Pharmaceuticals Export Promotion Council of India

(Set up by Ministry of Commerce & Industry, Government of India)

REGULATORY & MARKET PROFILE OF AUSTRALIA

Demography

SL. No	Parameter	Description
1	Region	Oceania
2	Country	Australia
3	Capital	Canberra
4	Population	23,332,413 (July 2017 est.)
5	Population growth rate (%)	1.03% (2017 est.)
6	GDP (purchasing power parity)	$ 1.235 trillion (2017 est.)
7	GDP - real growth rate (%)	2.2% (2017 est.)
8	GDP - per capita (PPP)	$ 49,900(2017 est.)
9	Epidemiology	Neuropsychiatric conditions, Cancer, Respiratory diseases and Cardio vascular diseases
10	Population below poverty line	N/A
11	Age structure (%)	0-14 years: 17.8%
		15-24 years: 12.79%
		25-54 years: 41.45%
		55-64 Years: 11.83%
		65 Years and above 16.14%
Source: CIA World Fact Book updated to July 2017 on 9th Feb 2018		

Introduction:

Against the backdrop of a growing and ageing population and an increasing demand for medicines, the Australian government will remain highly focused on cost containment within the pharmaceuticals and healthcare sector. The government's commitment to enforce drug price controls and promote the consumption of lower-value generic medicines in place of patented medicines, as a means to reduce pharmaceutical expenditure, will open more opportunities for generic producers.

Australia Pharma market:

During the year 2016 Australia's total pharma market was $ 10.03 bn. The market is expected to touch $ 10.6 bn by the end of 2017 with just 0.78 % growth. The forecast for the next three years indicates market may stagnate or at best minimal growth.

It is one of the most developed market in Asia-pacific region. Australian society has an ageing and affluent population, and this section mostly requires medicines of Central Nervous System & Cardiovascular System. India's exporters excel in the manufacture of generics of this therapeutic group and have record number of market authorizations.
However, it is considered a Saturated market with very few sub-populations lacking access to medicines thereby chances of its growth in volumes is very moderate.

Latest Updates

- In the government's announcement on September 30 2017, a list of 1,400 medicines that will be subjected to the price disclosure cycle from October 1 2017 was announced. These medicines will receive extra subsidies under the Pharmaceutical Benefits System (PBS).

- In December 2017, it was announced that more than USD300mn worth of medicine to treat lung cancer, multiple myeloma and cystic fibrosis will be added to the Pharmaceutical Benefits Scheme (PBS).

Market Overview:

The Australian government will continue to use drug price controls as a means to reduce healthcare expenditure.

Australia's pharmaceutical market is one of the five largest in the Asia Pacific region. On a per capita basis, at about USD416 in 2016, Australia has the region's second-highest annual spending on pharmaceuticals, after Japan. Much of this spending is on patented drugs, which accounts for 66% of total pharmaceutical expenditure – it is expected that their share will continue to be eroded by generic drugs.

