

## PART I

**ALL PORTFOLIOS ARE REQUESTED TO COMPLETE PART I.**

**If you cannot answer a question, please indicate whether the question is NOT APPLICABLE or if INFORMATION IS NOT AVAILABLE.**

**Section 1: Contact details**

1.1 Portfolio

1.2 Reporting and financial arrangements are governed by:  
(Please indicate with a 'X' whether one or more of the following Acts apply)

*Financial Management and Accountability Act 1997*

YES	NO
X	

*Commonwealth Authorities and Companies Act 1997*

YES	NO
	X

Other

1.3 Contact Officer

Position

Phone

Fax

Email

Address

**PART II**

**If your portfolio operated any cost recovery arrangements in 1999-2000, please complete this part. Please fill out a separate form for each sub-unit, cost recovery program or activity, or output or outcome for which you are reporting. Similar cost recovery arrangements may be reported in groups.**

**PART II(a)**

Name of sub-unit, agency, program or activity, output or outcome THERAPEUTIC GOODS ADMINISTRATION

**Section 4: Cost recovery arrangements in 1999-2000**

Descriptive material	
4.1	Nature of cost recovery arrangement (eg. licence fee, service charge, hypothecated excise tax or levy etc) <span style="border: 1px solid black; padding: 2px;">Range of fees and charges - application, evaluation, assessment and inspection fees. Annual charges.</span>
4.2	Basic description of arrangements: (Please attach any relevant documents.) <span style="border: 1px solid black; padding: 2px;">Special Account established under Therapeutic Goods Act (1989)</span>
4.3	Who pays the cost recovery charges? <span style="border: 1px solid black; padding: 2px;">Pharmaceutical, Medical Device and Complementary Medicines sponsors and manufacturers</span>
4.4	Who benefits from the program or activity, output or outcome? <span style="border: 1px solid black; padding: 2px;">Therapeutic Industries and the Public</span>
4.5	Do you attempt to measure these benefits? If YES, how? <span style="border: 1px solid black; padding: 2px;">Yes. Consultative forums with industry and consumers. Monitoring of processing times.</span>
4.6	Are there alternate providers or substitutes for this program or activity, output or outcome? (Please describe) <span style="border: 1px solid black; padding: 2px;">No</span>
4.7	When was this cost recovery arrangement introduced? <span style="border: 1px solid black; padding: 2px;">1990</span>

**PART II(b)**

Name of sub-unit, agency, program or activity, output or outcome THERAPEUTIC GOODS ADMINISTRATION

**Program or activity, output or outcome cost recovery arrangements in 1999-2000 (continued)**  
**(Please use \$'000)**

<b>Program or activity, output or outcome revenues</b>			
4.8	Cost recovery revenue paid to CRF earmarked for appropriation to same portfolio	\$	11.12
4.9	Cost recovery revenue paid to CRF earmarked for appropriation to a third party	\$	0
4.10	Cost recovery revenue paid to CRF and not earmarked for particular appropriation	\$	0
4.11	Cost recovery revenue paid to CRF (subtotal)	\$	11.12
4.12	Cost recovery not paid into CRF	\$	30.314
4.13	Total cost recovery revenue	\$	41.434
4.14	Appropriations not related to cost recovery	\$	0
4.15	Other sources (please specify)	\$	2.334
<b>4.16</b>	<b>Total program or activity, output or outcome revenues</b>	\$	<b>43.768</b>
<b>Program or activity, output or outcome expenses</b>			
4.17	Direct expenses	\$	41.314
4.18	Indirect expenses (including corporate overheads)	\$	7.704
4.19	Third party expenses (a)	\$	0
4.20	<b>Total program or activity, output or outcome expenses</b>	\$	<b>49.018</b>
<b>Administration costs</b>			
4.21	What costs are associated with administering the cost recovery arrangements?	\$	Not avail.

CRF Consolidated Revenue Fund. Direct costs are those directly related to a particular program. Indirect costs include indirect agency overheads and general running costs. (a) Include third party costs where third parties are involved in a program or activity a their costs are being recovered as part of the cost recovery arrangements.

