

Defined Blood Products Deed

Commonwealth of Australia

Novo Nordisk Pharmaceuticals Pty Ltd

Edited version for publication on NBA website

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

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

Table of contents

Parties.....	5
Background.....	5
THE PARTIES AGREE AS FOLLOWS	5
Section A: Interpretation and Term.....	5
1 Definitions	5
2 Rules of Interpretation	10
3 Term.....	10
Section B: Relationship Management	11
4 Relationship of the Parties	11
5 Provision of information to the NBA	11
6 Contacts and Notices.....	12
7 Review processes	13
8 Public Affairs Management	13
9 No provision of medical advice	14
10 Variations to this Deed	14
11 Subcontracting	15
12 Personnel	16
Section C: Product/Services obligations	18
13 Provision of Product and Services	18
14 Records and Reports	22
15 Compliance with Laws.....	23
16 Obligations under Therapeutic Goods Act	23
17 Safety and Quality Assurance.....	26
18 Performance Requirements	26
Section D: Payment obligations.....	28
19 Payments to be made by the NBA	28
20 Taxes	29
21 Invoicing Obligations.....	30
22 Recovery of moneys by the NBA.....	30
23 Right of Set Off	31
Section E: Ownership Issues	32
24 Passing of Ownership and Risk.....	32
25 Intellectual Property.....	32

26	NBA Material	33
	Section F: Protection of Information	34
27	Confidentiality	34
28	Data Security	35
29	Privacy.....	36
30	Conflict of Interest.....	38
	Section G: Treatment of Risks	40
31	Principles in relation to the allocation of risk.....	40
32	Risk Management Plan	40
33	Warranties	41
34	Indemnities	42
35	Performance Guarantee.....	42
36	Insurance	43
37	Force Majeure	43
	Section H: Other Commonwealth requirements.....	44
38	Records	44
39	Access to information and premises.....	44
40	Audit	45
41	Offences under Crimes Act and Criminal Code 1995	47
42	Compliance with Commonwealth policies.....	48
43	Equal Employment Opportunity.....	48
	Section I: Termination and Disputes	49
44	Termination for Default.....	49
45	Termination for Changes in Government Policy.....	50
46	Dispute Resolution.....	51
	Section J: Miscellaneous	53
47	Assignment.....	53
48	Costs	53
49	Entire agreement	53
50	Execution of separate documents	53
51	Further acts.....	53
52	Governing law and jurisdiction	54
53	Severability	54
54	Waiver.....	54
55	Time of the essence	54
56	No export sale of Product.....	54

Schedule 1 (Interpretation and Dates)	55
Schedule 2 (Product and Services)	58
Schedule 3 (Performance Measures)	68
Schedule 4 (Payments and Invoicing)	69
Schedule 5 (Records and Reports)	71
Schedule 6 (Contacts)	81
Schedule 7 (Public affairs management)	82
Schedule 8 (Insurance)	83
Schedule 9 (Performance Guarantee)	84

Parties

THIS DEED is made on _____ day of _____ 2006

BETWEEN

Commonwealth of Australia represented by the National Blood Authority, a statutory authority established by the *National Blood Authority Act 2003* of 19-23 Moore Street, TURNER, Australian Capital Territory, 2612 (**the NBA**)

and

Novo Nordisk Pharmaceuticals Pty Ltd ABN 40 002 879 996 of Level 3, 21 Solent Circuit, BAULKHAM HILLS, New South Wales, 2153 (**Supplier**)

Background

- A. The NBA requires the provision of certain Products and Services, including certain defined blood plasma-derived and recombinant products, in connection with its primary objective 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 Commonwealth funds.
- B. The Supplier has agreed to provide the Product and Services, and the NBA has agreed to make the Payments for the Product and Services, in accordance with the terms and conditions of this Deed.

THE PARTIES AGREE AS FOLLOWS

Section A: Interpretation and Term

1 Definitions

1.1 In this Deed, unless the contrary interpretation appears:

Deed means this deed, including the Schedules.

Approved Recipients means:

- (a) those persons who are specified in or determined under **item 5 of Schedule 2 (Product and Services)**; or
- (b) a person specified in an Order by a person under paragraph (a) above as the person to whom a Product must be delivered.

Business Day means a day that is not a Saturday, Sunday or a public holiday in the Australian Capital Territory.

Commencement Date means the date set out in **item 1 of Schedule 1 (Interpretation and Dates)**.

Commonwealth means the Commonwealth of Australia.

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

- (a) is designated by a Party as confidential; or
- (b) a Party knows or ought to know is confidential,

and includes the Contract Material, but does not include information which is or becomes public knowledge other than by breach of this Deed. The Parties agree that the terms and conditions of the Deed are not Confidential Information, except for the following matters which are deemed to be Confidential Information:

- (c) [Not disclosed.]

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 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 Product or the performance of the Services, whether through corporate, professional or personal relationships or otherwise.

Contract Material means all Material:

- (a) brought into existence by or on behalf of the Supplier for the purpose of performing its obligations under this Deed;
- (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).

Expiry Date means the date set out in **item 2 of Schedule 1 (Interpretation and Dates)**.

Financial Year means a year beginning on 1 July and ending on the following 30 June.

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

Insolvency Event, in respect of a Party, means the occurrence of:

- (a) a meeting of that Party's creditors being held or called for the purpose of discussing that Party's solvency;
- (b) the appointment of a liquidator, provisional liquidator or administrator to that Party;
- (c) the appointment of a controller (as defined in section 9 of the *Corporations Act 2001*) or analogous person appointed to that Party or any of its property;
- (d) that Party failing to comply, under paragraph 459F(1) of the *Corporations Act 2001*, with a statutory demand;
- (e) that Party being unable to pay its debts as they fall due or otherwise becoming insolvent;
- (f) that Party ceasing to exist, for whatever reason, or otherwise becoming incapable of managing its own affairs for any reason;
- (g) that Party taking any step that could result in that Party becoming insolvent under administration (as defined in section 9 of the *Corporations Act 2001*);
- (h) any action being commenced to bankrupt or wind-up the affairs of that Party; or
- (i) that Party 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 this Deed in Australia or elsewhere.

Item Number means an Item Number referred to in **item 2 of Schedule 2 (Products and Services)**.

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 includes the common law and any applicable industry codes of conduct.

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 (other than Product), information and data stored by any means.

[Not disclosed]

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 includes any department or authority which may from time to time have responsibility for the administration of the Deed on behalf of the Commonwealth.

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

Order means an order for the Product or Services placed under this Deed as set out in **clause 13.3**.

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 provision of the Product or the provision of the Services by the Supplier, or otherwise under this Deed, and which are set out or described in **Schedule 4 (Payments and Invoicing)**.

Performance Indicators means the performance indicators for the Product and Services which are set out in, or established in accordance with the process set out in, **Schedule 3 (Performance Measures)**.

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.

person includes any type of entity or body of persons, whether or not it is incorporated or has a separate legal entity and any executor, administrator or successor in law of the person.

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

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

Price means the price per Product determined in accordance with **Schedule 4 (Payments and Invoicing)**.

Product means the product to be provided by the Supplier under this Deed and which is specified in or, determined in accordance with the process set out in, **item 1 of Schedule 2 (Product and Services)**, and includes packaging material, labelling material and all documentation relating to the Product except any documentation created solely for the purpose of the Deed.

Risk Management Plan means the plan referred to in **clause 32**.

Safety and Quality Assurance Requirements means the quality assurance requirements, including safety and quality requirements, to be met by the Supplier and set out in, or agreed between the Parties in accordance with the process set out in, **Schedule 2 (Product and Services)**.

Services means the services to be provided by the Supplier under this Deed which are specified in, or determined in accordance with the process set out in, **Schedule 2 (Product and Services)** and includes other activities (if any) undertaken by the Supplier under **clause 13**.

Subcontract means any contract by which the Supplier brings about the provision of the Product or the performance of Services by another person, for the purpose of fulfilment of the Supplier's obligations under this Deed.

Subcontractor means a person to whom the Supplier has subcontracted the performance of any part of this Deed.

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

TG Act means the *Therapeutic Goods Act 1989 (Cth)* and all regulations and other subordinate legislation or instruments made under that Act as amended from time to time.

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 Rules of Interpretation

- 2.1 The rules set out in **Schedule 1 (Interpretation and Dates)** apply to the interpretation of this Deed.

3 Term

- 3.1 This Deed commences on the Commencement Date, and continues until the Expiry Date or until terminated in accordance with this Deed (whichever is the earlier).
- 3.2 Subject to **clause 3.3**, the NBA may, by notice in writing to the Supplier at least 9 months prior to the Expiry Date, extend the Term for a period of between one and three years from the Expiry Date.
- 3.3 If, three months prior to the Expiry Date, the Parties have not agreed the terms and conditions to apply following the Expiry Date, including but not limited to any term or condition relating to price, then, despite any notice by the NBA under **clause 3.2**, the Deed terminates on the Expiry Date.

Section B: Relationship Management

4 Relationship of the Parties

Principles guiding the relationship of the parties

- 4.1 The Parties recognise that their mutual objectives under this Deed are consistent and, in order to maximise achievement of the objectives of this Deed, intend to act towards each other on the basis of the following principles:
- 4.1.1 recognising the importance of maintaining an open and communicative relationship;
 - 4.1.2 identifying, managing and mitigating risks within their control;
 - 4.1.3 conducting themselves in a spirit of co-operation and good faith; and
 - 4.1.4 being flexible and realistic in managing the Deed and complying in full with procedures established under the Deed.
- 4.2 For the avoidance of doubt, the principles expressed in **clause 4.1** do not override or limit the provisions of this Deed.

No agency or partnership

- 4.3 No Party is an employee, agent, representative, or partner of the other Party by virtue of this Deed.
- 4.4 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

- 4.5 No Party has any power or authority to act for or to assume any obligation or responsibility on behalf of the other Party, bind the other Party to any agreement, negotiate or enter into any binding relationship for or on behalf of the other Party or pledge the credit of the other Party, except as specifically provided in this Deed or by express agreement between the Parties.

5 Provision of information to the NBA

Supplier to provide information

- 5.1 Subject to **clause 5.3**, the Supplier must, at its own expense, as soon as is practicable, provide the NBA with all information in relation to the Services or the Product, which is reasonably requested by the NBA from time to time.

Form of information

- 5.2 The information to be provided under **clause 5.1** must be provided in the form reasonably required by the NBA from time to time.

Commercially sensitive information

- 5.3 [Not disclosed.]

6 Contacts and Notices

Contacts

- 6.1 The relevant contact persons within each Party are specified in **Schedule 6 (Contacts)**.

Giving notices

- 6.2 A notice, consent, information, application or request that must or may be given or made to a Party under this Deed is only given or made if it is in writing and:
- 6.2.1 delivered or posted to that Party at the address for formal notices in **Schedule 6 (Contacts)**;
 - 6.2.2 faxed to that Party at its fax number for formal notices in **Schedule 6 (Contacts)**; or
 - 6.2.3 sent by electronic means to that Party at its e-mail address for formal notices in **Schedule 6 (Contacts)**.
- 6.3 If a Party gives the other Party 3 Business Days' notice of a change of its address or fax number for formal notices, a notice, consent, information, application or request is only given, or made, by that other Party if it is delivered, posted, faxed or sent by electronic means to the latest address or fax number or e-mail address.

Time notice is given

- 6.4 A notice, consent, information, application or request is taken to be received:
- 6.4.1 if it is delivered by hand, on the day of delivery if that is a Business Day, otherwise on the next Business Day;

- 6.4.2 if it is sent by post, on the third Business Day after posting;
- 6.4.3 if it is 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, otherwise on the next Business Day; or
- 6.4.4 if sent by electronic communication, at the time the sender receives notification that the notice has been transmitted satisfactorily

7 Review processes

NBA may conduct Reviews

- 7.1 The NBA may conduct a review in relation to the operation of this Deed (a **Review**).
- 7.2 A Review will not be conducted more than annually.
- 7.3 The NBA must:
 - 7.3.1 consult with and notify the Supplier in writing in relation to the timing and scope of a Review;
 - 7.3.2 after taking into account any matters raised by the Supplier, notify the Supplier of the scope of each Review; and
 - 7.3.3 confine each Review to the scope notified to the Supplier under **clause 7.3.2**.

