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EMA Finds Little Evidence That Testosterone Ups CV Risk

Lisa Nainggolan | October 10, 2014

There is no consistent evidence that the use of testosterone in men with hypogonadism increases the risk for cardiovascular problems, according to a new review by the Pharmacovigilance Risk Assessment Committee (PRAC) of the European Medicines Agency (EMA).

The EMA launched this review regarding the cardiovascular risk for testosterone-containing medicines in April, following a similar announcement by the US Food and Drug Administration (FDA) earlier in the year.

Now the PRAC says the evidence concerning the risks of serious cardiovascular side effects with these medicines "is inconsistent." While some studies do suggest an increased risk for cardiac problems in men using testosterone compared with men not taking it, these had some limitations, and other studies did not confirm this risk.

The committee has determined that the benefits of testosterone continue to outweigh its risks but stresses that testosterone-containing medicines should be used only where lack of testosterone has been confirmed by signs and symptoms as well as laboratory tests.

The EU product information for all testosterone-containing medicines should therefore be updated to reflect this, and warnings against use of testosterone in men suffering from severe heart, liver, or kidney problems should also be included on all such products, says the PRAC.

And the limited data on safety and effectiveness in patients over 65 years of age need to be recognized, as does the fact that testosterone levels decrease with age and that age-specific testosterone reference values do not exist — this will also need to be highlighted in the product information, the PRAC states.

"The safety of testosterone medicines should continue to be monitored," the PRAC adds. "In particular, a number of studies are still ongoing, and their results will be considered in future regular benefit/risk assessments for these medicines."

The PRAC recommendation will now be forwarded to the Coordination Group for Mutual Recognition and Decentralised Procedures — Human (CMDh), which will adopt a final position.

In the United States, an FDA advisory panel voted nearly unanimously last month to change the labeling for testosterone-replacement products, with the aim of tamping down on the current widespread use there of such agents for "age-related" hypogonadism.

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Cite this article: EMA Finds Little Evidence That Testosterone Ups CV Risk. *Medscape*. Oct 10, 2014.