

Prostheses List Reforms

# Key Stakeholder Meeting

12 December 2022

Agenda Item 4 - Update on the PL Reforms

Elizabeth Flynn



- Listing Pathways
- Regrouping of the PL and mixed benefits
- Cardiac Implantable Electronic Devices (CIEDs)
- Legislation
- Bundling of General Use Items
- Prostheses Reform Evaluation
- Post Listing Reviews
- Compliance Framework
- HPP Transition Plan
- Timeline of Reforms work



# Reforms Progress Highlights

- Review of the functions of PLAC completed – Governance for new advisory group is being drafted
- Fit for purpose listing pathways have been finalised following co-design workshops and final consultation in November 2022
- Hereco delivered the regrouped PL in November 2022
- The Independent Health and Aged Care Pricing Authority (IHACPA) completed the Bundling of General Use Items advice
- First tranche of legislative amendments introduced into Parliament 1 December 2022

# Listing Pathways Update

- Consultation Paper No 3(b) - Pathways for Applications to the PL - closed on 28 October 2022.
- 18 submissions were received. Concerns raised:
  - lack of payor scrutiny in Tier 1 applications
  - Class III device ineligibility for Tier 1 Pathway
  - lack of reduction in the timeframe from application to listing.
- Feedback was provided on the glossary of terms and the comparative table by stakeholders.
- A high-level analysis of the submissions was released on the website on 21 November 2022.



