The 10th Annual Drug and Devices Australia Webinar.

Reimbursement Update 2024

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Setting the Scene

- Australia has a universal healthcare system
- About half of all Australians also have private health insurance (PHI)
- PHI is hospital and limited ancillary cover only and excludes primary care and pharmaceuticals
- Consequently, a mix of public and private hospital systems
- Can be fragmented and there are lots of perverse incentives

Medical Technologies in Private Hospitals

- **Medical Benefits Schedule (MBS)** - List of medical procedures subsidised by Medicare
- A procedure must be included on the MBS to be covered by PHI
- Implantable devices – hips, pacemakers, vascular grafts etc. receive a payment over and above any other reimbursement – **PRESCRIBED LIST**
- Devices that are not implanted are at a disadvantage

Politics 2024

- Last full year of first term Labor Government – mainly implementation of 2023 policy announcements:
  - One-Stop Shop clinical trials
  - Implementation of Prescribed List Reforms
  - Additional 29 Medicare Urgent Care Clinics to relieve pressure on public hospitals
- Additional funding of MRIs so that all practices with an MRI have access to Medicare funding.

Politics 2024

- Federal opposition has released little policy other than a promise to provide incentives for young doctors to enter general practice.
- Election to be held by May 2025.
- Reasonable chance of a minority government.

Minister for Health and Aged Care, Mark Butler

Prescribed List - General Use Items (GUIs)

- In 2023 it was planned that GUIs were to be removed from the PL
- Hospitals and insurers were required to come to alternative arrangements.
- In May this year, the Minister announced that GUIs would continue to be funded under the PL arrangements and included in Part D .
- The Catch – No new clinical groups will be considered.
- The industry has pushed back on this, so far, without success.

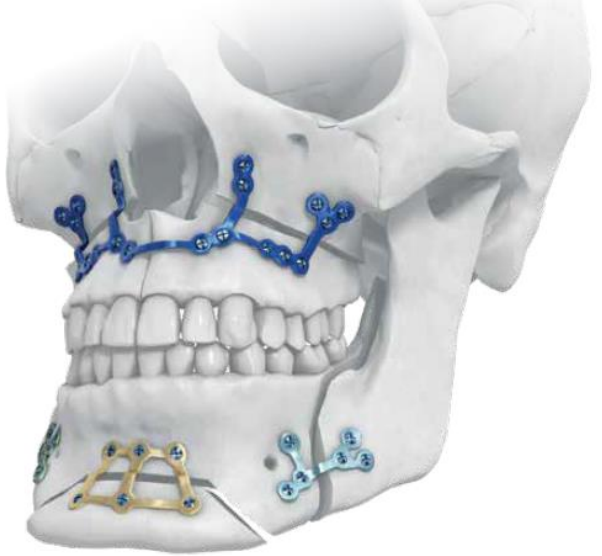
Prescribed List – Evidence Requirements

- Draft PL Guide released in December 2023.
- Unanticipated and onerous evidence requirements for
  - Ophthalmic devices (no Tier 1 applications)
  - Neurosurgical implantable pulse generators (published comparative clinical trials for each new device)
- Despite considerable industry lobbying, these requirements have not been modified.
- As there is a proviso in all evidence requirements that the '*final conclusion regarding acceptance will always be made in the context of the specific device*', there is a high degree of unpredictability.

Prescribed List – Part C

- The evaluation of Part C products has proved extremely disappointing for the industry
- Most, if not all Part C applications have been deferred primarily due to not being *'exceptional'* enough.
- MDHTAC noted there is a *'lack of clarity on the methods of assessing information provided'* and *'the expectations to the minimum level and quality of evidence….are required to be clarified'*
- There have been no public updates or consultation on this clarification.
- Part C applications may not be assessed.

Prescribed List – Other Issues



Surgical guides and biomodels

- Post-listing review in 2023
- Implemented February 2024
- Limit of 3 biomodels and 3 guides per procedure
- Limited to craniofacial procedures
- Must only be used in a specific device
- Stage 2 post-listing review focussing on cost-effectiveness announced a few days ago.

Prescribed List – Other Issues

Cardiac Implantable Electronic Devices (CIEDs)

- Cost of support services for CIEDs in the private sector included in PL benefit.
- Same services not offered in public.
- MSAC evaluated what proportion of the benefit can be allocated to the device and support services.
- Industry contends that MSAC made unreasonable and unsupported assumptions about the salaries of technicians and the cost of training.
- 56% of the benefit is allocated to the cost of the device and is subject to mandated price decreases.

New Fees

Cost Recovery Impact Statement (CRIS)

Pathway	Standard Fee	Clinical Assessment Fee	Economic Assessment Fee	Total
Tier 1	$1,420	n/a	n/a	$1,420
Tier 2a - Focussed HTA (Clinical only)	$1,420	$3,970	n/a	$5,390
Tier 2b -Focussed HTA (Clinical and Economic)	$1,420	$3,970	Simple -$9,250	$14,640
			Complex - $17,680	$23,070
			Other -$28,920	$34,310
Full HTA	$1,370	$2,990	n/a	$4,410

Practicalities

- Do applications early
- HPP is clunky and there are numerous glitches
- It can take several days to resolve an issue as support is random, although much improved
- The Secretariat response time has worsened, and responses are often non-existent.
- Invoicing is also quite random. Applications can be upgraded to Tier 2, incurring additional fees, without consultation with sponsor.
- Invoices received up to 10 months after application.

HTA Review

'Health Technology Assessment Policy and Methods Review'

- Technical review of HTA methodology
- Reported in 2024
- Highly technical recommendations
- Mainly in pharmaceuticals but with implications for MSAC,

Political Predictions for 2025

- Must be an election by May 2025
- High probability of hung Parliament with minority government
- Likely to be crisis in private hospital access - Current BUPA –Healthscope dispute
- Outcome of election unlikely to derail ongoing reforms in PL, overall HTA
- PHI will continue to lobby for further p decreases.

Thank you !

And over to George……

Let's just repeat our webinar title…

TENTH Annual!!

That's November 2015 to November 2024

Australian Reimbursement Update: Latest issues in Medical Technology Reimbursement

13th November 2015

Presented by Sarah Griffin and George Papadopoulos

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Experience Matters

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Major Policy Issues in Pharmaceutical Reimbursement in Australia in 2015

Survived Review and still operational
BUT HTA Review Recommendations

Developing a statement of rationale for the LSDP, covering principles and eligibility criteria, including value-for-money considerations (Recommendation 14).
Streamlining processes for the LSDP (Recommendation 4)
Expanding the role of the PBAC beyond the PBS to allow it to recommend medicines for inclusion on the LSDP (Recommendation 6).

Experience in Australia with MAP is still not extensive and there are limited publicly available learnings

Revisiting via HTA Review and Bridging Fund Recommendation

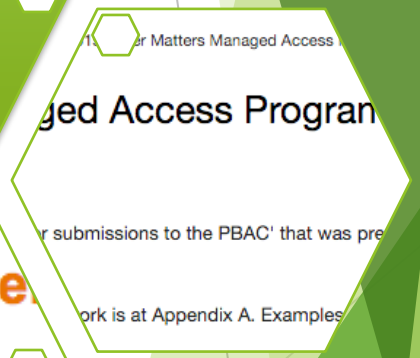
Norgine EAP with DoHAC

Life Savings Drug Program **Review**

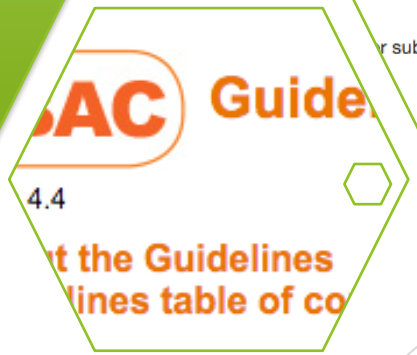
Australian Government
Department of Health

