

CONTRACT FOR SERVICES

Between

COMMONWEALTH OF AUSTRALIA

acting through the

Convenor of the Independent Review (PBS)

and

<REVIEWER'S FULL NAME>

**in relation to Services for
the Independent Review (PBS)**

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Sample Contract

CONTRACT

This Contract is made between the

COMMONWEALTH OF AUSTRALIA ('the Commonwealth') acting through the
Convenor of the Independent Review ('the Convenor')

and

[Insert Reviewer name and address]

.....
(‘the Reviewer’)

PURPOSE

- A The Commonwealth requires the provision of certain services as specified in the Schedule.
- B The Reviewer has fully informed himself or herself on all aspects of the work required to be performed under this contract.
- C The Commonwealth has agreed to engage the Reviewer to provide the Services upon the terms and conditions contained in this Contract.

OPERATIVE PART

1. INTERPRETATION AND OPERATION OF CONTRACT

1.1 In this Contract, unless the contrary intention appears:

‘**Auditor-General**’ means the office established under the *Auditor-General Act 1997* and includes any other entity that may, from time to time, perform the functions of that office;

‘**Business Day**’ means, in relation to the doing of any action in a place, any day other than a Saturday, Sunday, or public holiday in that place;

‘**Commonwealth Material**’ means any Material provided by the Commonwealth to the Reviewer for the purposes of this Contract, or derived at any time from the Material so provided;

‘**Confidential Information**’ means:

- (a) all Commonwealth Material which the Commonwealth designates as confidential;

- (ai) all Commonwealth Material relating to the Sponsor's submission as provided to the Convenor by the PBAC Secretariat, as listed in Item K;
- (b) all Contract Material unless the Commonwealth agrees otherwise;
- (c) other information (whether in writing or not) that:
 - (i) is by its nature confidential;
 - (ii) is designated by the Commonwealth as confidential, or the Reviewer knows or ought to know is confidential;

but does not include information which:

- (iii) is or becomes public knowledge (including information which becomes public by being posted on a public website of the Department) other than by breach of this Contract or by any other unlawful means;
- (iv) is in the possession of the Reviewer without restriction in relation to disclosure before the date of receipt from the Commonwealth; or
- (v) has been developed or acquired by the Reviewer other than for the purposes of the Contract;

'Contract Material' means all Material:

- (a) created for the purposes of this Contract;
- (b) provided or required under this Contract to be provided to the Commonwealth as part of the Services; or
- (c) derived at any time from the Material referred to in paragraphs (a) or (b);

'Convenor' means the person specified by name or position in Item J [*Convenor*] acting on behalf of the Commonwealth or any substitute notified by the Commonwealth in writing to the Reviewer;

'Department' means the Department of Health and Ageing and includes any department or agency of the Commonwealth which is from time to time responsible for the administration of this Contract;

'Drug or medicinal preparation' means the product which the Reviewer is required to review pursuant to this Contract;

'Intellectual Property' includes all copyright (including rights in relation to phonograms and broadcasts), all rights in relation to inventions (including patent rights), plant varieties, registered and unregistered trade marks (including service marks), registered and unregistered designs, circuit layouts, and all other rights

resulting from intellectual activity in the industrial, scientific, literary or artistic fields;

‘Independent Review’ means the Independent Review (PBS) which is the independent review mechanism established pursuant to Australia’s obligations under the Australia-United States Free Trade Agreement;

‘Material’ includes documents, equipment, software (including source code and object code), goods, information and data stored by any means including all copies and extracts of the same;

‘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;

‘PBAC’ means the Pharmaceutical Benefits Advisory Committee, a committee established under the *National Health Act 1953*;

‘PBS’ means the Pharmaceutical Benefits Scheme established by Part VII of the *National Health Act 1953*;

‘Reviewer’ is the person who has been contracted to undertake the Services;

‘Review Application’ means an application made by a Sponsor for review under Independent Review;

‘Secondary Reviewer’ is the person contracted by the Convenor to undertake additional work on a review if and when necessary;

‘Secondary Reviewer Contract’ is the Contract for Services between the Commonwealth and the Secondary Reviewer;

‘Services’ means the services described in Item A [*Services*] and includes the provision to the Commonwealth of the Material specified in Item B [*Required Contract Material*];

‘Specified Personnel’ means the personnel specified in Item I [*Specified Personnel*] (whether employees or subcontractors or otherwise) as personnel required to perform all or part of the work constituting the Services; and

‘Sponsor’ means the entity which makes the application for the listing of the Drug or medicinal preparation on the PBS.

1.2 In this Contract, unless the contrary intention appears:

- (a) words importing a gender include any other gender;
- (b) words importing persons include a partnership and a body whether corporate or otherwise;

- (c) words in the singular include the plural and words in the plural include the singular;
 - (d) clause headings are inserted for convenient reference only and have no effect in limiting or extending the language of provisions to which they refer;
 - (e) all references to dollars are to Australian dollars;
 - (f) reference to any statute or other legislation (whether primary or subordinate) is to a statute or other legislation of the Commonwealth of Australia as amended or replaced from time to time;
 - (g) where any word or phrase is given a defined meaning, any other part of speech or other grammatical form in respect of that word or phrase has a corresponding meaning;
 - (h) reference to an Item is to an Item in the Schedule;
 - (i) the Schedule and any attachments form part of this Contract;
 - (j) where any conflict arises between the terms and conditions contained in the clauses of this Contract and any part of the Schedule (and attachments if any), the terms and conditions of the clauses prevail;
 - (k) where any conflict arises between any part of the Schedule and any part of an attachment, the Schedule prevails; and
 - (l) reference to the Schedule (or an attachment) is a reference to the Schedule (or an attachment) to this Contract.
- 1.3 This Contract records the entire agreement between the parties in relation to its subject matter.
- 1.4 No variation of this Contract is binding unless it is agreed in writing between the parties.
- 1.5 Any reading down or severance of a particular provision does not affect the other provisions of this Contract.
- 1.6 The laws of the Australian Capital Territory apply to this Contract. The parties agree to submit to the non-exclusive jurisdiction of the courts of the Australian Capital Territory in respect of any dispute under this Contract.
- 1.7 The Reviewer cannot assign its obligations, and agrees not to assign its rights, under this Contract without, in either case, prior approval in writing from the Commonwealth.
- 1.8 The Reviewer agrees not to consult with any other person for the purposes of entering into an arrangement that will require novation of this Contract without first consulting the Commonwealth.