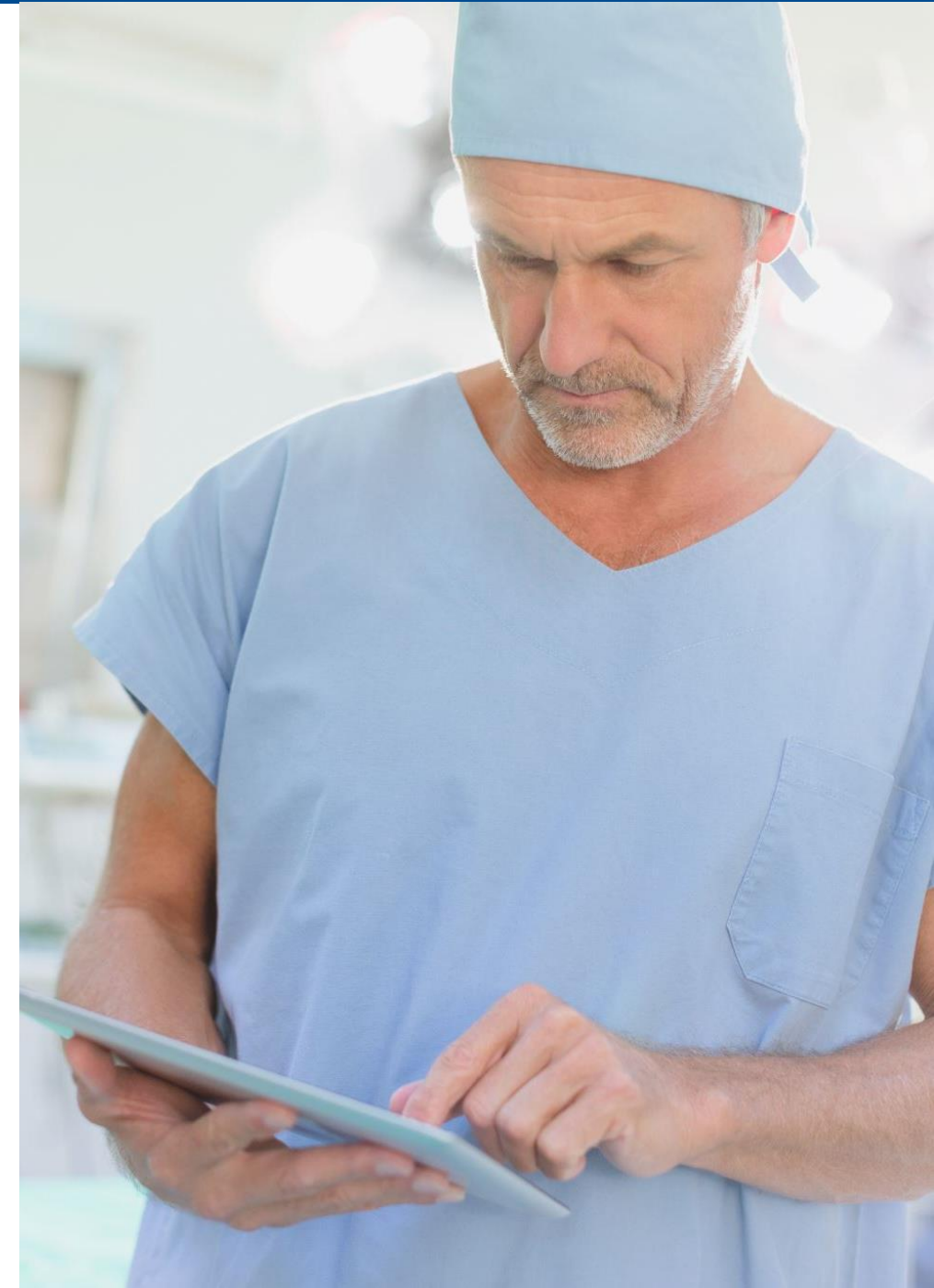
# Regrouping Update

- Hereco presented relevant stakeholder feedback and proposals received as part of the consultation process for consideration at CIRG Meeting # 8 on 28 October 2022.
- Hereco delivered the final proposed regrouped PL to the Department in November 2022.
- The Department has commenced work on the 'mixed benefit group' stage of the regrouping activity and will be engaging with relevant stakeholders shortly.
- The new grouping structure needs to be finalised by the end of March 2023
- CIRG will remain in place until 30 June 2023, allowing the department to readily seek expert clinical advice in relation to other measures being implemented as part of the Prostheses List reforms – including reviewing any further changes in 2023 as a result of the department's review of mixed benefit groups.



## Cardiac Implantable Electronic Devices (CIEDs)

- CIEDs are currently scheduled for the first PL benefit reduction of 40% of the gap between the PL benefit and the public price on 1 July 2023
- CIED Sponsors have made a submission (ADAR) to MSAC and this is being reviewed
- The Department is meeting with the Cardiac Forum in January 2023 to assess the status of the MSAC application, based on the reviewers commentary, to assess implications for the benefit reduction in July 2023
- ESC is scheduled to consider the application in February 2023 before proceeding to MSAC in March 2023



# Legislation Amendments

- The Department released exposure drafts and the draft explanatory memorandum for targeted consultation with key stakeholders that closed on 11 November 2022.
- The overall feedback from this and the previous webinars was largely supportive of the measures included in the initial three Bills. Concerns raised focussed on the lack of detail available that will be included in the legislative instruments.
- The amendments in the three Bills will:
  - Insert definitions of medical device and human tissue product
  - Change the name of the legislative instrument to better reflect its scope
  - Establish the authority for new fee for service cost recovery arrangements that are consistent with the Australian Government Charging Framework
- The work has now commenced to develop the details to be included in the legislative instruments (Rules and Regulations) – listing criteria and cost recovery will be the focus of consultation commencing early 2023



# General Use Items - Bundling

- IHACPA has completed the advice on bundling of General Use Items and provided it to the Department
- This advice does not determine a definitive path forward to implement the bundles following the scheduled removal of general use items from the PL on 1 July 2023.
- Private hospitals and private health insurance industries have been encouraged to commence discussions regarding alternative funding arrangements for the general use bundles.
- The IHACPA advice will be published on 14 December 2022 and will be accompanied by an announcement about alternative funding arrangements.





# Reforms Evaluation Update

- The PL Project Board has endorsed the Evaluation Framework
- The internal Evaluation team is currently considering the response to the Request for Quote from external evaluators
- The priority work for the remainder of 2022/23 will be to undertake a baseline evaluation.
- External advisory group will be convened once the Evaluator has been engaged and the baseline plan is ready for review in 2023.



