



# **Australian Government**

Australian Government response to the  
Senate Community Affairs References Committee report:

Issues related to menopause and perimenopause

FEBRUARY 2025

## Overview

On 6 November 2023, the Senate referred an inquiry into the Issues related to menopause and perimenopause to the Senate Community Affairs References Committee (Committee).

The Committee report highlights the challenges women experience in relation to perimenopause and menopause. This included issues related to accessing adequate healthcare and also the challenges experienced within workplaces. The Australian Government would like to thank those that gave their time and expertise to the Committee, particularly the women who shared their lived experience.

Supporting, protecting and promoting the health of all women, girls and gender diverse people is a key priority for the Government. This includes addressing the key risk factors that can reduce the quality of life, and better manage the varied needs of women, as they age. That is why the Government established the National Women's Health Advisory Council (the Council) in 2023, to bring together diverse expertise to examine the unique challenges that women and girls experience in the health system.

The Council provides advice and recommendations directly to Government to improve health outcomes for women and girls in Australia, along with advice on the implementation of the National Women's Health Strategy 2020–2030 (the Strategy). The Strategy outlines a national approach to improving health outcomes for all women and girls. A key action identified in the Strategy is to support women and their healthcare providers to manage the effects of menopause, which includes increasing training for health professionals. The Government recognises the importance of improving the awareness of, and encouraging further research and support services, for women experiencing perimenopause and menopause.

That is why the Government is investing \$64.5 million over three years from 2025-26 to increase access to specialist care for women's health with a focus on perimenopause and menopause. This includes:

- the development of a national campaign to raise awareness of the symptoms and management options for menopause,
- increased training and support for health professionals, including the development of national guidelines to provide consistent advice and support to women,
- expanding the scope of Endometriosis and Pelvic Pain Clinics to include specialised support relating to menopause and perimenopause,
- a new Medicare Benefits Schedule (MBS) health assessment service for menopause and perimenopause.

The Government is also continuing to invest in treatments for menopause through the Pharmaceutical Benefits Scheme (PBS).

This builds on the Government's 2024-25 Budget investment of over \$160 million in a tailored women's health package to tackle gender bias in the health system, upskill medical professionals and improve sexual and reproductive care.

The Government continues to support women experiencing perimenopause and menopause through a number of national policies, funding for public hospitals through the National Health Reform Agreement, MBS rebates for relevant health services including consultation and telehealth, subsidies for approved medications through the PBS, and funding for mental health services outside the MBS.

The Government also provides access to health information, investment for clinical care tools, health professional training, and provides funding for research initiatives and data collections relevant to menopause.

The Government's response supports (or supports in principle) 16 out of the 25 recommendations, and notes 9.

A number of recommendations given in-principle support, may relate to matters where further collaboration with stakeholders is required or where there are existing activities underway which go to addressing the intent of the recommendation.

The Government acknowledges other women-related policies, such as Working for Women: A Strategy for Gender Equality and the Senate inquiry into universal access to reproductive healthcare also reflect the Government's commitment to improve outcomes for women.

## Recommendation 1

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*1: The Committee recommends that the Department of Health and Aged Care commission research to establish a comprehensive evidence base about the impacts of menopause and perimenopause on women in Australia, including:*

- *Menopause differentiated from midlife stressors.*
- *Mental health impacts of menopause.*
- *Early menopause.*

*The research should also establish an understanding of experiences for:*

- *Culturally and linguistically diverse women.*
- *First Nations women.*
- *LGBTQIA+ individuals.*
- *Women living with a disability.*

The Australian Government **supports** this recommendation.

The Government recognises the importance of increasing the evidence base in women's health including the experiences of women from priority populations.

The Government provides direct support for health and medical research through the National Health and Medical Research Council (NHMRC), which focuses on supporting investigator-led research. Between 2010 and 2023 the NHMRC expended \$23.5 million towards research relevant to menopause and perimenopause.

To further support research development, up to \$25 million of funding over four years from 2024-25 has been made available for the 2024 Medical Research Future Fund (MRFF) Emerging Priorities and Consumer Driven Research (EPCDR) Infertility, Pregnancy Loss and Menopause Grant Opportunity which includes a focus on perimenopause and menopause research. The Grant Opportunity closed on 6 November 2024. Application outcomes are expected by May 2025, with research projects anticipated to be undertaken from 2025 to 2029.

Through the Grant Opportunity, two streams have a focus on perimenopause and menopause research and applications were invited for a large-scale multidisciplinary project, co-designed with consumers, to identify and evaluate the impacts of perimenopause and menopause on health and wellbeing, that will:

- Investigate menopause symptoms that impact on physical health, mental health and wellbeing, including psychosocial factors.
- Investigate impacts on workforce engagement and retention, including on paid and unpaid employment.
- Include research participants from metropolitan areas (MM1) and regional, rural and/or remote locations (MM2-7), according to the Modified Monash Model.
- Consider diverse populations (e.g. individuals from culturally and linguistically diverse communities).

- A research project to investigate the biological mechanisms or risk factors that underpin early or medically induced menopause.

The Government is also investing \$5.5 million over three years from 2024–25 for the Australian Institute of Health and Welfare (AIHW) to establish a sexual and reproductive health data set to help inform sexual and reproductive health policy and improve healthcare access outcomes.