2. PROVISION OF SERVICES

2.1 The Reviewer agrees to:

- (a) perform the Services in accordance with this Contract, with due care and skill and in accordance with relevant best practice, including any Commonwealth and industry standards and guidelines specified in Item C [*Standards and Best Practice*];
- (b) ensure that the Services and Contract Material are fit for the purpose for which they are provided;
- (c) comply with the time frame for the performance of the Services specified in Item D [*Time-frame*]; and
- (d) liaise with the Convenor, provide any information the Convenor or the Commonwealth may reasonably require, and comply with any reasonable directions of the Convenor or the Commonwealth.

3. FEES, ALLOWANCES AND ASSISTANCE

3.1 The Commonwealth agrees to:

- (a) pay the fees specified in Item E [*Fees*];
- (b) pay the allowances and meet the costs specified in Item F [*Allowances and Costs*]; and
- (c) provide the facilities and assistance specified in Item G [*Facilities and Assistance*].

3.2 The Commonwealth will be entitled, in addition to any other right it may have, to withhold any payment of fees or allowances until the Reviewer has completed to the satisfaction of the Commonwealth that part of the Services to which the payment relates.

3.3 The Reviewer agrees to submit invoices for payment in the manner specified in Item H [*Invoice Procedures*] and clause 4 [*Taxes, Duties and Government Charges*].

3.4 The Reviewer agrees to be responsible at his or her own expense for the compliance with all statutory obligations relating to superannuation and for provision of any compulsory superannuation contributions. This includes the payment of all superannuation contributions to any employee, subcontractor or agent of the Reviewer.

3.5 If the Commonwealth is held at any time to be liable to make superannuation contribution payments to the Reviewer or any of his or her employees, subcontractors or agents, the Reviewer will indemnify the Commonwealth for the full extent (allowable under law) of any contribution required to be paid by the Commonwealth (under the Superannuation Guarantee (Administration) Act 1992 or

other relevant legislation or legal obligation). In such an event, the Reviewer will immediately provide details of the appropriate superannuation fund into which the Commonwealth should pay the superannuation contributions.

3.6 Clause 3.5 shall survive the expiry or earlier termination of this Contract.

4. TAXES, DUTIES AND GOVERNMENT CHARGES

4.1 Subject to this clause, all taxes, duties and government charges imposed or levied in Australia or overseas in connection with this Contract will be borne by the Reviewer.

4.2 The provisions of this clause in respect of GST apply where the Reviewer is registered, or is required to be registered for GST.

4.3 The goods, services and other supplies made by the Reviewer under this Contract are Taxable Supplies within the meaning of the GST Law.

4.4 The Reviewer will issue the Commonwealth with a 'tax invoice' in accordance with the GST Act together with, or as a part of, each invoice submitted for payment in accordance with clause 3.3.

4.5 The amounts payable by the Commonwealth to the Reviewer, as determined under clause 3 [*Fees, Allowances and Assistance*], are stated inclusive of GST but must not include any amount which represents GST paid by the Reviewer for which the Reviewer may claim an input tax credit.

4.6 If a payment to satisfy a claim or a right to claim under or in connection with this Contract gives rise to a liability to pay GST, the payer must also pay, and indemnify the payee against the amount of that GST.

4.7 If a party has a claim under or in connection with this Contract for a cost on which that party must pay GST, the claim is for the cost plus all GST on that cost (except any GST for which that party is entitled to an input tax credit).

4.8 For the purposes of this clause 4, 'GST', 'GST Law' 'supply', 'input tax credit' and other terms relevant to GST, have any meanings given in the *A New Tax System (Goods and Services Tax) Act 1999* and any applicable rulings of the Australian Taxation Office.

5. SUBCONTRACTORS

5.1 The Reviewer agrees that any subcontractor specified in Item A will perform work in relation to the Services in accordance with this Contract.

5.2 Except as provided for in this Contract, the Reviewer agrees not to enter into any arrangement (including without limitation any subcontract) with another party in relation to the performance of the Services, unless the Reviewer is satisfied:

- (a) that the arrangement facilitates compliance by the Reviewer with its obligations under this Contract;

- (b) that the arrangement in no way conflicts with or detracts from the rights and entitlements of the Commonwealth under this Contract; and
 - (c) that such party is financially viable and has the relevant expertise necessary for the proper performance of the activity in question.
- 5.3 In any arrangement referred to in clause 5.2 the Reviewer agrees to secure for itself a right to terminate any arrangement on terms no less favourable than those accorded the Commonwealth by clauses 19 and 20, in the event of this Contract being terminated.
- 5.4 Where a subcontractor specified in Item A is unable to perform the work, the Reviewer agrees to notify the Convenor immediately.
- 5.5 Where clause 5.4 applies, the Commonwealth may request the Reviewer to arrange for a replacement subcontractor acceptable to the Commonwealth at no additional cost and at the earliest opportunity.
- 5.6 If the Reviewer does not comply with any request made under clause 5.5 the Commonwealth may terminate this Contract in accordance with the provisions of clause 20 [*Termination for Default*].
- 5.7 Except as specified in Item A, the Reviewer agrees not to subcontract the performance of any part of the Services without the prior approval in writing of the Commonwealth.
- 5.8 The Commonwealth may impose any terms and conditions it considers appropriate when giving its approval under clause 5.7.
- 6. SPECIFIED PERSONNEL AND OTHER PERSONNEL**
- 6.1 The Reviewer agrees that the Specified Personnel will perform work in relation to the Services in accordance with this Contract.
- 6.2 Where Specified Personnel are unable to perform the work, the Reviewer agrees to notify the Convenor immediately.
- 6.3 The Commonwealth may, at its absolute discretion, request the Reviewer to remove personnel (including Specified Personnel) from work in relation to the Services.
- 6.4 Where clauses 6.2 or 6.3 apply, the Commonwealth may request the Reviewer to provide acceptable replacement personnel at no additional cost and at the earliest opportunity.
- 6.5 If the Reviewer does not comply with any request made under clause 6.4 the Commonwealth may terminate this Contract in accordance with the provisions of clause 20 [*Termination for Default*].

