



Australian Government
Department of Health

CONSULTANCY CONTRACT

between the

COMMONWEALTH OF AUSTRALIA

as represented by the

Therapeutic Goods Administration

ABN 40 939 406 804

within the

Department of Health

and

The George Institute for Global Health

ABN 90 085 953 331

in relation to Services to

**Develop and produce an expert external review of the
safety and efficacy of low-dose codeine**

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This Contract is made between the

COMMONWEALTH OF AUSTRALIA for the purposes of this Contract represented by and acting through the Therapeutic Goods Administration, ABN 40 939 406 804 within the Department of Health

And

THE GEORGE INSTITUTE FOR GLOBAL HEALTH ABN 90 085 953 331, a public company limited by Guarantee, ('the Consultant')

RECITALS

- A. The Commonwealth requires the provision of certain services to the Department as specified in the Schedule.
- B. The Consultant has fully informed itself on all aspects of the work required to be performed and has submitted a proposal and quotation entitled Investigating the efficacy and safety of over-the-counter codeine containing combination analgesics for pain and codeine based antitussives, attached as Attachment A and dated 1 February 2016.
- C. The Department has agreed to engage the Consultant 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:

'Australian Standards' means the documents published under that name by Standards Australia;

'Auditor-General' means the office established under the *Auditor-General Act 1997* and includes any other person 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 the place where the act is to be performed;

'Commonwealth' means the Commonwealth of Australia;

'Commonwealth Material' means any Material:

- (a) provided by the Commonwealth to the Consultant for the purposes of this Contract; or
- (b) copied or derived at any time from the Material referred to in paragraph (a);

'Confidential Information' means information that:

- (a) is by its nature confidential;
- (b) is designated by the Commonwealth as confidential; or

- (c) the Consultant knows or ought to know is confidential;
but does not include information which:
- (d) is or becomes public knowledge other than by breach of this Contract or by any other unlawful means;
- (e) is in the possession of the Consultant without restriction in relation to disclosure before the date of receipt from the Commonwealth; or
- (f) has been independently developed or acquired by the Consultant;

'Conflict' means any conflict of interest, any risk of a conflict of interest and any apparent conflict of interest arising through the Consultant (or the Consultant Personnel) engaging in any activity or obtaining any interest that is likely to conflict with or restrict the Consultant in performing the Services fairly and independently;

'Consultant Personnel' means:

- (a) officers, employees, agents or subcontractors of the Consultant;
- (b) officers, employees, agents or subcontractors of the Consultant's subcontractors; and
- (c) includes those individuals (if any) engaged by the Consultant or its subcontractors on a voluntary basis;

engaged in the performance of the Services;

'Contract' means this document as amended from time to time and includes its Schedules and any attachments;

'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) copied or derived at any time from the Material referred to in paragraphs (a) or (b); and

including the Contract Material described in Item B;

'Department' means the Commonwealth as represented by the Department of Health or any department or agency of the Commonwealth that is from time to time responsible for the administration of this Contract;

'Existing Material' means all Material in existence prior to the commencement of this Contract that is:

- (a) incorporated in;
- (b) supplied with, or as part of; or
- (c) required to be supplied with, or as part of,

the Contract Material and includes Material identified as Existing Material in Item L but excludes Commonwealth Material;

'Government Agency' means:

- (a) a 'Commonwealth entity' or 'Commonwealth company' as defined in the *Public Governance, Performance and Accountability Act 2013*;
- (b) an unincorporated body established or constituted for a public purpose by Commonwealth legislation, or an instrument made under that legislation;
- (c) a body established by the Commonwealth Parliament, or either House of Parliament, or by the Governor-General or by a Minister of State of the Commonwealth; or
- (d) any body that may exercise any of the powers of the Commonwealth under the Commonwealth Constitution,

acting directly or through an agent;

'Indigenous Procurement Policy' means the policy of that name, as amended from time to time, available on the [Indigenous Procurement Website](#).

'Intellectual Property' means 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;

'Interest' means interest calculated at the 90 day bank-accepted bill rate (available from the Reserve Bank of Australia);

'Law' means any applicable statute, regulation, by-law, ordinance or subordinate legislation in force from time to time anywhere in Australia, whether made by a State, Territory, the Commonwealth, or a local government, and includes the common law as applicable from time to time;

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

'Moral Rights' includes the following rights of an author of copyright Material:

- (a) the right of attribution of authorship;
- (b) the right of integrity of authorship; and
- (c) the right not to have authorship falsely attributed;

'Ombudsman' means the office established under the *Ombudsman Act 1976* and includes any other person that may, from time to time, perform the functions of that office;

'Party' means a party to this Contract;

'Personal Information' has the meaning given in the *Privacy Act 1988*;

'Privacy Commissioner' means any of the information officers appointed under the *Australian Information Commissioner Act 2010* when performing the 'privacy functions' as defined in the Act;

'Services' means the services described in the Schedule including as set out in

Item A and the provision to the Commonwealth of the Material specified in Item B;

'Specified Personnel' means the Consultant Personnel specified in Item I; and

'Web Content Accessibility Guidelines 2.0' means the Guidelines available at [Web Accessibility Guidelines](#);

'WHS legislation' means the *Work Health and Safety Act 2011*, any regulations made under that act and any 'corresponding WHS law' within the meaning of section 4 of the *Work Health and Safety Act 2011* and Regulation 6A of the *Work Health and Safety Regulations 2011*; and

'World Wide Web Access: Disability Discrimination Act Advisory Notes, version 4.0 (2010)' means the advisory notes released by the Australian Human Rights Commission available at [Disability Discrimination Act Advisory Notes](#)

1.2 In this Contract, unless the contrary intention appears:

- (a) words in the singular include the plural and words in the plural include the singular;
- (b) words importing a gender include any other gender;
- (c) words importing persons include a partnership and a body whether corporate or otherwise;
- (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) where any word or phrase is given a defined meaning, any other form of that word or phrase has a corresponding meaning;
- (g) an uncertainty or ambiguity in the meaning of a provision of this Contract will not be interpreted against a Party just because that Party prepared the provision;
- (h) a reference to any statute or other legislation (whether primary or subordinate) is to a statute or other legislation of the Commonwealth as amended from time to time;
- (i) a reference to the word 'including' in any form is not to be construed or interpreted as a word of limitation; and
- (j) references to clauses are to clauses in this Contract, references to 'Items' are to Items in the Schedule to this Contract, references to 'Schedule' are to the Schedule to this Contract and references to Annexures or Attachments are references to documents attached to this Contract.

