AUSTRALASIAN MENOPAUSE SOCIETY
NEW DIRECTIONS IN WOMEN'S HEALTH

AHPRA Pharmacy Board of Australia
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To whom it may concern,

The Australasian Menopause Society (AMS) would like to thank you for the opportunity to make a submission to the AHPRA Pharmacy Board regarding the *Guidelines on compounding of medicines* and *Professional practice profile for pharmacists undertaking complex compounding*. This is an area of significant concern for our members and to facilitate appropriate care we have recently compiled two information sheets. We have attached these for your reference. We are also actively working with the New Zealand Medical Council to establish appropriate prescribing guidelines.

Compounded hormone therapies in many cases contain the same active ingredients as commercial pharmaceutical-grade hormone products. They are frequently marketed as having a superior safety and efficacy profile despite a lack of randomized controlled studies to support this. They are promoted as more natural and tailor-made to a patient's requirements. However, pharmacokinetic and quality control data are typically lacking. These medications do not have FDA approval or the endorsement of any reputable Menopause or Medical Society because individually mixed recipes have not been tested to prove that the active ingredients are absorbed appropriately or provide predictable levels in blood and tissue [1,2]. Furthermore, there is no scientific evidence that these compounded medications are safer or more effective than government-approved hormones.

Significant concerns have been raised about the safe use of these products as they may be prescribed without a full medical consultation and examination. They have the potential, if used inappropriately, to have significant adverse effects on a user's health. For instance, several cases of endometrial cancer have been reported as a result of the use of compounded hormone therapy [3].

We endorse the statement that "compounded medicine should be prepared only in circumstances where an appropriate commercial product is unavailable" but would suggest removing the additional phrase ".or unsuitable". It would be rare to find a situation where a commercial product was not suitable and the additional phrase opens up the option of using compounded hormone therapies for unproven and spurious reasons.

We endorse the moves to enhance quality standards and packaging and labeling requirements. The requirements, for those involved in complex compounding, to demonstrate superior CPD involvement are appropriate. Consideration needs to be given to policing these standards as well as the advertising restrictions.

The AMS believe that the existing standards need to be extended to cope with the complexity of these agents and that the pharmacists providing compounded hormone therapies should require TGA licensing. We believe that the status quo is not appropriate for these agents and tighter restrictions are required to cover the manufacture, quality control and marketing of compounded hormone therapies.

We are more than happy to discuss these issues in more detail with you.

Yours faithfully,

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1. http://www.menopause.org/publications/clinical-practice-materials/bioidentical-hormone-therapy
2. http://www.imsociety.org/pdf_files/position_papers/global_consensus_statement_on_menopausal_hormone_therapy_2013.pdf
3. https://mjainsight.com.au/system/files/issues/187_04_200807/ede10581_fm.pdf