Supplier to participate in Reviews

- 7.4 The Supplier must, at its own expense:
 - 7.4.1 participate in each Review as is reasonably requested by the NBA; and
 - 7.4.2 subject to **clauses 39.8 to 39.11** provide to the NBA any information or documents reasonably requested by the NBA for the purpose of the Review, within 10 Business Days of receiving the request.

8 Public Affairs Management

- 8.1 Each Party agrees to comply with the requirements of **Schedule 7 (Public Affairs Management)** in relation to all public announcements and the management of public affairs in relation to matters arising under or in connection with this Deed.

8.2 Subject to **clause 8.3** and **clause 27**, the Supplier acknowledges that the Deed may be published on the NBA website, and agrees to co-operate with the NBA to facilitate this process.

8.3 [Not disclosed]

9 No provision of medical advice

9.1 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 this Deed, unless that advice is given by a person who is qualified, competent and legally permitted to give that advice.

10 Variations to this Deed

General

10.1 No change may be made to this Deed without:

10.1.1 prior consultation between the Parties;

10.1.2 the Parties complying in full with the change control procedures included in this **clause 10**; and

10.1.3 the Parties executing a written agreement to vary this Deed;

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

Change Control

10.2 Either Party may propose a change to any part of this Deed. A proposal may include a proposal for the addition or removal of the Product or Services from the operation of this Deed.

10.3 For any such proposal, the proposer must provide detailed written information to the other Party about, and the Parties must agree, as appropriate, on:

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

10.3.2 any timing implications arising from the proposal;

10.3.3 the risks and a risk management strategy for the proposal;

- 10.3.4 the detailed amendments proposed to this Deed (including the Schedules); and
- 10.3.5 the changes to the Payments based on the payment basis set out in **Schedule 4 (Payments and Invoicing)** if the proposal cannot be performed within the existing payment regime in this Deed.
- 10.4 A Party must respond to a proposal submitted to it under **clause 10.3** within 10 Business Days.
- 10.5 Neither Party is obliged to agree to any proposal made by the other Party and, in particular, is not liable for any additional work undertaken or expenditure incurred by the other Party unless the change has been effected in accordance with this Deed.

New Developments

- 10.6 In addition to **clause 13.6**, but subject to **clause 10.8**, the Supplier must keep the NBA up-to-date on trends and new developments, including in technology and methodology, that are, in the Supplier's reasonable opinion, relevant to this Deed.
- 10.7 Subject to **clause 10.8**, the Supplier must actively participate, at no additional cost to the NBA, in activities related to this Deed or the subject matter of this Deed (including planning, policy development and public health investigation activities) as reasonably requested by the NBA, including:
 - 10.7.1 providing written analysis to the NBA of new technology or products or services relevant to this Deed within a reasonable period of time following the introduction of such technology products or services; and
 - 10.7.2 attendance at, and participation in, meetings with the NBA.
- 10.8 Despite **clauses 10.6** and **clause 10.7**, the Supplier is not required to provide any information to the NBA regarding trends or new developments that are, in the Supplier's reasonable opinion, commercially sensitive or which relate to a competitor's product.
- 10.9 [Not disclosed]

11 Subcontracting

- 11.1 The Supplier agrees, in relation to any Subcontract:
 - 11.1.1 to ensure that the Subcontract is appropriate, and is appropriately administered by the Supplier, to ensure the proper performance of the Supplier's obligations under this Deed; and

- 11.1.2 that notwithstanding the Subcontract, the Supplier remains fully responsible for the performance of this Deed.
- 11.2 The Supplier agrees to notify the NBA of Subcontracts in accordance with **Schedule 5 (Records and Reports)**.
- 11.3 Where the NBA notifies the Supplier of any reasonable concern about the performance or suitability of a Subcontractor in relation to Products or Services under this Deed, the Supplier must:
 - 11.3.1 have regard to the concerns raised by the NBA; and
 - 11.3.2 notify the NBA of, and implement, actions reasonably acceptable to the NBA to investigate and if necessary address the matter of concern.

12 Personnel

Employer obligations

- 12.1 Any Personnel of the Supplier providing the Product or performing Services on behalf of the Supplier under this Deed is and remains at all times an employee, independent contractor or agent of the Supplier.
- 12.2 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 2001*) in respect of its Personnel.
- 12.3 The Supplier indemnifies the NBA in respect of:
 - 12.3.1 any payment which the NBA is required to make (including but not limited to payments under the *Superannuation Guarantee (Administration) Act 1992*, 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 this 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
 - 12.3.2 any failure of the Supplier to comply with **clause 12.2**.

Warranty as to qualifications of Supplier's Personnel

- 12.4 The Supplier warrants to the NBA that:
 - 12.4.1 the Supplier and its Personnel have the necessary skills, competence, experience and ability to provide the Product and perform the Services required under this Deed; and

- 12.4.2 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 the Product and performance of Services under this Deed are true and not misleading.
- 12.5 If, at any time, the Supplier is unable to provide appropriately qualified Personnel to provide the Product and perform the Services under this Deed, such an inability is a breach of this Deed within the meaning of **clause 44.1.3** and the NBA may terminate this Deed in accordance with **clause 44**.

Section C: Product/Services obligations

13 Provision of Product and Services

Australian supply commitment

- 13.1 The Supplier agrees to:
- 13.1.1 take specific measures to ensure the planned supply of Product to Australia;
 - 13.1.2 take specific measures to supply Product to Australia in the event that forecast demand exceeds planned supply, either domestically or internationally; and
 - 13.1.3 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 Product to Australia;
- as set out in **Schedule 2 (Product and Services)**.

General

- 13.2 The Supplier must, on the terms and conditions of this Deed, provide the Product and Services in accordance with the procedures, including the procedures for the Ordering of Product set out in **Schedule 2 (Product and Services)**.

Orders for Product and/or Services

- 13.3 The Supplier agrees that:
- 13.3.1 subject to **clause 13.19.1**, Orders for Product may be placed under the Deed by persons nominated by the NBA and specified in, or determined in accordance with the procedures set out in, **Schedule 2 (Product and Services)**; and
 - 13.3.2 Orders placed under this Deed must be complied with on the terms of this Deed.

Provision of Product and/or Services

- 13.4 The Supplier must provide the Product and Services under this Deed:
- 13.4.1 only to the NBA or to Approved Recipients;

- 13.4.2 to meet all Orders placed under **clause 13.3**, up to [not disclosed] in any Financial Year;
 - 13.4.3 [Not disclosed.]
 - 13.4.4 at the times and in the manner provided in, or determined in accordance with the procedures set out in, **Schedule 2 (Product and Services)**;
 - 13.4.5 exercising high professional standards of skill, care and diligence;
 - 13.4.6 in a manner that ensures the Product and/or Services are fit for purpose for which they are intended;
 - 13.4.7 in a cost-effective manner; and
 - 13.4.8 so as to ensure that all Performance Indicators for the Product and Services are fully met.
- 13.5 In providing the Product and Services the Supplier must:
- 13.5.1 make available a person to whom telephone enquiries can be directed in relation to Orders;
 - 13.5.2 comply with any reasonable direction of the NBA that is consistent with this Deed; and
 - 13.5.3 liaise with the NBA in relation to Orders as reasonably requested by the NBA.
- 13.6 If the Supplier is able to supply any new or improved blood products or services that, in the Supplier's or NBA's reasonable opinion, may be clinically superior to any of the existing Product or Services or that may be supplied by the Supplier to the NBA in addition to the existing Product or Services, the Supplier or the NBA must:
- 13.6.1 notify the other Party of the new or improved blood product or service; and
 - 13.6.2 negotiate in good faith with the other Party regarding:
 - (a) the replacement of any existing Product or Service with the new or improved product or the addition of a new Product or Service; and
 - (b) the variation of the Deed, including the Price, if appropriate, in accordance with **clause 10**, to allow the replacement or addition negotiated under **clause 13.6.2(a)**.

- 13.7 The Supplier acknowledges and agrees that:
- 13.7.1 at any time, the NBA may enter into arrangements for the provision of the Product and/or Services, or products and/or services similar to the Product and/or Services, from one or more third parties;
 - 13.7.2 the arrangements under **clause 13.7.1** may affect the NBA's requirements for the provision of the Product and/or Services under this Deed;
 - 13.7.3 there is no obligation for any quantity of Orders or a minimum quantity of Orders for Product to be placed under this Deed; and
 - 13.7.4 the NBA may, if the Supplier is unable to supply the Product or Services or otherwise at the NBA's discretion, purchase products and services that are similar to or identical to the Product and Services from other persons.

Standard Operating Procedures

- 13.8 The Supplier must maintain a planned, systematic and documented approach, in accordance with good commercial practice, to the performance of obligations under the Deed.
- 13.9 In relation to the Supplier's standard operating procedures, the Supplier must:
- 13.9.1 provide a copy of any specified standard operating procedures relevant to the Supplier's performance of its obligations under this Deed to the NBA at the reasonable request of the NBA (the Parties agree that any such document may be subject to the operation of **clause 8** and **clause 27**);
 - 13.9.2 consider any reasonable suggestion made by the NBA for the development or revision of any specified standard operating procedures; and
 - 13.9.3 subject to the operation of **clause 27**, if applicable, engage in consultation with the NBA or any other relevant person in respect of any standard operating procedures, at the reasonable request of the NBA.

Intensive Product Management

- 13.10 The NBA may, following consultation with the Supplier, nominate the Product to be subject to Intensive Product Management if the In-country Reserve of Product falls below a level equivalent to two months of supply under this Deed (as determined under **item 12 of Schedule 2 (Product and Services)**).

- 13.11 Intensive Product Management may include any special arrangements (in addition to the obligations of the Supplier under **item 12 of Schedule 2 (Product and Services)** in relation to reinstatement of the In-country Reserve) to ensure that the In-country Reserve is reinstated in the shortest time period possible, whilst at the same time ensuring that demand for the Product continues to be met. Such special arrangements may apply, following reasonable consultation with the Supplier, to supply planning and inventory management, and would usually involve representation and participation by the Supplier at Intensive Product Management teleconferences arranged by the NBA.
- 13.12 The Supplier must comply with any reasonable Intensive Product Management arrangements nominated under **clause 13.11**.

Indemnity

[Clauses 13.13 to 13.15 not disclosed]

Timing for provision of the Product and Services

- 13.16 Subject to any arrangements entered into under **clause 13.4**, the Supplier must comply with the timing requirements for the provision of the Product or Services specified in **Schedule 2 (Product and Services)**, or the Order, as relevant.

Notice Obligations

- 13.17 The Supplier must notify the NBA as soon as practicable:
- 13.17.1 if, to the best of the Supplier's knowledge, 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 Product and/or Services in accordance with this Deed; and
- 13.17.2 of the Supplier's proposals for managing the problems or delay.
- 13.18 The Supplier must, in performing its obligations under this **clause 13**, continue to comply with its risk management obligations under **clause 32**.

Consignment arrangements

- 13.19 The Supplier may make arrangements with an Approved Recipient for the holding of a consignment stock of Products by the Approved Recipient, in which case, for the purposes of this Deed:
- 13.19.1 an Order will not be taken to have been made under **clause 13.3** until a vial of the Product is taken from the consignment stock for use by the Approved Recipient, and the Order will then be taken to have been made only for that vial of Product;

- 13.19.2 possession of the Product is not taken to have passed from the Supplier to the Approved Recipient for the purpose of **clause 24** until a vial of the Product is taken from the consignment stock for use by the Approved Recipient, and possession will then be taken to have passed in respect of that vial of Product;
- 13.19.3 an Order will not be taken to have been filled by the Supplier for the purpose of **Schedule 4 (Payments and Invoicing)** until a vial of the Product is taken from the consignment stock for use by the Approved Recipient, and the Order will then be taken to have been filled only in respect of that vial of Product; and
- 13.19.4 the consignment stock will not be taken to form part of the In-country Reserve required under **item 12 of Schedule 2 (Product and Services)**.

