



Media Release

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Review of HRT warnings could be a life-saving intervention for women

International changes to warnings placed on hormone replacement therapy (HRT) products have been welcomed by the Urological Society of Australia and New Zealand (USANZ), who are hopeful similar changes will be made locally.

The US Food and Drug Administration has announced that strong safety warnings on many hormone replacement therapy products will be removed, an especially important change for topical vaginal oestrogen, which plays a critical role in treating the genitourinary syndrome of menopause (GSM).

These warnings were introduced after an early 2000s study found some serious health risks, including increased risks of certain cancers, cardiovascular issues, and probable dementia, were associated with specific HRT formulations.

HRT replaces oestrogen that the female body stops producing during menopause. The aim is to alleviate symptoms, including hot flashes, brain fog, insomnia, night sweats and joint pain.

The genitourinary syndrome of menopause (GSM) affects nearly 60% of menopausal women. It can cause dryness, burning, irritation, and an increased risk of UTIs.

USANZ Female Urology Speciality Advisory Group Deputy Leader Dr Sandra Elmer said there has been years of research and advocacy for change with regards to removing the warnings.

“USANZ welcomes and supports the FDA’s decision to remove broad black box warnings from menopausal hormone therapies, advocating for greater education and support to help more women.” she said.

Dr Elmer said the removal of warnings on vaginal oestrogen is especially important.

“The impact of menopause on recurrent urinary tract infections (UTIs) is a pressing concern with significant consequences for both women’s health and healthcare resources.”

“UTIs alone lead to a staggering 76,000 hospitalisations annually in Australia, and account for 25% of all infections in older people, straining the healthcare system’s resources.” she added.

Data indicates that implementing local, low-dose hormonal strategies (vaginal oestrogen) can reduce UTI risk by over 50%, offering a potential life-saving intervention for peri and post-menopausal women.

Australia’s Therapeutic Goods Administration (TGA) has said it works closely with international regulators, including the US FDA, and Australian medicine sponsors, and will independently consider the data relied upon to support proposed changes to product labelling for menopausal hormone therapies in the United States.

About Urological Society of Australia and New Zealand

The Urological Society of Australia and New Zealand is the peak professional body for urological surgeons in Australia and New Zealand. Urologists are surgeons who treat men, women and children with problems involving the kidney, bladder, prostate and male reproductive organs. These conditions include cancer, stones, infection, incontinence, urination difficulties, sexual dysfunction and pelvic floor problems. <https://www.usanz.org.au/>