10. A Guide to Advocacy for Access to Innovative Medicines

Medicines Australia

Better health through research and innovation

How Medicines Become Available In Australia

> **We have developed this chapter as a guide for your constituents, should they wish to engage on these issues.**

For a medicine to be supplied and subsidised to treat a medical condition in Australia, two key processes, both at a Federal Government level, are required:

Step 1: Registration - Listing on the Australian Register of Therapeutic Goods (ARTG)

- This process commences when a Sponsor company (the 'Sponsor') submits a data dossier to the Therapeutic Goods Administration (TGA) for evaluation.
- This dossier evaluation focuses on the efficacy, safety and quality aspects of the medicine in the proposed population.
- For a new medicine, the overall timeframe, from dossier submission to ARTG listing, is between 12-18 months.
- A Product Information (for clinicians) and Consumer Medicine Information (for patients and caregivers) are approved as part of the process.
- Listing on the ARTG permits supply of the medicine in Australia. However, it will cost patients the full price set by the Sponsor.
- There is no formal process in place for consumer input to the evaluation of a new medicine.

Step 2: Reimbursement - Listing on the Pharmaceutical Benefits Scheme (PBS)

- The Sponsor company must prepare and lodge an economic evaluation comparing the new medicine with the most commonly used treatment(s) in Australia for the medical condition.
- The submission focuses on clinical need, health benefits, adverse events and costs. The potential impact on the health budget is also a consideration.
- The process of submission lodgement to consideration by the Pharmaceutical Benefits Advisory Committee (PBAC) takes 4 months. Following a PBAC positive recommendation, the Sponsor and Department of Health negotiate on the final pricing and conditions of PBS listing. This can take up to 6 months or longer in some circumstances.
- Medicines are only generally included on the PBS for treatment of conditions for which they are registered by the TGA.

Consumer comments are welcomed by the PBAC, and a formal process allows interested members of the community to provide input to PBAC considerations. For further details visit: http://www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/pbac-consumer-comments

First Point Of Contact.

To determine the status of a medicine in the registration and reimbursement processes, contact the Sponsor company Medical Information team. Contact details will be clearly displayed on the Australian website of the company.

If a medicine is not expected to be registered or reimbursed in Australia in a suitable timeframe, other avenues for access should be investigated. These include clinical trial participation; compassionate use programs; the Special Access Scheme; or overseas importation. The Sponsor company and clinicians can assist with this information.

Advocacy Preparation.

It is important to know where in the registration and reimbursement processes a medicine is before commencing advocacy activity. Additionally, the specific condition (indication) for which a medicine is being evaluated should be understood. This is because separate submissions are required for each different indication.

Information that will assist in advocacy preparations:

- Medicine name (the active compound and the BRAND name);
- Indication (what condition or disease does the medicine treat);
- Sponsor company (this should be readily available on the internet);
- Registration status of medicine in Australia; and
- Reimbursement status of the medicine in Australia.

Advocacy Opportunities

Government

Federal Member of Parliament (MP)

Access to medicines is managed by the Federal Government Department of Health. Writing to and meeting with your local MP is a good first step in your advocacy. You can find the contact details of your local MP by visiting www.aph.gov.au/Senators_and_Members and entering your postcode, electorate or the name of the MP. To help with your advocacy, please see the attached example of an advocacy letter.

Minister for Health

The Hon Greg Hunt MP
E: minister.hunt@health.gov.au **T:** (02) 6277 7220

A: PO Box 6022, House of Representatives,
Parliament House, Canberra ACT 2600

You can also find the contact details for the Federal Minister for Health by visiting https://health.gov.au/ministers

Shadow Minister for Health

The Hon Chris Bowen MP
E: chris.bowen.mp@aph.gov.au **T:** (02) 6277 4822 or (02) 9604 0710

A: PO Box 6022, House of Representatives,
Parliament House, Canberra ACT 2600

Pharmaceutical Benefits Advisory Committee (PBAC)

www.pbs.gov.au/info/industry/listing/participants/pbac

E: pbs@health.gov.au **T:** 1800 020 613

Patient Support Groups

There are numerous patient support groups at a local community, state and national level that may already be active in seeking access to the same medicine that you are.

Asking the Sponsor company, a medical practitioner or conducting research online ('disease name' patient group Australia) will be useful in identifying the most relevant group/s to contact.

Sponsor Companies & Industry

In addition to the information available via the Sponsor company of a medicine, the company may also be seeking patient input to a reimbursement submission and patient stories/experiences to better understand the patient perspective. To provide input to a possible reimbursement submission, you should contact the Sponsor company directly.

