



Australian Government

Department of Health

Therapeutic Goods Administration

Cost recovery implementation statement

Blood, blood components and biologicals
(human cell and tissue therapies)

Version 1.0, July 2015

TGA Health Safety
Regulation

Historical document

About the Therapeutic Goods Administration (TGA)

- The Therapeutic Goods Administration (TGA) is part of the Australian Government Department of Health, and is responsible for regulating medicines and medical devices.
- The TGA administers the *Therapeutic Goods Act 1989* (the Act), applying a risk management approach designed to ensure therapeutic goods supplied in Australia meet acceptable standards of quality, safety and efficacy (performance), when necessary.
- The work of the TGA is based on applying scientific and clinical expertise to decision-making, to ensure that the benefits to consumers outweigh any risks associated with the use of medicines and medical devices.
- The TGA relies on the public, healthcare professionals and industry to report problems with medicines or medical devices. TGA investigates reports received by it to determine any necessary regulatory action.
- To report a problem with a medicine or medical device, please see the information on the TGA website <<https://www.tga.gov.au>>.

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Introduction

Purpose of the Cost Recovery Implementation Statement (CRIS)

This CRIS provides information on how the Therapeutic Goods Administration (TGA) implements cost recovery of activities associated with the inclusion of biologicals (human cell and tissue therapies) onto the Australian Register of Therapeutic Goods (ARTG) and the regulation of blood, blood components and biologicals through inspection and licensing of manufacturers. It covers the ongoing monitoring and licensing of blood and biologicals. It also reports financial and non-financial performance information and contains financial forecasts for 2015-16. The TGA will maintain the CRIS until the activity or cost recovery for the activity has been discontinued.

Description of the activity

The TGA forms a part of the Department of Health and is responsible for evaluating the safety, quality and efficacy of medicines, medical devices and biologicals available for supply in, or export from Australia.

The TGA approves and regulates products based on an assessment of risks against benefits. All therapeutic goods carry potential risks, some of which are minor, some potentially serious. The TGA applies scientific and clinical expertise to its decision-making to ensure that the benefits of a product outweigh any risk. The level of TGA regulatory control increases with the level of risk the medicine or device can pose. The risk-benefit approach assures consumers that the products they take are safe for their intended use, while still providing access to products that are essential to their health needs.

Most products for which therapeutic claims are made must be assessed and entered on the ARTG before they can be marketed in Australia. The ARTG keeps a record of products that are approved for marketing, the ingredients contained in each product, the therapeutic claims made for medicines and biologicals, and the intended use of medical devices. Not all human cell and tissue therapies available in Australia are regulated by the TGA.

The TGA also regulates blood components. These products are not generally included on the ARTG; they are regulated through inspection of manufacturers based on an assessment of their ability to comply with relevant manufacturing standards.

Outputs and business processes of the activity

Blood, blood components and plasma derivatives are regulated under the *Therapeutic Goods Act 1989* (the Act). Plasma derivatives are prescription medicines subject to full regulation, including compliance with set standards, licensing of manufacture and inclusion in the ARTG after review of manufacturing, pre-clinical and clinical data. Under the Act 'blood' means whole blood extracted from human donors and 'blood components' means therapeutic components that have been manufactured from blood (including red cells, white cells, progenitor cells, platelets and plasma). 'Blood components' do not include products derived through fractionation of plasma.

Some blood and blood components are exempt from regulation by TGA including blood and blood components that are:

- collected by a medical practitioner in the course of medical treatment and for the purposes of diagnosis or testing for a medical condition
- manufactured by a medical practitioner for therapeutic application to a particular patient under the practitioner's care
- manufactured by a blood collection centre for a medical practitioner for therapeutic application to a particular patient under the practitioner's care

Manufacturers of blood components are required to demonstrate compliance with manufacturing principles equivalent to the Australian Code of Good Manufacturing for human blood and blood components, human tissues and human cellular therapy products (2013) and to submit a technical master file which demonstrates compliance to relevant standards

Biologicals include human tissue and cell therapy products. Tissue therapy products involve the use of tissues as therapeutic goods, while cell therapy products involve the use of isolated living cells either as therapeutic goods or as replacements for cells that are defective or deficient in particular disorders.

