

**MHRA
QUESTIONS AND ANSWERS RELATED TO HORMONE REPLACEMENT
THERAPY AND ENDOMETRIAL CANCER**

<u>New data</u>	Page
Q1 Why is HRT in the news?	2
Q2 What is the Million Women Study?	2
Q3 What types of HRT are available?	2
Q4 What does the new data show?	2
Q5 What has the Million Women Study previously shown?	3
Q6 What is the current CSM advice on HRT?	3
Q7 Does the latest data change the advice?	3
Q8 What is endometrial cancer?	3
Q9 Should women stop taking HRT as a result of the new data?	4
Q10 How common are endometrial and breast cancer?	
Q11 What are the other risks with HRT?	4

QUESTIONS AND ANSWERS RELATED TO HORMONE REPLACEMENT THERAPY AND ENDOMETRIAL CANCER

New data

Q1. Why is HRT in the news?

A. The reason for the current interest in HRT is the publication in the Lancet of the latest data from the Million Women Study. This study has examined the effect of different types of HRT available in the UK on the risk of endometrial cancer (cancer of the lining of the womb) in a large number of postmenopausal women and provides new evidence about risks of endometrial cancer with different types of HRT.

Q2. What is the Million Women Study?

A. The Million Women Study has followed over a million women in the UK who have been recruited when they attended for breast cancer screening (mammography). At the start of the study the women were required to fill in questionnaires on their medical history, number of children, use of HRT etc. If any of the women subsequently developed cancer, this was notified to the Study co-ordinators, who have looked at the patterns of cancer with different HRT use.

Q3. What types of HRT are available?

A. There are a large number of different HRT products that fall into two main types of HRT – oestrogen-only replacement therapy and combined oestrogen/progestogen replacement therapy. In some combined preparations, progestogen is given throughout the cycle (continuous combined HRT), in others it is given for part of the cycle (sequential HRT). Tibolone (Livial) is a type of synthetic HRT that has oestrogenic, progestogenic and androgenic properties.

Q4. What does the new data show?

A. The latest results from the Million Women Study show that the risk of endometrial cancer varies according to the type of HRT used.

The results confirm that oestrogen-only HRT causes an increase in the risk of endometrial cancer compared to the risk in women who have never used HRT.

Continuous combined (oestrogen plus progestogen) HRT products (where the progestogen is taken every day) reduced the risk of endometrial cancer compared to the risk in women who have never used HRT.

Sequential or cyclical combined (oestrogen plus progestogen) HRT products (where the progestogen is taken for 10 to 14 days each month) did not

increase the risk of endometrial cancer compared to the risk in women who have never used HRT.

The synthetic HRT product, tibolone (Livial®), increased the risk of endometrial cancer when used for more than 3 years. compared to the risk in women who have never used HRT. The risk was no different when used for less than 3 years.

Q5. What has the Million Women Study previously shown?

A. The Million Women Study published its findings for the risk of breast cancer in August 2003. A key finding was a doubling of the risk of breast cancer in users of combined HRT. Further information may be found on the MHRA website under 'What's new, press releases, 8th August 2003'.

Q6. What is the current CSM advice on HRT?

A. The current CSM advice is that:

- For short-term use of HRT for the relief of menopausal symptoms, the benefits outweigh the risks for many women.
- It is recommended to use the lowest effective dose for the shortest duration for the individual patient.
- Each decision to start HRT should be made on an *individual* basis and treatment should be regularly reappraised (at least once a year).
- For postmenopausal women over 50 years who are at an increased risk of fracture, HRT should be used to prevent osteoporosis *only* in those who are intolerant of, or contraindicated for, other osteoporosis therapies.

Q7. Does the latest data change the advice?

A. The latest data from the Million Women Study are unlikely to change the general advice from CSM. The CSM's experts on HRT will look closely at the data to see if further advice is needed.

Q8. What is endometrial cancer?

A. Endometrial cancer affects the lining of the womb. One of the first signs is bleeding from the vagina.

Unexpected or 'breakthrough' bleeding or spotting is quite common during the first few months of using HRT as the body gets used to the treatment and it is usually nothing to worry about. However, if the bleeding or spotting:

- Carries on for more than a few months
- Starts after you've been on HRT or tibolone for a while
- Carries on even after you've stopped taking HRT or tibolone
- Starts in post-menopausal women who do not use HRT or tibolone

You should make an appointment to see your doctor.

Q9. How common are endometrial and breast cancers?

A. In never-users of HRT in the Million Women Study about 1 in 330 women developed endometrial cancer and 1 in 75 women developed breast cancer.

Q10. Should women stop taking HRT as a result of the new data?

A. The decision on whether to take HRT and what type of HRT to take can only be made on discussion between a woman and her doctor, taking into account her own medical history and personal preferences. Women who are taking HRT and are concerned about their risks of endometrial cancer should make a routine appointment with their doctor to discuss treatment options. There are no serious consequences from stopping HRT, although stopping abruptly may cause menopausal symptoms to return. Any woman considering stopping HRT is advised to make a routine appointment with her doctor to discuss options.

Q11. What are the other risks with HRT?

A. Further information on the risks and benefits of HRT and can be found on the MHRA website (see HRT latest safety update under 'What's new').