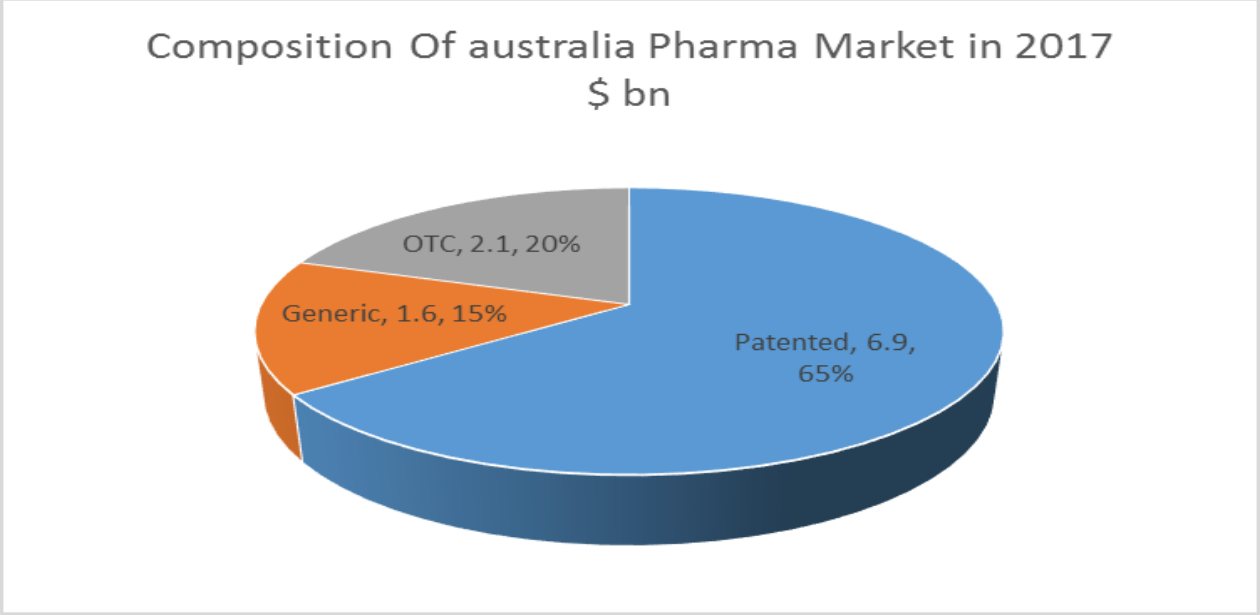
The regulatory regime is comparable to those in other developed states and pricing and reimbursement is fairly generous to research-based drug makers. The government also appreciates the industry's value-added benefits and provides tax incentives to start-up biopharmaceutical firms.

90% of the prescriptions generated are covered by the state run Pharmaceutical benefit scheme.

The market is dominated by incidences of Non communicable diseases like Neuropsychiatric conditions(33%), cancer (17%), respiratory diseases (15%)and Cardio vascular diseases (13%).

The competitive landscape is dominated by foreign firms selling patented drugs. Most multinationals – such as Pfizer, Novartis and Sanofi - are represented through local subsidiaries. AstraZeneca, Eli Lilly, Merck & Co and GlaxoSmithKline manufacture locally. Leading domestic generic drug firms include Sigma Pharmaceuticals, Australia Pharmaceutical Industries and Alphapharm (which is incorporated into USbased Mylan).

Pharmaceutical production in the country is fairly evenly divided between prescription and OTC products. Local producers tend to focus more on generic drugs, including those of branded and 'private label' varieties. Most major multinationals (such as Pfizer, Novartis and Sanofi) are represented through local subsidiaries, with AstraZeneca, Eli Lilly, Merck & Co and GlaxoSmithKline also manufacturing locally.



Generic Market

The generic market which was $1.43 bn in 2016 and has grown by 10.7% in 2017. It is expected to touch just $ 2.65 bn by the end of 2026 and the expected Cagr of 6.5% during the period. Prices of generic drugs in Australia remain higher than the average, it will constitute an opportunity for generic drug manufacturers. Profit margins will be higher if the drugs are exported to Australia as production costs are already low in countries like India.

The difference of cost between a patented and a generic in Australia is not significant like in USA or UK as a result Australia's generic market has been of a small size in comparison to similar economies.

Around 90% of the total market (75-80% of all prescriptions) is covered by the Pharmaceutical Benefit scheme (PBS), which tightly controls prices. The Pharmaceutical Benefits Advisory Committee (PBAC) recommends drugs for inclusion on the PBS based on clinical benefits, safety and cost-effectiveness.

When purchasing a medication under the PBS, the maximum price a consumer pays is the patient co-payment contribution, which is set annually. The maximum co-payment is $ 37 and minimum is $5.4(This is for certain concession holders like economically weaker sections, and high Medicine users like chronic patients and medicines for B.P., diabetes etc). There is no direct incentive for the end user to prefer a generic.

