



FDA TO REMOVE LONG-STANDING "BLACK BOX" WARNING LABEL ON MENOPAUSE THERAPIES

12 November 2025, Adelaide, Australia: Mayne Pharma Group Limited (**Mayne Pharma** or the **Company**) (ASX: MYX), is pleased to announce today that the U.S. Food & Drug Administration (FDA) will remove the "black box" warnings from a broad class of hormone replacement therapies (HRTs) used to manage menopausal symptoms. The decision reflects evolving clinical evidence and is expected to reshape prescribing practices, enhance patient and physician confidence, and expand the market for effective women's health therapies.

Importantly, this regulatory change could reduce the stigma and prescribing hesitation historically associated with HRT, potentially unlocking new patient segments and reinvigorating clinician confidence in menopausal products in the U.S. market through much improved prescribing practices.

Mayne Pharma's CEO & Managing Director, Mr Shawn Patrick O'Brien said *"We welcome the FDA's decision to remove outdated regulatory barriers that have discouraged the use of hormone therapies for symptomatic menopausal women. Over time, we believe this change will make a meaningful difference in the utilisation of Mayne Pharma's existing HRTs, namely BIJUVA® and IMVEXXY®. The Company remains committed to expanding the use of our branded Women's Health portfolio, driving commercial execution and delivering greater value for patients."*

Consistent with the FDA directive, Mayne Pharma anticipates obtaining FDA approval for updated language in the BIJUVA® and IMVEXXY® product labelling, to remove the Boxed Warnings related to risks of cardiovascular disorders, breast cancer, endometrial cancer and probable dementia.

According to the FDA commissioner Dr Martin A. Makary, "Tragically, tens of millions of women have been denied the life-changing and long-term health benefits of hormone replacement therapy because of a medical dogma rooted in a distortion of risk."

A copy of the FDA press release can be located [here](#).

- ENDS -

Authorised for release to the ASX by the Board Chair

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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.

INDICATIONS

BIJUVA (estradiol and progesterone) is a combination of an estrogen and progesterone indicated in a woman with a uterus for the treatment of moderate to severe vasomotor symptoms due to menopause.

IMVEXXY (estradiol vaginal inserts) is an estrogen indicated for the treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause.

IMVEXXY AND BIJUVA IMPORTANT SAFETY INFORMATION

Warning: Endometrial Cancer, Cardiovascular Disorders, Probable Dementia and Breast Cancer
See full prescribing information for complete boxed warnings

Estrogen-Alone Therapy

- There is an increased risk of endometrial cancer in a woman with a uterus who uses unopposed estrogens
- The Women's Health Initiative (WHI) estrogen-alone substudy reported increased risks of stroke and deep vein thrombosis (DVT)
- The WHI Memory Study (WHIMS) estrogen-alone ancillary study of WHI reported an increased risk of probable dementia in postmenopausal women 65 years of age and older
- Do not use estrogen-alone therapy for the prevention of cardiovascular disease or dementia

Estrogen Plus Progestin Therapy

- The WHI estrogen plus progestin substudy reported increased risks of stroke, DVT, pulmonary embolism (PE) and myocardial infarction (MI)
- The WHI estrogen plus progestin substudy reported increases risks of invasive breast cancer
- The WHIMS estrogen plus progestin ancillary study of WHI reported an increased risk of probable dementia in postmenopausal women 65 years and older
- Do not use estrogen plus progestogen therapy for the prevention of cardiovascular disease or dementia

IMVEXXY and BIJUVA have not been studied to be used together.
Please see the Full Prescribing Information, including BOXED WARNINGS, for BIJUVA and IMVEXXY