7. RESPONSIBILITY OF REVIEWER

7.1 The Reviewer agrees to be fully responsible for the performance of the Services and for ensuring compliance with the requirements of this Contract, and will not be relieved of that responsibility because of any:

- (a) involvement by the Convenor in the performance of the Services;
- (b) payment made to the Reviewer on account of the Services;
- (c) subcontracting of the Services; or
- (d) acceptance by the Convenor of replacement personnel.

8. COMMONWEALTH MATERIAL

8.1 The Commonwealth agrees to provide Material to the Reviewer as specified in Item K [*Material to be Provided by Commonwealth*].

8.2 The Commonwealth grants to the Reviewer a royalty-free, licence fee-free, non-exclusive licence to use, reproduce and adapt the Commonwealth Material for the purposes of this Contract.

8.3 The Reviewer agrees to ensure that all Commonwealth Material is used strictly in accordance with any conditions or restrictions set out in Item L [*Use of Commonwealth Material*], and any direction by the Commonwealth.

8.4 Property in any copy of Commonwealth Material (in the form of a document, article or removable medium) vests or remains vested in the Commonwealth. The Reviewer agrees:

- (a) to secure all copies within its control against loss and unauthorised use or disclosure; and
- (b) on the expiration or termination of this Contract, to deliver to the Commonwealth, or, in accordance with Commonwealth directions erase or otherwise deal with all such copies,

unless any provision to the contrary is set out in Item N [*Dealings with Copies*].

9. INTELLECTUAL PROPERTY IN CONTRACT MATERIAL

9.1 Intellectual Property in all Contract Material other than Contract Material brought into existence by a Sponsor vests or will vest in the Commonwealth.

9.2 Clause 9.1 does not affect the ownership of Intellectual Property in any existing Material which is specified in Item M [*Existing Material*], but the Reviewer grants to the Commonwealth a permanent, irrevocable, royalty-free, licence fee-free, world-wide, non-exclusive licence (including a right of sublicense) to use, reproduce, adapt and exploit any such existing Material in conjunction with the other Contract Material.

9.3 If requested by the Commonwealth, the Reviewer agrees to bring into existence, sign, execute or otherwise deal with any document which may be necessary or desirable to give effect to this clause 9.

9.4 The Reviewer warrants that it is entitled, or will be entitled at the relevant time, to deal with the Intellectual Property in the Contract Material in the manner provided for in this clause 9.

9.5 Property in any copy of Contract Material (in the form of a document, article or removable medium) vests or will vest in the Commonwealth. The Reviewer agrees:

- (a) to secure all copies within its control against loss and unauthorised use or disclosure; and
- (b) on the expiration or termination of this Contract, to deliver to the Commonwealth, or, in accordance with Commonwealth directions erase or otherwise deal with all such copies,

unless any provision to the contrary is set out in Item N [*Dealings with Copies*].

10. MORAL RIGHTS

10.1 For the purposes of this clause, 'Specified Acts' in relation to particular Material, means the following classes or types of acts or omissions performed by or on behalf of the Commonwealth:

- (a) those which would, but for this clause, infringe the author's right of attribution of authorship or the author's right of integrity of authorship,

but does not include:

- (b) those which would infringe the author's right not to have authorship falsely attributed.

10.2 The Reviewer agrees to ensure that:

- (a) the author of any Contract Material, other than existing Material specified in Item M [*Existing Material*], has given or will give a written consent to the Specified Acts (whether occurring before or after the consent is given) which is given expressly for the benefit of the Commonwealth; and
- (b) the author of any existing Material specified in Item M [*Existing Material*] has given or will give a written consent to the Specified Acts (whether occurring before or after the consent is given) which is given expressly for the benefit of the Commonwealth in relation to such Material being used, reproduced, adapted or exploited in conjunction with the other Contract Material.

10.3 The operation of this clause 10 survives the expiration or termination of this Contract.

11. DISCLOSURE OF INFORMATION

- 11.1 The Reviewer agrees not to disclose to any person other than the Commonwealth (or the Convenor or the Secondary Reviewer where it is necessary to do so for the purposes of Independent Review or the PBAC for the purpose of presenting and discussing the Reviewer's findings as requested by the Convenor), any Confidential Information relating to this Contract or the Services without prior approval in writing from the Commonwealth.
- 11.2 The Commonwealth may impose any conditions it considers appropriate when giving its approval under clause 11.1, and the Reviewer agrees to comply with these conditions.
- 11.3 The Commonwealth may at any time require the Reviewer to give, and to arrange for its officers, employees, agents and subcontractors engaged in the performance of the Services to give, undertakings in writing in a form required by the Commonwealth, relating to the non-disclosure of Confidential Information.
- 11.4 If the Reviewer receives a request under clause 11.3 it agrees to promptly arrange for all such undertakings to be given.
- 11.5 The obligations on the Reviewer under this clause 11 will not be taken to have been breached where the information referred to is legally required to be disclosed.
- 11.6 Property in any copy of Confidential Information (in the form of a document, article or removable medium) vests or will vest in the Commonwealth. The Reviewer agrees:
- (a) to secure all copies within its control against loss and unauthorised use or disclosure; and
 - (b) on the expiration or termination of this Contract, to deliver to the Convenor, or, in accordance with Convenor's directions erase or otherwise deal with all such copies,
- unless any provision to the contrary is set out in Item N [*Dealings with Copies*].
- 11.7 The Commonwealth gives no undertaking to treat Reviewer information, or this Contract, as confidential information. The Reviewer acknowledges that the Commonwealth may disclose information relevant to this Contract, or this Contract itself to any person:
- (a) to the extent required by law or by a lawful requirement of any government or governmental body, authority or agency;
 - (b) if required in connection with legal proceedings;
 - (c) for public accountability reasons, including a request for information by parliament or a parliamentary committee or a Commonwealth Minister;

- (d) to Commonwealth third party service providers for the purposes of providing goods and services to, or on behalf of, the Commonwealth; or
- (e) for any other requirements of the Commonwealth.

11.8 The Reviewer must seek the Commonwealth's approval (which may be withheld in the Commonwealth's absolute discretion) before the Reviewer:

- (a) makes any announcement or statement, whether orally or in writing that may reasonably be expected to become publicly available;
- (b) communicates with the media; or
- (c) communicates with a representative of another government or another agency,

on any matter relating to the Independent Review, PBAC, PBS, and/or the Services.

