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an IQVIA business

Introduction to the Therapeutics Industry
PHAR7816

21st April 2026

Presented to

University of Sydney
(PHAR7816)

Why Am I Here Today With You?

Lucid Health Consulting (LHC) provides expert advice in health economics, pricing & reimbursement, market access and regulatory affairs in Australia.

George Papadopoulos
Principle Consultant, Lucid Health Consulting, an IQVIA Business

Experience

- Director, Lucid Health Consulting
- Managing Director, Emerald Corporate Group
- Director, Global Market Access, Schering-Plough
- Director, Global HEOR, Johnson & Johnson

Expertise

- Global Pricing and Reimbursement
- Early Commercial Assessment
- Health Technology Assessment

Extended Team/Partners:

- Device Health Economics Consultant
- Senior Market Access Consultant
- Senior Health Economics Consultant
- Senior Statistician
- Health Economics Modelling Consultant
- Senior Market Access Consultant
- Statistician
- Systematic Literature Reviews Consultants
- Senior Regulatory Consultant
- New Zealand Market Access Consultant
- Japanese Market Access Partner
- UK Market Access Partner

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Goals for Today

Answer or Guide to the Following Questions

- What is Health Technology Assessment (HTA)
- What is a HTA or Market Access Strategy?

- What is the Australian Public Reimbursement system?
  - Understand the **Pharmaceutical Benefits Scheme (PBS)** and its relevance to public health and the Australian healthcare system
    - Identify steps involved in listing medicines on the PBS
  - Understand the **Medical Benefits Schedule (MBS)** and and its relevance to public health and the Australian healthcare system
    - Identify steps involved in listing medicines on the MBS
  - What is the **Prostheses List (PL)/Prescribed List** and and its relevance to private health and the Australian healthcare system
  - How/Where do product/service fit in the Australian Reimbursement system?
- Case Study……

What is Health Technology Assessment (HTA)?

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Health Technology Assessment (HTA) in Australia

The Australian Government and the Department of Health and Aged Care in particular use health technology assessments (HTAs) to inform their decisions about which health technologies can be sold in Australia, and which ones qualify for Australian Government subsidy (or reimbursement).

Australians benefit from HTAs because they ensure taxpayers' money supports safe, effective healthcare improvements.

Types of health technologies assessed

- pharmaceuticals (including vaccines)
- diagnostic tests
- medical devices
- surgically implanted prostheses
- medical procedures
- public health interventions.

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Main Health Technology Assessment (HTA) Bodies in Australia

In Australia, several advisory and regulatory bodies provide HTAs and advise us on their findings.

The Therapeutic Goods Administration (TGA) assesses the safety, quality and efficacy of new health technologies entering the Australian market. If they approve an item, they grant market authorisation and the item can be legally sold in Australia (not focus of todays presentation).

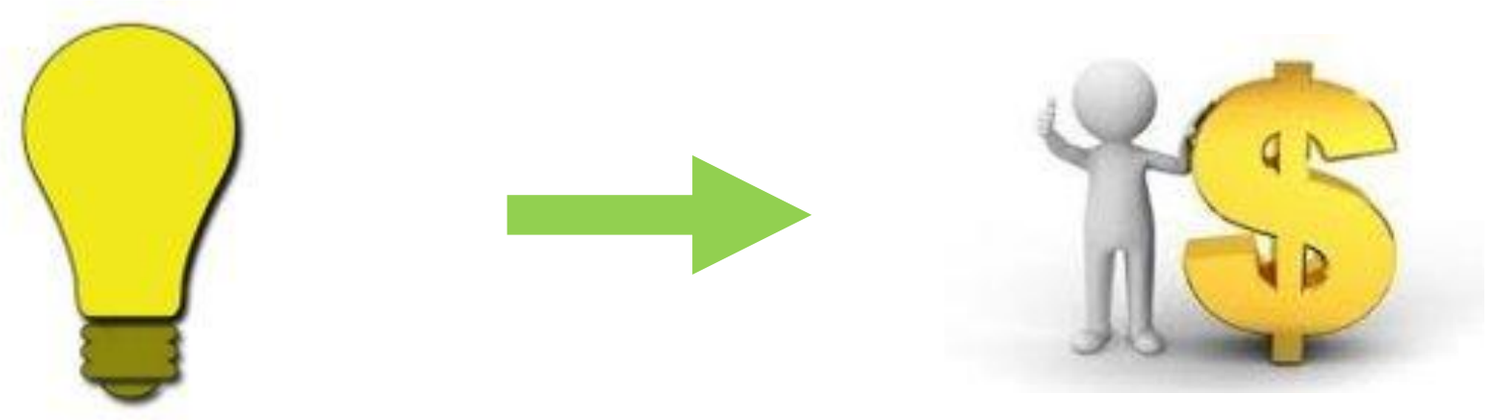
Three principal health technology advisory committees assess whether health technologies qualify for Australian Government subsidy:

- Medical Services Advisory Committee (MSAC)
  - Advise government on Medical Services, Cell Therapies and Blood Derived Products
- Pharmaceutical Benefits Advisory Committee (PBAC)
  - Advice government of pharmaceutical access in the community
- Medical Devices and Human Tissue Advisory Committee (MDHTAC).
  - Advice government on implantable medical devises (prostheses) and human tissues

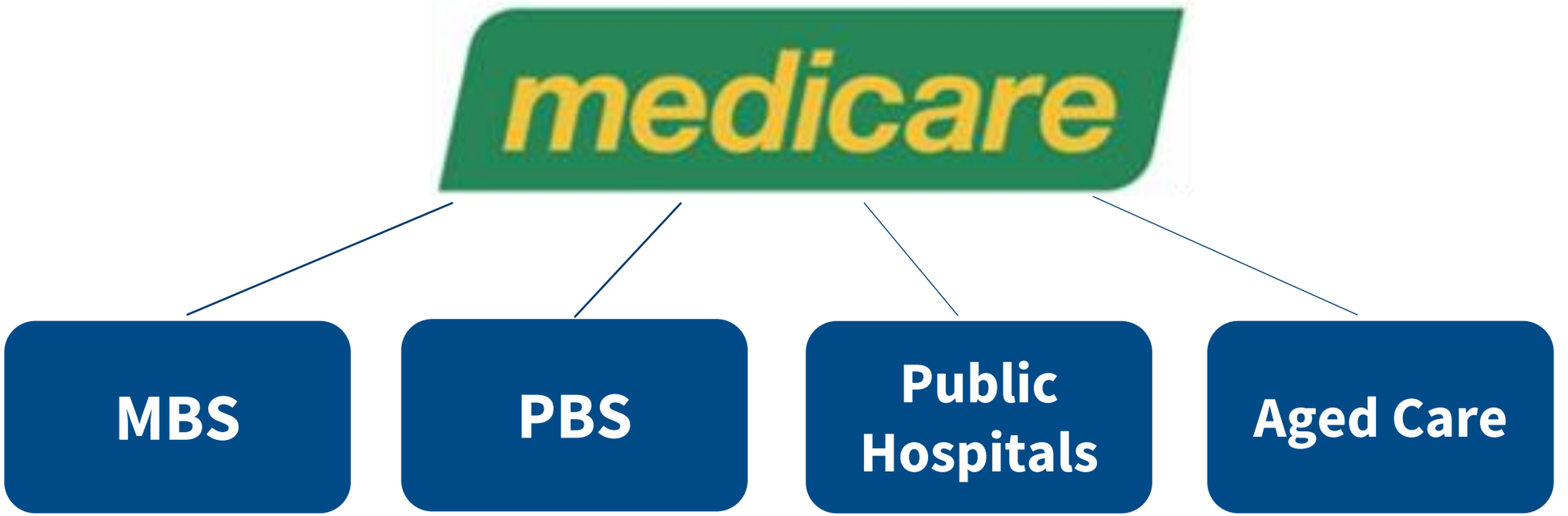
Will be concentrating on these three committees

Why HTA or Reimbursement or Australian Government subsidy?

In order for a new technology to be commercially successful someone has to be prepared to pay for it.



Australia's Public Healthcare System



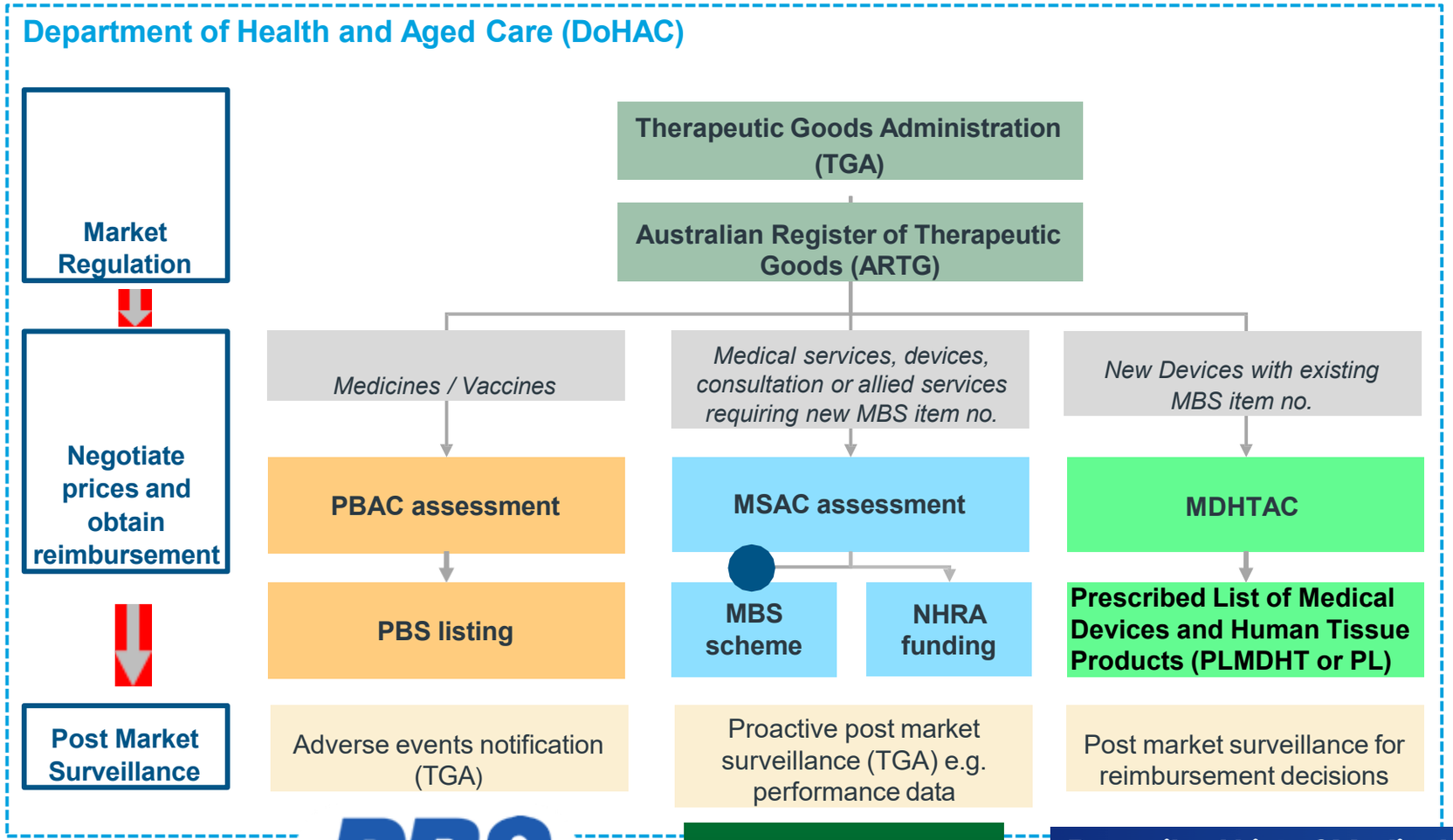
- Medicare is a universal healthcare system
- And nearly half of all Australians also have private health insurance (PHI)
- PHI is hospital and limited ancillary cover only
  - excludes primary care and pharmaceuticals
- Consequently, in Australia we have a mix of public and private hospital systems
- Somewhat fragmented – lots of perverse incentives