Supply outside this Deed

- 13.20 For the avoidance of doubt, nothing in this Deed prevents the Supplier from supplying products or services in Australia outside the terms of this Deed, provided that:
 - 13.20.1 no amount shall be payable under this Deed for any supply outside the terms of this Deed; and
 - 13.20.2 the Supplier shall not in any circumstances be relieved of any obligation or liability arising under this Deed (including without limitation the obligations under **Schedule 4 (Payments and Invoicing)** to deliver Product within a particular time or to hold a stock of Product in In-country Reserve for possible supply under this Deed) as a result of any supply of products or services outside the terms of this Deed.

14 Records and Reports

- 14.1 Subject to **clauses 39.8 to 39.11**, 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)**:
 - 14.1.1 which contain the information required by **Schedule 5 (Records and Reports)**; and
 - 14.1.2 at the frequency, and by the due dates, specified in, or determined in accordance with the procedures set out in **Schedule 5 (Records and Reports)**.
- 14.2 The Supplier must ensure that all reports are accurate, complete and not misleading in any respect.

- 14.3 The Supplier must provide a written report to the NBA as soon as practicable upon the occurrence of any of the following issues:
- 14.3.1 inability to supply Ordered Product within the required timeframe;
 - 14.3.2 extraordinary circumstances that may affect Product supply or quality; and
 - 14.3.3 difficulties with Ordering or delivery processes that were unable to be resolved.
- 14.4 Reporting under this **clause 14** does not affect any of the Supplier's other reporting obligations under this Deed.

15 Compliance with Laws

- 15.1 Without limiting any other clause in this Deed, the Supplier must supply the Product and perform the Services so as to comply with all applicable Laws, including:
- 15.1.1 all Commonwealth Laws;
 - 15.1.2 all Australian State and Territory Laws; and
 - 15.1.3 any requirements or directions relating to supply planning processes or requirements that are notified by the NBA from time to time and that are consistent with this Deed.

16 Obligations under Therapeutic Goods Act

Definitions

- 16.1 In this **clause 16**:
- 16.1.1 **licence** means a licence issued under Part 4 of the TG Act;
 - 16.1.2 **listed goods** has the same meaning as in the TG Act and listed means included as a listed good in the Register;
 - 16.1.3 **manufacturer** means a person engaged in the manufacture (as that term is defined in the TG Act) of therapeutic goods;
 - 16.1.4 **manufacturing principles** has the same meaning as in the TG Act;
 - 16.1.5 **registered goods** has the same meaning as in the TG Act and **registered** and **registration** means included as a registered good in the Register;

- 16.1.6 **Register** means the Australian Register of Therapeutic Goods maintained under the TG Act;
- 16.1.7 **sponsor** has the same meaning as in the TG Act;
- 16.1.8 **Sponsored Products** means any Products supplied by the Supplier under this Deed for which the Supplier has obligations as a sponsor under the TG Act; and
- 16.1.9 **therapeutic goods** has the same meaning as in the TG Act.

Supplier's Legislative Obligations

- 16.2 In addition to the Supplier's general obligations under **clause 15**, the Supplier must at all times during the Term comply with its obligations under the TG Act and any applicable State or Territory legislation.

Registration of Product

- 16.3 Unless otherwise agreed in writing by the NBA, the Supplier must maintain registration of the Product as a sponsor under the TG Act.

Supplier's Obligations as a Sponsor

- 16.4 The Supplier must, for all Sponsored Products:
- 16.4.1 do all things necessary to ensure that each of the Sponsored Products is and remains included in the Register during the Term, unless they are exempt from the requirement to be included in the Register under the TG Act;
 - 16.4.2 advise the NBA in writing as soon as practicable upon the Supplier becoming aware that a Sponsored Product is, or may be, included in the Register or that a Sponsored Product has ceased, or may cease to be, included in the Register;
 - 16.4.3 in relation to any Product which is to be, or which may or has ceased to be, included on the Register, take any action reasonably required by the NBA to ensure that the purposes of this Deed are fulfilled; and
 - 16.4.4 comply with all of the Supplier's obligations under the TG Act, including (without limitation):
 - (a) holding and making available all information in relation to the Sponsored Products which is required to meet the Supplier's obligations under the TG Act; and
 - (b) observing any and all conditions of the registration or listing of the Sponsored Products.

General Obligations

16.5 The Supplier must:

16.5.1 ensure that the Product complies with all labelling, packaging and advertising requirements of the TG Act; and

16.5.2 not make any statements about the Product which are inaccurate, misleading or deceptive.

Supplier's Obligations where the Supplier is not the manufacturer

16.6 If the Supplier is not the manufacturer for the Product supplied under the Deed, the Supplier must ensure that the Supplier obtains the Product (or part or parts of the Product) from a supplier which meets any obligations applying to that supplier as a manufacturer under the TG Act in respect of the Product (or part or parts of those Product).

Product compliance and return

16.7 The Supplier must not supply a vial of Product under this Deed if the Supplier is aware that the vial of Product does not meet the requirements of its registration or listing, or that there are reasonable grounds to believe that the vial of Product may not meet the requirements of its registration or listing.

16.8 If a vial of Product is supplied in accordance with this Deed and, before the use of the vial of Product, it is shown that the vial of Product as supplied by the Supplier does not meet the requirements of its registration or listing, or that there are reasonable grounds to believe that the vial of Product as supplied by the Supplier may not have met the requirements of its registration or listing, the Supplier must:

16.8.1 accept the return of the vial of Product; and

16.8.2 either:

(a) supply a replacement vial of Product at no additional cost to meet the requirements of the Approved Recipient who originally made the Order for the vial of Product; or

(b) if no replacement vial of Product can be supplied to meet the requirements of the Approved Recipient who originally made the Order for the vial of Product, credit the amount paid or payable under this Deed for the vial of Product against invoices for future Orders under this Deed.

16.9 If a vial of Product is supplied in accordance with this Deed and, after the use of the vial of Product, it is shown that the vial of Product did not meet

the requirements of its registration or listing, the Supplier agrees to, if reasonably requested by the NBA, credit the amount paid or payable under this Deed for the vial of Product against invoices for future Orders under this Deed.

- 16.10 If the NBA, or a person to whom the Supplier provides a Product in accordance with this Deed, considers on reasonable grounds that a Product does or may not meet the safety, quality, efficacy or any other requirements of its registration or listing, the Supplier must:
- 16.10.1 liaise with the NBA or other person in relation to the grounds on which the person considers that the vial of Product may not meet the safety, quality, efficacy or any other requirements of its registration or listing;
 - 16.10.2 accept return of the vial of Product in accordance with **clause 16.8**; and
 - 16.10.3 promptly conduct such testing, or arrange for such testing to be conducted, as is necessary to determine whether or not the returned vial of the Product complies with applicable safety, quality and efficacy or other requirements, and notify the NBA and the TGA of the results of that testing.

Other Remedies

- 16.11 The rights, obligations and remedies in this **clause 16** 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 this Deed or at Law.

17 Safety and Quality Assurance

- 17.1 The Supplier must comply with
- 17.1.1 the Safety and Quality Assurance Requirements; and
 - 17.1.2 the procedures in relation to the Safety and Quality Assurance Requirements,
- set out or referred to in **item 3 of Schedule 2 (Product and Services)**, in addition to all other safety and quality requirements deriving from applicable Laws.

18 Performance Requirements

Performance Requirements for Product and Services

- 18.1 The Supplier must:
- 18.1.1 provide the Product so as to meet in full the Performance Indicators specified in **Schedule 3 (Performance Measures)** in respect of that Product; and
 - 18.1.2 provide each of the Services so as to meet in full the Performance Indicators specified in **Schedule 3 (Performance Measures)** in respect of that Service.
- 18.2 The Parties must also comply with those parts of **Schedule 3 (Performance Measures)**
- 18.2.1 which Party is responsible for measuring the Supplier's performance against the Performance Indicators;
 - 18.2.2 when the Supplier's performance against the Performance Indicators is to be measured; and
 - 18.2.3 the reporting obligations in respect of the Supplier's performance against the Performance Indicators.

Consequences of Failure to meet Performance Requirements

- 18.3 If the Supplier does not meet a Performance Indicator set out in:
- 18.3.1 **Schedule 3 (Performance Measures)** for a particular Product, then the consequence set out in **Schedule 3 (Performance Measures)** in relation to that Product applies; and
 - 18.3.2 **Schedule 3 (Performance Measures)** for a particular Service, then the consequence set out in **Schedule 3 (Performance Measures)** in relation to that Service will apply.
- 18.4 **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 for a Product or Service or Safety and Quality Assurance Requirement. In that case, the NBA may elect (in its absolute discretion) that one or more of the listed consequences applies.
- 18.5 The Supplier acknowledges and agrees that the listed consequences in **Schedule 3 (Performance Measures)**, as applied under this Deed:
- 18.5.1 are reasonable and appropriate for managing adherence to the Performance Indicators and for providing some compensation for Loss, if applicable; and
 - 18.5.2 do not limit the NBA's rights or remedies arising from any defective performance under the Deed.

Section D: Payment obligations

19 Payments to be made by the NBA

Payments

- 19.1 Subject to the Supplier complying with the provisions of this Deed, the NBA agrees to make the Payments to the Supplier for the Product 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)**.
- 19.2 Unless otherwise specified in **Schedule 4 (Payments and Invoicing)**, payment of all Payments under this Deed is subject to:
- 19.2.1 satisfactory provision 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; and
- 19.2.2 the receipt by the NBA from the Supplier of a correctly rendered Tax Invoice which complies with **Schedule 4 (Payments and Invoicing)**.
- 19.3 The NBA agrees to use reasonable endeavours to notify the Supplier of any problems with an invoice identified by the NBA within 5 Business Days of receipt of the invoice, provided that a failure of the NBA to do so does not prevent or limit the NBA's right to later withhold any amount found to have been incorrectly invoiced.
- 19.4 The Supplier acknowledges and agrees that:
- 19.4.1 the amount of the Payments that may be payable under this Deed may be affected by the extent to which the Services meet the Performance Indicators; and
- 19.4.2 the value of the Services to the NBA is affected by the achievement or otherwise of the Performance Indicators.
- 19.5 The Supplier acknowledges that the making of any Payments by the NBA will not constitute an admission on the part of the NBA that the Product has been properly provided or the Services properly performed, or a waiver or release of the Supplier's obligations under this Deed.

Changes to the Payments

19.6 The Payments may be altered during the Term on the basis of the mechanism (if any) set out in **Schedule 4 (Payments and Invoicing)**.

20 Taxes

20.1 In this **clause 20** and elsewhere in this Deed:

20.1.1 the expression '**GST Legislation**' means the *A New Tax System (Goods and Services Tax) Act 1999* (Cth);

20.1.2 the expressions '**Adjustment Event**', '**Input Tax Credit**', '**Taxable Supply**' and '**Tax Invoice**' have the meanings provided in the GST Legislation;

20.1.3 '**Supplier**' means a Party who makes a Taxable Supply under or in connection with this Deed or in connection with any matter or thing occurring under this Deed to another Party; and

20.1.4 '**Recipient**' means a Party who receives a Taxable Supply under or in connection with this Deed or in connection with any matter or thing occurring under this Deed from the Supplier.

20.2 If the Payments are expressed to be *inclusive of GST*, the Payments are inclusive of GST and the NBA has no obligation to reimburse (except by payment of the Payments) the Supplier for any GST imposed on any Taxable Supply made by the Supplier pursuant to this Deed, to the extent that such Taxable Supply relates to the part of the Payments that are expressed to be *inclusive of GST*.