**PART II(c)**

Name of sub-unit, agency, program or activity, output or outcome THERAPEUTIC GOODS ADMINISTRATION

**Section 5: Institutional arrangements**

5.1 What was the rationale for introducing these cost recovery arrangements? (Please attach sources, eg. legislative objects clauses, press releases, second reading speeches.) The decision to recover TGA's costs of regulating medicines and devices was a Government decision consistent with its approach to user pays.

5.2 What was the legal basis for establishing these cost recovery arrangements: (Please name and attach relevant documents.)

Legislation (eg. s.31 of the Financial Management and Accountability Act, tax or levy acts)	Therapeutic Goods Charges Act and Regulations
Subordinate legislation (eg. regulations, standards)	Therapeutic Goods Act and Regulations - schedule 9
Co-regulation or quasi-regulation	
Commonwealth/State/Territory agreement	
Voluntary arrangements (eg. codes of practice)	
Other	

5.3 Who was consulted about introducing these cost recovery arrangements? (Please name relevant bodies and describe the consultation arrangements.)

Commonwealth government (DOFA etc)	DoFA
Other governments (state, territory, local)	State and Territory Governments
Industry	ASMI, CHC, APMA, MIAA
Consumers	Consumer Health Forum
Other	

5.4 What guidelines were consulted when establishing these cost recovery arrangements? (Please attach source of information, guidelines etc.)	Unknown										
5.5 Which agency is responsible for the following activities? (Please name relevant agency)	<table border="1"> <tr> <td data-bbox="416 612 568 639">Policy setting</td> <td data-bbox="904 612 1794 639">Therapeutic Goods Administration</td> </tr> <tr> <td data-bbox="416 644 557 671">Price setting</td> <td data-bbox="904 644 1794 671">Therapeutic Goods Administration</td> </tr> <tr> <td data-bbox="416 676 580 703">Administration</td> <td data-bbox="904 676 1794 703">Therapeutic Goods Administration</td> </tr> <tr> <td data-bbox="416 708 633 735">Revenue collection</td> <td data-bbox="904 708 1794 735">Therapeutic Goods Administration</td> </tr> </table>	Policy setting	Therapeutic Goods Administration	Price setting	Therapeutic Goods Administration	Administration	Therapeutic Goods Administration	Revenue collection	Therapeutic Goods Administration		
Policy setting	Therapeutic Goods Administration										
Price setting	Therapeutic Goods Administration										
Administration	Therapeutic Goods Administration										
Revenue collection	Therapeutic Goods Administration										
5.6 Is there any ongoing consultation about these cost recovery arrangements? With whom? (Please name relevant bodies.)	<table border="1"> <tr> <td data-bbox="416 807 875 834">Commonwealth government (DOFA etc)</td> <td data-bbox="904 807 1794 834">No</td> </tr> <tr> <td data-bbox="416 839 882 866">Other governments (state, territory, local)</td> <td data-bbox="904 839 1794 866">No</td> </tr> <tr> <td data-bbox="416 871 510 898">Industry</td> <td data-bbox="904 871 1794 898">Yes. ASMI, CHC, APMA, MIAA</td> </tr> <tr> <td data-bbox="416 903 546 930">Consumers</td> <td data-bbox="904 903 1794 930">Yes. Consumer Health Forum</td> </tr> <tr> <td data-bbox="416 935 483 962">Other</td> <td data-bbox="904 935 1794 962"></td> </tr> </table>	Commonwealth government (DOFA etc)	No	Other governments (state, territory, local)	No	Industry	Yes. ASMI, CHC, APMA, MIAA	Consumers	Yes. Consumer Health Forum	Other	
Commonwealth government (DOFA etc)	No										
Other governments (state, territory, local)	No										
Industry	Yes. ASMI, CHC, APMA, MIAA										
Consumers	Yes. Consumer Health Forum										
Other											
5.7 Please describe these consultation arrangements.	General twice yearly meetings. Other meetings held as required.										
5.8 Have the cost recovery arrangements been formally reviewed? What was the outcome? (Please attach copy of review)	No										