Perimenopause and menopause will be a key priority area in this work program, which will include an extensive consultation process to identify the information needs and data gaps (including those identified in the Senate Inquiry report), scope options for improved data collection and commence data development and collection where applicable. This work will contribute to the evidence base on perimenopause and menopause in Australia, including for populations groups such as women from CALD communities, First Nations women, women living with a disability and LGBTQIA+ individuals.

## Recommendation 2

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*2: The Committee recommends that the Australian Government launch a national menopause and perimenopause awareness campaign, providing information and resources for women and communities across Australia. This awareness campaign should be designed in consultation with experts and people with lived experience.*

The Australian Government **supports** this recommendation.

Recognising the low level of awareness and understanding of menopause in the general community, and even at times, the medical community, the Government will invest \$12.8 million over two years from 2025-26 to undertake a public health campaign to help raise awareness of perimenopause and menopause symptoms and management options. The campaign will aim to increase understanding of the impact perimenopause and menopause can have on the physical, mental and emotional wellbeing of women, seek to address misinformation, and support women to adopt preventive actions. The campaign will also target health practitioners to increase their understanding of the impacts of this life stage and promote resources for the treatment of menopause symptoms.

The Government continues to support the provision of factual, evidence-based and trusted health information. There are several existing sources of government-funded information on women's health, including through key life stages such as perimenopause and menopause, such as:

- Healthdirect Australia, a consumer health information website, app and telephone line providing free resources related to menopause, including information on perimenopause, early menopause, Hormone Replacement Therapy/Menopausal Hormone Therapy and post-menopause.
- Jean Hailes for Women's Health, a national, not-for-profit organisation providing free, evidenced-based information on women's health with a particular focus on menopause. Funding to Jean Hailes for Women's Health supports the development and publication of resources on menopause symptoms, causes, risk factors and management options. This includes tailored information for First Nations women, women from multicultural communities and Easy Read resources.
- Health in My Language (HIML) a national health education program delivering multilingual information to migrant and refugee communities from trained bicultural health educators across Australia. The program is conducted in culturally-safe conversations, in person and in their languages. HIML is managed by the Multicultural Centre for Women's Health.

### Recommendation 3

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*3: The Committee recommends that, in the next review of the Australian Curriculum, the Australian Curriculum, Assessment and Reporting Authority (ACARA) consider how menopause can be expressly referenced in the menstrual health and reproductive cycles content within the Health and Physical Education learning area.*

The Australian Government **notes** this recommendation.

The Australian Curriculum, Version 9.0 was signed off by Education Ministers on 1 April 2022.

The Australian Curriculum addresses reproductive and sexual health as part of the Health and Physical Education (HPE) curriculum in an age-appropriate way across the years of schooling from Foundation to Year 10.

In HPE, students learn about the different changes and transitions they may experience including physical, social and emotional changes associated with puberty.

Whilst the terms 'menstruation', 'period' and 'menopause' are not mentioned explicitly in the HPE curriculum, it is expected that menstruation and period would form part of the learning about the changes associated with puberty. Menopause may be addressed depending on the needs and interests of the local school context.

Education is a shared responsibility between the Government and state and territory governments. State and territory governments and the non-government school sector have responsibility for the implementation of the curriculum within their schools, including in the choice of resources to support teachers to implement the curriculum.

#### Recommendation 4

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*4: The Committee recommends that the Australian Government commission research to undertake a comprehensive study to assess the economic impacts of menopause which clearly delineates the impact of symptoms of menopause on women's workforce participation, income, superannuation, and age of retirement.*

The Australian Government **supports in-principle** this recommendation.

The 2024 MRFF EPCDR Infertility, Pregnancy Loss and Menopause Grant Opportunity (stream four, refer recommendation 1 response) has a focus on perimenopause and menopause research to investigate impacts on workforce engagement and retention, including on paid and unpaid employment. The Grant Opportunity closed on 6 November 2024, with funding expected to commence from June 2025.

The Government provides core funding to the Australian Longitudinal Study on Women's Health (ALSWH). The population-based survey examines the health and wellbeing of over 57,000 Australian women across 4 cohorts. The study has provided data on the health of Australian women since 1995 and supports evidence-based policy and practice in many areas of women's health. ALSWH has commenced collecting data on the potential impact of menopause on workforce participation.



**Recommendation 5**

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*5: The Committee recommends that the Australian Government introduce reforms to allow the Workplace Gender Equality Agency (WGEA) to re-commence data collection on the supports employers are providing, and their usage, for employees experiencing menopause and perimenopause, including specific workplace policies.*

The Australian Government **supports in-principle** this recommendation.

The Government is considering options to enable WGEA to collect data on the supports employers are providing for employees experiencing menopause and perimenopause, including specific workplace policies. This may require amendments to WGEA's legislative framework. The Government recognises the need to understand the nature of existing workplace supports and their impact on gender equality and the role WGEA could play in collecting this data as recommended by the Senate Inquiry.

## Recommendation 6

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*6: The Committee recommends that the Australian Government consider amendments to Section 65 of the Fair Work Act 2009, to ensure women can access flexible working arrangements during menopause.*

The Australian Government **notes** this recommendation.