20.3 Subject to **clause 20.5**, where the Supplier makes a Taxable Supply under or in connection with this Deed or in connection with any matter or thing occurring under this Deed to the Recipient and the consideration otherwise payable for the Taxable Supply does not include GST, the Supplier is entitled, in addition to any other consideration recoverable in respect of the Taxable Supply, to recover from the Recipient the amount of any GST on the Taxable Supply.

20.4 If the amount paid by the Recipient to the Supplier in respect of GST differs from the GST on the Taxable Supply (taking into account any Adjustment Events that occur in relation to the Taxable Supply), an adjustment must be made. If the amount paid by the Recipient exceeds the GST on the Taxable Supply, the Supplier must refund the excess to the Recipient. If the amount paid by the Recipient is less than the GST on the Taxable Supply, the Recipient must pay the deficiency to the Supplier.

20.5 Where a Party to this Deed is entitled, under or in connection with this Deed, or in connection with any matter or thing occurring under this Deed, to recover all or a proportion of its costs, or is entitled to be compensated

for all or a proportion of its costs, the amount of the recovery or compensation must be reduced by the amount of (or the same proportion of the amount of) any Input Tax Credits available in respect of those costs.

- 20.6 In addition to **clause 21**, the Supplier must ensure that each invoice given to the NBA by the Supplier complies with the requirements of a Tax Invoice under the GST Legislation.
- 20.7 The Parties agree that any amount recoverable by a Party under any indemnity under this Deed includes any GST payable on a cost or liability incurred by the Party which is the subject of the claim under the indemnity (less any corresponding input tax entitlement of that Party).

21 Invoicing Obligations

- 21.1 The Supplier must comply with all invoicing obligations set out in **Schedule 4 (Payments and Invoicing)**.
- 21.2 The Supplier must provide to the NBA any written statement required under section 127 of the *Industrial Relations Act 1996* (NSW) or any similar State or Territory law as amended or replaced from time to time, before any payment is made under this Deed or at such other time as is required by the relevant law verifying that no wages are due and owing by the Supplier, in respect of the work carried out under this Deed, at the time of the payment.
- 21.3 The Supplier acknowledges that the NBA may withhold any payment due to the Supplier under this Deed until the Supplier gives a written statement under this clause, for any period up to the date of the statement, and that any rights pertaining to late payment under this Deed do not apply to any payment withheld under this clause.
- 21.4 The Supplier must keep a copy of any written statement or documentary evidence provided under this **clause 21** for at least six years from the date it was provided to the NBA, or such longer period required by a law referred to in **clause 21.2**.
- 21.5 The Supplier warrants that the information on and amount claimed under each invoice will be true and correct.

22 Recovery of moneys by the NBA

- 22.1 If, at any time during the Term or after the expiry or earlier termination of this Deed, any Payments cannot be shown to the reasonable satisfaction of the NBA (after consultation with the Supplier) to have been properly payable under this Deed for Product or Services which were provided in accordance with this Deed, the NBA may 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 30 days of receipt of the Repayment Notice.

22.2 If the Supplier fails to repay the amount specified in the Repayment Notice:

22.2.1 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

22.2.2 the amount set out in the Repayment Notice, and interest owed under this **clause 22**, is recoverable by the NBA as a debt due to the NBA by the Supplier.

22.3 The Supplier acknowledges that interest calculated in accordance with **clause 22.2.1** 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.

22.4 This **clause 22** survives the expiration or earlier termination of this Deed.

23 Right of Set Off

23.1 Without limitation to the NBA's rights under this Deed or at Law, if the Supplier owes any amounts to the NBA in respect of this Deed or any subject matter of this 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 this Deed.

23.2 This **clause 23** survives the expiration or earlier termination of this Deed.

Section E: Ownership Issues

24 Passing of Ownership and Risk

24.1 Subject to **clause 13.15.2**, the Supplier acknowledges that it:

24.1.1 retains ownership of the Product; and

24.1.2 bears all risks associated with such ownership of the Product,

until possession of the Product passes from the Supplier to an Approved Recipient upon physical delivery by the Supplier to an Approved Recipient in accordance with **clause 13.4**.

25 Intellectual Property

[Clauses 25.1 to 25.3 not disclosed. The clauses relate to the Intellectual Property rights in the Contract Material.]

General

25.4 If requested by the NBA, the Supplier:

25.4.1 must bring into existence, sign, execute or otherwise deal with any document which may be necessary to give effect to this **clause 25**; and

25.4.2 must provide all or part of the Contract Material to the NBA in the form reasonably requested by the NBA.

IP warranty and indemnity

25.5 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 25**. For the purpose of this clause, a reference to 'Intellectual Property' includes a reference to an author's rights of attribution of authorship, to not have authorship falsely attributed, and of integrity of authorship.

25.6 [Not disclosed.]

25.7 [Not disclosed.]

25.8 [Not disclosed.]

25.9 For certainty, the Parties acknowledge and agree that the operation of this **clause 25** does not affect the potential operation of **clauses 8** or **27**.

26 NBA Material

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

26.2 Subject to this **clause 26**, 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 Product and performing the Services.

26.3 The NBA will inform the Supplier of any NBA Material provided to the Supplier under this 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.

26.4 The Supplier must:

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

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

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

26.5 As soon as practicable after expiration or earlier termination of this Deed, the Supplier must deliver the NBA Material and any copies of the NBA Material to the NBA.

Section F: Protection of Information

27 Confidentiality

- 27.1 Subject to **clause 27.2**, the Parties agree not to disclose to any other person any Confidential Information of a Party without prior written approval of the other Party.
- 27.2 In giving consent to the disclosure of Confidential Information under **clause 27.1**, a Party may impose any conditions or restrictions it considers appropriate when giving approval under **clause 27.1** and, subject to this **clause 27**, the other Party agrees to comply with such conditions or restrictions.
- 27.3 A Party may at any time require the other Party to give, and to arrange for:
- 27.3.1 its Personnel engaged in the provision of the Product or the performance of the Services; or
 - 27.3.2 any other third party, other than a NBA employee to whom information may be disclosed pursuant to **clauses 27.6.1, 27.6.2 or 27.6.5**,
- to give a deed of undertaking in the form reasonably required by the NBA, relating to the non-disclosure of Confidential Information.
- 27.4 If the other Party receives a request under **clause 27.3** it agrees to arrange promptly for all such undertakings to be given.
- 27.5 The obligations on the Supplier under this **clause 27** will not be taken to have been breached where the information referred to is legally required to be disclosed.
- 27.6 The obligations on the Parties under this **clause 27** will not be taken to have been breached to the extent that Confidential Information:
- 27.6.1 is disclosed by a Party to its advisers or employees solely in order to comply with obligations, or to exercise rights, under this Deed, provided they are under equivalent obligations of non-disclosure;
 - 27.6.2 is disclosed to a Party's internal management personnel, solely to enable effective management or auditing of contract-related activities, provided they are under equivalent obligations of non-disclosure;
 - 27.6.3 is disclosed by the NBA to the responsible Minister;

- 27.6.4 is disclosed by the NBA, in response to a request by a House or a Committee of the Parliament of the Commonwealth of Australia;
- 27.6.5 [Not disclosed.]
- 27.6.6 is authorised or required by law, including under this Deed, under a licence or otherwise, to be disclosed; or
- 27.6.7 is in the public domain otherwise than due to a breach of this **clause 27**;

provided that the disclosing Party must where reasonably practicable give advance notice to the other Party of disclosures made under this clause (individually or by class).

- 27.7 Nothing in this **clause 27** derogates from any obligation which either Party may have either under the Privacy Act or under this Deed in relation to the protection of Personal Information.
- 27.8 This **clause 27** survives the expiration or earlier termination of this Deed.

28 Data Security

- 28.1 In this **clause 28**, '**Official Information**' means any information developed, received or collected by or on behalf of the NBA, whether through the NBA or any other agency or any other NBA contracted service provider.
- 28.2 Without limiting its obligations under this Deed, the Supplier must comply with the security requirements for the protection of Official Information detailed in the Commonwealth's Protective Security Manual, as amended from time to time.
- 28.3 The Supplier must participate in security reviews of the procedures implemented in performance of this Deed at least annually, if requested by the NBA.
- 28.4 The Supplier must not permit any of its Personnel to have any access to security classified information unless:
 - 28.4.1 that person has been cleared, by the departmental security unit within the Australian Security Vetting Service of the Commonwealth Attorney-General's Department, to a security level considered appropriate by the NBA;
 - 28.4.2 the NBA has given approval in writing for that person to have access to the specific items of security classified information; and
 - 28.4.3 that person has undergone the training required by the NBA relating to the access to and use of security classified information.

- 28.5 The Supplier must notify the NBA as soon as practicable upon becoming aware that any unauthorised person has had access to security classified information.
- 28.6 The Supplier acknowledges that failure by the Supplier to notify the NBA as required by **clause 28.5** is a breach of this Deed within the meaning of **clause 44.1.3 (Termination for Default)**.
- 28.7 If an incident set out in **clause 28.5** occurs, the Supplier must comply with any reasonable directions of the NBA in order to rectify the security problem.
- 28.8 The Supplier must not, at any time, perform any part of this Deed outside Australia without the prior written consent of the NBA. In granting its consent, the NBA may impose whatever conditions it considers necessary.
- 28.9 The Supplier must perform its security obligations under this Deed to the highest professional standards described or indicated in the Commonwealth's Protective Security Manual.
- 28.10 The Supplier must warrant, if required by the NBA, that it has complied with this **clause 28**.
- 28.11 The rights and obligations arising in connection with this **clause 28** survive the expiry or earlier termination of this Deed.

29 Privacy

- 29.1 The Supplier must, with respect to all Personal Information relating to or concerning the Product or Services provided under this Deed:
- 29.1.1 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 concerning the security, use and disclosure of information to which the NBA is subject in respect of that information and which affects the Product or Services;
- 29.1.2 only use such information for the purposes of fulfilling its obligations under this Deed or as required by Law;
- 29.1.3 not disclose any Personal Information obtained in connection with this Deed unless such disclosure is:
- (a) required for the purposes of fulfilling its obligations under this Deed or as required by Law; and
 - (b) made in accordance with the Privacy Act;

- 29.1.4 cooperate with any reasonable demands or inquiries made by the Privacy Commissioner;
- 29.1.5 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 29**;
- 29.1.6 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;
- 29.1.7 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;
- 29.1.8 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;
- 29.1.9 inform any person, on his or her request, in writing of the content of any provision of this Deed that is inconsistent with an approved privacy code binding the Supplier or a National Privacy Principle as set out in the Privacy Act;
- 29.1.10 not transfer Personal Information outside Australia, or allow parties outside Australia to have access to it, without the prior written approval of the NBA;
- 29.1.11 notify the NBA as soon as practicable if the Supplier becomes aware of a breach of any obligation concerning security, use and disclosure of Personal Information;
- 29.1.12 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;
- 29.1.13 notify the NBA as soon as practicable of, and cooperate with the NBA in the resolution of, any complaint alleging an interference with privacy; and

- 29.1.14 indemnify the NBA in respect of; any Loss suffered or incurred by the NBA arising out of or in connection with a breach of the obligations of the Supplier under this **clause 29**; or any misuse of information or disclosure, in breach of an obligation under the Privacy Act, except to the extent that the Loss is directly caused by a negligent or wilfully wrongful act or omission of the NBA or any of its Personnel.
- 29.2 The Supplier must ensure that all Subcontractors are obliged under their contracts to meet obligations that are equivalent to those of the Supplier under this Deed.
- 29.3 The Supplier's obligations in this **clause 29** are in addition to, and do not restrict, any obligations it may have under:
- 29.3.1 the *Privacy Act 1988* (Cth); or
- 29.3.2 any:
- (a) privacy codes; or
- (b) privacy principles contained in, authorised by or registered under any Law,
- including any such privacy codes or principles that would apply to the Supplier but for the application of the other provisions of this **clause 29**.
- 29.4 This **clause 29** will survive the expiration or earlier termination of this Deed.

