



| | |
|----------------|--|
| Operations | Office of Prescription (OPM) |
| Procedure | OPM SOP – External Evaluation Services |
| Written by: | Julian Natera & Cathy Sellick |
| Authorised by: | Dr Leonie Hunt |
| Date Issued | July 2009 |
| Revision # | |

1. AIM/PURPOSE/SCOPE

This SOP details the specific steps required to approach the market for external evaluation services.

The SOP applies to staff undertaking this task (i.e. the Office of Prescription Medicines (OPM) Finance Officer, Clinical Evaluation Unit, Toxicology Evaluation Unit, and Pharmaceutical Chemistry Evaluation Unit, Clinical Executive Assistants and the Head Office of Prescription Medicines).

2. RESPONSIBILITY

TGA procurement processes must comply with the requirements of the Financial Management Accountability Regulations (FMARs) 8 to 13 (including Commonwealth Procurement Guidelines CPGs). The Department of Health and Ageing have published procedures on how to apply the FMARs and CPGs; with the detailed procedures included in (e.g.) the DOHA Procurement Manual and the Chief Executive Instructions (CEIs).

All staff with a financial delegation are responsible for ensuring compliance with the FMAR 8 to 13 and CPGs in all OPM procurement processes (including external evaluation services).

Note: An officer performing the duties in relation to the procurement of goods and services must have regard to the CPG's (FMA Reg 8(1)).

An approver must not approve a proposal to spend public money unless the approver is satisfied, after making such inquiries as are reasonable, that:

- the proposed expenditure is in accordance with the policies of the Commonwealth; and
- the proposed expenditure will make efficient and effective use of the public money (FMA Reg 9)

The approval must be documented (FMA Reg 12).

A person must not enter into a contract, agreement or arrangement unless it has been approved under Regulation 9 and, if applicable, Regulation 10(FMA Reg 13).

3. INTRODUCTION/BACKGROUND

This SOP details the steps required to approach the market for external evaluation services from the TGA Product Evaluation Panel. The SOP extends to outline arrangements for sourcing services outside of the TGA Product Evaluation Panel.

The TGA established an Expert Panel to provide external evaluation services to the TGA. The Panel became operational on 1 September 2007.

The Deeds of Standing Offer under the Panel do not mandate exclusivity; however Panel members must be considered first for the completion of external product evaluation activities. Proposals to procure external evaluation services from non-Panel External Evaluators must have prior approval from the Head, OPM and be based on the appropriate processes outlined in the (CEI's) Chief Executive Instructions.

The following are examples of when it may be appropriate to source services from non-Panel External Evaluators:

All suitable Panel Members have been invited to tender, however, they declined to submit quotations. For example, the evaluator may not have the capacity to undertake additional evaluation work within the desired timeframe;

A previous approach to the Panel did not yield any quotations which truly represent value for money (VFM). For example, Panel members subsequently over state the value of the evaluation services and submit higher than (VFM) acceptable quotations.

4. PROCEDURE/POLICY

4.1 Sourcing Evaluation Services from TGA External Evaluator Panel

A mail in database – OPM.External.Contracts@tga.gov.au - has been created where all requests from the Delegate for a Finance Officer to seek a quote for an External evaluation should be sent. This database is checked on a daily basis by Finance Officers. This database is also used for external communication regarding the quotation process for External Evaluators.

Once a decision has been made to send data out for External Evaluation the following steps must be followed

Step 1

- A *permission to seek quote* (Attachment A) form must be completed by the Evaluation Unit Delegate and sent to the Head, OPM for approval.

Refer to the TGA Product Evaluation Panel Guidelines on the intranet for the *permission to seek quote and invitation to quote forms* at TGA Product Evaluation Panel Guidelines.

