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Community Affairs Committee
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AUSTRALIA

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15 March 2024

Dear Secretary,

Submission to the Standing Committee on Community Affairs - Inquiry into issues related to menopause and perimenopause.

Besins Healthcare Australia (Besins) wishes to commend the Committee for initiating this important inquiry and thank you for the opportunity to make a submission. Besins are aligned with the intention of this Inquiry to improve the health and wellbeing of women experiencing and about to experience menopause and ensure health services are meeting their needs. We would welcome the opportunity to appear before the Committee, at a Public Hearing, to answer questions about this submission, or provide further information on any of the areas covered.

As a pharmaceutical company with more than a century of expertise in developing hormone therapies for women managing the intricacies of menopause, our in-depth understanding of the scientific and medical aspects of this stage of women's lives uniquely qualifies us to make a substantial contribution to the Senate Inquiry. Our extensive research, development, and provision of hormone-based treatments (Estrogel (estradiol), Prometrium (micronised progesterone) and EstrogelPro (estradiol and micronised progesterone)) have afforded us unparalleled insights into the physiological, psychological, and societal ramifications of menopause. Through years of dedicated collaboration and interaction with healthcare professionals and patients experiencing menopause symptoms, we have amassed a wealth of understanding about the challenges faced during this critical life transition. Our contributions to this inquiry aim not only to offer comprehensive insights into the multifaceted impacts of menopause but also to advocate for more informed policies and support mechanisms that prioritise women's health and well-being during this transformative life-stage.

In discussing the topic of menopause, it is important to recognise and respect the diverse range of individuals who may undergo this natural life stage. While we will primarily refer to women in this document, it is crucial to acknowledge that not all individuals assigned female at birth who experience menopause identify as women.

Any queries regarding this submission may be directed to Lorna Elliott at
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Summary

Menopause and its impacts on women, their families, their work and their ability to contribute to society has long been neglected. Some women may feel ashamed or embarrassed that they have reached this stage in their lives while others may find it liberating. Some experience debilitating symptoms that severely impact their daily lives while others may experience no symptoms at all. One thing is certain: all women, who live long enough, will transition through menopause at some point in their lives.

There is significant stigma associated with this life stage. It is not often a topic of conversation at a family level, in social groups or at work and so many women feel like they must experience it alone. For those that seek treatment for symptoms from the health system they are sometimes dismissed and told to put up with it, as it's a "normal" part of life. There are recommended treatments for symptoms and yet these are not always offered, even though they may have long term health benefits, because a stigma exists around those as well.

- Up to 80% of Australian women will experience symptoms of menopause and 30% of these women have symptoms so severe that they significantly interfere with daily life.¹
- Many women are not aware of the full extent of symptoms that can be attributed to menopause and are also unaware of the long-term health implications of estrogen deficiency.²
- Women may live longer than men but they spend 25% more of their lives in debilitating health.³
- Almost 1 in 5 women aged 45-64, with bothersome symptoms attributed to menopause, take extended leave, or break from work or study.⁴

There are substantial barriers to improving menopause awareness and treatment in Australia, including:

- A lack of a condition-specific policy framework to inform menopause care.
- Menopause stigma, including lack of health literacy and public awareness of early menopause, perimenopause, menopause, and symptom management options.
- Suboptimal healthcare workforce capability, including lack of widespread knowledge about the symptoms and management options amongst health professionals, including GPs.
- Suboptimal health service accessibility and capacity.
- Lack of adequate funding for research leading to significant gaps in evidence.

In collaboration with relevant stakeholders, we believe there is significant scope for government to address these barriers.

¹ Herson, M., Kulkarni, J. Hormonal Agents for the Treatment of Depression Associated with the Menopause. *Drugs Aging* 39, 607–618 (2022). <https://doi.org/10.1007/s40266-022-00962-x>

² D. Herbert, R. J. Bell, K. Young, H. Brown, J. Y. Coles & S. R. Davis (2020) Australian women's understanding of menopause and its consequences: a qualitative study, *Climacteric*, 23:6, 622-628, DOI: 10.1080/13697137.2020.1791072

³ WEF Closing the Women's Health Gap: A \$1 Trillion Opportunity to Improve Lives and Economies. <https://www.weforum.org/publications/closing-the-women-s-health-gap-a-1-trillion-opportunity-to-improve-lives-and-economies/> (last accessed 15 March 2024).

⁴ Jean Hailes for Women 2023 National Women's Health Survey <https://www.jeanhailes.org.au/research/womens-health-survey/menopause-in-australian-women> (last accessed 15 March 2024)

Summary of Recommendations

Recommendation 1: Develop a national policy framework and action plan specifically for perimenopause and menopause and appoint a National Menopause Champion whose role it is to drive the implementation of the Menopause Action Plan and report on progress to Government.

Recommendation 2: Develop methodology to quantify the cost of menopause on the individual, businesses, and the Australian economy.

Recommendation 3: Reform the Medicare benefits schedule (MBS) to encourage and incentivise comprehensive assessment and management of women's health through the creation of a specific MBS Item number for a women's mid-life health assessment, enabling GPs to have the longer consult required to discuss future health and her treatment options.

Recommendation 4: Invest more in evidence-based research to cover women's perimenopausal and menopausal healthy ageing addressing the gaps in our evidence base.

Recommendation 5: Develop and deliver a range of accredited educational resources for GPs, and where appropriate other health care providers, covering perimenopause and menopause diagnosis, management, and treatment.

Recommendation 6: Design and disseminate up to date clinical practice guidelines for women going through menopause, in line with international and local guidelines, that are based on the latest evidence and advice.

Recommendation 7: Conduct a national awareness campaign to empower women with evidence-based information about perimenopause and menopause and that discusses the range of options for treatment of their symptoms.

Recommendation 8: Create a national website for women in mid-life to access appropriate resources and increase health literacy, regarding perimenopause and menopause. This should include culturally relevant information in a variety of languages to reach the different communities we have in Australia.

Recommendation 9: To optimise patient access to newer Menopause Hormone Therapy, the HTA Policy and Methods Review should consider how the Pharmaceutical Benefits Advisory Committee (PBAC) evaluates new menopause therapies. This would include addressing issues such as comparator selection and inclusion of societal benefits, to promote a sustainable PBAC outcome for Sponsors.

Recommendation 10: Implement employment policies to establish supportive working environments for women experiencing menopause.