30 Conflict of Interest

- 30.1 The Supplier warrants that, to the best of its knowledge, at the date of signing this Deed, no Conflict of Interest exists or is likely to arise in the performance of its obligations under this Deed, by it or its Personnel.
- 30.2 The Supplier must use its best endeavours (including making all appropriate enquires) to:
- 30.2.1 ensure that a situation does not arise which may result in such a Conflict of Interest; and
- 30.2.2 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 this Deed fairly and independently.
- 30.3 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 30.4** and the NBA has given its written approval for the Supplier to engage in that activity.

- 30.4 Where a Conflict of Interest arises in the performance of the Supplier's obligations under this Deed, the Supplier must as soon as practicable notify the NBA 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.
- 30.5 Without limiting the NBA's rights, a failure to comply with this **clause 30** is a breach of this Deed within the meaning of **clause 44.1.3** and the Supplier may terminate this Deed in accordance with **clause 44**.

Section G: Treatment of Risks

31 Principles in relation to the allocation of risk

- 31.1 The Parties agree that the provision of the Product and the performance of the Services gives rise to a range of risks and agree that, as basic principles and subject to this Deed:
- 31.1.1 risks should be borne by the Party best placed to manage those risks; and
 - 31.1.2 each Party is fully liable for the performance of its obligations under this Deed, including obligations in relation to Orders placed under the Deed.
- 31.2 For the avoidance of doubt, the principles expressed in **clause 31.1** do not override or limit the provisions of this Deed.

32 Risk Management Plan

- 32.1 The Supplier must within 10 Business Days of the Commencement Date, provide to the NBA a Risk Management Plan that complies with the requirements of this **clause 32**. After the Risk Management Plan is approved by the NBA, it will become part of this Deed.
- 32.2 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 4.1** 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.
- 32.3 The Supplier must notify the NBA of:
- 32.3.1 any new risks which arise during the Term which are not appropriately or adequately dealt with in the Risk Management Plan;
 - 32.3.2 any changes to existing risks in the Risk Management Plan during the Term; and
 - 32.3.3 the Supplier's proposed method for dealing with any new risks or changes to existing risks which arise during the Term.
- 32.4 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).

33 Warranties

Product Warranties

33.1 The Supplier warrants that:

33.1.1 The Product provided under this Deed:

- (a) has been manufactured, produced, processed, prepared and packaged, labelled, presented and described as required by Law and otherwise comply with all applicable Laws;
- (b) complies with all representations made to the NBA by the Supplier in relation to the Product or any samples of the Product, including representations as to the standard, quality, value, grade, composition, style, model, capacity, history and previous use of the Product;
- (c) meets any requirements under the TG Act and satisfies other quality performance, capacity, regulatory compliance requirements;
- (d) is of merchantable quality, made of good material and workmanship, and free from defects; and
- (e) is fit for the purpose for which goods of the same kind are commonly supplied, if goods of the same kind exist, and/or any other purpose made known to the Supplier;

33.1.2 it has all rights and title necessary to enable it to supply the Product under this Deed including the right to sell the Product at the time when title to the Product is to pass to an Approved Recipient or to the NBA (as the case may be) in accordance with this Deed;

33.1.3 on delivery, the Product 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;

33.1.4 to the best of its knowledge as at the Commencement Date, the manufacture and sale of the Product does not infringe the rights of any other person, including rights in relation to patents, trademarks, designs and copyright;

- 33.1.5 on delivery, the Approved Recipient or the NBA (as the case may be) will enjoy quiet possession of the Product;
- 33.1.6 the Product will be delivered in the correct quantity and at the required times; and
- 33.1.7 it has the capacity and power to enter into and perform this Deed.

Services Warranties

- 33.2 The Supplier warrants that all Services performed under this Deed:
 - 33.2.1 comply with all representations made to the NBA by the Supplier in relation to the standard, quality and timing of the Service;
 - 33.2.2 will be rendered with due care and skill;
 - 33.2.3 along with any materials supplied under this Deed in connexion 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 this Deed; and
 - 33.2.4 comply with any requirements under the TG Act and satisfy all other quality performance and regulatory compliance requirements.
- 33.3 The warranties in this **clause 33** will survive the expiry or earlier termination of the Deed.

34 Indemnities

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

35 Performance Guarantee

- 35.1 The Supplier must, at its expense, provide to the NBA, 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 9 (Performance Guarantee)**.
- 35.2 Without prejudice to its rights at law or under any other provision of this Deed, the NBA may exercise its rights under the performance guarantee in any circumstances where the NBA would be entitled to terminate this Deed in whole or in part under **clause 44.1** (including having complied with any procedures specified under **clause 44.1** as required prior to termination).

36 Insurance

36.1 The Supplier must comply with all obligations of **Schedule 8 (Insurance)**.

37 Force Majeure

Force Majeure Event

37.1 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):

37.1.1 as a result of an act or event beyond the reasonable control of that Party or its Personnel (**Force Majeure Event**);and

37.1.2 the Force Majeure Event continues for a period for less than 10 Business Days,

it must promptly give a notice to the other Party that complies with **clause 37.3**.

[Clauses 37.2 to 37.8 not disclosed.]

Section H: Other Commonwealth requirements

38 Records

- 38.1 The Supplier must keep comprehensive written records and accounts of all matters related to its performance of this Deed, including the provision of the Product and Services, the receipt of Payments, compliance with obligations under the TG Act, the creation of Contract Material and the creation of Intellectual Property rights in connection with this 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 2 (Product and Services)**.
- 38.2 The Supplier must ensure that all records and accounts:
- 38.2.1 to the best of its knowledge, are true and accurate;
 - 38.2.2 are kept in a manner that permits them to be conveniently and properly audited, in accordance with the normal practices of the Supplier; and
 - 38.2.3 enable the extraction of all information relevant to this Deed.
- 38.3 In addition to the obligations in **clause 38.2**, the Supplier must ensure all accounts are drawn and maintained in accordance with any applicable Australian accounting standards.

39 Access to information and premises

- 39.1 For the purposes of this **clause 39** and **clause 40**, 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 this Deed, however and wherever stored or located, under the Supplier's custody, possession or control for inspection and/or copying.
- 39.2 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.
- 39.3 Without limiting any other provision of this Deed, the NBA, the Auditor-General or a delegate of the Auditor-General or the Privacy Commissioner or a delegate of the Privacy Commissioner, for the purpose of performing the Auditor-General's or Privacy Commissioner's statutory functions and/or powers respectively, may, at reasonable times:

- 39.3.1 access the premises of the Supplier;
 - 39.3.2 require the provision by the Supplier of records and other information which are related to this Deed; and
 - 39.3.3 access, inspect and copy documentation and records or any other matter relevant to the Supplier's obligations or performance of this Deed, however stored, in the custody or under the control of the Supplier.
- 39.4 The Supplier must ensure that any subcontract entered into for the purpose of this Deed contains an equivalent clause granting the rights specified in this **clause 39** with respect to the Subcontractors' premises, data, records, accounts, financial Material and information and those of its Personnel.
- 39.5 This **clause 39** applies for the term of this Deed and for a period of 7 years from the date of its expiration or earlier termination.
- 39.6 Nothing in this 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. The rights of the NBA under this 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.
- 39.7 The NBA must ensure that its Personnel who have access to the Supplier's premises, are made aware of the need to comply with the Supplier's reasonable directions and procedures relating to health and safety, and security, when such directions and procedures are brought to their attention.
- 39.8 [Not disclosed.]
- 39.9 [Not disclosed.]
- 39.10 [Not disclosed.]
- 39.11 [Not disclosed.]

40 Audit

- 40.1 The NBA may, in accordance with **clause 39** and this **clause 40**, conduct audits of:
- 40.1.1 the manner in which the Supplier performs its obligations under this Deed;

- 40.1.2 the Supplier's compliance with its general obligations under this Deed;
 - 40.1.3 the compliance of the Supplier's invoices and reports with its obligations under this Deed;
 - 40.1.4 the Supplier's compliance with its confidentiality, privacy, security and NBA policy obligations under this Deed; and
 - 40.1.5 any other matters reasonably determined by the NBA to be relevant to auditing the performance of the Supplier's obligations under this Deed.
- 40.2 Subject to **clause 40.3**, the NBA may, by notice to the Supplier, advise the Supplier that it will conduct an audit of the Supplier at a reasonable time set out in the notice.
- 40.3 The Supplier may propose a different time for the audit to that set out in the notice under **clause 40.2** and the audit will be conducted:
- 40.3.1 at such other time if agreed by the NBA; or
 - 40.3.2 at the time notified by the NBA under **clause 40.2**, if the Parties cannot agree under **clause 40.3** within 2 Business Days of the proposition by the Supplier.
- 40.4 The Supplier must participate in audits of this 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 this Deed is being properly performed and administered. The NBA may appoint an independent person to assist in the audits. Audits may consider all aspects of the Supplier's performance including but not limited to any performance indicators, benchmarks or targets.
- 40.5 The Supplier must participate promptly and cooperatively in any audits conducted by the NBA or its nominee.
- 40.6 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 and/or class of documents the auditor may require.
- 40.7 The Parties agree that if an audit reveals facts which establish a material breach of this Deed, the Supplier must, on request, reimburse the NBA an amount that represents the total cost incurred by the NBA of the Audit.

- 40.8 The requirement for, and participation in, audits does not in any way reduce the Supplier's responsibility to perform its obligations in accordance with this Deed.
- 40.9 The NBA must use reasonable endeavours to ensure that audits performed pursuant to this **clause 40** do not unreasonably delay or disrupt in any material respect the Supplier's performance of its obligations under this Deed.
- 40.10 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 this Deed:
- 40.10.1 supplied any Product or Services;
 - 40.10.2 maintained any accounts or records; or
 - 40.10.3 calculated Payments, or any other amounts or charges billed to or claimed from the NBA.
- 40.11 This **clause 40** survives the expiry or earlier termination of this Deed for a period of 7 years.

41 Offences under Crimes Act and Criminal Code 1995

- 41.1 The Supplier acknowledges that:
- 41.1.1 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 Commonwealth 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;
 - 41.1.2 the giving of false and misleading information to the Commonwealth or its Personnel is a serious offence under Division 137 of the Criminal Code (Cth); and
 - 41.1.3 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.

42 Compliance with Commonwealth policies

- 42.1 The Supplier must ensure that its Personnel who have access to the NBA's premises, are made aware of the need to comply with the NBA's reasonable directions and procedures relating to health and safety (including the Commonwealth's smoke free work place policy), and security, when such directions and procedures are brought to their attention.
- 42.2 The Supplier must comply with all other reasonable Commonwealth, State or Territory policies which are notified to it from time to time.

43 Equal Employment Opportunity

- 43.1 The Supplier must comply with its obligations, if any, under the *Equal Employment Opportunity for Women in the Workplace Act 1999 (Cth)* (**the Act**).
- 43.2 The Supplier must not enter into a subcontract in respect of this 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.
- 43.3 Any subcontract must include a provision which requires the Subcontractor to notify the Equal Opportunity for Women in the Workplace Agency of any failure to comply with the Act.

Section I: Termination and Disputes

44 Termination for Default

44.1 Without prejudice to its rights at common law or under any statute, the NBA may, by notice in writing to the Supplier, terminate this Deed immediately in whole or in part (a partial termination being a **Reduction**) if:

44.1.1 an Insolvency Event occurs in respect of the Supplier;

44.1.2 the Supplier fails, in NBA's opinion, to commence performance of this Deed or to proceed at a rate of progress so as to ensure the due and proper performance of this Deed;

44.1.3 the Supplier commits a breach of this 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 this Deed to the NBA;

44.1.4 the Supplier fails to take action to remedy a breach of another obligation under this Deed and does not commence to remedy the breach within 5 Business Days after being given notice by the NBA requiring the Supplier to remedy the breach or fails to remedy the breach within 15 Business Days after being given that notice;

44.1.5 the Supplier assigns its rights otherwise than in accordance with the requirements of this Deed; or

44.1.6 as permitted under **clause 37**.