The Government is committed to gender equality and has implemented a number of reforms to help more employees access flexible working arrangements including through the *Fair Work Amendment (Secure Jobs, Better Pay) Act 2022*. An independent statutory review of the Secure Jobs, Better Pay Act has commenced. It will consider whether changes to the right to request flexible working arrangements are operating appropriately and effectively and whether there are any unintended consequences of the reforms. Any further changes to flexible work arrangements should be considered in light of the outcomes of this review.

### *Flexibility entitlements within the Fair Work Act 2009*

The National Employment Standards (NES) in the *Fair Work Act 2009* include a right to request flexible working arrangements for eligible employees. The Secure Jobs, Better Pay reforms, strengthened the right including by:

- Introducing a new procedure for how employers must respond to requests such as requiring employers to respond within 21 days and only refuse on reasonable business grounds after taking certain steps.
- Enabling the Fair Work Commission to deal with disputes.
- Expanding eligibility to employees who are pregnant as well as to situations where employees or members of their family, or household, are experiencing family or domestic violence.

Employees who are 55 or older and meet eligibility criteria have the right to request flexible working arrangements.

The Government is also committed to protecting and facilitating workers' access to their entitlements. Recent legislative reform to the Fair Work Act as part of *the Fair Work Legislation Amendment (Closing Loopholes No.2) Act 2024* included measures to change the defence to sham contracting and restore a fair, objective definition of employment and casual work which seeks to ensure fewer workers miss out on entitlements, including their right to request flexible working arrangements, due to misclassification.

### *Other mechanisms for accessing flexible working arrangements*

The Government recognises many employees experiencing menopause will be under the age of 55 and may not meet any of the other circumstances to have a right to request flexible working arrangements under the NES. Employees without a right to request flexible working arrangements under the NES may be able to access flexible work in other ways.

In May 2023, employees whose wages are set by modern awards or registered agreements made up 57.2%<sup>1</sup> of Australian employees. These employees can access flexible work through Individual Flexibility Arrangements which enable an employee and employer to agree to vary the effect of the award or agreement to meet the genuine needs of the employee and employer.

Employees may also be able to access flexible working arrangements through workplace policies, conversations with their managers or by bargaining for access to better entitlements.

The Government has improved access to bargaining through the supported bargaining stream which will help workers in lower paid and feminised sectors to negotiate better pay and conditions for themselves.

The Fair Work Commission is currently considering including a working from home term in the *Clerks – Private Sector Award 2020* which set the pay for 91,506 employees<sup>2</sup> (80.8%<sup>3</sup> of whom are female) in May 2021. The Fair Work Commission has indicated that this may serve as a model term for other awards.

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<sup>1</sup> Australian Bureau of Statistics, <https://www.abs.gov.au/statistics/labour/earnings-and-working-conditions/employee-earnings-and-hours-australia/latest-release#method-of-setting-pay>

<sup>2</sup> Fair Work Commission, <https://www.fwc.gov.au/documents/wage-reviews/2022-23/profile-of-employee-characteristics-across-modern-awards-2023-03-03.pdf>

<sup>3</sup> Fair Work Commission, [am202321-gender-prism-180724.pdf \(fwc.gov.au\)](https://www.fwc.gov.au/documents/wage-reviews/2022-23/profile-of-employee-characteristics-across-modern-awards-2023-03-03.pdf)

## Recommendation 7

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*7: The Committee encourages Australian workplaces develop perimenopause and menopause workplace policies in consultation with their employees.*

The Australian Government **notes** this recommendation recognising it is directed towards all Australian workplaces.

As a model employer, the Government supports Australian Public Service (APS) agencies to establish policies that will progress gender equality and contribute to positive economic and work outcomes for Australian women. The Australian Public Service Commission will support APS agencies to develop workplace policies on perimenopause and menopause.

Currently, APS agencies can leverage existing entitlements to support employees experiencing symptoms associated with perimenopause and menopause. This includes the forward leaning ability to request flexible working arrangements and accrual of at least 18 days paid personal leave per year for full-time employees.

## Recommendation 8

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*8: The Committee recommends that the Australian Government task the Department of Employment and Workplace Relations to undertake further research on the impact and effectiveness of sexual and reproductive health leave where it has been implemented in Australia and overseas, while giving consideration to introducing paid gender-inclusive reproductive leave in the National Employment Standards (NES) and modern awards.*

The Australian Government **notes** this recommendation.

The Department of Employment and Workplace Relations monitors and considers developments related to sexual and reproductive health leave using publicly available information. This includes high-level monitoring of domestic and international examples of reproductive health leave.

The Department of Employment and Workplace Relations is aware some countries have legislated menstrual leave and some are considering reproductive leave. The Department of Employment and Workplace Relations will continue to monitor these at a high-level but notes evidence of effectiveness may be limited or inaccessible. The relevancy of international examples may also be low given many countries have very different workplace relations contexts. For example, Spain has implemented menstrual leave however it is social security based not employer funded like Australian personal/carer's leave entitlements.

The *Fair Work Act 2009* NES provide permanent employees with an entitlement to paid personal/carer's leave, which can be taken when an employee is unfit for work because of a personal illness or injury, or caring responsibilities.

The Government acknowledges that reproductive health leave provisions are being adopted in some workplaces in Australia, directly by employers or through enterprise agreements. The Department of Employment and Workplace Relations has captured IVF/reproductive leave, menstrual leave and menopause leave in its database of approved enterprise agreements since 2023. This information will continue to be captured, providing insights into the implementation of reproductive health leave entitlements in Australian workplaces.

