



SOP: ENGAGEMENT OF EXTERNAL EVALUATORS FOR ASSESSMENT OF MEDICINES FOR REGISTRATION ON THE AUSTRALIAN REGISTER OF THERAPEUTIC GOODS (ARTG)

Operations	Therapeutic Goods Administration
Procedure	SOP: Engagement of External Evaluators using External Evaluator Panel and the circumstances in which External Evaluators can be engaged using AGS External Evaluator Contract
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1. Aim/Purpose/Scope

The purpose of this Standard Operating Procedure (SOP) is to set out the procedures, and guidance on the requirements for:

- the engagement of External Evaluators for conducting scientific evaluations using the Therapeutic Products Assessment and Advisory Services Panel (the **External Evaluator Panel**) and:
- in circumstances where no External Evaluators are available using the External Evaluator Panel, directly engaging External Evaluators using the Australian Government Solicitor (AGS) contract template containing an indemnity from the Commonwealth to the External Evaluator.

2. Responsibility

Financial delegates are required to comply with the Financial Management and Accountability framework (eg the *Financial Management and Accountability Act 1997* (FMA Act); FMA Regulations and subordinate legislation and Government (Cth and Departmental policy).

All staff involved in the engagement of External Evaluators **MUST** comply with this SOP;

The TGA Comcover contact currently is Mr Philip Cooley from the Office of Regulatory Integrity is responsible for notifying Comcover when the TGA enters into contracts that contain contingent liabilities (indemnities).

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3. Introduction/Background

The Australian community expects therapeutic goods in the marketplace to be safe, of high quality and of a standard at least equal to that of comparable countries. Therapeutic goods are divided into two classes: medicines and medical devices. Medicines must be entered as either “registered” or “listed” medicines and medical devices must be “included” on the ARTG before they may be supplied in or exported from Australia (unless exempted).

In undertaking the assessment of medicines for registration on the ARTG, the TGA seeks the advice and assistance from external experts (External Evaluators) relating to the assessment process. External Evaluators are required to use their expertise to review the data provided by the applicant and prepare a report to the TGA.

The TGA has established the External Evaluator Panel using an open approach to market in 2010. The unavailability of External Evaluator from the External Evaluator Panel has meant in some circumstances the TGA, is not able to obtain the necessary expertise required to complete the evaluations.

After undertaking due diligence and a comprehensive risk assessment the TGA has sought approval from Comcover, in certain circumstances, to enter into arrangements with individual External Evaluators for scientific evaluations which contain an indemnity from the Commonwealth to the individual External Evaluator and which also do not contain any requirement for the External Evaluator to maintain insurance (AGS External Evaluator Contract).

Comcover have agreed to the TGA entering into the AGS External Evaluator agreements **ONLY in the circumstances as set out below** under the heading Procedure/Policy for Engagement of an External Evaluator using the AGS External Evaluator Contract.

4. Policy/Procedure

The Process for the Engagement of External Evaluators using the External Evaluator Panel.

STEP 1

An application is accepted for assessment within the TGA. The applications received by the TGA undergo a preliminary check by relevant managers within the TGA to ensure the application meets the requirements for the lodging of an application and sufficient data is available for the evaluation process.

Once an application moves to the assessment stage different data parts are allocated to the various sections. The various areas of the TGA examine the application and determine whether the assistance of an external expert is required. The three areas of assessment and the areas within TGA responsible for the initial assessment are:

- **Chemistry and quality aspects:** assessed by the Pharmaceutical Chemistry Section and the Office of Laboratories and Scientific Services
- **Pharmacological and toxicological aspects:** assessed by the Medicines Toxicology Evaluation Section
- **Clinical data aspect:** assessed by the Clinical Evaluation Section

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STEP 2

The Stream Leader completes a Data Assessment Form listing precisely the evaluation that is required. Once the evaluation and determination of internal or external evaluation is decided, the Master Control Spreadsheet is updated by the Application Entry Team. The External Evaluation Team (currently Cathy Sellick on ext 8347 and Bev Boulton on ext 8128) then access the Master Control Spreadsheet determine which submissions have been allocated externally and which have the PPF forms assessed as being complete.

The External Evaluation Team reviews the request, drafts a statement of requirement and seeks a Request for Quotation (RFQ) from those panellists from the External Evaluation Panel who have the qualifications to undertake the Services and are available.

STEP 3

Step 3A – If available Panellists from the External Evaluation Panel to undertake the Services

The External Evaluation Team undertakes an evaluation of the Quotations that are received by TGA from the available panellists.

A panellist is selected on the basis of the evaluation of the quotes and their availability The External evaluation Team then advises the panellists who have quoted of the outcome.