Some examples of tissue therapies currently being used are:

- Skin replacement after severe burns
- Transplantation of heart, kidney, liver, lung or pancreas
- Bone, tendons and ligaments to repair injuries
- Heart valves to replace defective heart valves
- Corneas to restore eyesight

Some examples of cell therapies currently being used, or currently under development are:

- Chondrocytes used for cartilage regeneration
- Isolated pancreatic islet cells for the treatment of diabetes
- Mesenchymal progenitor cells for the treatment of musculoskeletal defects and in a range of other clinical applications such as cardiovascular repair

Inclusion on the ARTG

The regulatory activities for biologicals involve the following registration and approval activities:

- Management of applications for inclusion in the ARTG
- Sponsors of Class 1 biologicals are required to attest compliance with relevant mandatory standards
- Class 2, 3 and 4 biologicals undergo pre-market evaluation prior to ARTG inclusion
- Highly manipulated Class 3 and 4 biologicals are subject to the highest levels of pre-market evaluation
- Manufacturers of Class 2, 3 and 4 biologicals are required to demonstrate compliance with manufacturing principles equivalent to the Australian Code of Good Manufacturing for

human blood and blood components, human tissues and human cellular therapy products (2013).

Compliance monitoring and enforcement

- Post-market controls include ongoing manufacturing inspections, managing adverse event reporting, investigations and recalls.
- The TGA also provides information and support to the regulated industry and consumers and is responsible for the maintenance of the regulatory framework.

Policy and statutory authority to cost recover

The Australian Government's overarching cost recovery policy is that, where appropriate, non-government recipients of specific government activities should be charged some or all of the costs of those activities. The cost recovery policy promotes consistent, transparent and accountable charging for government activities and supports the proper use of public resources¹.

Cost recovery involves government entities charging individuals or non-government organisations some or all of the efficient costs of a specific government activity. This may include goods, services or regulation, or a combination of these. The [Australian Government Cost Recovery Guidelines](#) (CRGs) set out the overarching framework under which government entities design, implement and review cost recovered activities.

In the 1997-98 Budget, Budget Paper No.2, Part II: Revenue Measures it was stated that the TGA would fully recover all costs from industry from 1998-99. The TGA recovers the full costs of its regulatory activities through fees and charges imposed on sponsors and manufacturers of blood, blood components and biologicals (human cell and tissue therapies) therapeutic products.

The *Therapeutic Goods Act 1989* (the Act) provides a legal authority for the TGA to charge for its regulatory activities within the scope of the Act. Applicable fees and charges are prescribed in regulations made under the Act and the *Therapeutic Goods (Charges) Act 1989* (the Charges Act).

Cost recovery model

Design of cost recovery charges

Fees and charges

The characteristics of a government activity determine the type of cost recovery charge used (<http://www.finance.gov.au/resource-management/cost-recover/>). There are two types of cost recovery charges:

- **Cost recovery fees:** fees charged when a good, service or regulation (in certain circumstances) is provided directly to a specific individual or organisation

¹ Under the Public Governance, Performance and Accountability Act 2013 (PGPA Act), revenue from cost recovery is a public resource for both corporate and non-corporate Commonwealth entities. Section 8 of the PGPA Act defines 'proper' use or management of public resources as efficient, effective, economical and ethical.

- **Cost recovery levies:** charges imposed when a good, service or regulation is provided to a group of individuals or organisations (e.g. an industry sector) rather than to a specific individual or organisation. A cost recovery levy is a tax and is imposed via a separate taxation Act. It differs from general taxation as it is 'earmarked' to fund activities provided to the group that pays the levy.

Fees are used to recover the cost of the evaluation required before a product can be included on the ARTG.

Fees are also charged to cover the cost of manufacturing compliance inspections except where the costs have been included in annual licence charges, e. g. for primary blood site audits.

Annual charges are payable by manufacturers that produce human tissues (biologicals), and for products registered on the ARTG.

Annual charges are used to recover the cost of activities, usually post market, where

- They cannot reasonably be assigned to individual manufacturers and/or sponsors
- They maintain the integrity of the regulated industry to the benefit of all manufacturers and/or sponsors
- Assigning costs to individual manufacturers and/or sponsors would deter manufacturers and/or sponsors from disclosing important public health information, such as reporting adverse events

For the 2015-16 financial year, fees and charges were indexed by 2.12 percent in conjunction with other charges as outlined in this CRIS.

In past years, TGA fees and charges increases have been based on an indexation factor combining the Wage Price Index (50 percent) and the Consumer Price Index (50 percent). If we applied this formula to 2015-16 the increase would be 2.5 percent. However, based on an assessment of our budget outlook for the 2015-16 financial year of known direct cost increases an increase in fees and charges of 2.12 percent is required.