44.2 In addition to the NBA's rights under **clause 22**, where, before termination or Reduction of this 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 the Product or Services which have been provided by the Supplier in accordance with this Deed, the portion of that Payment that does not relate to the Product or Services provided must be repaid by the Supplier to the NBA on termination and whether the NBA issues a Repayment Notice under **clause 22** or not, that amount, if not repaid, is recoverable by the NBA from the Supplier as a debt.

44.3 [Not disclosed]

44.4 If this Deed is terminated under this **clause 44**:

44.4.1 subject to this Deed, the Parties are relieved from future performance, without prejudice to any right of action that has accrued at the date of termination;

- 44.4.2 a Party's rights to recover damages are not affected;
 - 44.4.3 the Supplier must deliver any NBA Material, Contract Material or other Confidential Information of the NBA held by it to the NBA. Any fee, expense or charge that is associated with the delivery of such Material will be borne by the Supplier;
 - 44.4.4 the Supplier must comply with all obligations in this Deed relating to NBA Material, Contract Material and other Material referred to in this Deed; and
 - 44.4.5 the NBA may at its option by written notice to the Supplier within 10 Business Days of the date of termination elect to purchase (for delivery to the NBA or to a third party nominated by the NBA) any or all of the vials of Product held in the In- country Reserve at the date of termination, subject to the NBA making payment for the vials of Product to the Supplier on delivery (subject to a reasonable opportunity for inspection and acceptance) and otherwise in accordance with the terms of this Deed as applying at the date of termination.
- 44.5 For the avoidance of doubt, nothing in this Deed shall be taken to limit or exclude any right of a Party to terminate this Deed arising at common law or by statute.

45 Termination for Changes in Government Policy

- 45.1 The NBA may, at any time by written notice, terminate this Deed. Termination takes effect on and from the time specified in the notice, which must be not less than three months from the date of the notice. If this Deed is so terminated, the NBA will be liable only for:
- 45.1.1 payment of the Payments for the Product provided or Services provided before the effective date of termination, provided that those Services have or the Product has been provided in accordance with this Deed and the Supplier is not otherwise in breach of this Deed; and
 - 45.1.2 [Not disclosed. This clause relates to the parties' financial obligations in the event of termination for a change in Government policy.]
- 45.2 Where, before termination of this Deed under **clause 45.1**, the NBA has made any Payment in advance to the Supplier and all or part of that Payment does not relate to the Product or Services which have been provided by the Supplier in accordance with this Deed, the portion of that Payment that does not relate to the Product 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.

- 45.3 Upon receipt of a notice of termination the Supplier must:
- 45.3.1 stop work 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;
 - 45.3.2 comply with all obligations in this Deed relating to NBA Material and Contract Material;
 - 45.3.3 take all available steps to minimise or avoid any loss or damage resulting from that termination and to protect NBA Material and Contract Material; and
 - 45.3.4 continue to provide the Product and the Services until the date of effect of the termination.
- 45.4 [Not disclosed. This clause relates to the parties' financial obligations in the event of termination for a change in Government policy.]
- 45.5 For the avoidance of doubt, the NBA has an unfettered discretion to terminate this Deed under this **clause 45**.
- 45.6 Within two calendar months from the giving of notice by the NBA under **clause 45.1**, the NBA may at its option by written notice to the Supplier elect to purchase (for delivery to the NBA or to a third party nominated by the NBA at any time from the giving of notice under this **clause 45.6** to the effective date of termination under **clause 45.1**, as specified in the notice under this **clause 45.6**) any or all of the vials of Product held in the In-country Reserve by the Supplier in accordance with **item 7 of Schedule 4** at the date of the notice under this **clause 45.6**, subject to the NBA making payment for the vials of Product to the Supplier on delivery (subject to a reasonable opportunity for inspection and acceptance) and otherwise in accordance with the terms of this Deed as applying at the date of delivery or termination (whichever occurs first).

46 Dispute Resolution

- 46.1 The Parties undertake to use all reasonable efforts in good faith to resolve any disputes which arise between them in connection with this Deed.
- 46.2 A Party may give the other Party a notice of dispute (**dispute notice**) in connection with this Deed. Following the giving of a dispute notice, the dispute must initially be referred to the contact officers in **Schedule 6 (Contacts)**, who will use reasonable efforts to resolve the dispute within 10 Business Days of the giving of the dispute notice.

- 46.3 If the Parties have not been able to resolve the dispute in accordance with **clause 46.2**, then the Parties may agree on a process for resolving the dispute through means other than litigation or arbitration, including by mediation or conciliation.
- 46.4 In the event that the dispute, controversy or claim has not been resolved within 30 Business Days (or such other period as agreed between the Parties in writing) after the Parties have commenced action to resolve the dispute under **clause 46.2**, then either Party may, if it wishes, commence legal proceedings.
- 46.5 Nothing in this **clause 46** prevents either Party from seeking urgent injunctive relief.

Section J: Miscellaneous

47 Assignment

- 47.1 Subject to **clause 47.2** and **47.3**, neither Party may assign or novate any of its rights under this Deed without the prior written consent of the other Party (which may not be unreasonably withheld).
- 47.2 The Supplier may assign its rights and obligations under this Deed to any related body corporate, as that term is defined in the *Corporations Act 2001*, without requiring the NBA's consent.
- 47.3 The NBA may assign its rights and obligations under this Deed to any Commonwealth, State or Territory government department or authority without requiring the Supplier's consent.

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 this Deed and any document related to this Deed.

49 Entire agreement

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

50 Execution of separate documents

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

51 Further acts

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

52 Governing law and jurisdiction

- 52.1 This Deed is governed by the law of the Australian Capital Territory. The Parties submit to the non-exclusive jurisdiction of its courts. The Parties will not object to the exercise of jurisdiction by those courts on any basis.

53 Severability

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

54 Waiver

- 54.1 The fact that a Party fails to do, or delays in doing, something the Party is entitled to do under this Deed, does not amount to a waiver of any obligation, or breach of obligation by, another Party. A waiver by a Party is only effective if it is in writing. A written waiver by a Party is only effective in relation to the particular obligation or breach in respect of which it is given. 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.

55 Time of the essence

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

56 No export sale of Product

- 56.1 The NBA must not, solely or in conjunction with any other person, supply (as defined in the *Therapeutic Goods Act 1989*), sell or arrange the sale of Product supplied under Deed for export from Australia, or otherwise arrange for the supply of Product supplied under this Deed except in accordance with the NBA's functions under the *National Blood Authority Act 2003* in relation to Australia.

Schedule 1 (Interpretation and Dates)

1 Commencement Date

1 July 2006

2 Expiry Date

30 June 2009

3 Rules of interpretation

3.1 In this Deed, unless otherwise expressly provided, the following rules of interpretation apply:

- 3.1.1 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;
- 3.1.2 a reference to any agreement or document is to that agreement or document as amended, novated, supplemented or replaced from time to time;
- 3.1.3 a reference to a clause, part, schedule or attachment is a reference to a clause, part, schedule or attachment of or to this Deed unless otherwise stated;
- 3.1.4 an expression importing a natural person includes any company, trust, partnership, joint venture, association, corporation, body corporate or governmental agency;
- 3.1.5 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;
- 3.1.6 a covenant or agreement on the part of two or more persons binds them jointly and severally;
- 3.1.7 where the context permits, words suggesting the singular number should be read as including the plural and vice versa;
- 3.1.8 headings are included merely to assist the reader and should not be used to assist with the interpretation of any other part of this Deed;
- 3.1.9 the Schedules and any attachments or annexures form part of this Deed;
- 3.1.10 to the extent that there is any inconsistency between anything in:

- (a) the clauses of this Deed;
- (b) the Schedules; or
- (c) any attachments or annexures,

then the document ranked higher in the list above will prevail; and

3.1.11 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”.

3.2 The Supplier agrees to use reasonable endeavours to use the following accepted abbreviations.

Accepted Abbreviations

And	&	New South Wales	NSW
Associates	Assoc	North	Nth
Australian Capital Territory	ACT	Northern Territory	NT
Building	Bldg	Parade	Pde
Canberra Hospital	TCH	Pathology	Path
Centre	Ctr	Place	Pl
Circuit	Cct	Point	Pt
Corner	Cnr	Post Office Box	PO Box
Court	Crt	Practice	Prac
Creek	Ck	Private	Priv
Department	Dept	Proprietary	Pty
Drive	Dr	Public	Pub
Estate	Est	Queensland	QLD
Floor	Fl	Road	Rd
General	Gen	Room	Rm
Health	Hlth	Services/Service	Serv
Highway	Hwy	Shopping	Shop

Hospital	Hosp	Societies	Soc
House	Hse	South	Sth
Institute	Inst	South Australia	SA
Laboratory	Lab	Street	St
Lane	La	Surgery	Surg
Level	Lv	Tasmania	TAS
Limited	Ltd	Terrace	Tce
Medical	Med	University	Uni
Memorial	Mem	Victoria	VIC
Mount	Mt	Western Australia	WA

Schedule 2 (Product and Services)

1 Product

1.1 The Product is recombinant Factor VIIa available as follows:

PRODUCT NAME	ARTG NUMBER
NovoSeven® 1.2mg	Aust R 67085
NovoSeven® 2.4mg	Aust R 67086
NovoSeven® 4.8mg	Aust R 67087

1.2 The Product is indicated for the control of bleeding in patients with haemophilia with inhibitors and for patients with rare bleeding disorders.

1.3 The Product must have a shelf life of no less than:

1.3.1 30 months for NovoSeven® 1.2mg; and

1.3.2 36 months for NovoSeven® 2.4mg and 4.8mg;

from date of manufacture.

1.4 The Product labelling must state the name of the Product, its concentration level, expiry date and batch number.

1.5 The Product Information Sheet must be included in the packaging of each Product. If not already included in the Product Information Sheet, information on reconstitution and administration of the Product must be provided in addition.

1.6 The product packaging will be bar coded with a 13 digit number in EAN format.

1.7 Each concentration of the Product must be colour coded on the carton to facilitate easy recognition by users.

1.8 The Supplier must:

1.8.1 use reasonable endeavours in all circumstances to maximise the remaining shelf life of Product on delivery to an Approved Recipient;

1.8.2 ensure that for any Financial Year of the operation of this Deed:

(a) for no less than 80% of Product delivered during the Financial Year, the expiry date on delivery is no less

than 15 months from the date of delivery to the Approved Recipient; and

- (b) for all Product delivered during the Financial Year, the expiry date on delivery is no less than 9 months from the date of delivery of the Product to the Approved Recipient.

1.9 Despite **item 1.8** of this **Schedule 2 (Product and Services)**, the Supplier may deliver to an Approved Recipient a Product having an expiry date of less than 9 months from the date of delivery if:

1.9.1 prior to delivery, the Supplier has notified the relevant Approved Recipient placing the Order that the Product has an expiry date of less than 9 months from the date of delivery; and

1.9.2 prior to the Supplier submitting an invoice under this Deed for the delivery, the Approved Recipient making the Order has confirmed in writing to the Supplier that the Order may be filled with Product having an expiry date of less than 9 months from the date of delivery.

1.10 If a Product having an expiry date of less than 9 months after the date of delivery is delivered in accordance with **item 1.9** of this **Schedule 2 (Product and Services)**, for emergency treatment, and the Product is not used prior to the expiry date of the Product, the Supplier must, on request from the NBA or the relevant Approved Recipient either:

1.10.1 supply a replacement vial of Product at no additional cost to meet the requirements of the Approved Recipient who originally made the Order for the vial of Product; or

1.10.2 if no replacement vial of Product can be supplied to meet the requirements of the Approved Recipient who originally made the Order for the vial of Product, credit the amount paid or payable under this Deed for the vial of Product against invoices for future Orders under this Deed, on return of unused vials.