Private Hospitals
Private Health Insurance

Prescribed List of Medical Devices and Human Tissue Products (PLMDHT or PL)

HTA Assessment routes applicable to health technologies include the PBAC for PBS, MSAC Assessments for the MBS and PLAC for Prosthesis List

Assessment routes for health technology (drug, devices, diagnostics)



Other Reimbursement Programs administered by the DoHAC

- Life Savings Drug Program (LSDP)
  - LSDP pays for specific essential medicines to treat patients with rare and life-threatening diseases.
- National Immunisation Program (NIP) Schedule
  - NIP Schedule is a series of immunisations given at specific times throughout your life. The immunisations range from birth through to adulthood.
- National Blood Authority (NBA)
  - NBA is a statutory agency within the Australian Government Health portfolio that manages and coordinates arrangements for the supply of blood and blood products and services on behalf of the Australian Government and state and territory governments.

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Hurdles to Access

Safety

Efficacy

Quality

Cost-Effectiveness

Budget Impact

TGA

PBS/PBAC
MBS/MSAC
NBA/MSAC
LSPD/PBAC
PL/MDHTAC/MSAC

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What is the PBS?

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What is the PBS

- Australia has a universal healthcare system (Medicare)

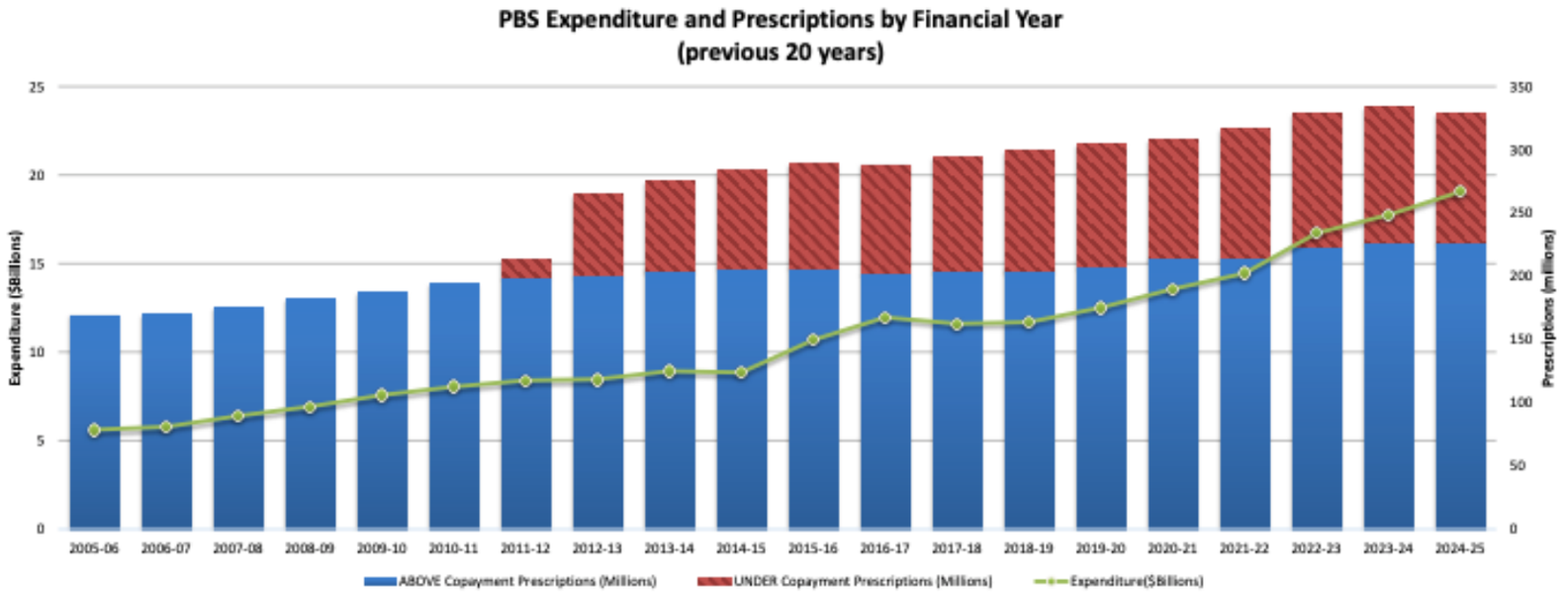
Australian Government
Department of Health
PBS
The Pharmaceutical Benefits Scheme

- The Pharmaceutical Benefits Scheme, or PBS, helps keep medicines affordable.
- The PBS lists brand name, generic, biologic and biosimilar medicines.
- The PBS is part of Australia's broader National Medicines Policy.
- Procedure guidance for listing medicines on the PBS, including consideration of vaccines for the National Immunisation Program (Version 2.2, October 2021)
- PBAC Guidelines (Version 5.0, September 2016)
- Australians only pay some of the cost of most PBS medicines if they are enrolled in Medicare. The Australian Government pays the rest. You pay even less if you have a concession card.

Pharmaceutical Benefits Scheme (PBS) (Jul 2024-Jun 2025)

- Total Pharmaceutical Benefits Scheme (PBS) Government expense for the supply of medicines under Section 85 and Section 100 on an accrual accounting basis for the 2024-25 financial year was **$19.1 billion** (excluding revenue), versus $17.7 billion in 2023-24.
- **Total Government Expenditure:** $19.1 billion.
- **Total Patient Contribution:** $1.7 billion.
- **Total Subsidized Prescriptions:** 226 million (a 0.2% decrease from 2023–24).
- **Average Dispensed Price:** $91.62 (up from $85.10 in 2023–24).
- **Growth:** Expenditure grew by 7.4% compared to 2023-24.

Figure 1: PBS Expenditure and Prescription Volume, 2005-06 to 2024-25
Section 85 and Section 100 including Prescriber Bag and under co-payment prescriptions*



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atters.

Source: https://www.pbs.gov.au/statistics/expenditure-prescriptions/2024-2025/Expenditure-prescriptions-report-tables-2024-25.PDF

The Pharmaceutical Benefits Scheme (PBS) and Reimbursement System

Introduction to the Australian HTA and pricing system

Australia has a rigorous HTA system based on cost-effectiveness and reference pricing

PBAC
Pharmaceutical Benefits Advisory Committee (PBAC)

Recommends

PBS
Pharmaceutical Benefits Scheme (PBS)

Influences

Reference Pricing System

- The submission is evaluated by **an academic center** plus an assessment by the **PBAC's Economic Sub-Committee**
- Decision-making process considers:
  - **clinical need** and **effectiveness**
  - **cost-effectiveness**
  - overall **financial implications**
  - **uncertainty** around the clinical, economic and financial evidence

- Upon **positive recommendations**, a new medicine will be listed on the national reimbursement scheme (PBS).
- Annual net expenditure is approximately **$14B AUD (9 B USD)**

- Particularly **for products with non-inferior efficacy (and safety)** with pricing based on a cost-minimization analysis

Increasingly, the PBAC may consider a **risk-sharing agreement** (RSA) to deal with specific areas of uncertainty that are covered under a **Deed of Agreement**, a commercial agreement between the **Commonwealth Government** and medicine's **sponsor.**

Submission's clinical claim	PBAC recommendation	Form of economic evaluation	Basis of pricing	
Superiority claim	Superiority	Cost-utility analysis	Price based on an acceptable ICER	Key decision driver for PBAC: **clinical** and **economic uncertainty**
Non-inferiority claim	Non-inferiority	Cost-minimization analysis	Same cost as the lowest cost comparator	Reference pricing
Inferiority claim	Inferiority	Cost-minimization analysis	Lower cost than the lowest cost comparator	

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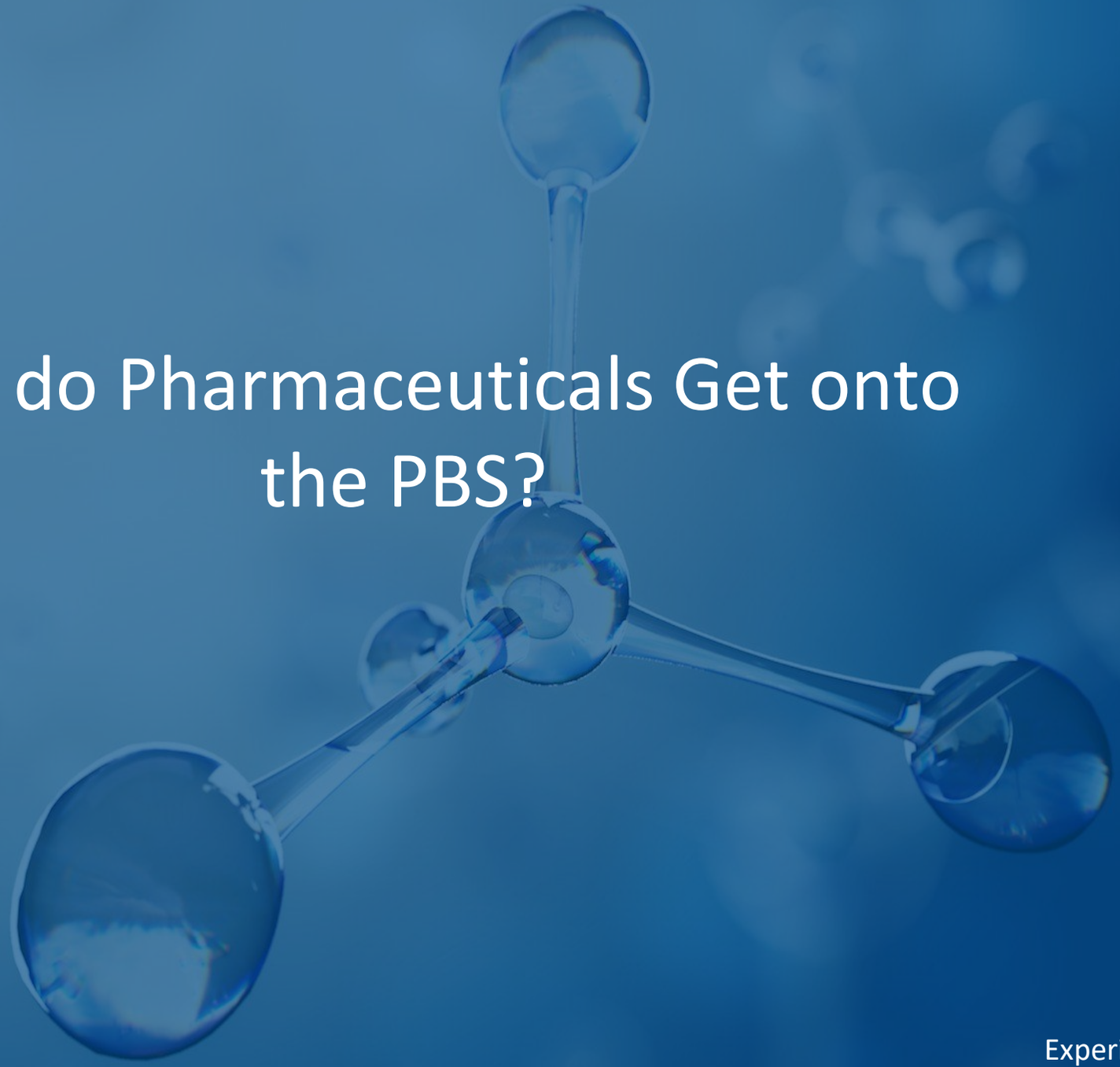
► **Abbreviations:** HTA: Health Technology Assessment; PBAC: Pharmaceutical Benefits Advisory Committee; PBS: Pharmaceutical Benefits Scheme

How do Pharmaceuticals Get onto the PBS?