The operation of this clause 11 survives the expiration or termination of this Contract.

12. PROTECTION OF PERSONAL INFORMATION

12.1 This clause applies only if the Reviewer deals with Personal Information when, and for the purpose of, providing the Services under this Contract.

12.2 In this clause 12, the terms 'approved privacy code' (APC), 'Information Privacy Principles' (IPPs) and 'National Privacy Principles' (NPPs) have the same meaning as they have in section 6 of the *Privacy Act 1988* (the Privacy Act).

12.3 The Reviewer acknowledges that it is a 'contracted service provider' within the meaning of section 6 of the Privacy Act, and agrees in respect of the provision of the Services under this Contract:

- (a) to use Personal Information obtained during the course of providing the Services under this Contract, only for the purposes of this Contract;
- (b) not to do any act or engage in any practice that would breach an IPP contained in section 14 of the Privacy Act, which if done or engaged in by the Commonwealth, would be a breach of that IPP;
- (c) to carry out and discharge the obligations contained in the IPPs as if it were the Commonwealth under the Privacy Act;
- (d) to notify individuals whose Personal Information the Reviewer holds, that complaints about acts or practices of the Reviewer may be investigated by the Privacy Commissioner who has power to award compensation against the Reviewer in appropriate circumstances;
- (e) not to use or disclose Personal Information or engage in an act or practice that would breach section 16F (direct marketing) of the Privacy Act, any

NPP (particularly NPPS 7 to 10) or an APC where that section, NPP or APC is applicable to the Reviewer, unless:

- (i) in the case of section 16F, the use or disclosure is necessary, directly or indirectly, to discharge an obligation under this Contract; or
 - (ii) in the case of an NPP or an APC, where the activity or practice is engaged in for the purpose of discharging, directly or indirectly, an obligation under this Contract, and the activity or practice which is authorised by this Contract is inconsistent with the NPP or APC;
- (f) to disclose in writing to any person who asks, the content of the provisions of this Contract (if any) that are inconsistent with an NPP or an APC binding a party to this Contract;
 - (g) to immediately notify the Convenor if the Reviewer becomes aware of a breach or possible breach of any of the obligations contained in, or referred to in, this clause 12, whether by the Reviewer or any subcontractor; and
 - (h) to ensure that any employee of the Reviewer who is required to deal with Personal Information for the purposes of this Contract is made aware of the obligations of the Reviewer set out in this clause 12.

12.4 The Reviewer agrees to ensure that any subcontract entered into for the purpose of fulfilling its obligations under this Contract contains provisions to ensure that the subcontractor has the same awareness and obligations as the Reviewer has under this clause, including the requirement in relation to subcontracts.

12.5 The Reviewer agrees to indemnify the Commonwealth in respect of any loss, liability or expense suffered or incurred by the Commonwealth which arises directly or indirectly from a breach of any of the obligations of the Reviewer under this clause 12, or a subcontractor under the subcontract provisions referred to in clause 12.4.

12.6 The operation of this clause 12 survives the expiration or termination of this Contract.

13. COMPLIANCE WITH LAWS AND POLICIES

13.1 The Reviewer agrees, in carrying out this Contract, to comply with:

- (a) all relevant legislation of the Commonwealth (particularly the *Crimes Act 1914*, *Criminal Code Act 1995*, *Racial Discrimination Act 1975*, *Sex Discrimination Act 1984*, *Disability Discrimination Act 1992*, *Equal Opportunity for Women in the Workplace Act 1999*, *Age Discrimination Act 2004* and *Auditor-General Act 1997*), or of any State, Territory or local authority; and

- (b) any policies notified to the Reviewer in writing, or listed in Item C.
- 13.2 The Reviewer acknowledges that under subsection 137.1 of the *Criminal Code Act 1995*, giving false or misleading information to the Commonwealth is a serious offence.
- 13.3 The Reviewer agrees, when using the Commonwealth's premises or facilities, to comply with all reasonable directions and procedures relating to occupational health, safety and security in operation at those premises or in regard to those facilities (including the Commonwealth's smoke-free work-place policy) whether specifically drawn to the attention of the Reviewer or as might reasonably be inferred from the circumstances.
- 13.4 The Reviewer shall comply with, and require its officers, employees, agents and subcontractors to comply with, the behaviours set out in the Code of Conduct in section 13 of the *Public Service Act 1999*.

14. CONFLICT OF INTEREST

- 14.1 The Reviewer warrants that, to the best of its knowledge after making diligent inquiry, at the date of signing this Contract no conflict with the interests of the Commonwealth exists or is likely to arise in the performance of the Services by the Reviewer or its employees, agents or subcontractors.
- 14.2 If, during the performance of the Services a conflict of interest arises, or appears likely to arise in respect of the Reviewer or any of its employees, agents or subcontractors, the Reviewer agrees to:
 - (a) notify the Convenor immediately in writing of that conflict or apparent conflict and the steps the Reviewer proposes to take to resolve or otherwise deal with the conflict or apparent conflict;
 - (b) make full disclosure of all relevant information relating to the conflict or apparent conflict; and
 - (c) take such steps as have been proposed by the Reviewer, or at the discretion of the Commonwealth, take such steps as the Commonwealth may reasonably require to resolve or otherwise deal with the conflict.
- 14.3 If the Reviewer does not notify the Convenor or is unable or unwilling to resolve or deal with the conflict as required, the Commonwealth may terminate this Contract in accordance with the provisions of clause 20 [*Termination for Default*].
- 14.4 The Reviewer agrees that it will not, and will use its best endeavours to ensure that any officer, employee, agent or subcontractor of the Reviewer does not, engage in any activity or obtain any interest during the course of this Contract that is likely to conflict with or restrict the Reviewer in providing the Services to the Commonwealth fairly and independently.

15. ACCOUNTABILITY

15.1 The Reviewer agrees to give to the Convenor and any persons authorised in writing by the Commonwealth (including but not limited to, the Auditor-General and the Privacy Commissioner) the right of access to premises:

- (a) at which Material associated with this Contract is stored; and
- (b) where work associated with this Contract is undertaken,

at all reasonable times. The right of access will include (but not be limited to) the right to inspect and copy documents, records and other Material for purposes associated with this Contract or any review of performance under this Contract.