Background

Up to 80% of menopausal women experience symptoms, and 30% of these women have symptoms so severe that they significantly interfere with daily life.⁵ Most women's symptoms persist for 7-10 years, and 42% of women aged 60-65 years continue to experience significant symptoms beyond that time.⁶ Menopause also increases vulnerability to depression and anxiety.^{7,8} Twenty percent of Australian midlife women are taking an anti-depressant and this incidence increases with age.⁹ Menopause isn't a phase women go through. The fall in estrogen, that happens at the end of a women's reproductive life, remains low for the rest of her life. This has implications for a women's long-term health including an increased risk of osteoporosis and cardiovascular disease.^{10,11}

Over 85% of Australian women with moderate-severe menopausal symptoms go largely untreated.¹² Many women who go to their doctor do not get the support and treatment they need. Those more informed women who are not satisfied with their first GP consult, may "doctor shop" seeking someone who will provide the necessary care, with many resorting to spending significant money on ineffective and unproven alternative therapies (such as unregulated supplements).¹³ This has an unnecessary and adverse impact on women's lives and results in inefficiencies and waste in the healthcare system, at a time when the health sector is under significant and increasing strain.

The National Women's Health Strategy 2020-2030 identifies the key health issues for women and girls in Australia and aims to drive continuing improvement in the health and wellbeing of all women in Australia.¹⁴ It outlines the importance of directing health system resources towards addressing these health issues and identifies five priority areas:

1. Maternal, sexual, and reproductive health
2. Healthy ageing
3. Chronic conditions and preventive health
4. Mental health
5. Health impacts of violence against women and girls

⁵ Gartoulla P, Bell RJ, Worsley R, Davis SR. Moderate-severely bothersome vasomotor symptoms are associated with lowered psychological general wellbeing in women at midlife. *Maturitas* 2015;81(4):487-92. DOI: 10.1016/j.maturitas.2015.06.004.

⁶ Ibid

⁷ Alblooshi S. et al. Does menopause elevate the risk for developing depression and anxiety? *Australasian Psychiatry* 2023, Vol. 31(2) 165–173

⁸ Herson, M., Kulkarni, J. Hormonal Agents for the Treatment of Depression Associated with the Menopause. *Drugs Aging* 39, 607–618 (2022). <https://doi.org/10.1007/s40266-022-00962-x>

⁹ Changes in antidepressant use in Australia: A nationwide analysis (2015–2021) Juliana de Oliveira Costa, Malcolm B. Gillies, Andrea L. Schaffer, David Peiris, Helga Zoega, and Sallie-Anne Pearson

¹⁰ Weitzmann and Pacifici Estrogen deficiency and bone loss. *J Clin Invest.* 2006;116(5):1186-1194. <https://doi.org/10.1172/JCI28550>.

¹¹ Dr G. M. C. Rosano, C. Vitale, G. Marazzi & M. Volterrani (2007) Menopause and cardiovascular disease: the evidence, *Climacteric*, 10:sup1, 19-24, DOI: [10.1080/13697130601114917](https://doi.org/10.1080/13697130601114917)

¹² Worsley R, Bell RJ, Gartoulla P, Davis SR. Low use of effective and safe therapies for moderate to severe menopausal symptoms: a cross-sectional community study of Australian women. *Menopause* 2015;23(1):11-17. DOI: 10.1097/GME.0000000000000495. (<http://www.ncbi.nlm.nih.gov/pubmed/26224187>).

¹³ Gartoulla P, Davis SR, Worsley R, et al. Use of complementary and alternative medicines for menopausal symptoms in Australian women aged 40-65 years. *Med J Aust* 2015;203(3):146. (<http://www.ncbi.nlm.nih.gov/pubmed/26224187>).

¹⁴ Dept. of Health, Australian Government: National Women's Health Strategy 2020-2030. <https://www.health.gov.au/resources/publications/national-womens-health-strategy-2020-2030?language=en> (last accessed 15 March 2024).



We are aligned with the goals of the strategy and acknowledge that menopause is mentioned in three of the five priorities (1, 2 and 4).

However, implementing a condition-specific national policy for menopause is crucial as it addresses the unique healthcare needs and challenges faced by women during this life stage. Four years into the strategy and there has been little tangible action taken to improving menopausal awareness and care. Some women are accessing well-respected non-government websites such as the [Australasian Menopause Society](#), [Jean Hailes for Women](#) and [Wellfemme](#) for information about menopause but many are getting their menopause information and advice from social media, which is obviously uncontrolled and not always accurate. Menopause brings about hormonal changes that can lead to various physical and psychological symptoms. A dedicated policy will ensure that healthcare providers are equipped with the necessary knowledge and resources to offer personalised care, encompassing treatments, mental health support, and preventive measures for associated health risks. By recognising menopause as a distinct health concern, a national policy fosters awareness, research, and education enhancing the overall wellbeing of women navigating this life-stage and promoting gender-sensitive healthcare practices.

The Women's Health Strategy highlights how Australia is well placed to lead and develop research into improving health outcomes for women and girls. However, this has not yet been accompanied by dedicated, and strategic investment in research into key issues in women's health, such as menopause. Now is the time to develop a future research agenda for women's health research that is informed by Australia's existing research expertise, and the needs of Australian women.

To achieve this, it is critical to first understand what current expertise exists and can be leveraged and what systems, structures and enablers are needed to create a collaborative and coordinated approach. This will enable the sector to develop a future research and funding agenda and structures for implementation that are impactful and sustainable.

Besins Healthcare is working in partnership with Research Australia to take this first step in developing a women's health research agenda, combining rapid information scans of research funding, activity and outputs with online consultation with researchers across the sector. This project will explore Australia's existing strengths and identify where there are gaps in research and/or funding as well as gather information on the experience of the research community, identifying key priorities and enablers for effective research and its translation. Findings will be translated into actionable insights for government and sector stakeholders. While it covers all of women's health, Research Australia will be specifically pulling out menopause as a case study. They hope to have the results of this research available in June and we would welcome the opportunity to present the report to the inquiry committee when it is available.

The Australian Government is committed to advancing women's economic equality recognising that women face multifaceted barriers to participation and opportunities in the workforce. The Government has recognised that older women are one of the groups that face multiple and compounding disadvantages in the workforce.¹⁵ In a recent report from Jean Hailes for Women, funded by the Government, almost 1 in 5 women aged 45-64, with bothersome symptoms attributed to menopause, had taken extended leave or a break from work or study.¹⁶ Addressing menopause

¹⁵ Government of Australia Women's Economic Equality <https://www.pmc.gov.au/office-women/womens-economic-equality> (last 15 March 2024)

¹⁶ Jean Hailes for Women 2023 National Women's Health Survey <https://www.jeanhailes.org.au/research/womens-health-survey/menopause-in-australian-women> (last accessed 15 March 2024)

related issues for women in the workforce could reduce this and have a positive impact on women's participation in the workforce.