Managed Access Programme **Framework**

PBAC Stakeholder Meetings **Update**



PBAC Guidelines **Review**



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Version 5.0, September 2016

BUT HTA Review Recommendations

Discount Rate
Comparator Selection

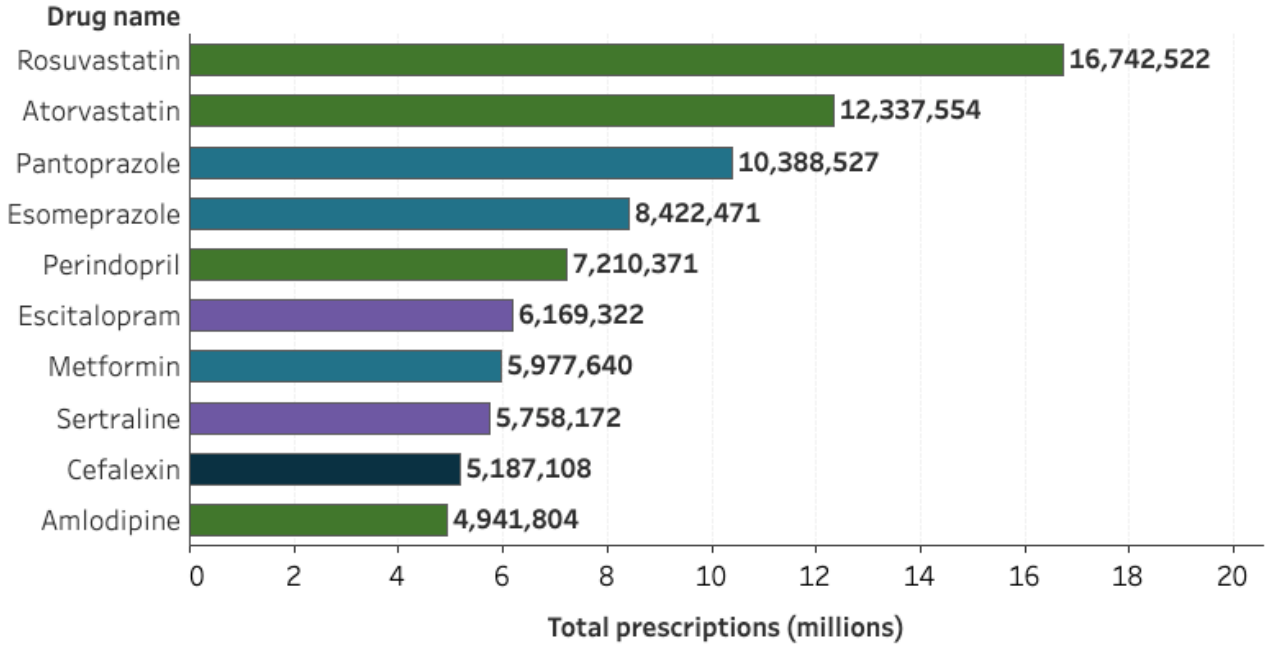
EMERALD CG

Table C: Top 10 drugs by prescription counts, 2015

Drug	PBS/RPBS	Under co-payment	Total
ATORVASTATIN	7,634,687	2,922,825	10,557,512
ROSUVASTATIN	6,667,654	2,764,678	9,432,332
ESOMEPRAZOLE	7,184,175	1,684,090	8,868,265
PARACETAMOL	7,003,988	361,643	7,365,631
PANTOPRAZOLE	4,618,171	1,738,738	6,356,909
PERINDOPRIL	4,005,504	2,114,337	6,119,841
AMOXYCILLIN	2,377,339	3,487,319	5,864,658
CEFALEXIN	2,851,477	2,753,113	5,604,590
METFORMIN HYDROCHLORIDE	3,570,613	1,585,270	5,155,883
AMOXYCILLIN with CLAVULANIC ACID	2,256,829	2,810,399	5,067,228

Source: https://www.pbs.gov.au/info/statistics/asm/asm-2015

Top 10 Drugs by prescription counts 2023



Source: https://www.aihw.gov.au/reports/medicines/medicines-in-the-health-system

Australia's Public Healthcare System

Australian Government
Department of Health and Aged Care

medicare

MBS | **PBS** | **Public Hospitals** | **Aged Care**

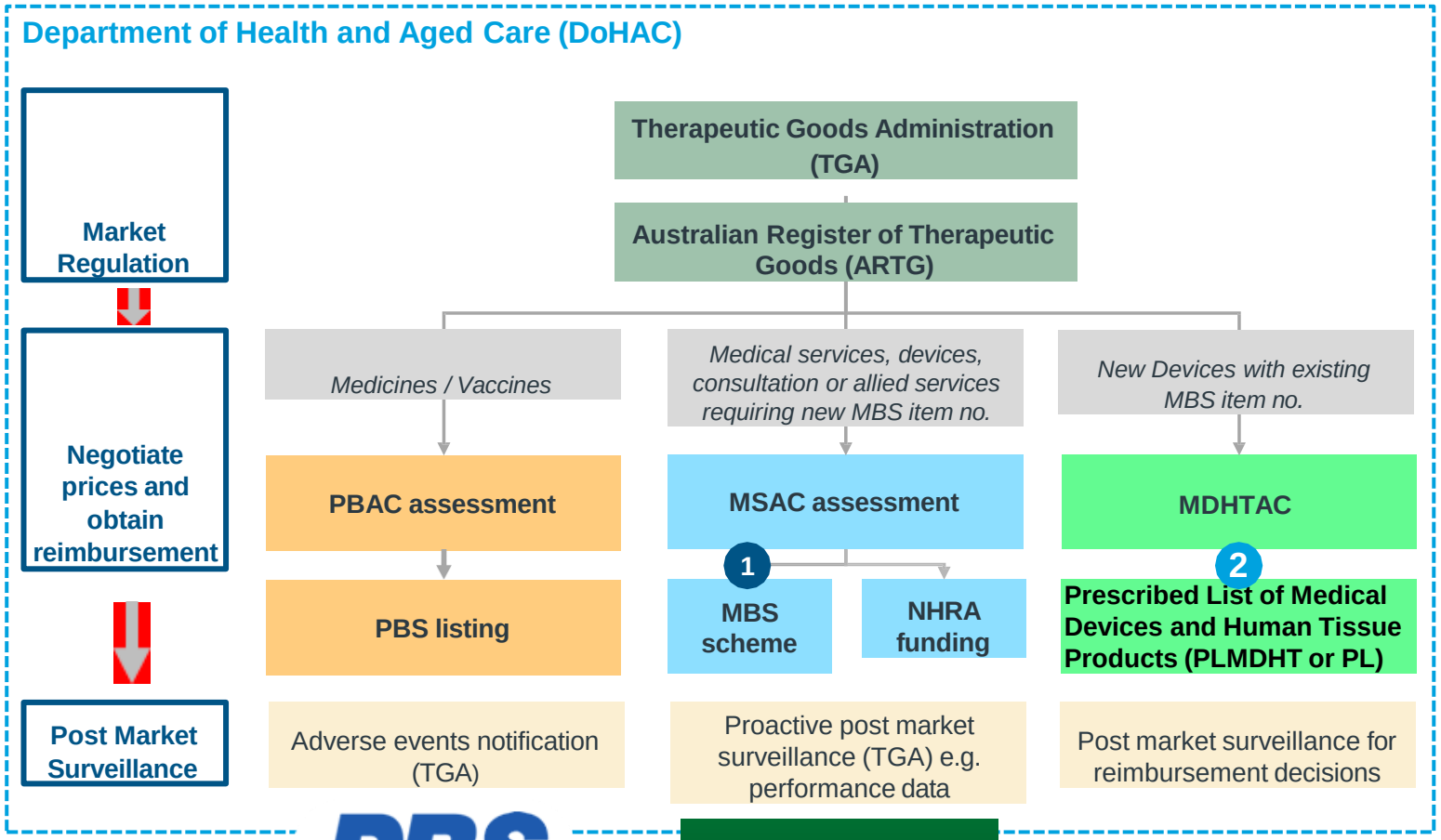
- Medicare is a universal healthcare system
- And nearly half of all Australians also have private health insurance (PHI)
- PHI is hospital and limited ancillary cover only
  - excludes primary care and pharmaceuticals
- Consequently, in Australia we have a mix of public and private hospital systems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

Private Hospitals

Private Health Insurance

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.

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	

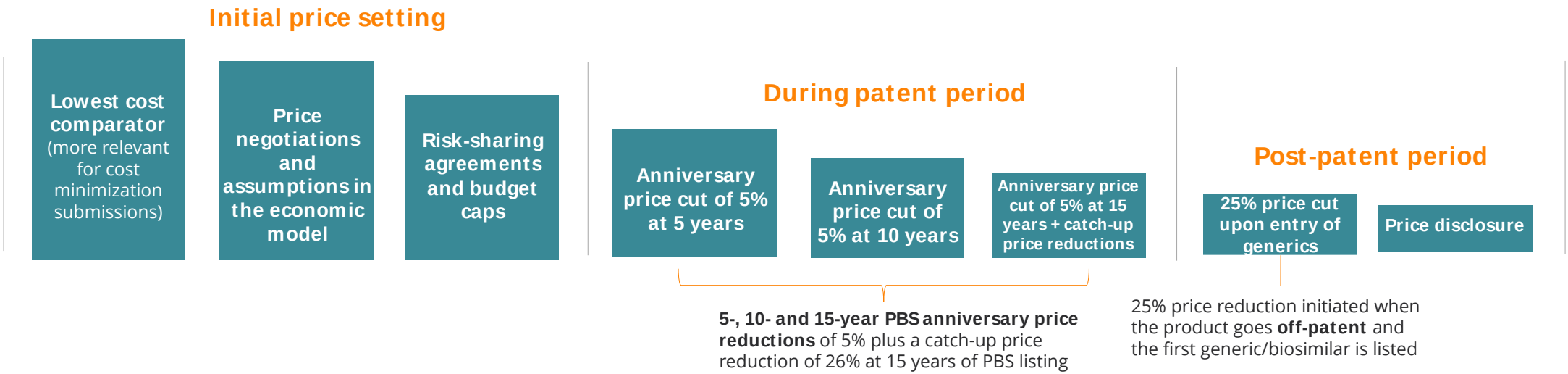
Abbreviations: HTA: Health Technology Assessment; PBAC: Pharmaceutical Benefits Advisory Committee; PBS: Pharmaceutical Benefits Scheme

Source: Slides prepared by S. Crowley, Lucid Health Consulting, presented at Global Payer Forum

Price Evolution of Drugs on the Pharmaceutical Benefits Scheme (PBS) list

Overview of dynamic pricing in Australia

Even though historically PBS prices have been relatively stable until patent expiry, the PBS system is associated with dynamic prices, where prices reduce over time or may vary by year



Dynamic pricing examples

- **In risk-sharing agreements (RSAs):** medicines that are subject to financial-based or outcome-based RSAs, may have **different "effective" prices each year** depending on whether financial caps are exceeded or health outcomes in the real world are less than that specified in the sponsor's submission to the PBAC.
- **Administrative price reductions:** if an on-patent product with the same efficacy and safety as existing PBS listed product(s) is listed on the PBS at a lower price, the price may flow onto the existing PBS product(s).