1.3 If there is any conflict or inconsistency between:

- (a) the terms and conditions contained in the clauses of this Contract and any part of the Schedule, then the terms and conditions of the clauses will prevail to the extent of the conflict or inconsistency;

- (b) the terms and conditions contained in the clauses of this Contract and any part of the Annexures or Attachments (if any), then the terms and conditions of the clauses will prevail to the extent of the conflict or inconsistency; and
 - (c) any part of the Schedule and any part of the Annexures or Attachments (if any), then the Schedule will prevail to the extent of the conflict or inconsistency.
- 1.4 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.
- 1.5 This Contract records the entire contract between the Parties in relation to its subject matter.
- 1.6 This Contract may be executed in counterparts, each of which shall be deemed to be an original and all of which, taken together, shall constitute one and the same agreement.
- 1.7 No variation of this Contract is binding unless agreed in writing between the Parties.
- 1.8 Any reading down or severance of a particular provision does not affect the other provisions of this Contract.
- 1.9 A waiver of any provision of this Contract must be in writing.
- 1.10 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.
- 1.11 If a Party does not exercise, or delays in exercising, any of its rights under this Contract or at Law, that failure or delay does not operate as a waiver of those rights.
- 1.12 A single or partial exercise by a Party of any of its rights under this Contract or at Law does not prevent the further exercise of any right.
- 1.13 The Consultant must not assign or transfer its rights or obligations under this Contract without prior approval in writing from the Department.
- 1.14 The Consultant agrees not to consult with any person for the purposes of entering into an arrangement that will require novation of this Contract without first consulting the Department.

2. PROVISION OF SERVICES

- 2.1 The Consultant must:
 - (a) perform the Services in accordance with this Contract, with due care and skill and in accordance with relevant best practice, including any applicable Australian Standards and any Commonwealth and industry standards and guidelines specified in either Item B or Item C;
 - (b) ensure that the Services and Contract Material are fit for the purpose for which they are provided;

- (c) ensure that any Contract Material which is to be placed on a Departmental website or the intranet complies with the:
 - (i) Level AA accessibility requirements in the Web Content Accessibility Guidelines 2.0; and
 - (ii) World Wide Web Access: Disability Discrimination Act Advisory Notes, version 4.0 (2010);
 - (d) comply with the time frame for the performance of the Services specified in Item D;
 - (e) liaise with the Department, provide any information the Department may reasonably require, and comply with any reasonable directions of the Department; and
 - (f) ensure that it and its Consultant Personnel, when carrying out their duties and performing work under this Contract, do not:
 - (i) cause any unreasonable or unnecessary disruption to the routines, procedures and responsibilities of the Commonwealth; or
 - (ii) damage the reputation of the Department or the Commonwealth more broadly in the community.
- 2.2 The Consultant acknowledges that:
- (a) the Department collects or may come into possession of information concerning the Consultant that is either publicly available information or information obtained through the course of the Department conducting its affairs; and
 - (b) subject to clause 2.3, the Department may use that information when considering the Consultant's ability to perform this Contract.
- 2.3 The Department may consult with the Consultant if any information referred to under clause 2.2 is a cause of concern to the Department.
- 2.4 Subject to clauses 12 and 13, no right or obligation in this Contract is to be read or understood as limiting the Consultant's rights to enter into public debate or criticism of the Commonwealth, its entities, officers, employees or agents.

3. FEES, ALLOWANCES AND ASSISTANCE

- 3.1 The Department agrees to:
- (a) pay the fees specified in Item E;
 - (b) pay the allowances and meet the costs, if any, specified in Item F; and
 - (c) provide the facilities and assistance, if any, specified in Item G.
- 3.2 The Department will be entitled, in addition to any other right it may have, to withhold or reduce any payment of fees or allowances until the Consultant has completed to the satisfaction of the Department that part of the Services to which the payment relates.

- 3.3 If an overpayment occurs at any time and for any reason (including where an invoice is found to have been incorrectly rendered after payment), the Department may issue the Consultant with a written notice requiring repayment of the full amount of the overpayment.
- 3.4 The Consultant must pay to the Department the full amount of the overpayment specified in the notice referred to in clause 3.3 in the manner specified in the notice, and within twenty (20) Business Days of the date of the notice.
- 3.5 The Department may, at its sole and absolute discretion, recover the overpayment specified in the notice referred to in clause 3.3, from the Consultant by offsetting that overpayment against any amount subsequently due to the Consultant under this Contract.
- 3.6 If the Consultant fails to repay the full amount of an overpayment in accordance with a notice given pursuant to clause 3.3, the Department may (at its sole discretion) require that Interest be paid on the amount after the expiry of the twenty (20) Business Days' notice referred to in clause 3.4, until the amount is paid to the Department in full.
- 3.7 The Consultant must provide the Department with an adjustment note if required by the *A New Tax System (Goods and Services Tax) Act 1999*, including where the Consultant repays to the Department some or all of the fees or expenses.
- 3.8 The Consultant agrees to submit invoices for payment in the manner specified in Item H and clause 5.

4. PAYMENTS

- 4.1 The Department will pay the Consultant within 30 days after receipt of a correctly rendered invoice. If this period ends on a day that is not a Business Day, payment is due on the next Business Day.
- 4.2 For payments made by the Department more than 30 days after the amount became due and payable, the Department must pay the interest accrued on the payment where:
- (a) the value of this Contract is not more than A\$1 million (GST inclusive);
 - (b) the amount of the interest payable exceeds A\$10; and
 - (c) the fee will be paid by the Department from Departmental items.
- 4.3 Interest payable under clause 4.2 will be simple interest on the unpaid amount at the General Interest Charge Rate, calculated in respect of each day from the day after the amount was due and payable, up to and including the day that the Department effects payment as represented by the following formula:

$$SI = UA \times GIC \times D$$

Where:

SI = simple interest amount;

UA = the unpaid amount;

GIC = General Interest Charge Rate daily rate; and

- D = the number of days from the day after payment was due up to and including the day that payment is made.
- 4.4 In this clause 'General Interest Charge Rate' means the general interest charge rate determined under section 8AAD of the *Taxation Administration Act 1953* on the day payment is due, expressed as a decimal rate per day.
- 4.5 For the purposes of this clause an invoice is correctly rendered if it:
- (a) is correctly addressed and calculated in accordance with this Contract; and
 - (b) relates only to supplies that have been delivered to the Department in accordance with this Contract; and
 - (c) is a valid tax invoice in accordance with *A New Tax System (Goods and Services Tax) Act 1999*.

