Australian Government
Department of Health, Disability and Ageing

The Prescribed List Post-listing Review Framework

January 2026

Version control

This table is to record the document's history as changes are made. As each version is drafted and submitted for acceptance, update the version number and in the table record the changes made to the prior version.

Major changes should increment the version number by 1.0 and minor changes should increment the version number by 0.1.

Version	Date	Author	Distribution	Change description
1.0	June 2022	Department of Health and Aged Care	Online publication	Draft version
2.0	December 2024	Department of Health and Aged Care	Online publication	Final version
2.1	January 2026	Department of Health, Disability and Ageing	Online publication	Minor updates to: -clarify when we will seek stakeholder input -reflect name changes to, and within the department

Document location

Department of Health, Disability and Ageing website: Prescribed List post-listing review framework | Australian Government Department of Health, Disability and Ageing

Related documents

Document Location	Document name
Online	Prescribed List Guide of Medical Devices and Human Tissue Products
Online	Prescribed List Compliance Strategy

Contents

Abbreviations and acronyms

ACCC	Australian Competition & Consumer Commission
ARTG	Australian Register of Therapeutic Goods
department	The Department of Health, Disability and Ageing
device	Medical device
ECAG	Expert Clinical Advisory Group
framework	Post-listing review framework
HPP	Health Products Portal
HTA	Health Technology Assessment
MSDAB	Medical Services and Device Assessment Branch
MBS	Medicare Benefits Schedule
MDHTAC	Medical Devices and Human Tissue Products Advisory Committee
MRAC	MBS Review Advisory Committee
MSAC	Medical Services Advisory Committee
PHI	Private health insurance
PL	Prescribed List
PL executive	Assistant Secretary responsible for the Prescribed List
product	Human tissue product
TAAD	Technology Assessment & Access Division
TGA	Therapeutic Goods Administration

1. Background

The Australian health system operates under a mixed model of private and public health care, with private health insurance and private hospitals playing an important role. Australians with private health insurance may choose to receive care as a private patient in a public or private hospital.

The Prescribed List of Medical Devices and Human Tissue Products (the PL) is a list of medical devices and human tissue products (devices and products) for which private health insurers must pay minimum benefits when these devices or products are provided to or used for a privately insured patient in a hospital or hospital substitute setting. The purpose of the PL is to ensure that privately insured Australians who have appropriate health insurance cover have access to clinically effective devices or products that meet their healthcare needs.

The arrangements for listing products on the PL help to ensure that the benefits paid by insurers are relative to comparative clinical effectiveness and are comparable to prices paid in other sectors. For further information see the *Prescribed List of Medical Devices and Human Tissue Products Guide.*

In the 2021-22 Budget, the Australian Government announced an investment of $22 million over four years to improve the PL and its arrangements. A process for formalised post-listing reviews was introduced as part of the reforms aimed at safeguarding the settings of the PL.

Details of current and completed post-listing reviews are available on the PL post-listing review website.

1.1 Introduction

The Department of Health, Disability and Ageing (the department) administers the PL.

The department, through the Prescribed List Administration Section, assesses applications for a device or product to be listed on the PL. A recommendation for listing on the PL is based on the evidence and clinical context available at the time of assessment. Over time, new information may become available that raises uncertainties about device eligibility or the benefits payable for a device. For example, clinical guidelines may change, new devices may become available and/or data on safety, effectiveness or usage may become available. Post-listing reviews of devices on the PL contribute to ensuring that Australians, with relevant health insurance cover, continue to have access to appropriate clinically effective devices that meet their healthcare needs.

Post-listing reviews can be initiated at any time after an item is listed on the PL. This post-listing review framework (the framework) provides a systematic and transparent approach to evaluate devices on the PL and implement measures to address identified issues.

Benefits continue to be payable during a review. Any changes to benefits, that occur as a result of the review, will apply after the review outcome is implemented.

1.2 The post-listing review framework

The framework described in this document relates to post-listing reviews for devices listed on the PL. The purpose of the framework is to promote a consistent approach for each review while providing flexibility to accommodate different review requirements. It is not intended to be prescriptive. A post-listing review may use a range of methodologies depending on the review scope and Terms of Reference (ToR). Information on timeframes for each review and how stakeholders can be involved will be communicated on the post-listing review website as it becomes available.

The PL compliance strategy is consistent with the operation of this framework.

Any PL reforms related matters, including post-listing review and framework updates are communicated via Private Health Insurance (PHI) circulars. To receive PHI circular notifications, or to provide feedback on the framework or the post-listing review process please contact us via prescribedlist.reviews@health.gov.au.