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Procedure guidance for listing medicines on the Pharmaceutical Benefits Scheme

(including consideration of vaccines for the National Immunisation Program)

Version 2.2

Australian Government
Department of Health

Describes the processes undertaken by the Department of Health in considering and listing medicines and vaccines on the Pharmaceutical Benefits Scheme (PBS) and the National Immunisation Program (NIP).

Provides information on processes, procedures, timelines and documents required.

Information on cost recovery administrative processes is located on the PBS website and should be referred to for in conjunction with this document.

Source: How to List on the PBS: https://www.pbs.gov.au/pbs/industry/listing/listing-steps

Guidelines for preparing a submission to the Pharmaceutical Benefits Advisory Committee

Version 5.0

September 2016

Australian Government
Department of Health

The PBAC Guidelines explain in detail how to prepare a submission to list a new medicine or medicinal product on the Pharmaceutical Benefits Schedule (ie for public funding).

The guidelines provide detailed instructions on what information is required by the PBAC and the Economic Sub-Committee (ESC) to support a proposed new medicine, and the most appropriate form of clinical evidence and economic evaluation for specific submissions.

Source: PBAC Guidelines: https://pbac.pbs.gov.au/

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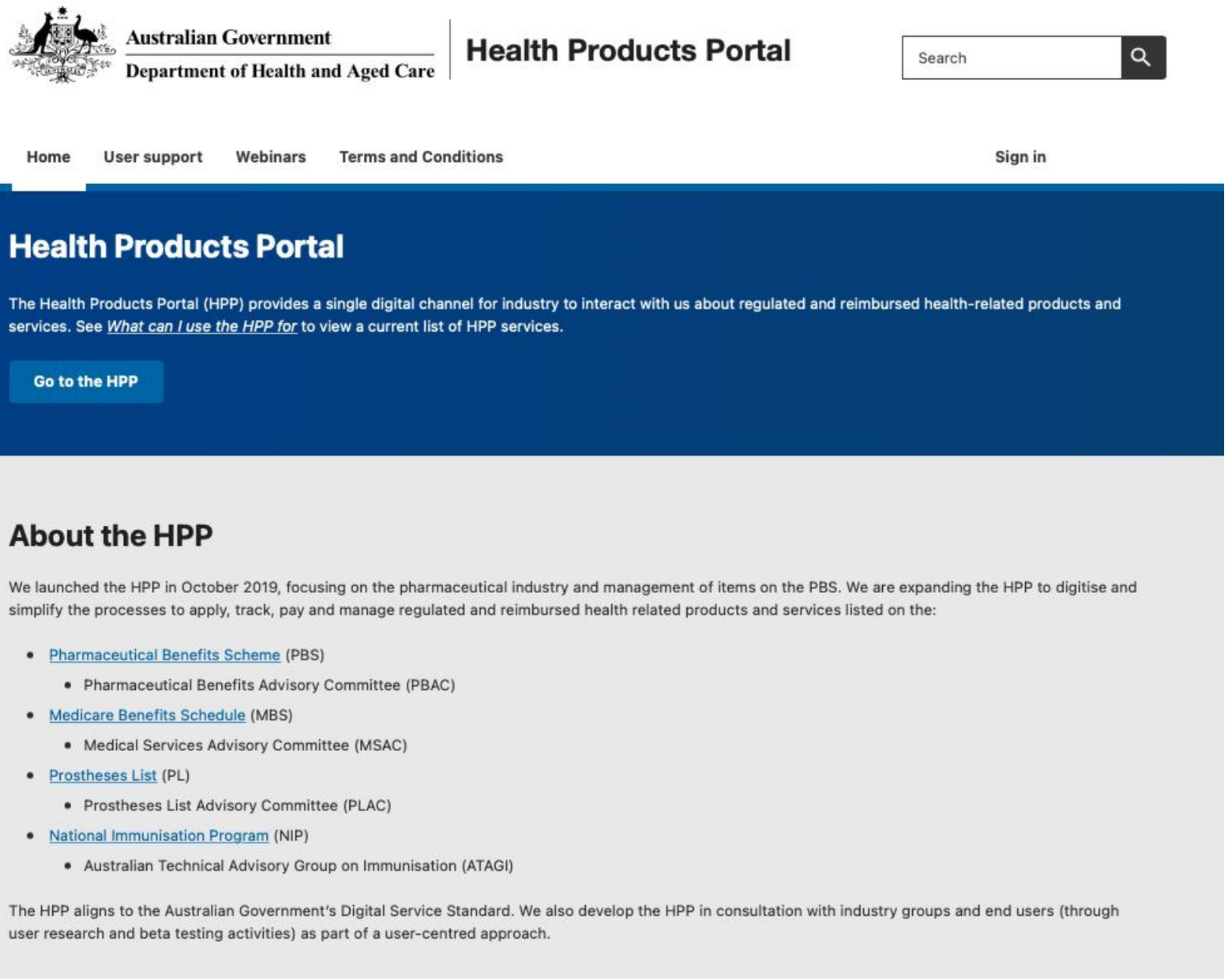
The Health Products Portal (HPP) provides a single digital channel for industry to interact with us about regulated and reimbursed health-related products and services.



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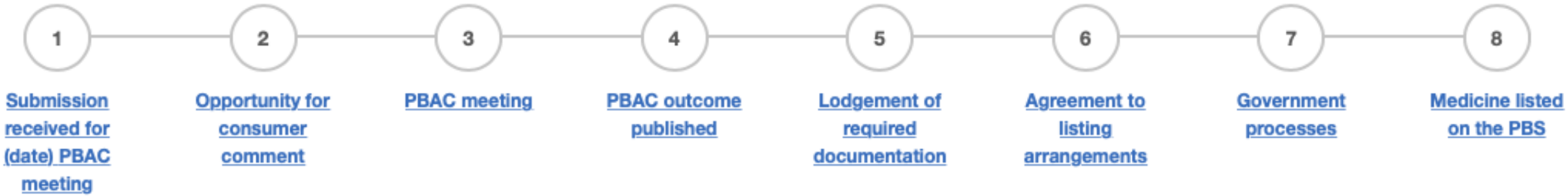
PBS Listing Process

What does the PBS listing process look like?

The below diagram provides an overview of the PBS listing process. Click each step of the below diagram to learn more.



PBS/PBAC Process – Complex and Long

Application to TGA and/or delegate's overview/advice to ACPM resolution and/or TGA registration granted

WEEK -8
Intent to Apply deadline for integrated codependent submissions

WEEK -4
Intent to Apply deadline for Category 1-4, Committee Secretariat submissions and Standard Re-entry resubmissions
Submission due day for integrated codependent submissions

WEEK 0
Submission due day for Category 1-4, Committee Secretariat submissions and Standard Re-entry resubmissions

WEEK 3
Publication of the PBAC Agenda and Consumer Comments open

WEEK 8
Publication of the updated PBAC Agenda

WEEK 9
Pre-submission meetings - 8 week cut-off

WEEK 10
Submission Commentaries to applicants for Category 1-2 submissions

WEEK 11
Applicants' pre-subcommittee responses to department and Consumer Comments close

WEEK 12
DUSC meeting

WEEK 13
ESC meeting

WEEK 15
Submission Overviews for Category 3-4 submissions, ESC, DUSC and ATAGI advice
Consumer Comments summary to applicants

WEEK 16
Applicants' pre-PBAC responses to the department

WEEK 18
PBAC outcome advice (via email)

WEEK 20
Ratified PBAC Minutes to applicants (positive recommendations)

WEEK 22
Ratified PBAC Minutes to applicants (all other recommendations)

WEEK 23
Post-PBAC meetings with the PBAC Chair and publication of PBAC outcomes
Intent to Apply deadline for Early Resolution and Early Re-entry Pathway resubmissions

WEEK 24
Submission due day for Early Resolution and Early Re-entry Pathway resubmissions

WEEK 25
Publication of updated PBAC Agenda (to include early resubmissions)

WEEK 27
Draft Public Summary Documents to 'Responsible Persons'

WEEK 28
Applicants' redaction requests to department

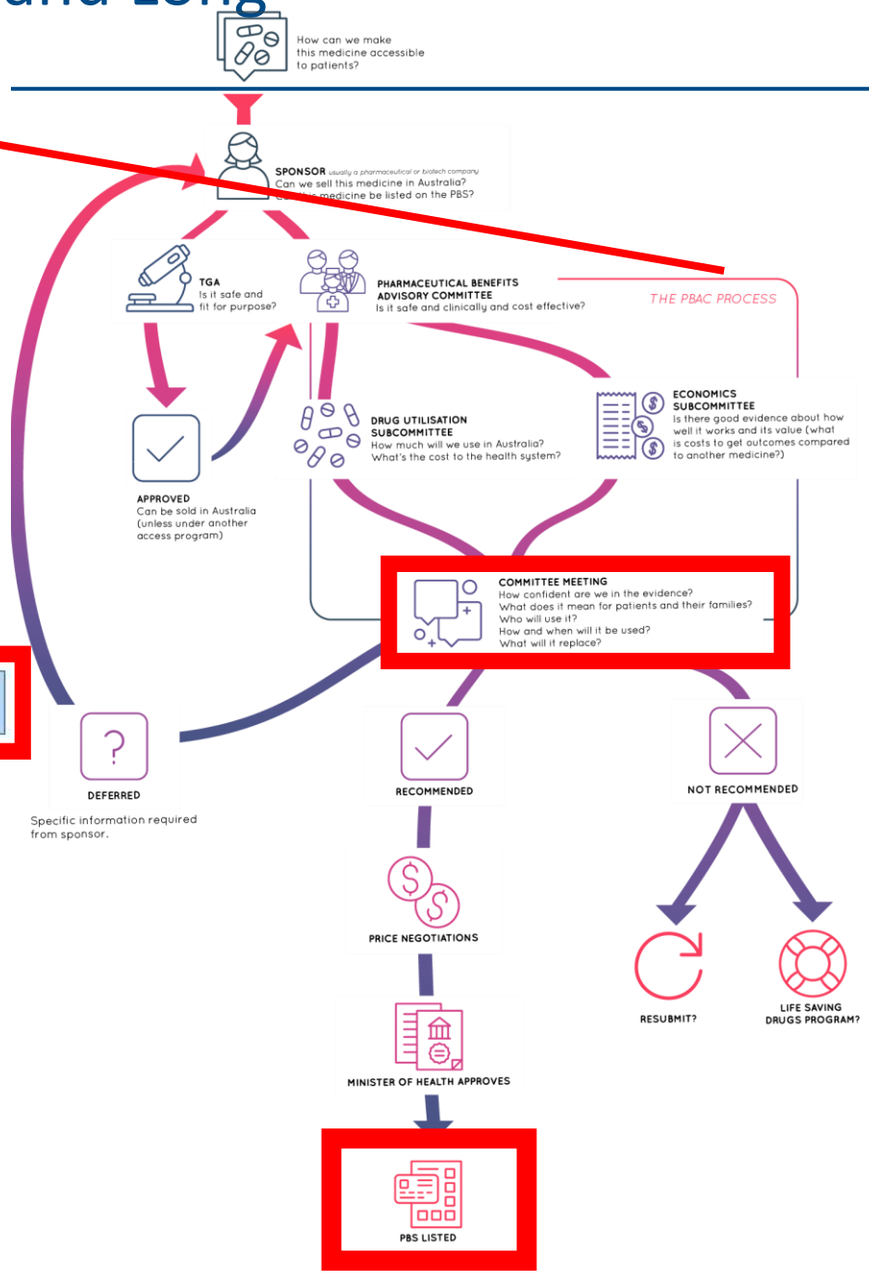
WEEK 31
Final Public Summary Documents to 'Responsible Persons'