A Procurement Registration Number is obtained and relevant approvals are sought from the financial delegate eg Financial Management and Accountability Regulations (FMAR), Regulation 9 delegate to approve the proposal to spend public money etc.

The letter of offer and Official Order sent to the successful panellist to engage them.

Step 3B – If NO available Panellists from the External Evaluation Panel to undertake the Services

If the External Evaluation Team has not received any quotations from all available panellists or there are no suitable panellist with the relevant expertise, a file note is made of the list of panellists from whom quotations were sought and their responses (if any) or reasons as to why there are not suitable panellists on the External Evaluator Panel. The file note is placed on the file.

Determination as to who to approach

The External Evaluation Team will seek guidance from the relevant professionals within TGA as to individual experts that are able to undertake the Services. A file note of this will be made and placed on file.

Request for Quotation Stage

The External Evaluation Team will contact the relevant expert asking them to advise their interest. If they agree the relevant expert will be asked to provide a copy of their Curriculum Vitae (CV) for assessment by the relevant Stream Leader for assessment within TGA.

Assessment of Professional Qualifications

The professional qualifications and experience of the External Evaluator MUST be confirmed suitable by the relevant Stream Leader before entering into the AGS External Evaluator Contract. External Evaluators for clinical aspects of a medicine MUST be Australian Registered medical practitioners usually with a recognised specialist qualification in an area of medical practice relevant to the medicine being evaluated. The assessment of the External

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Evaluator's professional qualifications and experience is documented and this is placed on the file.

Risk Assessment

If the External Evaluator's qualifications are confirmed as appropriate for the specific task, an individual risk assessment is undertaken based on the individual External Evaluator providing the services using the AGS External Evaluator template. The DoHA or TGA template risk assessment form can be used to undertake the risk assessment. An example risk assessment is attached here for guidance. See Attachment A for an example of a risk assessment.

If the CV is assessed as suitable and the risk assessment is completed and acceptable, the relevant expert will then be sent the Conflict of Interest statement and the Deed of Confidentiality for their review, completion and signature. Once the Conflict of Interest declaration has been reviewed and the Deed of Confidentiality has been signed and returned to TGA, a RFQ containing details of the evaluation and a copy of the template AGS External Evaluator Contract (with the instructions removed) is provided to the individual expert seeking a quote.

The quotation is assessed by the External Evaluation Team.

Standard review Controls are in place

The services to be provided by the External Evaluator under the AGS External Evaluator Contract **MUST** have the standard review controls as follows:

- review of the External Evaluator's evaluation assessment by an internal TGA staff member before acceptance of the external evaluation;
- review of the external evaluation report by the applicant seeking to register the product; and
- possible further review by an independent external expert advisory group (if required).

The External Evaluator Team is to make a file note to the effect that the standard review controls are in place for each AGS External Evaluator Contract.

Assessment as to whether Superannuation Guarantee (Administration) Act 1992 applicable

The External Evaluator Team will undertake an assessment as to whether superannuation is payable under the *Superannuation Guarantee (Administration) Act 1992* by using the Australian Taxation Office (ATO) Superannuation Guarantee (SG) Eligibility Decision Tool linked as follows:

[<http://www.ato.gov.au/businesses/content.aspx?doc=/content/85201.htm>]

Each proposed AGS External Evaluator Contract requires an assessment to be undertaken as to whether superannuation is payable. A copy of the SG Eligibility Report is to be printed out for each External Evaluator and placed on file.

Superannuation is NOT payable to external evaluators over 70 years, if this is the case, a file note is made and placed on file.

If superannuation is payable you will need to contact the Finance Area of TGA for guidance on how to make payments. *[Please note: the expectation is that superannuation will NOT be payable under these arrangements as the TGA is seeking independent professional advice to produce a result, that is, the evaluation report. If you are unsure after using the*

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Superannuation Guarantee (SG) Eligibility Decision Tool, please seek Office of Legal Services advice.

If superannuation is not payable, place copy of the SG Eligibility Report on file (as above).

Procurement Reporting Schedule

A Procurement Reporting Schedule Number must be obtained from the TGA Procurement Section.

Step 1

Complete a Procurement Reporting Schedule (PRS) form available at <http://intranet.tga/finance/ofps-forms.htm>. Once form has been completed, email the form to the TGA Procurement inbox, print two copies and send one signed hard copy to the relevant TGA Procurement Officer currently (Eric Soriano x8223). The second copy is to be held for your records.

Note: this number is required to be included in the Reg 9 Approval Minute.

Step 2

When PRS number is received attached email to relevant contract paperwork and notate PRS number on your copy of PRS form.

