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Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Office of Complementary Medicines

Operations	Office of Complementary Medicines
Procedure	Engagement of evaluators from the TGA External Evaluator Panel
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1. Aim/Purpose/Scope

This SOP details the specific steps required to approach the TGA External Evaluator Panel (the Panel) for external evaluation services.

The SOP applies to staff undertaking specific procurement tasks (i.e., the Office of Complementary Medicines (OCM) Finance Liaison Officer (FLO), the OCM Section Heads, and the OCM Head.

2. Responsibility

The maintenance of the SOP is the responsibility of the OCM FLO.

The Director of the OCM's Pre-Market Assessment Section (PREMAS) is responsible for providing advice on the capability and capacity of Panel members to those seeking to use Panel members and assisting in the selection of the most suitable Panel members to be Invited to Quote. (this information is provided by Julian Natera using the list of Panel members)

The TGA officer seeking the external evaluation services ("the Project Officer") is responsible for developing the Statement of Requirement, the Invitation to Quote, assessing responses, developing the Official Order, monitoring the performance of the Panel member and completing the evaluation sheet.

The Delegate/Financial Delegate (usually the OCM Head) is responsible for providing authorisation to proceed with procurement of external evaluation services, signing the Official Order/Contract for services, and approving all expenditure.

3. Introduction/Background

The TGA established an expert panel to provide external evaluation services to the TGA in September 2007. The Panel arrangement offers consistency in the procurement and management of external evaluators, in accordance with the Commonwealth Procurement Guidelines and departmental best practice in procurement.

Panel members have entered into a Deed of Standing Offer arrangement with the TGA. A Standing Offer arrangement enables the TGA to procure evaluation services from the Panel as and when required through the issue of an Official Order. If the Official Order is accepted by the Panel member, a separate Contract is created on the same terms as the Deed. ~~The Panel arrangement offers consistency in the procurement and management of external evaluators, in accordance with the Commonwealth Procurement Guidelines and departmental best practice in procurement~~. (as above)

While use of Panel members is not a totally exclusive arrangement, Panel members must be considered first for the completion of external product evaluation activities. Any proposal to procure external evaluation services from outside the Panel must have Office Head approval and be based on the appropriate processes outlined in the Chief Executive Instructions (CEIs) which can be found at: http://intranet.central.health/intranet/wcms/publishing.nsf/Content/managingourmoney-governance-content

4. Policy/Procedure

4.1 Identification of suitable Panel member/s

Once the need for use of the Panel for a particular project has been identified (e.g., specialist knowledge and skills are required which are not available within the Office), the Project Officer should review the Panel membership and determine those members who could undertake the Evaluation Services required. A list of the Panel members and their expertise is provided on the TGA Intranet at: http://intranet.tga/pdf/procurement-panel-productevaluation-members.pdf

If necessary, discuss your requirement and your choice of Panel members with the Director of PREMAS to ascertain the Panel member's capacity and capability.

4.2 Seeking and Reviewing Quotes

Once a suitable Panel member/s has been identified a permission to seek quote form must be completed and sent to the FLO to obtain the Delegate's approval. A link to the "Permission to Seek Quote" template is provided under Step 2 of the Panel Guidelines on the TGA Intranet at: http://intranet.tga/finance/procurement-panel-productevaluation.htm

The Permission to Seek Quote should be forwarded to the FLO for checking and then to the Delegate for approval.

[Initial approach is by email in order to find out if the Panel member(s) is/are available or willing to undertake the work within the proposed time frame. If available, more than one panel member should be invited to quote for services.]

Once approval has been given by the Delegate, the selected Panel member/s should be sent an "Invitation to Quote" form to confirm availability, ascertain any conflicts of interest and provide a quote for the evaluation services. This should include the following issues:

a. a closing date for quotes – this can be up to ten (10) working days;
b. timeframes for completion of the evaluation, e.g. three (3) months;
c. details of Specified Personnel, their roles and responsibilities;

d. details of any conflict of interest issues raised by the required Services and how they are to be managed by the Panel member; and

e. other matters relevant to the particular required Services, including particular standards or requirements, or relevant additional contract provisions.

Links to the "Invitation to Quote" and "Statement of requirement" templates are provided under Step 3 of the Panel Guidelines on the TGA Intranet: http://intranet.tga/finance/procurement-panel-productevaluation.htm

The Invitation to Quote (including Statement of requirement) should be forwarded to the FLO for signature prior to mail-out.

Response/s from the Panel member/s should be reviewed by the Project Officer to ensure that it meets the requirements for the evaluation service. The Project Officer must document the decision to use a Panel member, including justification of why the Panel member was selected if more than one panel member submits a quote.