5. TAXES, DUTIES AND GOVERNMENT CHARGES

- 5.1 Subject to this clause, all taxes, duties and government charges imposed or levied in Australia or overseas in connection with this Contract must be paid by the Consultant or as the Consultant might arrange.
- 5.2 The provisions of this clause in respect of GST apply where the Consultant is registered, or is required to be registered for GST.
- 5.3 The goods, services and other supplies made by the Consultant under this Contract are Taxable Supplies within the meaning of the GST Law.
- 5.4 The Consultant will issue the Department 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 3.8.
- 5.5 The amounts payable by the Department to the Consultant, as determined under clause 3, are stated inclusive of GST but must not include any amount which represents GST paid by the Consultant for which the Consultant may claim an input tax credit.
- 5.6 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.
- 5.7 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).
- 5.8 For the purposes of this clause, '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.

6. SUBCONTRACTORS

- 6.1 The Consultant agrees that:
- (a) it will not subcontract the performance of any part of the Services without the prior approval in writing of the Department; and

- (b) the subcontractors, if any, specified in Item A will perform work in relation to the Services in accordance with this Contract and are approved by the Department to do so.
- 6.2 The Department may impose any terms and conditions it considers appropriate when giving its approval under clause 6.1(a).
- 6.3 Where a subcontractor specified in Item A or approved by the Department under clause 6.1(a) is unable to perform the work, the Consultant agrees to notify the Department immediately.
- 6.4 Where clause 6.3 applies, the Department may request the Consultant to secure a replacement subcontractor acceptable to the Department at no additional cost and at the earliest opportunity.
- 6.5 If the Consultant does not comply with any request made under clause 6.4 the Department may terminate this Contract in accordance with the provisions of clause 22.
- 6.6 In respect of subcontractors listed in Item A or approved by the Department under this clause, the Consultant must ensure that:
 - (a) the subcontract facilitates compliance by the Consultant with its obligations under this Contract;
 - (b) the subcontract will not conflict with or detract from the rights and entitlements of the Department under this Contract;
 - (c) the other party to the subcontract, has the necessary relevant expertise and the appropriate types and amounts of insurance to perform work in relation to the Services;
 - (d) the other party to the subcontract has consented to the public disclosure of its name in connection with the performance of the Services;
 - (e) the subcontract contains all the relevant terms of this Contract including those relating to compliance with the Law, subcontracting, intellectual property, audit and access, privacy, confidentiality, warranties and indemnities, disclosure and termination and in particular that the Consultant has or will secure for itself a right to terminate the subcontract on terms no less favourable than those accorded the Department by clauses 21 and 22, in the event of this Contract being terminated;
 - (f) the other party to the subcontract acknowledges that it may be considered a 'Department service provider' for the purposes of the *Ombudsman Act 1976* and subject to investigation by the Ombudsman under that Act and that the Department will not be liable for the cost of any such investigation by the Ombudsman in connection with the subject matter of the subcontract or the subject matter of this Contract;
 - (g) the other party to the subcontract is prohibited from further subcontracting the Services without the prior written approval of the Department; and
 - (h) if requested, the Consultant will promptly provide a copy of the relevant subcontract to the Department.

7. SPECIFIED PERSONNEL AND OTHER PERSONNEL

- 7.1 The Consultant agrees that the Specified Personnel will perform the activities specified in Item I.
- 7.2 Where Specified Personnel are unable to perform the activities, the Consultant must notify the Department immediately.
- 7.3 The Department may, at its absolute discretion, request the Consultant to remove Consultant Personnel (including Specified Personnel) from work in relation to the Services.
- 7.4 Where clauses 7.2 or 7.3 apply, the Department may request the Consultant to provide replacement personnel acceptable to the Department at no additional cost and at the earliest opportunity.
- 7.5 If the Consultant does not comply with any request made under clause 7.3 or clause 7.4, the Department may terminate this Contract in accordance with the provisions of clause 22.

8. RESPONSIBILITY OF CONSULTANT

- 8.1 The Consultant 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 Commonwealth in the performance of the Services;
 - (b) payment made to the Consultant on account of the Services;
 - (c) subcontracting of the Services; or
 - (d) acceptance by the Department of replacement Consultant Personnel (including Specified Personnel).

9. COMMONWEALTH MATERIAL

- 9.1 The Commonwealth agrees to provide Material to the Consultant as specified in Item J.
- 9.2 The Commonwealth grants to the Consultant a royalty-free, licence fee-free, non-exclusive licence (including a limited right of sub-licence to sub-licence to a subcontractor specified in Item A or approved by the Department under clause 6) to use, reproduce, modify, adapt, publish, perform, broadcast and communicate the Intellectual Property in the Commonwealth Material for the purposes of this Contract.
- 9.3 The Consultant agrees to ensure that all Commonwealth Material is used strictly in accordance with any conditions or restrictions set out in Item K, and any direction by the Department.
- 9.4 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 Consultant 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 Department, or, in accordance with Department directions erase or otherwise deal with all such copies,

unless any provision to the contrary is set out in Item M.

