

The HRT debate:

How should the new evidence affect policy?

- What is the ADEC (Australian Drug Evaluation Committee)?
- How was the expert committee convened.
- What were the recommendations of the expert committee?
- What happens now?

What is the ADEC & why was it involved?

- The ADEC advises the TGA & the Parliamentary Secretary concerning the efficacy & safety of prescription medicines.
- The chairman of the Adverse Drug Reactions Advisory Ctee (ADRAC) is a core member of ADEC.
- The ADEC does not have any responsibility for the PBS.

What is the ADEC & why was it involved?

- The WHI trial report & an editorial was posted on the JAMA website on 9 July.
- Press releases from Graham Colditz & NSW Ca Council highlighted a 26% ↑ in breast cancer risk.
- On 10 July the Australian media were awash with headlines & reports that fuelled considerable alarm among women on HRT.

What is the ADEC & why was it involved?

On 10 July, the TGA requested ADEC establish an expert committee to examine the JAMA article & provide advice:

- on the significance of the study outcomes in the Australian context;
- the necessary & appropriate action of the TGA;
- what information should be provided to Australian health professionals & patients.

ADEC expert committee.

- Members drawn from ADEC & ADRAC with addition of Bruce Armstrong:
 - LF Arnolda (cardiologist), BK Armstrong, RA Ayton (gynaecologist), JJ McNeil (epidemiol), M Michael (oncologist), DJ Topliss (endocrinol & ADRAC chair), MHN Tattersall (ADEC chair)
- Expert Ctee report completed < 30 hrs & released on TGA website on 11 July 6 pm.

Conclusions of ADEC expert Committee.

Agrees with authors of paper that comb HRT in any form should not be used for long term disease prevention in post menop because the benefits are not sufficient to justify the risks of such use.

The Ctee believes that this conclusion is not necessarily restricted to the particular products used in the trial, but could potentially apply to all oestrogen/progestin combination products.

Conclusions of ADEC expert Committee.

The relevance of findings to use of HRT in short term treatment of symptoms ... menopause is less certain. Women can be assured that short term use of comb HRT .. to manage symptoms of menopause remains an appropriate Rx option, but women should discuss their particular circumstance with their doctor. This is even more so for younger women with premature menopause, in whom the benefits of HR would be greater & risks are probably smaller.

Conclusions of ADEC expert Committee.

- The continued use of combined HRT for women with established osteoporosis is an acceptable option for many but women should discuss the benefits & risks with their treating doctor.
- The use of oestrogen alone for the prev of disease continues under investigation. It is unsafe for women who have a uterus to use oestrogen without progestin....

ADEC expert committee recommendations for future action.

- supports the TGA in its actions to ensure updating of product & consumer information for all products used in combination HRT.
- Recommends a full review of the use of combination HRT in long term treatment & prevention of osteoporosis;
- recommends the TGA review all ongoing Australian trials using combination HRT for chronic disease.

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What happens now?

- MJA editorial on 19 August.
- this meeting;
- review of WISDOM study;
- TGA convening groups to review PI & CMI of combined hrt;
- TGA review of combined hrt in long term Rx & prevention of osteoporosis.