In addition to cost recovery, appropriation funding has been received on an annual basis since 2012-13 to fund activities outside of this CRIS. For example, the function of administering compliance frameworks for controlled drugs was transferred to the TGA group of the Department of Health in August 2014 and continues to be funded from the departmental appropriation. As a result, TGA now has multiple funding sources for its activities which all contribute to Outcome 7 'Health infrastructure, regulation, safety and quality'.

Annual charges exemption scheme (ACE)

The ACE scheme replaces the low value turnover (LVT) scheme.

A sponsor of an ARTG entry that has not commenced generating turnover will be exempt from the requirement to pay an annual charge in respect of that entry, up until the first year that turnover occurs. The annual charge would then apply to the entry until it was removed from the ARTG. The rationale for this option is that, as these products have not yet generated turnover, they require minimal post-market surveillance and monitoring by the TGA. For example, if a product has not commenced sales in Australia, the TGA is not required to undertake pharmacovigilance activities related to domestic recalls, product testing or adverse drug reactions for the vast majority of these products; however must retain the capacity to do so.

We recognise that pharmacovigilance requirements apply after a product is first supplied (which could feasibly be earlier than when the product starts generating turnover), our assessment is that most products would generate turnover at the same time as they commence

supply. Accordingly, no significant issue would arise from a cost recovery perspective as there are minimal administrative costs in relation to maintaining the entry on the ARTG until the entry is generating turnover.

Consultation was conducted on the previous LVT scheme and proposed alternative models. Although several submissions to the public consultation did not explicitly support a single model among those proposed for discussion, most submissions supported amendments to the LVT scheme and/or a scheme wherein exemptions from TGA annual charges be granted to those therapeutic goods which had not been supplied to the Australian market.

Several submissions proposed that a self-declaration of sales turnover of a product seeking exemption (rather than a statement of turnover certified by a third party accountant) should be sufficient for confirming a products' eligibility for an exemption. The submissions acknowledged that a move to self-declaration would need to be complemented by an audit program to detect and identify any undesired behaviour.

The ACE scheme better aligns with the CRGs, as those who create the need for post-market activities bear the costs of such activities, whilst still providing some relief to sponsors who have products which are yet to generate turnover.

It is estimated that approximately 74 percent of the ARTG entries which are expected to be exempted under the LVT scheme in 2014-15 would continue to be exempted under ACE (until first turnover). A likely impact of the implementation of the scheme is the removal of some products with low turnover from the ARTG that would no longer be exempt from annual charges. To address the risk that a public health issue is presented where the sponsor of an essential product proposes to remove that product from the ARTG due to the cost of the annual charge, a new waiver provision has been added to the Regulations in conjunction with the ACE scheme.

The benefits of the ACE scheme are:

- Reduction in the rates of annual charges for non-biological prescription medicines and medical devices class IIa and above
- No application fee (saving around \$2.4m p.a. to industry)
- Automatic granting of exemption upon entry on the ARTG, until turnover first commences
- Administrative processes will be simpler as sponsors will only be required to provide a self-declaration of \$0 turnover to confirm their exemption. This will particularly assist sponsors (in particular small businesses) who may not have dedicated regulatory affairs officers and third-party accountants
- A reduction in regulatory burden to industry of an estimated \$30 million over the next ten years
- Relief from annual charges until the ARTG entry is generating turnover
- Annual charge invoices will only be issued for non-exempt entries
- A new waiver option will be introduced on public health/financial viability grounds.

For further information about the options considered to replace the LVT scheme please refer to the [Regulation impact statement - Review of the low value turnover annual charge exemption scheme](#). For further information on the new ACE scheme please refer to the TGA website.

Fees and charges

[Attachment 1: schedule of fees and charges from 1 July 2015.](#)

Risk assessment

A cost recovery risk assessment for this activity was undertaken in May 2015 resulting in a medium risk rating.

The cost recovery risk rating of medium is based on assessment of the criteria on the [Cost Recovery Risk Assessment](#) (CRRA) template. The key medium to high risks for the cost recovery of this activity are that the amount to cost recover exceeds \$20.0 million, the recovery is sourced through fees and levies, they involve an Act of Parliament and many stakeholders will be affected.