The World Economic Forum in collaboration with the McKinsey Health Institute recently released a report "Closing the Women's Health Gap: A US\$1 trillion opportunity to improve lives and economies".¹⁷ In this report they highlight that **although women may live longer than men, they will spend 25% more of their lives in debilitating health.** By addressing the gaps and shortcomings in women's health this could reduce the time women spend in poor health by almost two-thirds. Menopause is specifically mentioned as an area of high unmet need with a lack of data to identify the true health burden associated with it. It suggests that, adjusting for actual disease burden, the impact of closing the women's health gap associated with menopause **would place menopause among the top two conditions in terms of global GDP impact with an estimated impact of ~\$120 billion.**¹⁸ The report suggests that moving forward requires driving action on five fronts:

- Invest in women-centric research to fill the gaps in under-researched, often undiagnosed, women-specific conditions.
- Strengthen the systematic collection, analysis and reporting of sex and gender-specific data.
- Increase access to women-specific care in all areas from prevention to treatment.
- Create incentives for investment in women's health innovation and develop new financing models.
- Implement policies supporting women's health, such as academic institutions updating medical school curricula and employers creating pregnancy and menopause-friendly workspaces.

We believe addressing the above drivers, including a specific focus on perimenopause and menopause, will reap rewards for Australian women, their families, their communities, their workplaces, and the economy.

Terms of Reference B: Access to healthcare services

Recommendation:

- Recommendation: Reform the Medicare benefits schedule (MBS) to encourage and incentivise comprehensive assessment and management of women's health through the creation of a specific MBS Item number for a women's mid-life health assessment. This will enable GPs to have the longer consults required to comprehensively discuss women's future health and her treatment options.

While many women do have access to reasonable menopause care via their GP, many others struggle to access appropriate assessment and treatment. The rise in private menopause clinics (such as [Wellfemme](#), [Femina](#), [Hera Menopause](#), [Australian Menopause Centre](#), [My Menopause Doctor](#), and

¹⁷ WEF Closing the Women's Health Gap: A \$1 Trillion Opportunity to Improve Lives and Economies. <https://www.weforum.org/publications/closing-the-women-s-health-gap-a-1-trillion-opportunity-to-improve-lives-and-economies/> (last accessed 15 March 2024).

¹⁸ Ibid

[Melbourne Menopause Clinic](#)) is an indicator that this cohort of perimenopausal and menopausal women are being underserved by the Medicare system.

Appropriate assessment, diagnosis, and management of menopause, as well as risk assessment for chronic disease, cannot usually be achieved in a 10-minute consultation. The Medicare system incentivises short consultations for simple issues, whereas menopause can affect multiple body systems and be quite complex. Due to underfunding and staff shortages, GPs come under pressure to increase throughput and find it increasingly difficult to offer longer appointments. This can particularly affect patients in rural or disadvantaged areas. Longer consultations are required and need to be adequately remunerated to encourage GPs to undertake a comprehensive consultation.

There is an existing Medicare benefits schedule Health Assessment for a person aged 45–49 years with a chronic disease risk. This does not currently include menopause as menopause is not a chronic disease. As an estimated 50–60% of women experience perimenopause and menopause before the age of 45 or after 49, even if “chronic disease” included menopause, limiting a health assessment to this age group would mean that most women would slip through the diagnostic gap.

Another barrier to comprehensive menopause care is the lack of integration of healthcare services in primary care. Nurses and allied health practitioners can play a key role in promoting women’s wellbeing during perimenopause and post-menopause. Current systems make it difficult or expensive for patients to access these practitioners. Specialist menopause clinics or accredited menopause practitioners would improve access to treatment, particularly for women with complex care needs. However, we believe that most clinical care of women at menopause will likely continue to occur in general practice and so GPs need to be supported to be able to adequately fulfil this role.

Terms of Reference F: The level of awareness amongst medical professionals and patients of the symptoms of menopause and perimenopause and the treatments, including the affordability and availability of treatments;

Recommendations:

- Create a menopause specific website for women in mid-life to access appropriate resources and increase health literacy and overhaul the Healthdirect website to better reflect current guidelines and recommendations regarding perimenopause and menopause.
- Fund a relevant patient organisation to provide culturally relevant and comprehensive information on perimenopause and menopause in a variety of languages and media to reach the different communities we have in Australia. Make these materials available via electronic media and print media.
- Conduct a national awareness campaign to empower women with evidence-based information about perimenopause and menopause and encourage women to talk to their doctors about their symptoms and treatments.
 - Invest in research and a co-design process to understand how best to address indigenous Australians awareness and management of menopause.
- Support the Australasian Menopause Society to manage the ongoing development and widespread delivery of a range of accredited educational resources for GPs covering menopause diagnosis and management.

- Design and introduce up to date Australian Government clinical practice guidelines for women going through menopause, in line with international and local guidelines that are based on the latest evidence and advice.
- To optimise patient access to newer Menopause Hormone Therapy, the HTA Policy and Methods Review should consider how the Pharmaceutical Benefits Advisory Committee (PBAC) evaluates newer Menopause Hormone Therapy. This would include addressing issues such as comparator selection and inclusion of societal benefits, to promotes a sustainable PBAC outcome for Sponsors.

Level of awareness amongst medical professionals:

In a 2021 study by Prof. S. Davis exploring Australian healthcare professionals' knowledge of menopause, it's consequences and their views about menopause related healthcare, it was found that while most clinicians appeared somewhat knowledgeable about menopause, they were uncertain about its treatment and required upskilling with respect to the indications for and prescribing of Menopause Hormone Therapy.¹⁹

In the daily operation of our business, we are talking to General Practitioners (GPs), Gynaecologists and Endocrinologists about the symptoms of menopause and the treatments available for women experiencing symptoms. We have observed huge disparities in the level of knowledge amongst GPs and Specialists, including their awareness of the fundamental process of menopause, the impact of a lack of estrogen on different body systems and the benefits and risks of treatments available.

In a perspectives piece for the Medical Journal of Australia in June 2023, Prof. Susan Davis and ex-President of the Australasian Menopause Society, Dr Karen Magraith, state *"Contributing to this health care knowledge gap are two decades of widespread dissemination of conflicting, and often frightening, information about menopause treatment, and omission of menopause from most undergraduate and post-graduate medical and allied health training. Thus, state-of-the-art menopause care is not available to most Australian women."*²⁰

Many of the myths and misinformation about menopause and Menopause Hormone Therapy came from the Women's Health Initiative Study of 2002.²¹ This study, initiated in the 1990s and stopped early due to health concerns, aimed to investigate several health issues in postmenopausal women particularly in regards to heart disease, cancer, and osteoporosis and included Menopause Hormone Therapy and its effects on women's health outcomes. The headlines of the time reported an increased risk of breast cancer; coronary heart disease; stroke; and blood clots and suggested that there was an overall harm with Menopause Hormone Therapy that outweighed benefits for chronic disease prevention.

¹⁹ Davis SR, Herbert D, Reading M, Bell RJ. Health-care providers' views of menopause and its management: a qualitative study. *Climacteric*. 2021 Dec;24(6):612-617. doi: 10.1080/13697137.2021.1936486. Epub 2021 Jul 9. PMID: 34240683.