The Government notes the Fair Work Commission, Australia's independent industrial relations tribunal, is responsible for setting award wages and conditions for national system employees. While the Government does not have standing to apply to vary modern awards, employees and employers covered by an award, or organisations entitled to represent their industrial interests, can apply to the Fair Work Commission at any time to vary award wages and conditions.

## Recommendation 9

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*9: The Committee recommends that the Australian Government encourage the Australian Medical Council to consider explicitly including menopause and perimenopause in the Graduate Outcome Statements of the Standards for Assessment and Accreditation of Primary Medical Programs. The committee further recommends that menopause and perimenopause be included in graduate outcomes for other health professionals, including nurses and physiotherapists.*

The Australian Government **supports in-principle** this recommendation.

Changes to the Australian Medical Council (AMC) accreditation standards including graduate outcomes will require a consultation process (including public consultation). This is a requirement under the *Health Practitioner Regulation National Law Act 2009* as in force in each state and territory. This recommendation links with recommendation 10.

The Department of Health and Aged Care has raised with the AMC opportunities to further strengthen accreditation processes to improve medical practitioner, knowledge and skills on menopause/perimenopause and broader women's health issues. The department has recently written to the AMC requesting formal consultation on improvements to Accreditation standards to include references to menopause and perimenopause.

## Recommendation 10

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*10: The Committee recommends that the Australian Medical Council work with Medical Deans Australia and New Zealand to ensure that menopause and perimenopause modules are included in all medical university curriculums.*

The Australian Government **supports-in-principle** this recommendation.

In its formal request to the Australian Medical Council (AMC), the Government will encourage the AMC to work with the Medical Deans Australia and New Zealand to prioritise health practitioner knowledge and skills in menopause within upcoming *accreditation reviews of medical programs of study*, undertaken by AMC.

The Medical Deans Australia and New Zealand attended a roundtable on health care to support diverse communities in June 2024, where they discussed strategies to address bias within the health system for women and diverse population groups, including through education curricula.

As part of its 2024-25 workplan, the National Women's Health Advisory Council have agreed to an activity to support an audit of health and medical education curricula to ensure the inclusion of sex and gender awareness, to help address bias in the health system for women and diverse population groups. This could include ensuring that topics specific to women and gender diverse people, like menopause and perimenopause, are included in all medical university curriculums.

This recommendation links with recommendation 9.

**Recommendation 11**

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*11: The Committee recommends that all governments and the medical colleges work together to require and facilitate further education on menopause and perimenopause for physicians practising in the public health system across Australia.*

The Australian Government **supports-in-principle** this recommendation.

Medical colleges are independent membership-based organisations. Governments do not have authority to direct medical colleges. The Independent review of complexity in the National Registration and Accreditation Scheme is currently under way. Its Terms of Reference includes whether additional levers should be available to governments to direct accreditation authorities. The final report is expected in April 2025. This recommendation links with recommendation 9.

The Government is also investing \$2.9 million over three years from 2025-26 to develop national clinical guidelines for perimenopause and menopause. National clinical guidelines will ensure information for clinicians is nationally consistent, evidence based and readily available to support consistent care for women experiencing perimenopause and menopause.



**Recommendation 12**

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*12: The Committee recommends that the Australian Government considers increasing funding and expand the recipient base for the delivery of incentivised continuing professional development to medical practitioners on perimenopause and menopause.*

The Australian Government **supports** this recommendation.

Medical practitioners are responsible for choosing continuing professional development that aligns with their patient and community needs.

The 2024-25 Budget included investment of approximately \$1.2 million over two years from 2024-25 to support training for up to 11,000 health professionals to better treat, care and manage women's health during menopause and perimenopause. The measure aims to support placements for health professionals on a Continuing Professional Development (CPD) course on managing menopause, offered by Jean Hailes for Women's Health.

An additional investment of \$1.5 million over three years from 2025-26 has been provided for targeted promotion and incentive opportunities to encourage more health professionals to undertake CPD training to prioritise menopause specific professional development.

### Recommendation 13

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*13: The Committee recommends that the Australian Government consider how to expand the scope of practice of nurse practitioners to ensure better support for women experiencing menopause in rural and regional areas.*

The Australian Government **supports** this recommendation.

Nurse practitioners support women with menopause and perimenopause, across all settings, including rural and remote. The Government recognises barriers exist which prevent nurse practitioners providing complete care and health services to women. Accordingly, it has implemented the following measures to increase access to nurse practitioner care:

- From 1 July 2024, patient benefits for general attendances by a nurse practitioner increased by 30 per cent.
- From 1 July 2024, nurse practitioners became eligible to participate in multidisciplinary case conferences for patients with chronic conditions.
- From 1 November 2024, nurse practitioners no longer need to be in a legislated collaborative arrangement with a medical practitioner to render MBS services or prescribe PBS medications.

Initial and subsequent consultations with women experiencing perimenopause and menopause symptoms are often complex and require longer appointments for comprehensive consultation, assessment, planning of care, and any interventions that may be required. Women in rural and remote areas often travel long distances for appointments. From 1 March 2025, the Government will introduce two new general attendance MBS items for nurse practitioners (face-to-face and telehealth) of at least 60 minutes duration. These measures will support the time needed for women seeking support for perimenopause and menopause to engage meaningfully with a nurse practitioner and time for a nurse practitioner to provide comprehensive, high-quality care for women.

