 15.2**.

***Warranty as to qualifications of Supplier's Personnel***

- 15.5 The Supplier warrants to the NBA that:
- 15.5.1 the Supplier and its Personnel have the necessary skills, competence, experience and ability to provide Products and perform Services required under the Deed; and
  - 15.5.2 all statements made to the NBA by the Supplier regarding the skills, competence, experience and ability of the Supplier and its Personnel in relation to the provision of Products and performance of Services under the Deed are true and not misleading.
- 15.6 At any time the NBA is concerned that the warranties in **clause 15.5** may not be met, then (without limitation to any other rights of the NBA under the Deed or at Law):
- 15.6.1 the NBA may notify the Supplier of the concern and the reasons for the concern; and
  - 15.6.2 the Supplier 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.

***No provision of medical advice***

- 15.7 The Supplier must not, and must ensure that its Personnel do not, 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 the Supplier's obligations under the Deed, unless that advice is given by a person who is qualified, competent and legally permitted to give that advice.

**16 Data security**

- 16.1 In this **clause 16** „Official Information” means any information developed, received or collected by or on behalf of the Commonwealth, whether through the NBA or any other agency or any other Commonwealth contracted service provider.
- 16.2 Without limiting its obligations under the Deed, the Supplier must comply with the security requirements for the protection of Official Information provided by the NBA to the Supplier

detailed in the Commonwealth's Protective Security Manual, as amended from time to time and as notified to the Supplier by the NBA.

- 16.3 The Supplier must participate in security reviews of the procedures implemented in performance of the Deed if reasonably requested by the NBA.
- 16.4 The Supplier must not permit any of its Personnel to have any access to security classified information provided by the NBA to the Supplier unless:
- 16.4.1 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;
  - 16.4.2 the NBA has given approval in writing for that person to have access to the specific items of security classified information; and
  - 16.4.3 that person has undergone the training required by the NBA relating to the access to and use of security classified information.
- 16.5 The Supplier must notify the NBA promptly upon becoming aware that any unauthorised person has had access to security classified information.
- 16.6 If an incident set out in **clause 16.5** occurs, the Supplier must comply with any reasonable directions of the NBA in order to rectify the security problem.
- 16.7 In granting approval under **clause 16.4.2** the NBA may impose any conditions it considers necessary.
- 16.8 The rights and obligations arising in connection with this **clause 16** will survive the expiry or earlier termination of the Deed.

## **17 Confidentiality**

- 17.1 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).
- 17.2 In giving consent under **clause 17.1**, a Party may impose any reasonable conditions or restrictions it considers appropriate, and the other Party agrees to comply with such conditions or restrictions.
- 17.3 Notwithstanding **clause 17.1**, a Party may disclose Confidential Information if the Confidential Information is:
- 17.3.1 disclosed to its advisers or Personnel solely in order to comply with obligations, or to exercise rights, under the Deed;
  - 17.3.2 disclosed to internal management personnel, solely to enable effective management or auditing of deed-related activities;

- 17.3.3 disclosed by the Supplier to external auditors where required for mandatory auditing or reporting requirements under the Corporations Act or the rules of the Australian Stock Exchange;
  - 17.3.4 in the case of the NBA, disclosed by the NBA to the responsible Minister or Cabinet;
  - 17.3.5 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;
  - 17.3.6 in the case of the NBA, disclosed or shared by the NBA to the Commonwealth, or another Commonwealth, or with another agency or authority of the Commonwealth, where this serves the Commonwealth's legitimate interests;
  - 17.3.7 in the case of the NBA, shared or disclosed by the NBA to State or Territory government agency in Australia, for the purposes of the National Blood Arrangements;
  - 17.3.8 [ Not disclosed.]
  - 17.3.9 authorised or required by Law, or under the Deed, under a licence or otherwise, to be disclosed.
- 17.4 Nothing in this **clause 17** derogates from any obligation which either Party may have either under the Privacy Act as amended from time to time, or under the Deed, in relation to the protection of Personal Information.
- 17.5 This **clause 17** survives the expiration or earlier termination of the Deed.

## **18 Privacy**

- 18.1 The Supplier must, with respect to all Personal Information relating to or concerning the Products or Services:
- 18.1.1 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;
  - 18.1.2 only use such information for the purposes of fulfilling its obligations under the Deed or as required by Law;
  - 18.1.3 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;

- 18.1.4 co-operate with any reasonable demands or inquiries made by the Privacy Commissioner;
  - 18.1.5 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 18**;
  - 18.1.6 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 the Supplier 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;
  - 18.1.7 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 the Supplier, except to the extent that the Supplier is required or authorised by Law to refuse to provide the person with access to that information;
  - 18.1.8 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;
  - 18.1.9 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 the Supplier or a National Privacy Principle as set out in the Privacy Act;
  - 18.1.10 not transfer Personal Information outside Australia, or allow parties outside Australia to have access to it, without the prior written approval of the NBA or the person concerned;
  - 18.1.11 immediately notify the NBA if the Supplier becomes aware of a breach of any obligation concerning security, use or disclosure of Personal Information;
  - 18.1.12 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 the Supplier; and
  - 18.1.13 immediately notify the NBA of, and co-operate with the NBA in the resolution of, any complaint alleging an interference with privacy.
- 18.2 The Supplier must ensure that all Subcontractors are obliged under their contracts to meet privacy obligations that are equivalent to those of the Supplier under the Deed, including the requirement in relation to Subcontracts.
- 18.3 The Supplier's obligations in this **clause 18** are in addition to, and do not restrict, any obligations it may have under:
- 18.3.1 the Privacy Act;

18.3.2 any State or Territory law relating to the privacy of individuals; or

18.3.3 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 the Supplier but for the application of the other provisions of this **clause 18**.

18.4 The Supplier must only make disclosures of Personal Information in accordance with the Privacy Act and any Law.

18.5 This **clause 18** survives the expiration or earlier termination of the Deed.

## **19 Conflict of Interest**

19.1 The Supplier warrants that, at the Commencement Date, no Conflict of Interest exists or is likely to arise in the performance of its obligations under the Deed, by it or its Personnel.

19.2 The Supplier must use its best endeavours (including making all appropriate enquiries) to:

19.2.1 ensure that a situation does not arise that may result in such a Conflict of Interest; and

19.2.2 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 the Supplier in, performing its obligations under the Deed fairly and independently.

19.3 The Supplier must not during the Term, engage in any activity, transaction or arrangement that may 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 the Supplier has complied with **clause 19.4** and the NBA has given its written approval for the Supplier to engage in that activity.

19.4 Where a Conflict of Interest arises in the performance of the Supplier's obligations under the Deed, the Supplier must notify the NBA immediately 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.

## **20 Intellectual Property**

### ***Contract Material***

[Clauses 20.1 to 20.5 not disclosed. These clauses relate to Intellectual Property rights in the Contract Material.]

### ***General***

20.6 If requested by the NBA, the Supplier must bring into existence, sign, execute or otherwise deal with any document which may be necessary to give effect to this **clause 20**.