The framework is divided into 3 sections - activities preceding a review, the review process and implementing outcomes.

1.2.1 Framework development

The framework was developed:

- considering the post market review processes and frameworks from other areas of the department
- consulting with stakeholders
- aligning with the objectives of the PL reforms.

The initial framework was used to guide 4 pilot post-listing reviews which commenced between 2022 and 2024. After the pilot post-listing reviews were completed, participating stakeholders were asked for feedback on their experience with the process. This targeted feedback, general stakeholder feedback and internal department experience was used to adjust the initial framework.

2. Governance

2.1 Role of the responsible Minister

The Minister for Health, Disability and Ageing (the Minister) is responsible for the administration of the *Private Health Insurance Act 2007* (PHI Act). The Minister makes decisions on whether to list a device or product on the PL, subject to an application being made or to amend the existing billing code or to place a condition on an existing billing code. The Minister is responsible for giving effect to these decisions by making or updating the *Medical Devices and Human Tissue Product Rules (MDHTP Rules)*.

Under section 333-1 of the PHI Act, the Minister may delegate responsibility to people occupying certain positions within the department (the Delegate). The Delegate makes decisions about implementing the findings from a post-listing review.

2.2 Role of the department

The PL Assurance team oversees post-listing reviews. This includes:

- managing the process for identifying and prioritising review topics
- preparing agenda papers and workplans seeking advice from the Medical Device and Human Tissue Advisory Committee (MDHTAC)
- establishing ToR for a review
- conducting research including utilisation reviews
- establishing a reference group if requested by the PL executive
- procuring and managing contracts for research and assessment conducted by external consultants
- undertaking public consultation
- drafting, reviewing and/or editing a post-listing review report.

The PL executive:

- approves the ToR for each review
- approves commencement of a review
- makes formal appointments of expert advisors to a reference group if required
- will determine the number and type of reviews on the workplan to be completed at any time.

2.3 Role of the MDHTAC

The primary role of the MDHTAC is to make recommendations to the Minister and advise the department about:

- the suitability of a device for listing, and their associated benefits
- amending an existing billing code
- any other post-listing activities as required.

The MDHTAC may also recommend placing a condition on an existing billing code restricting the circumstances in which the insurers are obliged to pay benefits for the billing code. For example, limiting payment to the use of the device in the procedures described by specified MBS items.

When making recommendations, MDHTAC considers the eligibility of a device for listing on the PL, the criteria for listing, the correctness of the grouping for all devices in the application, comparative clinical effectiveness, comparative cost effectiveness, predicted use, financial implications on the PL, and other related matters.

The MDHTAC's recommendations use the best available evidence compared with similar devices already listed on the PL or alternative treatments. The MDHTAC may request further information from the department or from sponsors to inform their recommendation.

The MDHTAC membership and ToR can be found on the department's website.

2.4 Role of the Expert Clinical Advisory Groups (ECAGs)

The ECAG are subcommittees of the MDHTAC, with membership that reflects a broad cross-section of contemporary clinical practice in Australia. The primary role of the ECAG is to assess the clinical functionalities and comparative clinical effectiveness of devices (and in some cases products) or for existing billing codes.

The ECAG also consider the comparator listed on the PL or alternative treatment, and appropriateness of the proposed groupings, and advise on the correct grouping (where required) and other matters as applicable.

There are currently 6 ECAG that represent different clinical specialities. The ECAG membership and ToR can be found on the department's website.

2.5 The role of other areas in the department

At any stage in the review process, other areas in the department may be involved including but not limited to the those discussed below.

2.5.1 The Therapeutic Goods Administration (TGA)

The department will refer to the TGA when safety, performance and/or associated regulatory issues are reported. Some reviews may occur simultaneously with a TGA review. In such instances, MSDAB will work with the TGA and the TGA findings will be a major consideration for the review. TGA activities may have flow-on effects for the PL, including when there are changes to the Australian Register of Therapeutic Goods (ARTG). If a device is cancelled from the ARTG it will be removed from the PL.

2.5.2 The Medicare Benefits and Digital Health Division (MBDHD)

The MBDHD may raise PL usage issues or provide requested data on Medicare billing to support reviews. As outlined in the table under subsection 72-1(2) of the PHI Act, a PL benefit must be paid for the provision of a listed device or product if it is provided as part of an MBS

service. The MBDHD may also be provided with communications following reviews that may help inform development of the Medicare Benefits Schedule (MBS). The Medical Services Advisory Committee (MSAC) and MBS Review Advisory Committee (MRAC) are committees that inform the MBS. More information can be found on the MSAC website and MBS MRAC website

2.5.3 Health Systems Strategy Division (HSSD)

The HSSD may provide data as part of reviews, such as Hospital Casemix Protocol data.