9.5 This clause survives the expiration or earlier termination of this Contract.

10. INTELLECTUAL PROPERTY IN CONTRACT MATERIAL

- 10.1 Intellectual Property in all Contract Material vests or will vest in the Commonwealth.
- 10.2 Clause 10.1 does not affect the ownership of Intellectual Property in any Existing Material but the Consultant grants, or undertakes to arrange for a third party to grant, to the Commonwealth a permanent, irrevocable, royalty-free, licence fee-free, world-wide, non-exclusive licence (including a right of sublicense) to use, reproduce, modify, adapt, publish, perform, broadcast, communicate, commercialise and exploit the Intellectual Property in any such Existing Material in conjunction with the other Contract Material.
- 10.3 If requested by the Commonwealth, the Consultant 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.
- 10.4 The Consultant 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.
- 10.5 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 Consultant agrees:
 - (a) to secure all copies within its control against loss and unauthorised use or disclosure; and
 - (b) on the expiration or earlier termination of this Contract, to deliver to the Department, or, in accordance with Department directions, erase or otherwise deal with all such copies,unless any provision to the contrary is set out in Item M.
- 10.6 This clause survives the expiration or earlier termination of this Contract.
- 10.7 The Commonwealth grants to the Consultant, a permanent, irrevocable, royalty-free, licence fee-free, world-wide, non-exclusive licence (including a right of sublicense) to use, reproduce, modify, adapt, publish, perform, broadcast, communicate, commercialise and exploit the Intellectual Property in the Contract Material subject to the Consultant agreeing to seek written approval from the Commonwealth prior to any publication or public broadcast, or communication of the Contract Material, or any part of the Contract Material.

11. MORAL RIGHTS

- 11.1 For the purposes of this clause, the 'Specified Acts' relating to Moral Rights means any of the following classes or types of acts or omissions by or on behalf of the

Commonwealth:

- (a) using, reproducing, modifying, adapting, publishing, performing, broadcasting, communicating, commercialising or exploiting all or any part of the Contract Material, with or without attribution of authorship;
- (b) supplementing the Contract Material with any other Material; and
- (c) using the Contract Material in a different context to that originally envisaged; but does not include false attribution of authorship.

11.2 The Consultant must use its best endeavours to ensure that:

- (a) where there is no consent already in place, a written consent will be given by the author of any Contract Material, other than Existing Material, to the Specified Acts (whether occurring before or after the consent is given) which extends directly or indirectly to the performance of the Specified Acts by the Commonwealth or any person claiming under or through the Commonwealth; and
- (b) where there is no consent already in place, the author of any Existing Material will give a written consent to the Specified Acts (whether occurring before or after the consent is given) which extends directly or indirectly for the benefit of the Commonwealth in relation to the Commonwealth's licensed use of such Material.

11.3 This clause survives the expiration or earlier termination of this Contract.

12. DISCLOSURE OF INFORMATION

12.1 The Consultant agrees not to disclose any Confidential Information relating to this Contract or the Services without prior approval in writing from the Department.

12.2 The Department may impose any conditions it considers appropriate when giving its approval under clause 12.1 and the Consultant agrees to comply with these conditions.

12.3 The Department may at any time require the Consultant to give, and to arrange for Consultant Personnel to give, undertakings in writing in a form required by the Department, relating to the non-disclosure of Confidential Information.

12.4 If the Consultant receives a request under clause 12.3, it agrees to promptly arrange for all such undertakings to be given.

12.5 The obligations on the Consultant under this clause will not be taken to have been breached where the information referred to is required by Law to be disclosed.

12.6 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 Consultant agrees:

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

otherwise deal with all such copies,
unless any provision to the contrary is set out in Item M.

- 12.7 The Commonwealth gives no undertaking to treat Consultant information, or this Contract, as confidential information. The Consultant 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 disclosure on request to other Government Agencies, and 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.
- 12.8 This clause survives the expiration or earlier termination of this Contract.

13. ACCESS TO DOCUMENTS

- 13.1 In this clause, 'document' and 'Commonwealth contract' have the same meaning as in the *Freedom of Information Act 1982*.
- 13.2 This clause only applies if this is a Contract which complies with the description of 'Commonwealth contract'.
- 13.3 Where the Commonwealth has received a request for access to a document created by or in the possession of, the Consultant or any subcontractor that relates to the performance of this Contract (and not to the entry into this Contract), the Commonwealth may at any time by written notice require the Consultant to provide the document to the Commonwealth and the Consultant must, at no additional cost to the Commonwealth, promptly comply with the notice.
- 13.4 The Consultant must include in any subcontract relating to the performance of this Contract provisions that will enable the Consultant to comply with its obligations under this clause.

14. PROTECTION OF PERSONAL INFORMATION

- 14.1 This clause applies only where the Consultant deals with Personal Information when, and for the purpose of, providing the Services under this Contract.
- 14.2 In this clause, the terms:
- (a) agency;
 - (b) contracted service provider;
 - (c) registered APP code (RAC); and
 - (d) Australian Privacy Principle (APP),

have the same meaning as they have in the *Privacy Act 1988* ('the Privacy Act') and 'subcontract' and other grammatical forms of that word have the meaning given in section 95B(4) of the Privacy Act.

- 14.3 The Consultant acknowledges that it may be treated as a 'contracted service provider' and agrees in respect of the provision of the Services under this Contract:
- (a) to use or disclose 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 which if done or engaged in by an agency, would be a breach of an APP;
 - (c) to notify individuals whose Personal Information the Consultant holds, that complaints about acts or practices of the Consultant may be investigated by the Privacy Commissioner who has power to award compensation against the Consultant in appropriate circumstances;
 - (d) comply with the obligations in the APPs that apply to the Consultant;
 - (e) not to use or disclose Personal Information or engage in an act or practice that would breach an APP or a RAC, whichever is applicable to the Consultant, unless 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 APP or RAC, whichever is applicable to the Consultant;
 - (f) to comply with any request under section 95C of the Privacy Act;
 - (g) to immediately notify the Department if the Consultant becomes aware of a breach or possible breach of any of the obligations contained in, or referred to in this clause, whether by the Consultant or any subcontractor;
 - (h) to comply with any directions, guidelines, determinations or recommendations of the Privacy Commissioner to the extent that they are consistent with the requirements of this clause; and
 - (i) to ensure that any officers, employees or agents of the Consultant who are required to deal with Personal Information for the purposes of this Contract are made aware of the obligations of the Consultant set out in this clause.
- 14.4 The Consultant agrees to ensure that any subcontract entered into for the purpose of fulfilling its obligations under this Contract imposes on the subcontractor the same obligations as the Consultant has under this clause, including the requirement in relation to subcontracts.
- 14.5 The Department may at any time require the Consultant to give, and to arrange for Consultant Personnel to give, undertakings in writing in a form required by the Department, relating to the non-disclosure of Personal Information.
- 14.6 If the Consultant receives a request under clause 14.5, it agrees to promptly arrange for all such undertakings to be given.
- 14.7 The Consultant 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 Consultant under this clause, or a subcontractor under the subcontract provisions referred to in clause 14.4.