15.2 The rights referred to in clause 15.1 are subject to:

- (a) the provision of reasonable prior notice from the Commonwealth (except where there is an actual or apprehended breach of the law); and
- (b) the reasonable security procedures of the Reviewer.

15.3 The Reviewer agrees to provide all reasonable assistance requested by the Commonwealth in respect of any inquiry into or concerning the Services or this Contract.

15.4 Without limitation to the generality of clause 15.3:

- (a) the assistance to be provided by the Reviewer under clause 15.3 will include, as appropriate, the provision of documents, records or other Material, and making available relevant personnel of the Reviewer to provide information or answer questions on any matters relevant to or arising from this Contract or the performance of the Services which might reasonably be expected to be within the knowledge of the Reviewer; and
- (b) an inquiry referred to in clause 15.3 will include any administrative or statutory review, audit or inquiry (whether within or external to the Department), any request for information directed to the Commonwealth, and any inquiry conducted by Parliament or any Parliamentary committee.

15.5 The Commonwealth will endeavour to notify the Reviewer as early as possible of any assistance required under clause 15.3, provided always that the Reviewer acknowledges that such notice may be oral and is not subject to any minimum notice period requirement.

15.6 The requirement for access under this clause does not in any way reduce the responsibility of the Reviewer to perform its obligations in accordance with this Contract.

15.7 The Reviewer agrees to ensure that any subcontract entered into for the purpose of this Contract contains an equivalent clause permitting the Convenor, and other persons authorised by the Convenor, to have access as specified in these clauses.

15.8 The operation of this clause 15 survives the expiration or termination of this Contract for a period of seven years.

16. INDEMNITY

16.1 The Reviewer agrees to indemnify the Commonwealth, its officers, employees and agents ('those indemnified') from and against any:

- (a) loss or liability incurred by the Commonwealth;
- (b) loss of or damage to property of the Commonwealth; or
- (c) loss or expense incurred by the Commonwealth in dealing with any claim against it including legal costs and expenses on a solicitor/own client basis and the cost of time spent, resources used or disbursements paid by the Commonwealth,

arising from:

- (d) any act or omission by the Reviewer, its officers, employees, agents or subcontractors in connection with this Contract, where there was fault (including, without limitation, any negligent or otherwise tortious act or omission) on the part of the person whose conduct gave rise to that liability, loss, damage or expense; or
- (e) any breach by the Reviewer of its obligations or warranties under this Contract.

16.2 The Reviewer's liability to indemnify the Commonwealth under clause 16.1 will be reduced proportionately to the extent that any negligent or other tortious act or omission of the Commonwealth contributed to the relevant liability, loss or damage, or loss or expense.

16.3 The right of the Commonwealth to be indemnified under this clause 16:

- (a) is in addition to, and not exclusive of, any other right, power or remedy provided by law; and
- (b) does not entitle the Commonwealth to be compensated in excess of the amount of the relevant loss, damage, expense or liability.

16.4 The Reviewer agrees that the Commonwealth will be taken to be acting as agent or trustee for and on behalf of those indemnified from time to time.

16.5 The operation of this clause 16 survives the expiration or termination of this Contract.

17. INSURANCE

17.1 The Reviewer warrants that it has taken out or shall take out, and shall maintain for the period specified in clause 17.2 or 17.3 as applicable, the relevant types

and amounts of insurance for all the Reviewer's obligations under this Contract, including but not limited to the types and corresponding amounts of insurance specified in Item O [*Insurance*].

- 17.2 If the Reviewer takes out a 'claims made policy', which requires all claims and any fact situation or circumstance that might result in a claim to be notified within the period of insurance, the Reviewer must maintain the policy during the term of this Contract and for 7 years after the expiry or earlier termination of this Contract.
- 17.3 If the Reviewer takes out an 'occurrence' policy, which requires the circumstances to which a claim relates to occur during the period of insurance whilst the notification of event can occur at any time subsequently, the Reviewer must maintain the policy during the term of this Contract.
- 17.4 The Reviewer must, on request, promptly provide to the Conventor any relevant insurance policies and certificates of currency for inspection.
- 17.5 This clause 17 survives the expiration or earlier termination of this Contract.

18. DISPUTE RESOLUTION

- 18.1 The parties agree that any dispute arising during the course of this Contract will be dealt with as follows:
- (a) first, the party claiming that there is a dispute will send to the other a notice setting out the nature of the dispute;
 - (b) secondly, the parties will try to resolve the dispute by direct negotiation, including by referring the matter to persons who have authority to intervene and direct some form of resolution;
 - (c) thirdly, the parties have 10 Business Days from the receipt of the notice to reach a resolution or to agree that the dispute will be submitted to mediation or some other form of alternative dispute resolution procedure; and
 - (d) lastly, if:
 - (i) there is no resolution or agreement; or
 - (ii) there is a submission to mediation or some other form of alternative dispute resolution procedure, but there is no resolution within 15 Business Days of the submission, or such extended time as the parties may agree in writing before the expiration of the 15 Business Days,

then, either party may commence legal proceedings.

- 18.2 Despite the existence of a dispute, the Reviewer will (unless requested in writing not to do so) continue to perform the Services.

18.3 This clause 18:

- (a) does not apply to action by either party under or purportedly under clause 3.2 [*Fees, Allowances and Assistance*], clause 19 [*Termination for Convenience*] or clause 20 [*Termination For Default*]; and
- (b) does not preclude either party from commencing legal proceedings for urgent interlocutory relief.

19. TERMINATION FOR CONVENIENCE

19.1 The Commonwealth may, at any time by notice, terminate this Contract immediately.

19.2 Upon receipt of a notice of termination the Reviewer agrees to:

- (a) stop work on this Contract; and
- (b) take all available steps to minimise loss resulting from that termination and to protect Commonwealth Material and Contract Material.

19.3 Where there has been a termination under clause 19.1, the Commonwealth will be liable only for:

- (a) payments and assistance under clause 3 [*Fees, Allowances and Assistance*] for services properly rendered before the effective date of termination; and
- (b) reasonable costs unavoidably incurred by the Reviewer and directly attributable to the termination.

19.4 The Commonwealth will not be liable to pay compensation under clause 19.3(b) in an amount which would, in addition to any amounts paid or due, or becoming due, to the Reviewer under this Contract, together exceed the fees set out in Item E [*Fees*].