Source: Slides prepared by S. Crowley, Lucid Health Consulting, presented at Global Payer Forum

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PBAC chair, MSAC chair, and deputy chairs EOI outcome

New chair and deputy chair appointments announced for health technology assessment committees. This includes appointments for the Pharmaceutical Benefits Advisory Committee (PBAC) and the Medical Services Advisory Committee (MSAC).

Date published: 21 March 2024

Audience: General public

Following an expressions of interest process, we are pleased to announce the upcoming appointment of:

- Professor Robyn Ward AM as the Chair of PBAC from 5 May 2024
- Professor Jonathan Craig as the Chair of MSAC from 1 April 2024
- Professor Kwun Fong as Co-Deputy Chair of MSAC from 1 April 2024
- Associate Professor Sarah Norris as Co-Deputy Chair of MSAC from 1 July 2024.

We extend our gratitude to:

- Chair Professor Andrew Wilson (PBAC)
- Chair Professor Robyn Ward (MSAC)
- Deputy Chair Professor Timothy Davis (MSAC).

Thank you for your leadership and expertise.

Learn more about the PBAC and MSAC appointments in our background document.

New HTA Committee Announcements:

PBAC

• Professor Robyn Ward AM as the Chair of PBAC from 5 May 2024

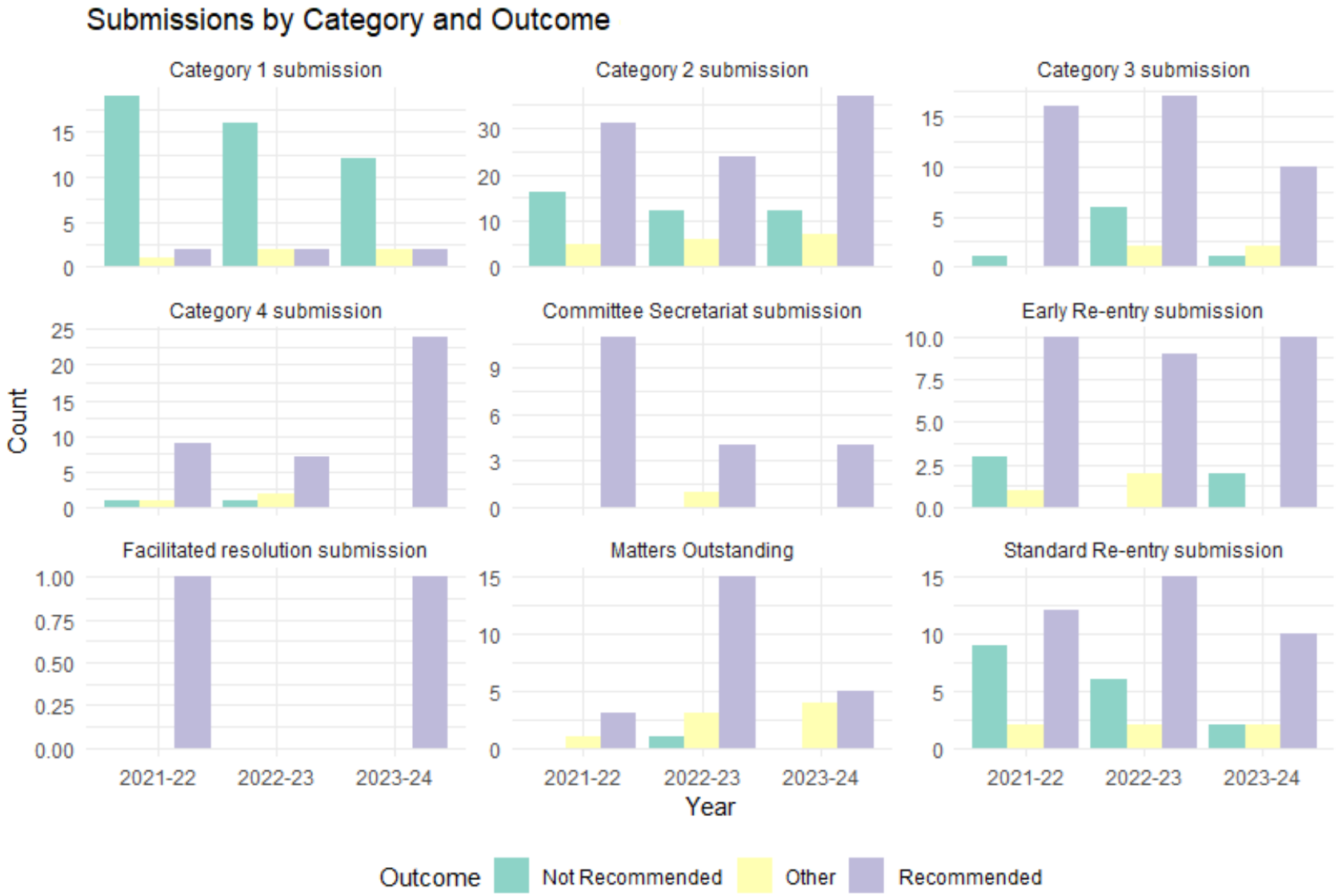
MSAC

• Professor Jonathan Craig as the Chair of MSAC from 1 April 2024

• Professor Kwun Fong as Co-Deputy Chair of MSAC from 1 April 2024

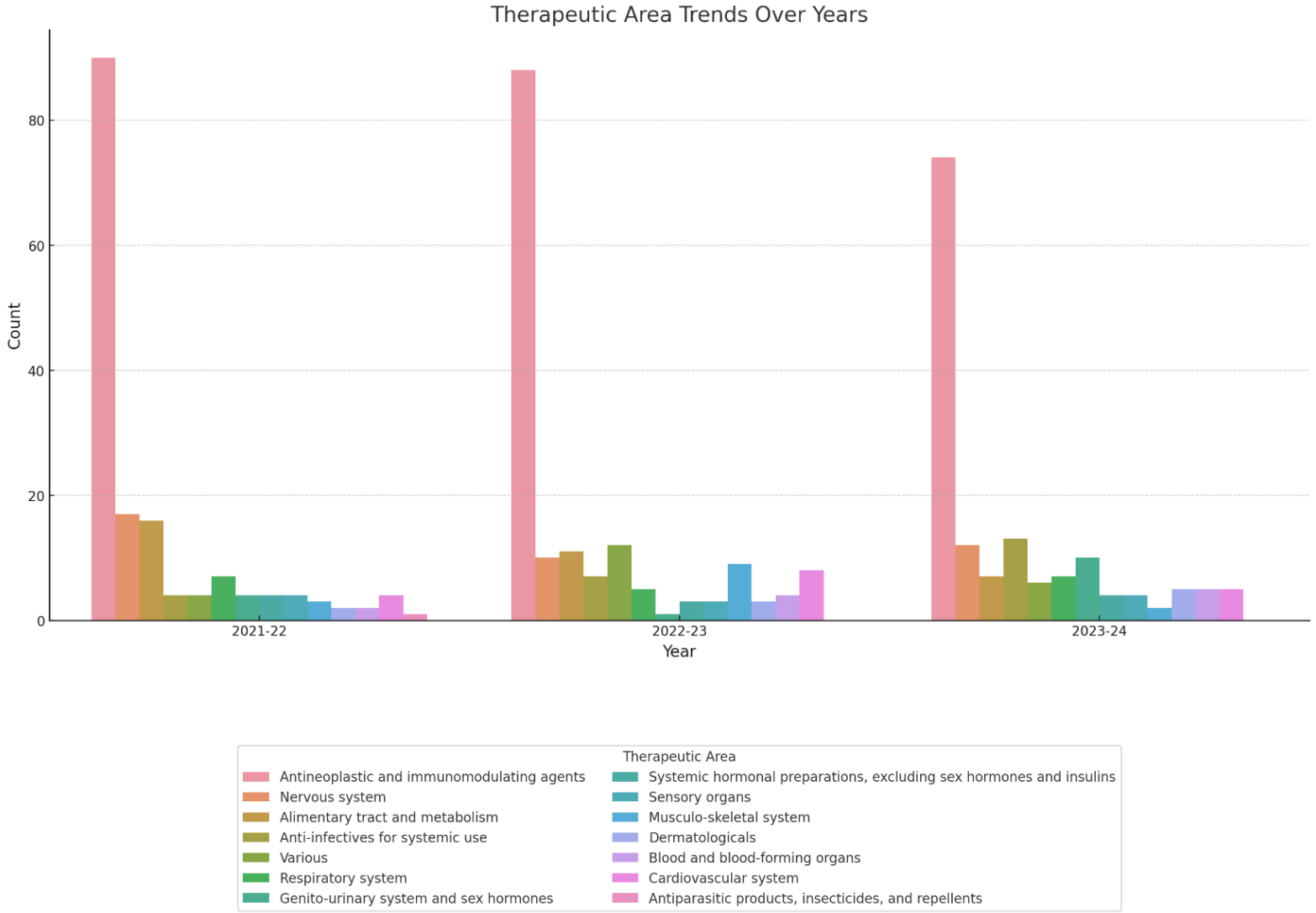
• Associate Professor Sarah Norris as Co-Deputy Chair of MSAC from 1 July 2024.