14.8 The Consultant's obligations under this clause are in addition to, and do not restrict, any obligations it may have under the Privacy Act or any privacy codes or privacy principles contained in, authorised by or registered under any law including any such privacy codes or principles that would apply to the Consultant but for the application of this clause.

14.9 This clause survives the expiration or earlier termination of this Contract.

15. COMPLIANCE WITH LAWS AND POLICIES

15.1 The Consultant agrees, in carrying out this Contract, to comply with all Laws and any relevant policies, including:

- (a) the *Crimes Act 1914*;
- (a) the *Racial Discrimination Act 1975*;
- (b) the *Sex Discrimination Act 1984*;
- (d) the *Disability Discrimination Act 1992*;
- (e) the *Charter of United Nations Act 1945* and the *Charter of United Nations (Dealing with Assets) Regulations 2008*;
- (f) the *Archives Act 1983*;
- (g) the *Privacy Act 1988*;
- (h) the *Freedom of Information Act 1982*;
- (i) the *Criminal Code Act 1995*;
- (j) the *Public Interest Disclosure Act 2013*;
- (k) any occupational health and safety legislation applicable to the Consultant;
- (l) the Australian Government's *Lobbying Code of Conduct*;
- (m) the *Protective Security Policy Framework* which is available at: [Protective Security Policy Framework Website](#);
- (n) any fraud control guidelines issued by the Department of Finance from time to time; and
- (o) any other policies notified to the Consultant in writing or listed in Item C.

15.2 The Consultant acknowledges that under section 137.1 of the Schedule to the *Criminal Code Act 1995*, giving false or misleading information to the Commonwealth is a serious offence.

15.3 The Consultant agrees, when using the Department'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 Department's smoke-free work-place policy) whether

- specifically drawn to the attention of the Consultant or as might reasonably be inferred from the circumstances.
- 15.4 Without limiting the effect of clause 25, the Consultant must comply with, and require Consultant Personnel to comply with, the behaviours specified in:
- (a) the Code of Conduct in section 13 of the *Public Service Act 1999* as if the Consultant and those Consultant Personnel were APS employees as defined in that Act; and
 - (b) the general duties of officials at sections 25-29 of the *Public Governance, Performance and Accountability Act 2013* as if the Consultant and those Consultant Personnel were officials as defined in that Act.
- 15.5 Clauses 15.6 to 15.9 only apply to the extent that:
- (a) this Contract is entered into following a procurement which is at, or above, the relevant procurement thresholds as defined in the *Commonwealth Procurement Rules*, but not where that procurement is listed in Appendix A to those Rules; and
 - (b) the Consultant is a 'relevant employer' for the purposes of the *Workplace Gender Equality Act 2012* ('the WGE Act').
- 15.6 The Consultant must comply with its obligations, if any, under the WGE Act.
- 15.7 If the Consultant becomes non-compliant with the WGE Act during the term of this Contract, the Consultant must notify the Department.
- 15.8 If the term of this Contract exceeds 18 months, the Consultant must provide a current letter of compliance within 18 months from the commencement date of this Contract and following this, annually, to the Department.
- 15.9 Compliance with the WGE Act does not relieve the Consultant from its responsibility to comply with its other obligations under this Contract.
- 16. INDIGENOUS PROCUREMENT POLICY**
- 16.1 NOT APPLICABLE
- 17. CONFLICT OF INTEREST**
- 17.1 The Consultant warrants that, to the best of its knowledge after making diligent inquiry, at the date of signing this Contract no Conflict exists or is likely to arise in the performance of obligations under this Contract by the Consultant or the Consultant Personnel.
- 17.2 If, during the term of this Contract, a Conflict arises, or appears likely to arise, in respect of the Consultant or any of the Consultant Personnel, the Consultant agrees to:
- (a) notify the Department immediately in writing of the Conflict making a full disclosure of all relevant information relating to the Conflict and setting out the steps the Consultant proposes to take to resolve or otherwise deal with the Conflict; and
 - (b) take such steps as have been proposed by the Consultant, or at the discretion

of the Department, take such steps as the Department may reasonably require to resolve or otherwise deal with the Conflict.

- 17.3 If the Consultant fails to notify the Department under this clause or is unable or unwilling to resolve or deal with the Conflict as required, the Department may terminate this Contract in accordance with the provisions of clause 23.
- 17.4 The Consultant agrees that it will not, and will use its best endeavours to ensure that any Consultant Personnel do not, engage in any activity or obtain any interest during the course of this Contract that is likely to conflict with or restrict the Consultant in providing the Services to the Department fairly and independently.

18. ACCOUNTABILITY AND ACCESS

- 18.1 The Consultant must give to:
- (a) the Auditor-General or his/her delegate;
 - (b) the Privacy Commissioner or his/her delegate;
 - (c) the Ombudsman or his/her delegate;
 - (d) the persons appointed under the *Australian Information Commissioner Act 2010* as the Information Commissioner and the FOI Commissioner or his/her delegate; and
 - (e) any persons authorised in writing by the Commonwealth,
- (referred to in this clause collectively as 'those permitted') access to premises :
- (f) at which Materials associated with this Contract are stored; or
 - (g) work associated with this Contract is undertaken, and
 - (h) to the Consultant Personnel,
- in order for those permitted to be able to inspect and copy Material for purposes associated with this Contract or any review of performance under this Contract.
- 18.2 The rights referred to in clause 18.1 are, wherever practicable, subject to:
- (a) the provision of reasonable prior notice from the Commonwealth (except where there is an actual or apprehended breach of the Law);
 - (b) access being sought during reasonable times (except where the Commonwealth believes there is an actual or apprehended breach of the Law); and
 - (c) the Consultant's reasonable security procedures.
- 18.3 The Consultant agrees to provide all reasonable assistance requested by the Commonwealth in respect of any inquiry into or concerning the Services or this Contract.
- 18.4 Without limitation to the generality of clause 18.3:
- (a) the assistance to be provided by the Consultant under clause 18.3 will include, as appropriate, the provision of Material, and making available relevant Consultant Personnel 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 Consultant; and

