

# Changes to the Prostheses List timeframes (2023/24)

Prostheses List Reform



Australian Government  
Department of Health

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# Housekeeping

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Questions can be posted at any time during the webinar but will be answered after our presentation.

Out-of-scope questions (not related to the topics discussed today) will not be addressed at this webinar.



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# What to expect from this webinar

1. Overview of the timing and impact of bypassing the March 2024 update.
2. Information on the Prostheses List reforms and consultations planned for 2023.
3. Opportunity for stakeholders to ask questions or raise concerns about the proposed changes.



# Prostheses List (PL) Reforms and the HPP

The parallel development of the PL Reforms and the HPP presents an opportunity to align the transition of reforms from a policy perspective with the transition to the HPP from a process and technology perspective.

## Prostheses List Reforms

The Prostheses List Reforms currently in development will update four key elements of the Prostheses List:

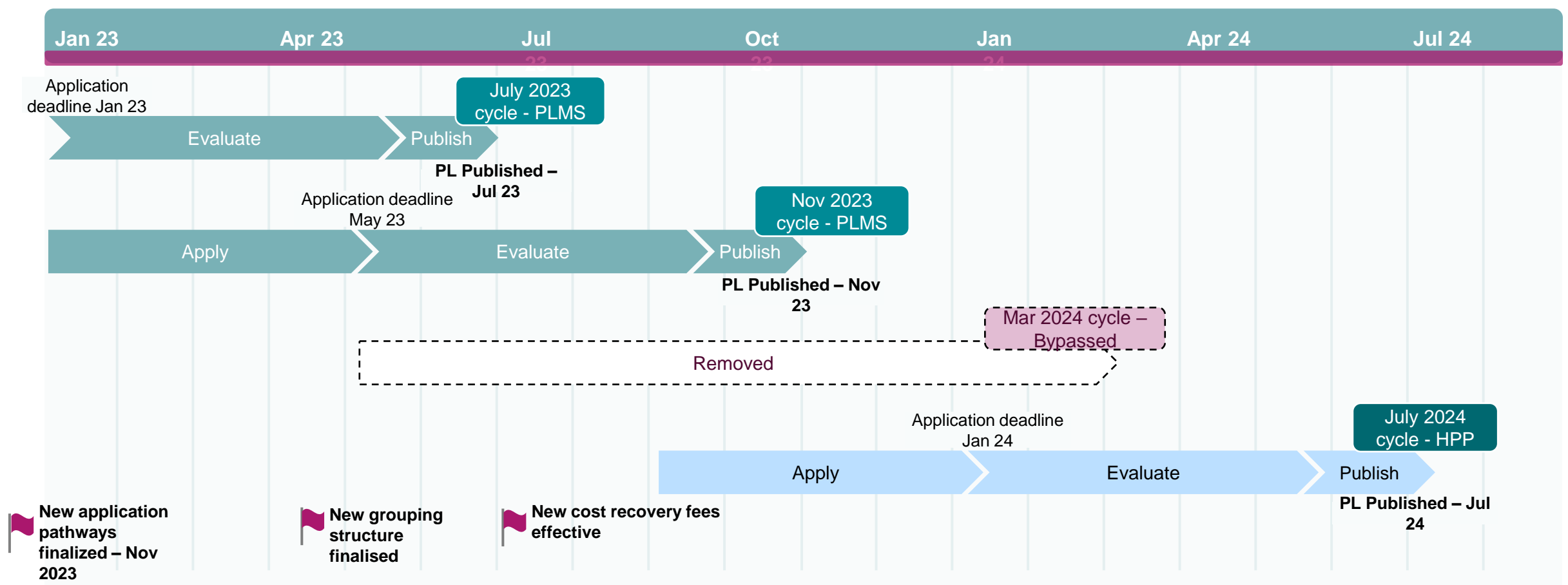
- 1 New Application Pathways** Define new application pathways where prostheses are eligible for inclusion on the PL and removing ineligible items – to be finalised **by November 2022**
- 2 New Grouping Structure** New grouping structure of items on the PL to better align devices with similar intended usage or health outcomes – to be finalised **by March 2023**
- 3 Benefit reductions** Benefit reductions will need to be supported – these will occur in **March 2023 and July 2023**
- 4 Updated cost recovery fees** Update existing cost recovery arrangements including structure and fees – to take effect on **1 July 2023**