If the response from the Panel member/s does not meet the evaluation needs, Delegate approval to Direct Source services outside the Panel may be sought. In this case, a new "Permission to Seek Quote" form will need to be prepared.

4.3 Obtaining approval to enter a Contract

Once a suitable Panel member has been chosen, the Project Officer needs to obtain Delegate approval to enter into a Contract with the Panel member. Such approval must comply with Regulation 9 of the Financial Management and Accountability Regulations 1997, which requires that any proposals to spend public money are in accordance with Commonwealth policies and will make efficient and effective use of public money.

A link to the "Regulation 9 Minute" template is provided under Step 3 of the Panel Guidelines on the TGA Intranet: http://intranet.tga/finance/procurement-panel-productevaluation.htm

The Regulation 9 Minute (including a copy of the quote from the Panel member) should be forwarded to the FLO for checking and then to the Delegate for approval.

Note: any contracts that have payments in the next financial year must have REG 10 approval before the contract can be sent. Refer TGA Finance & Property Circular 3/2007 FMA REG 10 applications

4.4 Preparation and Clearance of the Contract

Once the approval to enter a contract has been obtained, an "Official Order/Contract for the Evaluation of Contract Services" should be drafted. The successful Panel member may need to be consulted before finalising the contract. A link to the "Official Order" template is provided under Step 4 of the Panel Guidelines on the TGA Intranet at: http://intranet.tga/finance/procurement-panel-productevaluation.htm

The draft contract should be forwarded to the FLO for checking prior to being sent to the Panel member for signature.

Once the contract has been signed by the external evaluator and returned to the Project Officer, the contract should be submitted to the Delegate to be countersigned. Copies of the signed documents should be provided to the Panel member and the FLO. The relevant evaluation data should also be sent to the Panel member.

The FLO will then arrange for a Purchase Order to be raised and forwarded electronically to the Delegate for approval. The FLO will then put a hard copy of the signed contract in the Procurements In-tray in the Finance area. The contract will be entered on the TGA's Contracts Register and will also be included as part of the Department's reporting in the Annual Report.

4.5 Monitoring of Evaluation Progress

6. Evaluate services provided and pay Panel member	a) Evaluate the services provided by completing an evaluation sheet. If you are satisfied with the services provided, arrange ~~to~~ for the TGA to pay the Panel member (after receipt of a correctly rendered invoice). b) Send a copy of the evaluation sheet to TGA's Authorised Officer to enable the TGA to keep a record of the quality of work, and extent to which standards and timelines were met. (this was not required by Julian for OCM work?; evaluation sheet was kept on the application file)	Template: Evaluation Sheet (Word,29kb)

4.6 Payment of Panel Members

4.2.1 How received
The OCM ~~Finance Officer~~ FLO receives written notification that an acceptable evaluation report has been received, and that payment action for fees can proceed.

The External Evaluation Report Payment Authorisation form (blue) is placed onto the drug product Coordination file by the Clinical Executive Assistants and the file forwarded to the OCM Finance Officer. Tax Invoices for clinical (not just clinical) evaluation reports are requested by the OCM Finance Officer upon receipt of the payment authorisation. (not sure about this process?)

4.2.2 What to do
External Evaluation fees (and all/any claim/s for payment >$5,000.00) must be registered in Workplace to document the audit trail from the purchase request through to its approval, the receipt of goods and services, the receipt of invoice(s) and the payment of funds.

Step 1
The OCM Finance Officer should retrieve the following documents from the External Evaluation Contracts Folder: copy of the External Evaluation contract; signed Purchase Order Request form; signed back page of the contract; and if received, the tax invoice; and the Details for the Direct Deposit of Payments form.

If all of the above documents have been received proceed directly to Step 2. If a tax invoice, GST registration details (new vendors), or Direct Credit Details are required, the OCM Finance Officer must contact the evaluator and request the information, preferably by telephone.

Step 2

The payment claim must be registered in Great Plains / Workplace, and a purchase requisition / purchase order raised. To raise a purchase requisition / purchase order, the evaluator must either:

(a) already be registered as a vendor in Great Plains or,

(b) have provided the relevant information to have a new Great Plains vendor ID number allocated.

It is now that the "Details for the Direct Deposit of Payments" form is required.

A Great Plains Vendor ID will be created for the evaluator upon presentation of a completed "Details for the Direct Deposit of Payments" form to the Purchasing Officer, Financial Services Group (FSG).

The Purchasing Officer in FSG is responsible for creating new vendors in Great Plains (from the details provided on the form), and then notifying the new vendor ID number to the OCM Finance Officer so that processing of the payment claim may continue.