In addition, the independent *Unleashing the Potential of our Health Workforce (Scope of Practice) Review* was released on 5 November 2024. This review made recommendations to all Health Ministers regarding enabling health professionals, including nurse practitioners, to work to their full scope of practice. The Government will carefully consider the findings and recommendations of this review alongside other recently-released primary care and workforce reviews.

## Recommendation 14 and Recommendation 15

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*14: The Committee recommends that the Department of Health and Aged Care, through the Medicare Benefits Schedule (MBS) Continuous Review, review existing MBS item numbers relevant for menopause and perimenopause consultations, including for longer consultations and mid-life health checks, to assess whether these items are adequate to meet the needs of women experiencing menopause.*

*15: The Committee recommends that the Australian Government consider whether a new MBS item number or the expansion of criteria for the mid-life health check, is needed to support greater access to primary care consultations for women during the menopause transition.*

The Australian Government **supports** these recommendations.

The Government will establish a new MBS health assessment service for women experiencing menopause or perimenopause. The Government has committed funding of \$26 million over two years, commencing from 2025-26, to introduce temporary items for this assessment service. Ongoing arrangements for the item will be informed by outcomes from the review of MBS health assessment services within primary care, expected in 2025.

All MBS health assessment items, including the 45–49-year-old health assessment (referred to by some as the mid-life health check), are currently being reviewed with a view to ensuring they align with current evidence and support contemporary clinical practice. As part of this, a systematic literature review of the evidence base supporting health assessments and a detailed analysis of MBS data have been undertaken. A public consultation period on the items and potential changes closed on 30 September 2024.

The key MBS items for the management of all health conditions in primary care, including menopause are currently under review through the MBS Continuous Review process.

The MBS Review Advisory Committee (MRAC) commenced a review of time-tiered items for primary care in August 2024. The review will consider issues such as item consistency, opportunities to streamline, and whether the current time-tiers appropriately support contemporary clinical practice. The review is anticipated to be finalised and provided to Government at the end of 2025.

As part of the MBS Continuous Review, the Government has also committed to undertake an evidence review on bone densitometry testing for women experiencing menopause. This review will complement other review processes and will ensure existing MBS items are adequate to meet the needs of women experiencing or transitioning to menopause.

Recommendations are expected to be provided to Government in early 2025. Any recommendations will need to improve the framework in relation to alignment with current evidence and supporting contemporary clinical practice.

## Recommendation 16

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*16: The Committee recommends that the Department of Health and Aged Care, including the Therapeutic Goods Administration, consider action to address the shortages of menopause hormonal therapy (MHT) in the Australian market and consider options to secure sufficient supply, including a review of the supply chains and pricing trends of MHT, with a view to enabling universal affordable access to treatment and care.*

The Australian Government **notes** this recommendation.

### Medicine shortages

The Therapeutic Goods Administration (TGA) recognises the importance of Menopausal Hormone Therapy (MHT) and Hormone Replacement Therapy (HRT) medicines and the need to have reliable access. Shortages of these medicines have a significant impact on the health and wellbeing of many women in Australia.

Mandatory reporting of medicine shortages commenced in January 2019, with pharmaceutical companies required to report to the TGA any current or anticipated supply disruptions for all prescription medicines and certain over the counter (OTC) medicines. The TGA publishes shortage information on the medicine shortage reports database and works collaboratively with medicine sponsors, wholesalers and health professionals to determine whether additional actions are needed to mitigate supply impacts.

The TGA proactively manages medicine shortages to reduce the impact on patients wherever possible. Depending on the cause of the shortage, the TGA can take the following management actions:

- Working with medicine sponsors and other stakeholders to manage inventory, including supporting the fair distribution of stock in Australia.
- Approving the supply of overseas-registered alternative products under section 19A of the *Therapeutic Goods Act 1989* (Act).
- Allowing pharmacists to dispense certain identified substitute medicines when a medicine is in shortage, by making a Serious Scarcity Substitution Instrument.
- Working with pharmaceutical companies to expedite regulatory processes that may otherwise delay the supply of medicines.
- Collaborating with health professional and consumer groups to provide guidance on managing demand during a shortage, including on prioritising prescribing for certain conditions.

The TGA has been notified of shortages for numerous HRT patches, including all strengths of Estradot, Estraderm MX and Estalis products, as well as the discontinuation of Climara patches.

The ongoing shortages of HRT patches is a global issue and is driven by various factors, including manufacturing issues and unexpected increases in demand. The discontinuation of the Climara brand of patches put additional strain on supply.

To support ongoing access for patients, the TGA has provided temporary approval for the supply of multiple HRT medicines from overseas under section 19A of the Act.

From 1 June 2024, the Estradiol (Sandoz, USA) brand of HRT patches (several strengths) is also listed on the PBS to provide subsidised access to this alternative product.

The Department of Health and Aged Care has also issued a Notice under the Community Service Obligation (CSO) Deed, enabling CSO Distributors (CSODs) to constrain available supplies and facilitate equitable distribution of PBS-listed estradiol transdermal patches. This notice allows individual CSODs to utilise their expertise in relation to the supply of medicines, to independently determine the practices they can adopt to support equitable supply of these patches and prevent stockpiling.