Submission Types to the PBAC



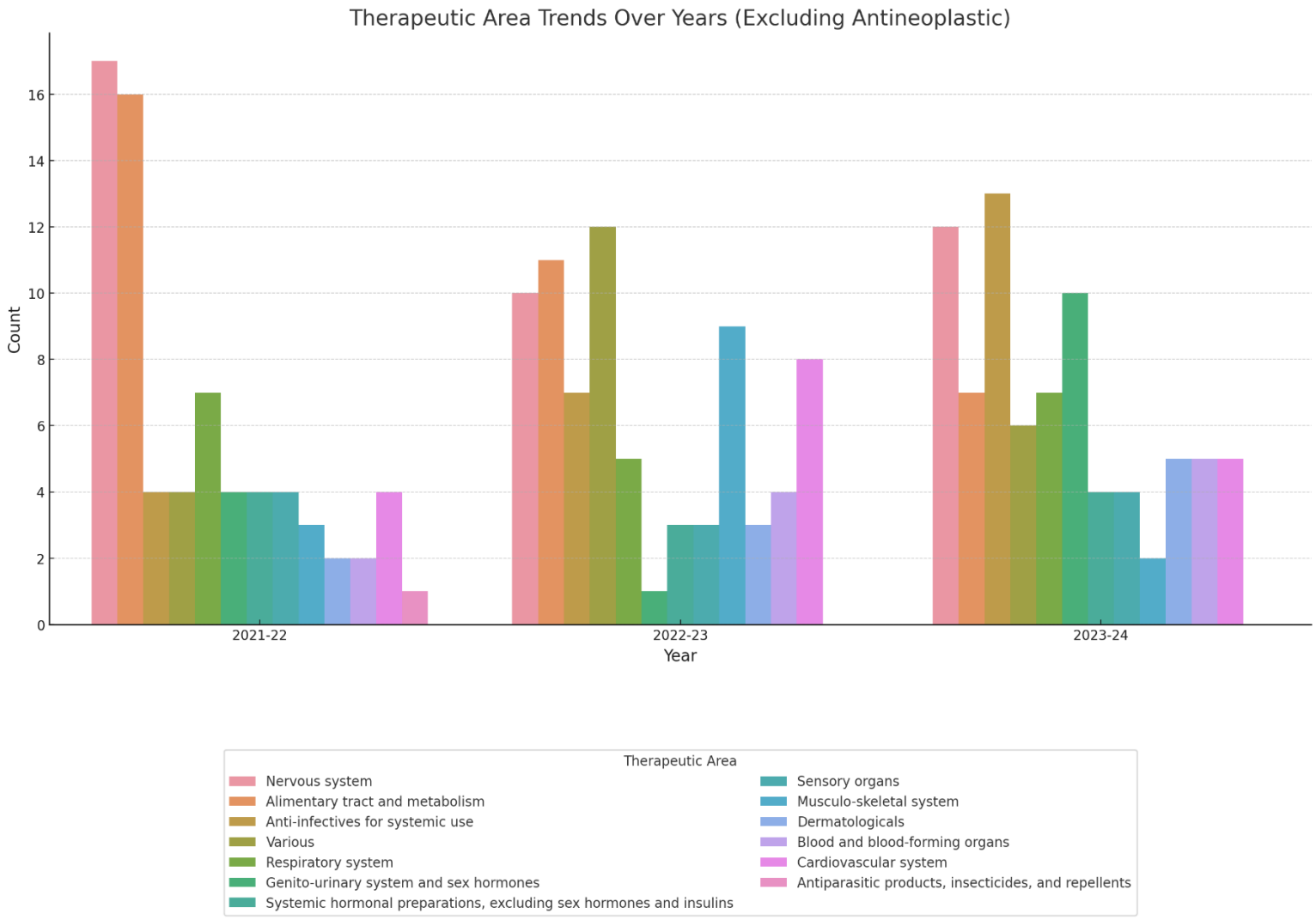
Source: Analyses via MAOSS https://maoss.com.au/dashboard/

Therapeutic Area Submissions to the PBAC (1)



Source: Analyses via MAOSS https://maoss.com.au/dashboard/

Therapeutic Area Submissions to the PBAC (2)



Source: Analyses via MAOSS https://maoss.com.au/dashboard/

AUSTRALIAN PATIENT ACCESS GAP

January 2021 – April 2024

MEASUREMENT MATTERS

Throughout the HTA Review, Amgen Australia has advocated for the systematic collection, collation and publication of data on the performance of the PBS listing process.

In particular, Amgen believes that measurement of the Patient Access Gap (PAG)—the time between TGA authorisation when a medicine is deemed clinically safe and effective, and PBS listing when a patient gets effective access to that medicine—is vitally important.

Not only do Australians deserve to know how long they're waiting for equitable access to medicines, data on a well-defined set of metrics are essential to determine those elements of the current reimbursement system that are working effectively, and those that require improvement.

It was the absence of any centralised data on the PAG that first prompted Amgen Australia to conduct a 'time to listing' analysis of every TGA approved medicine listed on the PBS for the period 2010 – 2017[1].

Completed in 2020, this analysis showed that, on average, patients had to wait **820 days** before medicines that may be considered superior to current treatment options were listed on the PBS. **The wait for many medicines, including orphan medicines, was even longer.**

During the same period however, the access gap for the subset of medicines that had gone through the parallel **TGA-PBAC process** was smaller, at **520 days**, demonstrating the impact of intelligent reform.

PATIENT ACCESS GAP AT A GLANCE

Between Jan '21 and April '24, the average time to access innovative medicines that demonstrate superiority over existing medicines was...

591 DAYS

between registration and PBS listing.

81%

...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.**

Of the 43 medicine + population pairings that received a positive PBAC recommendation but were not PBS listed in this period, 22 are particularly slow with an access gap that is...

1,000+ DAYS

...and still counting.

CONTEMPORARY TIME TO LISTING ANALYSIS

January 2021 to April 2024[2]

AMGEN

- Last year we said….
- Looking forward to 2024…..

Medicines Australia

Reforming Australia's Health Technology Assessment (HTA) System

Australian Government
Department of Health and Aged Care

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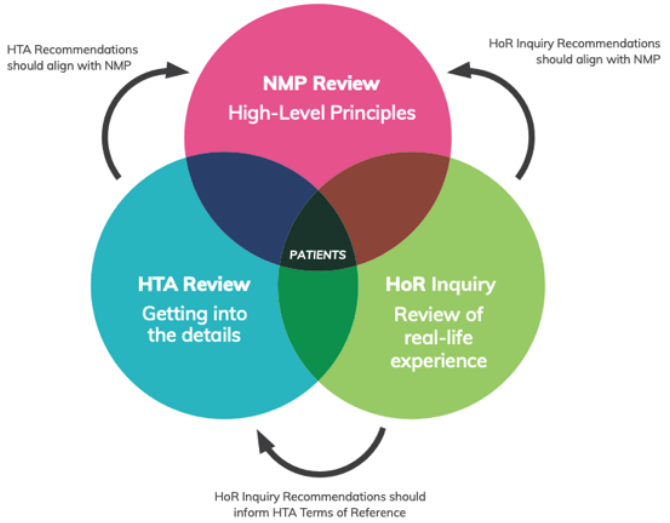
Health Technology Assessment Policy and Methods Review

The Health Technology Assessment (HTA) Policy and Methods Review is an opportunity to ensure Australia's HTA policy is constantly improving under evaluation.

Linking the HTA Reform, NMP Review and HoR Inquiry

These three reviews/inquiries are all important in ensuring Australia's medicines policy is fit-for-future.

They all have a different focus but should be fully aligned.