²⁰ Susan R Davis and Karen Magraith. Advancing Menopause care in Australia: barriers and opportunities. *MJA* June 2023; <https://doi.org/10.5694/mja2.51981>

²¹ Writing Group for the Women's Health Initiative Investigators. Risks and Benefits of Estrogen Plus Progestin in Healthy Postmenopausal Women: Principal Results From the Women's Health Initiative Randomized Controlled Trial. *JAMA*. 2002;288(3):321-333. doi:10.1001/jama.288.3.321

However, since that time, the study has been heavily criticised and devalued for numerous flaws in design, analysis, interpretation of the data and reporting that affected its findings and subsequent media representation.^{22,23,24} Some of the criticisms are listed in Appendix A.

In a 2006 critique of Women's Health Initiative Studies (2002-2006), the author summarised ***"In summary, the findings of the E+P [Estrogen + Progestogen] study should have been: no significant risks were found for cardiovascular disease, invasive breast cancer, stroke, and venous thromboembolism. Instead, the [Women's Health Initiative] authors and the [National Heart, Lung, and Blood Institute] concluded that post-menopausal hormone treatment increased the risks for all these diseases. When this was released to the news media it resulted in considerable confusion among patients and doctors alike and caused an untold number of women to go without potentially beneficial hormone therapy. The final consequences of these incorrect conclusions are yet to be determined but it is likely that an untold number of women will suffer from diseases which post-menopausal hormone treatment could have prevented."***²⁵

In an editorial in the British Medical Journal (Heart) discussing the very real cardiovascular risk that women face after menopause the authors state: ***"The time has arrived to shelve the [Women's Health Initiative study] and its limited applicability to the lives of menopausal women.....Menopause has a powerful negative impact on the cardiovascular health of women. They deserve to be offered [Menopause Hormone Therapy], using hormones identical to those produced by human ovaries, and the hormones should be prescribed in the most physiological manner possible. More research is needed, but it is time now to acknowledge the impact of menopause— of ovarian senescence [or the aging of ovaries]— on the cardiovascular health of women and treat them with physiological doses of human-identical hormones, prior to the development of serious [consequences of] cardiovascular disease."***²⁶

In 2011, the International Menopause Society (IMS) updated their recommendations on postmenopausal hormone therapy and preventive strategies for midlife health. In their conclusions they stated ***"The excessive conservatism engendered by the presentation to the media of the first results of the [Women's Health Initiative] in 2002 has disadvantaged nearly a decade of women who may have unnecessarily suffered severe menopausal symptoms and who may have missed the potential therapeutic window to reduce their future cardiovascular, fracture and dementia risk"***.

Once news of links to breast cancer and cardiovascular disease hit the headlines in 2002 many healthcare professionals immediately ceased prescribing Menopause Hormone Therapy and suggested their patients halt therapy if already taking it. This led to prescribing rates for combined Menopause Hormone Therapy (estrogen and progesterone) in Australia dropping by 38% in the first year after publication of the Women's Health Initiative study and over 50% by three years after publication.²⁷

The misinterpretation of the Women's Health Initiative data created the stigma and myths that, twenty years later, continue to persist. As a result, many healthcare professionals and patients remain

²² Gambrell R.Don. The Women's Health Initiative Reports in perspective: facts or fallacies? Climateric 2004;7:225-228

²³ Blumin A. and Hodis H. 'Tis but a scratch: a critical review of the Women's Health Initiative evidence associating menopausal hormone therapy with the risk of breast cancer. Menopause (New York, N.Y.) October 2023 DOI: 10.1097/GME.0000000000002267

²⁴ Clark JH. A critique of Women's Health Initiative Studies (2002-2006). Nucl Recept Signal. 2006 Oct 30;4:e023. doi: 10.1621/nrs.04023. PMID: 17088939; PMCID: PMC1630688.

²⁵ Ibid

²⁶ Gersh, Felice L., and Carl J. Lavie. "Menopause and hormone replacement therapy in the 21st century." Heart 106, no. 7 (2020): 479-481.

²⁷ Main, P. and Robinson, M., 2008. Changes in utilisation of hormone replacement therapy in Australia following publication of the findings of the Women's Health Initiative. pharmacoepidemiology and drug safety, 17(9), pp.861-868.

reluctant, or refuse, to prescribe Menopause Hormone Therapy and continue to believe that the risks of Menopause Hormone Therapy outweigh the benefits. This has long-term health consequences for women. There needs to be a re-education campaign to dispel the myths about Menopause Hormone Therapy amongst Healthcare Providers – and the community - so that women can get the evidence-based information, advice, and treatment they need.

The impact of the Women's Health Initiative study on menopausal women underscores the importance of clear and balanced communication of scientific findings, as well as the need for individualised healthcare decision-making. **All women deserve access to individualised perimenopause and menopause care.**

Level of awareness of menopause symptoms among the population

A 2020 study found that women in Australia had a “concerning” lack of knowledge about the long-term effects of menopause on their health, such as osteoporosis and cardiovascular disease and suggested **“the knowledge gaps among women urgently need to be addressed to enable women to make informed health choices”** around the management of menopausal symptoms.²⁸ The study also suggested that despite the effectiveness and safety of Menopause Hormone Therapy, **“the overall attitude to Menopause Hormone Therapy remains negative.”**²⁹

The government funded website for health information “[Healthdirect](#)” provides minimal information about menopause and is out of date.³⁰ It needs significant updates to bring it in line with current local³¹ and global³² guidelines:

- While the site briefly touches upon perimenopause, discussing hormonal fluctuations and irregular periods, it fails to explicitly link the onset of symptoms to this stage in a woman's life. Perimenopausal symptoms commonly emerge in a woman's forties, and for a small percentage of women even earlier in her thirties.
- Apart from changes to your period, the website only mentions eight symptoms of menopause whereas the Australasian Menopause Society checklist lists 20 symptoms³³ and other websites list up to 48³⁴.
- There is no mention of vaginal atrophy or genitourinary syndrome of menopause (GSM), except a brief mention of vaginal dryness as a symptom of menopause, and no mention that this can be treated with ultra-low doses of vaginal hormones.
- It identifies early menopause can occur due to surgery or medications but doesn't describe that the onset of symptoms could be almost instantaneous and what the impact of this could be in younger women specifically.
- It states that Menopause Hormone Therapy is ruled out if a patient has current thrombosis (such as DVT) when local and global guidelines state topical vaginal estrogen

²⁸ D. Herbert, R. J. Bell, K. Young, H. Brown, J. Y. Coles & S. R. Davis (2020) Australian women's understanding of menopause and its consequences: a qualitative study, *Climacteric*, 23:6, 622-628, DOI: 10.1080/13697137.2020.1791072

²⁹ Ibid

³⁰ Health Direct website <https://www.healthdirect.gov.au/search-results/menopause> (last accessed 15 March 2024)

³¹ RANZCOG Clinical Guidelines for Managing Menopausal Symptoms <https://ranzocg.edu.au/wp-content/uploads/2022/05/Managing-menopausal-symptoms.pdf> (last accessed 15 March 2024)

³² R. J. Baber, N. Panay & A. Fenton the IMS Writing Group (2016) 2016 IMS Recommendations on women's midlife health and menopause hormone therapy, *Climacteric*, 19:2, 109-150, DOI: 10.3109/13697137.2015.1129166 <http://dx.doi.org/10.3109/13697137.2015.1129166> (last accessed 15 March 2024).