3. Activities preceding a post-listing review

3.1 Potential triggers of a post-listing review

A review may involve a single device, a class or category of devices, or multiple classes of devices. A review may be initiated at any time, and be triggered by a number of issues including, but not limited to:

- concerns the device is not in the appropriate grouping on the PL
- concerns about comparative clinical effectiveness
- concerns about comparative cost-effectiveness
- use that appears inconsistent with the evidence provided by the sponsor when the device was listed

These issues may be identified through a number of sources (in no particular order), including:

- recommendations from MDHTAC or ECAG
- recommendations from other advisory committees, such as MSAC, MRAC
- findings from HTA or other reports
- a request by the Minister or the PL executive
- advice from the PHI industry
- an academic publication or media release
- a request by a stakeholder, such as clinicians or consumer groups
- government sources (for example, the TGA)
- a request by medical device sponsors or other industry representatives
- surveillance of PL data
- referral of issues from other internal or external stakeholders
- outcome of compliance activities.

The department may request evidence from sponsors, stakeholders, complete preliminary research and/or seek advice from MDHTAC or ECAGs to inform the ToR and prioritise potential post-listing review topics.

3.2 Terms of Reference (ToR)

A ToR will be developed for each post-listing review. The ToR will outline the key issues and focus of the post-listing review, including the research questions the review is proposing to address. The ToR will describe the type/s of Health Technology Assessments (HTA) that will be used to answer each research question. A review may occur in multiple stages involving multiple HTAs. These may include:

- Internal review: may involve review of internal data, publicly available research and data provided by device sponsors and other stakeholders.

- Economic analysis: to analyse the impact of actual device use, the cost of comparators, downstream costs of the device or comparators.
- Literature review: to look at comparative clinical effectiveness and/or comparative cost effectiveness of a device/s.
- Utilisation review: analysis of utilisation data about how the device is used in practice compared to the intent when the device was listed.
- Other HTAs.

The department will prepare the ToR for each review seeking advice from MDHTAC/ECAG where appropriate. Sponsors and stakeholders may be invited to provide information and evidence to inform the ToR.

Relevant areas of the department such as the TGA and/or the Medicare Benefits and Digital Health Division (MBDHD) may also be asked to provide input.

An ongoing review does not necessarily interrupt or prevent the usual application processes for new or amended listings of devices on the PL. However, new devices that are recommended for PL listing during a review may be affected by any subsequent recommendations arising from the review.

The PL executive approves the ToR for each review. Once approved the ToR will be published on the department's website The ToR may be modified at any time after approval, if it is identified that the scope of the review needs to be expanded or refined.

3.3 Post-listing review workplan

The department will maintain an annual workplan of post-listing review topics. The workplan will include the post-listing review topic, area of concern and estimated project timeline. The workplan will be prioritised by the department seeking advice from MDHTAC where appropriate. The workplan will be available on the department's website and updated on a regular basis.

Factors that may be considered (in no particular order) to assist with prioritising topics include:

- concerns about comparative clinical effectiveness
- concerns about comparative cost-effectiveness
- concerns about use outside the intent of the PL listing
- available data to investigate identified issues
- available resources to undertake the review
- capacity of the department to resolve the issues and implement outcomes
- impact of potential interventions on the issue raised
- urgency of a gap in clinical care and/or service provision
- extent of public interest
- magnitude of the issues raised balanced against the resources required to address them

- priorities of the Australian Government.

The PL executive will determine the number and type of reviews on the workplan to be completed at any time. The department may also consider additional topics, not on the workplan, at any time, as concerns/issues arise. When considering the workplan the PL executive may decide:

- not to undertake a review at the present time
- to monitor an issue, maintain on the workplan and consider a review at a future date
- to consult and make relevant changes to PL listing based on available information
- to ask for more information before deciding to progress a review, such as:
    - requesting information from sponsors (including clinical evidence or product information) or other sources
    - examining use of the device
    - assessment of clinical evidence.

Any changes to the workplan will be communicated via updates on the department's website and alerts via PHI circulars.

Following consideration of the workplan the PL executive will approve the commencement of a post-listing review. A post-listing review is considered to have commenced when the review is announced online. Relevant sponsors will be advised after the decision to commence a post-listing review.

4. Post-listing review process

4.1 Review commencement

Once approved, further details, including timeframes for consultation, will be posted on the post-listing review webpage and announced in a PHI circular. All sponsors with devices included in the review will be notified by email.

4.2 Evidence collation and evaluation

A post-listing review considers the most recent and relevant evidence on comparative clinical and cost effectiveness and utilisation guided by the questions and scope outlined in the ToR.