### ***IP warranty***

20.7 The Supplier warrants that 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 any Contract Material and other Material in the manner provided for in this **clause 20**.

## **21 NBA Material**

21.1 The Supplier acknowledges the NBA's ownership or control by licence of the NBA Material and all Intellectual Property rights in the NBA Material.

21.2 Subject to this **clause 21**, the NBA grants a non-exclusive, non-transferable, royalty-free licence to the Supplier for the Term to use the NBA Material solely for the purpose of providing the Products and performing the Services.

21.3 The NBA will inform the Supplier of any NBA Material provided to the Supplier under the Deed in which third parties hold the Intellectual Property rights, and of any conditions attaching to the use of that NBA Material because of such Intellectual Property rights.

21.4 The Supplier must:

21.4.1 ensure that NBA Material is used, copied, supplied or reproduced only for the purposes of the Deed;

21.4.2 ensure the safe keeping and maintenance of NBA Material; and

21.4.3 use NBA Material strictly in accordance with any conditions or restrictions set out in the Deed, or as detailed or informed by the NBA to the Supplier from time to time.

21.5 On expiration or earlier termination of the Deed, the Supplier must immediately deliver the NBA Material, and any copies of the NBA Material, to the NBA.

## **22 Records**

22.1 The Supplier must keep comprehensive written records and accounts of all matters related to its performance of the Deed, including the supply of the Products and Services, the receipt of Payments, compliance with obligations under the TG Act, the creation of

Contract Material, creation of Intellectual Property rights in connection with the Deed, and in particular, must comply with other specific record keeping obligations specified in, or determined in accordance with the procedures set out in **Schedule 5 (Records and Reports)**.

22.2 The Supplier must ensure that in all material respects all records and accounts:

22.2.1 are true and accurate;

22.2.2 are complete and maintained so as to be up-to-date;

22.2.3 are kept in a manner that permits them to be conveniently and properly audited; and

22.2.4 enable the extraction of all information relevant to the performance of the Deed.

22.3 In addition to the obligations under **clause 22.2**, the Supplier must ensure that all accounts are drawn in accordance with any applicable Australian accounting standards.

## **23 Reports**

23.1 The Supplier must provide the NBA with the reports set out in, or determined in accordance with the process set out in, **Schedule 5 (Records and Reports)**:

23.1.1 which contain the information required by **Schedule 5 (Records and Reports)**; and

23.1.2 at the frequency, and by the due dates, specified in **Schedule 5 (Records and Reports)**.

## **24 Provision of information to the NBA**

### ***Supplier to provide information***

24.1 The Supplier must, at its own expense, immediately provide the NBA with all information in relation to the Products or Services which is reasonably requested by the NBA from time to time.

### ***Form of information***

24.2 The information to be provided under **clause 24.1** must be provided in the form reasonably required by the NBA from time to time.

### ***New Developments***

24.3 The Supplier must ensure the NBA is kept up-to-date on industry trends and new developments, including in technology and methodology, that are, in the Supplier's reasonable opinion, relevant to the Deed.

24.4 The Supplier 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 the Supplier, including:

- 24.4.1 providing written analysis to the NBA of new technology, products or services relevant to the Deed within a reasonable period of time following the introduction of such technology, products or services; and
- 24.4.2 attendance at, and participation in, meetings with the NBA.

### ***Notifiable Events***

24.5 In addition to **clause 24.1**, the Supplier must immediately notify the NBA:

- 24.5.1 if an act or omission of the Supplier, a Subcontractor or its or their Personnel, or any other circumstances, will or may cause a problem or delay that will or may have an impact on the Supplier's ability to provide the Products and Services in accordance with the Deed; and
- 24.5.2 of the Supplier's proposals for managing the problems or delay.

24.6 The Supplier must provide a written report to the NBA immediately upon the occurrence of any of the following events:

- 24.6.1 inability to supply Ordered Product or a Service within the required timeframe;
- 24.6.2 extraordinary circumstances that may affect Product or Service supply or quality;
- 24.6.3 difficulties with Ordering or delivery processes that were unable to be resolved; and
- 24.6.4 a meeting of the Supplier's creditors being held or called;

24.7 The Supplier must ensure that all reports are accurate, complete and not misleading in any respect.

## **25 Access to information and premises and Audit**

### ***Access to information and premises***

- 25.1 The Supplier must grant the NBA, the Auditor-General, the Privacy Commissioner or their nominees, access, as they may require, to the Supplier's premises and data, records, accounts and other financial Material or other Material relevant to the Deed, however and wherever stored or located, under the Supplier's custody, possession or control, for inspection and copying.
- 25.2 In the case of documents or records stored on a medium other than in writing, the Supplier 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.

- 25.3 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 NBA s, Auditor-General's or Privacy Commissioner's functions and powers respectively, may, at reasonable times:
- 25.3.1 access the premises of the Supplier;
  - 25.3.2 require the provision by the Supplier of records and other information which are related to the Deed; and
  - 25.3.3 access, inspect and copy documentation and records or any other matter relevant to the Supplier s obligations or performance of the Deed, however stored, in the custody or under the control of the Supplier.
- 25.4 The Supplier must ensure that any Subcontract entered into for the purpose of the Deed contains an equivalent clause granting the rights specified in this **clause 25** with respect to the Subcontractors' premises, data, records, accounts, financial Material and information and those of its Personnel.
- 25.5 This **clause 25** applies for the term of the Deed and for a period of 7 years from the date of its expiration or termination.
- 25.6 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.
- 25.7** The rights of the NBA, the Auditor-General or a delegate of the Auditor-General or the Privacy Commissioner or a delegate of the Privacy Commissioner 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.

### ***Audit***

- 25.8 The NBA may, from time to time, conduct audits of:
- 25.8.1 the Supplier s practices and procedures as they relate to the Deed, including security procedures;
  - 25.8.2 the manner in which the Supplier performs its obligations under the Deed;
  - 25.8.3 the compliance of the Supplier s invoices and reports with its obligations under the Deed;
  - 25.8.4 the Supplier s compliance with its obligations under the Deed;
  - 25.8.5 the Supplier s compliance with its confidentiality, privacy, security and Commonwealth policy obligations under the Deed; and
  - 25.8.6 any other matters determined by the NBA to be relevant to the performance of the Supplier s obligations under the Deed.