19.5 The Reviewer will not be entitled to compensation for loss of prospective profits.

Note: The Convenor will promptly advise the Commonwealth and the Sponsor if termination occurs under this clause.

20. TERMINATION FOR DEFAULT

20.1 Where a party fails to satisfy any of its obligations under this Contract, the other party may:

- (a) if it considers that the failure is not capable of remedy - by notice, terminate this Contract immediately;

- (b) if it considers that the failure is capable of remedy - by notice, require that the failure be remedied within a time specified in the notice (being not less than seven days); and
- (c) if the failure is not remedied in accordance with a notice given under paragraph (b) - by further notice, terminate this Contract immediately.

20.2 The Commonwealth may also, by notice, terminate this Contract immediately (but without prejudice to any prior right of action or remedy which either party has or may have) if the Reviewer:

- (a) being a corporation, comes under one of the forms of external administration referred to in chapter 5 of the *Corporations Act 2001*, or an order has been made for the purpose of placing the corporation under external administration; or
- (b) being an individual, becomes bankrupt or enters into a scheme of arrangement with creditors.

Note: The Convenor will promptly advise the Commonwealth and the Sponsor if termination occurs under this clause.

21. NEGATION OF EMPLOYMENT, PARTNERSHIP AND AGENCY

- 21.1 The Reviewer agrees not to represent itself, and to use its best endeavours to ensure that its officers, employees, agents and subcontractors do not represent themselves, as being an officer, employee, partner or agent of the Commonwealth, or as otherwise able to bind or represent the Commonwealth.
- 21.2 The Reviewer is not, by virtue of this Contract, an officer, employee, partner or agent of the Commonwealth, nor does the Reviewer have any power or authority to bind or represent the Commonwealth.

22. WAIVER

- 22.1 A waiver of any provision in this Contract must be in writing.
- 22.2 No waiver of a term or condition of this Contract will operate as a waiver of another breach of the same or of any other term or condition contained in this Contract.
- 22.3 If a party does not exercise (or delays in exercising) any of its rights, that failure or delay does not operate as a waiver of those rights.
- 22.4 A single or partial exercise by a party of any of its rights does not prevent the further exercise of any right.

23. NOTICES

- 23.1 A party giving notice under this Contract must do so in writing, including by facsimile that is:

- (a) directed to the recipient's address, as varied by any notice; and
- (b) hand delivered or sent by pre-paid post or facsimile to that address.

The parties' address details are as specified in Item P [*Address for Notices*].

23.2 The parties agree that a notice given in accordance with clause 23.1 is received:

- (a) if hand delivered, on delivery;
- (b) if sent by pre-paid post, on the third Business Day after the date of posting;
- (c) if sent by facsimile, at the time the sender receives notification that the notice has been transmitted satisfactorily.

Sample Contract

THE SCHEDULE

A. Services (see clauses 1.1 and 2.1)

From 1 January 2005, independent review has been available to any applicant whose submission to the PBAC has not resulted in a recommendation to list the drug on the PBS. From the July 2006 PBAC meeting, independent review is also available in certain circumstances where the PBAC has declined to recommend an extension of the listing of an already listed drug.

The review will be conducted in accordance with the guidelines contained in the *Australia-United States Free Trade Agreement (AUSFTA) & the Pharmaceutical Benefits Scheme (PBS) Statement on the Implementation of Australia's AUSFTA Commitments* by the Minister for Health and Ageing dated February 2005.

In undertaking the Services the Reviewer must conduct an independent review and report upon [Insert Total Page Count] pages of relevant documentation as stated in Item K in relation to:

Drug or Medicinal Preparation: [Insert generic name and trade name in brackets]

Sponsor: [Insert Sponsor's name in full]

Indication/s [Insert indication/s from submission]

Dosage Form/Strength: [Insert dosage form and strength/s]

Date of PBAC Meeting: [Insert date of PBAC meeting when the Sponsor's submission was considered]

Agenda Item Number: [Insert Agenda Item number from the above PBAC meeting]

The Reviewer must read the following:

- (a) *Independent Review (PBS) Conflict of Interest Guidelines for Prospective Reviewers.*
- (b) *Australia-United States Free Trade Agreement (AUSFTA) & the Pharmaceutical Benefits Scheme (PBS) Statement on the Implementation of Australia's AUSFTA Commitments* by the Minister for Health and Ageing dated February 2005.
- (c) *Instructions for Reviewers and Suggested Template.*
- (d) *Schedule Items A, B, C, D and K of the Secondary Reviewer Contract (if a Secondary Reviewer is appointed by the Convenor).*

Conduct of Reviews

The Reviewer must carry out the review in a manner consistent with the above guidelines (as amended from time to time) and any other guidelines as notified by the Convenor.

The Reviewer must only focus on the issues that are in dispute that are relevant to his or her qualifications and field/s of expertise.

The Reviewer must consider all available documents, information and other written material relating to the issues in dispute that were available to the PBAC including the arguments and submissions upon the matters under consideration. The Reviewer must not consider any new information or other information on the drug or medicinal preparation that was not available to the PBAC.

Reporting Requirements

The Reviewer must provide a *Progress Report* by email or by a telephone conference to the Convenor (as instructed by the Convenor) by the date specified in Item B. The Reviewer must also submit the *Draft Review Report* and *Final Review Report* to the Convenor by the dates specified in Item B.

The Reviewer is encouraged to use the *Suggested Template* including the structure and format contained therein in his or her preparation of the *Draft Review Report* and *Final Review Report*. The *Draft Review Report* and the *Final Review Report* must incorporate all information, facts or opinions that the Reviewer considers important and relevant in documenting his or her findings on the issues in dispute. The *Draft Review Report* and the *Final Review Report* must also identify any person(s) consulted in the context of the Review. The Reviewer must obtain the consent of any such person(s) to disclose their personal information and/or views in the reports, prior to doing so.

If requested by the Convenor, the Reviewer must revise or modify the *Draft Review Report* and/or the *Final Review Report* to the reasonable satisfaction of the Convenor. Such revision or modification is limited to:

- (a) re-evaluating the documentation relevant to the issues in dispute to reconfirm any findings or conclusions; and
- (b) altering the structure, formatting or clarity of the report.

The *Final Review Report* must be concise, thorough, accurate and professionally constructed in sufficient detail to enable the PBAC to consider the issues raised by the Sponsor in its Review Application.