Purchase Requisition (No.)

As indicated above, to raise a purchase order, the OCM Finance Officer must first raise an electronic purchase requisition* in Great Plains/Workplace.

*A "Great Plains Project Officer Responsibilities" training course must be undertaken before access is permitted by individuals to this module of Great Plains. Consequently, this SOP does not discuss the steps required to raise an actual purchase requisition in Great Plains. The procedure for doing so is covered in the training program.

When the purchase requisition (PR) is entered correctly into Workplace, a PR Number will be allocated by the system*. This number must be notified (by email) to the Purchasing Officer, Financial Services Group. The Purchasing Officer then uses the specific information provided in the PR to raise the purchase order (PO). When the PO is created, it is work flowed to the OCM Expenditure Delegate (OCM Branch Head) for on-line approval.

*IMPORTANT. The PR Number is used to identify and track the work-flow progress of the purchase order, it is therefore imperative that the person creating the purchase requisition writes the PR Number on the tax invoice, so it is not forgotten.

Step 3

Purchase Order Approval Process.

When the purchase order has been raised, it will automatically workflow onto the OCM Expenditure Delegate (Branch Head) for approval. For the Delegate to approve the purchase order (on-line), the OCM Finance Officer will need to avail him/her of all details relevant to the payment claim. This entails passing all hard copy documentation (payment authorisation, tax invoice, contract, Coordination file, etc) to the Delegate for consideration/perusal.

If the details in the PO are correct, the Delegate will approve it and a workflow notification will be sent to the FSG Purchasing Officer. The FSG Purchasing Officer will then raise a hard copy of the PO that will be printed form Workplace by the OCM Finance Officer for further action.

If the details in the PO are incorrect, (rare but happens), the Delegate will reject it and it will workflow back to the OCM Finance Officer (not the FSG Purchasing Officer) for corrective action. When corrective action is complete, the PR/PO must be resubmitted to the FSG Purchasing Officer and the approval process repeated.

Step 4

Goods Receipting the Purchase Order.
When the hard copy PO is received, the PO must be goods receipted in Workplace and the Goods Receipt Number written on the hard copy PO.
Note: The same access rule that applies to creating Purchase Requisitions, also applies to Goods Receipting. Training must be undertaken before access is permitted.

4.7 Subheading 3

Final Minuting & Sign-Off
The last step of the process entails drafting a Minute to FSG requesting the payment. The Minute must include the (a) Purchase Order Number, (b) Goods Receipt Number, (c) Payee Name, and the invoice/contract amount payable.
The OCM Finance Officer then enters details of the payment (including amount paid, date report received and date forwarded to FSG) onto the current FY "Contract Summary" Excel spreadsheet located in the S:\CO\TGA\OCM\COORD\Finance\Individual Ext Eval Spreadsheets folder.
The OCM Finance Officer signs off as the Requesting Officer, and then passes all documents to the Delegate for signature. The signed documents are then passed back to the OCM Finance Officer who photocopies the documents (1 x green copy for the corporate file, 1 x yellow copy for external evaluator payments file, plus two extra white copies of the PO only) before passing the original Minute, Purchase Order, and Tax Invoice to the Accounts Payable Officer, FSG. The remaining copies are filed as follows:
One copy of the signed purchase order is sent to the Purchasing Officer, FSG.
The second copy is placed (alphabetically) in the OCM "Purchase Orders Paid" Folder.
The Yellow copy is placed onto the External Evaluator Payments File.
The Green copy is placed onto the Coordination file.
The file should be marked to Eval Resubmit for one calendar month from the date of the Minute. This will permit time for the payment to be sent to the evaluator (the TGA prescribe that payments must be finalised and sent within 28 days).
When the file is returned from Resubmit, the OCM Finance Officer confirms (in Great Plains) that the payment has been sent to the evaluator, and then updates the relevant External Evaluator Spreadsheet: Action Complete.

4.1 Record-keeping

All relevant documentation leading up to the contract has been filed in accordance with Corporate Business Rule 2: Information Management and Record Keeping on file number XXXXXXXX.

A copy of the signed response and any drafts along with input from other areas should be filed with the original request on the following corporate file (currently located in Drawer 3 of Cabinet 7, located near the EAs):

Liaison – Community Groups – NPMB Liaison with Various Media Outlets

New pages should be folioed and the file index page on the front inside cover of the file should be completed.

The action officer adds the clearance date to the OCM Excel workflow spreadsheet.

5. References

[List any other relevant documents. For example: legislation, agreements, standards.]

6. Attachments