- 25.9 The Supplier must participate in audits of the Deed at the frequency and in relation to the matters specified by the NBA (including on an ad hoc basis if requested by the NBA) for the purpose of ensuring that the Deed is being properly performed and administered.
- 25.10 The NBA may appoint an independent person to assist in audits under this **clause 25**.
- 25.11 Audits under this **clause 25** may consider all aspects of the Supplier's performance including but not limited to any Performance Indicators, benchmarks or targets.
- 25.12 The Supplier must participate promptly and cooperatively in any audits conducted by the NBA or its nominee.
- 25.13 Except for those circumstances in which notice is not practicable or appropriate (for example, caused by a regulatory request with shorter notice or investigation of theft or breach of contract), and without limiting any other right, recourse or remedy of the NBA, the NBA must give the Supplier reasonable notice of an audit and where reasonably practicable an indication of which documents or class of documents the auditor may require.
- 25.14 Each Party must bear its own costs of any audits.
- 25.15 The requirement for, and participation in, audits does not in any way reduce the Supplier's responsibility to perform its obligations in accordance with the Deed.
- 25.16 The NBA must use reasonable endeavours to ensure that audits performed pursuant to this **clause 25** do not unreasonably delay or disrupt in any material respect the Supplier's performance of its obligations under the Deed.
- 25.17 The Supplier must promptly take, at no additional cost to the NBA, corrective action to rectify any error, non-compliance or inaccuracy identified in any audit in the way the Supplier has under the Deed:
- 25.17.1 supplied any Products or Services;
- 25.17.2 maintained any accounts or records; or
- 25.17.3 calculated Payments, or any other amounts or charges billed to or claimed from the NBA.
- 25.18 This **clause 25** survives the expiration or earlier termination of the Deed.

## **26 Public Affairs Management**

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

## **27 Review processes**

### ***The NBA may conduct Reviews***

27.1 The NBA may conduct Reviews in relation to the operation of the Deed. The NBA anticipates that, subject to unforeseen circumstances, it will conduct no more than one Review of the Deed in any calendar year.

### ***Supplier to participate in Reviews***

27.2 The Supplier must, at its own expense:

27.2.1 participate in each Review as is reasonably requested by the NBA; and

27.2.2 within ten Business Days (in the Australian Capital Territory) of a request by the NBA, and in addition to other obligations under the Deed, provide any information, access to records, and advice in relation to the Review requested by the NBA.

### ***Results of the Review***

27.3 Subject to **clause 28.1**, if, in the NBA's opinion, the results of a Review indicate that any changes should be made to the Deed, the NBA must, in accordance with **clause 28** propose one or more changes to the Deed to implement the results of the Review.

27.4 The Parties must negotiate any changes under **clause 27.3** in accordance with **clause 28.1**.

## **28 Variations to the Deed**

### ***General***

28.1 Subject to **clause 28.2**, no change may be made to the Deed without:

28.1.1 prior consultation between the Parties;

28.1.2 the Parties complying in full with the change control procedures included in this **clause 28**, unless agreed otherwise; and

28.1.3 the Parties executing a written agreement to vary the Deed,

unless the Deed expressly provides an alternative method for a change to be made to it.

### ***Change Control***

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

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

28.3.1 the detailed requirements and specifications of the proposal and any change to the Performance Indicators required by the proposal;

28.3.2 any timing implications arising from the proposal;

- 28.3.3 if applicable, the risks and a risk management strategy for the proposal;
  - 28.3.4 the detailed amendments proposed to the Deed (including the Schedules); and
  - 28.3.5 if the change cannot be performed within the existing payment regime in the Deed, as substantiated by the Supplier, the changes to the Payments based on the payment basis set out in **Schedule 4 (Payments and Invoicing)**.
- 28.4 A Party must respond to a proposal provided to it under **clause 28.3** within 15 Business Days (in the Australian Capital Territory).
- 28.5 Subject to **clause 28.5**, the Parties must agree on the proposal under **clause 28.3** within 30 days of the provision of the proposal under **clause 28.3**.
- 28.6 Despite **clause 28.4**, the NBA is not obliged to agree to any proposal made by the Supplier and, in particular, the NBA is not liable for any additional work undertaken or expenditure incurred by the Supplier unless the change has been effected in accordance with the Deed.

## **29 Compliance with Laws**

- 29.1 Without limiting any other clause in the Deed, the Supplier must supply Products and perform Services so as to comply with all applicable Laws, including:
- 29.1.1 all Commonwealth Laws; and
  - 29.1.2 all Australian State and Territory Laws.

## **30 Offences under Crimes Act and Criminal Code 1995**

- 30.1 The Supplier acknowledges that:
- 30.1.1 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 contract 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;
  - 30.1.2 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
  - 30.1.3 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 the Supplier is authorised to publish or disclose the fact or document) may be an offence under sections 70 and 79 of the *Crimes Act 1914*, the maximum penalty for which is seven years' imprisonment.

## **31 Compliance with Commonwealth policies**

- 31.1 The Supplier must, when using the NBA's premises or facilities, comply with 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, as notified by the NBA or as might reasonably be inferred from the use to which the premises or facilities are being put.
- 31.2 The Supplier must comply with all other reasonable policies of the NBA or the Commonwealth which are notified to it from time to time.

## **32 Equal Employment Opportunity**

- 32.1 The Supplier must comply with its obligations, if any, under the *Equal Employment Opportunity for Women in the Workplace Act 1999* (Cth) (the Act).
- 32.2 The Supplier 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.
- 32.3 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.

## **33 Assignment**

### ***Assignment by the Supplier***

- 33.1 The Supplier 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***

- 33.2 The NBA may assign its rights and obligations under the Deed to a third party with the Supplier's consent. The Supplier's consent shall not be unreasonably withheld.

## **34 Further acts**

- 34.1 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.

## **35      Contacts and Notices**

### ***Contacts***

35.1      The relevant contact persons within each Party are specified in **items 3 or 4 of Schedule 1 (Deed Details)**.

### ***Giving notices***

35.2      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:

35.2.1    delivered or posted to that Party at the address for formal notices of **Schedule 1 (Deed Details)**; or

35.2.2    faxed to that Party at its fax number for formal notices in **Schedule 1 (Deed Details)**; or

35.2.3    sent by electronic mail to the address for electronic mail notices in **Schedule 1 (Deed Details)**.

35.3      If a Party gives the other party three Business Days (in the Australian Capital Territory) notice of a change of its postal address, fax number or electronic mail address for formal notices, a notice, consent, information, application or request is only given or made by that other Party if it is delivered, posted, sent by electronic mail, or faxed to the latest address or fax number.

### ***Time notice is given***

35.4      A notice, consent, information, application or request is taken to be received if it is:

35.4.1    delivered by hand, when it is left with Personnel of the other Party at the relevant address;

35.4.2    sent by post, on the third Business Day (in the Australian Capital Territory) after posting;

35.4.3    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 Business Day (in the Australian Capital Territory), otherwise on the next Business Day (in the Australian Capital Territory); or

35.4.4    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.

## Section E: Treatment of Risks

### 36 Principles in relation to the allocation of risk

- 36.1 The Parties agree that the provision of the Products and the performance of the Services gives rise to a range of risks and agree that, as basic principles and subject to this Deed:
- 36.1.1 risks should be borne by the Party best placed to manage those risks; and
  - 36.1.2 each Party is fully liable for the performance of its obligations under this Deed, including obligations in relation to Orders placed under the Deed.
- 36.2 For the avoidance of doubt, the principles expressed in **clause 36.1** do not override or limit the provisions of this Deed.

