AdPha submission to public consultation on items to be considered by the PBAC (November 2024) – Women's Health

September 2024

Introduction

Formerly known as the Society of Hospital Pharmacists of Australia (SHPA), Advanced Pharmacy Australia (AdPha) is the progressive voice of Australian pharmacists and technicians, built on 80 years of hospital innovation that puts people and patients first. AdPha supports all practitioners across hospitals, transitions of care, aged care and general practice clinics to realise their full potential. We are the peak body committed to forging stronger connections in health care by extending advanced pharmacy expertise from hospitals to everywhere medicines are used.

AdPha convenes a Women's and Newborn Health Specialty Practice Group, comprising of a network of specialist pharmacists who promote the health and wellbeing of women and newborns by improving medication management across all aspects of women's health – covering menarche to menopause and medicine use in pregnancy and breastfeeding; and medicine – covering healthy newborns to those who require special and intensive care.

AdPha appreciates the opportunity to provide feedback on the PBAC's consideration of essential medications for women's health.

If you have any queries or would like to discuss our submission further, please contact Jerry Yik, Head of Policy and Advocacy at policy@adpha.au

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Response to PBAC public consultation survey

AdPha appreciates the opportunity to provide feedback on the PBAC's consideration of essential medications for women's health.

Our members have provided feedback to an inquiry and support the following medications for PBS listings:

1. DROSPIRENONE- Slinda®: Contraception
2. ESTRADIOL- Estrogel®: Menopausal hormone therapy
3. ESTRADIOL AND PROGESTERONE- Estrogel® Pro: Menopausal hormone therapy
4. PERGOVERIS – In vitro fertilisation (IVF) change to streamlined authority
5. PROGESTERONE- Prometrium®: Menopausal hormone therapy
6. RELUGOLIX WITH ESTRADIOL AND WITH NORETHISTERONE ACETATE- Ryeqo®: Endometriosis

Question 2: How is the medical condition currently treated?

What is the effect of your current treatment on your health condition? Are there any symptoms which cannot be controlled with the current treatment? What side-effects have you experienced with current treatments? Are these manageable? Do you have any issues accessing your current treatment? (For example, where or how it is given, how it is funded, whether you fit the criteria to qualify for access)

Drospirenone (Slinda®): Contraception

Current PBS listed options for contraception include combined oral contraceptives (COCs), progesterone only pills (POPs) and long-acting reversible contraceptives (LARCs) such as intra-uterine devices, injections and implants. However, many women may have risk factors or contraindications to use of a COC and may not wish for insertion of a LARC. Oral progesterone only products have a short missed-pill window which is not practical for some women, especially if unintended pregnancy would pose medical or psychological harm.

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Estradiol (Estrogel®), Estradiol and progesterone (Estrogel® Pro) and Progesterone (Prometrium®): Menopausal hormone therapy

Hormone Replacement Therapy (HRT) plays a critical role in managing menopause symptoms, such as vasomotor symptoms, elevated cholesterol levels, bone mineral density loss, and cognitive issues like brain fog, allowing women to maintain their quality of life, including work and libido retention. Furthermore, HRT has been shown to reduce all-cause mortality in women, particularly when initiated in those under 60 years of age or within 10 years post-menopause.[1] Key HRT options include Estrogel®, Estrogel® Pro, and Prometrium®.

Over the last two decades, access to Menopausal Hormone Therapy (MHT) has diminished, partly due to the 2002 Women's Health Initiative (WHI) study[2], which raised concerns about the risks of HRT and led to a significant decline in its use. Many HRT products were progressively removed from the Australian market in response to this reduced utilisation. However, subsequent evidence, particularly from 2013 onward, has clarified that MHT is safe and beneficial for women under 60 years of age or within 10 years of menopause. Despite this, the lingering effects of negative media coverage from the WHI study, coupled with uncertainty among healthcare providers, restrictive health policies, limited medicine availability, and the high cost of MHT, continue to suppress its use.

Pharmacists are allowed to substitute HRT products in cases of serious scarcity under the Serious Shortages Substitution Notices (SSSNs). While these are much appreciated and important to facilitate access, it has been observed that the frequent changes to these notices create uncertainty for both women and healthcare providers. These changes, necessitated by shortages, can disrupt continuity of care, adding administrative burdens for pharmacists who are already stretched, and create a lack of clarity for women navigating HRT options.