³³ Australasian Menopause Society Symptom Score (Modified Greene Scale) <https://www.menopause.org.au/hp/information-sheets/ams-symptom-score-card> (last accessed 15 March 2024)

³⁴ Gen M website <https://gen-m.com/symptoms/> (last accessed 15 March 2024)

for genitourinary syndrome of menopause or vaginal atrophy is safe for women with thrombosis.

- It lists a range of unproven complementary medications with no mention of the risks. One such suggestion is black cohosh which has been linked to liver issues and sometimes death.³⁵

Our search of available information on menopause and perimenopause for different communities in Australia has highlighted a paucity of information. Women in rural areas, women from culturally and linguistically diverse backgrounds, Indigenous women, women with diverse abilities, the LGBTQI+ community, financially disadvantaged and gender diverse people, have poorer access to information and appropriate health care and these groups should receive particular attention.

The Jean Hailes for Women website provides a short menopause leaflet in the following languages: Chinese (simplified); Dari; Farsi; Greek; Hindi; Italian; Portuguese; Turkish and Vietnamese.³⁶ This is a start, but more comprehensive and tailored information needs to be made available to these groups. We know that different ethnicities can experience menopause differently, such as women of Afro-Caribbean origin having the highest prevalence and longest duration of vasomotor symptoms and women from Southeast Asian backgrounds often going through menopause earlier than their European counterparts. Women from these communities need comprehensive information they can relate to that discusses their specific situations and potential experience of menopause.

We know very little about the indigenous experience of menopause which makes designing culturally specific resources and treatment challenging. A small study conducted with a group of women from the Yamatji region of WA in 2011 and 2012 suggested they don't have a word for "menopause" in Yamatji, or any other language the women were aware of.³⁷ Instead, they refer to it as "the change" and recognise it as a time of life when they transition to a senior role within the community, become grandmothers and gain respect within the community. They also said that they were not prepared as it isn't really spoken about, and many wondered what was wrong with them when they started to experience symptoms³⁸. Specific research needs to be conducted to understand how women in indigenous communities' experience menopause and what support and treatments they need.

We need to have a national awareness campaign and digital resources that can inform women from diverse backgrounds and cultures about perimenopause, menopause and the symptoms of menopause.

³⁵ Lynch, C.R., Folkers, M.E. and Hutson, W.R. (2006), Fulminant hepatic failure associated with the use of black cohosh: A case report. *Liver Transpl*, 12: 989-992. <https://doi.org/10.1002/lt.20778>

³⁶ Jean Hailes for Women Resources Multicultural: <https://www.jeanhailes.org.au/resources?audience%5B0%5D=Multicultural> (last accessed 15 March 2024)

³⁷ Jones, E.K., Jurgenson, J.R., Katzenellenbogen, J.M. et al. Menopause and the influence of culture: another gap for Indigenous Australian women? *BMC Women's Health* 12, 43 (2012). <https://doi.org/10.1186/1472-6874-12-43>

³⁸ Jones, E.K., Jurgenson, J.R., Katzenellenbogen, J.M. et al. Menopause and the influence of culture: another gap for Indigenous Australian women? *BMC Women's Health* 12, 43 (2012). <https://doi.org/10.1186/1472-6874-12-43>

Affordability and availability (access) of treatments

The Pharmaceutical Benefit Scheme (PBS) aims to provide timely, reliable, and affordable access to necessary medicines for Australians. Under the PBS, the government subsidises the cost of medicines which helps to optimise both health and economic outcomes in Australia.

Regarding Menopause Hormone Therapy, women are currently limited to accessing older, less preferred molecules via the PBS and there is mounting pressure from consumers, politicians, and advocacy groups to increase reimbursed access to newer Menopause Hormone Therapy options. These are currently only available as a private prescription, at a cost to patients that is not dissimilar to the PBS general co-payment (\$31.60) and includes Besins' micronised progesterone capsules, Prometrium (approximately \$38.00 in pharmacy with a private prescription³⁹).

As a healthcare organisation, we are committed to optimising the availability and accessibility of our medicines for those who need them. In alignment with this commitment, Besins undertook an independent PBS feasibility assessment for Prometrium. Regrettably, the assessment concluded that submitting Prometrium for consideration by the PBAC would be unlikely to yield a sustainable outcome for Besins, primarily due to the current PBS treatment landscape and Pharmaceutical Benefits Advisory Committee (PBAC) decision making criteria.

Despite clinicians and patients opting against their use in clinical practice, PBS-listed synthetic progestogens are likely to be considered the appropriate comparator in such a PBAC submission. Notably, these synthetic progestogens have been listed on the PBS for an extended period, with some being available for over 30 years and the cost to the Government for these items is exceptionally low. Additionally, the current guidelines require sponsors to adopt a narrow healthcare perspective in PBAC submissions, which fails to value the significant societal benefits of Menopause Hormone Therapy. This dynamic poses a challenge for Besins in achieving a sustainable PBAC outcome and for this reason, Besins have not, at this stage, made a submission to the PBAC.

Availability (supply) of treatments

In the past year, Australian women have grappled with severe shortages in certain Menopause Hormone Therapy formulations, including a widely prescribed estradiol transdermal patch. The persistent supply challenges with various hormone presentations have led to frequent stockouts, leaving patients in a precarious situation. Compounding this issue, one manufacturer has discontinued their estradiol patch range from the Australian market, compelling patients to transition to alternative therapies.

The erratic availability of hormone therapies emerges as a significant source of stress for women. Beyond the inconvenience of frequent pharmacy visits to secure their prescriptions, this situation prompts additional appointments with healthcare professionals for alternative scripts, placing strain on the health system. Furthermore, the potential delay in obtaining their hormone treatment may result in a resurgence of debilitating symptoms for women, underscoring the critical importance of ensuring timely access to these essential medications.