### 37 Risk Management Plan

- 37.1 The Supplier must within 30 Business Days of the Commencement Date, provide to the NBA a Risk Management Plan that complies with the requirements of this **clause 37**. After the Risk Management Plan is approved by the NBA, it will become part of this Deed.
- 37.2 The Supplier agrees to implement the Risk Management Plan to manage the risks in relation to the Product, including but not limited to risks listed in **item 4 of Schedule 2**. In addition, the Parties at all times, to the extent possible, agree to comply with the requirements or procedures identified in the Risk Management Plan.
- 37.3 The Supplier must notify the NBA of:
- 37.3.1 any new risks which arise during the Term which are not appropriately or adequately dealt with in the Risk Management Plan;
  - 37.3.2 any changes to existing risks in the Risk Management Plan during the Term; and
  - 37.3.3 the Supplier's proposed method for dealing with any new risks or changes to existing risks which arise during the Term.
- 37.4 The Parties must conduct negotiations 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 the Supplier from time to time).

## 38 Indemnities

[Not disclosed. This clause contains information about the indemnities provided under this Deed.]

## 39 Undertakings

### *Financial Undertaking*

- 39.1 The Supplier must, at its expense, provide to the NBA, within 10 Business Days (in the Australian Capital Territory) of the Commencement Date, security in the form of an unconditional and irrevocable financial undertaking (**the Financial Undertaking**) which must be:
- 39.1.1 executed by a financial institution approved by the NBA (**the Financial Institution**) and stamped;
  - 39.1.2 substantially in the form of the undertaking appearing at **Schedule 7 (Financial Undertaking and Performance Guarantee)**; and
  - 39.1.3 for the sum specified in **Schedule 7 (Financial Undertaking and Performance Guarantee)**.
- 39.2 The Financial Undertaking is for the purpose of ensuring the due and proper performance of the Deed by the Supplier and the NBA may demand any sum under the Financial Undertaking from the Financial Institution in respect of:
- 39.2.1 amounts owed to the NBA by the Supplier;
  - 39.2.2 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 its Personnel as a result of a breach of the Deed by the Supplier; and
  - 39.2.3 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 its Personnel that is the subject of an indemnity under the Deed.

### *Performance Guarantee*

- 39.3 The Supplier must, at its expense, provide to the NBA, within 10 Business Days (in the Australian Capital Territory) of the Commencement Date, a performance guarantee guaranteeing the performance by the Supplier of its obligations under the Deed, which must be given by a guarantor specified in, and be substantially in the form of the performance guarantee appearing at, **Schedule 7 (Financial Undertaking and Performance Guarantee)**.
- 39.4 The Supplier acknowledges that the Performance Guarantee may be exercised by the NBA on its own behalf, or on behalf of any Approved Recipients under the Deed

## 40 Insurance

- 40.1 The Supplier must comply with all obligations of **Schedule 6 (Insurance)**.

## **41 Force Majeure**

### ***Force Majeure Event***

- 41.1 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):
- 41.1.1 as a result of an act or event beyond the reasonable control of that Party or its Personnel (Force Majeure Event);and
  - 41.1.2 the Force Majeure Event continues for a period for less than 14 days,
- it must promptly give a notice to the other Party that complies with **clause 41.3**.

[Remainder of clause 41 not disclosed. It contains further Force Majeure requirements.]

## **42 Dispute Resolution**

- 42.1 The Parties undertake to use all reasonable efforts in good faith to resolve any disputes which arise between them in connection with the Deed.
- 42.2 A Party may give the other Party a notice of dispute (**dispute notice**) in connection with the Deed.
- 42.3 Following the giving of a dispute notice under **clause 42.2**, the dispute must initially be referred to the contact officers in **item 5 of Schedule 1 (Deed Details)**, who must use reasonable efforts to resolve the dispute within 10 Business Days (in the Australian Capital Territory) of the giving of the dispute notice.
- 42.4 If the Parties have not been able to resolve the dispute in accordance with **clause 42.2**, then the Parties may agree on a process for resolving the dispute through means other than litigation or arbitration, including by mediation or conciliation.
- 42.5 In the event that the dispute, controversy or claim has not been resolved within 30 Business Days (in the Australian Capital Territory) (or such other period as agreed between the Parties in writing) after the Parties have commenced action to resolve the dispute under **clause 42.2**, then either Party may, if it wishes, commence legal proceedings.
- 42.6 Nothing in this **clause 42** prevents either Party from seeking urgent injunctive relief.

## Section F: Termination and Transition Management

### 43 Termination for Default

- 43.1 Without prejudice to its rights at common law or under any statute, the NBA may, by notice in writing to the Supplier, terminate the Deed immediately in whole or in part (a partial termination being a **Reduction**):
- 43.1.1 as permitted under **clause 41 (Force Majeure)**,
  - or if;
  - 43.1.2 an Insolvency Event occurs in respect of the Supplier;
  - 43.1.3 the Supplier commits a breach of the Deed which is not capable of remedy and which, in the reasonable opinion of the NBA, has a material adverse effect on the benefit of the Deed to the NBA;
  - 43.1.4 the Supplier fails to take action to remedy a breach of another obligation under the Deed and does not commence to remedy the breach within 5 Business Days (in the Australian Capital Territory) after being given notice by the NBA requiring the Supplier to remedy the breach or fails to remedy the breach within 15 Business Days (in the Australian Capital Territory) after being given that notice; or
  - 43.1.5 the Supplier assigns its rights otherwise than in accordance with the requirements of the Deed.
- 43.2 In addition to the NBA's rights under **clause 12**, where, before termination or Reduction of the Deed under **clause 43.1**, the NBA has made any Payment in advance to the Supplier and all or part of that Payment does not relate to Products or Services which have been provided by the Supplier in accordance with the Deed, the portion of that Payment that does not relate to the Products or Services provided must be repaid by the Supplier to the NBA on termination and whether the NBA issues a Repayment Notice under **clause 12** or not, that amount, if not repaid, is recoverable by the NBA from the Supplier as a debt.
- 43.3 If the Deed is terminated under this **clause 43**:
- 43.3.1 subject to the Deed, the Parties are relieved from future performance, without prejudice to any right of action that has accrued at the date of termination;
  - 43.3.2 the NBA's rights to recover damages are not affected;
  - 43.3.3 the Supplier must:
    - (a) deliver any NBA Material, or the NBA Confidential Information held by it to the NBA;

- (b) bear any reasonable fee, expense or charge that is associated with the delivery of such Material by the Supplier to the NBA; and
- (c) comply with all obligations in the Deed relating to NBA Material, Contract Material and other Material referred to in the Deed.