Government aims to increase generic medicines consumption. In early May 2017, it was reported that the government intends to change the prescribing software used by doctors, with the default setting switched to the active ingredient. Improving generic drug consumption to match the levels in the US and the UK is also being prioritised - only 58% of all scripts dispensed in Australia are for generic drugs, compared to 84% in the US and 83% in the UK.

The actual Generic market potential of Australia would emerge after 2018 and it would virtually leap to catch with economies of its size.

Regulatory Review:

Australia is a highly developed, westernised market. Its domestic procedures are largely in line with international norms, with the operating environment regarded as reasonably fair and transparent. The main regulatory body is the Therapeutic Goods Administration (TGA). The TGA is one of the world's most respected regulators. It frequently collaborates with other agencies, such as the US FDA the European Medicines Agency (EMA) Health Canada and the New Zealand Medicines and Medical Devices Safety Authority (Medsafe).

Faster Australian approvals for products that are already approved in the US and Europe, including new drugs, drugs approved via the 505(b)(2) pathway, generics, biologics and devices, via greater reliance on foreign approval processes to reduce duplication of regulatory efforts.

The basis for market regulation is the Therapeutic Goods Act of 1989, which requires that all medical products to be imported into, supplied in, or exported from Australia be included in the Australian Register of Therapeutic Goods (ARTG). The Advisory Committee on Prescription Medicines (ACPM) is the body tasked with providing independent, scientific advice on new drugs. The committee, appointed by the Minister for Health and Ageing, makes recommendations through the TGA. The TGA evaluates the quality, safety, and efficacy of drugs submitted for registration on the ARTG. The sponsor of the drug submits the preclinical and clinical trial data to a delegate who makes the decision on registration, taking into account advice from the ACPM. The process is a risk-based approach that balances the benefits with the risks of a drug.

Australia Member of IGDRP and also PICS

Australia is also a group member of International Generic Drug Regulators Pilot (IGDRP) which commenced in July 2014 (Constitutes EU members and Australia, Canada, Taiwan & Switzerland). This group intends to share their assessments of applications of companies seeking market authorisations.

This would help India companies with market authorisations in Australia to apply for the same in EU and vice versa with reduced cost and the hassle of documentation including bio-availability tests.

The ongoing India-Australia CECA Proposal's clauses regarding grant of market authorisation is well conceived and is in the best interest of both the countries.

Pharma Trade:

The country is facing increasing competition from established production hubs within the region, such as South Korea and Singapore, which have further reinforced their attractiveness through government support. Moreover, the Australian pharmaceutical industry continues to be hampered by an uncertain policy environment due to the government's push for austerity.

In 2016, pharmaceutical imports were valued at USD8.28bn. This is forecast to grow to USD9.43bn by 2021 with a five-year compound annual growth (CAGR) of 2.6%.

Statistics:

India's Pharmaceutical exports to AUSTRALIA $ Million						
Category	**2015-16**	**2016-17**	**2017-18**	**GR%**	**contbn%**	**Contbn to Region**
BULK DRUGS AND DRUG INTERMEDIATES	15.54	11.70	12.68	8.33	4.99	84.91
DRUG FORMULATIONS AND BIOLOGICALS	200.09	208.81	222.25	6.44	87.57	79.51
AYUSH	0.71	1.81	2.67	46.88	1.05	78.17
Herbal Products	5.30	6.85	6.75	-1.42	2.66	95.34
Surgicals	11.13	7.68	9.44	22.85	3.72	72.20
Vaccines	0.00	0.01	0.02	142.67	0.01	0.97
Total	232.78	236.87	253.80	7.15	100.00	79.27

Australia was Ninth largest Destination country of India's exports during 2017-18.

