



## **South African Menopause Society (SAMS) Response to FDA Removal of Black Box Warnings on Menopausal Hormone Therapy (MHT)**

The South African Menopause Society (SAMS) notes the recent decision by the United States Food and Drug Administration (FDA) to remove the Black Box warnings from all oestrogen-containing menopausal hormone therapy (MHT) products. This change has attracted international attention, but it is important to emphasise that the scientific evidence supporting the safe, effective use of MHT in appropriately selected women has been well-established for many years.

SAMS aligns with the European Menopause and Andropause Society (EMAS), which has issued a formal statement and will be hosting a global expert roundtable to explain the clinical implications of this regulatory update. The removal of the Black Box does not mean MHT is risk-free; rather, it reflects a correction of outdated warnings that no longer represent the current evidence. A nuanced approach, based on current available evidence, should be taken when initiating systemic MHT, as a wide range of formulations containing different oestrogens and progestogens/progesterone are available. Care should be taken not to overstate benefits or minimise possible risks.

SAMS is also concerned about the surge of misinformation circulating online, including the incorrect claim that MHT reduces dementia risk by 35%. This statement is not supported by scientific evidence and may expose women to inappropriate treatment decisions. SAMS commends clinicians like Prof Pauline Maki who have taken to social media to correct these inaccuracies, including informative posts such as this widely shared evidence-based explainer:

<https://www.instagram.com/reel/DQ90hhoASo5/?igsh=YzRtaWV0a3YwZ2Js>. SAMS also notes that MHT is not recommended to prevent primary or secondary cardiovascular disease in asymptomatic women.

For South African women, the message remains clear:

- **MHT is the most effective treatment for managing vasomotor symptoms, and prevention of bone loss (though not as a treatment for osteoporosis). MHT may also have beneficial effects on sleep and mood.**
- **The benefit-risk profile is favourable for healthy women under 60 or within 10 years of menopause onset, and**
- **Treatment should always be individualised and guided by a healthcare professional.**
- **Low-dose vaginal oestrogen is safe and effective for the management of vaginal and urinary symptoms of menopause**

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SAMS will continue to provide clinicians and the public with balanced, evidence-based guidance and encourages all stakeholders to rely on reputable menopause organisations when interpreting this regulatory update.

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