- (b) an inquiry referred to in clause 18.3 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.
- 18.5 The Commonwealth will endeavour to notify the Consultant as early as possible of any assistance required under clause 18.4, provided always that the Consultant acknowledges that such notice may be oral and is not subject to any minimum notice period requirement.
- 18.6 The requirement for access under this clause does not in any way reduce the responsibility of the Consultant to perform its obligations in accordance with this Contract.
- 18.7 The Consultant agrees to ensure that any subcontract entered into for the purpose of this Contract contains an equivalent clause permitting those permitted to have access as specified in this clause.
- 18.8 Nothing in this Contract limits or restricts in any way any duly authorised function, power, right or entitlement of the Auditor-General, the Ombudsman, the Privacy Commissioner, the Information Commissioner, the FOI Commissioner or their respective delegates. The rights of the Commonwealth under this Contract are in addition to any other duly authorised power, right or entitlement of the Auditor-General, the Commonwealth Ombudsman, the Privacy Commissioner, the Information Commissioner, the FOI Commissioner or their respective delegates.
- 18.9 This clause survives the expiration or earlier termination of this Contract for a period of seven years.

19. INDEMNITY

- 19.1 To the extent permitted by Law, the operation of any legislative proportionate liability regime is excluded in relation to any claim against the Consultant under or in connection with this Contract.
- 19.2 The Consultant indemnifies the Commonwealth, its officers, employees and agents 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,directly arising from:
 - (d) any act or omission by the Consultant or the Consultant Personnel 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 Consultant of its obligations or warranties under this Contract.

19.3 The Consultant's liability to indemnify the Commonwealth under clause 19.2 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, damage, or expense.

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

- (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 liability, loss, damage, or expense.

19.5 The Consultant agrees that the Commonwealth will be taken to be acting as agent or trustee for and on behalf of its officers, employees and agents from time to time.

19.6 This clause survives the expiration or earlier termination of this Contract.

19.7 Despite any other clause of this Contract, all liability is excluded for loss of revenue, loss of management time and all special, indirect and consequential losses.

20. INSURANCE

20.1 The Consultant warrants that it has taken out or will take out, and will maintain for the period specified in clause 20.2 or 20.3 as applicable, all appropriate types and amounts of insurance to cover the Consultant's obligations under this Contract, including those which survive its expiration or earlier termination, which insurance must include but is not limited to the types and corresponding amounts of insurance specified in Item N.

20.2 If the Consultant 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 Consultant must maintain the policy during the term of this Contract and a policy in like terms for seven years after the expiry or earlier termination of this Contract.

20.3 If the Consultant 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 Consultant must maintain the policy during the term of this Contract.

20.4 The Consultant must, on request, promptly provide to the Department any relevant insurance policies or certificates of currency for inspection.

20.5 This clause survives the expiration or earlier termination of this Contract.

21. DISPUTE RESOLUTION

21.1 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 in clause 21.1(a) 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.

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

21.3 This clause:

- (a) does not apply to action by the Department under or purportedly under clauses 3.2, 22 or 23; and
- (b) does not preclude either Party from commencing legal proceedings for urgent interlocutory relief.

22. TERMINATION AND REDUCTION FOR CONVENIENCE

22.1 The Department may, at any time by notice and at its sole discretion, terminate this Contract in whole or reduce the scope of the Services immediately.

22.2 Upon receipt of a notice of termination or reduction the Consultant must:

- (a) stop or reduce work as specified in the notice; and
- (b) take all available steps to minimise loss resulting from that termination or reduction and to protect Department Material and Contract Material.

22.3 Where there has been a termination under clause 22.1, the Department will be liable only for:

- (a) payments and assistance under clause 3 for Services properly rendered before the effective date of termination; and
- (b) reasonable costs unavoidably incurred by the Consultant and directly attributable to the termination and which the Consultant fully substantiates.

- 22.4 The Department will not be liable to pay compensation under clause 22.3(b) in an amount which would, in addition to any amounts paid or due, or becoming due, to the Consultant under this Contract, together exceed the fees set out in Item E.
- 22.5 The Consultant will not be entitled to compensation for loss of prospective profits.
- 22.6 If there is a reduction in the Services, the Department's obligation to pay any fee will abate proportionately to the reduction in the Services.
- 22.7 To avoid doubt, the Department has an unfettered discretion to terminate this Contract or reduce the scope of the Services in accordance with this clause.

23. TERMINATION FOR DEFAULT

- 23.1 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 clause 23.1(b), by further notice, terminate this Contract immediately.
- 23.2 The Department 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 Consultant:
- (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;
 - (b) being an individual, becomes bankrupt or enters into a scheme of arrangement with creditors; or
 - (c) breaches a warranty listed in clause 25.

24. DEEMED TERMINATION FOR CONVENIENCE

- 24.1 If a purported termination for cause by the Department under clause 23 is determined by a competent authority not to be properly a termination for cause, then that termination by the Department will be deemed to be a termination for convenience under clause 22 which termination has effect from the date of the notice of termination referred to in clause 23.