The Reviewer must be available on the request of the Convenor to present and discuss his or her approach and findings at the PBAC meeting in which the *Final Review Report* will be considered.

Responsibilities of Reviewer if Secondary Reviewer appointed

The Convenor may, at his or her sole and absolute discretion, appoint a Secondary Reviewer in circumstances where there are disparate issues in dispute or if specialised and/or additional expertise is required to ensure the effective completion of a review.

In circumstances in which a Reviewer identifies issues that require specialised and/or additional expertise, the Reviewer may consult with the Convenor who will consider if this expertise should be procured through the engagement of a Secondary Reviewer.

If the Convenors exercises his or discretion to appoint a Secondary Reviewer, the Reviewer retains overall responsibility for the review. In particular, the Reviewer is responsible for:

- (a) ensuring the timely delivery and quality of the *Draft Review Report* and the *Final Review Report*;
- (b) monitoring the Secondary Reviewer's performance against Schedule Items A, B, C and D of the Secondary Reviewer Contract;
- (c) notifying the Convenor immediately if there are issues or concerns about the Secondary Reviewer's performance against Schedule Items A, B, C and D of the Secondary Reviewer Contract;
- (d) ensuring the Secondary Reviewer completes and delivers the required *Progress Reports, Draft Secondary Review Report and Final Secondary Review Report* as required under Schedule Items A, B, C and D of the Secondary Reviewer Contract;
- (e) providing comments and feedback to the Secondary Reviewer on the required *Progress Reports, Draft Secondary Review Report and Final Secondary Review Report*. The Convenor must be copied into these communications; and
- (f) incorporating and summarising (as appropriate) the findings contained in the *Secondary Review Final Report* into the *Final Review Report* and making the *Secondary Review Final Report* an attachment to the *Final Review Report*.

In providing feedback to the Secondary Reviewer on the *Draft Secondary Review Report* and/or the *Final Secondary Review Report*, the Reviewer may only request modifications and revisions which are limited to:

- (i) re-evaluating the documentation relevant to the issues in dispute to reconfirm any findings or conclusions; and
- (ii) altering the structure, formatting or clarity of the report.

The Reviewer must not under any circumstances provide a Secondary Reviewer with input for the content of the *Secondary Review Draft Report* or the *Secondary Review Final Report* or request that the Secondary Reviewer change his or her findings.

B. Required Contract Material (see clauses 1.1 and 2.1)

The Reviewer shall produce and deliver the following Contract Material:

- (a) *Progress Report* by way of email and/or teleconference (as directed by the Convenor) to the Convenor in the fifth and tenth weeks of the review and no later than COB on:
 - (i) [insert day/month/year]
 - (ii) [insert date/month/year]

The *Progress Report* must contain the following information:

- the Reviewer's progress and findings to date;
 - any issues or potential issues that might impact on the Review;
 - whether or not the Reviewer is on schedule to complete and deliver the *Draft Review Report* and the *Final Review Report* by their due dates;
 - what steps, if any, the Reviewer is taking or proposes to take to ensure that the *Draft Review Report* and the *Final Review Report* will be completed and delivered by their due dates (if applicable).
- (b) *Draft Review Report* as per Item A on [insert day/month/year and no later than the end of week 14]
 - (c) *Final Review Report* as per Item A by COB on [insert day/month/year and no later than the end of week 16].
 - (d) On the request of the Convenor a presentation on the approach and findings of the review to the [insert date] PBAC meeting.

The Reviewer must submit a typed electronic copy (by floppy disk or CD ROM in a format that may be read using Microsoft Word) and a typed paper copy of the *Draft Review Report* and *Final Review Report*.

The *Final Review Report* will not be considered complete until the Convenor or his or her office notifies the Reviewer that the report has been accepted.

The *Draft Review Report* and *Final Review Report* must be dispatched by courier to:

The Convenor
Independent Review (PBS)
MDP 133
GPO Box 9848
CANBERRA ACT 2601

C. Standards and Best Practice (see clause 2.1)

The Services must be undertaken with the application of a high degree of professional skill, competence, care and diligence as would be expected of a professional undertaking the Services.

The Reviewer must undertake the Services in accordance with the administrative instructions and procedural guidelines provided by the Convenor and referred to in Item A.

The Reviewer must immediately notify the Convenor if (s)he encounters any unforeseen events or circumstances that may or will affect his or her ability to conduct the review.

The Reviewer must not in any circumstances publicly discuss, or communicate with the media any matter pertaining to the review or the review process. The Reviewer must not contact the Sponsor or any other party or person about any matter pertaining to the Review. The Reviewer must immediately notify the Convenor if (s)he is contacted by any party or person other than the Convenor on matters relating to the review.

If, and as, required the Reviewer may request that the Convenor make appropriate arrangements for discussions with the Sponsor or the Department or its contractors to seek clarification. The Convenor must be part of these discussions by way of telephone conference or in person. All such discussions must be documented by the Reviewer in the *Draft Review Report* and the *Final Review Report*.

In relation to the issue of conflict of interest, the Reviewer shall have regard to the *Independent Review (PBS) Conflict of Interest Guidelines for Prospective Reviewers* including the *Prospective Reviewer Conflict of Interest Declaration* and the *Reviewer Conflict of Interest Declaration* contained at Attachments A and B of this document.

D. Time-frame (see clause 2.1)

The Reviewer must ensure that the *Draft Review Report* and the *Final Review Report* is completed and delivered to the Convenor **no later than the due dates specified in Item B.**

The *Final Review Report* will not be considered complete until the Convenor or his or her office notifies the Reviewer that the *Final Review Report* has been accepted.

The Reviewer may also be required to attend a PBAC meeting to present and discuss the findings of the review on [insert date].

The Reviewer acknowledges and accepts that the timeframes for the completion of the Services in Item A and the deliverables in Item B are of the essence.

E. Fees (see clauses 3.1 and 19.5)

The fee payable on the receipt and the Convenor's acceptance of the *Final Review Report* is [Insert Reviewer's fee including GST]. This fee includes Goods and Services Tax (GST).

An additional fee will be paid to the Reviewer if (s)he is required to present and discuss the findings of the *Final Review Report* at abovementioned PBAC meeting. The additional fee will be paid in accordance with the rates set out for members of Professional Committees in

the Health and Ageing, and Family and Community Services Portfolios as stated in *Remuneration Tribunal Determination 2005/05* and any updates that may be made to this Determination from time to time.