#### **44 Termination by the NBA**

- 44.1 The NBA may, at any time by written notice, terminate the Deed, in whole or in part (a partial termination being a **Reduction**).
- 44.2 Termination or Reduction under **clause 44.1** takes effect on and from the time specified in the notice.
- 44.3 If the Deed is terminated or reduced under **clause 44.1**, the NBA will be liable only for:
  - 44.3.1 Payments for the Products or Services provided before the effective date of termination or Reduction, provided that those Services or Products have, in the NBA's opinion, been provided in accordance with the Deed and the Supplier is not otherwise in breach of the Deed; and
  - 44.3.2 [Not disclosed. This clause relates to the parties' financial obligations in the event of termination or Reduction.]
- 44.4 Where, before termination or Reduction of the Deed under **clause 44.1**, the NBA has made any Payment in advance to the Supplier and all or part of that Payment does not relate to Products or Services which have been provided by the Supplier in accordance with the Deed, the portion of that Payment that does not relate to Products or Services so provided must be repaid by the Supplier to the NBA on termination and, if not repaid, is recoverable by the NBA from the Supplier as a debt.
- 44.5 Upon receipt of a notice of termination or Reduction the Supplier must:
  - 44.5.1 stop the supply of Products and Services as specified in the notice and comply with any other directions or requests included in the notice, in particular in relation to NBA Material, Contract Material and other Material;
  - 44.5.2 comply with all obligations in the Deed relating to NBA Material and Contract Material;
  - 44.5.3 take all available steps to minimise or avoid any loss or damage resulting from that termination or Reduction and to protect NBA Material and Contract Material; and
  - 44.5.4 continue to supply any Products and work on any part of the Services not affected by the notice.
- 44.6 In the event of a Reduction, the NBA's liability to pay Payments will, in the absence of agreement to the contrary, abate proportionately to the reduction in the Products or Services.

44.7 [Not disclosed. This clause relates to the parties' financial obligations in the event of termination or Reduction.]

44.8 [Not disclosed. This clause relates to the parties' financial obligations in the event of termination or Reduction.]

## **45 Transition Management**

45.1 The Supplier must prepare, and provide to the NBA for approval:

45.1.1 a Transition In Plan, by no later than 10 Business Days after the Commencement Date; and

45.1.2 a Transition Out Plan, by no later than 30 Business Days after the Commencement Date.

45.2 The Supplier must implement the Transition In Plan approved by the NBA.

45.3 Upon termination or expiry of the Deed for any reason, the Supplier 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 the Supplier to the NBA or its nominee.

45.4 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 the Supplier must, on request, update the Transition Out Plan in accordance with any reasonable requirements of the NBA.

45.5 The Supplier agrees that it will not hinder in any way, the handover of the provision of services similar to the Services and/or the supply of products similar to the Products to a new service provider upon termination or expiration of the Deed or part of the Deed.

## Section G: Interpretation and Operation of Deed

### 46 Rules of Interpretation

- 46.1 In this Deed, unless otherwise expressly provided, the following rules of interpretation apply:
- 46.1.1 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;
  - 46.1.2 a reference to any agreement or document is to that agreement or document as amended, novated, supplemented or replaced from time to time;
  - 46.1.3 a reference to an item is to an item of the Schedules;
  - 46.1.4 a reference to a clause, item, part, schedule or attachment is a reference to a clause, item, part, schedule or attachment of or to the Deed unless otherwise stated;
  - 46.1.5 an expression importing a natural person includes any company, trust, partnership, joint venture, association, corporation, body corporate or governmental agency;
  - 46.1.6 subject to **clause 54**, if the day on which any act, matter or thing is to be done under this document is not a Business Day, that act, matter or thing may be done on the next Business Day;
  - 46.1.7 a covenant or agreement on the part of two or more persons binds them jointly and severally;
  - 46.1.8 where the context permits, words suggesting the singular number should be read as including the plural and vice versa;
  - 46.1.9 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;
  - 46.1.10 the Schedules and any attachments or annexures form part of the Deed;
  - 46.1.11 all references to „dollars or „\$ are to Australian dollars;
  - 46.1.12 to the extent that there is any inconsistency between anything in:
    - (a) the clauses of the Deed;
    - (b) the Schedules;
    - (c) any attachments or annexures; or
    - (d) an Order,

then, subject to the Deed, the document ranked higher in the list above will prevail; and

- 46.1.13 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”.

## **47 Relationship of the Parties**

### ***No agency or partnership***

- 47.1 No Party is an employee, agent, representative, or partner of the other Party by virtue of the Deed.
- 47.2 A Party must not represent itself, and must ensure that its Personnel do not represent themselves, as being an employee, agent, representative or partner of the other Party.

### ***No authority to act***

- 47.3 No Party has any power or authority to:
- 47.3.1 act for, or to assume any obligation or responsibility on behalf of, the other Party;
  - 47.3.2 bind the other Party to any agreement;
  - 47.3.3 negotiate or enter into any binding relationship for, or on behalf of, the other Party; or
  - 47.3.4 pledge the credit of the other Party,

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

## **48 Costs**

- 48.1 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.

## **49 Entire agreement**

- 49.1 The Deed contains everything the Parties have agreed to in relation to the matters it deals with.
- 49.2 No Party can rely on an earlier document, or anything said or done by another Party, or by any Personnel of that Party, before the Deed was executed, save as permitted by Law.

## **50 Execution of separate documents**

50.1 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.

## **51 Governing law and jurisdiction**

51.1 The Deed is governed by the law of the Australian Capital Territory.

51.2 The Parties submit to the non-exclusive jurisdiction of the courts of the Australian Capital Territory.

51.3 The Parties must not object to the exercise of jurisdiction by the courts of the Australian Capital Territory on any basis.

## **52 Severability**

52.1 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.

52.2 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.

## **53 Waiver**

53.1 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.

53.2 A waiver by a Party is only effective if it is in writing.

53.3 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.

## **54 Time of the essence**

54.1 Time is of the essence in relation to any timing to any obligations in the Deed relating directly to the supply of Products and Services under the Deed.

## Schedule 1 (Deed details)

### Term

Item 1	(Commencement Date):	Date on which this Deed is executed
Item 2	(Commencement of Supply Date):	1 July 2006
Item 3	(Expiry Date):	1 July 2009

### Contacts for delivery of formal notices under the Deed:

Item 3

NBA:

[Not disclosed.]

Supplier:

[Not disclosed.]

### Contacts for resolution of disputes under the Deed:

Item 4

NBA:

[Not disclosed.]

Supplier:

[Not disclosed.]

### Confidential Information

Item 5 No information specified.

## Schedule 2 (Products and Services)

### 1 Products

1.1. The following Products are available for supply under this Deed:

Product	ARTG Number
Advate 1500 IU	Aust R 100387
Advate 1000 IU	Aust R 100386
Advate 500 IU	Aust R 100385
Advate 250 IU	Aust R 100384
Recombinate 1000 IU	Aust R 65848
Recombinate 500 IU	Aust R 65857
Recombinate 250 IU	Aust R 65814
Plasma derived factor VII	Supplied under SAS arrangements
FEIBA	Supplied under SAS arrangements
Ceprotrin 1000 IU	Aust R 104538
Ceprotrin 500 IU	Aust R 104537
WinRho SDF	Aust R 74722

1.2 The Supplier must:

1.2.1 within 5 Business Days of the Commencement Date, notify the NBA in writing of the Supplier's unique identification number, if any, for each Product; and

1.2.2 notify the NBA from time to time of any change in the identification number advised under **item 1.2.1** of this **Schedule 2 (Products and Services)**.

