



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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## Review of testosterone-containing medicines started

The European Medicines Agency has started a review of testosterone-containing medicines, mainly used in men who do not produce enough testosterone (a condition known as hypogonadism).

The review was triggered by the Estonian medicines agency, the State Agency of Medicines, over concerns about side effects of medicines containing testosterone on the heart. The safety concerns were raised following the recent publication of a study<sup>1</sup> suggesting that the use of testosterone increases the risk of myocardial infarction (heart attack) in men aged over 65 years, as well as in younger men with pre-existing heart disease. This study follows other studies including the Veterans Health Care Study<sup>2</sup>, which suggests that men with pre-existing heart disease who received treatment with testosterone had a higher risk of heart problems than men who did not receive testosterone.

The European Medicines Agency will now review all available data on the benefit-risk balance of testosterone-containing medicines (in men and women), and issue an opinion on whether their marketing authorisations should be maintained, varied, suspended or withdrawn across the EU.

While the review is ongoing, patients should speak to their doctor or pharmacist if they have any questions or concerns.

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### More about the medicine

Testosterone-containing medicines have been authorised in several EU Member States via national procedures under various trade names. They are available as various formulations such as oral capsules, implants to be injected under the skin and as patches, gels or solutions to be applied to the skin.

Testosterone-containing medicines are used to replace testosterone in men with hypogonadism. The use of testosterone in healthy older men is not an authorised use in the EU. Testosterone-containing medicines can also be used in women in combination with oestrogens in the management of menopausal symptoms.

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<sup>1</sup> Finkle et al. "Increased risk of non-fatal myocardial infarction following testosterone therapy prescription in men." PLoS One. 2014 Jan 29; 9(1): e85805.

<sup>2</sup> Vigen et al. "Association of testosterone therapy with mortality, myocardial infarction, and stroke in men with low testosterone levels" JAMA. 2013 Nov 6; 310 (17): 1829-1836.



Testosterone is a natural hormone, known as an androgen, found in men and women. In men with hypogonadism, testosterone levels are abnormally low affecting normal sexual development. Testosterone-containing medicines work by replacing the missing testosterone, helping to restore normal testosterone levels to ensure normal sexual development in men.

**More about the procedure**

The review of testosterone has been initiated at the request of Estonia, under Article 31 of Directive 2001/83/EC.

The review is being carried out by the Pharmacovigilance Risk Assessment Committee (PRAC), the Committee responsible for the evaluation of safety issues for human medicines, which will make a set of recommendations. As testosterone-containing medicines are all authorised nationally, the PRAC recommendation will be forwarded to the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh), which will adopt a final position. The CMDh, a body representing EU Member States, is responsible for ensuring harmonised safety standards for medicines authorised via national procedures across the EU.