2 Item Number

2.1 The Item Numbers for the Product are:

2.1.1 NS12MG for NovoSeven® 1.2mg;

2.1.2 NS24MG for NovoSeven® 2.4mg; and

2.1.3 NS48MG for NovoSeven® 4.8mg.

3 Safety and Quality Assurance

3.1 The Supplier must:

- 3.1.1 provide on the reasonable request from the NBA a copy of the certificate of analysis, including information in relation to the production date and composition of the relevant batch, for Product supplied or available for supply under this Deed; and
- 3.1.2 have established processes to ensure quality of product and supply arrangements 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 Product 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 Product are :

5.1.1 any hospital, where the Product is ordered specifically for the indications in **item 1.2 of Schedule 2 (Product and Services)**; and;

5.1.2 other hospitals approved by the NBA, as notified by the NBA to the Supplier from time to time.

5.2 For the purpose of this item, “hospital” has the same meaning as in the *Health Insurance Act 1973 (Cth)*.

5.3 The Supplier must allocate a unique identifying number (Approved Recipient number) to each Approved Recipient, including new Approved Recipients under **items 5.1.1 and 5.1.2 of this Schedule 2 (Products and Services)** and must notify the NBA of that number in accordance with **Schedule 5 (Records and Reports)**.

5.3.1 [Not disclosed.]

6 Ordering Product

6.1 The Supplier must only accept an Order from an Approved Recipient.

6.2 Subject to **item 6.3 of this Schedule 2 (Product and Services)** all Orders must be able to be received by the Supplier from an Approved Recipient by telephone (subject to facsimile confirmation next day) or facsimile during the normal business hours of 7.30am to 4.00pm (EST) of each Business Day (“Normal Business Hours”).

6.3 Despite **item 6.2 of this Schedule 2 (Product and Services)**, an urgent Order (which is an Order made only in the case of an emergency) must be able to be received by the Supplier as a phone request from an Approved Recipient outside Normal Business Hours each day of the year.

6.4 The Supplier must not accept an Order from an Approved Recipient unless it details:

6.4.1 date of order;

6.4.2 name and position of person placing order;

- 6.4.3 the name of the Product to be delivered by the Supplier;
- 6.4.4 the Item Number of the Product to be delivered by the Supplier;
- 6.4.5 the quantity of Product to be delivered by the Supplier;
- 6.4.6 the Product strength required by the Approved Recipient;
- 6.4.7 the name of the Approved Recipient;
- 6.4.8 the shipping address details as follows: [Not disclosed. Contains data format.]

- 6.4.9 timeframe, if any, within which delivery of the Product is required; and
- 6.4.10 other special requirements (if any).

7 Delivery of Product

- 7.1 Subject to this Deed, the Supplier must deliver Product to Approved Recipients in accordance with Orders.
- 7.2 The following timeframes apply for supply of the Product upon acceptance of an Order by the Supplier:
 - 7.2.1 subject to **items 7.2.2 and 7.2.3** of this **Schedule 2 (Product and Services)**, Product must be delivered within 24 hours of receipt of the Order where an Order is specified as urgent by the person making the Order;
 - 7.2.2 subject to **item 7.2.3** of this **Schedule 2 (Product and Services)**, for a non-urgent Order Product must be delivered within 48 hours from receipt of an Order, or where the Order is made on a Friday, within the next Business Day in the place in which the Approved Recipient is located; and
 - 7.2.3 for Remote Approved Recipients where an Order is specified as urgent by the person making the Order, Product must be delivered within the applicable period agreed between the Parties under **item 7.3** of this **Schedule 2 (Product and Services)**.
- 7.3 For the purposes of **item 7.2.3** of this **Schedule 2 (Product and Services)**, the Parties:
 - 7.3.1 must agree, within 5 Business Days of the commencement of this Deed; and

7.3.2 may review and agree to amend, from time to time, and at least annually;

a map of Australia showing areas agreed to be treated as Remote, and the applicable maximum timeframes for delivery in each Remote area (which timeframes must be no longer than 48 hours).

8 Acceptance of the Product

- 8.1 The Supplier must ensure that at all times the Approved Recipient signs for or otherwise acknowledges the receipt of the Product received by the Approved Recipient.
- 8.2 The Supplier must meet any reasonable requirements issued in writing by the NBA from time to time, after reasonable consultation with the Supplier, about the manner or form of acknowledgement of receipt, or the manner, form or process for maintaining records, verifying or reporting acknowledgement of receipt, for the purposes of **item 8.1** of this **Schedule 2 (Product and Services)**.

9 Quantity and Concentration of Product

- 9.1 The Product must be able to be provided in:
- 9.1.1 the quantity ranges requested; and
- 9.1.2 the following strengths: 1.2 milligram vials, 2.4 milligram vials and 4.8 milligram vials.

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, 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 via the World Foundation of Haemophilia's Haemophilia Treatment Centre directories.

12 In-country Reserve

12.1 [Not disclosed].

12.2 [Not disclosed]

12.3 [Not disclosed]

12.4 Subject to **items 12.5 and 12.6** of this **Schedule 2 (Product and Services)**, the Supplier may only supply Product held in the In-Country Reserve:

12.4.1 if, in the Supplier's reasonable opinion, it is required for treatment of a condition described in **item 1.2** of this **Schedule 2 (Product and Services)** and the Supplier has received the NBA's prior written or oral approval for the use;

12.4.2 for stock rotation (that is, where at least an equivalent number of units of Product are placed in In-country Reserve as are taken from the In-country Reserve for supply) to ensure that product held in In-country Reserve complies with **item 1.8** of this **Schedule 2 (Product and Services)**; or

12.4.3 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.

12.5 In the event that units of Product are supplied from the In-country Reserve for the purposes of **items 12.4.1 or 12.4.3** of this **Schedule 2 (Product and Services)**, the Supplier must promptly:

12.5.1 notify the NBA that the supply has taken place; and

12.5.2 initiate action to reinstate the In-country Reserve to the level required under **items 12.1 and 12.2** of this **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 Reserve for the purposes of **items 12.4.1 or 12.4.3** of this **Schedule 2 (Product and Services)**.

12.6 The Parties may from time to time agree, and if agreed must comply with, protocols to apply in relation to the processes for:

12.6.1 the Supplier seeking and receiving the NBA's approval under **item 12.4.1** of this **Schedule 2 (Product and Services)**; and

12.6.2 the Supplier notifying the NBA of supply in accordance with **item 12.5** of this **Schedule 2 (Product and Services)**.

- 12.7 In accordance with **clause 13.19.4** the In-country Reserve will not include stock held on consignment under arrangements referred to in **clause 13.19**.
- 12.8 For the purposes of **clause 13.11**, and **item 12.1** of this **Schedule 2 (Product and Services)**, the estimated annual volume of Products will be determined by the NBA and notified to the Supplier, based on a methodology agreed between the Parties from time to time.

13 Storage and Transport

- 13.1 The Supplier must store Products in temperature controlled and monitored facilities that meet the Product specific requirements, according to the Supplier's quality system, and also have arrangements in place with third party logistics providers should additional capacity be required.
- 13.2 The Supplier must maintain a distribution process which:
- 13.2.1 allows for cold chain storage of Products (where 'cold' means between 2 and 8 degrees Celsius); and
 - 13.2.2 allows for transport of Products between the Supplier and Approved Recipients throughout Australia.

Information on the actual storage locations

- 13.3 The Supplier must, on request by the NBA, provide the following information on the storage location for a Product.

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

Information on Consignment stock

- 13.4 The Supplier must provide the following information on Product held as Consignment stock, within the meaning of **clause 13**:

13.4.1 Name of Approved Recipient where Consignment stock is held;
and

13.4.2 Approved Recipient's Contact details.

14 Records

14.1 Without limitation to **clause 38**, the Supplier must retain the following records:

14.1.1 original order documentation;

14.1.2 shipping documentation;

14.1.3 copies of delivery receipts;

14.1.4 copies of invoices;

14.1.5 copies of all contact details of Approved Recipients;

14.1.6 data relating to Product supplied and distributed to be held for 7 years.

15 Product support

15.1 The Supplier agrees to provide the following Product support in the form of training programs:

15.1.1 conduct a training and education needs assessment with Haemophilia Treatment Centre Nurses within six months of commencement of the Deed;

15.1.2 develop a draft training and education and support program based on the identified needs assessment, and provide this needs assessment to the NBA as part of the background material;

15.1.3 review the draft program, including the development of a pilot program, and the associated implementation plan with the NBA within six months of commencement of the Deed; and

15.1.4 commencing with the conduct of a pilot program, implement the training program as part of an 18 month implementation plan.

16 Australian Supply Commitment

[Not disclosed]

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.]

COMMERCIAL-IN-CONFIDENCE

Schedule 4 (Payments and Invoicing)

1 Product price

- 1.1 The Price of the Product is [Not disclosed] per milligram, GST inclusive, for the 2006-07 Financial Year.
- 1.2 The Price of the Product is [Not disclosed] per milligram, GST inclusive, for the 2007-08 Financial Year.
- 1.3 The Price of the Product is [Not disclosed] per milligram, GST inclusive, for the 2008-09 Financial Year.
- 1.4 The Product Price may be invoiced monthly in arrears based on the volume of Product supplied under this Deed during the relevant month.

2 Payments

- 2.1 Payments will be made by the NBA to the Supplier upon receipt by the NBA of a Tax Invoice, in accordance with **clause 21** and subject to the satisfactory provision of the Product and performance of the Services by the Supplier (including in meeting any Key Performance Indicators for the Product and Services as described in **Schedule 3 (Performance Measures)**, in accordance with this Deed.
- 2.2 Subject to the Deed, Payments will be made in arrears 30 days from submission of a correctly rendered Tax Invoice. The Tax Invoice must include the requirements set out in this **Schedule 4 (Payments and Invoicing)**.

3 Invoicing Obligations

- 3.1 The Supplier must provide a Tax Invoice within 14 days of the end of a calendar month. This invoice will be in the form of a digital data file (using a software program reasonably acceptable to the NBA) comprising a work book containing two spread sheets in the form of a Tax Invoice and a schedule to the Tax Invoice, in accordance with this **Schedule 4 (Payments and Invoicing)**. The Supplier must also provide supporting documentation in accordance with this **Schedule 4 (Payments and Invoicing)**.
- 3.2 **Tax Invoice.** This spread sheet must be a Tax Invoice that summarises the data on the spread sheet titled [Not disclosed] (below) and contains the following: [Not disclosed]
- 3.3 **Schedule to Tax Invoice.** This work sheet is to be titled [Not disclosed] and contain the following: [Not disclosed. Contains data format.]

- 3.4 **Supporting Documentation.** If the Approved Recipient is an Approved Recipient within the meaning of **item 5 of Schedule 2 (Product and Services)**, the Supplier must include the name of the Approved Recipient, and substantiation, reasonably acceptable to the NBA, that the Order was made specifically for treatment for the indications in **item 1.2 of Schedule 2 (Product and Services)**.
- 3.5 Any other supporting documentation in support of information contained in the Tax Invoice that the NBA reasonably requires from time to time.

Schedule 5 (Records and Reports)

1 Regular Reporting

Within 14 Business Days of the commencement of each month, the Supplier must provide an electronic report to the NBA regarding the previous month which details:

- 1.1.1 achievement or otherwise of the requirements of each Order; including Product/s either withdrawn, incorrectly supplied, recalled, lost, damaged or destroyed.
- 1.1.2 the supply by the Supplier of any Product referred to in **item 1.9 of Schedule 2 (Product and Services)**;
- 1.1.3 the maintenance of reserves as required under **item 12 of Schedule 2 (Product and Services)**, to be reported in an MS Excel spreadsheet as below: [Not disclosed. Contains data format.]
- 1.1.4 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;
- 1.1.5 [Not disclosed.]
- 1.1.6 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 (if applicable).