Imports of Australia and India's position:

Top Ten Formulations Importing Partners of AuatrLlia $ mn						
Rank	Country	2014	2015	2016	Gr%	Share%
1	Ireland	531.85	751.46	1280.08	70.35	16.53
2	Germany	1263.13	1131.61	1204.28	6.42	15.55
3	USA	1246.57	1055.63	1135.96	7.61	14.67
4	Switzerland	778.16	883.09	736.79	-16.57	9.51
5	United Kingdom	731.74	469.20	428.54	-8.67	5.53
6	France	587.47	401.98	382.81	-4.77	4.94
7	Belgium	471.98	400.70	332.56	-17.00	4.29
8	Italy	343.60	248.03	302.75	22.06	3.91
9	Netherlands	251.93	230.56	287.43	24.67	3.71
10	India	203.55	210.82	257.73	22.25	3.33
	World	8434.83	7227.43	7743.92	7.15	100.00
Source: UN comtrade						

India is the tenth largest formulations importing partner of Australia and probably would be the largest importing partner when only generics are considered.

India holds 14% share of Australia's generic market.

REGISTRATION AND LICENSING REQUIREMENTS

- Regulatory Authority : **Therapeutic Goods Administration**
- Website of regulatory Authority : https://www.tga.gov.au/
- Fees for Drug Registration : AUD 91,600
- Normal time taken for registration : 12-24 Months
- Registration Requirement [Dossier Format] : CTD
- Whether plant inspection is mandatory : Yes, if no PIC/S GMP certification available
- Requirement of Local agent/ Subsidiary : Subsidiary is Required to operate locally

About the TGA:

The Therapeutic Goods Administration (TGA) is part of the Australian Government Department of Health, and is responsible for regulating therapeutic goods including prescription medicines, vaccines, sunscreens, vitamins and minerals, medical devices, blood and blood products.

The TGA is responsible for regulating the supply, import, export, manufacturing and advertising of therapeutic goods The TGA regulates therapeutic goods through: pre-market assessment, post-market monitoring and enforcement of standards, licensing of Australian manufacturers and verifying overseas manufacturers' compliance with the same standards as their Australian counterparts.

The Therapeutic Goods Administration is part of the Health Products Regulation Group (HPRG) in the Australian Government Department of Health. The Health Products Regulation Group includes the Therapeutic Goods Administration (TGA) and the Office of Drug Control.

Legislation: The Therapeutic Goods Act 1989, Regulations and Orders set out the requirements for inclusion of therapeutic goods in the Australian Register of Therapeutic Goods, including advertising, labelling, product appearance and appeal guidelines. Some provisions such as the scheduling of substances and the safe storage of therapeutic goods, are covered by the relevant State or Territory legislation.

Australian legislation in full text is available from the Attorney General's Federal Register of Legislation.

Medicines Regulation Division: The Medicines Regulation Division evaluates applications to approve new medicines for supply in Australia. The division is also responsible for monitoring medicines approved for supply in Australia after they are on the market.

The Division includes:

- Prescription Medicines Authorisation: Responsible for evaluating new prescription medicines, leading to an approval or rejection decision.

- Complementary and Over-the-counter Medicines: Responsible for regulating over the counter medicines as well as complementary medicines, which include traditional and herbal medicines, and vitamin and mineral supplements.

- Scientific Evaluation: Responsible for approving applications to market biologicals and generic medicines in Australia. The Branch also provides scientific advice to support the decisions made by the Medicines Regulation Division, in particular evaluating the toxicological and pharmaceutical chemistry aspects of therapeutic products and provide expertise in the biological sciences.

- Pharmacovigilance and Special Access Branch: Oversight of medicines and vaccines to ensure they maintain an appropriate level of quality, safety and efficacy following entry into the Australian marketplace. The branch also evaluates and authorises certain clinical trials and special access arrangements for all types of therapeutic products.

Medical Devices and Product Quality Division: The Medical Devices and Product Quality Division monitors medical devices approved for supply in Australia and works to ensure Australian and international therapeutic goods manufacturers meet specified standards.