Up-to-date supply details, comprehensive background information, and advice about the HRT patch shortages is available on a dedicated 'HRT shortage' webpage on the TGA website.

There are currently no reported shortages of alternative HRT presentations such as tablets, topical creams or pessaries.

Medicine sponsors are private businesses and make their own decisions regarding if and how to market a product in Australia. The TGA cannot compel them to register, market, manufacture or continue supply of a medicine in Australia. However, the TGA does work with these companies to try to minimise the effects of medicine shortages on patients.

The department continues to consider ways to better anticipate, manage and communicate medicine shortages and discontinuations. Following a 2021 consultation on proposals to help ensure reliable supply of important medicines, the TGA initiated mechanisms to prioritise evaluation of applications for registration of medicines vulnerable to shortage. In 2024, the TGA extensively consulted to better understand challenges and barriers experienced by consumers, health professionals and industry relating to medicine shortages and discontinuations. This feedback is being used to develop a work-plan for potential future reform.

Medicine shortages occur for many reasons and, unfortunately an uninterrupted supply chain can never be guaranteed. Medicine sponsors generally maintain continuity of medicine supply through demand forecasting, stock control, and back-up supply routes. However, situations may arise where a disruption to the supply of a medicine cannot be avoided. The Government administers several policies to ensure pharmaceutical companies supply PBS-subsidised medicines where possible.

For newly listed products on the PBS, pharmaceutical companies are required to provide an assurance of supply, undertaking that sufficient stock of the product to meet demand will be available in time for the first PBS listing day. In addition, Guarantee of Supply requirements outlined in Division C, Part VII of the *National Health Act 1953* apply to newly listed brands that are bioequivalent or biosimilar to an existing listed brand and where a pharmaceutical company offers a lower price. The Guarantee of Supply period ends after 24 months or until another brand assumes the obligation.

In the event of a serious shortage, the TGA may also publish a Serious Scarcity Substitution Instrument (SSSI) which allows community pharmacists to substitute specific medicines without prior approval from the prescriber. The Government has implemented changes that allow PBS subsidy in circumstances where the TGA has issued a SSSI. A list of scarce medicines that may be substituted with specific medicines under the PBS is available on the PBS website at: [www.pbs.gov.au/info/browse/medicine-shortages](http://www.pbs.gov.au/info/browse/medicine-shortages).

Where an overseas marketed medicine has been approved under Section 19A of the Act for import or supply in Australia, these medicines (s19A products) may be subsidised on the PBS via one of the following methods:

1. Eligible for existing subsidy: the s19A product may be automatically listed on the PBS, if the drug, form, brand and manner of administration, as well as the cost are all the same as the PBS-listed product in shortage. The responsible person of the PBS-listed product and the s19A product must also be the same.
2. Recommended listing: where the supplier of the s19A product and the PBS-listed product are not the same, or the form, brand and/or manner of administration differ the supplier of the s19A product must make an application to list the item on the PBS. The Pharmaceutical Benefits Advisory Committee (PBAC) advises the Government on whether the s19A medicine should be subsidised through the PBS and under what conditions. The PBAC, an independent expert advisory body, advises the Government about whether the section 19A medicine should be subsidised through the PBS and under what conditions.

Where the TGA has provided temporary approval for supply of an alternative brand of a medicine under s19A, the Government works with the sponsor to expedite subsidisation of that brand through the PBS. However, ultimately it is a decision made by the sponsor to list their s19A product. A sponsor cannot be compelled by the Government to list a medicine on the PBS.

A list of current s19A products that are PBS listed is available on the PBS website at: [www.pbs.gov.au/info/browse/section-19A](http://www.pbs.gov.au/info/browse/section-19A).

To date, there are three strengths of s19A estradiol patches [brand Estradiol Transdermal System (Sandoz, USA)] temporarily listed on the PBS since 1 June 2024 to mitigate the shortages of estradiol patches. The Department of Health and Aged Care is working with s19A suppliers to list additional s19A estradiol patches on the PBS.

## Recommendation 17

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*17: The Committee recommends the Therapeutic Goods Administration continue to monitor the advertising of alternative medicines and treatments in Australia and take action as appropriate. The committee further recommends the Department of Health and Aged Care consider reviewing the labelling of TGA approved medicines.*

The Australian Government **supports** the recommendation for the TGA to continue to monitor advertising alternative medicines and treatments in Australia as appropriate.

Detection and deterrence of the unlawful import, advertising and supply of medicines and medical devices advertised as traditional or alternative treatments remains a TGA compliance priority in the 2024-25 financial year<sup>4</sup>.

The TGA will continue to monitor for potential unlawful advertising of therapeutic goods, including alternative medicine and treatment products, in line with our regulatory compliance framework<sup>5</sup>. A range of monitoring strategies are used to support the TGA's compliance programs, which are both proactive and responsive. This is important, given that areas of non-compliance are not limited to current compliance priorities.

The TGA will also continue to work with online platforms, including social media platforms, to deter and disrupt potential unlawful advertising via proactive engagement and monitoring of online activity.

The Australian Government **notes** the recommendation for the Department of Health and Aged Care to consider reviewing the labelling of TGA approved medicines.

The TGA will continue to monitor and review the labelling of TGA-approved medicines in Australia and take action as appropriate. There are legislative requirements governing the information that must be included on the labelling of therapeutic goods. Changes to these requirements would require further consideration and public consultation.