1.3 The Supplier must ensure that the shelf life of each Product at the date of manufacture and at the date of delivery of the Product to an Approved Recipient in accordance with **clause 4.3** is no less than the period set out in the following table:

<b>Product</b>	<b>Shelf life at date of manufacture</b>	<b>Remaining shelf life at date of delivery to Approved Recipient</b>
Advate	24 months	14 months
Recombinate	36 months	20 months
Plasma derived factor VII	24 months	20 months
FEIBA	24 months	4 months
Ceprotin	24 months	4 months
WinRho SDF	24 months	16 months

1.4 The Supplier must include the following information in English in the packaging of each Product:

1.4.1 the Product Information Sheet; and

1.4.2 in addition, if not already detailed in the Product Information Sheet, information on reconstitution and administration of the Product.

1.5 Each dosage strength of the Product must be barcoded with a Global Trade Identification Number (GTIN) in the UCC/EAN 128 barcode format, showing the Product batch number and expiry date.

1.6 All components required for the reconstitution and administration of the Product must be provided at the time of supply of each Product, unless (where practicable) the Approved Recipient has requested otherwise.

1.7 The components required for the reconstitution and administration of each Product are as set out in the following table:

<b>Product</b>	<b>Components for reconstitution and administration</b>
Advate	1 x Water for Injection 1 x BaxJet II needle-less transfer device 1 x 10mL syringe 1 x infusion set butterfly 23G 1 x plaster 2 x alcohol wipes

Recombinate	Water for Injection 1 x needle-less transfer device 1 x 20mL syringe 1 x infusion set 23G 2 x alcohol wipes
Plasma derived factor VII	1 x vial of water for injection 10mL 1 x disposable syringe 1 x transfer needle 1 x filter needle 1 x aeration needle 1 x winged IV infusion set 23G
FEIBA	1 x vial of water for injection 1 x transfer needle 1 x filter needle 1 x aeration needle 1 x infusion set butterfly 23G or 25G
Ceprotin	1 x vial of solvent for reconstitution 1 x transfer needle 1 x filter needle
WinRho SDF	1 x vial 0.9% Sodium Chloride diluent

Alternative or additional components must be supplied free of charge with the Product if requested by the Approved Recipient at the time of Order.

- 1.8 Each dosage strength of Advate and Recombinate must be supplied with packaging and labelling which is colour coded and easily distinguishable and recognisable.

## 2 Australian Valued customer status

2.1 The Supplier agrees to work with its ultimate supplier to:

apply robust production planning process with provision of rolling forecasts and adequate planning lead times as well as holding of sufficient safety inventory of in process materials to ensure the volume of finished products produced will be sufficient to meet aggregate global demand at all times;

ensure that, in the event that international demand for any product exceeds available international supply, the ultimate supplier will guarantee Australia to obtain its fair share of product allocation so that the proportion of back order fulfilled is no worse than that of any other country; and

secure reasonable alternative products at no additional cost in the event that the Supplier is unable to meet its obligations under this Deed to supply Products to Australia.

### **3 Safety and Quality Assurance**

- 3.1 The Supplier must provide, on request from the NBA, a copy of the quality control analysis (including the date of manufacture) that accompanied any deliveries of Product to the Supplier.
- 3.2 The Supplier must ensure that the vial dosage strength of all Products conforms to TGA regulatory specifications and standards, and provide full technical details of the potency assay used to assign the label claim if required to do so by the NBA.
- 3.3 The Supplier must have established processes to ensure quality of product and supply arrangements for the purposes of this Deed that are at least consistent with the requirements of AS/NZ ISO 9001:2000 or ISO 9002:1994.

### **4 Risk Management**

- 4.1 The Supplier must implement and maintain appropriate risk management strategies that will identify, mitigate and control all risks which may affect the supply of the Products including but not limited to risks of:
  - 4.1.1 failure of subcontract arrangements (including alternative subcontract arrangements, performance guarantees etc);
  - 4.1.2 failure to supply Products (including alternative supply arrangements);
  - 4.1.3 Product recall (including strategies to retrieve recalled products and to supply replacement products);
  - 4.1.4 unauthorised access or use of, loss or destruction of, or damage to, Products (strategies to immediately identify damaged products and replace damaged products);
  - 4.1.5 delivery failure (strategies to immediately identify delivery failure and implement alternative suitable delivery arrangements);
  - 4.1.6 theft of Products (appropriate security arrangements including security of premises and delivery arrangements and arrangements to provide replacement of product); and
  - 4.1.7 fraud.
- 4.2 The Risk Management Plan must also incorporate a disaster/emergency action plan, which sets out:
  - 4.2.1 the steps which the Parties will take in the event of a disaster or emergency occurring;
  - 4.2.2 the responsibilities of each Party, and particularly the Supplier, and the tasks to be performed; and

- 4.2.3 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.

## **5 Approved Recipients**

- 5.1 Approved Recipients for the Products are any person who is determined by the NBA and notified in writing to the Supplier.
- 5.2 The Supplier must allocate a unique identifying number to each Approved Recipient, and must notify the NBA of that number in accordance with **Schedule 5 (Records and Reports)**.
- 5.3 The NBA will notify the Supplier following the Commencement Date and during January and July of each year commencing January 2007 of its list of Approved Recipients.
- 5.4 The Supplier will check that list and notify the NBA of any amendments necessary within 14 business days.

## **6 Orders**

- 6.1 The Supplier must only accept an Order from an Approved Recipient.
- 6.2 An Order must be able to be received by the Supplier as either a phone, fax or email request from the Approved Recipient 24 hours, 7 days a week, each day of the year, with customer service personnel on 24 hour “on call” availability.
- 6.3 The Supplier must not accept an Order from an Approved Recipient unless it can substantiate:
  - 6.3.1 date of order;
  - 6.3.2 the name of the Product to be delivered by the Supplier;
  - 6.3.3 the Item Number of the Product to be delivered by the Supplier;
  - 6.3.4 the quantity of Product to be delivered by the Supplier;
  - 6.3.5 the Product dosage strength required by the Approved Recipient;
  - 6.3.6 the name of the Approved Recipient;
  - 6.3.7 the timeframe for delivery specified in the Order;
  - 6.3.8 if the Order is specified as being an urgent Order, that there are reasonable grounds for the urgency; and
  - 6.3.9 the shipping address details as follows:

[Not disclosed. Contains data format.]

6.4 The Supplier must allocate a unique identifier to each Order for traceability.

## **7 Delivery**

7.1 The Supplier must:

7.1.1 maintain a 24 hours, 7 day a week delivery service; and

7.1.2 comply with the delivery requirements specified in the Order to ensure delivery of Product ordered to metropolitan and regional delivery points, including hospitals, clinicians and home deliveries anywhere in Australia.

7.2 The Supplier must meet the following timeframes for supply of the Product upon acceptance of an Order:

7.2.1 in the timeframe specified in an Order or as soon as practicable thereafter, or in any case by no later than 24 hours from receipt of the Order, for an Order specified as urgent by the person making the Order; or

7.2.2 in all other cases, delivery within no more than 48 hours of a receipt of an Order, or where the Order is made on a Friday then the next Business Day in the place which the Approved Recipient is located.

## **8 Acceptance of the Product**

8.1 The Supplier ensure all times that the Approved Recipient signs for or otherwise acknowledges the receipt of the Product received by the Approved Recipient, and must retain such acknowledgment.