The Division includes:

- Medical Devices Branch: Responsible for evaluating medical devices,
- Laboratories Branch: Responsible for conducting laboratory testing,
- Manufacturing Quality Branch :Responsible for inspection of manufacturing facilities

Regulatory Practice and Support Division: The Regulatory Practice and Support Division which provides operational regulatory policy advice and specific support services that ensure efficient, best practice regulatory operations to the Health Products Regulation Group.

The Division includes:

- Regulatory Services and Improvement Branch
- Regulatory Practice, Education and Compliance Branch
- Regulatory Engagement and Planning Branch
- Office of Drug Control: Regulates and provides advice on the import, export and manufacture of controlled drugs to support Australia's obligations under the Narcotic Drugs Conventions.

Role of the sponsor:

A sponsor is a person or company who does one or more of the following:

- exports therapeutic goods from Australia
- imports therapeutic goods into Australia
- manufactures therapeutic goods for supply in Australia or elsewhere
- Arranges for another party to import, export or manufacture therapeutic goods.

The sponsor is responsible for applying to the TGA to have their therapeutic good included on the Australian Register of Therapeutic Goods (ARTG).

The sponsor must be a resident of Australia or be an incorporated body in Australia and conducting business in Australia where the representative of the company is residing in Australia.

Medicines and TGA classifications:

Australia has a two-tiered system for the regulation of medicines, including complementary medicines:

- Higher risk medicines must be registered on the Australian Register of Therapeutic Goods (ARTG), which involves individually evaluating the quality, safety and effectiveness of the product.
- Lower risk medicines containing pre-approved, low-risk ingredients and that make limited claims can be listed on the ARTG.

Within the regulatory framework, medicines are classified as either **registered or listed**:

Registered medicines

Registered medicines are assessed by the TGA for quality, safety and efficacy.

- All prescription medicines are registered.
- Most over-the-counter medicines are registered.
- Some complementary medicines are registered.

Listed medicines

Listed medicines are assessed by the TGA for quality and safety but not efficacy.

- Some over-the-counter medicines are listed.
- Most complementary medicines are listed.

Australian regulation of prescription medical products

In order for a prescription medicine to be included in the ARTG, a sponsoring company is required to submit an application to the TGA. A submission to register a prescription medicine consists of:

- Data that support the quality, safety and efficacy of the product for its intended use,
- Completed forms, and
- The payment of fees.

Data packages should be in the Common Technical Document (CTD) format. The data submitted with an application is divided into three types.

- Quality data
  - The composition of the drug substance and the drug product
  - Batch consistency
  - Stability data
  - Sterility data (if applicable)
  - The impurity content
- Nonclinical data
  - Pharmacology data
  - Toxicology data
- Clinical data
  - Mostly results of clinical trials

Appeal processes

If the sponsoring company does not agree with the decision made by the TGA, the Act provides a comprehensive system for review of administrative decisions. The appeal mechanisms are described in more detail in the Australian Regulatory Guidelines for Prescription Medicines (ARGPM). Briefly, the formal appeal process usually involves: An appeal under Section 60 of the Act. This can be followed by: An appeal to the Administrative Appeals tribunal (AAT).

Publication of regulatory decisions: AusPARs:

An AusPAR (Australian Public Assessment Report) provides information about the evaluation of a prescription medicine and the considerations that led the TGA to approve or not approve an application. For applications that are approved, the AusPAR will generally be published no more than a month after the product has been registered on the ARTG. For an application that has been rejected, the AusPAR cannot be published until a 90 day appeal period is complete.

Access to medicines that are unregistered:

There are some legal exemptions to the requirement for a prescription medicine to be registered on the ARTG. These are implemented through:

- The Special Access Scheme (SAS)
- The clinical trials systems (CTX and CTN)

The framework for prescription medicines includes the following categories which are subject to legislated timeframes:

- Category 1 application: An application to register a new prescription medicine (other than an additional trade name) or to make a variation to an existing medicine that involves the evaluation of clinical, pre clinical or bio-equivalence data. For example, new chemical entities, extensions of indication and new routes of administration.