F. Allowances and Costs (see clause 3.1)

Where the Reviewer is required by the Convenor to undertake travel to attend the abovementioned PBAC meeting or another scheduled meeting approved by the Convenor, the Commonwealth will arrange the Reviewer's travel and pay expenses and allowances in accordance with the rates set out for Official Travel by Office Holders in *Remuneration Tribunal Determination 2004/03* and any updates that may be made to this Determination from time to time.

G. Facilities and Assistance (see clause 3.1)

The Commonwealth shall provide assistance directly relevant to the review, and such other information requested by the Reviewer as is considered reasonable by the Convenor, free of charge to the Reviewer to assist in the performance of the Services.

H. Invoice Procedures (see clause 3.3)

After the Convenor's acceptance of the *Final Review Report*, the Reviewer must forward a correctly addressed and signed tax invoice to the Convenor which includes the following information:

- (a) Generic name and trade name of product under review;
- (b) Sponsor's name;
- (c) Date of PBAC Meeting and Agenda Item number;
- (d) Name of Convenor;
- (e) Fees and expenses; and
- (f) Australian Business Number (ABN) if applicable.

I. Specified Personnel (see clauses 1.1 and 6)

The Reviewer agrees that all Services will be undertaken by [Insert Name of Reviewer] and that employment and/or sub-contracting arrangements will not be permitted under this Contract unless agreed to prior in writing by the Convenor.

J. Convenor (see clauses 1.1 and 2.1)

The Convenor shall be the person for the time being holding, occupying or performing the duties of Convenor of the Independent Review (PBS), or such other person as is notified by the Commonwealth in writing to the Reviewer.

The Convenor has responsibility for supervision of the Contract on behalf of the Commonwealth, including responsibility for issuing and receiving any written notification under the Contract. The Convenor at the date of this Contract is Linda Webb. The Convenor may be contacted on (02) 6289 9760.

K. Material to be Provided by Commonwealth (see clause 8.1)

The Commonwealth will provide the following documentation to the Reviewer:

- 1 *Australia-United States Free Trade Agreement (AUSFTA) Statement on the Implementation of Australia's AUSFTA Commitments* by the Minister of Health and Ageing dated February 2005.
- 2 *Instructions for Reviewers and Suggested Template.*
- 3 The following documentation relating to the Sponsor's submission as provided to the Convenor by the PBAC Secretariat:
[Delete if not applicable]
 - (a) Sponsor's Review Application;
 - (b) Letter of Application to the PBAC;
 - (c) Sponsor's submission (including all appendices, references and copies of any files provided only in electronic format);
 - (d) PBAC Secretariat Overview including:
 - i. ADEC Resolution or relevant extract of Minutes (if applicable);
 - ii. Therapeutic Goods Administration (TGA) Delegate's Summary (if applicable);
 - iii. TGA Clinical Evaluation Report (if applicable);
 - iv. Approved or draft Product Information;
 - v. Relevant past PBAC minutes (applicable if re-submission);
 - vi. Relevant past Economics Sub-Committee (ESC) Advice (applicable if re-submission);
 - vii. Relevant past Pharmaceutical Evaluation Section (PES) commentary (applicable if re-submission);
 - (e) Supporting documents and letters (if applicable);
 - (f) PES Commentary;
 - (g) Drug Utilisation Sub-Committee (DUSC) Commentary (if applicable);
 - (h) Pre Sub-Committee Response;
 - (i) PES Addendum (if applicable);
 - (j) ESC Advice;
 - (k) DUSC Advice (if applicable);
 - (l) Restrictions Working Group Advice (if applicable);
 - (m) Pre PBAC Response from Sponsor;
 - (n) Short PBAC Minutes; and
 - (o) Public Summary Document (PSD) (when available).

L. Use of Commonwealth Material (see clause 8.3)

The Reviewer must ensure that all Commonwealth Material remains confidential and secure at all times. The Reviewer is required to use secure storage for all Commonwealth Material including locked rooms and locked filing cabinets. Adequate arrangements are required for receiving and dispatching all Material to ensure the security of Commonwealth Material at all times.

Where computer systems are used in the performance of the Services, all material relating to the Services must be stored on removeable media. No electronic material is to be stored on any centralised computer system.

All Commonwealth Material shall remain the property of the Commonwealth and is to be returned to the Commonwealth as and when requested by the Convenor to the address at Item P.

The Reviewer shall ensure that all Commonwealth Material is used, copied, supplied or reproduced, only for the purposes of the Contract. In returning the Commonwealth Material (including all copies) the Reviewer must ensure that the Material is packed in strong, plain packages with each package being clearly labelled with the address at Item P and the name of the Reviewer as the sender. Nothing on the outside of the package should reveal the content of the package, the name of the Sponsor or the drug or medicinal preparation. The package should not exceed 16 kgs in weight and should be fully protected from deterioration and physical damage during handling and transportation.

M. Existing Material (see clause 9.2)

None specified.

N. Dealings with Copies (see clauses 8.4, 9.5 and 11.6)

The security arrangements set out in item L must be applied to all copies.

All copies must be included in the dispatch of the Material which is returned to the Convenor on his or her request.

O. Insurance (see clause 17.1)

The Reviewer agrees to maintain:

- (a) public liability insurance for an amount of not less than five million dollars (\$5 million);
- (b) professional indemnity insurance for an amount of not less than two million dollars (\$2 million); and
- (c) workers' compensation insurance for an amount required by the relevant State or Territory legislation.

P. Addresses for Notices (see clause 23.1)

Commonwealth's Address for Notices:

The Convenor
Independent Review (PBS)
MDP 133
GPO Box 9848
CANBERRA ACT 2601

Facsimile Number: (02) 6289 9747

Reviewer's Address for Notices:

<Insert Reviewer's Name and Address>

Sample Contract

SIGNED as a contract.

SIGNED for and on behalf of the)
COMMONWEALTH OF AUSTRALIA)
acting through the Department of Health)
and Ageing)

Date

by:

Name of signatory

Position of signatory
in the presence of:

Name of witness

Signature

Signature of witness

SIGNED by:

Name of Reviewer

on:

Date
in the presence of:

Name of witness

Signature

Signature of witness

Sample Contract