National Medicines Policy (NMP) Review

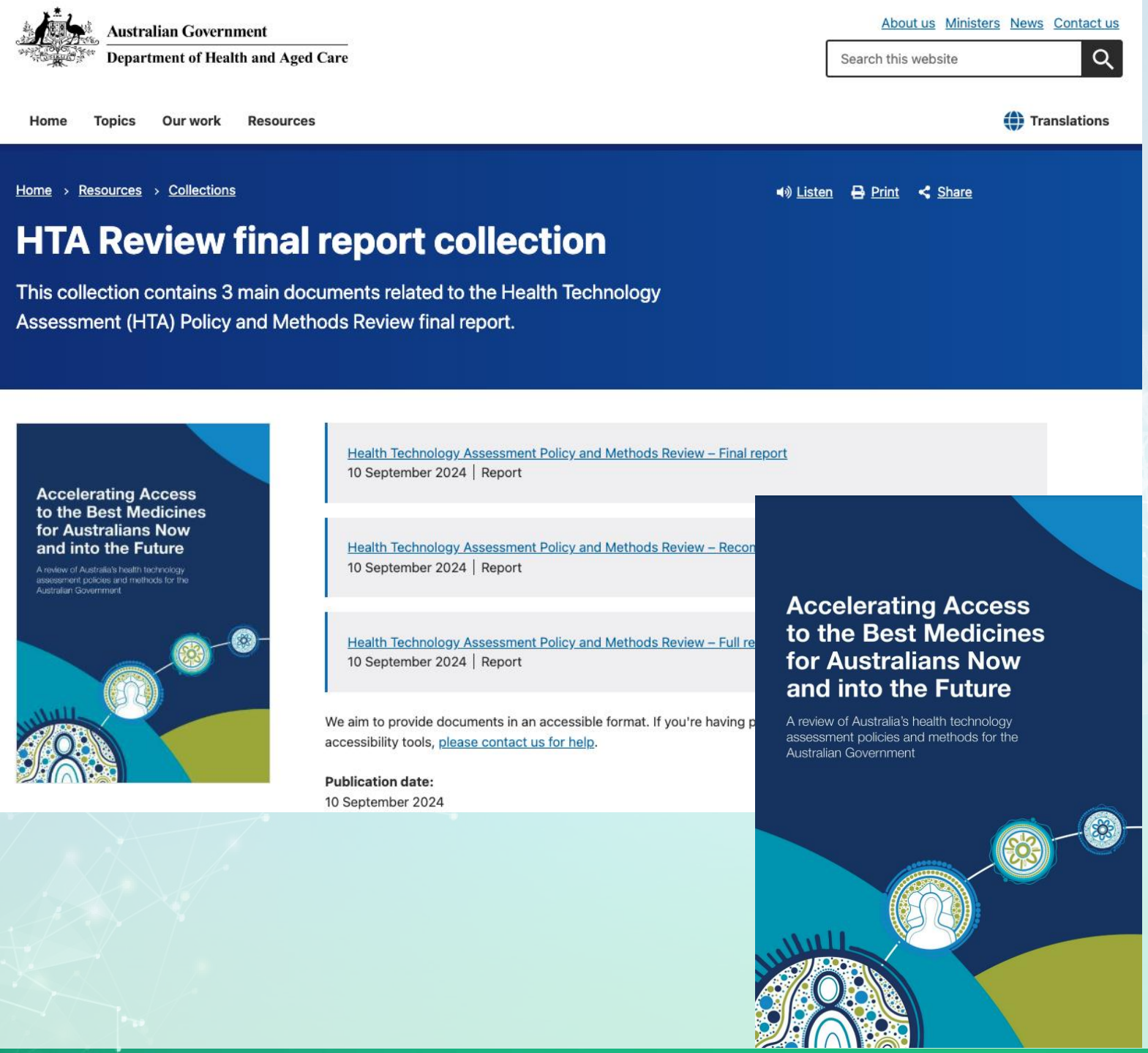
High-level policy review that will set the objectives for access to and use of medicines.

House of Representatives (HoR) Inquiry

Broad Parliamentary Inquiry into approval processes for new drugs and medical technologies.

Independent HTA Policy and Methods Reform

Focused review of Health Technology Assessment (HTA) methods and policies for medicines.

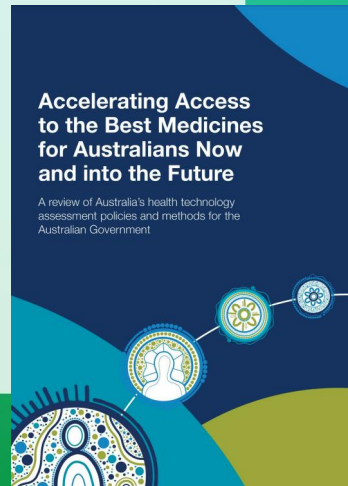


The review was one of the main commitments under the 2022–27 Strategic Agreement between the Commonwealth and Medicines Australia. Under the agreement, the Australian Government committed to supporting and resourcing the review, overseen by the HTA Review Reference Committee.

- The HTA Review started on 27 October 2022 and was completed on 4 May 2024.
- The HTA Review Report made 50 recommendations across a range of areas, including improving access to new technologies, ensuring equity, and making HTA processes simpler for consumers and clinicians.

7 main areas of recommendations

- Providing more equitable access to under-represented patient groups
- Streamlined pathways for more timely access
- Policies, methods and processes supporting the translation of HTA recommendations into patient access
- Transparency and stakeholder involvement
- Enhancing real-word data and real-world evidence for HTAs
- Methods for confident decisions
- Supporting architecture for HTAs



Health Technology Assessment (HTA) Review Implementation Advisory Group (IAG) includes a robust mix of representatives from government, industry, consumers and clinical.

The HTA Review Report made 50 recommendations across a range of areas, including improving access to new technologies, ensuring equity, and making HTA processes simpler for consumers and clinicians.

The IAG will also consider the findings of the *Enhance HTA and the new frontier – Delivering better health for all Australians* (Nov 2021) report.

The IAG will co-design a draft Government response to the HTA review.

Ministers
Department of Health and Aged Care

Home | Media centre | Mark Butler | Anika Wells | Ged Kearney | Emma McBride | Kate Thwaites

Home > The Hon Mark Butler MP > Minister Butler's media

Broad expertise to lead health technology assessment reform

The Australian Government has today announced the members of the Health Technology Assessment (HTA) Review Implementation Advisory Group (IAG).

The Hon Mark Butler MP
Minister for Health and Aged Care

Media event date: 20 November 2024

Date published: 20 November 2024

Media type: Media release

Audience: General public

The Australian Government has today announced the members of the Health Technology Assessment (HTA) Review Implementation Advisory Group (IAG).

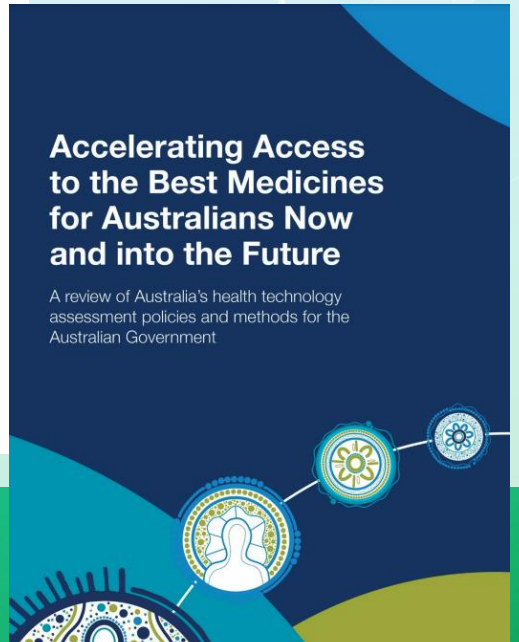
The IAG will help guide critical reforms in response to the findings and recommendations of the HTA Review Report which was released in September.

Health technology assessment is the process of reviewing the quality, safety, efficacy and value for money of new health technologies before they are funded or subsidised by government.

Renowned cardiologist and Co-director of the Menzies Centre for Health Policy at the University of Sydney, Professor Andrew Wilson will chair the IAG.

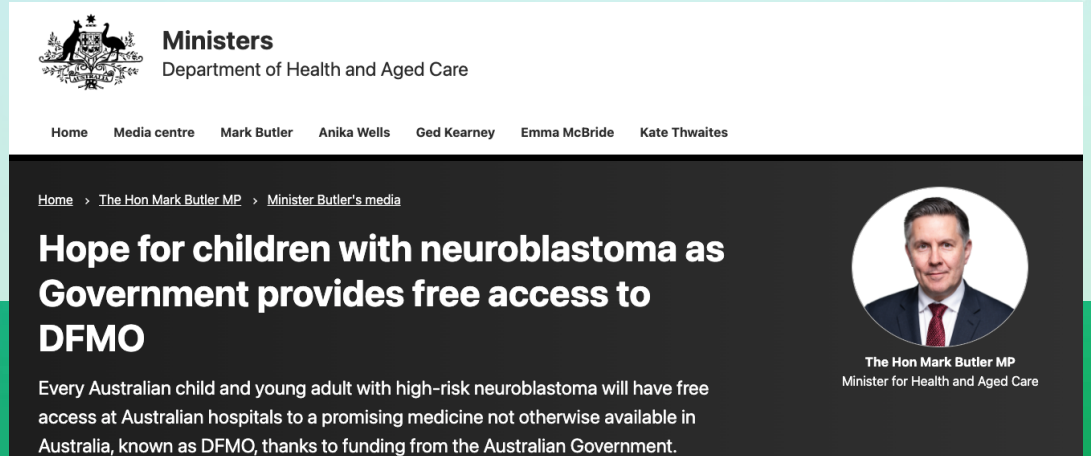
He will be joined by:

- Dr Richard Mitchell – Head of Clinical Services, Kids Cancer Centre
- Dr Lorraine Anderson – Medical Director, Kimberley Aboriginal Medical Services
- Nicole Millis – Chief Executive Officer, Rare Voices Australia
- Kirsten Pilatti – Chief Executive Officer, Breast Cancer Network Australia
- Elizabeth de Somer – Chief Executive Officer, Medicines Australia
- Anne Harris – Deputy Chair, Medicines Australia Board
- Prof Emily Lancsar – Chief Health Economist in the Department of Health and Aged Care
- Duncan McIntyre – First Assistant Secretary, Technology Assessment and Access Division, Department of Health and Aged Care.



Expanded Access Program (EAP) organized by DoHAC and Norgine

- Every Australian young adult and child with the rare cancer has free access to the treatment DFMO (eflornithine) in hospitals across the country.
- The drug is “not otherwise available in Australia”.
- DFMO, an orphan drug shown to improve survival and reduce the risk of relapse, costs between $500,000 and $700,000.
- The fully Commonwealth-funded scheme can begin immediately, as soon as the Committees of the major public hospitals approve the administration of DFMO in their hospitals. The Government has committed to reimburse states and territories for the costs of purchasing the medicine for eligible patients and is further supporting treatment through the national public hospital funding agreement.
- In parallel, Norgine is pursuing regulatory approvals from the Therapeutic Goods Administration (TGA) and listing on the Pharmaceutical Benefits Scheme (PBS).
- Around 20 patients are expected to benefit each year over the next two years.
- The one-off funding will remove the financial barriers to DFMO access while Norgine’s compassionate access scheme is established and the application is considered by the Therapeutic Goods Administration.