The legislated timeframes for the two stages of a Category 1 application are: 40 working days for notification of acceptance or rejection of the application and 255 working days for the completion of the evaluation and notification of the decision.

- Category 2 application: An application accompanied by two independent evaluation reports from comparable overseas regulators in whose jurisdiction the product is approved for the same indication.

The legislated timeframes for the two stages of a Category 2 application are: 20 working days for notification of acceptance or rejection of an application and 175 working days to notify the applicant of the decision.

- Category 3 application: An application to register or to vary the registration of a prescription medicine where the application does not require the support of clinical, pre clinical or bio-equivalence data. For example, a change in the site of manufacture, a change to the synthetic route, a change in the product specifications, a change in the steps of manufacture or a change in trade name.

The legislated timeframe for a Category 3 application is 45 working days for notification of acceptance or rejection of an application, completion of evaluation and notification of the decision.

Australian Regulatory Guidelines for Prescription Medicines (ARGPM)

Overview: Prescription medicines registration process

Sponsors may now apply to register a prescription medicine under the provisional approval pathway, priority review pathway or the standard prescription medicines registration pathway.

Introduction

The TGA registration process for prescription medicine applications, that need to be supported by nonclinical, clinical and/or bioequivalence data (category 1 and category 2). This regulatory process is designed to improve the efficiency and timeliness of the registration of prescription medicines without compromising the scientific rigour of the evaluation process, thus ensuring the maintenance of appropriate standards of quality, safety, and efficacy.

The key elements of this process are:

- management by milestones
- an improved quality of dossiers prepared in accordance with common technical document (CTD) format and other TGA regulatory requirements
- a pre-submission planning phase where applicants lodge details of a proposed application at least 2¼ months prior to lodgement of the dossier allowing the TGA to identify milestone dates and plan resource requirements (this is not required for submissions lodged in eCTD format if the sponsor selects the PPF-only option)
- a submission phase where the applicant must lodge a complete dossier, there being no opportunity to deliver new data after the submission date except as required by the *Therapeutic Goods Act 1989* (the Act)

Regulatory and supporting documents

Category 1 and 2 applications for new registrations are made under section 23 of the Act, in CTD format.

Category 1 and 2 requests to vary the entry in the Australian Register of Therapeutic Goods (ARTG) of registered therapeutic goods are made under section 9D of the Act in CTD format.

The CTD format is described in the following documents:

- CTD Module 1: Administrative information and prescribing information for Australia
- ICH M4Q Common technical document for the registration of pharmaceuticals for human use - Quality (CPMP/ICH/2887/99 Rev 1 Quality)
- ICH M4S Common technical document for the registration of pharmaceuticals for human use - Safety (CPMP/ICH/2997/99 Rev 1 Safety)
- ICH M4E Common technical document for the registration of pharmaceuticals for human use - Efficacy (CPMP/ICH/2887/99 Rev 1 Efficacy).

For category 1 and 2 applications, other than applications solely for an additional trade name, the section 23 and section 9D instruments specify applications must comply with the following regulatory documents:

- Mandatory requirements for an effective application
- Pre-submission planning form
- prescription medicines (PREMIER) electronic lodgement facility (for applications to register a new chemical entity, new fixed combination, similar biological medicinal product or a new generic medicine)

or

- the form Application for the registration, or to vary the conditions of registration, of prescription medicines (all other applications)

In addition to the documents specified by the section 9D and section 23 instruments, the TGA has produced other documents which provide further assistance for applicants who are lodging a PPF or dossier. These include:

- Prescription medicine registration process (this document)
- Information for applicants completing a pre-submission planning form
- Electronic format requirements for industry for providing regulatory information: Non eCTD electronic submissions (NeeS) for human medicinal products
- Prescription medicine registration process Q&A
- General dossier requirements for prescription medicines