WEEK 33
Publication of Public Summary Documents (positive and subsequent rejections)

WEEK 34
Submission due day for Facilitated Resolution Pathway resubmissions

WEEK 35
Publication of Public Summary Documents (first time rejections and deferrals)

WEEK 17
PBAC Meeting



Upto 1.5 years

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Sources: https://www.pbs.gov.au/info/industry/listing/procedure-guidance/2-listing-process/listing-process
https://www.patientvoiceinitiative.org/patient-experience-and-participation/pharmaceutical-benefits-scheme/

Elements of PBAC Submission?

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PBAC Information | Submission structure for submissions requiring evaluation | Requests for Product Types | Appendixes | Contacts

Guidelines for preparing submissions to the Pharmaceutical Benefits Advisory Committee (PBAC)

Version 5.0

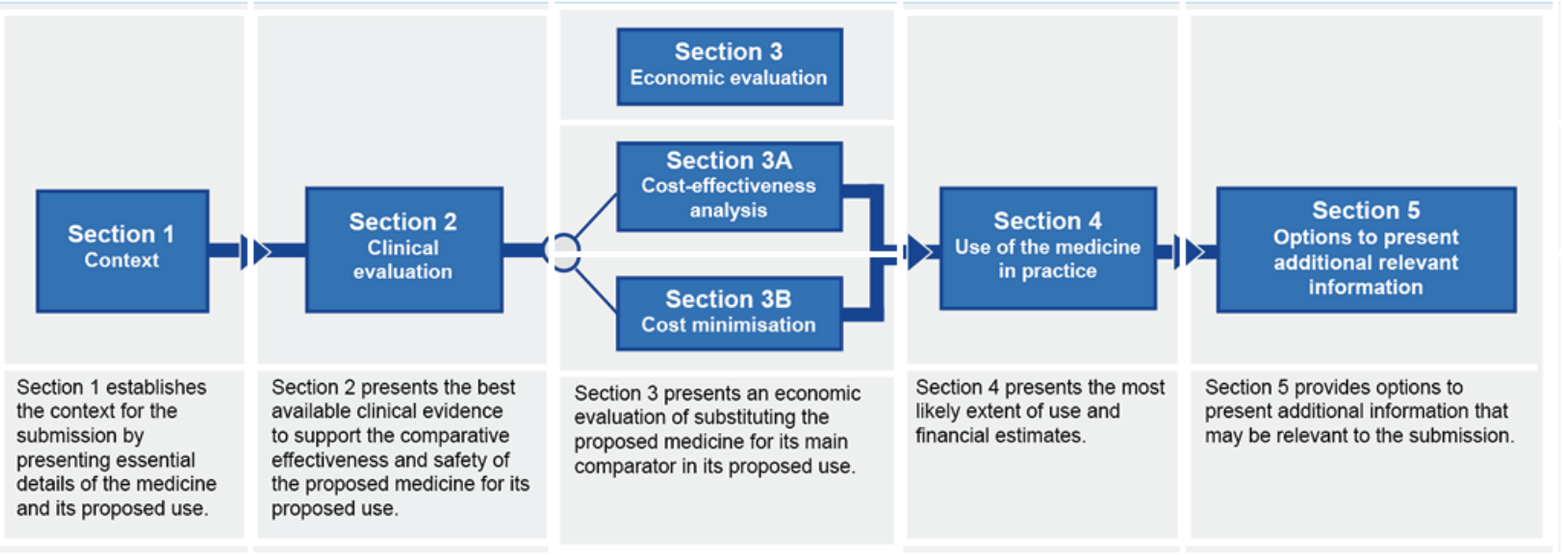
September 2016

The PBAC Guidelines explain in detail how to prepare a submission to list a new medicine or medicinal product on the Pharmaceutical Benefits Schedule (ie for public funding). The guidelines provide detailed instructions on what information is required by the PBAC and the Economic Sub-Committee (ESC) to support a proposed new medicine, and the most appropriate form of clinical evidence and economic evaluation for specific submissions.

Whilst submissions to the PBAC will now need to follow the guidance provided in the PBAC Guidelines version 5.0, the PBAC has approved a transitional arrangement of two PBAC cycles in regard to the structure of submissions. That is, submissions to the PBAC for consideration at either the March or July 2017 PBAC meetings may follow the structure of either version 4.5 or version 5.0 of the Guidelines. Submissions for consideration at the November 2017 meeting must follow the structure of version 5.0 of the PBAC Guidelines.

For information on processes, procedures, timelines and documents required, refer to the Procedure guidance for listing medicines on the Pharmaceutical Benefits Scheme.

Submission structure for submissions requiring evaluation



Source: https://pbac.pbs.gov.au/

Who is the PBAC and its Sub-committees

A-Z Medicines FAQ Subscribe Search for general PBS information

Australian Government Department of Health and Aged Care

PBS The Pharmaceutical Benefits Scheme

Enter a medicine, drug, brand name or item number PBS MEDICINE SEARCH

PBS Information | Browse the PBS | For Health Professionals | For Industry | News | Publications & Downloads | Contacts

Home / Industry / Listing / Participants / Pbac

Pharmaceutical Benefits Advisory Committee (PBAC) Membership

Page last updated: 14 September 2021

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.

PBAC has two sub-committees to assist with analysis and advice in these areas:

- Drug Utilisation Sub Committee; and
- Economics Sub Committee.

Contact details for the PBAC can be found in PBS Contacts

Agendas, outcomes and public summary documents of PBAC meetings can be found under elements of the listing process

See also

PBAC Agendas
PBAC Outcomes
Public Summary Documents

PBAC Membership
PBAC Executive
PBAC Contacts
PBAC Guidelines

Guidelines for Initiation of Stakeholder Meetings

Records of Stakeholder Meetings

Managing conflicts of Interest – PBAC and its subcommittees

Current Membership

Professor Andrew Wilson is the Chair of the PBAC. He has specialist professional qualifications in clinical medicine and public health medicine and a PhD in epidemiology.

Ms Jo Watson is the Deputy Chair of the PBAC. She is also the Chair of the Health Technology Assessment Consumer Consultative Committee, Deputy Chair of the Consumers Health Forum, and a long standing consumer nominee and advocate.

Dr Peggy Brown is a psychiatrist from Queensland and is a Fellow of the Australian and New Zealand College of Psychiatrists.

Ms Michelle Burke is the industry nominee. She has more than 20 years of experience in the pharmaceutical industry, contributing in areas which include access to medicines and industry development.

Professor Jonathan Craig is the Vice President and Executive Dean of the College of Medicine & Public Health at Flinders University, SA. He is also the President of the Australia-NZ Society of Nephrology, a member of the National Health and Medical Research Council (NHMRC) Advisory Group on the Synthesis and Translation of Research Evidence and a member of Medical Services Advisory Committee (MSAC).

Professor Christopher Etherton-Beer is a clinical academic in Geriatric Medicine at the University of Western Australia and is a Geriatrician/ Clinical Pharmacologist at Royal Perth Hospital. Professor Etherton-Beer has research interests in ageing and aged care, stroke, medical education and pharmaco-geriatrics. He is also Chair of the Drug Utilisation Sub Committee of the PBAC.

Source: https://www.pbs.gov.au/info/industry/listing/participants/pbac

Independent of government and industry

Consumer represented (PBAC co-chair = consumer)

PBAC

- 17 members (clinicians, health economics, pharmacy, consumers)

Economic Sub-Committee ESC) and Drug Utilisation Sub-Committee (DUSC)

- Up to 12-16 members with technical and clinical expertise

All supported by DoHAC Secretariats with very strong technical skills

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Post PBAC Process?

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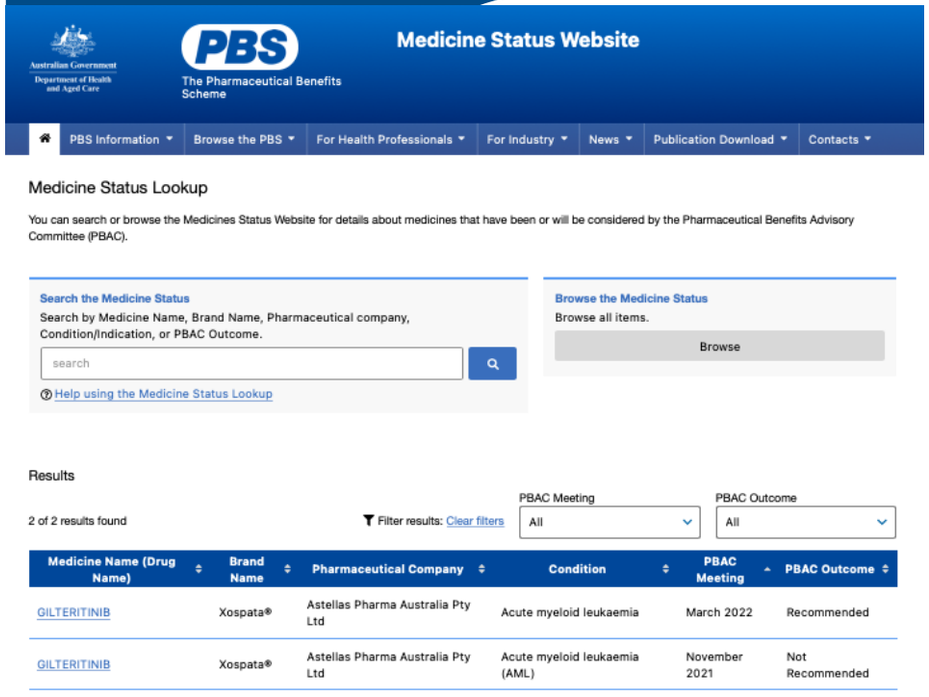
Positive PBAC Recommendation Procedures?