Ministers
Department of Health and Aged Care

Home | Media centre | Mark Butler | Anika Wells | Ged Kearney | Emma McBride | Kate Thwaites

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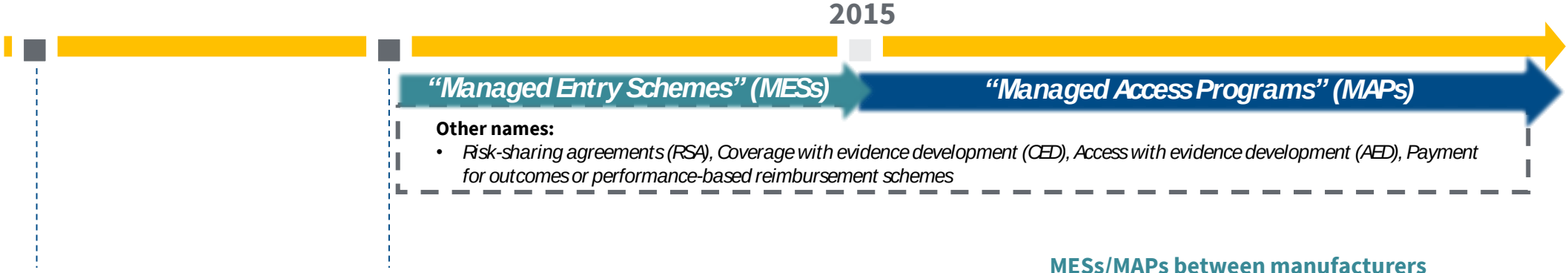
Hope for children with neuroblastoma as Government provides free access to DFMO

Every Australian child and young adult with high-risk neuroblastoma will have free access at Australian hospitals to a promising medicine not otherwise available in Australia, known as DFMO, thanks to funding from the Australian Government.

The Hon Mark Butler MP
Minister for Health and Aged Care

The Evolution of MES/MAP in Australia



> Traditionally, PBAC reimbursement decisions have fallen into **one of three categories:**

1. Recommended

2. Not recommended

3. Deferred

> PBAC infrequently **adopts innovative reimbursement approaches** based on value-based contracts

> **Aim:** overcome the tension between **funding new but high-cost** medicines while **obtaining value for money.**

Major reason: uncertainty regarding **clinical, economic and financial data**

MESs/MAPs between manufacturers and payers allow for:

> **Reimbursement** of the medicine

> Tracking actual **utilization** or **performance** of the product in a clearly specified patient population,

> Tie the **level of reimbursement** to an **outcome**.

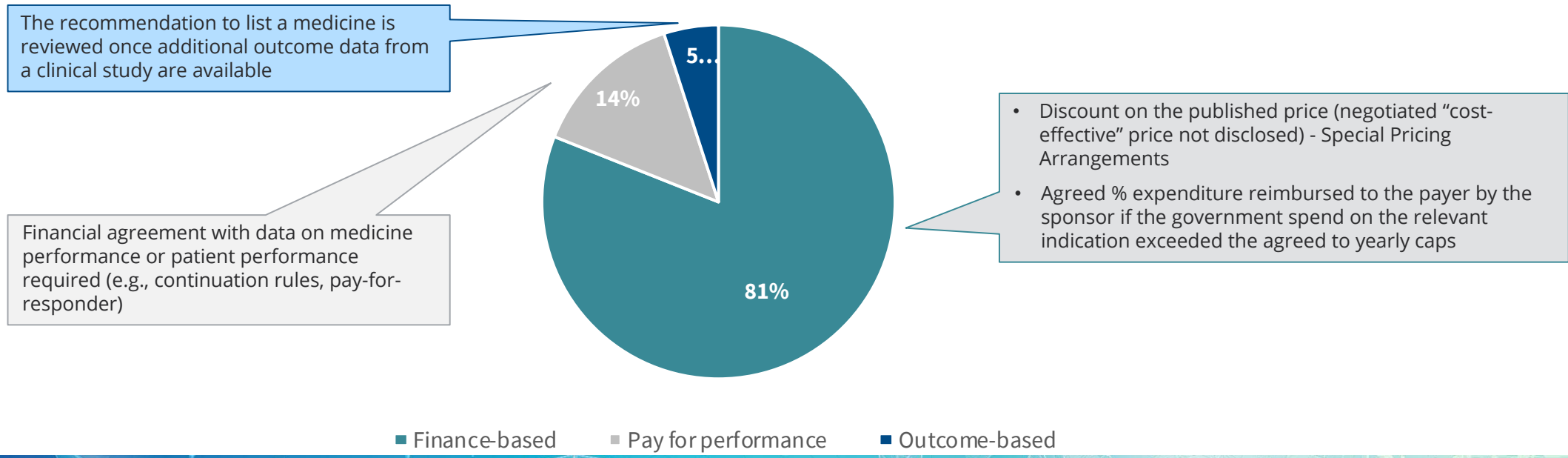
> **Both parties share the risk** in case the medicine does **not** perform to expectation or according to expected utilization or budget impact, as agreed to in advance between manufacturer and payer.

Historical Review of Managed Entry Schemes (MES) in Australia

Robinson 2018[1] – MESs are categorized as:

Financial agreements that **reduce the payer's expenditure**	Financial agreements **with payments adjusted according to real-life health outcomes data** from patients (i.e. "pay-for-performance")	Outcome-based agreements that **collect information on outcomes** ("coverage with evidence development") **with consequent effect on payments** after review

Analysis of Managed Entry Schemes (January 2012 to May 2016)



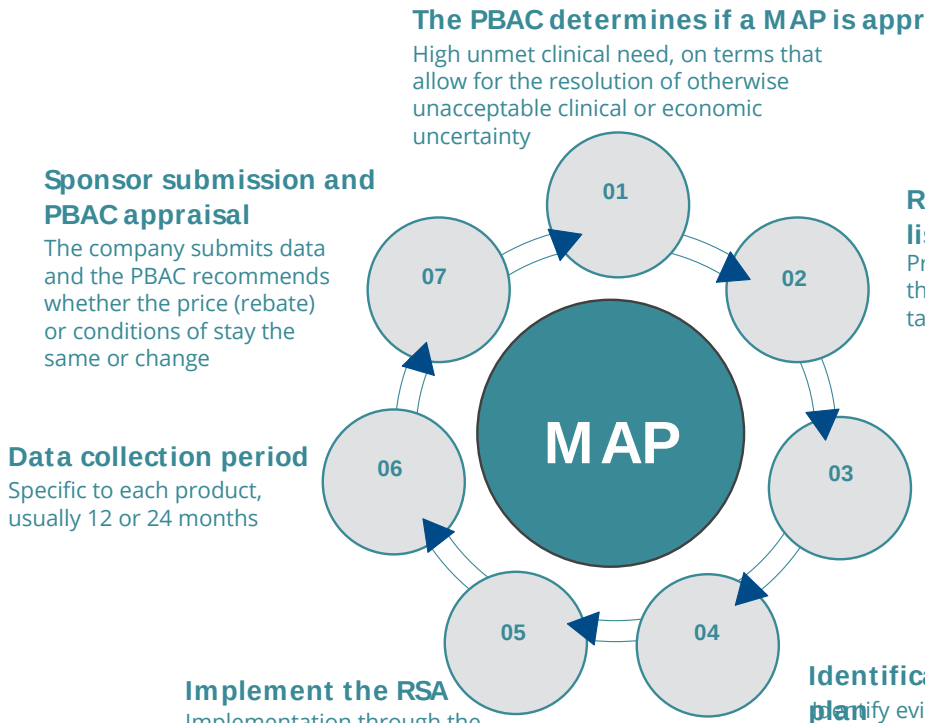
References: 1. Int J Technol Assess Health Care. 2018 Jan;34(1):46-55

Managed Access Program (MAP) Framework in Australia

A MAP is a mechanism that enables PBS listing of products, under special circumstances of high unmet clinical need, on terms that allow for the resolution of otherwise unacceptable clinical or economic uncertainty for the PBAC

The PBAC determines if a MAP is appropriate and may:

- **Make a recommendation on listing and price** based on the evidence available at the time of its initial consideration
- **Identify the key areas of uncertainty** and **required evidence**, the timeframe for submission of that evidence, and the potential consequences of the evidence outcomes
- **Review a submission** once the additional evidence becomes available and to reconsider the listing in light of the new evidence
- Articulate the risk-sharing agreement in a **Deed of Agreement**



Managed Access Program: the Deed of Agreement

Two broad types of arrangements which are covered by a 'Deed'

A Deed of Agreement (legal contract) between the Commonwealth Government and the sponsor contains:

- Agreed **initial price**
- Areas of **uncertainty**
- **Time frame** for resubmission
- **Statement of intent by the PBAC** to reconsider the submission once the evidence to support the clinical and economic claim becomes available
- **Acknowledgment of other areas of uncertainty** yet to be identified which could impact the initial ICER
- **Customised renegotiation clause** acknowledging managed entry as a trigger (currently change in the ICER or an increase in price is a trigger for renegotiations)
- **Guarantee of supply at the original price** agreed to by the company if it fails to produce satisfactory evidence
- **Commitment by the sponsor to disclose information**, in the resubmission, about anticipated/unanticipated changes that impact the clinical effect or evidence

1 Special Pricing Arrangements

The sponsor negotiates **a higher 'published' vs 'effective' (cost-effective) price**, managed through a rebate arrangement