In 2021 Besins recognised the significant global demand occurring for menopause hormonal therapies, driven in part by the consumer led conversation that was happening in the UK. As a result,

³⁹ Chemist Warehouse price of Prometrium 100mg Soft capsules pack of 30 is \$37.99

<https://www.chemistwarehouse.com.au/buy/81825/prometrium-100mg-soft-capsules-30-progesterone> (last accessed 15 March 2024)



Besins set about planning and executing several short, medium, and long-term actions to increase our manufacturing capacity:

- In late 2021 the company set about acquiring a pharmaceutical gel manufacturing site, previously operated by a large manufacturing group, to enable us to become solely focused on the production of hormonal products including our own Menopause Hormone Therapy gel. This was a strategic purchase to allow Besins Healthcare to increase production of our own products and allow greater integration into the company's supply line.
- In 2022, the company increased the number of shifts and production lines available within its existing facilities to enable it to meet the increased demand it was experiencing globally.
- Also in 2022, to meet future forecasted demand, the company commenced the build of a new manufacturing facility in Spain to augment the existing facilities in operation. This state-of-the-art factory was opened in September 2023 and has the opportunity to expand its operations on the same site over the coming years if demand for our products grows beyond current expectations.

We recognise the profound impact on individuals when they face challenges accessing their medication. Locally, in response to the increasing demand for our hormone therapies and to ensure ongoing supply and patient accessibility, we made the decision after COVID to airfreight our products into Australia, despite the considerable expense to the business. At a time when some companies are disinvesting and withdrawing products, Besins is investing and increasing our production capacity and ability to supply.

Terms of Reference H: Existing Commonwealth, state and territory government policies, programs, and healthcare initiatives addressing menopause and perimenopause;

Recommendation:

- Develop a national policy framework and action plan specifically for menopause and encourage the States and Territories to implement specific menopause policies for their own State or Territory.

A substantial disparity exists among the States and Territories concerning the support provided to women navigating menopause. Some states have taken commendable steps to offer support, specifically targeting the enhancement of women's health, including addressing menopause-related challenges. In contrast, several other regions have yet to incorporate menopause into their health and women's strategies.

To foster equality for all women in Australia, a cohesive, national approach spanning across States and Territories is imperative. A unified strategy would ensure consistent and comprehensive support for women experiencing menopause, eliminating the current discrepancies, and promoting a more equitable healthcare landscape nationwide.

Implementing a national menopause policy framework and menopause action plan, holds the potential to positively impact women's well-being and work life. This framework would address specific challenges and needs, unique to women during this life stage.

Data collection is essential for ongoing health surveillance. Implementation requires collaboration between governments, healthcare professionals, employers, and advocacy groups. Aligning state policies with a national framework ensures a consistent, supportive approach nationwide. This comprehensive strategy contributes to gender equality and enhances the well-being of women experiencing menopause.

Terms of Reference I: How other jurisdictions support individuals experiencing menopause and perimenopause from a health and workplace policy perspective; and any other related matter.

Recommendations:

- Appoint a National Menopause Champion whose role it is to drive the implementation of a Menopause Action Plan and report on progress to Government.
- Develop methodology to quantify the cost of menopause on the individual, businesses, and the Australian economy.
- Invest more in evidence-based research to cover women's perimenopausal and menopausal healthy ageing addressing the gaps in our evidence base.
- Implement employment policies to establish a more supportive working environment for women experiencing menopause, facilitating the retention and progression of these women in the workplace.

There are a few countries that have taken the initiative to consider the impact of menopause on women's health, their quality of life, their families, communities, work life and the economy. Some are making huge strides in addressing the issues raised by women in their country while others are just embarking on their journey. Australia can learn from those that are advanced while also positioning itself as one of the leaders in addressing the healthy ageing of women and reaping the economic benefits of ensuring this cohort of women continue to contribute to society and the economy through their post-menopausal years.

United Kingdom (UK) ⁴⁰

Over the last few years, the UK Government has implemented several menopause specific policies and actions recognising the significance of this topic and the impact it has on women's lives, society and the economy as follows:

In July 2021, the then Minister for Employment commissioned an independent report to look at the issue of menopause and employment, given the impact menopause can have on women's working lives, particularly when women are at the peak of their careers. This independent report—Menopause and the Workplace: How to enable fulfilling working lives —was published in November

⁴⁰ House of Commons Library. General Debate on Menopause. 26 October 2023. <https://commonslibrary.parliament.uk/research-briefings/cdp-2023-0203/#:~:text=The%20Government%20announced%20a%20%C2%A3,first%20ever%20Menopause%20Employment%20Champion>. (last accessed 15 March 2024)

2021.⁴¹ The report contained 10 recommendations aimed at bringing about comprehensive change and support for those experiencing menopause, in key areas of government policy, employer practice and wider societal and financial change. In 2022, the UK Government published a response to this report, in which they accepted in whole or in part, most of the recommendations made.⁴²

In October 2021, the UK Government established the Menopause Taskforce to tackle issues surrounding menopause including increasing access to treatment and ending the taboos and stigmas that surround conversations about menopause, including in the workplace.⁴³

In June 2022, the UK Government appointed a Women's Health Ambassador to oversee the implementation of the 10-year Women's Health Strategy for England, which was launched in July 2022.⁴⁴ The strategy was developed after a call for evidence in 2021, which garnered almost 100,000 responses from organisations and individuals. Notably, 48% of respondents selected menopause as a topic for inclusion in the strategy.⁴⁵

In March 2023, the UK Government announced a £25 million investment to expedite the development of women's health hubs, aiming to enhance access to essential services for menstrual problems, contraception, pelvic pain, and menopause care.⁴⁶

Concurrently, Helen Tomlinson was appointed as the inaugural Menopause Employment Champion, with a mandate to raise awareness of menopause-related issues in the workplace.⁴⁷ On October 18, 2023, the Department for Work and Pensions released the policy paper titled 'No Time to Step Back: the government's Menopause Employment Champion.' This report provides guidance for employers to establish a more supportive environment, facilitating the retention and progression of women experiencing menopause in the workplace.⁴⁸

The UK Government also recognised the importance of having a suitable methodology to quantify the cost of menopause to individuals, businesses, health services and wider society. They are in the process of establishing how such a methodology might be best developed.⁴⁹

⁴¹ UK Department for Work and Pensions Policy Paper: Menopause and the Workplace: How to enable working lives: Government Response July 2022 <https://www.gov.uk/government/publications/menopause-and-the-workplace-how-to-enable-fulfilling-working-lives-government-response/menopause-and-the-workplace-how-to-enable-fulfilling-working-lives-government-response> (last accessed 15 March 2024)

⁴² House of Commons Women and Equalities Committee Menopause and the workplace: Government Response to the Committee's First Report of Session 2022–2023. <https://committees.parliament.uk/publications/33631/documents/183795/default/#:~:text=The%20government%20agrees%20with%20the,can%20support%20women%20at%20work.> (last accessed 15 March 2024)

⁴³ UK Government Department of Health and Social Care Press Release: More Support for women experiencing menopause <https://www.gov.uk/government/news/more-support-for-women-experiencing-the-menopause> (last accessed 15 March 2024)