Our members, who work directly with patients, report witnessing the significant challenges faced by women during medication transitions necessitated by shortages. Women who have only just stabilised on a particular HRT regimen often experience a distressing resurgence of menopausal symptoms, negatively impacting their physical and emotional wellbeing. For many, this disruption occurs at a critical stage of life when they are managing multiple responsibilities, including careers, caring for children, and supporting aging parents[3]

The frequent reintroduction of symptoms due to medication changes not only undermines patient health outcomes but also places additional strain on health services. Many women seek further consultations with healthcare professionals to address symptom management, leading to increased healthcare utilisation. Stabilising the supply of HRT medications through PBS listing would alleviate these pressures by ensuring consistent

access to treatment, minimising unnecessary medication changes, and supporting women in managing their health at a pivotal stage in life.

Furthermore, limited access to PBAC-subsidised options, such as oral progesterone, places HRT out of reach for many women as they age. Listing products like Estrogel® Pro and Prometrium® on the PBS would provide much-needed stability and affordability for women who rely on these therapies.

follitropin alfa (rch)/lutropin alfa (rch) (Pergoveris®): IVF change to streamlined authority

A change to a streamlined authority listing for Pergoveris® on the PBS would significantly reduce administrative barriers for prescribers, supporting timely access to essential medication for women undergoing IVF. This would provide more timely and equitable access to fertility treatment, improving overall outcomes and reducing the financial and emotional burden associated with delayed treatments. Currently, access to fertility treatments like Pergoveris® requires individual PBS authority approvals, which can delay the initiation of treatment for women undergoing IVF. This adds unnecessary stress to an already challenging process, particularly for those dealing with infertility.

Relugolix with estradiol and with norethisterone acetate (Ryeqo®): Endometriosis

Endometriosis treatment options aim to reduce pain and improve fertility. These treatments include pain relief, progestogen-only medicines, COCs, and Gonadotropin-releasing hormone (GnRH) analogues, which induce temporary menopause and often require hormone replacement therapy (HRT) as "add-back" therapy. Many of the medicines currently used to manage endometriosis are prescribed off-label, as they were not specifically approved for this condition.

Early and effective treatment with a COC can improve fertility outcomes and reduce the financial burden associated with future IVF treatments. However, current PBS-listed medications address either pain or fertility, often requiring women to take multiple medications to comprehensively manage their condition. Ryeqo® offers an opportunity to manage both pain and fertility in a single treatment, potentially improving patient adherence and reducing the overall treatment burden.

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Question 3: What do you see as the advantages of this proposed medicine, in particular for those with the medical condition and/or family members?

What are the specific positive impacts that you hope this treatment will have on your health condition? (for example, reducing pain). What impact would you like it to have on your quality of life? (for example, enabling you to return to work). If you have used this medicine what was your experience? What changed for you? Are there advantages in the way the medicine is delivered? (For example, where it is delivered (for example, home, GP, hospital), or how it is given (for example, tablets rather than injection))

Slinda®

Slinda® is an effective progestogen-only contraceptive with antiandrogenic and antimineralocorticoid properties, offering a low ovulation rate (1.1-2.0%) comparable to COCs.[4] It provides a more flexible and effective option compared to traditional POPs, such as levonorgestrel, with no delay in the return to fertility after discontinuation.

Slinda® is well-established as a contraceptive and is approved by the TGA, FDA, and multiple European regulatory bodies. The 4mg dosage provides distinct advantages, particularly its 24-hour missed-pill window, which is a key benefit for women who may struggle with adherence, including postpartum women and vulnerable groups where pregnancy poses a significant risk. In addition, Slinda® reduces unscheduled bleeding and spotting, leading to lower discontinuation rates compared to traditional POPs.[5] Studies indicate a discontinuation rate of just 1.9-4.2% with Slinda® versus up to 22.5% for traditional POPs[6] [7] [8] [9]

Slinda® is also suitable for women at risk of cardiovascular issues, smokers, those over 35, and breastfeeding mothers.[4,6],[10] As it does not contain estrogen, it avoids estrogen-related side effects such as headaches, breast tenderness, and weight gain.[6] Listing Slinda® on the PBS would ensure access to a reliable and effective contraceptive option, particularly valuable due to its flexibility, low side-effect profile, and the potential to serve as an alternative during supply shortages.

