

FDA CONFIRMS FULFILMENT OF IMVEXXY® POST-MARKETING STUDY REQUIREMENTS

Key Points

- The US Food and Drug Administration (FDA) has confirmed the Company has fulfilled its post-approval obligations by completing the post-marketing requirement (PMR) safety study for IMVEXXY® (estradiol vaginal inserts)
- The study was one of the largest real-world analyses of very-low-dose vaginal estrogen (VLDVE) undertaken to date, covering more than 9.5 million US postmenopausal women
- The study demonstrated no association between very-low-dose vaginal estrogen use as prescribed and endometrial cancer risk (pooled hazard ratio 1.00; 95% CI 0.69–1.45)¹
- Completion of the PMR closes all outstanding FDA post-marketing regulatory requirements for IMVEXXY® and reinforces the favourable benefit–risk profile of IMVEXXY® and other VLDVE therapy
- New real-world evidence published in 2026 and joint US urology and urogynaecology guidelines further support the role of local low-dose vaginal estrogen in genitourinary syndrome of menopause (GSM), including reducing the risk of recurrent urinary tract infections (rUTIs)
- IMVEXXY® delivered FY26 net sales of US\$29.3 million (+8%), total prescription growth of 6% and is well positioned to capture structural growth in the US menopause market

9 October 2026, Adelaide, Australia: Mayne Pharma Group Limited (Mayne Pharma or the Company) (ASX: MYX) today announces that it has received a letter from the US Food and Drug Administration (FDA) confirming that the Company has fulfilled its post-marketing requirement (PMR) for IMVEXXY® (estradiol vaginal inserts). IMVEXXY® is FDA-approved for the treatment of moderate-to-severe dyspareunia, a symptom of vulvar and vaginal atrophy (VVA) due to menopause.

The PMR study was an observational study with a primary endpoint designed to evaluate the risk of endometrial cancer in postmenopausal women prescribed very-low-dose vaginal estrogen (VLDVE) products, including IMVEXXY®. The FDA reviewed the final study report submitted by Mayne Pharma and concluded that the requirement has been fulfilled. With this outcome, Mayne Pharma has no remaining post-marketing requirements with the FDA for IMVEXXY®.

Largest real-world analysis of very-low-dose vaginal estrogen safety

The study was conducted by independent research organisation RTI Health Solutions using two large US health-insurance claims databases spanning commercial and Medicare Advantage populations. As previously announced to ASX on 20 August 2026, the results were presented at the International Society for Pharmacoepidemiology (ISPE) 2026 annual meeting in Milan, Italy.

The analysis included more than 9.5 million postmenopausal women, of whom approximately 86,700 used VLDVE products. In propensity score-matched comparative analyses, and in the pooled meta-analysis across both data sources, there was no evidence of an association between

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use of VLDVE products as prescribed and endometrial cancer risk relative to non-use. The pooled hazard ratio was 1.00 (95% confidence interval 0.69–1.45), indicating that the risk of endometrial cancer was approximately the same for VLDVE users as for nonusers.¹

The study also found that approximately 89% of VLDVE treatment episodes involved no concomitant systemic estrogen use, consistent with the targeted, local mode of action of very-low-dose vaginal therapy.

Mr Aaron Gray, CEO of Mayne Pharma said *“Receipt of the FDA’s confirmation that we have fulfilled the IMVEXXY® post-marketing requirement is an important milestone for Mayne Pharma and for the women who rely on vaginal estrogen therapy. The study is one of the largest real-world safety analyses of very-low-dose vaginal estrogen ever undertaken and its conclusion shows no association with endometrial cancer when used as prescribed. Together with the removal of the black box warning from certain menopausal hormone therapy labelling, including BIJUVA® and growing evidence of the broader health benefits of local estrogen therapy, this strengthens the confidence of prescribers and patients in IMVEXXY® and potentially supports its black box warning removal in the future. Menopause remains one of the largest and most under-served markets in US women’s health, and with IMVEXXY® delivering continued prescription and sales growth, we are well positioned for growth across our Women’s Health portfolio.”*

Dr Frank Casty, Global Head of R&D and Chief Medical Officer of Mayne Pharma said *“This study adds high-quality real-world evidence to the benefit–risk assessment of very-low-dose vaginal estrogen, drawing on data from more than nine and a half million women. It directly addresses a long-standing concern among clinicians and patients regarding endometrial safety and complements a growing body of evidence and guideline support for local vaginal estrogen in the management of genitourinary syndrome of menopause.”*