⁴⁴ UK Government Women's Health Strategy for England <https://www.gov.uk/government/publications/womens-health-strategy-for-england/womens-health-strategy-for-england#menopause> (last accessed 15 March 2024)

⁴⁵ ibid

⁴⁶ UK Government Press Release <https://www.gov.uk/government/news/25-million-for-womens-health-hub-expansion> (last accessed 15 March 2024)

⁴⁷ UK Government Department for Work and Pensions Press Release: Government appoints first Menopause Employment Champion to improve workplace support <https://www.gov.uk/government/news/government-appoints-first-menopause-employment-champion-to-improve-workplace-support> (last accessed 15 March 2024)

⁴⁸ UK Government Department for Work and Pensions Policy paper: No Time to Step Back: the government's Menopause Employment Champion <https://www.gov.uk/government/publications/no-time-to-step-back-the-governments-menopause-employment-champion> (last accessed 15 March 2024)

⁴⁹ UK Government Policy Paper: Menopause and the Workplace: How to enable fulfilling working lives: government response. <https://www.gov.uk/government/publications/menopause-and-the-workplace-how-to-enable-fulfilling-working-lives-government-response/menopause-and-the-workplace-how-to-enable-fulfilling-working-lives-government-response> (last accessed 15 March 2024)

In three out of four countries within the UK (Scotland, Wales and Northern Ireland), prescribed menopause treatments are available to all citizens free of charge. In England, following a high-profile campaign, the Government introduced a new hormone replacement therapy prescription prepayment certificate (PPC) on 1 April 2023.^{50,51} This reduces prescription costs for hormone replacement therapy medication in England to a total of £19.30 per year effectively reducing the cost for many women by up to 91%.⁵²

The National Institute for Health and Care research have commissioned a menopause research prioritisation exercise, which is considering research recommendations from experts, including the National Institute for Health and Care Excellence and the UK Menopause Taskforce. The exercise also considered the priority areas identified through the Women's Health Strategy's call for evidence.⁵³

In July 2023, marking one year from the publication of the UK Women's Health Strategy, the UK Government announced a number of measures to improve the health of women and girls. This included the launch of a women's health area on the NHS website (<https://www.nhs.uk/womens-health/menopause/>) including content on menopause and Menopause Hormone Therapy. It sits alongside a new Menopause Hormone Therapy hub on the same site (<https://www.nhs.uk/medicines/hormone-replacement-therapy-hrt/>). These sites provide women in the UK with relevant, factual information on Menopause and information on potential treatments including the different menopause hormone therapies available.

The Republic of Ireland

The Republic of Ireland is another country that has sought to make women's health a top priority in recognition of the need to tackle a wide range of issues impacting women's health outcomes in Ireland. They have specifically put in place policies and actions to support women experiencing menopause.⁵⁴

In September 2021 the Irish Minister for Health, Stephen Donnelly, announced a new approach to menopause care in Ireland. He made a commitment to establish dedicated specialist menopause clinics across Ireland. These clinics will form a core part of their new approach to menopause care for women in Ireland and will be supported by enhanced community and primary care supports as well as the publication of targeted and trusted sources of information for women experiencing menopause. The development follows the advice of the Women's Health Taskforce (established in 2019 to improve women's health outcomes) and ring-fenced investment through the Women's Health Fund.⁵⁵

⁵⁰ UK Government department of Health and Social Care Press Release: Hundreds of thousands of women experiencing menopause symptoms to get cheaper HRT <https://www.gov.uk/government/news/hundreds-of-thousands-of-women-experiencing-menopause-symptoms-to-get-cheaper-hormone-replacement-therapy> (last accessed 15 March 2024)

⁵¹ UK Government Department of Health and Social Care Impact assessment: Introducing the HRT PPC: equality impact assessment <https://www.gov.uk/government/publications/hormone-replacement-therapy-prescription-prepayment-certificate-equality-impact-assessment/introducing-the-hrt-ppc-equality-impact-assessment> (last accessed 15 March 2024)

⁵² UK Government: Get a prescription prepayment certificate <https://www.gov.uk/get-a-ppc/hrt-ppc> (last accessed 15 March 2024)

⁵³ UK Parliament Menopause: Research. Government response to Question for Department of Health and Social [Questions-statements UK parliament](https://www.parliament.uk/questions-statements/uk-parliament). (last accessed 15 March 2024)

⁵⁴ Government of Ireland Department of Health Press release: Minister for health announces a new approach to menopause care for women in Ireland <https://www.gov.ie/en/press-release/bf7d4-minister-for-health-announces-a-new-approach-to-menopause-care-for-women-in-ireland/> (last accessed 15 March 2024)

⁵⁵ Government of Ireland Women Health Taskforce: <https://www.gov.ie/en/campaigns/-womens-health/> (last accessed 15 March 2024)

In March 2022, the Irish Health Minister also launched the Women's Health Action Plan 2022-2023.⁵⁶ This plan started and ended by listening to women to understand where the government could do more. It was the culmination of close collaboration across Government, and between colleagues in the Department of Health, the Health Service Executive (HSE) and the wider health sector. Political representatives, many of whom championed some of the measures in the Action Plan, played a pivotal role.

The plan brings a strategic approach to women's healthcare. It identifies gaps in services, improvements needed in women's experiences of healthcare, vulnerable groups who need additional support as well as opportunities for new research and innovation. The plan specifically mentions menopause and the establishment of four dedicated clinics across Ireland.⁵⁷ The Women's Health Action Plan is underpinned by funding of €48million in the first year which increased to €69.9million in 2023 and is proposed to increase each year.⁵⁸

In October of 2022, the Irish Government launched a menopause awareness campaign.⁵⁹ The campaign was a direct response to the demand from Irish women for greater knowledge and understanding of menopause as well as better access to accurate information and supports so that they can proactively manage their experience. Its aim was to increase awareness of menopause and the symptoms associated with it and encourage open conversation to reduce the stigma associated with this phase of life.

The nationwide campaign included a 30-second advertisement in national and local radio, print ads in national newspapers and magazines, out-of-home advertising on digital displays and bus shelters nationwide, along with ads on digital and social media.

In October 2022, the Ireland Department of Health also developed their website [gov.ie/menopause](https://www.gov.ie/en/publication/232af-womens-health-action-plan-2022-2023/),⁶⁰ a one stop shop for information about menopause and menopause symptoms, advice on proactive management, how to support someone going through menopause and links to appropriate clinical expertise with the aim of ensuring women get accurate information about this stage of their lives and the treatments available to them.

In October 2023 the Government of Ireland also launched their Menopause in the Workplace Policy Framework for civil organisations.⁶¹ This Framework is intended to support persons who are experiencing, or who may in the future experience, menopausal symptoms. Within the Irish Civil Service, this cohort currently accounts for over 50% of the workforce, most of whom continue to work while experiencing symptoms associated with menopause. They have recognised that employees experiencing menopausal symptoms may require additional consideration, support and adjustments in the workplace and should therefore be considered as an organisational and workplace issue.

