Statement from the International Menopause Society
in reply to the decision by the EMEA not to recommend
hormone replacement therapy for the indication for
prevention of osteoporosis

December 3, 2003

The International Menopause Society has issued the following statement in response to
the decision of the EMEA not to recommend hormone replacement therapy as first-line
therapy for the indication for prevention of osteoporosis.

The International Menopause Society (IMS) is profoundly concerned that the European Medicines
Evaluation Agency (EMEA) has ignored important information in its decision to recommend that the
risk/benefit balance of hormone replacement therapy (HRT) does not justify its use as first-line therapy
for the indication for prevention of osteoporosis in women.

HRT is a most effective therapy for the prevention of osteoporosis and related fractures; indeed, the
Women’s Health Initiative (WHI) confirmed the fracture reduction at both the spine and hip. No other
intervention has been shown to be so cost-effective in reducing hip and spine fractures.

In early postmenopausal women, there is no evidence that alternative treatments are as beneficial.
Individual risk/benefit considerations should be left to the woman and her doctor.

Because of the age of the population studied in the WHI, safety concerns cannot be extrapolated to early
postmenopausal women. The Million Women Study did not make any assessment of the risk/benefit ratio
for osteoporosis and related fractures in postmenopausal women.

Therefore, the IMS considers that the EMEA recommendations are unjustified and potentially harmful
for the health of postmenopausal women.