8.2 The Supplier must comply with any reasonable instructions issued in writing by the NBA from time to time about the matters specified in this **item 7** of this **Schedule 2 (Products and Services)**.

## **9 Quantity and dosage strength of Product**

9.1 The Product must be able to be provided in the quantity and dosage strength specified in an Order by an Approved Recipient

## **10 Supply of Product strengths**

10.1 The Supplier must supply the Product in a combination of Products strengths that is most efficient to meet the requirements of an Order.

## **11 Overseas Supply**

11.1 The Supplier agrees to use reasonable endeavours to assist in making the Product accessible to Australians overseas under this Deed, dependant on local laws and regulations, through its network of affiliates, through relationships with prescribers, and by providing contact details for haemophilia treatment centres and national haemophilia organisations throughout the world .

## 12 In-country Inventory

12.1 The Supplier must establish, maintain, store, safeguard, manage and deal with a reserve of Products (the In-country Inventory) in Australia available for supply under this Deed, in an amount determined in accordance with **items 12.3 and 12.4** of this **Schedule 2 (Products and Services)**.

12.2 The NBA must convene, and the Supplier must participate in, a 6-monthly review process to review levels of each Product supplied during the previous 6 months in order to determine the In-country Inventory stock to be held by the Supplier for the following 6-months (commencing in respect of the 6 months beginning January 2007).

12.2.1 This review process will include usage, expiry and pricing related matters for WinRho as well as opportunities to improve the shelf life at delivery to Approved Recipients for Advate.

12.3 The final volumes of Product (which may be specified by Product size) to be held in the In-country Inventory by the Supplier in each 6 month period will be as determined by the NBA and notified to the Supplier (acting reasonably and taking into account the review under **item 12.2** of this **Schedule 2 (Products and Services)**), and may be no more than 25% of the estimated annual demand for each Product as determined through the review.

12.4 The Supplier must, prior to the Supply Commencement Date, establish the levels of In-country Inventory set out in the following table to be held for the 6 month period commencing on 1 July 2006:

<b>Product</b>	<b>In-Country Inventory level for 6 month period commencing on 1 July 2006</b>
Advate / Recombinate Total	[Not disclosed]
Plasma derived factor VII	[Not disclosed]
FEIBA	[Not disclosed]
Ceprothin	[Not disclosed]
WinRho SDF	[Not disclosed]

12.5 The use of WinRho, unless otherwise agreed by the NBA, is for access to an intravenous (IV) Rh D Ig preparation (WinRho). Some of the indications for such use include inadvertent or emergency transfusion of Rh(D) positive blood to an Rh(D) negative female of childbearing potential, or as a result of a large foetal maternal haemorrhage.

12.5.1 Due to the potential limited availability of WinRho by the Supplier during the first six months from Commencement of Supply Date, the Parties agree that this Product will be subject to Intensive Product Management in accordance with **clauses 4.13 and 4.14** in order to ensure supply during this period.

- 12.6 Within five business days of Commencement Date, the Supplier and the NBA must agree on a formula for the relative proportions of Advate and Recombinate to be held in the In-country Inventory for the six month period commencing 1 July 2006. The agreed formula for the relative proportions of the Advate and Recombinate is to be based on the Supplier's estimate of the proportional take-up of Advate on a month by month basis for the six month period commencing 1 July 2006. Taken together, the total IUs for Advate and Recombinate must not be less than the total shown in the Table at **item 12.4** above.
- 12.7 The Supplier may only supply Product held in the In-Country Inventory:
- 12.7.1 for supply in accordance with Orders under this Deed, if the Supplier has received the NBA's prior written approval for the supply;
  - 12.7.2 for stock rotation (that is, where at least an equivalent number of units of Product are placed in In-country Inventory as are taken from the In-country Inventory for supply), under a stock rotation management plan developed by the Supplier approved by the NBA, to ensure that all Products held in In-country Inventory comply with **item 1.3** of this **Schedule 2 (Products and Services)**; or
  - 12.7.3 if, in the Supplier's reasonable opinion, the Product is required in an emergency situation, and no other units of Product are reasonably available to be supplied or otherwise made available to meet that emergency.
- 12.8 In the event that units of Product are supplied from the In-country Inventory for the purposes of **items 12.7.1** or **12.7.3** of this **Schedule 2 (Products and Services)**, the Supplier must promptly:
- 12.8.1 notify the NBA that the supply has taken place; and
  - 12.8.2 initiate action to reinstate the In-country Inventory to the level required under this **item 12** of **Schedule 2 (Product and Services)** in accordance with this Deed and as soon as is reasonably practicable, and in any case must achieve reinstatement within 20 Business Days of the last occurring supply of Product from the In-country Inventory for the purposes of **items 12.5.1** or **12.5.3** of this **Schedule 2 (Product and Services)**.
- 12.9 The NBA may from time to time notify the Supplier (after reasonable consultation with the Supplier), and the Supplier must comply with, protocols to apply under this Deed in relation to the processes for:
- 12.9.1 the Supplier seeking and receiving the NBA's approval under **item 12.7.1** of this **Schedule 2 (Product and Services)**; and
  - 12.9.2 the Supplier notifying the NBA of supply in accordance with **item 12.8.1** of this **Schedule 2 (Product and Services)**.

### 13 Storage

- 13.1 The Supplier must maintain temperature alarmed and monitored cool rooms in which to store Products, and have arrangements in place with third party logistics providers should additional capacity be required.
- 13.2 The Supplier must maintain a national warehousing, cold chain transport and customer service network which covers all areas of Australia.
- 13.3 The Supplier must, on request by the NBA, provide the following information on each Product storage location.

Name	Name of storage facility
Store type	
Suburb/Town	location of the facility
State	
Postcode	
Phone No	Phone Number of Store
Fax No	Fax Number of Store

### 14 Product Support

- 14.1 The Supplier agrees to provide the following Product support in the form of training programs:
- 14.1.1 conduct a training and education needs assessment with Haemophilia Treatment Centre Nurses within six months of the Commencement of Supply Date;
  - 14.1.2 develop a draft training and education and support program based on the identified needs assessment, and provide this training package to the NBA as part of the background material for the program;
  - 14.1.3 review the draft program, including the development of a pilot program, and the associated implementation plan with the NBA within six months of the Commencement of Supply Date; and
  - 14.1.4 commencing with the conduct of a pilot program, implement the training program as part of an 18 month implementation plan.

### **Schedule 3 (Performance Measures)**

[Not disclosed. Schedule 3 describes the Key Performance Indicators and the financial implications of the Supplier's failure to meet the performance targets.]