The most likely risks identified were:

- Cost recovery fees creating a disincentive to products entering the market
- Inherent risks in implementing diverse cost recovery arrangements, and
- Potential for misunderstanding of how fees and charges are calculated.

These risks are addressed by:

- Continued improvements in regulatory and administrative functions;
- Implementing current best practice in activity based costing (ABC) methodology;
- Working closely with stakeholders and industry representatives to mitigate the cost impact to business; and
- Ensuring charging practices are aligned to our services and are transparent and defensible.

From a regulatory perspective risk management is applied to regulating therapeutic goods by:

- Identifying, assessing, and evaluating the risks posed by therapeutic goods before they can be approved for use in Australia (pre-market assessment or evaluation);
- Identifying, assessing, and evaluating the risks posed by manufacturing processes before a manufacturer is issued with a licence to manufacture therapeutic goods (licensing of manufacturers); and
- Identifying, assessing, and evaluating the risks that may arise following approval of the product and licensing of the manufacturer (post-market surveillance).

Stakeholder engagement

The TGA external communication and education framework; Priorities and projects 2013-2015 describes the TGA's approach to providing:

- Better information that is easily understood by consumers
- Therapeutic goods information that can be received and shared by health professionals
- Information that will provide greater certainty on regulatory arrangements for the therapeutic goods industry

It also details specific communication and education projects that will target consumers, health professionals or industry.

TGA consults with industry associations separately on regulatory matters and cost impacts relating to specific sectors. Industry associations are also consulted in the process of regulatory development and reform, and feedback is taken into account in developing regulatory implementation statements, and in developing cost recovery arrangements. Meetings are held with key industry representative bodies each year to discuss financial forecasts and as a part of the consultation process on cost recovery. The TGA also reports to stakeholders against a set of agreed Key Performance Indicators (KPIs).

TGA has worked with industry stakeholders regarding the development of new fees for OTC medicines that would align the business process reforms to a new fee schedule and as a result cease the use of the page count fee structure. In February 2015 TGA spoke with representatives from the Australian Self Medication Industry (ASMI) on the proposed new fee schedule where they raised concerns over the date of introduction resulting in an agreed start date of 1 January 2016.

In September and October 2014 meetings and teleconferences were held with key laboratory stakeholders to discuss the release of the IVD RIS and the proposed reforms for Class 4 in-house IVDs. The teleconferences were held with the National Association of Testing Authorities (NATA), the Public Health Laboratory Network (PHLN), the Royal College of Pathologists of Australasia (RCPA), the National Pathology Accreditation Advisory Council (NPAAC), the Australian Red Cross Blood Service (ARCBS) & the Biotherapeutics Association of Australia (BAA).

The TGA met with industry representative bodies in October and November 2014, and with consumer health advocacy groups in December 2014, to discuss proposed changes to annual charges exemption arrangements, and follow-up communications were done in writing. Subsequent sectoral meetings were held with these groups to discuss the proposed changes and a targeted industry information session was held in late March 2015.

Consultation also occurred at meetings with industry representative bodies in March 2015 for the proposed general increase to fees and charges from 1 July 2015, along with all other changes to fees and charges to take effect in 2015-16. At the meetings it was proposed that fees and charges would be increased from 1 July 2015 at a rate less than the relevant CPI/WPI rate (2.5 percent). Following the meetings, TGA wrote to industry representative bodies with the final rate proposed for a general increase to fees and charges of 2.12 percent.

Financial estimates

Volumes

The TGA estimates demand for its services based on prior years' volumes which are adjusted for forecast changes in the industry operations and changes in the regulatory framework and/or service delivery models.

Compliance monitoring and enforcement

Estimates for the number of products on the register incorporate expected cancellations and new goods. New goods estimates include the outcomes of work on assessing products for registering on the ARTG.

The activity level assumptions are based on the number of premises for manufacture of blood, blood components and human tissues; human cell and tissue therapy products; and good manufacturing practice inspections for manufacturers of human cell and tissue therapy products that are subject to annual licence charges and/or inspection fees.

Annual licence charges for manufacturers of blood, blood components and biologicals

Number of premises	2014-15	2015-16
Blood Primary Site	5	5
Blood Secondary Site	80	77
Single Step and Single Human Tissue	14	10

Audits of manufacturers of primary blood sites are entitled to three free inspections within a three year period under the terms of their annual licence charge.

Annual charges for biologicals

Number of annual charges	2014-15	2015-16
Class 2 biological products	2	8

Costs of the activity

Fees and charges are established to cover the cost of all direct and indirect costs for the sector. The costing methodology allows costs to be allocated to activities based on their resource consumption at each stage of the process through to the final product or service.