25. CONSULTANT WARRANTIES AND UNDERTAKINGS

- 25.1 The Consultant represents, warrants and undertakes to the Department that:
- (a) it will promptly notify and fully disclose to the Department in writing any event or occurrence actual or threatened which could have an adverse effect on the Consultant's ability to perform any of its obligations under this Contract;

- (b) it has full power and authority to enter into, perform and observe its obligations under this Contract;
- (c) the execution, delivery and performance of this Contract has been duly and validly authorised by the Consultant;
- (d) it will promptly notify and fully disclose to the Department in writing if
 - (i) it becomes insolvent or is wound up;
 - (ii) it makes an assignment of its estate for the benefit of creditors or enters into any arrangement or composition with its creditors or has a receiver, manager or administrator appointed on behalf of creditors;
 - (iii) it goes into liquidation or passes a resolution to go into liquidation, or becomes subject to any petition or proceedings in a court for its compulsory winding up or becomes subject to the supervision of a court or regulatory authority, either voluntarily or otherwise;
 - (iv) it suffers any execution against its assets; or
 - (v) anything analogous to, or of a similar effect to anything described above under the Law occurs in respect of the Consultant;
- (e) the unconditional execution and delivery of, and compliance with its obligations by it under this Contract do not:
 - (i) contravene any Law to which it or any of its property is subject or any order or directive from a Government Agency binding on it or any of its property;
 - (ii) contravene its constituent documents;
 - (iii) contravene any contract or instrument to which it is a party;
 - (iv) contravene any obligation of it to any other person; or
 - (v) require it to make any payment or delivery in respect of any financial indebtedness before the scheduled date for that payment or delivery;
- (f) no litigation, arbitration, mediation, conciliation or proceedings including any investigations, are taking place, pending, or are threatened against the Consultant which could have an adverse effect upon either the Consultant's capacity to perform its obligations under this Contract or the Consultant's reputation;
- (g) it has not had a judicial decision (excluding decisions under appeal) made against it in relation to employee entitlements where that claim has not been paid;
- (h) unless otherwise disclosed in this Contract, it is not entering into this Contract as trustee of any trust or settlement;
- (i) it has not made any false declaration in respect of any current or past dealings with the Department or any Government Agency, including in any tender or application process or in any contract;
- (j) it has had no significant deficiency in the performance of any substantive

requirement or obligation under any prior contract with the Department or any Government Agency;

- (k) it has, and will continue to have and to use, the skills, qualifications and experience to perform the Services in an efficient and controlled manner with a high degree of quality and responsiveness and to a standard that complies with this Contract; and
- (l) it has and will continue to have the necessary resources, including financial resources, to perform the Services and will use those resources to perform the Services.

25.2 The Consultant acknowledges that the Department in entering into this Contract is relying on the warranties and representations contained in this Contract.

25.3 The Consultant:

- (a) acknowledges that it has been chosen to provide the Services in an area of expertise that is outside those of the Department; and
- (b) represents to the Department that it has the necessary knowledge and expertise to provide the Services,

and the Department:

- (c) relies on the Consultant's representation that it is an expert; and
- (d) has engaged the Consultant to provide the Services on that basis.

25.4 Each representation and warranty survives the execution of this Contract.

26. NEGATION OF EMPLOYMENT, PARTNERSHIP AND AGENCY

26.1 The Consultant is not, by virtue of this Contract, an officer, employee, partner or agent of the Commonwealth, nor does the Consultant have any power or authority to bind or represent the Commonwealth

26.2 The Consultant agrees not to represent itself, and to use its best endeavours to ensure that its Consultant Personnel 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.

27. WORK HEALTH AND SAFETY

27.1 In carrying out this Contract the Consultant must ensure that the Services are performed in a safe manner and in compliance with the WHS legislation.

28. NOTICES

28.1 A Party giving notice under this Contract must do so in writing, including by email or 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, email or facsimile to that address.

The Parties' address details are as specified in Item O.

28.2 The Parties agree that a notice given in accordance with clause 28.1 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 email or facsimile, when received by the addressee or when the sender's computer or facsimile machine generates written notification that the notice has been received by the addressee, whichever is earlier.

THE SCHEDULE

Item A Services and Subcontractors

The Consultant is required to develop and produce an expert external review of the safety and efficacy of low-dose codeine (**Codeine Review**).

The Consultant is required to undertake the Codeine Review consistent with the Research Plan in **ATTACHMENT A**, titled Investigating the efficacy and safety of over the counter codeine containing combination analgesics for pain and codeine based antitussives dated 1st February 2016 addressing the Codeine Review in two parts.

1. Part A: Efficacy of Over-the-Counter (OTC) codeine combination products.
2. Part B: Safety and adverse events related to codeine combination products.

The Consultant is required to provide a draft report (**Draft Codeine Review Report**) by **22 FEBRUARY 2016** for consideration by the TGA for review and feedback. The Consultant is required to incorporate the agreed amendments and clarifications into the final report (**Final Codeine Review Report**) as requested by the TGA.

The Consultant is required to provide the **Final Codeine Review Report** (incorporating the proposed amendments and clarifications) by **1 MARCH 2016**.

Item B Required Contract Material

The Draft Codeine Review Report.

The Final Codeine Review Report.

Item C Standards and Best Practice

No additional standards and practices beyond those applicable to the Services.

Item D Time-frame

Commencement date 5 February 2016 to 10 March 2016

Item E Fees

The total fees for Services are \$60,000 INCLUSIVE OF GST and are payable in the following instalments:

- \$40,000 following the delivery of the draft Codeine Review Report (as described in Item A and B)
- \$20,000 following the delivery of the Final Codeine Review Report (as described in Item A and B)

Item F Allowances and Costs

Not applicable

Item G Facilities and Assistance

Not applicable

Item H Invoice Procedures

The Consultant must forward correctly addressed invoices that are in the form of a tax invoice and include the following:

- (a) the title of the Services or other identification of this Contract;
- (b) the name of a Commonwealth contact officer
- (c) the fees, allowances and costs due; and
- (d) a written statement signed by the Consultant/Contractor, or where the Consultant/Contractor is a body corporate, by a representative of the Consultant/Contractor authorised to sign on behalf of the body corporate, verifying that no wages are due and owing by the Consultant/Contractor in respect of the performance of the Services at the time the claim for payment is made.

Item I Specified Personnel

The Specified Personnel will be in accordance with the Research Plan located at ATTACHMENT A to this Contract.

Item J Commonwealth Material to be provided by Commonwealth

NOT APPLICABLE

Item K Use of Commonwealth Material

NOT APPLICABLE

Item L Existing Material

NOT APPLICABLE

Item M Dealing with Copies

NO ADDITIONAL REQUIREMENTS SPECIFIED

Item N Insurance

The Consultant agrees to maintain:

- (a) workers compensation insurance for an amount required by the relevant State or Territory
- (b) public liability insurance for an amount of not less than five million dollars (\$5,000,000); and
- (c) professional indemnity insurance for an amount of not less than two million dollars (\$2,000,000).