**PART II(d)**

Name of sub-unit, agency, program or activity, output or outcome

THERAPEUTIC GOODS ADMINISTRATION

**Section 6: Price setting arrangements**

6.1 How are these cost recovery charges determined? (Please attach any relevant documents)

- |  |  |
|--|--|
| (i) How are charges set? (eg. by formula in legislation or based on 'market prices')   | By cost of program then set in legislation.  |
| (ii) Are charges directly related to the costs of particular activities, outcomes or outputs, or charged on some other basis? (eg. levies on users' turnover, profits or assets) | Yes - charges and fees are required to recover the cost of all activities that come within the scope of the Therapeutic Goods Act 1989. This includes both pre and post market activities. |

6.2 If charges are directly related to the costs of particular activities, outputs or outcomes:

- |  |   |
|--|---|
| (i) What costs do charges aim to recover? (eg. only direct costs or indirect costs such as overheads)                                  | All - refer 6.1 (ii)  |
| (ii) What proportion of these costs do charges aim to recover? (%)   | 100%  |
| (iii) Does the charging regime require assets to be valued? (eg. to allow the calculation of user cost of capital or return on assets) | Yes   |
| (iv) If 'YES' to (iii), on what basis are assets valued? (eg. historic, replacement, deprival or replacement cost)                     | Deprival  |
| (v) Do charges include a user cost of capital?   | No  |
| (vi) If 'YES' to (iv), how is it calculated?   | N/A   |
| (vii) Do charges include return on assets? (eg. profit)  | No  |
| (viii) If 'YES' to (vii), on what basis?   | N/A   |
| (ix) Do charges discriminate between types of users?   | Yes   |
| (x) If 'YES' to (ix), on what basis?   | Level of risk of products which is related to level of assessment |

(xi) Do charges allow for access and equity considerations (eg. waivers, discounts)?	Yes
(xii) If 'YES' to (xi), on what basis?	Low volume low value sales. Where similar data has already been evaluated. etc
(xiii) Other (Please describe other significant features)	
6.3 How are indirect costs allocated for cost recovery arrangements? (eg. activity based costing, according to share of direct costs or other rule.)	Activity Based Costing
6.4 Are there any price controls on these charges?	Yes. Fees & charges reflect costs & are negotiated with industry representatives, who have a strong influence in relation to cost / resource trade-off.
6.5 How often is the level of charges changed?	Approximately annually
6.6 What happens if revenue recovered is greater than costs incurred?	Agency retains extra dollars against future revenue shortfalls. Excess can also be used to limit future price increases.

**End of Part II. Thank you for your cooperation. Please return the questionnaire and attachments to the Commission (see front sheet for instructions)**

**This section asks about your portfolio’s total revenues, charges and expenses (but not including the revenues, charges and expenses of agencies that will be completing separate responses to this questionnaire - see Attachment A). All portfolios should complete this section, whether or not you consider you undertake cost recovery.**

**Section 2: Portfolio revenues, charges and expenses**

(Please indicate with a 'X' which response applies)

2.1 Has your portfolio charged any cost recovery fees, levies or other charges in the last five financial years?

YES	NO
X	

*Relevant charges include any fees, levies, taxes (including some customs and excise duties earmarked for specific purposes) or other charges which arise from the services, programs or business activities of your portfolio, and which are collected by your portfolio, or by another agency on your behalf. For example, application fees, processing charges, consultancy fees, publication sales, special industry duties, excises or levies other than general taxation.*

2.2 Were any of the appropriations allocated to your portfolio in the last five financial years linked (hypothecated) to revenue collected from fees, levies or charges (for example, levies paid to the Consolidated Revenue Fund but earmarked for allocation to your portfolio)? (Whether the revenue was collected by your portfolio or by another agency on your behalf).

YES	NO
X	

2.3 Has your portfolio considered introducing any cost recovery arrangements in the past that were not implemented?  
(Please attach any relevant reviews, analysis or other information.)

YES	NO
X	

2.4 Is your portfolio considering introducing any cost recovery arrangements in the future?  
(Please attach any relevant reviews, analysis or other information.)