# Post-Listing Review Update

- **Surgical guides and biomodels review** - followed the Department's Post Market Review methodology and practices (adapted to the PL context). The status is:
  - All sponsors and stakeholders involved have provided input through written submissions and/or interviews with the external consultant
  - Draft report was released on 30 November 2022 to all participating sponsors and stakeholders for review and response by 6 January 2023
  - Draft report is being provided to PLAC in December 2022 for initial feedback
- **Metal-backed patellae review** – internal review by the Department. Sponsors asked to provide input by 1 September 2022. The status is:
  - Paper provided to KPCAG in October 2022 for advice
  - Paper being provided to PLAC in December 2022 for consideration before consultation with sponsors
- **Spinal cord stimulators review** - using the focussed HTA approach by external evaluator. The status is:
  - Sponsors invited to provide information/data to inform the review in October 2022
  - Review Scope finalised with external evaluator December 2022
  - Sponsors and stakeholders to be invited to consider the review scope and provide further input (information/data) to inform the review December 2022 with a closing date of 31 January 2023.
- **Urogynaecological mesh devices (mid-urethral slings)** – using the focussed HTA approach by external evaluator. Status is:
  - Sponsors advised of the intention to undertake the review November 2022
  - Review scope being drafted for release to Sponsors and stakeholders in December 2022

# PL Compliance and Assurance

- Key Objectives:
  - Identify the principles which govern the Department's compliance and enforcement functions, and associated priorities.
  - Assist medical device sponsors to understand their compliance obligations within the context of the proposed legislative amendments.
  - Outline the steps the Department may take after implementation where there are concerns about non-compliance.
  - Inform key PL stakeholders of the compliance regulatory framework for safeguarding the PL settings consistently.
- Stakeholder consultation on the PL Compliance Strategy has concluded and the outcome paper due to released shortly.
- Current Priorities:
  - Drive improved focus on compliance matters to encourage voluntary compliance and a culture of compliance through education and guidance activities.
  - Establish data access and analysis of available data to support verification activities.
  - Developing case prioritisation capability.
  - Continue to foster collaboration to amplify compliance activities using relationships with peak bodies to support the PL compliance program.
  - Engage with other regulators to influence and learn from best practices to further refine and strengthen the compliance program.

# HPP Transition Plan

- On 11 September 2023, applications will commence in the Health Products Portal (HPP)
- Transition from the PLMS to the HPP will involve removing the March 2024 PL Update
- The key implications are:
  - External access to PLMS will be closed from 14 May 2023
  - March 2024 PL Update will be removed
  - Applications submitted in the HPP will commence 11 September 2023 through to 14 January 2024 – for the first PL Update from the HPP on 1 July 2024
- An email to all sponsors and stakeholders will be sent this week, outlining further details of the transition plan
- All sponsors and stakeholders will be invited to attend a webinar in January 2023 to discuss concerns



# Next Steps

# Stakeholder Engagement

We are working on a stakeholder engagement plan for 2023, as part of our commitment to communicating and working with sponsors and peak bodies on the PL reforms. Your input will be requested to inform the following deliverables in 2023:

- **Part B** – late January/early February 2023  
Consultation with Part B stakeholders on the proposed grouping structure and listing pathways.
- **Legislation Instruments** (including listing criteria, application requirements, system caps, bundling and new cost recovery arrangements) – January - April 2023  
Ongoing workshops, consultation and webinars with stakeholders
- **Transition to HPP** (including pathways, new guidelines, education, improved applications) – January – June 2023  
Ongoing consultation through workshops and webinars
- **Mixed benefits** – commencing January 2023
- **New governance arrangements** - TBC