## Health Products Portal

The HPP simplifies the process of applying, tracking, paying and managing regulated and reimbursed health products and services:

- Vision and strategy** In line with the RRTP vision and the HTA strategy, all HTA value streams (from application through to publishing) will be supported by HPP capability over the coming years.
- PL functionality development** PL functionality is in the process of being developed in the HPP.  
The RRTP program team is working closely with the PL Reforms team to build the capability to support future policy and processes.

# 1. Overview of the timing and impact of bypassing the March 2024 update



# What this means – Cycles, Systems and Policy

July 23 and  
November 23 cycles

Supported by **PLMS**, using **existing PL policy** and process.

March 24 cycle

Cycle bypassed

July 24 cycle

Full cycle **supported by the HPP**, using **new PL policy** and process developed through PL Reforms.



## 2. Information on the Prostheses List reforms and consultations planned for 2023

# Prostheses List Reforms

## LISTING PATHWAYS

A three-tiered pathway will be implemented:

### Tier 1

- Devices that are a well-established technology
- Medium or lower-risk devices
- Devices with substantially similar characteristics, intended use and proven clinical effectiveness.

### Tier 2

- High risk devices
- Devices that are not a well-established technology
- Devices with incremental improvements or different characteristics compared with comparator devices on the PL
- Applications requiring clinical input
- Applications requiring health economic evaluation (e.g. requiring a new group).

### Tier 3

- No relevant MBS item for the use of the device
- Device is novel technology and there are no comparators listed on the PL.

## GROUPING STRUCTURE

### Part A

Hereco delivered proposed new structure in December 2022.

A webinar will be held in early 2023 to inform the benefits for the new structure, followed by consultation with sponsors.

### Part B

PWC has been engaged to deliver a new grouping structure in 2023 and is currently running targeted consultation workshops (following consultation paper from 2022).

### Part C

These devices will continue to be approved by the Minister, but the eligibility criteria will be clarified (more information in next slide).

### Part D (General Use Items)

Further benefits reductions will apply to the billing codes for these products in March 2023, and all will be removed from 1 July 2023.

New funding arrangements will mandate insurers to pay benefits for the General Use Items (more information in next slide).

## COST RECOVERY

### New Cost Recovery arrangements

New Cost Recovery arrangements are scheduled from 1 July 2023.

Fees applied to all sponsor-initiated services, including new listing, amendment to existing listing, and listing deletion.

The new Cost Recovery arrangements will also include a Cost Recovery Levy, which will need to be paid by sponsors for each listed item on the PL.

Cost Recovery arrangements will be aligned with the Listing Pathways.

The Cost Recovery Implementation Statement (CRIS) will provide detailed information on fee amounts.

Consultation on CRIS scheduled for the second quarter of 2023, prior to planned implementation from 1 July 2023.



# Prostheses List Reforms (continued)

## LEGISLATIVE CHANGES

### Tranche 1

Name change, definition change and cost recovery provisions

Supported by stakeholders. Bills in Parliament, awaiting debate.

### Tranche 2

Bundling arrangements for general use items on the PL

New funding arrangements will mandate insurers to pay benefits, informed by IHACPA advice

IHACPA is running an information webinar tomorrow - 25 January

Consultation on arrangements scheduled for first quarter 2023.

Listing criteria for Part A and Part C

Consultation scheduled for first quarter of 2023

Cost-recovery fees

## POST-LISTING REVIEWS

We are conducting pilot reviews for four device types:

- Surgical guides and biomodels
- Spinal cord stimulators
- Metal-backed patellae
- Urogynaecological mesh devices

Targeted consultation with sponsors of these device types, in first half of 2023.

Further reviews are expected to commence early 2023.

Learnings from these reviews will be used to finalise the PL post-listing review framework.

## COMPLIANCE

The Compliance Strategy was open for consultation until October 2022.

Feedback was considered in finalising the strategy. A response paper was also prepared to address stakeholder feedback.