2 Risk-sharing Agreements Managing Uncertainty

Uncertainty in the extent of overall gain in **health outcomes** (e.g., immature trial data, single-arm study, reliance on surrogate endpoints, long-term safety)

Uncertainty in **cost-effectiveness** (ICER) (time horizon, extrapolation methods, cost-offsets, duration of use, utilities etc)

Uncertainty in estimating the overall **financial cost** to the PBS (prevalence/incidence, duration of use, dose, potential out-of-indication use)

- **Abbreviation:** ICER: incremental cost-effectiveness ratio

Pros and Cons of Managed Access Programs for Industry and Government

	PROS	CONS
Industry	> **Early access to innovative medicines for patients in Australia** in the face of clinical and/or economic uncertainty at a price that may not be warranted by existing evidence > **Allows evidence generation in real world** that can support commercial and medical strategies in increasing market uptake and share of market	> Setting up a MAP can be **both resource intensive and costly** > **The inability of real-world data to mirror the strong internal validity of a clinical trial** • Risk of evidence and ICERs that are worse than in the initial application for reimbursement possibly resulting in rebates or price decreases
Payer	> **Ability to share the risks with industry** in case of reimbursement decisions based on uncertain evidence > **Provides mechanisms to list products with high clinical need** but with immature or uncertain evidence and cost-effectiveness	> Reluctancy of manufacturers **to take on the risk of a MAP** when they cannot predict how their product will be used and how it will perform in the real-world > **Difficulty (politically) to significantly change the reimbursement conditions** if the evidence is worse than in the reimbursement application and the product is shown to **not** be effective or cost-effective

Source: Slides prepared by S. Crowley, Lucid Health Consulting, presented at Global Payer Forum

Key Implications of Managed Access Programs: Risks & Mitigations

Recent trend of sponsors having immature evidence at launch → **Increased uncertainty** in clinical and economic evidence → **Increasing role of MAPs** in early patient access to innovative medicines

RISKS

- Experience in Australia with MAP is not extensive and there are limited publicly available learnings
- Industry appears to be reluctant to proactively offer MAPs in their reimbursement applications, in part due to risks associated with entering such agreements:
  - Implementing a MAP can be both **resource-intensive and costly**
  - Australia does **NOT have an integrated and linked healthcare and drug utilization dataset**, and patient registries may not be available for some disease areas
  - Real world evidence may not reflect outcomes found in regulatory RCTs, and thus **future product prices may be unpredictable and/or reduced**

MITIGATIONS

- **Transparency** is needed on **when a MAP would be considered** appropriate to solve issues of uncertainty
- Given the complexity and high cost of establishing a MAP and the lack of routine datasets to collect high-quality evidence, **pragmatic solutions** need to be found to **solve any remaining clinical and/or economic uncertainty**
- Given the reluctance from the industry to offer MAPs as part of the reimbursement package, the PBAC considers providing **incentives to companies**:
  - E.g., reduced time to reimbursement, offering “acceptable” initial listing prices to industry, and the potential to increase price if real-world evidence exceeds expectations.

Managed Entry Schemes / Managed Access Programs in Australia

Pre-Managed Entry Scheme

Managed Entry Scheme January 2011

Managed Access Program PBAC endorsed December 2015

2004	**Bosentan**	PAH	Condition that a registry was established to monitor mortality
2012	**Ipilimumab**	Metastatic melanoma	PfP, rebates based on OS at 24 months
2014	**Ivacaftor**	Cystic fibrosis	PfP, rebates based on non-responders
2014	**Eculizumab**	Atypical haemolytic uraemic syndrome	PfP, rebates based on complete remission
2014	**Trametinib**	Metastatic melanoma	PfP, rebates based on OS results at 12 months
2014	**Crizotinib**	NSCLC	PfP rebates based on OS results at 12 months
2015	**Pembrolizumab**	Metastatic melanoma	PBS list with provision for future clinical trial evidence on OS to support the price
2016	**Blinatumomab**	Ph-B-precursor ALL	PfP , rebates based on OS results at 12 months
2019	**Lumacaftor and Ivacaftor**	Cystic fibrosis	PfP, rebates based on non-responders

Abbreviation: NSCLC: Non-small cell lung cancer; PfP: pay for performance

- Last year we said….
- Looking forward to 2024…..

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Department of Health and Aged Care

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Review of National Hospital Funding Agreement

The five-year agreement on public hospital funding between the Australian Government and all states and territories is being independently reviewed

The Hon Mark Butler MP
Minister for Health and Aged Care

- The five-year agreement on public hospital funding between the Australian Government and all states and territories is being independently reviewed as agreed and commissioned by all Australian Health Ministers.
- The funding and delivery of public hospital services in Australia is governed by the National Health Reform Agreement (NHRA), as agreed by all state and territory governments with the Commonwealth in 2020 and runs to 2025.
- Under Clause 21 of the Addendum an **external review process** started in February 2023 to be completed by **December 2023** and will involve the Commonwealth, States &Territories and IHACPA
- Two independent reviewers, Ms Rosemary Huxtable PSM and Mr Michael Walsh PSM, have been appointed to the review and will commence work immediately.
- **Report Expected December 2023**

Source: https://www.health.gov.au/ministers/the-hon-mark-butler-mp/media/review-of-national-hospital-funding-agreement
https://federalfinancialrelations.gov.au/sites/federalfinancialrelations.gov.au/files/2021-07/NHRA_2020-25_Addendum_consolidated.pdf

ADDENDUM TO NATIONAL HEALTH REFORM AGREEMENT 2020-2025

Funding arrangements for new high cost, highly specialised therapies (HSTs, eg CAR-Ts), recommended for delivery in a public hospital setting by the Medical Services Advisory Committee, will be determined on the basis of hospital funding contributions specified in Schedule A with the following exceptions for the term of this Addendum

Interim review, potentially, implications for CAR-T funding in Australia after 30 June 2025

2020–25 National Health Reform Agreement (NHRA)

The NHRA recognises the states and territories as system managers of public hospitals. As such, the states and territories are responsible for:

- determining the mix of the services and functions delivered in their jurisdiction
- system-wide public hospital service planning and performance.

The Australian Government will contribute about $133.6 billion between **1 July 2020 and 30 June 2025** for public hospital services.

Mid-Term Review of the National Health Reform Agreement Addendum 2020-2025

Final Report

Rosemary Huxtable AO PSM | 24 October 2023

Financial sustainability

Access to novel and effective medicines is a core attribute of the National Medicines Policy which impacts how medicines are used in the hospital system. The increasing specificity of the medicines is often linked to upfront genetic testing and profiling which influences treatment selection. It is noted that where these close links exist that the approval process requires coordination between both the PBAC and the MSAC.

The specific nature of some upfront genotyping investigations can see diagnostic testing occurring outside of Australia. This results in out of pocket or unfunded costs to patients or health services to optimise access to appropriate medicines. Added to this is the concentration of some specialist services to major metropolitan health services (e.g., access to CAR-T cell therapy). These circumstances have an impact on equitable access to medicines needed for individual conditions.

96

Mid-Term Review of the National Health Reform Agreement Addendum 2020-2025 – Final Report

Recommendation 29: A structured **horizon scanning process** should be established for high-cost, highly specialised therapies, with involvement of all jurisdictions, and with input from relevant stakeholders, including but not limited to the National Blood Authority, Organ and Tissue Donation Authority, Pharmaceutical Benefits Advisory Committee and Medical Services Advisory Committee, to support forward planning and priority setting.

Recommendation 30: A **unified national HTA process for the assessment and delivery of high-cost, highly specialised therapies under the NHRA should be progressed,** that addresses issues of national consistency, risk sharing, access (including the potential for private sector delivery), affordability, timeliness and information sharing.

Recommendation 31: The unified HTA framework and methodology at Recommendation 30 should:

a) **Drive consistency** in identification of all costs associated with delivery (Commonwealth, State and Territory funded), but also lifetime potential avoided health system costs, through strengthened data collection and analysis.

b) **Take a cross-modal approach** that compares new high-cost, highly specialised therapies to the range of treatments/technologies for the same indication (e.g., medicines, devices, surgery).

Source:
https://www.health.gov.au/sites/default/files/2023-12/nhra-mid-term-review-final-report-october-2023.pdf
https://www.health.gov.au/our-work/2020-25-national-health-reform-agreement-nhra

2024 Horizon Scanning Forum

Medicines of Tomorrow

Medicines Australia

Theme 1: Disruptive therapeutic advances present amazing opportunities for patients – but we must prepare the system now.

The presentations and discussions across each of the four therapeutic areas made evident that the health system, regulatory and reimbursement policies and processes must be reformed now, to enable timely access to these new technologies. Many of the therapies discussed are being introduced overseas and Australian patients will miss out on accessing timely treatment because our regulatory and reimbursement system is lagging.

Theme 2: A co-designed horizon scanning process, with input from all stakeholders, will help to identify unmet needs and enable system readiness to support timely access to new therapies.

Robust horizon scanning is critically important to enable effective planning for regulatory processes, HTA and health systems, so that patients can access new therapies as they become available. There are many stakeholders with a strong interest in horizon scanning as evidenced by the delegates who attended the Horizon Scanning Forum, including Commonwealth and State Government representatives, public and private hospital leaders, clinicians, researchers, patient groups and industry. For Australia to reap the benefits of truly effective horizon scanning, input from all stakeholders through a co-design process will be important.