2 Tracking of the Product Released from In-country Reserve

Despite the Supplier's reporting obligations under **Schedule 4 (Payments and Invoicing)**, the Supplier must provide within 14 Business Days of the commencement of each month a report in writing to the NBA using the following information for the tracking of the Product released from In-country Reserve to either Approved Recipients or to Consignment Stock: [Not disclosed]

3 Approved Recipient details

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
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:	
Telephone Number:	Format – 00 0000 0000
Facsimile Number:	
Email Address:	

4 Reporting against Key Performance Measures (Schedule 3)

4.1 Within 14 Business Days of the commencement of each month, the Supplier must provide an electronic report to the NBA regarding the previous month which details: [Not disclosed. Contains information about Key Performance Measures.]

5 Summary reporting table

5.1 The Parties acknowledge and agree that the following table, which summarises all reporting and notice obligations between the Parties under the Deed, is provided for the convenience and reference of the Parties only, and does not add to or modify the obligations of the Parties arising under the other provisions of the Deed.

Document	Section	Type	Obligation	Frequency
Deed	5.1	Information	Provide NBA with information about services and Product	As requested by NBA - ASAP
Deed	7.3.2	Scope of Review	NBA to provide the Supplier with the scope of the Review	Annually

Document	Section	Type	Obligation	Frequency
Deed	7.4.2	Information	Provide NBA with information or documents relevant to the Review	Within 10 Business Days of an NBA request.
Deed	10.3	Change control	Either party must provide detail information about change control request.	A party must respond within 10 Business Days to the proposal issued by the other party.
Deed	10.6	New developments	The Supplier must keep the NBA up to date with trends and new developments that impact the deed.	Supplier to advise as the information becomes available
Deed	10.7.1	New developments	The Supplier to provide written analysis to the NBA of new technology or products or services relevant to this Deed.	Within a reasonable period of time following the introduction of such technology products or services
Deed	10.9	[Not disclosed]	[Not disclosed]	[Not disclosed]
Deed	11.2	Subcontracts	Notify NBA of subcontracts	In accordance with Schedule 5 - Monthly
Deed	11.3.2	Subcontracts	The Supplier is to notify the NBA of actions taken to address concerns relating to the use of a specific subcontractor	As the situation arises
Deed	13.6.1	Provision of products and service	Either party to notify the other of the new or improved blood product or service	As the situation arises
Deed	13.9.1	Standard operating procedure	Provide copy of any specific SOP at the reasonable request of the NBA	As requested by NBA - ASAP
Deed	13.17	Notice obligation	The Supplier to notify the NBA if there is a problem that impacts the provision of Product or service.	As the situation arises

Document	Section	Type	Obligation	Frequency
Deed	14.1	Reports	The Supplier to provide reports to the NBA as per Schedule 5 (Reports)	As per schedule 5 (Reports)
Deed	14.3	Reports	The Supplier must provide a report to the NBA advising issues relating to the fulfilment of Orders.	As the situation arises
Deed	16.4.2	Australian Register of Therapeutic Goods (ARTG)	The Supplier to report changes in the status of the Product on the ARTG to the NBA.	As the situation arises
Deed	16.10.3	Results of Product testing	The Supplier is to notify the NBA and the TGA of the results of testing of a Product conducted as a result of the NBA concern over the quality and or efficacy of the Product.	As the situation arises
Deed	19.2.2	Payments	Supplier to provide correctly render Tax Invoice	Monthly
Deed	19.3	Payments	NBA to notify Supplier if there is a problem with the invoice rendered by the Supplier.	Within 5 days of receipt of Tax Invoice.
Deed	21.2	Invoicing	The Supplier to provide the NBA with written statement under s127 IR Act 1996	Before any payments are made under deed
Deed	22.1	Repayment Notice	The NBA may provide the Supplier with a request to repay the NBA for amounts that are considered not properly payable.	As the situation arises
Deed	25.4.1	Intellectual Property	The Supplier must provide the NBA with signed document to effect ownership of intellectual property	As the situation arises
Deed	25.4.2	Intellectual Property	The Supplier must provide Contract Material upon reasonable request from NBA	As the situation arises

Document	Section	Type	Obligation	Frequency
Deed	26.3	Intellectual Property and conditions of use.	[Not disclosed.]	As the situation arises
Deed	26.5	NBA Material	[Not disclosed.]	Upon termination of the Deed.
Deed	27.3	Deed of Confidentiality	The NBA may request the Supplier to organise an employee or other third party to provide a Deed of Non Disclosure of Confidential Information.	As the situation arises
Deed	28.5	Data Security	The Supplier must notify the NBA if we become aware of an authorised person accessing security classified information.	As the situation arises
Deed	29.1.11	Privacy	The Supplier must notify the NBA if we become aware of a breach of obligations concerning security, use and disclosure of Personal Information	As the situation arises
Deed	29.1.13	Privacy	The Supplier must notify the NBA if we become aware of a complaint alleging interference with privacy.	As the situation arises
Deed	30.4	Conflict of interest	The Supplier must notify the NBA of conflict of interest upon becoming aware of the conflict.	As the situation arises
Deed	32.1	Risk Management	The Supplier must provide the NBA with a Risk Management Plan	Within 10 Business Days of the Commencement Date.
Deed	32.3.1	Risk management	The Supplier must notify the NBA of new risks not adequately dealt with in the Risk Management Plan.	As the situation arises

Document	Section	Type	Obligation	Frequency
Deed	32.3.2	Risk management	The Supplier must notify the NBA of a change in existing risks not adequately dealt with in the Risk Management Plan.	As the situation arises
Deed	32.3.3	Risk management	The Supplier must notify the NBA of the method in dealing with a new risks or change in existing risks in Risk Management Plan.	As the situation arises
Deed	34.6	Indemnities	[Not disclosed]	As the situation arises
Deed	34.8	Indemnities	[Not disclosed]	As the situation arises
Deed	34.9	Indemnities	[Not disclosed]	As the situation arises
Deed	34.10.2	Indemnities	[Not disclosed]	As the situation arises
Deed	34.10.3	Indemnities	[Not disclosed]	As the situation arises
Deed	35.1	Performance Guarantee	The Supplier is to provided the NBA with a Performance Guarantee covering the Supplier's obligations under the Deed.	At Commencement of the Deed.
Deed	37.1	Force Majeure	Either Party must notify the other Party upon a force majeure event impacting the ability to meet it's obligations under the deed.	As the situation arises
Deed	39	Access to information	The Supplier must enable access to information to enable the NBA to deal with the Audit function in Clause 40	As the situation arises
Deed	40.2	Audit	The NBA must notify the Supplier that an audit is to be conducted	As the situation arises

Document	Section	Type	Obligation	Frequency
Deed	44.1	Termination for default	The NBA may by notice in writing to the Supplier, terminate this Deed.	As the situation arises
Deed	44.3	Termination for default	[Not disclosed]	As the situation arises
Deed	44.4.3	Termination for default	The Supplier must return NBA Material, Contract Material and/or Confidential Information to the NBA	As the situation arises
Deed	44.4.5	Termination for default	The NBA may notify the Supplier that it elects to purchase Product held in In-country Reserve	Notice to be provided within 10 Business Days of termination.
Deed	45.1	Termination for Change in Government Policy	The NBA may by notice in writing to the Supplier, terminate this Deed.	As the situation arises
Deed	45.6	Termination for Change in Government Policy	The NBA may notify the Supplier that it elects to purchase Product held in In-country Reserve	Notice to be provided within 2 calendar months of termination.
Deed	46.2	Dispute Resolution	A Party may give the other Party a notice of dispute in connection with this Deed.	As the situation arises
Schedule 2	1.9.1	Product	The Supplier must notify an Approved Recipient that the Product does not comply with Sch 2 clause 1.8	As the situation arises
Schedule 2	1.9.2	Product	The Approved Recipient to have confirmed the acceptance of Product with less than 9 months shelf life.	As the situation arises
Schedule 2	3.1.1	Safety & Quality Assurance	The Supplier must provide the NBA a copy of certificate of analysis.	On request from the NBA

Document	Section	Type	Obligation	Frequency
Schedule 2	5.1.2	Approved Recipients	The NBA to provide the Supplier with a list of Approved Recipient.	As the situation arises
Schedule 2	5.3	Approved Recipients	The Supplier to provide the NBA of unique identifying number of each Approved Recipient	In accordance with Schedule 5
Schedule 2	6.1	Ordering Product	The Supplier must only accept an Order from an Approved Recipient	As the situation arises
Schedule 2	8.1	Acceptance of Product	The Approved Recipient must provide the Supplier with acknowledgement that Product has been received.	As the situation arises
Schedule 2	8.2	Acceptance of Product	The Supplier must comply with reasonable instructions from NBA about recording and reporting of acceptance of Product by an Approved Recipient	As the situation arises
Schedule 2	12.4.1	In-country Reserve	The NBA must give prior written approval for use of In-country Reserve	As the situation arises
Schedule 2	12.5.1	In-country Reserve	The Supplier must notify the NBA as to the situation that caused In-country Reserves to be used.	As the situation arises
Schedule 2	12.8	In-country Reserve	The NBA to notify the Supplier of the In-country Reserve.	As the situation arises
Schedule 2	13.3	Storage locations	The Supplier must provide the NBA with details of storage location of Product.	On request from NBA
Schedule 2	13.4	Consignment stock	The Supplier must provide the NBA with details of consignment stock.	On request from NBA

Document	Section	Type	Obligation	Frequency
Schedule 2	15.1.2	Product support	The Supplier must provide the NBA with a needs assessment and draft training plan for comment.	Within 6 months from Commencement Date
Schedule 2	16	Australian Supply Commitment	[Not disclosed]	As the situation arises
Schedule 3		Performance Measures	See schedule 3	
Schedule 4	2.1	Payments	The Supplier must provide the NBA a correctly rendered Tax Invoice.	As the situation arises
Schedule 4	3.1	Invoicing Obligations	The Supplier must provide the NBA with a Tax Invoice in a digital format.	Within 14 days of end of calendar month
Schedule 4	3.4	Invoicing Obligations	The Supplier must supporting documentation that the Order was made for treatment within the indications.	As the situation arises
Schedule 4	3.5	Invoicing Obligations	The Supplier must provide the NBA with any additional supporting documentation for the Tax Invoice.	On request from NBA
Schedule 5	1	Regular Reporting	The Supplier must provide the NBA with an electronic report regarding the previous month, detailing issues covered in clause 1.1.1, 1.1.2, 1.1.3, 1.1.4, 1.1.5 and 1.1.6.	Within 14 Business Days of the commencement of each month.
Schedule 5	2	Tracking of the Product Released from In-country Reserve.	The Supplier must provide the NBA with a report advising movements of Product in the In-country Reserve.	Within 14 Business Days of the commencement of each month.
Schedule 5	3	Approved Recipient details	The Supplier must advise the NBA of requested information relating to the creation of a new Approved Recipient.	On request from NBA, or as the situation arises

Document	Section	Type	Obligation	Frequency
Schedule 5	4	Reporting against Key Performance Indicators	[Not disclosed]	Within 14 Business Days of the commencement of each month.
Schedule 7	1	Public affairs management	[Not disclosed]	As the situation arises

Schedule 6 (Contacts)

1 Contacts for delivery of formal notices under the Deed:

NBA: [Not disclosed]

Supplier: [Not disclosed]

2 Contacts for resolution of disputes under the Deed:

NBA: [Not disclosed]

Supplier: [Not disclosed]

3 Contact details (day-to-day):

NBA: [Not disclosed]

Supplier: [Not disclosed]

Schedule 7 (Public affairs management)

[Not disclosed]

Schedule 8 (Insurance)

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

- industrial special risks covering accidental loss and/or damage for all real and personal property and business interruption; and
- public and product liability insurance.]

Schedule 9 (Performance Guarantee)

[Not disclosed. Schedule 9 contains details of the 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:

.....
Name of authorised officer

.....
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
NOVO NORDISK PHARMACEUTICALS PTY LTD ABN 40 002 879 996 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