Step 2

Once approval to seek a quote has been obtained

- The Evaluation Unit Delegate sends the *invitations to quote* containing Statement of Requirement (Attachment B) via email to the OPM.External.Contracts@tga.gov.au. The statement of requirement should clearly define the work involved in doing the evaluation so the tenderer/s can provide a quote. ie Broad description of material to be reviewed, Services to be provided, Timeframes etc. Included in the email from the Evaluation Unit Delegate should be advice regarding the type of expertise required. **Note: end date for the contract should be no longer than 4 months from the receipt of the data.**
- An OPM Finance Officer reviews the Panel membership and identifies suitable Panel members to undertake the Evaluation Services required. All qualified members of the Panel should be approached (at least 3 qualified members should be approached). If a full approach is not undertaken, then reasons for limited selection from the Panel must be documented. **Note: check external evaluator contract register to see the workload of the evaluators to ensure that the evaluator is able to quote.**
- Identified Panel member/s will be sent *invitations to quote* containing Statement of Requirements (Attachment B) to confirm availability, ascertain any conflicts of interest and provide a quote for the evaluation services. Allow 2 weeks for a response to a request for quote.
- Panel member responses are reviewed by the Finance Officer to ensure that they meet the requirements for the evaluation service. To assess quotations effectively, the Finance Officer must take into account the Panel member hourly/daily rates as per their Deed of Standing Offer. Panel member hourly/daily rates are available from the OPM Finance Officer.
- Before drafting a Reg 9 Minute for approval by the Office Head check whether Reg 10 approval is required. **External contracts that have or likely to have payments in the next financial year must have FMA Regulation 10 approval (Attachment D) before the Contract can be executed.**
- A Reg 9 Minute including justification of the preferred panel member, is drafted and sent to the Head, OPM for approval. This Minute can be found at <s:/co/tga/DSEB/Finance/External Evaluators RFQ>.
- Upon approval the Finance Officer completes the TGA Procurement Registration Schedule located at <s:/co/tga/DSEB/Finance/External Evaluators RFQ>, and prints, signs and dates form, makes a copy for the Coord file and hands the original to the Procurement Officer in the Office of Financial and Property Services for allocation of a Procurement Registration number.
- Once the procurement number has been received it must be noted on the copy of the Procurement Registration form.
- Copy the Reg 9 Minute and the Procurement form to the Clin file and the originals relating to the RFQ, Reg 9 Minute, and Procurement Registration number on the Coord file.

- The Submission is then allocated on PREMIER including details of information to be sent to the External Evaluator identified in the Statement of Requirements completed by the Evaluation Delegate and a Consultancy Contract/Official Order is prepared. (refer to SOP on preparing Consultancy Contract/Official Orders)

Step 3

- Update External Evaluator Workload Spreadsheet
- The Finance Manager in OPM reviews the Contract/Official Order for quality assurance
- Once checked the Contract/Official Order is sent out the External Evaluator for signature.
- When a signed copy of the Contract is returned then send to Head, OPM for counter signature along with the Purchase Order for signature (see Step 4)
- Upon signature from both the External Evaluator and the Head OPM the contract is copied and sent back to the External Evaluator with any miscellaneous data
- TGA Records Management are then sent an email to despatch the data to the External Evaluator.

Step 4

- When preparing the contract a purchase order request must be prepared and signed by Head OPM (see Step3)
- The purchase order commitment is then recorded on the Contracts Register and Purchase Requisition raised in Workplace. (The Purchase Requisition is work-flowed electronically to the Financial Delegate for online approval.)
- Once the Purchase Order is generated, the Purchase Order is printed (from Workplace) and attached to the signed Contract. All documentation must then be filed in the External Evaluator Contracts Register folder with the exception of the Reg 9 Minute of which a copy is placed on the Procurement Process to Engage an External Evaluator file.

4.2 Sourcing Evaluation Services outside the TGA External Evaluator Panel

Step 1

If suitable evaluators **cannot** be sourced from the Panel, a *Permission to seek quote* form must be completed and sent to the Head, OPM for approval.

Note: The Panel must be the first point for sourcing evaluation services. Panel members may be justified as unsuitable if their quotation is assessed as not representing value for money, or they are unavailable to complete the work.

Once approval to seek a quote outside the Panel has been obtained, the Finance Officer must seek quotes from (more than one) non-Panel External Evaluator.