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<sup>4</sup> <https://www.tga.gov.au/how-we-regulate/compliance-and-enforcement-hub/compliance-management/import-advertising-and-supply-compliance-priorities-2023-24>

<sup>5</sup> <https://www.tga.gov.au/how-we-regulate/compliance-and-enforcement-hub/compliance-management/import-advertising-and-supply-compliance-priorities-2023-24>

## Recommendation 18

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*18: The Committee recommends that the Australian Government examine options to implement a means of ensuring that MHT items are affordable and accessible, including consideration of domestic manufacturing and alternate means of subsidising costs to the consumer. Such examination should include, but not be limited to, considering ways to encourage pharmaceutical sponsors to list a broader range of MHT items, such as body identical hormone therapy products, on the Pharmaceutical Benefits Scheme to ensure appropriate access and lowered costs for all women who need it.*

The Australian Government **notes** this recommendation.

The Government understands that there are legitimate concerns from clinicians and consumers about subsidised access to Menopausal Hormonal Therapy (MHT). The Government supports MHT being affordable and accessible for all who need them. The PBS is the main mechanism through which the Government subsidises medicines, including MHT.

Under legislation, the Government cannot list a medicine on the PBS unless the Pharmaceutical Benefits Advisory Committee (PBAC) makes a recommendation in favour of listing. The PBAC is an independent and expert body, comprising doctors, health professionals, health economists and consumer representatives.

To address barriers to accessing MHT, the Minister for Health and Aged Care referred the matter to the PBAC for review.

When considering a medicine proposed for PBS listing, the PBAC is legally required to take into account the comparative effectiveness and cost-effectiveness of the medicine compared to other available therapies.

The PBAC's consideration is generally initiated by the pharmaceutical company responsible for a medicine, applying for the medicine to be considered for PBS listing. Although nothing prevents other stakeholders from lodging PBAC submissions, the responsible pharmaceutical company usually holds the scientific data and other information necessary to inform the PBAC's consideration.

Pharmaceutical companies are private businesses that make their own decisions about whether to apply for subsidy through the PBS. The Government cannot compel pharmaceutical companies to seek PBS subsidies for their medicines.

At its November 2024 meeting, the PBAC recommended PBS listing of estradiol gel (Estrogel®), the micronized progesterone product Prometrium®, and Estrogel Pro, a combination product containing Estrogel and Prometrium. The outcomes from the November 2024 PBAC meeting are available on the PBS website.

Alternate means of subsidy outside the PBS would risk undermining health technology assessment processes that ensure value-for-money for taxpayers. The Government will continue to consider how policies can encourage the appropriate availability of subsidised MHT.



## Recommendation 19

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*19: The Committee recommends that the Pharmaceutical Benefits Advisory Committee (PBAC) reforms comparator selection during evaluation of new MHT items to include quality of life health impacts. The committee also recommends that the PBAC regards body identical hormone therapy products in a separate drug class to remove the lowest cost comparator to synthetic therapies.*

The Australian Government **notes** this recommendation.

Measures of quality of life are routinely considered by the PBAC in its assessment of the clinical effectiveness and cost effectiveness of a new medicine compared to alternative therapies, as required under the *National Health Act 1953*. The PBAC considers the information that is provided in submissions, including information on quality-of-life impacts. Comments from consumers and other stakeholders about a medicine are also provided to the PBAC for consideration. The PBAC is committed to understanding consumer perspectives and integrating them into its consideration of medicines.

The PBAC guidelines provide guidance to applicants regarding choice of appropriate comparators. The *National Health Act 1953* requires that for the PBAC to recommend PBS listing of medicine that is more costly than alternatives, it must be satisfied that the new medicine delivers better health outcomes than these alternatives.

The Government recognises the importance of ensuring that Health Technology Assessment (HTA) policies and methods are continually evaluated and updated so that they remain fit for purpose, keep pace with rapid advances in health technology, maintain the sustainability of the PBS, and minimise barriers to access. The HTA Policy and Methods Review (HTA Review) was completed on 4 May 2024, and the final report published in September 2024. The HTA Review makes 50 recommendations for reform to the Australia's health technology assessment and funding arrangements. An Implementation Advisory Group chaired by the former Chair of the PBAC, Professor Andrew Wilson, will guide the reform process.

## Recommendation 20

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*20: The Committee recommends the Australasian Menopause Society regularly review and update their guidance for medical practitioners around best practices in the treatment and management of mental health symptoms.*

### Response:

The Australian Government **notes** this recommendation, recognising it is directed towards the Australasian Menopause Society.

## Recommendation 21

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*21: The Committee recommends that the Australian Government work with state and territory governments to implement or leverage existing women's health facilities with multidisciplinary care, including in the public health system, to better support women during the menopause transition across Australia.*

The Australian Government **supports** this recommendation.

The National Health Reform Agreement (NHRA) recognises state governments are the system managers of their public hospital systems, responsible for system-wide public hospital service planning and performance, and for determining arrangements for the delivery of public hospital services within their jurisdiction. The NHRA does not provide the Government with a role or powers to intervene in state government decisions regarding the organisation and delivery of their health and hospital systems.