In line with the Australian Government's CRGs total costs are categorised into the following groups for cost allocation and transparency purposes.

- **Direct costs:** can be easily traced to a cost object with a high degree of accuracy. The allocation of direct costs to a cost object is relatively straightforward if the entity's financial system is able to generate relevant information. The most common direct costs are staff salaries (including oncosts, such as training, superannuation and leave) and supplier costs (e.g. office supplies and workers compensation premiums).
- **Indirect costs:** are the costs that cannot be easily linked to a cost object or for which the costs of tracking this outweigh the benefits. Indirect costs should be apportioned to a cost object using the entity's documented internal costing methodology. Common indirect costs include overhead costs such as salaries of staff in corporate (e.g. finance, human resources) and technical support (e.g. legal) areas, or accommodation costs (e.g. rent, maintenance, utilities).

A new software solution is being installed to improve TGA's ABC capability. Staff work effort surveys will be undertaken periodically and they will identify the time regulatory staff spend on our activities. A review of the results against current fees and charges will be carried out in 2015-16.

Direct and indirect costs of the activity

	2014-15 Estimated outcome \$m	2015-16 Forecast \$m	2016-17 Forward estimate \$m	2017-18 Forward estimate \$m
Direct Costs	1.2	1.3	1.3	1.4
Indirect Costs	1.0	1.1	1.1	1.1
Total	2.2	2.4	2.4	2.5

Financial performance

Cost recovery revenue will be reported in the Department of Health's Annual Report in accordance with the Public Governance, Performance and Accountability (Financial Reporting) Rule 2015.

In 2015-16 total revenue for the Blood, blood components and biologicals (human cell and tissue therapies) sector is forecast to be \$3.3 million. The total costs associated in generating that revenue are forecast to be \$2.4 million. In 2013-14 TGA began an extensive review of its activities and cost drivers using current ABC best practice methodology. This project involves each of the six sectors that TGA regulates. In 2014-15 TGA began the implementation of an advanced ABC software tool. This tool will provide improved transparency of costs and the associated revenue. This information will be used to inform management and external stakeholders of where improved alignment of revenue and costs needs to occur. The initial results of this work are expected to be available in 2015-16. The forward estimates below are estimates only and are based on the anticipated results of the ABC project and will be reviewed and adjusted through consultation with industry.

TGA aims to maintain reserves to provide a buffer for volatility in revenue streams (the number and type of evaluation applications) and respond to major external or unplanned impacts (recall, product tampering). Depreciation is also accumulated for the replacement of assets. The Government expects the TGA group to manage within its cost recovery resources and therefore investment, such as the Business Improvement Programme, must also come from the responsible management of these reserves. The target for the reserve balance is set to be at least one quarter of operating expenses. During 2015-16 we expect our reserves to remain above that target.

Estimated revenue and expenses

	2014-15 Estimated outcome \$m	2015-16 Forecast \$m	2016-17 Forward estimate \$m	2017-18 Forward estimate \$m
Expenses	2.2	2.4	2.4	2.5
Revenue	3.6	3.3	3.3	3.4
Balance	1.4	0.9	0.9	0.9

Non-financial performance

Reform of business processes

The TGA has continued to work on a series of reforms to improve understanding of the regulatory processes by its stakeholders; significantly enhance post-market and surveillance capabilities and enhance public trust in the safety and quality of therapeutic goods. For blood, and biologicals, these reforms aim to:

- Provide more information on the regulatory framework so that stakeholders understand regulatory processes and requirements
- Improve the usability, accuracy and consistency of guidelines
- Improve the management of adverse event reporting in support of consumer safety
- Promote the distribution of therapeutic goods safety information so that consumers are alert to warning signals
- Align recall procedures including communication of alerts to the public and health professionals
- Develop technology to support business processes

Performance reporting

The TGA reports to stakeholders at six monthly intervals on our progress in delivery against a set of agreed performance reporting KPIs. The KPIs have been endorsed by the Australian Therapeutic Goods Advisory Council following consultation with the TGA-Industry Consultative Committee. For more information on the TGA's KPI's please visit [TGA key performance indicators](#).

The KPIs are high-level indicators for the TGA's overall performance against our broad strategic intent. Within that matrix of KPIs is a requirement for measuring whether 'business operations are consistent and meet agreed service and timeliness standards'. Measures of specific business activities will continue to be documented in our half-yearly performance reports.