Documents submitted via HPP by Sponsor and Public Tracking via Medicines Status Website

What does the PBS listing process look like?

The below diagram provides an overview of the PBS listing process. Click each step of the below diagram to learn more.

1. Submission received for (date) PBAC meeting
2. Opportunity for consumer comment
3. PBAC meeting
4. PBAC outcome published
5. Lodgement of required documentation
6. Agreement to listing arrangements
7. Government processes
8. Medicine listed on the PBS



Medicine Status Website

The Pharmaceutical Benefits Scheme

PBS Information | Browse the PBS | For Health Professionals | For Industry | News | Publication Download | Contacts

Medicine Status Lookup

You can search or browse the Medicines Status Website for details about medicines that have been or will be considered by the Pharmaceutical Benefits Advisory Committee (PBAC).

Search the Medicine Status

Search by Medicine Name, Brand Name, Pharmaceutical company, Condition/Indication, or PBAC Outcome.

search

Help using the Medicine Status Lookup

Browse the Medicine Status

Browse all items.

Browse

Results

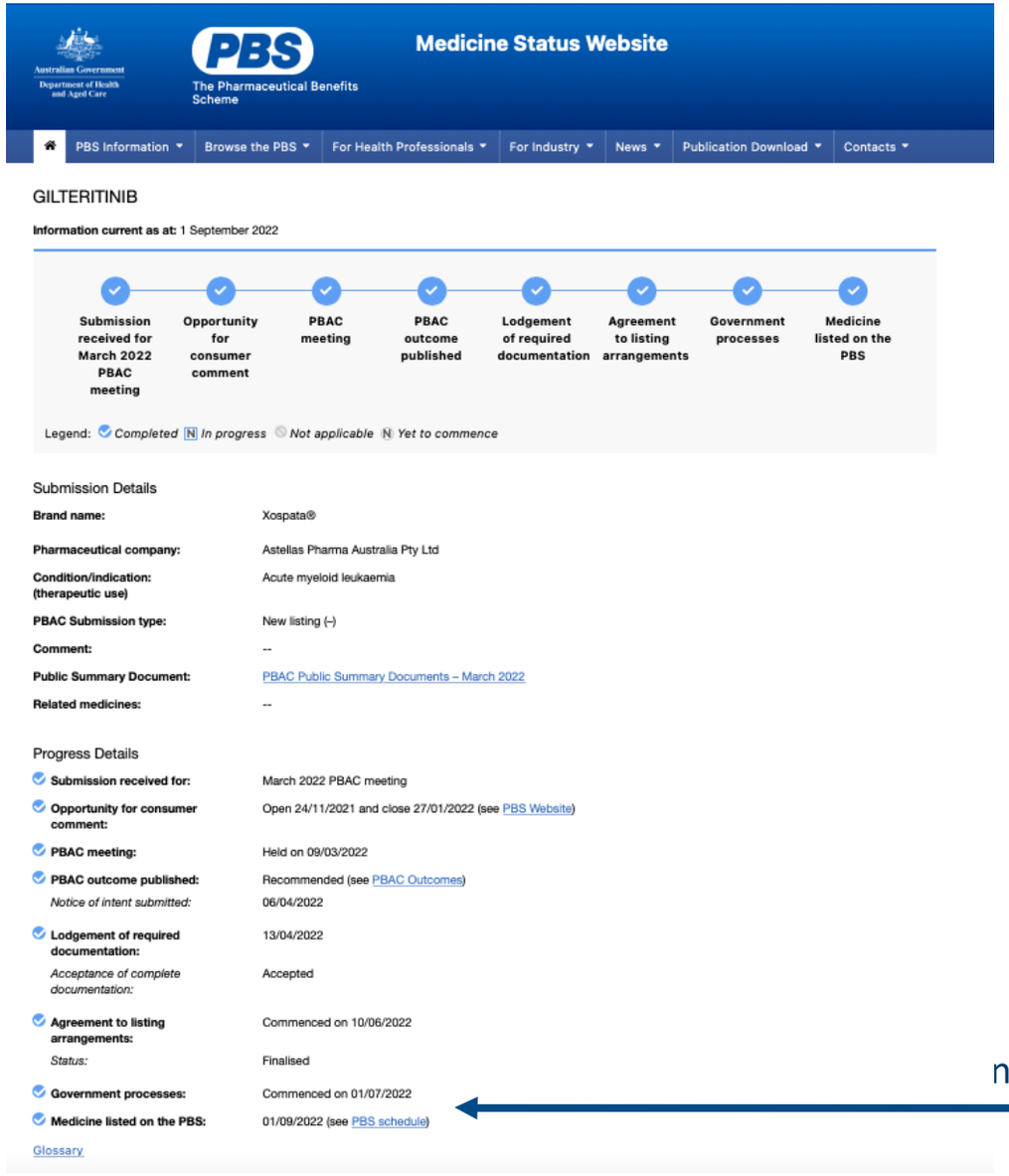
2 of 2 results found

Filter results: Clear filters

PBAC Meeting: All

PBAC Outcome: All

Medicine Name (Drug Name)	Brand Name	Pharmaceutical Company	Condition	PBAC Meeting	PBAC Outcome
GILTERITINIB	Xospata®	Astellas Pharma Australia Pty Ltd	Acute myeloid leukaemia	March 2022	Recommended
GILTERITINIB	Xospata®	Astellas Pharma Australia Pty Ltd	Acute myeloid leukaemia (AML)	November 2021	Not Recommended



Medicine Status Website

The Pharmaceutical Benefits Scheme

PBS Information | Browse the PBS | For Health Professionals | For Industry | News | Publication Download | Contacts

GILTERITINIB

Information current as at: 1 September 2022

Submission received for March 2022 PBAC meeting | Opportunity for consumer comment | PBAC meeting | PBAC outcome published | Lodgement of required documentation | Agreement to listing arrangements | Government processes | Medicine listed on the PBS

Legend: Completed | In progress | Not applicable | Yet to commence

Submission Details

Brand name:	Xospata®
Pharmaceutical company:	Astellas Pharma Australia Pty Ltd
Condition/indication: (therapeutic use)	Acute myeloid leukaemia
PBAC Submission type:	New listing (–)
Comment:	--
Public Summary Document:	PBAC Public Summary Documents – March 2022
Related medicines:	--

Progress Details

Submission received for:	March 2022 PBAC meeting
Opportunity for consumer comment:	Open 24/11/2021 and close 27/01/2022 (see PBS Website)
PBAC meeting:	Held on 09/03/2022
PBAC outcome published:	Recommended (see PBAC Outcomes)
Notice of intent submitted:	06/04/2022
Lodgement of required documentation:	13/04/2022
Acceptance of complete documentation:	Accepted
Agreement to listing arrangements:	Commenced on 10/06/2022
Status:	Finalised
Government processes:	Commenced on 01/07/2022
Medicine listed on the PBS:	01/09/2022 (see PBS schedule)

Glossary

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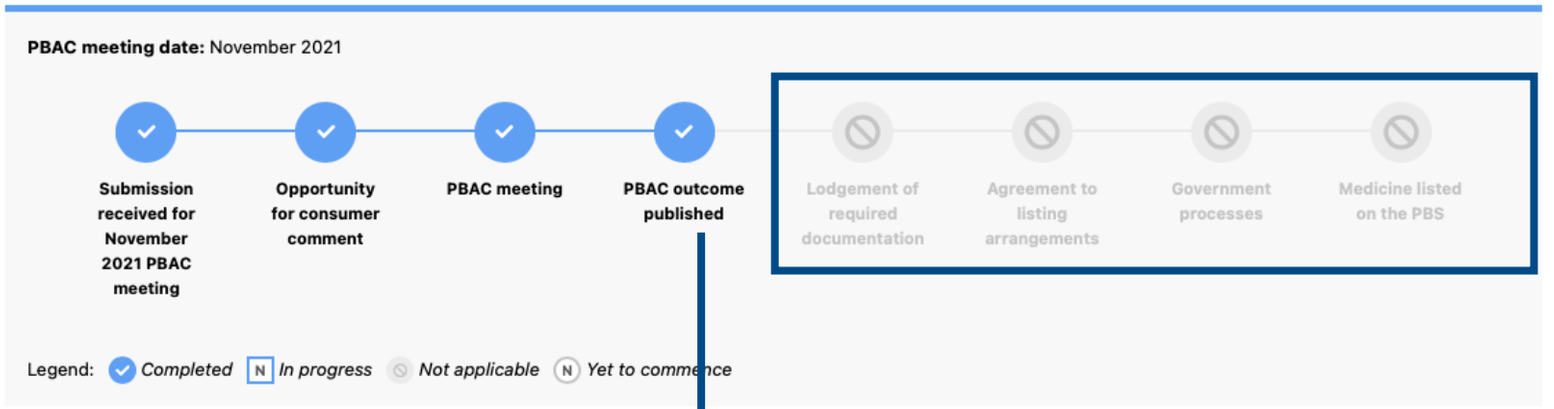
Negative PBAC Recommendation?



- Essentially start the submission process again
- The PBAC will nominate a resubmission pathway based on the PBAC's independent assessment of:

  1.the issues for resolution; and
  2.whether the medicine or vaccine represented High Added Therapeutic Value (HATV) for the proposed population:
    - the medicine or vaccine addresses a high and urgent unmet clinical need; and
    - the medicine or vaccine is expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity, over any alternative therapies.