FMAR Regulation 10 and/or 10A Approval

FMAR Regulation 10

FMAR Regulation applies to circumstances where the relevant agency has an insufficient appropriation of money under the provisions of an existing law, or a Bill that is before the Parliament, to meet the full expenditure that might be payable under the arrangement. FMAR Regulation 10 must be complied with before entering into an arrangement.

Regulation 10 provides that the existing, or proposed appropriation authority must be sufficient to meet expenditure than might be payable under the arrangement. This includes all the costs that the Commonwealth is committing to pay under the arrangement, including the costs of any contingent liabilities.

The AGS External Evaluator Contract template contains an indemnity from the Commonwealth to the individual external evaluator and no insurance obligations on the External Evaluator. The indemnity is a contingent liability and a contingent liability is a commitment that may give rise to a liability as a result of a future event. However a contingent liability will not trigger the need for agreement under FMAR Regulation 10, if the person who is proposing to enter into the arrangement is satisfied, after making reasonable inquiries, that the contingent event is both "remote" and also that, if the event did occur, the "most probable expenditure" would be non-material.

FMAR Regulation 10A

FMAR Regulation 10A defines remote as a probability of less than 5% that it will occur. Regulation 10A defines "material" as \$5 million if the Finance Minister has not specified another amount in a legislative instrument. The amount set for the Department of Health and Ageing (DoHA) is \$5 million.

The External Evaluation Team is required to seek approval FMAR Regulation 10A from the relevant delegate prior to entering into this arrangement. The relevant delegate would be the person who approves the proposal to expend public money (eg the FMAR Reg 9 delegate) as there are no delegations for Regulation 10A under the FMARs.

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The following is the form of declaration that can be made by the delegate if FMAR Regulation 10A is applicable.

Contingent Liability Declaration

*In accordance with Regulation 10A of the Financial Management and Accountability Regulations 1997,
It is my opinion that:*

- 1. there is less than a 5% chance of this indemnity being drawn on making it remote; and*
- 2. in the event that it does occur, materially the amount involved will be less than \$5,000,000.*

Signed:..... Date:...../...../.....
[insert position], Therapeutic Goods Administration

FMAR Regulation 9 Approval

The External Evaluation Team is required to seek approval FMAR Regulation 9 for the relevant delegate prior to entering into this arrangement. FMAR Regulation 9 establishes a single test, an approver must balance the various elements in order to determine whether the spending proposal, if given effect, would be a *proper use* of Commonwealth resources.

Proper use is defined in section 44 of the FMA Act as “*efficient, effective, economical and ethical use of Commonwealth resources that is not inconsistent with the policies of the Commonwealth.*”

An approver needs to exercise judgement, taking into consideration the nature, significance and value of the spending proposal and any associated risks. Ideally, FMAR Regulation 9 approval should be sought as soon as there is sufficient information available to consider a spending proposal. A FMAR Regulation 9 approver may approve a spending proposal orally or in writing. If the approval is oral, according to FMAR Regulation 12 the terms of the approval need to be documented as soon as practicable. While Regulations 9 and 12 do not specify the wording to be used by the approver, wording such as “I approve this spending proposal” or other language is sufficient.

STEP 4 SENDING THE AGS EXTERNAL EVALUATOR CONTRACT TO THE EXTERNAL EVALUATOR

The letter of offer and the AGS External Evaluation Contract sent to the successful External Evaluator.

STEP 5 REPORTING TO COMCOVER

Every AGS External Evaluator Contract entered into by the TGA will need to be recorded on the TGA Register of Contingent Liabilities AND reported to Comcover.

You will need to provide a copy of the signed AGS External Evaluator Contract; the risk assessment and the FMAR Regulation 10 approval /or 10A decision to the Office of Regulatory Integrity, Phil Cooley (x8473) for placing on the TGA Register of Contingent Liabilities and for Comcover Reporting.

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- Only **INDIVIDUAL** External Evaluators can be engaged using the AGS External Evaluator Contract.
- AGS External Evaluator Contracts can **ONLY** be used for contracts with a total value under \$80,000 (including GST).
- The professional qualifications and experience of the External Evaluator **MUST** be confirmed before entering into the AGS External Evaluator Contract. Evaluators for clinical aspects of a medicine **MUST** be Australian Registered medical practitioners.
- The services **MUST** be provided to a “high professional standard” (as required by the AGS External Evaluator contracts therefore do **NOT** change the templates without first seeking legal advice);

5. References

- *Financial Management and Accountability Act 1997*
- Financial Management and Accountability Regulations 1997
- *Superannuation Guarantee (Administration) Act 1992*
- Finance Circular 2011/01 Commitments to spend public money (FMA Regulations 7 to 12)
- Superannuation Eligibility Decision Tool (SG Decision Tool)

6. Attachments

- Example of Risk Assessment for External Evaluator using the AGS External Evaluator Contract.