YES	NO
X	

**If you answered NO to questions 2.1 and 2.2, you need not answer any further questions. Thank you for your cooperation. Please return the questionnaire to the Commission (see front sheet for instructions).**

**If you answered YES to EITHER question 2.1 OR question 2.2 OR both, please complete section 3 below, and Part II on the following worksheet.**

**Section 3: Portfolio revenues and expenses**

**Please do not include the revenues and expenses in this section of agencies that will be completing separate responses to this questionnaire (see Attachment A).**

3.1 Does your portfolio classify revenues and expenses as agency and administered?

*Agency revenues and expenses are those controlled by the department/agency (for example, employee and administrative expenses). Administered revenues and expenses are those which are controlled by Government and managed or oversighted by the department/agency on behalf of the Government (for example, social security payments).*

YES	NO
X	

**If your portfolio classifies revenues and expenses as 'agency' and 'administered' then please fill in both tables below. If your portfolio does not classify revenues and expenses as 'agency' and 'administered' then please put all revenues and expenses in the 'agency' table below.**

<b>AGENCY portfolio revenues and expenses (Please use \$'000)</b>					
	1995-96	1996-97	1997-98	1998-99	1999-2000
<b>Agency revenue from cost recovery (a)</b>					
3.2 Cost recovery revenue retained by your portfolio	17.464	19.4	24.495	26.808	30.314
3.3 Cost recovery revenue paid to CRF and appropriated to your portfolio (or another agency for a specific purpose (ie. annotated, hypothecated or earmarked revenues)	5.814	7.419	8.255	10.632	11.12
3.4 Cost recovery revenue paid to CRF and not specifically appropriated to your portfolio (or another agency)	0	0	0	0	0
<b>3.5 Total agency revenue from cost recovery</b>	<b>23.278</b>	<b>26.819</b>	<b>32.75</b>	<b>37.44</b>	<b>41.434</b>
<b>Agency revenue from other sources</b>					
3.6 Other appropriations	21.757	16.076	9.844	0	0
3.7 Other sources (eg. asset sales, dividends, interest, funding from other government agencies)	1.716	1.556	2.759	1.466	2.334
<b>3.8 Total agency revenue from other sources</b>	<b>23.473</b>	<b>17.632</b>	<b>12.603</b>	<b>1.466</b>	<b>2.334</b>
<b>3.9 Total portfolio agency revenue</b>	<b>46.751</b>	<b>44.451</b>	<b>45.353</b>	<b>38.906</b>	<b>43.768</b>
<b>3.10 Total agency expenses</b>	<b>39.647</b>	<b>40.733</b>	<b>41.742</b>	<b>49.114</b>	<b>49.018</b>
<b>CRF Consolidated Revenue Fund</b>					
(a) Include all revenue from fees, levies, excises and other charges which arise from the services or activities of your portfolio, and which is paid to your portfolio, to another agency or to the Consolidated Revenue Fund.					

**ADMINISTERED portfolio revenues and expenses (Please use \$'000)**

	1995-96	1996-97	1997-98	1998-99	1999-2000
<b>Administered revenue from cost recovery (a)</b>					
3.11 Cost recovery revenue retained by your portfolio					
3.12 Cost recovery revenue paid to CRF and appropriated to your portfolio (or another agency for a specific purpose (ie. annotated,	5.814	7.419	8.255	10.632	11.12
3.13 Cost recovery revenue paid to CRF and not specifically appropriated to your portfolio (or another agency)					
<b>3.14 Total administered revenue from cost recovery</b>	<b>5.814</b>	<b>7.419</b>	<b>8.255</b>	<b>10.632</b>	<b>11.12</b>
<b>Administered revenue from other sources</b>					
3.15 Other appropriations					
3.16 Other sources (eg. asset sales, dividends, interest, funding from other government agencies)					
<b>3.17 Total administered revenue from other sources</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>
<b>3.18 Total portfolio administered revenue</b>	<b>5.814</b>	<b>7.419</b>	<b>8.255</b>	<b>10.632</b>	<b>11.12</b>
<b>3.19 Total administered expenses</b>	<b>5.814</b>	<b>7.419</b>	<b>8.255</b>	<b>10.632</b>	<b>11.12</b>

**CRF Consolidated Revenue Fund**

(a) Include all revenue from fees, levies, excises and other charges which arise from the services or activities of your portfolio, and which is paid to your portfolio, to another agency or to the Consolidated Revenue Fund.

**End of Part I. Please complete Part II, which is on a separate worksheet.**