These reports are provided to members of the TGA-Industry Consultative Committee to enable us to report on specific parameters of relevance to industry stakeholders and to enable stakeholders to provide performance feedback. They provide detailed quantitative information about our performance on the timeliness of business activities as well as information for industry about the volumes of work performed by the TGA.

Key forward events

An independent Review of Medicines and Medical Devices Regulation (Expert Review) was announced on 24 October 2014. The aim of the Expert Review was to examine the TGA's regulatory framework and processes with a view to identifying:

- Areas of unnecessary, duplicative, or ineffective regulation that could be removed or streamlined without undermining the safety or quality of therapeutic goods available in Australia; and

- Opportunities to enhance the regulatory framework so that Australia continues to be well positioned to respond effectively to global trends in the development, manufacture, marketing and regulation of therapeutic goods.

During 2015-16 implementation of Government agreed recommendations from the Expert Review will begin. The Government has committed to boost productivity and reduce regulation through its deregulation agenda. The deregulation agenda is guided by the principle that regulation should only be imposed where absolutely necessary, and should not be the default position for dealing with public policy issues.

Key forward events schedule	Next scheduled update
Forward (financial) estimates	30 June 2016
Update of actual (financial) results	Reported in the Department of Health's Annual Report
Stakeholder engagement round	Second quarter 2015-16
Scheduled portfolio charging review	2017-18

CRIS approval and change register

Date of CRIS change	Approver	CRIS change
01/07/2014	Secretary Department of Health	CRIS for 1 July 2014
01/07/2014	Assistant Minister for Health	CRIS for 1 July 2014
01/07/2015	Secretary Department of Health (noted by Assistant Minister for Health)	CRIS updated for 1 July 2015

Attachments

1. Schedule of fees and charges from 1 July 2015

Evaluation fees – per submission for blood, blood components and human tissues	Pages	Fee \$
Page Counts – Blood Plasma Master File & Blood Technical Master File	1 - 10	1,235
	11 - 50	10,600
	51 - 100	23,700
	101 - 1000	31,900
	1001 - 3000	49,700
	3001 - 4000	66,200
	> 4000	80,700

Good manufacturing practice (GMP) inspections	Hourly rate per inspector
GMP inspection of primary site of Manufacturers of Blood and Blood Components except Haematopoietic Progenitor Cells	\$850
GMP inspection of site other than primary site of Manufacturers of Blood and Blood Components except Haematopoietic Progenitor Cells	\$630
GMP inspection of Manufacturers of Haematopoietic Progenitor Cells	\$630
GMP Audit of Manufacturers of Human Tissues	\$630

Application and notification fees for human cell and tissue therapy products	Fee \$
Application for manufacturing licence	1,025
Application for variation	1,025
Application for inclusion of a Class 1,2,3,4 biological	1,025
Notification Fee for a biological (CTN)	320

Evaluation fees for human cell and tissue therapy products	Fee \$
Evaluation of dossier for a Class 2 biological	68,200

Evaluation fees for human cell and tissue therapy products	Fee \$
Evaluation of dossier for a Class 3 biological	136,300
Evaluation of dossier for a Class 4 biological	221,600
Variation Class 2 biological	6,255
Minor Variation Class 3 and 4	16,400
Major Variation Class 3 and 4	32,400
Evaluation of an ingredient/component	22,100
Evaluation Clinical Trial Exemption	24,600

Inspection fees for human cell and tissue therapy products	Fee \$
Domestic initial manufacturing inspection	20,300
Domestic subsequent manufacturing inspection	15,400
Overseas initial manufacturing inspection	20,300
Overseas subsequent manufacturing inspection	15,400
Inspection Fee - in addition to initial or subsequent inspection fee outside Australia	630

Annual charges	Fee \$
Primary site of manufacturers of blood and blood components except haematopoietic progenitor cells	151,300
Additional fixed site (non-mobile) of manufacturers of blood and blood components except haematopoietic progenitor cells	7,445
Manufacturing premises of haematopoietic progenitor cells	6,515
Single step and single human tissue of manufacturers of human tissues	6,515
Two or more steps of manufacturers of human tissues	12,700

Annual charges	Fee \$
Annual charge for Class 1 biological	630
Annual charge for Class 2,3,4 biological	6,255

Historical document

Historical document

Therapeutic Goods Administration

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