Compliance Strategy (and response paper) will be published in the first quarter of 2023).

## PL GUIDE

The Guide has been developed to assist applicants to prepare an application to include a medical device or human tissue product on the PL.

The Guide will be a reference point on how to collect and compile clinical evidence to meet Government requirements.

Consultation on the Guide is scheduled to commence in the first quarter of 2023.

# Summary - Consultation schedule for 2023

Jan-Mar

- **25 January (12pm AEDT)** - IHACPA webinar on Advice on Bundling Arrangements for General Use Items on the Prostheses List
- PLRT webinar to provide an overview of the regrouping approach for Part A and C, including methodology to address mixed benefits groups
- Consultation on mixed benefits groups for Part A and C
- Targeted consultation on regrouping part B
- Targeted consultation on pilot post-listing reviews
- Consultation on Prostheses List Guide
- Consultation on Tranche 2 legislative changes - listing criteria, bundling arrangements and cost-recovery arrangement
- **Sponsor participation in PL Apply public Beta testing (led by HPP)**
- **Consultation on bundling arrangements for general use items (in conjunction with IHACPA)**

Apr-Jun

- Targeted consultation on pilot post-listing reviews
- Consultation on Prostheses List Guide
- Consultation on Tranche 2 legislative changes – listing criteria, bundling arrangements and cost-recovery arrangement
- **Sponsor participation in PL Apply public Beta testing (led by HPP)**
- **Consultation on bundling arrangements for general use items (in conjunction with IHACPA)**

Jul-Sep

- Consultation on post-listing review framework
- **PL Apply user onboarding and training activities (led by HPP)**

Oct-Dec

- **PL Apply user onboarding and training activities (led by HPP)**
- **Hospitals and Insurers participate in PL Publish private Beta (led by HPP)**



# Reminder – important dates

Activity	Date
Shutdown of external access for sponsors to the PLMS	14 May 2023
Remove the March 2024 PL update – applications cannot be submitted after this date	14 May 2023
Applications can be submitted in the HPP	11 September 2023
Last PL update published from PLMS	November 2023
First PL update published from the HPP	July 2024

# Questions we have received so far

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## Why does the PL update need to be bypassed?

The reason the cycle needs to be bypassed is due to the intersection of the timing of the PL reforms and the PL publications cycles, and aligning these so that capability can be built to support them.

The Department will continue to have access to PLMS to assess applications submitted on or before 14 May 2023. The last PL update from PLMS will take place in November 2023

## What alternatives are available to submit an application during the bypass period?

There is no alternative mechanism for submitting an application during this time.

Sponsors either have to submit an application in PLMS on or before 14 May 2023, or wait until 11 September 2023 and lodge it in the HPP for the next round.

# Questions we have received so far

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If the Department will continue to have access to PLMS, can sponsors email the Department to finalise/add documents to an application on their behalf?

What options are available to finalise applications that have already been recommended but are pending ARTG or MBS number (in-flight applications)?

Will transfer of sponsor applications be available?

The Department is working through these questions and will provide answers in the coming months.

We are committed to working through as many current outstanding applications as possible to limit the number of unfinished applications which need to be transferred to the HPP.

### 3. Opportunity for stakeholders to ask questions or raise concerns on the proposed changes

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Please note that out-of-scope questions (i.e. not related to the changes related to transition to the HPP) will not be answered at this webinar.





# Getting in touch with us

## Prostheses List

Applications

[prostheses@health.gov.au](mailto:prostheses@health.gov.au)

Reforms

[prosthesesreform@health.gov.au](mailto:prosthesesreform@health.gov.au)

Post-listing reviews

[PLReviews@health.gov.au](mailto:PLReviews@health.gov.au)

Compliance

[prosthesescompliance@health.gov.au](mailto:prosthesescompliance@health.gov.au)

## Health Products Portal (HPP)

[hpp.support@health.gov.au](mailto:hpp.support@health.gov.au)

## Bundling arrangements for General Use Items (IHACPA)

[enquiries.ihacpa@ihacpa.gov.au](mailto:enquiries.ihacpa@ihacpa.gov.au)