



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 January 2018
EMA/CHMP/54473/2018
EMA/H/C/004198

Refusal of the marketing authorisation for EnCyzix (enclomifene)

On 25 January 2018, the Committee for Medicinal Products for Human Use (CHMP) adopted a negative opinion, recommending the refusal of the marketing authorisation for the medicinal product EnCyzix, intended for the treatment of hypogonadotropic hypogonadism in men.

The company that applied for authorisation is Renable Pharma Limited. It may request a re-examination of the opinion within 15 days of receipt of notification of this negative opinion.

What is EnCyzix?

EnCyzix is a medicine that contains the active substance enclomifene. It was to be available as capsules to be taken by mouth.

What was EnCyzix expected to be used for?

EnCyzix was expected to be used to treat hypogonadotropic hypogonadism in men. In this condition, the sex organs (the testes in men) do not work properly resulting in symptoms such as infertility, low libido, impotence, weakened bones and weight gain. EnCyzix was to be used in overweight men with a body mass index (BMI) of at least 25 kg/m².

How does EnCyzix work?

Overweight men with hypogonadotropic hypogonadism produce too much of the hormone oestrogen. This stops the release of other hormones called gonadotrophins, which are needed for the testes to produce testosterone and to work normally. EnCyzix blocks the excess oestrogen enabling release of gonadotrophins and normal testicular function.



What did the company present to support its application?

The company presented the results of 4 main studies involving a total of 588 patients. Patients were given either EnCyzix, or placebo (a dummy treatment) with and without application of a testosterone gel. The main measures of effectiveness were the amount of sperm produced and testosterone levels.

What were the CHMP's main concerns that led to the refusal?

The CHMP noted that although the studies showed an increase in testosterone levels with EnCyzix, they did not look at whether EnCyzix would improve symptoms such as bone strength, weight gain, impotence and libido. In addition, there is a risk of venous thromboembolism (problems due to the formation of blood clots in the veins) with the medicine. Therefore, the CHMP was of the opinion that the benefits of EnCyzix did not outweigh its risks and recommended that it be refused marketing authorisation.

What consequences does this refusal have for patients in clinical trials or compassionate use programmes?

The company informed the CHMP that there are no ongoing clinical trials or compassionate use programmes with EnCyzix.