## Schedule 4 (Payments and Invoicing)

### 1 Product price

1.1. The Prices for the Products under this Deed are as set out in the following table:

<b>Product</b>	<b>Price (including GST) from 1 July 2006 to 30 June 2007</b>	<b>Price (including GST) from 1 July 2007 to 30 June 2008</b>	<b>Price (including GST) from 1 July 2008 to 30 June 2009</b>
Advate 1500 IU	[ Not disclosed.]		
Advate 1000 IU	[ Not disclosed.]		
Advate 500 IU	[ Not disclosed.]		
Advate 250 IU	[ Not disclosed.]		
Recombinate 1000 IU	[ Not disclosed.]		
Recombinate 500 IU	[ Not disclosed.]		
Recombinate 250 IU	[ Not disclosed.]		
Plasma derived factor VII	\$2.365/IU	\$2.365/IU	\$2.365/IU
FEIBA	[ Not disclosed.]		
Ceprotrin 1000 IU	\$2365.00	\$2365.00	\$2365.00
Ceprotrin 500 IU	\$1182.50	\$1182.50	\$1182.50
WinRho SDF	\$0.253/IU	\$0.253/IU	\$0.253/IU

### 2 Invoicing

- 2.1 The Supplier may be invoiced monthly in arrears based on the volume of Product supplied under this Deed during the relevant month.
- 2.2 The Supplier must provide a tax invoice within 14 Business Days of the end of each calendar month. This invoice must be in the form of a digital data file (using a software program reasonably acceptable to the NBA) in the form of a tax invoice and a schedule to the tax invoice, in accordance with this Schedule. The Supplier must also provide supporting documentation in accordance with this Schedule.

- 2.3 The digital data file referred to in **item 2.2** of this **Schedule 3 (Payments and Invoicing)** must be a tax invoice that summarises the data on the spread sheet titled [Not disclosed.] referred to in **item 2.4** of this **Schedule 3 (Payments and Invoicing)**, and must contain the following:
- 2.3.1 Supplier s Name, Address and Australian Business Number;
  - 2.3.2 tax Invoice date and number;
  - 2.3.3 the month covered by the Tax Invoice;
  - 2.3.4 bank account details (name BSB and account Number) for electronic funds transfer; and
  - 2.3.5 the following information for each Product:
    - (a) unique Product identifier;
    - (b) Product name and volume;
    - (c) price of Product excluding GST;
    - (d) quantity of Product summarised from spread sheet BILEP020;
    - (e) value of Product (ie quantity multiplied by Product price);
    - (f) GST applicable; and
    - (g) line total;
  - 2.3.6 total value, total GST and tax Invoice total;
  - 2.3.7 general ledger account number (supplied by the NBA);
  - 2.3.8 cost centre number (supplied by the NBA); and
  - 2.3.9 any other requirement for a valid Tax Invoice under the GST law.

### **Schedule to Tax Invoice**

- 2.4 The tax invoice referred to in **item 2.2** of this **Schedule 3 (Payments and Invoicing)** must be accompanied by a digital work sheet titled [Not disclosed.], and containing the following:

[Not disclosed. Describes format of digital work sheet.]

### **3 Payment**

- 3.1 Payment will be made by the NBA to the Supplier upon receipt by the NBA of a Tax Invoice, in accordance with **clause 9** and subject to the satisfactory supply of the

Product and performance of the Services by the Supplier (including in meeting any Performance Indicators for the Product and Services), as determined by the NBA.

- 3.2 Subject to the Deed, the NBA must make payments 30 days from submission of a correctly rendered Tax Invoice.

## Schedule 5 (Records and Reports)

### 1 Recordkeeping

- 1.1 Without limitation to **clause 22**, the Supplier must retain the following records:
- 1.1.1 original order documentation;
  - 1.1.2 shipping documentation;
  - 1.1.3 copies of signed delivery receipts;
  - 1.1.4 copies of invoices; and
  - 1.1.5 copies of all contact details of Approved Recipients.
- 1.2 The Supplier must retain all records in relation to Products or Services provided under this Deed for a period of 20 years.

### 2 Regular reporting

- 2.1 Within 14 Business Days of the commencement of each month, the Supplier must provide an report in electronic form to the NBA regarding the previous month which details:
- 2.1.1 achievement or otherwise of the requirements of each Order including Product/s either withdrawn, incorrectly supplied, recalled, lost, damaged or destroyed;
  - 2.1.2 the supply of any Product Ordered on an urgent basis under **item 7.2.1 of Schedule 2 (Products and Services)**;
  - 2.1.3 the maintenance of In- country Inventory as required under **item 12 of Schedule 2 (Product and Services)**, to be reported in an MS Excel spreadsheet as below: [Not disclosed]
  - 2.1.4 achievement or otherwise of the Key Performance Indicators;
  - 2.1.5 any complaints received or problems faced by the Supplier in the supply of the Product or otherwise in complying with its obligations under the Deed, including how such complaints or problems have been managed and resolved;
  - 2.1.6 copies of any adverse drug reaction reports notified by the Supplier to the TGA;
  - 2.1.7 details (dates and locations) of Product Support provided;

2.1.8 summary details of all Subcontracts entered into by the Supplier, or material changes to subcontracts, during the previous month, including the following:

- (a) identity of the Subcontractor (trading name, company or other organisational name, ABN or ACN, country of incorporation or establishment);
- (b) general purpose and nature of goods/services to be provided under the Subcontract; and
- (c) period of Subcontract; and

2.1.9 for any specific item of the report, provides a nil response when appropriate.

### 3 Approved Recipient details

3.1 The Supplier must, on request from the NBA or promptly after allocating a new Approved Recipient number, notify the NBA of contact details and Approved Recipient numbers allocated by the Supplier for Approved Recipients, including the following information:

Approved Recipient number:	
Organisation Name:	Business name
Organisation Sub Unit:	Additional qualifying information on business unit
HIC Provider No. (if applicable)	Complete if applicant is a doctor with an HIC provider number
Title	(Mr/Mrs/Miss/Ms/Dr/Prof):
Last Name	Last name of contact person
First Name:	
Unit/Building/Floor/Department:	Qualifying information on Address
Suburb/Town/City:	
State/Territory:	
Post Code:	
Facsimile Number:	
Email Address:	

## **Schedule 6 (Insurance)**

[Not disclosed. However, the Supplier must maintain the following types of insurance:

All risks material damage and business interruption;

Generally liability including personal injury and product liability;

Professional indemnity; and

Workers' compensation.]

The Supplier must provide evidence of the currency and consistency of its insurance with the above requirements when requested by the NBA.

## **Schedule 7 (Financial Undertaking and Performance Guarantee)**

[Not disclosed. Schedule 7 contains details of the financial undertaking and performance guarantee under this Deed.]

**Executed as a Deed:**

SIGNED SEALED AND DELIVERED for and on behalf of the  
COMMONWEALTH OF AUSTRALIA on:

.....  
*Date*  
by:

.....  
Alison Turner  
.....  
*Signature of authorised officer*

.....  
*Position of authorised officer*  
in the presence of:

.....  
*Name of witness*  
.....  
*Signature of Witness*

SIGNED SEALED AND DELIVERED for and on behalf of  
BAXTER HEALTHCARE PTY LIMITED ABN 43 000 392 781 on:

.....  
*Date*  
by:

.....  
*Name of authorised officer*  
.....  
*Signature of authorised officer*

.....  
*Position of authorised officer*  
in the presence of:

.....  
*Name of authorised officer*  
.....  
*Signature of authorised officer*

.....  
*Position of authorised officer*