# Timeline

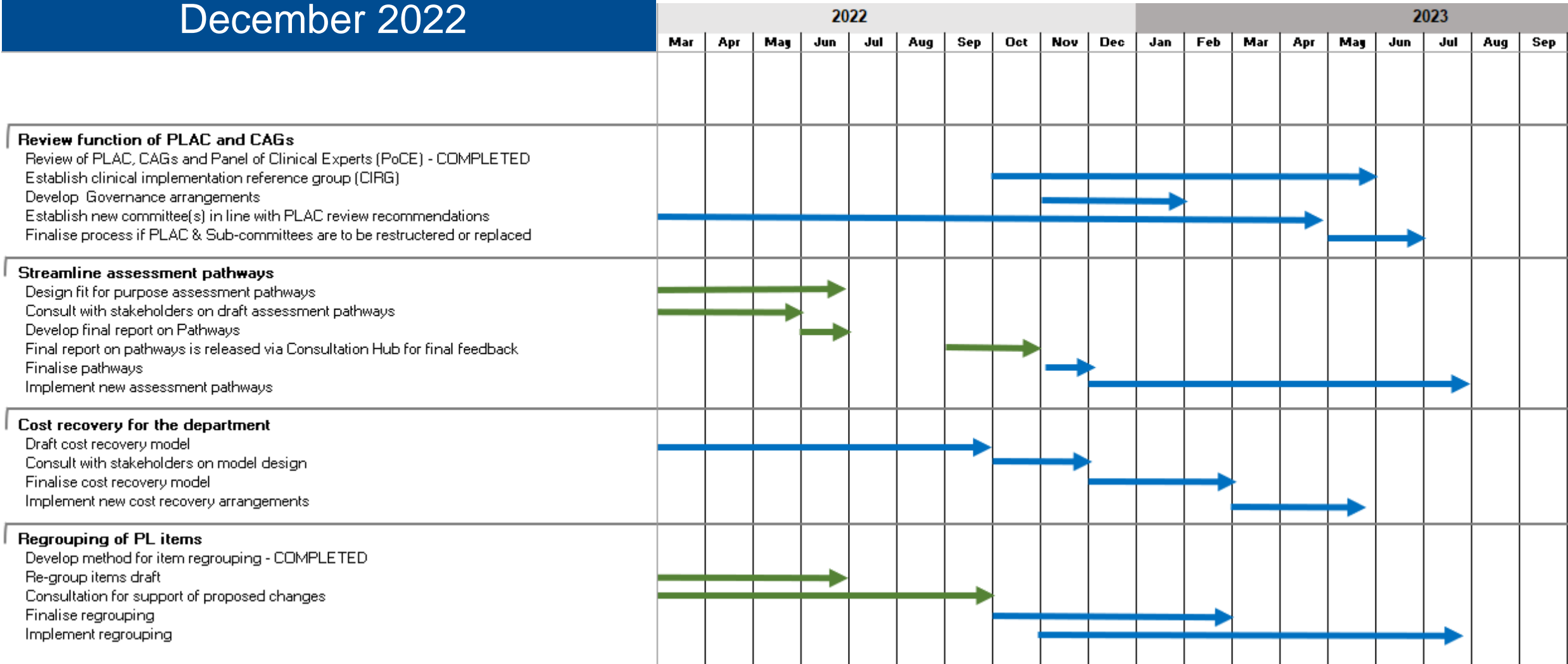
as at December 2022



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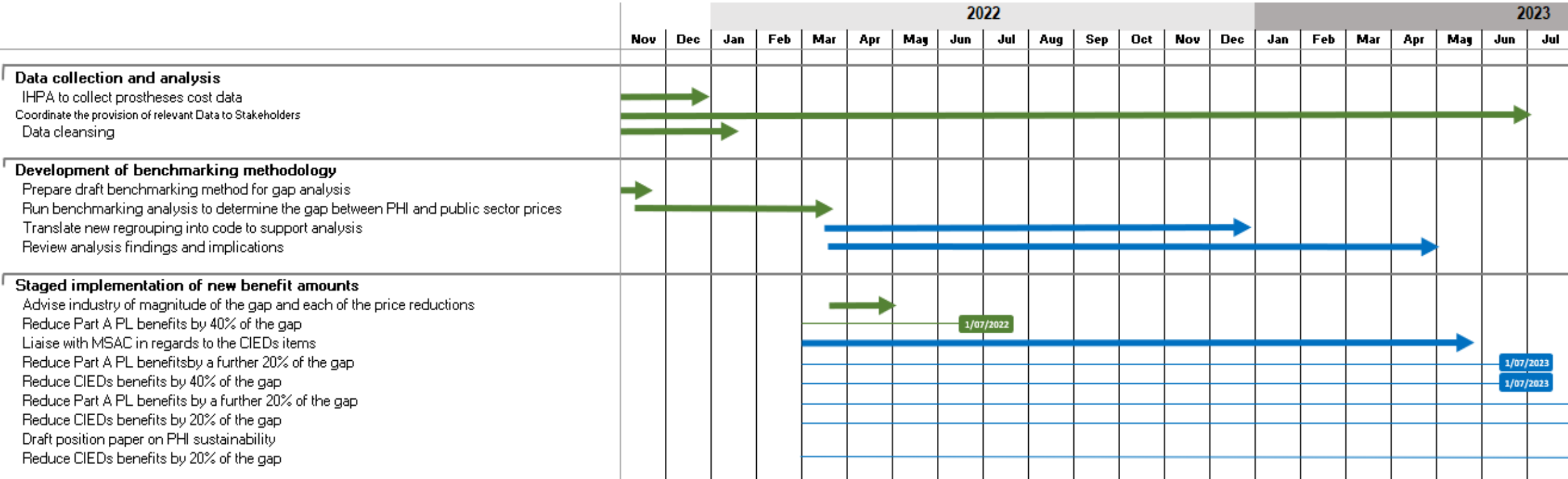


