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Europe watchdog advises suspending 'risky' osteoporosis drug

January 10 2014

A committee of Europe's medicines watchdog on Friday recommended suspending the use of an osteoporosis drug, saying the risks, including heart attacks, outweighed the benefits.

The drug, Protelos/Osseor, is prescribed for people with the bone-crumbling disease who often suffer debilitating fractures.

A product of French firm Servier Laboratories, the medicine is said to make bones stronger and prevent breaks.

But the PRAC risk assessment committee of the European Medicines Agency (EMA) said the risks of serious heart problems, including heart attacks, blood clots and blocked arteries, were just too great.

For every 1,000 treated patients, there were four additional cases of serious heart problems and four of clotting among people using Protelos/Osseor compared to those given a placebo or dummy treatment.

Other risks include seizures and liver inflammation.

As an osteoporosis treatment, the drug has shown a "modest effect"—preventing about five non-spinal bone fractures, 15 spinal fractures and 0.4 hip fractures per 1,000 patients, the committee said.

"The PRAC weighed the benefits of the medicine against the known risks and concluded that the balance was no longer favourable, and

recommended Protelos/Osseor be suspended until there are new data showing a favourable balance in a defined patient group," a statement said.

The recommendation will next be considered by the EMA's Committee for Medicinal Products for Human Use for a final decision.

Servier in a statement informed national health agencies of Friday's announcement, and said it would provide further information once the EMA review is concluded.