Priority review designated applications:

TGA now has a formal Priority review pathway for faster assessment of vital and life-saving prescription medicines for which a complete data dossier is available. The target timeframe of 150 working days is up to three months shorter than the standard prescription medicines registration process. A valid Priority review designation must be held in order to access the Priority review pathway. More information on Priority review is available at:

- Priority review designation: A step-by-step guide for prescription medicines
- Priority review designation eligibility criteria: Including supporting documentation
- Priority review registration process

Provisional approval pathway

The TGA now has a formal Provisional approval pathway for the provisional registration of prescription medicines on the basis of preliminary clinical data, where there is the potential for a substantial benefit to Australian patients. A valid Provisional determination must be held in order to access this pathway.

More information on Provisional approval is available at:

- Provisional approval determination: A step-by-step guide for prescription medicines
- Provisional approval determination eligibility criteria: Including supporting documentation
- Provisional registration process: a step-by step guide for prescription medicines
- Provisional registration extension and transition to full registration

Management by milestones:

The registration process consists of eight phases with eight milestones, allowing effective planning and tracking by the TGA and applicants. Each phase has established timeframes.

To facilitate management by milestones, all applications received in a given intake will proceed as a group through the phases and milestones, a process known as 'batch processing'.

Milestones of the various phases in the regulatory process		
Phase	Relevant milestone	
1 - Pre-submission	MS1	Outcome of pre-submission planning sent
2 - Submission	MS2	Outcome of application consideration sent
3 - First round assessment	MS3	Outcome of first round assessment and section 31 request for information or documents sent
4 - Consolidated section 31 request response	MS4	End of section 31 request response period
5 - Second round assessment	MS5	Outcome of second round assessments sent
6 - Expert advisory review	MS6	Outcome of expert advisory committee review sent
7 - Decision	MS7	Decision made by delegate

Fee Structure:

Fees and charges: summary - from 1 July 2018 can be identified at https://www.tga.gov.au/book-page/prescription-medicines-3#pm-app

Annual charges: These charges are in the *Therapeutic Goods (Charges) Regulations 2018*.

Type of prescription medicine	**Charge**
Biological medicine	$7,120
Non-biological medicine (chemical entity) - subsection 3-10 of regulation 8	$4,060
Non-biological medicine (chemical entity) - otherwise	$3,290
Provisionally registered biological medicine	$16,100
Provisionally registered non-biological medicine	$13,100

Prescription medicine application and evaluation fees: These applications have both an application fee and an evaluation fee. These fees are in Schedule 9, *Therapeutic Goods Regulations 1990*.

Prescription medicine application type	**Application fee**	**Evaluation fee**
New chemical entity*	$47,800	$191,800
Extension of indications*	$28,500	$113,800
Major variations*^	$18,600	$74,200
Minor variation applications applied for under section 23 of the Act (Change in formulation, composition, design specifications, type of container or change of trade name)^	$1,100	$4,360
Variations to an ARTG entry involving the evaluation of clinical, pre-clinical or bio-equivalence data, applied for under 9D(3) of the Act. Includes applications for changes to Product Information involving the evaluation of clinical, pre-clinical or bio-equivalence data*^	$1,100	$4,360
Additional trade name^	$3,020	$12,100
New generic product*	**$18,400**	**$73,200**
Extension of indications of a generic medicine to maintain currency with indications already registered to the corresponding innovator product and where clinical and/or bioequivalence data are not required	$1,100	$4,350

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Details of importing country embassy in India: **http://india.embassy.gov.au/**

Contact details of Indian Embassy abroad**: http://www.hcicanberra.gov.in/**

List of Local Pharma Associations:

- Pharmaceutical Society of Australia - Ph:(+)61 2 6283 4777. psa.nat@psa.org.au www.psa.org.au
- Australian Pharmaceutical Industries (API) http://www.api.net.au/