# Administrative Arrangements December 2022



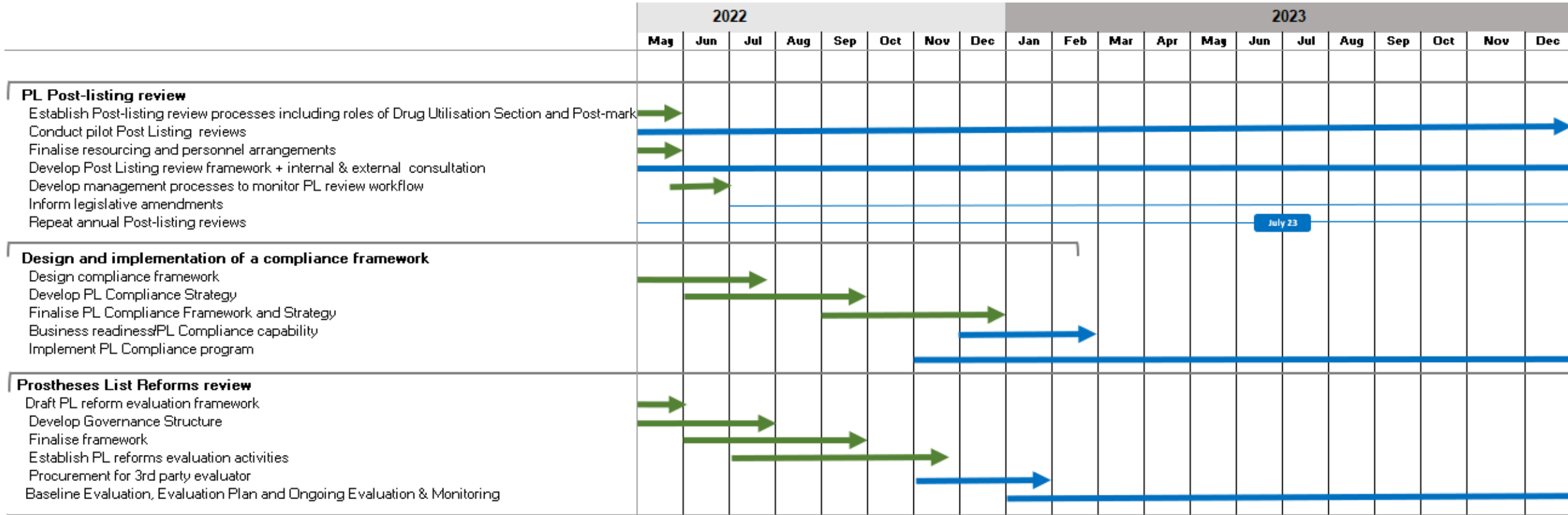


# Reducing the gap December 2022



# Safeguarding the reforms

## December 2022







# **Australian Government**

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## **Department of Health and Aged Care**

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