Medicines Australia is the representative association of the research-based pharmaceutical companies (Sponsors) who invent, develop, manufacture and supply innovative medicines and vaccines to the Australian community. In partnership with their member companies, other healthcare organisations and consumer groups, Medicines Australia collaborates with Government to deliver a supportive policy and fiscal environment for the availability of new medicines.

A list of member companies is available at https://medicinesaustralia.com.au/about-us/our-members/ and includes links to company webpages and contact details.

Example Advocacy Letter

[Sender's name]
[Full Address]
[Contact details]

[Recipient's name]
[Full Address]

[Date]

Dear ***[Recipient]***,

RE: ***[medicine name]*** for the treatment of [medical condition].

My name is ***[Sender's name]*** and I am a resident of your electorate. As ***[a carer/ parent to OR a]*** patient with ***[medical condition]***, I am writing to ask for your support to access a new medicine.

[Brief description of medical condition and impact on those with the disease and their families. Number of Australians with the medical condition.]

[Insert personal story of diagnosis (when, symptoms leading up to etc); treatments received (medicine names and if effective or not); current challenges and outlook. Why the new medicine is needed].

[Medicine name] is in clinical trials / available in the US and Europe. Clinical results …. ***[Clinician/Patient support group input required].***

In Australia the medicine is currently under evaluation by the TGA and PBAC/ has been approved by the TGA but rejected for reimbursement by the PBAC. ***[Clinician/ Patient support group input required]***.

I would appreciate the opportunity to discuss the challenges faced by Australian patients with ***[medical condition]*** and the importance of immediate access to ***[new medicine]***.

I look forward to your reply and talking with you soon.

Sincerely,

[Sender's signature]

[Sender's full name]

[Contact details for reply]

Glossary

Advisory Committee on Medicines (ACM)

The ACM advises and makes recommendations regarding the entry of medicines on the ARTG The ACM provides independent medical and scientific advice to the Minister for Health and the Therapeutic Goods Administration (TGA) on issues relating to the safety, quality and efficacy of medicines supplied in Australia including issues relating to pre-market and post-market functions for medicines. https://www.tga.gov.au/committee/advisory-committee-medicines-acm

Australian Register of Therapeutic Goods (ARTG)

List of therapeutic goods that can be lawfully supplied in Australia. Responsibility of TGA. Almost any product for which therapeutic claims are made must be entered in the Australian Register of Therapeutic Goods (ARTG) before it can be supplied in Australia.

There were approximately 86,896 products on the Australian Register of Therapeutic Goods as at April 2016. https://www.tga.gov.au/artg

Medicine

Medicines are compounds used to treat disease. These may be small molecules (developed by an originator company, and sold as generic brands after patent expiry) or biologic (biosimilar brands after patent expiry) or termed co-dependent if a diagnostic or other test is required to determine who should be treated with a medicine.

Pharmaceutical Benefits Advisory Committee (PBAC)

The PBAC is an independent expert body appointed by the Australian Government. Members include doctors, health professionals, health economists and consumer representatives.

Its primary role is to recommend new medicines for listing on the PBS. No new medicine can be listed unless the committee makes a positive recommendation. The PBAC meets three times a year, usually in March, July and November.

When recommending a medicine for listing, the PBAC takes into account the medical conditions for which the medicine was registered for use in Australia, its clinical effectiveness, safety and cost-effectiveness ('value for money') compared with other treatments. http://www.pbs.gov.au/info/industry/listing/participants/pbac

Pharmaceutical Benefits Scheme (PBS)

The PBS provides timely, reliable and affordable access to necessary medicines for Australians. Under the PBS, the government subsidises the cost of medicine for most medical conditions. Most of the listed medicines are dispensed by pharmacists and used by patients at home.

Some medicines are dangerous to administer and need medical supervision (such as chemotherapy drugs) and are only accessible at specialised medical services, usually hospitals. http://www.pbs.gov.au/pbs/home

Product Information (PI)

Information relating to the safe and effective use of the medicine (TGA approved as part of listing on ARTG).

Special Access Scheme (SAS)

Health practitioners who wish to access therapeutic goods that are not in the ARTG may use SAS pathways to access an unapproved therapeutic good for an individual patient on a case-by-case basis. https://www.tga.gov.au/form/special-access-scheme

Sponsor

The legal representative of a medicine in Australia. The company in relation to whom the medicine is included in the ARTG.

Therapeutic Goods Administration (TGA)

The TGA is part of the Australian Government Department of Health, and is responsible for regulating the supply, import, export, manufacturing and advertising of therapeutic goods including prescription medicines, vaccines, sunscreens, vitamins and minerals, medical devices, blood and blood products.

Any product for which therapeutic claims are made must be entered in the ARTG before it can be supplied in Australia.

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www.medaus.com.au