Most post-listing reviews will involve an internal review and/or literature review. Activities may be undertaken by an external consultant with demonstrated subject matter and technical expertise or by the department.

Research activities may include:

- reviewing clinical evidence provided by sponsors and/or from a literature search
- obtaining and analysing data from internal and external sources
- considering PL eligibility and compliance matters
- obtaining clinical, economic or policy advice
- considering communications obtained from different sources
- undertaking a HTA or systematic review
- undertaking an impact assessment.

4.2.1 Data sources

The following data sources may be used in a review:

- data provided by sponsors
- product information
- Hospital Casemix Protocol data (submitted by private insurers to the department under the PHI Act)
- data from the Independent Health and Aged Care Pricing Authority (IHACPA)
- Australian Prudential Regulation Authority (APRA) data
- MBS data
- Prostheses List Management System (PLMS) data and/or Health Products Portal (HPP) data
- data from peer reviewed publications
- registry data
- publicly available information
- data from reports or investigations conducted by other agencies.

4.2.2 Targeted consultation

The department will determine the stakeholder consultation approach for each review, ensuring the principles of transparency and procedural fairness are upheld and accounting for commercial-in-confidence information. Targeted consultation may be undertaken by the department, or an external consultant at any point of the review process. The timeframe for consultation will depend on the nature of each review, but the standard submission period will be 2-6 weeks.

Stakeholders from the following sectors may be invited to provide information and evidence to be considered as part of the review (in no particular order):

- medical device industry
- private health insurance
- private hospitals
- clinicians and other health professionals
- consumers
- medical associations, or colleges/societies.

Evidence and information provided by sponsors (on invitation) may be used to prepare standalone reports. These reports may be provided to stakeholders for feedback (accounting for commercial-in-confidence information). Summaries from these reports may be included in the department report.

Stakeholders may be invited to participate in:

- meetings
- interviews
- written submissions.

Evidence provided by stakeholders should be the best quality available, noting it would be subjected to critical analysis. Evidence on the effectiveness of a device outside the clinical trial setting and evidence not provided during the assessment process is valuable.

4.3 Expert advice

The department may seek expert advice to provide input into any aspect of the post-listing review at any stage. This is in addition to the department seeking expert advice from committees such as MDHTAC or ECAG. The department requires all expert advisors to declare any conflicts of interest.

If required, experts will be selected based on their relevant expertise and may include:

- clinicians
- researchers
- health professional organisations representatives (associations/colleges)
- health economic and HTA specialists
- health educators
- consumer representatives

- industry group representatives.

The nature and extent of expert advice sought will be proportionate to the risk and complexity of the review and departmental resources. Expert advice may involve a formal request for a written commentary, verbal advice in meetings, workshops or roundtables or other forms of written or verbal advice. Expert commentary or advice will generally not be provided to stakeholders for feedback. In some instances, the PL executive may make formal appointments of expert advisors to a reference group. Appointment will follow departmental processes. If a formalised reference group is appointed, information on membership will be published on the department website after the relevant review is published.

The department may request expert advice at any time during the review.

4.4 Department report

The department report incorporates the results from the post-listing review process. The department report may be prepared by the department and/or an external consultant.

The department report may include:

- background to the issue
- methods used to collect and analyse evidence and other information
- results/summary of evidence and consultation
- economic analysis
- expert opinion
- findings and/or outcomes
- impact assessment

The department will complete an impact assessment prior to presenting findings and/or outcomes to the Delegate. An impact assessment allows the department to make an informed analysis of proposed recommendations. Key stakeholders will be invited to participate in the impact assessment. The impact assessment will inform the timeframe for implementing any review outcomes.

4.5 Review outcomes

The department will consider the department report, outcomes of the impact assessment, and expert/committee advice to determine the final outcomes for consideration by the Delegate. Outcomes will align with the research questions and the ToR.

The recommended actions and outcomes will be included in a final review report that will be published on the website. Outcomes may include a range of actions that can be implemented through existing PL processes. These include:

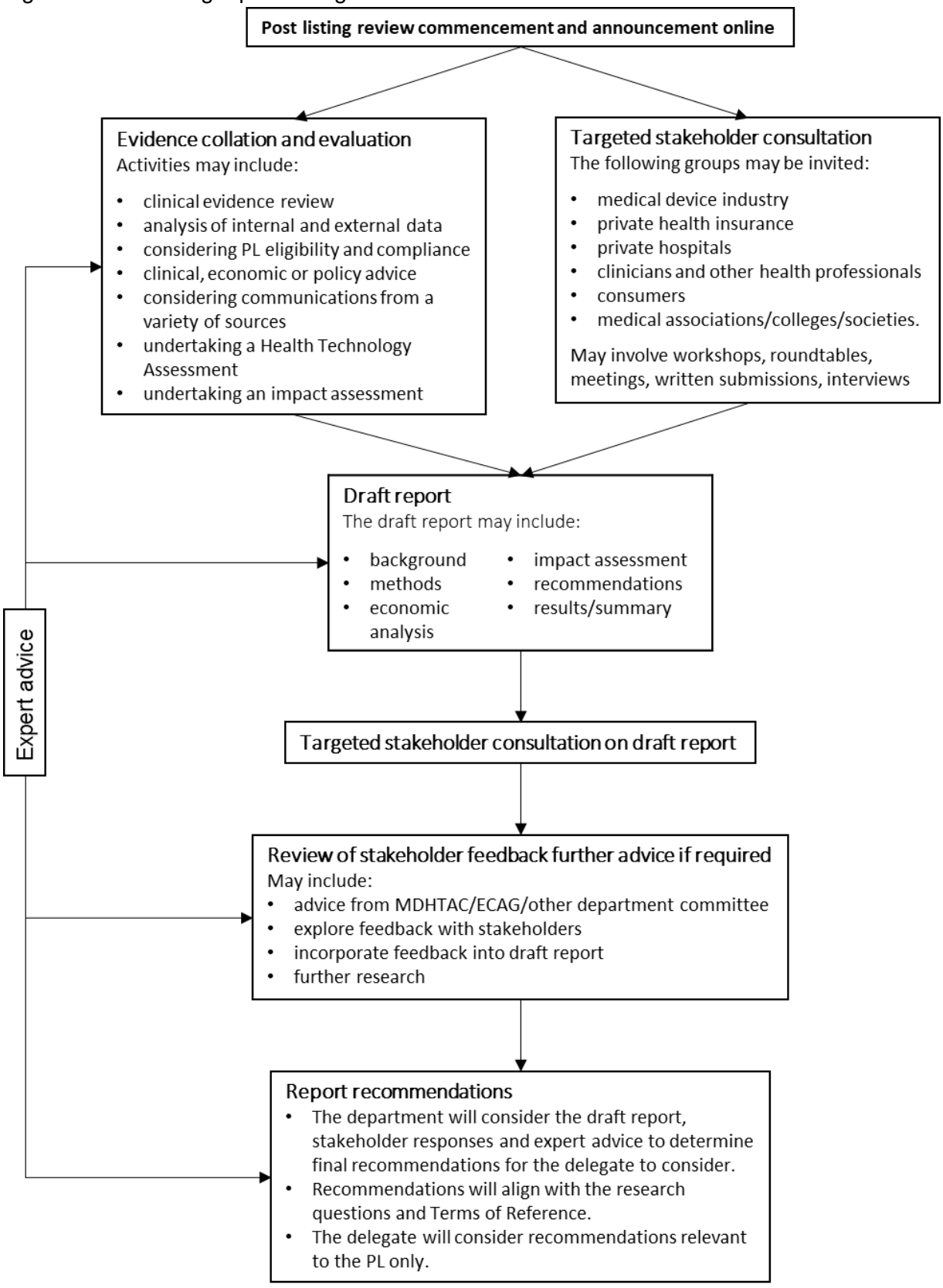
- taking no action (no changes to PL listing)
- change to the PL benefit

- apply a condition to the PL listing
- remove billing code/s from the PL
- referral to other regulators (e.g. TGA, ACCC)
- the continued monitoring of clinical evidence and/or utilisation patterns
- a request for more information/analyses to be provided
    - stakeholders and/or sponsors would be provided with relevant background information and invited to submit a further response.

Recommendations from the review that do not directly relate to the PL will be shared with the most relevant department/organisation. These may include:

- recommend relevant clinical organisation/s consider updating clinical guidelines and/or provide relevant messages to clinicians
- education for health professionals or consumers
- recommend relevant organisation/s consider establishing a device registry or other quality initiative
- recommending changes to MBS items associated with the device/s

Figure 1. Conducting a post-listing review



5. Implementing outcomes

Impacted sponsors will be notified of decisions arising from the review outcome via email. All other stakeholders will be notified by PHI circular. The notification will include a plan for implementation, including any final decisions and relevant timeframes.

A post-listing review is considered complete when the outcome is announced on the department's website.

In some cases, regulatory changes can result in unintended consequences that may impact consumers. We encourage stakeholders to keep the department informed about any unintended consequences by contacting prescribedlist.reviews@health.gov.au

Health.gov.au

All information in this publication is correct as at January 2026