From 2025-26, the Government will invest \$19.6 million over three years to expand the number of Endometriosis and Pelvic Pain Clinics (EPPCs) across Australia and continue service delivery for the existing EPPCs. Funding will also enable expanded scope of services to include perimenopause and menopause. The EPPCs deliver improved access to a range of support mechanisms, education, and assessment from a multidisciplinary team. Evidence received from several existing EPPCs highlights an increased confidence in providers to successfully establish and deliver comprehensive and holistic services for women in the community. This will bring the total number of clinics to 33 – amounting to one in each Primary Health Network (PHN) across the country.

Funding for the additional EPPCs will be implemented through PHNs with priority given to setting up clinics in locations with greatest need that have been identified through consultation with PHNs and Aboriginal Community Controlled Health Organisations (ACCHOs).

The Government has also committed \$79.4 million over four years (2023-24 – 2026-27) for PHNs to commission multidisciplinary team care, as part of the Strengthening Medicare reforms. All PHNs were eligible to receive this funding to commission allied health professionals, nurses, nurse practitioners, midwives, and/or Aboriginal and Torres Strait Islander Health Workers or Practitioners. Multidisciplinary care will fill an identified need in each PHN region. Each PHN will determine the priority for commissioning based on their health needs assessments.

**Recommendation 22**

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*22: The Committee recommends that organisations tasked with improving menopause care utilise learnings from international best practice.*

The Australian Government **notes** this recommendation, recognising that it is directed towards organisations tasked with improving menopause care.

To support best practice and to improve menopause care, the Government is investing \$2.9 million over three years from 2025-26 to develop national clinical guidelines for perimenopause and menopause. National clinical guidelines will ensure information for clinicians is nationally consistent, evidence based and readily available to support consistent care for women experiencing perimenopause and menopause.

## Recommendation 23

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*23: The Committee recommends that the Australian Government investigate improvements to the collection and use of data to assist with research into the experience of menopause and perimenopause, and surveillance of the outcomes of the use of MHT.*

The Australian Government **supports** this recommendation.

The Department of Health and Aged Care Data Strategy 2022-25 outlines the Department of Health and Aged Care's commitment to ongoing data quality improvement and data integration activities for evidence-based policy and programs.

The Commonwealth safely and securely shares health data for public benefit. For example, MBS and PBS data are integrated in the National Health Data Hub (managed by the Australian Institute of Health and Welfare (AIHW)) and the Person-Level Integrated Data Asset (PLIDA, managed by the Australian Bureau of Statistics). These types of data linkages enable approved government and non-government researchers to analyse patient journeys and to derive whole-of-life insights about various population groups in Australia, such as the interactions between their characteristics, use of services like healthcare and education, and outcomes like improved health and employment.

Linked data regarding Menopause Hormonal Therapy (MHT), for example specific PBS and/or MBS items (if applicable), could support population-level insights regarding MHT use, trends and health outcomes.

In the 2024–25 Budget the Government provided \$5.5 million over three years from 2024–25 for the AIHW to establish a sexual and reproductive health data set to help inform sexual and reproductive health policy and improve healthcare access outcomes. Perimenopause and menopause will be a key priority area in this work program, which will include an extensive consultation process to identify the information needs and data gaps (including those identified in the Senate Inquiry report), scope options for improved data collection and commence data development and collection where applicable. This work will contribute to the evidence base on perimenopause and menopause in Australia.

To further support research development, the Government has made up to \$25 million of funding over four years from 2024-25 available for the 2024 Medical Research Future Fund (MRFF) Emerging Priorities and Consumer Driven Research (EPCDR) Infertility, Pregnancy Loss and Menopause Grant Opportunity which includes a focus on perimenopause and menopause research. The Grant Opportunity closed on 6 November 2024. Application outcomes are expected by May 2025, with research projects anticipated to be undertaken from 2025 to 2029.

**Recommendation 24**

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*24: The Committee recommends that the Australian Government task the National Women's Health Advisory Council to assist state and territory governments to deliver a National Menopause Action Plan which considers best practices in menopause care.*

The Australian Government **supports-in-principle** this recommendation.

The National Women's Health Advisory Council (Council) was established in 2023 to provide strategic advice and recommendations directly to Government to improve health outcomes for Australian women and girls. The Council also provides advice on the implementation of the National Women's Health Strategy 2020-2030 (Strategy).

The Strategy outlines a national approach to improving health outcomes for all Australian women and girls, particularly those at greatest risk of poor health, and aims to reduce inequities in health outcomes. This includes actions to improve the awareness of, and encourage further research and support services, for menopause.

The Government will consider the feasibility of this recommendation in the context of the Council's advisory capacity and in consultation with relevant stakeholders, including state and territory governments.

## Recommendation 25

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*25: The Committee recommends that the Australian Government task the Department of Health and Aged Care and the Department of Employment and Workplace Relations to monitor international best practices to ensure Australia is at the forefront of menopause and perimenopause care.*

The Australian Government **supports** this recommendation.

The Department of Health and Aged Care and the Department of Employment and Workplace Relations monitor international policies, expert advice and academic publications to inform and shape its health, employment and workplace relations policy advice to Government, including in relation to menopause.

### Coalition Senators Recommendation

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*The Senate Education and Employment Standing Committee to review the adequacy of existing legal frameworks, including Section 65 of the Fair Work Act 2009, to ensure women can access flexible working arrangements during menopause.*

The Australian Government **notes** this recommendation. Decisions on Senate Committee reviews are a matter for the Senate.