Step 2

Once approval to seek a quote outside the Panel has been obtained

- The Evaluation Unit Delegate sends the *invitations to quote* containing Statement of Requirement (Attachment B) via email to the OPM.External.Contracts@tga.gov.au. The statement of requirement should clearly define the work involved in doing the evaluation so the tenderer/s can provide a quote. ie Broad description of material to be reviewed, Services to be provided, Timeframes etc. Included in the email from the Evaluation Unit Delegate should be advice regarding the type of expertise required. **Note: end date for the contract should be no longer than 4 months from the receipt of the data.**
- An OPM Finance Officer reviews the Non Panel evaluators list and identifies suitable tenderers to undertake the Evaluation Services required. All qualified members outside of the Panel should be approached (at least 3 qualified members should be approached). If a full approach is not undertaken, then reasons for limited selection must be documented. **Note: check external evaluator contract register to see the workload of the evaluators to ensure that the evaluator is able to quote.**
- Identified non Panel evaluators will be sent *invitations to quote* containing Statement of Requirements (Attachment B) to confirm availability, ascertain any conflicts of interest and provide a quote for the evaluation services.
- Non Panel evaluators must also have appropriate insurance before being offered any External Consultancy Services. Information on Insurance can be obtained from the OPM Finance Officer.
- Non Panel evaluator responses are reviewed by the Finance Officer to ensure that they meet the requirements for the evaluation service. To assess quotations effectively, the Finance Officer must take into account the Panel member hourly/daily rates as per their Deed of Standing Offer. Panel member hourly/daily rates are available from the OPM Finance Officer.
- Before drafting a Reg 9 Minute for approval by the Office Head check whether Reg 10 approval is required. **External contracts that have or likely to have payments in**

the next financial year must have FMA Regulation 10 approval (Attachment D) before the Contract can be executed.

- A Reg 9 Minute including justification of the preferred tenderer is drafted and sent to the Head, OPM for approval. This Minute can be found at s:/co/tga/COORD/DSEB/Finance/External Evaluators RFQ.
- Upon approval the Finance Officer completes the TGA Procurement Registration Schedule located at s:/co/tga/COORD/DSEB/Finance/External Evaluators RFQ, and prints, signs and dates form, makes a copy for the Coord file and hands the original to the Procurement Officer in the Office of Financial and Property Services for allocation of a Procurement Registration number.
- Once the procurement number has been received it must be noted on the copy of the Procurement Registration form.
- Copy the Reg 9 Minute and the Procurement form to the Clin file and the originals relating to the RFQ, Reg 9 Minute, and Procurement Registration number on the Coord file.
- The Submission is then allocated on PREMIER including details of information to be sent to the External Evaluator identified in the Statement of Requirements completed by the Evaluation Delegate and a External Consultancy Contract is prepared. (refer to SOP on preparing External Consultancy Contract)

Step 3

- Update External Evaluator Workload Spreadsheet
- The Finance Manager in OPM reviews the External Consultancy Contract for quality assurance
- Once checked the contract is sent out to the External Evaluator for signature.
- When a signed copy of the Contract is returned then send to Head, OPM for counter signature along with the Purchase Order for signature (see Step 4)
- Upon signature from both the External Evaluator and the Head OPM the contract is copied and sent back to the External Evaluator with any miscellaneous data
- TGA Records Management are then sent an email to despatch the data to the External Evaluator.

Step 4

- When preparing the contract a purchase order request must be prepared and signed by Head OPM (see Step 3) The Purchase Order template is located at s:/co/tga/DSEB/COORD/Finance/External Evaluation Contract Templates
- The purchase order commitment is then recorded on the Contracts Register and Purchase Requisition raised in Workplace. (The Purchase Requisition is work-flowed electronically to the Financial Delegate for online approval.)
- Once the Purchase Order is generated, the Purchase Order is printed (from Workplace) and attached to the signed Contract. All documentation must then be filed in the External Evaluator Contracts Register folder with the exception of the Reg 9

| | |
|---------------------------------------|----------------------|
| TGA Fieldname & Path Print Date | 6 of 7 10/05/2012 |
|---------------------------------------|----------------------|

Minute of which a copy is placed on the Procurement Process to Engage an External Evaluator file.

5. PRIMARY CONTACTS

OPM Finance Officer

Julian Natera

PH 6232 8058

OPM Expenditure Delegate <\$50k Consultancies

Ph. 6232 8100

Dr Leonie Hunt

Head

Office of Prescription Medicines