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Therapeutic Goods Administration

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DSEB

Operations	Drug Safety and Evaluation Branch
Procedure	DSEB SOP – 0915
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1. AIM/PURPOSE/SCOPE

This SOP details the specific steps required to prepare a claim for payment of external evaluation fees. The SOP applies staff undertaking this task (ie. the Drug Safety and Evaluation Branch (DSEB) Finance Officer, 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 to process payment of fees for the satisfactory completion of an external evaluation report. It includes relevant rules and references concerning the Goods and Services Tax (GST) requirements of contracted evaluators, and applicable references in the Financial Management Act.

The timely payment of supplier invoices is a key expectation of all government agencies. Agencies are expected to achieve better than 95% payment of claims by the due date (usually 28 days after receipt of both goods/services and a correctly rendered tax-invoice).

The Financial Services Group has an invoice processing standard of 48 hours from the receipt of a correctly prepared claim for payment (coded, approved, invoice attached etc.) It is the responsibility of the DSEB Finance Officer, and the (applicable) DSEB Finance Expenditure Delegate to prepare the claim for payment. This SOP details the specific steps and rules required to prepare a payment claim for external evaluation report fees, upon receipt of a satisfactory external evaluation report.

4. PROCEDURE/POLICY

4.1 Staff Responsibilities

4.1.1 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. Although the steps for processing evaluation fees are common to within the Branch, the three work areas (of each evaluation section) have minor variations on how they authorise, and then notify that payment actions are required.

Pharmaceutical Chemistry Evaluation Section

The Part 2 / Module 3 External Evaluation Report Payment Authorisation form (white) is received with a copy of the tax invoice from the PCES clerical staff via internal mail.

Drug Toxicology Evaluation Section

The Part 3 / Module 4 External Evaluation Report Payment Authorisation form (white) may be received with or without a tax invoice from the DTES clerical staff by hand, or via internal mail. If a tax invoice is not received, it is the responsibility of the DSEB Finance Officer to arrange for one to be sent by the evaluator.

Clinical Evaluation Section

The Part 4 / Module 5 External Evaluation Report Payment Authorisation form (blue) is placed onto the drug product Coordination file by an Application Support Team staff member 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.

4.1.2 What to do

External Evaluation fees (*and all/any claim/s for payment > \$2,000.00*) must be registered in SAP Fi 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

Retrieve the following documents from the External Evaluation Contracts Folder:

The DSEB Finance Officer 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. If the evaluator is unclear of GST requirements, the DSEB Finance Officer may advise him of the following:

Australian Business Number (ABN)

- Before an organisation can register for the GST it must apply for an ABN. Every Australian business is eligible to apply for an ABN. The ABN replaces the Australian Company Number (ACN) for active organisations. It does not replace the Tax File Number (TFN).
- Organisations need to register for an ABN in order to meet the requirements of the tax system. An organisation that does not obtain an ABN will not be able to register for the GST.
- Organisations will have to enter the ABN for GST on every GST Tax Invoice that is issued. A Tax Invoice is NOT valid unless it shows the business' ABN.

- An organisation may have an ABN and not be registered for GST if annual turnover is less than \$50,000.00 or \$100,000.00 for non-profit organisations.
- The ABN is intended as a unique identifying number that must be quoted on all business dealings and with the Australian government, especially the Australian Tax Office. Tax file numbers are still used by individuals for tax returns.
- The TGA's ABN is 40 939 406 804.

Withholding Tax

- The withholding tax rules state that any entity that sends out an invoice for payment without an ABN, the recipient will be required to withhold income tax from the payment at the highest marginal rate of 48.5%, plus Medicare levy from 1 July 2000 (unless the supplier is exempt). If an invoice is received without an ABN, the supplier should be contacted to obtain the ABN, rather than automatically deducting withholding tax. Withholding tax should only be deducted if the supplier advises that no ABN exists for the organisation.
- Suppliers have 28 days from the invoice effective date to provide the TGA with an ABN.

Exceptions to Withholding Tax Rules

- If an entity is an individual and the payment is wholly of a private or domestic nature and the payment does not exceed \$50.00.
- The entity is an enterprise and has made a written, signed statement that the supply is private or domestic in nature, or relates to a hobby.
- The whole of the payment is exempt income of the supplier (eg the supplier is a charity organisation etc.).
- There is already a requirement to withhold the payment because the entity is an investment body paying an amount for which no TFN has been quoted.
- Where an entity is claiming exemption from withholding tax as the payment is exempt income the department needs to ascertain 100% that an entity is exempt from the withholding tax rules. To confirm the entity's exempt income status, written evidence of the exemption should be obtained from the supplier and retained on file.

Copies of relevant forms eg **Details for the Direct Deposit of Payments** form can be faxed or e-mailed directly to the evaluator if required. A (return) faxed tax invoice and/or Details for the Direct Deposit of Payments form are acceptable to progress processing of the payment claim but the actual payment will not be finalised until the originals are received.

Upon receipt of all relevant invoices and forms detailed in Step 1, processing of the payment claim may proceed.

Step 2

SAP Vendor ID

The payment claim must be registered in SAP Fi, 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 SAP or, (b) have provided the relevant information to have a new SAP vendor ID number allocated.

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

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A SAP 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 SAP Fi (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 SAP-ESS.

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

When the purchase requisition (PR) is entered correctly into SAP-ESS, 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 (selected by the DSEB Finance Officer when raising the PR) 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.

NB. Under the Segregation of Duties rule, the person raising the PR cannot also raise the PO. Full details available at <http://intranet/finnet/ceis/cei1-2.htm#Segregation>. Specific clauses detailed over page.

Procedural Rule 1.1.2

Managing Risk & Internal Accountability

Delegations & Authorisations

Clause 23

The segregation of duties involves the dividing of responsibility for related transactions among two or more officials. This is to ensure that no single official is placed in such a position that the officer can perpetrate and conceal errors or irregularities while performing their normal duties.

Clause 24

Functions that typically should be segregated are indicated in the following examples:

- for expenditure in excess of \$5,000, an expenditure approver is not to certify a claim relating to the expenditure they have approved
- Certifying Officers should not:
 - certify claims which include transactions relating to their personal use of a AGCC;

- certify reimbursement of their own cash advances.
- officers controlling assets, or officers who have access to asset records, should not be:
 - stocktaking officers; or
 - an expenditure approver of asset acquisitions;
 - Collectors of Public Moneys should not have duties associated with the debtors ledger and the issuing of debit invoices.

Step 3

Purchase Order Approval Process.

When the purchase order has been raised, it will automatically workflow onto the DSEB Expenditure Delegate 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 print a hard copy of the PO and pass to 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 SAP Fi (Code MIGO refers) and the Goods Receipt Number written on the hard copy PO.

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. Delegate signatures are required on both the Minute to FSG, and on the hard copy Purchase Order.

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 work group 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 WGF.

The Green copy is placed onto the relevant Corporate file (ie. Chem/Biol, Tox Cat 1, or Coordination). 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 SAP Fi) that the payment has been sent to the evaluator, then updates the relevant evaluator payment field in DART and/or Premier.

Action Complete.

PRIMARY CONTACTS

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5. REFERENCES

Nil

6. ATTACHMENTS

Nil

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