Standard Re-entry Pathway

Early Re-entry Pathway

Early Resolution Pathway

Facilitated Resolution Pathway

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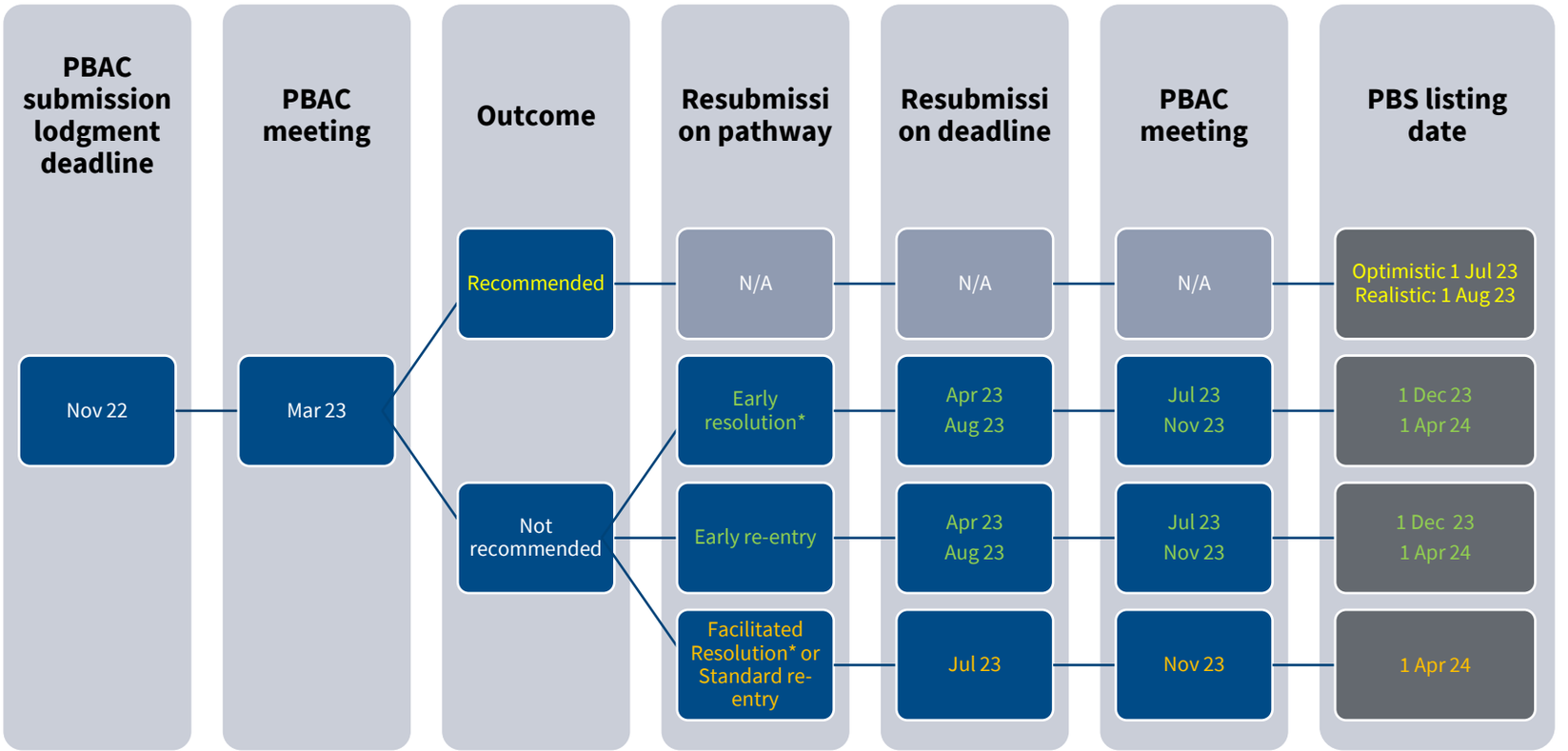
Source: https://www.pbs.gov.au/info/industry/listing/procedure-guidance/9-review-pbs-listings/9-1-Resubmission-pathways

Estimated time to reimbursement by PBAC Outcome Scenarios

Impact on DRUG X:

- Cost utility analysis to SoC/Placebo
- PBAC/DoH may request risk share agreement
- Not recommendation with Early Re-entry Resubmission is considered Base Case (1 Dec 2023 PBS listing)
- First time recommendation is considered Best Case (1 Aug PBS Listing)

Scenario	PBS list date
Best case (optimistic)	1 Jul 23
Best case (realistic)	1 Aug 23
Base case	1 Dec 23
Worst case	1 Apr 24



Assumptions	Likelihood
PBAC +ve Recommendation	Med
PBAC -ve Recommendation	High
PBAC Early Re-entry	Med
PBAC Standard re-entry	High
PBAC Minutes to SPONSOR Positive 1 April, Other 14 April	n/a
PBAC Outcome 22nd April 2023	n/a
PSD Positive – 1 Jul 2023 Others - 15 Jul 2023	n/a
PBS Listing Date 1 Dec 2023	Med

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* Assumes HATV criteria met

How does HTA Shape Access to Pharmaceuticals for Australians?

PATIENT ACCESS GAP AT A GLANCE

Between Jan '21 and Apr '26, the average time to access medicine + population pairings that were recommended by the PBAC in that period was...

712 DAYS

between registration and PBS listing.

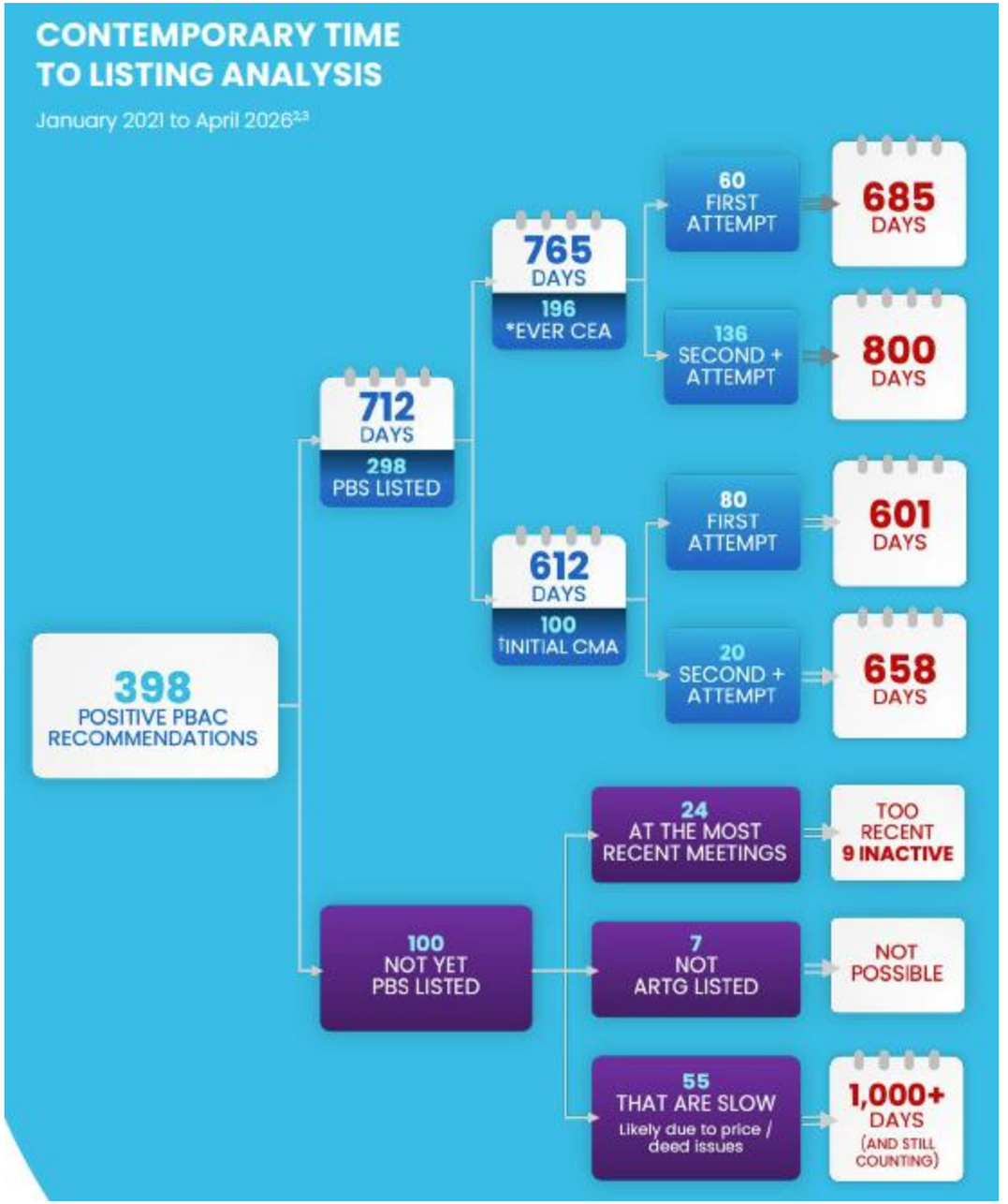
...of 'ever CEA' medicine + population pairings in this period required multiple attempts to secure a positive PBAC recommendation. **This is a major contributor to the delay.**

69%

Of the 114 medicine + population pairings that received a positive PBAC recommendation but were not PBS listed in this period, **55** are particularly slow – or inactive – with an access gap that is...

1,000+ DAYS

...and still counting.



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Source: AUSTRALIAN PATIENT ACCESS GAP TRACKER. Edition 9 - January 2021 to April 2026

What is the the MBS?

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What is the MBS

Medicare Benefits Schedule (MBS), a listing of the Medicare services subsidised by the Australian Government.

Why is the MBS Important?

- Provides patient access to affordable healthcare
- Influences market access and adoption of medical devices
- Essential for reimbursement and funding of new technologies
- Used in the outpatient setting – not in patient hospitals

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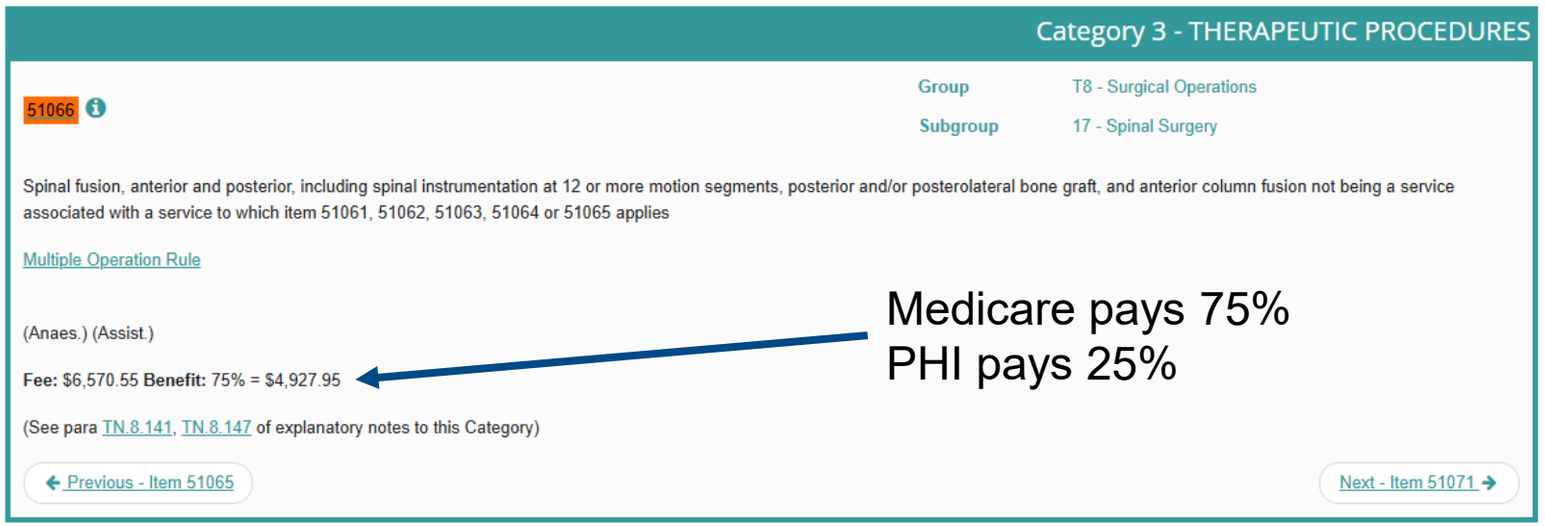
The Medicare Benefits Schedule (MBS)

Provides fee-for-service for health care professionals providing the service for which benefits are payable are engaged in private business

- Health care professionals can charge a gap on top of MBS fee
- Gap is paid by the patient (patient co-pay)
- Does not fund medical devices / equipment