Estrogel®

One of the key advantages of Estrogel® is its topical application, which provides a more flexible and convenient option for women compared to oral treatments. Topical treatment offers an alternative for women who may experience gastrointestinal side effects from oral medications or who have contraindications to oral HRT. Additionally, Estrogel® allows for better control of estrogen absorption, avoiding the "first-pass" metabolism in the liver, potentially leading to fewer side effects, such as headaches or

bloating, commonly associated with oral HRT. This offers a safer and more patient-friendly approach to managing menopause symptoms, particularly for those who cannot tolerate oral forms of estrogen.

Estrogel® Pro

Estrogel® Pro offers a combined estrogen and progesterone treatment in a single formulation, which simplifies the regimen for women who need both hormones. This can be especially beneficial in times of medication shortages when separate progesterone products, like Prometrium®, are unavailable. Listing Estrogel® Pro on the PBS would ensure that women can continue to manage their menopausal symptoms without having to juggle multiple prescriptions, improving both adherence and outcomes. The availability of a combined product on the PBS would be crucial during periods of supply chain disruptions.

Pergoveris®

A change to streamlined authority for Pergoveris® on the PBS would improve access to fertility treatments by simplifying the approval process. This would reduce delays in accessing medication for IVF cycles, improving treatment outcomes for women experiencing infertility. Faster access to fertility medications through a streamlined process can also lessen the emotional and financial burden associated with IVF, ensuring more women can start their treatment on time without unnecessary administrative barriers.

Prometrium®

Prometrium® offers flexible dosing options for menopausal hormone therapy, allowing for personalised treatment based on symptom severity. When combined with varying doses of estrogen, Prometrium® can be taken as 100mg of micronised progesterone orally for 25 days of a 28-day cycle, or 200mg orally for 12 days of a 28-day cycle. These tailored regimens provide low, medium, and high-dose options to effectively manage menopausal symptoms.[11]

Ryeqo®

Ryeqo® is the first oral medication approved by the TGA in 13 years for the treatment of endometriosis, offering a significant advancement in managing endometriosis-related symptoms. Its approval provides an effective, long-term oral option to reduce endometriosis-associated pain and dysmenorrhea, while also decreasing reliance on analgesics, including opioids.

Unlike injectable treatments such as goserelin (Zoladex®), Ryeqo® offers a safer, non-invasive administration method, reducing the potential for injection-related pain, distress, or needle-stick injuries. Additionally, Ryeqo® provides good value for money, particularly

when compared to the combination of Zoladex® and Syneral® and does not require the additional appointments necessary for injections. It can also serve as a contraceptive, further enhancing its utility for women managing endometriosis.

With established data supporting its long-term safety and minimal bone mass reduction, Ryeqo® represents a breakthrough for endometriosis treatment, offering a convenient and effective solution with minimal side effects.[12] [13]

Question 4: What do you see as the main disadvantages of this proposed medicine?

Are there disadvantages in how you can access the medicine, for example whether you meet the criteria, where it is delivered (for example, home, GP, hospital), or how it is given (for example, tablets rather than injection)? Have you heard of any side effects from this medicine? Do you consider these to be manageable? What side effects would stop you from taking this medicine? If you have used this medicine, what did you consider to be the disadvantages?

Cost of Medications (General for all listed medicines)

A major disadvantage of the current situation is the high cost of medications not listed on the PBS, which creates financial barriers for many women. Without PBS subsidies, the out-of-pocket costs for treatments like hormone replacement therapy, endometriosis management, and fertility drugs can be prohibitively expensive. For conditions like menopause and endometriosis, women often require multiple medications, leading to significant out of pocket treatment costs each month. This inequity in access due to financial constraints is a significant disadvantage, particularly for women in lower socioeconomic groups, and emphasises the need for PBS listing to make these essential medicines affordable.

Question 5: Please provide any additional comments you would like the PBAC to consider.

The PBS listing of these medications would fill essential gaps in women's healthcare by ensuring broader access to safe and effective contraceptive options, reliable menopause treatments, and improved management of endometriosis. This would not only alleviate financial burdens for women but also enhance equity in healthcare access across Australia.

Additionally, several Australian studies have explored the impact of menopause and hormone therapy on women's health, offering valuable insights into the need for improved access to treatment. These include research on the bidirectional relationship between vasomotor symptoms and depression,[14] the long-term effects of the Women's Health

Initiative on decision-making in menopause management,[15] and the ongoing influence of WHI findings on hormone therapy use in Australia.[16]

By addressing these gaps, the PBS listing of these medications would provide much-needed support to women's health, ensuring more equitable, timely, and affordable access to treatments.

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