In addition, Government commitment to reform, additional resourcing and measures to enhance workforce capability will be required.

Theme 3: The recently completed HTA Review has provided some good options to take horizon scanning forward in partnership.

Discussion across each of the four therapeutic areas highlighted the need and potential benefit of a nationally coordinated horizon scanning system and process, and the urgent need for broader HTA reforms, so that Australia can capitalise on the full potential of accelerating innovations in medicines, vaccines and biopharmaceuticals.

Medicines Australia supports the coordinated implementation of all three horizon scanning priorities proposed in the HTA Review Options Paper. These are:

- For advanced therapies and other potentially disruptive technologies.
- To meet priority areas (including addressing equity and high unmet clinical need).
- To help operational and capacity planning for HTA and health systems.[2]

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Join the new chair driving the development of the National Health and Medical Research Strategy

Join Ms Rosemary Huxtable AO PSM at 2:00pm AEDT on 5 December 2024 to learn about the National Health and Medical Research Strategy.

Date published: 15 November 2024

Audience: General public

The National Strategy will build on Australia's strengths in health and medical research and leverage Australia's world-leading research capability. It will aim to attract researchers and investors and improve health outcomes in communities.

The Australian Government has appointed Ms Rosemary Huxtable AO PSM as chair of the National Strategy.

We invite you to join Ms Huxtable and Ms Natasha Ploenges, chief executive officer of the Health and Medical Research Office, to learn about:

- the approach for development of the national strategy
- next steps
- ways in which you can get involved.

The webinar will be at 2:00pm AEDT on 5 December 2024.

You will have an opportunity to ask questions following the presentation.

Visit National Health and Medical Research Strategy – chair webinar to register.

And much more we can't cover today……

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Establishing Genomics Australia

We are establishing Genomics Australia from 1 July 2025 to provide national leadership and coordination to better integrate genomics into the health system.

Date published: 22 November 2024

Audience: General public

Genomics Australia will support the transition from a research focus to clinical service delivery. This move will achieve efficiencies and better health outcomes for all Australians.

Read the media release to find out more.

Australian Government
Department of Health and Aged Care

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New Aged Care Bill passes Parliament

Parliament passed the Aged Care Bill on 25 November which means that after Royal Assent the new Aged Care Act will start from 1 July 2025.

Date published: 26 November 2024

Audience: General public

A new Act was the number one recommendation of the Royal Commission into Aged Care Quality and Safety. It will bring a range of improvements for older people. This includes:

- a new regulatory model
- strengthened Aged Care Quality Standards
- a Statement of Rights to ensure older people and their needs are at the centre of the new aged care system.

Forecasts for the 20th Annual Annual Drug and Devices Australia Webinar

A digital blueprint for strengthening our health system

The Digital Health Blueprint 2023–2033 articulates our vision for the role digital health capabilities will continue to play in delivering a more person-centred and sustainable health system by 2033:

Trusted, timely and accessible use of digital and data underpins a personalised and connected health and wellbeing experience for all Australians.

For consumers, healthcare providers, researchers and innovators, the Blueprint reflects our vision for the use of digital health and our role in its use. For example:

- **digitally enabled services are changing how people, clinicians, businesses and governments work together**. A contemporary health service should reflect the digital experiences people expect from other industries
- digital health can play an important part in **better supporting a health workforce** that is under pressure to deliver timely and high-quality care
- there is a need for the adoption of national **digital health capabilities** in areas where we hold responsibility for policy, legislation and funding.

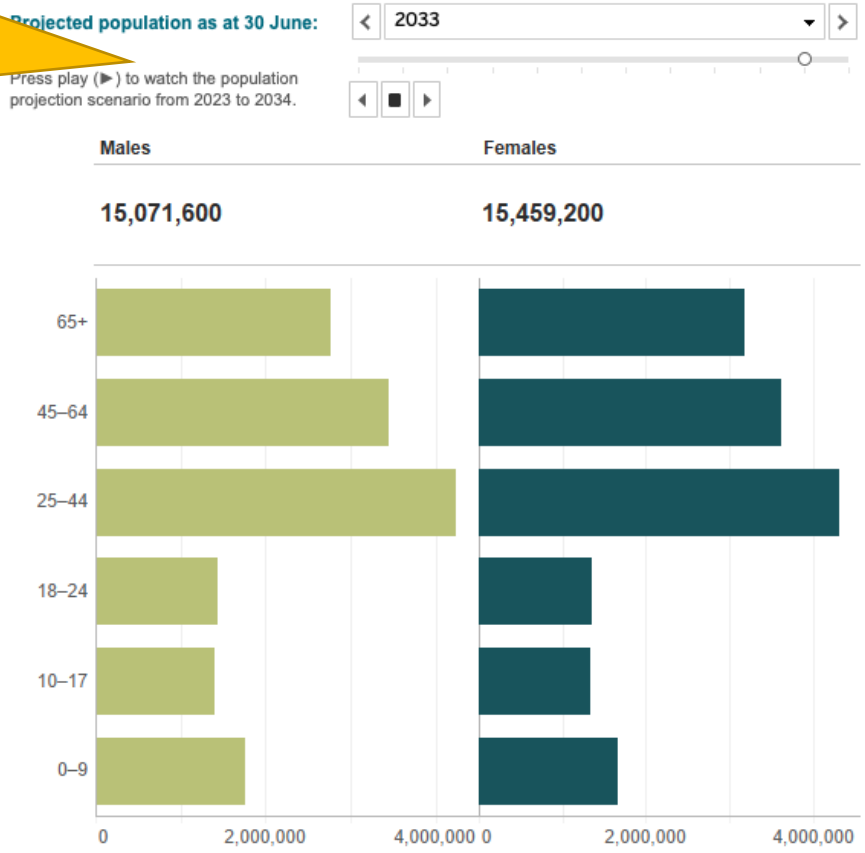
Year 2033

30M Population

Population projections, by sex and age, 30 June 2023 to 30 June 2034
Australia

Projected population as at 30 June: 2033

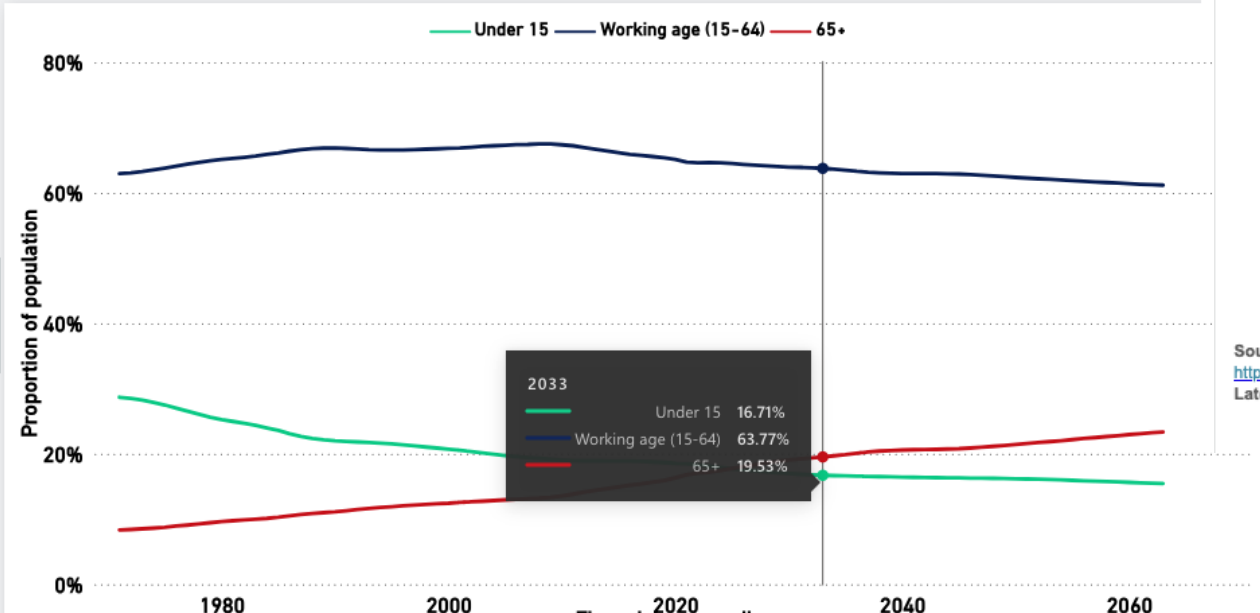
Press play (▶) to watch the population projection scenario from 2023 to 2034.



Source: Centre for Population, 2023 Population Statement
https://population.gov.au/publications/statements/2023-population-statement
Latest data: December 2023

Figure 3-3: Ageing population, 1970-71 to 2062-63

Figure 3-1: Gross debt
Figure 3-2: Interest payments
Figure 3-3: Ageing population
Figure 3-4: Scenarios
Figure 3-5: Combined UCB scenarios



2033 – 67 not out and still riding

QUESTIONS ???

WE'RE SURE YOU HAVE NONE, RIGHT?

LUCID HEALTH CONSULTING

Director – George Papadopoulos

W: lucidhealthcon.com

M: +61 435 934 394

E: george@lucidhealthcon.com

Connect with George on LinkedIn:

www.linkedin.com/in/gpapadopoulos

MedTechnique CONSULTING

Director – Sarah Griffin

W: medtechnique.com.au

M: +61 448 058 600

E: sarah@medtechnique.com.au

Connect with Sarah on LinkedIn:

www.linkedin.com/in/griffin-sarah/