Item O Address for Notices

Department's Address for Notices:



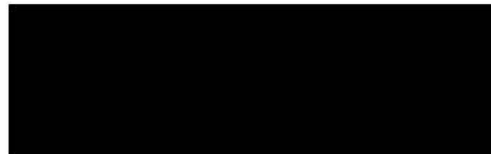
Signal Investigation Unit

Pharmacovigilance and Special Access Branch



Email: [REDACTED]@tga.gov.au

Consultant's Address for Notices:



Phone: [REDACTED]

Email: [REDACTED]@georgeinstitute.org.au

This Contract is **SIGNED** as a contract.

SIGNED for and on behalf of the **COMMONWEALTH OF AUSTRALIA** acting through the Therapeutic Goods Administration ABN 40 939 406 804 within the Department of Health on:

Date

by:

Printed name of signatory

Signature

Position of signatory

in the presence of:

Printed name of witness

Signature of witness

SIGNED for and on behalf of **THE GEORGE INSTITUTE FOR GLOBAL HEALTH ABN 90 085 953 331**, in accordance with the requirements of section 127 of the *Corporations Act 2001* on:

23 February 2016

Date

by:

Printed name of Director

Signature of Director

and:

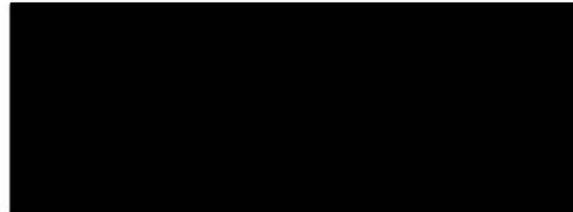
Printed name of Director / Secretary

Signature of Director / Secretary

Title:

Investigating the efficacy and safety of over-the-counter codeine containing combination analgesics for pain and codeine based antitussives

Contributors:



1st February, 2016

Research plan

This research protocol will address the research question in 2 parts.

PART A – Efficacy of OTC codeine combination products

Aim(s):

- i) To determine the efficacy of over-the-counter codeine combination analgesics (ibuprofen + codeine or aspirin + codeine or paracetamol + codeine or doxylamine + paracetamol + codeine) for the treatment of any pain condition;
- ii) To determine the efficacy of OTC codeine based products as an antitussive.

Methods: One reviewer to screen titles and abstracts for eligible RCTs. Two reviewers drawn from a pool of three reviewers [REDACTED] will inspect the full manuscript for eligibility.

Databases: MEDLINE, EMBASE, CINAHL, Cochrane database of systematic reviews and PsycINFO.

Search Strategy Summary:

Systematic review OR Systematic overview OR Systematic adj25 analysis OR Random\$ controlled trial\$ or RCT OR placebo-controlled adj25 trial

Medicines:

(Codeine adj25 acetaminophen) OR (Codeine adj25 paracetamol) OR (Codeine adj25 ibuprofen) OR (Codeine adj25 aspirin) OR (Codeine adj25 acetylsalicylic acid) OR (codeine adj25 doxylamine

+ Adverse event OR adverse effect OR side effect OR dependency OR addiction

+ Efficacy OR effectiveness OR effect

Inclusion criteria for studies: Placebo-controlled randomised controlled trials (RCTs) written in the English language evaluating any OTC codeine combination for pain or OTC codeine based product as an antitussive. Studies comparing codeine combinations with simple analgesic to simple analgesics alone will also be included. **Note:** While studies compare a range of dose intensities of codeine, studies will be included which can be achieved using OTC products at recommended doses.

Outcome measures:

The *primary* outcome measure will be short term (< 3 months) pain relief, measured on the visual analogue scale or numerical rating scale (for OTC codeine combinations used for analgesia).

For studies evaluating codeine based products as an antitussive, the primary outcome measure will be the number of coughs or reduction in number of coughs.

We will treat other outcomes as *secondary* outcomes and these will be presented descriptively in a table and not be included in the meta-analysis.

Data Analysis: Data will be extracted by two reviewers. Trial methodological quality will be assessed using the PEDro scale. Overall strength of evidence will be rated using the GRADE criteria. Meta-analysis will be carried out using a random effects model using Review Manager (RevMan) if we locate sufficient homogenous trials.

Efficacy data: For pain outcomes, the summary measure of treatment effect will be the weighted mean differences (on the 100 point scale) and 95% CI.

For antitussive outcomes we will report number of coughs or reduction in number of coughs.

PART B – Safety and adverse events related to codeine combination products

Aim(s):

- i) *To investigate the safety of codeine based products which are available over-the-counter.*

Methods: One reviewer to screen titles and abstracts for eligible systematic or narrative based reviews.

Databases: Medline, Embase, Cochrane Database of Systematic Reviews.

Studies: Original studies, systematic or narrative reviews of codeine based products which report on adverse events (including dependence) from reports including (but not limited to) case reports and case series, RCTs, Coronal Information System or cohort studies.

Data Analysis: Safety data will be extracted from systematic reviews or narrative reviews in the area and tabulated. These findings will be appended to the main document. We will capture data on short term and long term safety outcomes where these are available.

Additionally, we will extract the proportion of participants experiencing one or more adverse event from eligible RCTs in Part A and calculate relative risk.

Deliverable:

A draft report of findings will be provided to the TGA for review and feedback. Clarifications and amendments will be made before a final report is submitted to the TGA in accordance with the timeframe agreed.

Timeline: Intended completion of draft report 22 February 2016. Final Report acceptable to the TGA by 1 March 2016.

Publication: It is agreed that the TGA will have the right to review and comment on any manuscript that might arise as part of this work before submission to a peer review journal. The financial support of the TGA will be acknowledged in any manuscript related to the findings of this work.

Team Contributions: This research will be led by [REDACTED] and supported by Professors [REDACTED] (see attached Curriculum Vitae).

Role	Contributor(s)
Literature Search	[REDACTED]
Screening of titles and abstracts	
Full inspection of eligible trials	
Data Extraction	
Rating of study methodological quality	
Data Synthesis	
Writing Up	
Reviewing/Editing	

Estimated time commitment

Part	Time commitment (h)	Estimated cost (@ \$300 / h)
A	135	\$40,500
B	65	\$19,500
Total	200	\$60,000

ATTACHMENT A

Protocol