Growing evidence for local vaginal estrogen in genitourinary health

Recently published real-world evidence reinforces the substantial clinical burden of recurrent urinary tract infections (rUTIs) in women and the potential role of local vaginal estrogen therapy. In an observational analysis of approximately 1.9 million women with rUTIs published in the journal Urology in 2026, women with a documented vaginal estrogen prescription within two months of rUTI diagnosis had lower observed rates of sepsis, hospital admission and all-cause mortality across all age groups than women without a recorded vaginal estrogen prescription. Sepsis occurred in 4.2%–10.4% of vaginal estrogen recipients compared with 8.5%–24.1% of nonrecipients, hospitalisation in 7.5%–12.0% compared with 15.7%–27.5% with mortality lower among estrogen recipients at 0.3%–3.9% vs 0.8%–9.6%.²

The study was retrospective and observational, its findings demonstrate association rather than causation, and they were not specific to IMVEXXY®; however, this study highlights the value of vaginal estrogens, including IMVEXXY®. The findings are consistent with US clinical guidelines. The joint American Urological Association Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction and the American Urogynecologic Society Guideline on Genitourinary Syndrome of Menopause (GSM) recommends local low-dose vaginal estrogen for appropriate patients with GSM and rUTIs to reduce the risk of future UTIs, and states that local low-dose vaginal estrogen does not increase the risk of endometrial hyperplasia with atypia or endometrial cancer.³

Collectively, the completed FDA post-marketing requirement, established US guideline support and growing real-world evidence underscore the importance of continued research, education and access to local vaginal estrogen therapy for women in menopause.

IMVEXXY® and the US menopause opportunity

IMVEXXY® is a core product in Mayne Pharma's US Women's Health portfolio, alongside BIJUVA®, NEXTSTELLIS® and ANNOVERA®. In FY26, IMVEXXY® total prescriptions grew 6% and net sales increased 8% to US\$29.3 million. Approximately 75 million US women are now in peri- or post-menopause, and the US menopause market is forecast to reach US\$15–25 billion by 2030.⁴ Prescriber and patient confidence in hormone therapy continues to strengthen following the FDA's removal of the boxed warning from menopausal hormone therapy labelling, including for BIJUVA® in February 2026.

Click [here](#) to view this announcement on Mayne Pharma's Investor Hub.

IMVEXXY® (estradiol) is a vaginal insert indicated for the treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause. The most common adverse reaction with Imvexxy (≥3%) was headache. Serious adverse reactions associated with estrogen-alone therapy include endometrial cancer, cardiovascular disorders, and probable dementia among others. Please see full prescribing information [here](#).

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About Mayne Pharma

Mayne Pharma is an ASX-listed specialty pharmaceutical company focused on commercialising novel pharmaceuticals, offering patients better, safe and more accessible medicines. Mayne Pharma is a leader in dermatology and women's health in the United States and also provides contract development and manufacturing services to clients worldwide. Mayne Pharma has a 40-year track record of innovation and success in developing new oral drug delivery systems. These technologies have been successfully commercialised in numerous products that continue to be marketed around the world. To learn more about Mayne Pharma, please visit maynepharma.com.

IMVEXXY®, BIJUVA®, NEXTSTELLIS® and ANNOVERA® are trademarks of third parties.

References

1. See ASX announcement dated 20 August 2026. Saltus CW, et al. Risk of Endometrial Cancer in Postmenopausal Women Prescribed Very-Low-Dose Vaginal Estrogen Products in the US. Poster presented at ISPE 2026; 29 August – 2 September 2026; Milan, Italy. Study funded by Mayne Pharma. VLDVE defined as ≤ 10 μ g estradiol or ≤ 0.30 mg conjugated estrogens daily.
2. LaClair J, et al. Vaginal Estrogen Prescription is Associated with Reduced Risk of Serious Adverse Outcomes in Women of All Age Groups with Recurrent Urinary Tract Infection: An Epic Cosmos Database Analysis. *Urology*. 2026;215:43–48. Ranges reflect results across age groups (20–39, 40–54, 55–69 and 70–99 years).
3. American Urological Association, Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction and American Urogynecologic Society. Genitourinary Syndrome of Menopause: AUA/SUFU/AUGS Guideline. Sept 2025.
4. PWC - Unlocking the menopause opportunity: A defining category in women's health.