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Therapeutic Goods Administration

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DSEB

Operations	Drug Safety and Evaluation Branch
Procedure	DSEB SOP – 0884
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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 (ie. the Drug Safety and Evaluation Branch (DSEB) Finance Officer, DSEB Section Heads of Clinical, Toxicology, and PCE, Clinical Executive Assistants and the (applicable) DSEB Expenditure Delegate).

2. RESPONSIBILITY

The maintenance of the SOP is the responsibility of the DSEB Finance Officer.

3. INTRODUCTION/BACKGROUND

This SOP provides details of the steps required when approaching the market for external evaluation work.

The TGA recently established an expert panel to provide external evaluation services to the TGA. The Panel became operational on 1 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.

The Panel is not a totally exclusive arrangement; however 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 branch head approval and be based on the appropriate processes outlined in the Chief Executive Instructions (CEI's) Chief Executive Instructions which can be found at:

<http://intranet.health.gov.au/intranet/wcms/publishing.nsf/Content/chief-executive-instructions-1-lp>

4. PROCEDURE/POLICY

4.1

Step 1

Authorised Section Heads will review the Panels membership and identify suitable Panel members that could undertake the Evaluation Services required. Once a suitable Panel member has been identified a *permission to seek quote* form must be completed and sent to the Finance Officer for Branch Head for approval.

Step 2

Once approval has been given by the Branch Head the panel member may be sent an *invitation to quote* form to confirm availability, ascertain any conflicts of interest and provide a quote for the evaluation services. The response from the Panel member needs to be reviewed by the authorised officer (eg Section Head or acting Section Head) to ensure that it meets the requirements for the evaluation service. The authorised officer must document the decision to use the Panel member with justification of why the Panel member was selected (eg the consultant has specialist knowledge and skills that are not available within the Branch). The invitation to quote, once completed, should be sent to the Clinical EA's who will copy, file and submit to the Finance Officer.

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 3

The authorised officer must then complete a Regulation 9 minute (including the quote from the Panel member) and forward to the Clinical EA's who will take a copy and send to the DSEB Finance Officer. The Finance Officer will check the documentation for completeness before sending to the Financial Delegate (Branch Head) for approval to enter into a contract.

Step 4

Once the Regulation 9 minute has been approved by the Branch Head it should be forwarded to the Clinical Executive Assistants for the contract to be drafted. The completed contract is then sent to the Finance Officer to check and then onto the Financial Delegate (Branch Head) for signature. The signed contract is then sent back to the Clinical Executive Assistants to be sent to the external evaluator for signature.

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

Step 5

Once a signed copy of the contract (signed by the external evaluator) is received, by the Clinical EA's who attach a Purchase Order request form and forward to the Finance Officer for Branch Head approval. Once the Branch Head has approved the documents are sent back to the Clinical EA's for filing and sending of data to the Evaluator.

The Clinical EA's will then forward to the Finance Officer a signed purchase order request form to be recorded on the Contracts Register and have a Purchase Requisition / Purchase Order raised in Workplace. The Purchase Requisition / Purchase Order will be sent electronically to the Financial Delate for approval.

Once the Purchase Requisition / Purchase Order has been approved it can be printed (from Workplace) and along with the contract should be stored in the External Evaluator Contracts Register Folder.

4.2 Payments to External Evaluators

4.2.1 How received

The DSEB Finance Officer 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 DSEB Finance Officer. Tax Invoices for clinical evaluation reports are requested by the DSEB Finance Officer upon receipt of the payment authorisation.

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 DSEB 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 DSEB 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 DSEB Finance Officer so that processing of the payment claim may continue.

Purchase Requisition (No.)

As indicated above, to raise a purchase order, the DSEB 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 DSEB Expenditure Delegate (DSEB 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 DSEB Expenditure Delegate (Branch Head) for approval. For the Delegate to approve the purchase order (on-line), the DSEB 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 from Workplace by the DSEB 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 DSEB 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.

Step 5

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 DSEB 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\DSEB\COORD\Finance\Individual Ext Eval Spreadsheets folder.

The DSEB 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 DSEB 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 DSEB “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 DSEB 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.

5. REFERENCES

PRIMARY CONTACTS

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6. ATTACHMENTS

Nil

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