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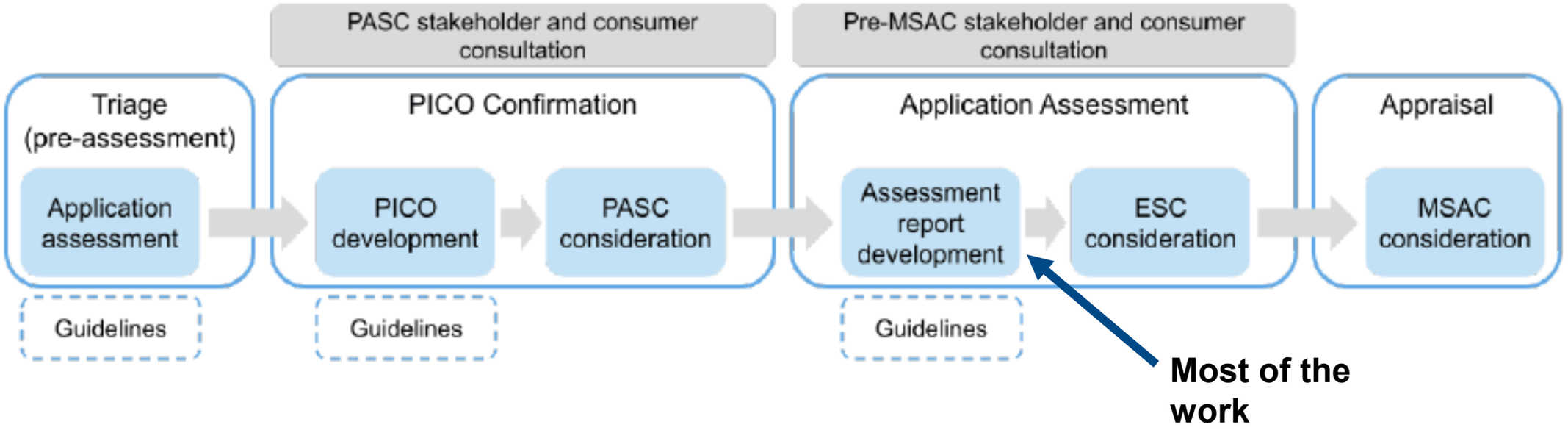
Experience Matters.

Medical Services Advisory Committee (MSAC)

- Committee that evaluates new procedures to include on the **Medical Benefits Schedule**
- Full HTA is usually required
- Less access to **contracted assessment**

Reimbursement application process for MSAC



Applicant lodges Application
Eligibility
Formulate PICO
Clinical endorsement

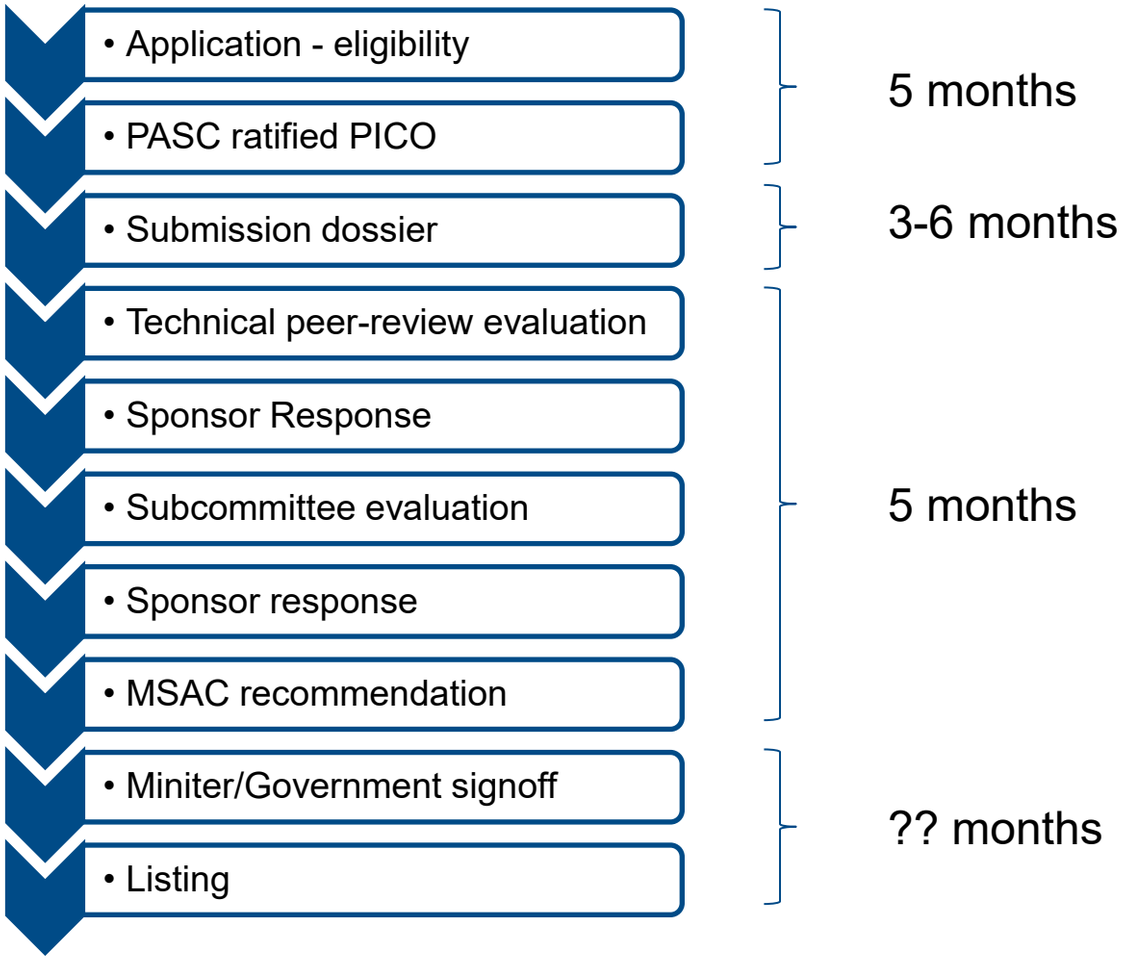
PICO developed by HTA group / Ratified by PASC
Applicant / experts part of the process

Applicant lodges ADAR
or
HTA group lodges DCAR (on behalf of Applicant)

Evaluation
HTA group
ESC
Applicant has opportunity to respond

ADAR, applicant developed assessment report; DCAR, Department Contracted Assessment Report

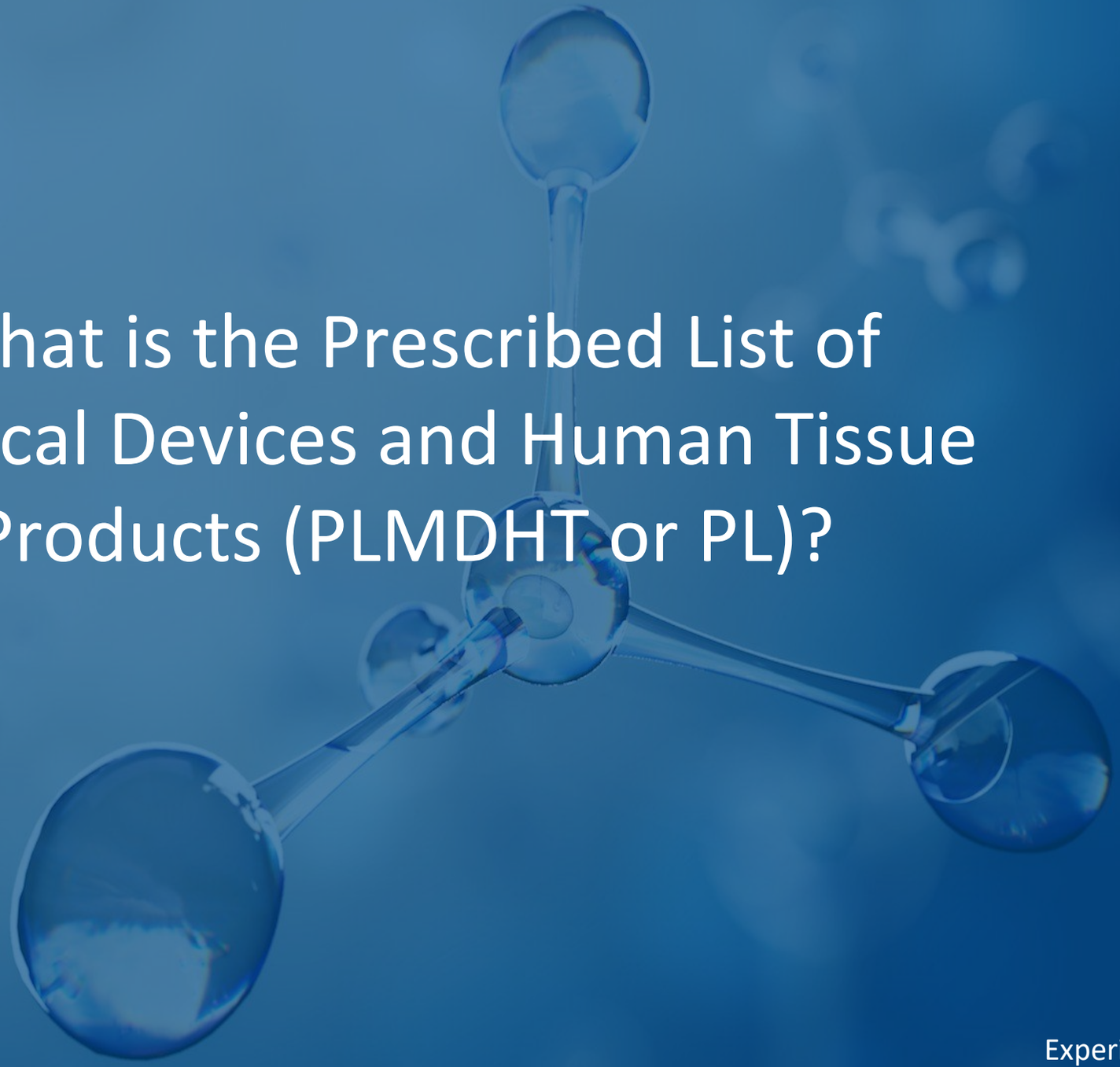
Timelines reimbursement application process for MSAC



MSAC Process – Our Recent Experience

- Very high evidence bar
- New technologies may be held to a higher standard than existing technologies
- Tendency for MSAC to have expectations of outcome measures or modelling not specified in the PICO
- If possible, try and anticipate any further requirements outside of the PICO
- Support of the clinician groups is critical and good engagement is imperative

What is the Prescribed List of Medical Devices and Human Tissue Products (PLMDHT or PL)?