⁵⁶ Government of Ireland Women's Health Action Plan: <https://www.gov.ie/en/publication/232af-womens-health-action-plan-2022-2023/> (last accessed 15 March 2024)

⁵⁷ Government of Ireland Women's Health Action Plan: <https://www.gov.ie/en/publication/232af-womens-health-action-plan-2022-2023/> (last accessed 15 March 2024)

⁵⁸ European Observatory Health Systems and Policy Monitor <https://eurohealthobservatory.who.int/monitors/health-systems-monitor/analyses/hspm/ireland-2009/women-s-health-action-plan-2022-2023-published> (last accessed 15 March 2024)

⁵⁹ Government of Ireland Press release: Minister for Health launches Menopause Campaign. <https://www.gov.ie/en/press-release/b7b4e-minister-for-health-launches-menopause-awareness-campaign/> (last accessed 15 March 2024)

⁶⁰ Government of Ireland Menopause website. <https://www.gov.ie/en/campaigns/menopause/> (last accessed 15 March 2024)

⁶¹ Government of Ireland Publication: Civil Service Menopause in the Workplace Policy Framework <https://www.cpsa.ie/en/publication/e1674-menopause-policy-framework-and-guidelines/#> (last accessed 15 March 2024)



USA

On November 13th 2023, President Biden announced the first-ever White House Initiative on Women's Health Research, an effort led by First Lady Jill Biden and the White House Gender Policy Council.⁶² Despite making up more than half the population, women have historically been understudied and underrepresented in health research. This new Initiative will fundamentally change how the USA approach and fund women's health research, and it will pioneer the next generation of discoveries in women's health.

The Initiative is committed to galvanizing the Federal government and the private and philanthropic sectors to spur innovation, unleash transformative investment to close research gaps, and improve women's health. They are designing a targeted approach which specifically mentions menopause as an area of discovery.

About Besins Healthcare

Besins Healthcare is a family-owned pharmaceutical company specialising in hormones for women and men. Our long-term commitment to women's and men's health spans over a century and five generations of the Besins family. Over time and through significant and continuing investment, we have become leaders in reproductive body-identical hormones for the treatment of gynaecological and fertility conditions as well as androgen deficiency.

Besins' products are manufactured in France, Belgium and Spain. Our medicines are distributed in more than 100 countries via subsidiary companies and a network of business partners.

Besins Healthcare Australia was established in 2013 and have over the past decade brought our niche body-identical hormone medications to Australia to support women experiencing fertility issues, menopause, pre-term birth, threatened miscarriage, contraception and men experiencing androgen deficiency.

We pride ourselves in putting patients first while also supporting healthcare professionals in Australia to continue their professional development in our therapeutic areas of interest.

Once again, Besins thank the Committee for the opportunity to contribute to this Inquiry.

⁶² White House Briefing Room: Launch of White House Initiative on Women's Health Research <https://www.whitehouse.gov/gpc/briefing-room/2023/11/17/launch-of-white-house-initiative-on-womens-health-research/> (last accessed 15 March 2024)

Appendix A

Concerns associated with the Women's Health Initiative study 2002: ⁶³

The following are some of the issues that have been highlighted as driving the misinformation and myths associated with menopause within the medical community and patients. ^{64,65,66}

Age of Participants: The study primarily focused on women aged 50-79, with an average age of 63 years, which is over 10 years above the average age of menopause in Australia. This demographic wasn't reflective of the broader population of women using Menopause Hormone Therapy, leading to a limited understanding of how Menopause Hormone Therapy might affect younger women or those closer to menopause onset.

Types of Hormones: The Women's Health Initiative study predominantly used a specific type of Menopausal Hormone Therapy—conjugated equine estrogen (CEE) and medroxyprogesterone acetate (MPA) —which is not representative of the variety of hormone formulations available today. Different hormone combinations and administration methods can yield varied outcomes and have different side-effects and safety profiles, but the study did not explore these alternatives or make it clear about the particular Menopause Hormone Therapy that was studied. Results were assumed to be attributable to all types of Menopause Hormone Therapy, despite subsequent studies suggesting that today's body-identical hormones have a more favourable safety profile, compared to CEE and MPA.

Study Duration: The study was halted prematurely after indicating potential risks associated with Menopause Hormone Therapy, particularly an increased risk of breast cancer and cardiovascular disease. However, the long-term effects of Menopause Hormone Therapy were not fully explored due to the early cessation of the trial, leading to an incomplete understanding of its overall impact.

Misinterpretation by Media: Media reports at the time focused on the increased risks of breast cancer and cardiovascular disease emphasising increases in relative risk rather than absolute risk. This led to confusion and unnecessary fear among many women who might have benefited from Menopause Hormone Therapy.

Failure to Distinguish Subgroups: The Women's Health Initiative study did not adequately differentiate between subgroups of women who might respond differently to Menopause Hormone Therapy. Factors such as age, timing of menopause onset, and individual health characteristics could significantly impact how women respond to hormone therapy, but these distinctions were not thoroughly examined in the study.

Re-evaluation and subsequent research: Subsequent re-analyses indicates that the risks associated with Menopause Hormone Therapy are not as initially portrayed with risks that were

⁶³ Writing Group for the Women's Health Initiative Investigators. Risks and Benefits of Estrogen Plus Progestin in Healthy Postmenopausal Women: Principal Results From the Women's Health Initiative Randomized Controlled Trial. JAMA. 2002;288(3):321–333. doi:10.1001/jama.288.3.321

⁶⁴ Clark JH. A critique of Women's Health Initiative Studies (2002–2006). Nucl Recept Signal. 2006 Oct 30;4:e023. doi: 10.1621/nrs.04023. PMID: 17088939; PMCID: PMC1630688.

⁶⁵ Gambrell R.Don. The Women's Health Initiative Reports in perspective: facts or fallacies? Climateric 2004;7:225-228

⁶⁶ Blumin A. and Hodis H. 'Tis but a scratch: a critical review of the Women's Health Initiative evidence associating menopausal hormone therapy with the risk of breast cancer. Menopause (New York, N.Y.) October 2023 DOI: 10.1097/GME.0000000000002267



not statistically significant reported in the Women's Health Initiative trial as if they had reached statistical significance. The statistical methods used to analyse the data from the Women's Health Initiative study have also been called into question on more than one occasion leading to misinterpretation of the data and incorrect conclusions. Women's Health Initiative publications themselves now acknowledge Menopause Hormone Therapy as the most effective treatment for managing menopausal vasomotor symptoms and report that CEE alone reduces the risk of breast cancer while also reducing breast cancer death.