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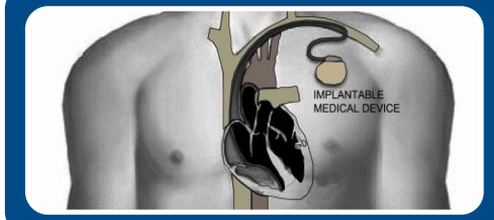
Private Setting: Who pays for what

Private Hospital

- Accommodation/theatre
- Funded by Federal/Private Health Insurance (PHI)

Medical service

- Doctor fee for service
- Funded by MBS (and some by PHI)



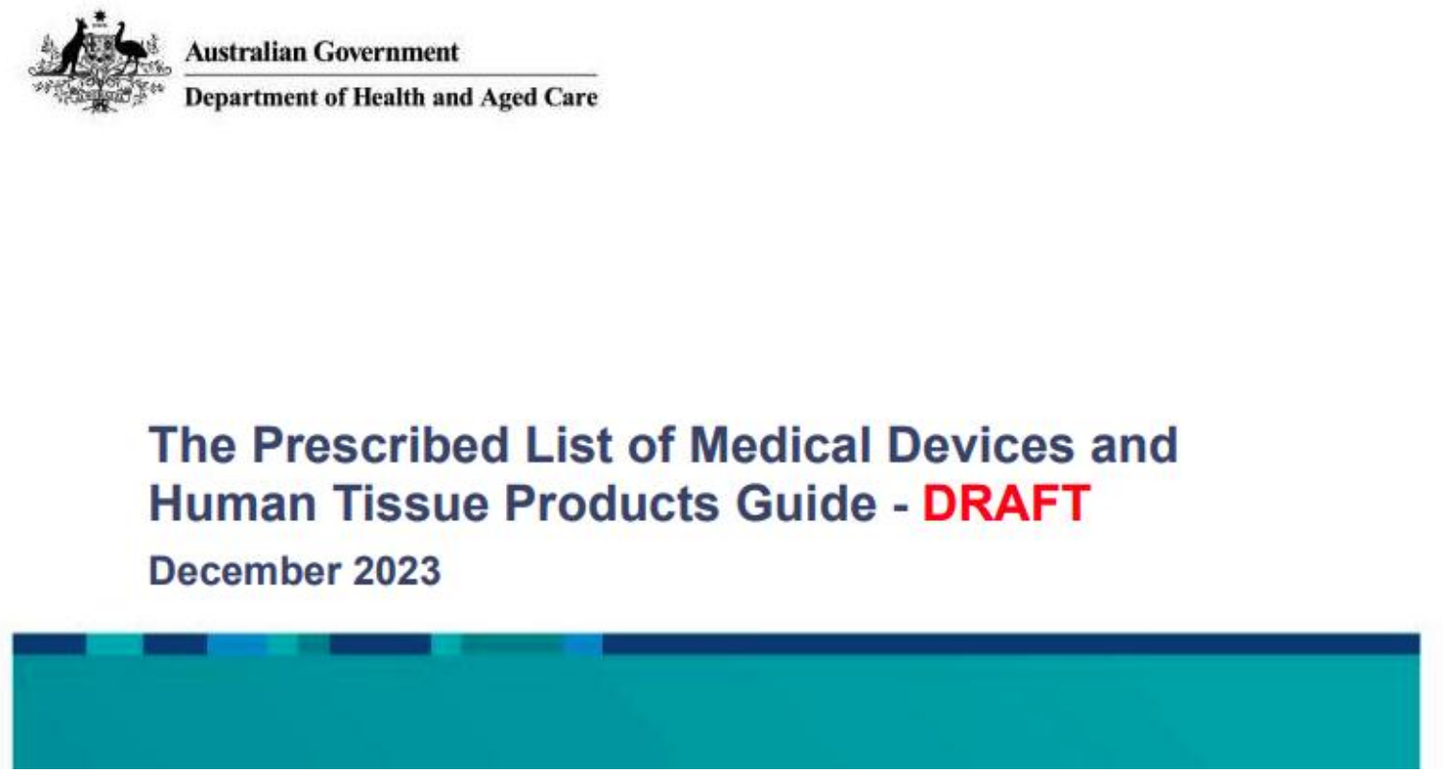
Implantable device

- Implantable device listed On Prescribed List (formerly Prostheses List)
- Funded by PHI

Medical Equipment

- Not funded by Commonwealth, minor equipment covered by MBS larger capital covered by hospital
- Cost often passed on to patients

Guide to prepare an application to the Prescribed List of Benefits for Medical Devices and Human Tissue Products



- The Guide to prepare an application to the Prescribed List of Benefits for Medical Devices and Human Tissue Products (the Guide) will assist applicants to prepare an application to list an eligible medical device or human tissue product on the Prescribed List of Benefits for Medical Devices and Human Tissue Products (the PL), or to amend an existing PL billing code.
- The information in this document is provided as a guide only.

Structure of the Prescribed List

A Part A

Medical devices
- not used for diagnosis, prediction or prognosis
- must be for a specific treatment and indication
- either surgically implantable or
- essential and specifically designed as an integral single-use aid for implanting a device or
- critical to continuing function of surgically implanted device

B Part B

Human tissue products that are
- substantially derived from human tissue, where the tissue has been subject to processing or treatments,
- whose supply is governed by state or territory law

C Part C

Medical devices
- specified groups stated in the Rules
- do not meet the listing criteria for Part A, but the Minister for Health and Aged Care decided to add these devices on the PL
- Currently include: insulin infusion pumps, ILR, remote monitors, cardiac ablation devices, vascular and cardiac eluting balloon catheters

D Part D

General Use Items

**These items are scheduled to be removed from the PL on 1 July 2024*

Application cut-off dates are midnights of the 2nd Sundays in January, May or September for the July, November and March (following calendar year) Prescribed List

Expert Clinical Advisory Groups (ECAG)

The ECAG assess clinical functions and comparative clinical effectiveness of medical devices in listing new applications or variation applications submitted through Tier 2 and Tier 3 pathways (or in different circumstances as required)

- **Specialist Orthopaedic ECAG (SOECAG)**
  (Including shoulder, ankle, foot, upper limb and skeletal reconstruction)
- **Spinal and Neurosurgical ECAG (SNECAG)**
- **Hip and Knee ECAG (HKECAG)**
- **Cardiovascular (CVECAG)**
  (Including cardiac, cardiothoracic and vascular)
- **Ophthalmic ECAG (OECAG)**
- **General Surgery (GSECAG)**
  (Including ear, nose and throat, plastic and reconstructive surgery, urogenital and all other general surgery devices)

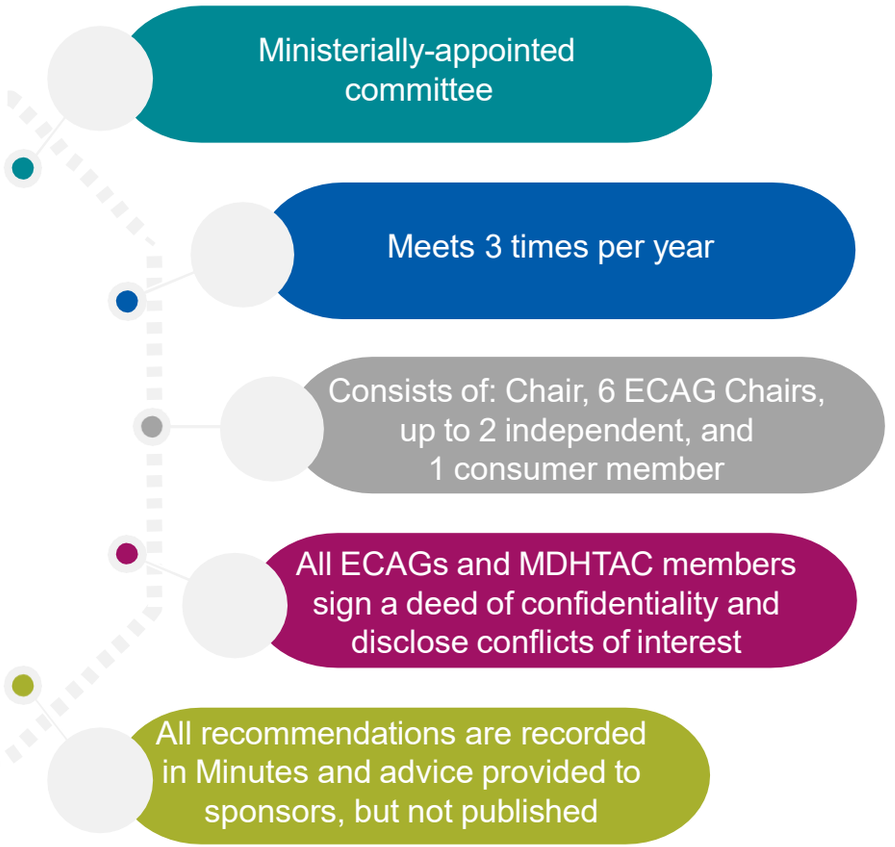
Medical Devices and Human Tissue Advisory Committee (MDHTAC)

The MDHTAC provides recommendations on:

- suitability of devices for listing and associated benefits
- amending of existing billing codes
- other matters

MDHTAC considers:

- eligibility
- correctness of the grouping
- criteria for listing [including comparative clinical effectiveness, comparative cost-effectiveness as applicable
- predicted use
- financial implications for the PL
- and other related matters

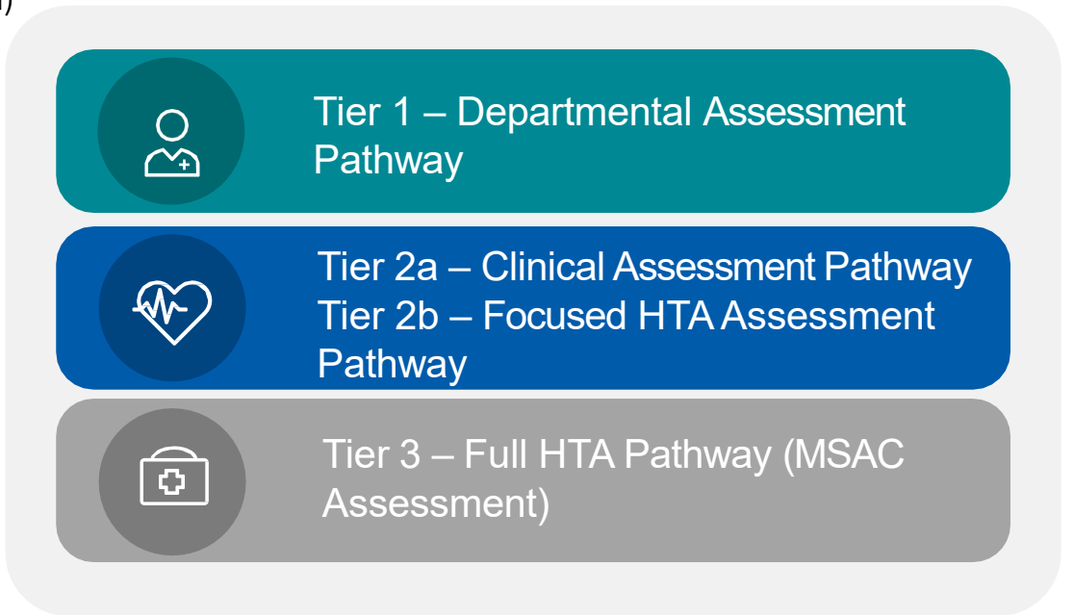


Source: Prescribed List Application Training, DoHAC 2023

Prescribed List – Application Type Overview

- In September 2022, the Department of Health released the proposed new listing pathways for the Prosthesis List
- These pathways grouped pre-listing assessments of PL applications into three tiers:
  - Tier 1 – Departmental Assessment Pathway (medical devices classified by the TGA as **Class IIb or lower**, and they are well-established technology
  - Tier 2 Clinical/Focused HTA Pathway includes the devices classified by the TGA as **Class III**, or any Part C applications separated into two components to reflect the varying levels of HTA involvement of external expertise:
    - Tier 2a – clinical assessment only
    - Tier 2b – a clinical assessment plus health economic evaluation
  - Tier 3 – Full HTA Pathway (via MSAC and MSAC Application)

Tiered assessment pathway



QUESTIONS ???

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