

German firm shelves libido-boosting drug for women

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German drug firm Boehringer Ingelheim has shelved development of a libido-booster for women after it was given the thumbs down by the US Food and Drug Administration (FDA), the company said.

"The response of the authorities and the complexity and extent of further questions that would need to be addressed to potentially obtain registration for flibanserin have impacted the company's decision to focus on other pipeline projects," Boehringer said in the statement published on its website.

Originally intended as an anti-depressant, the drug flibanserin -- in the form of a pink pill -- began being tested years ago as a potential libido aid after women said it failed to fight the blues but did boost their sex drive.

Lack of desire is the most common sexual problem in women aged 30 to 60, just as erectile dysfunction is the most common sexual disorder among men in the same age bracket, researchers said.

Clinical trials to test flibanserin's efficacy in raising the level of sexual desire in women were held in Canada, Europe and the United States.

The FDA said in June that two US trials with the drug and a placebo "both failed to demonstrate a statistically significant improvement on the co-primary endpoint of sexual desire."



"Therefore, neither study met the agreed-upon criteria for success in establishing the efficacy of flibanserin for the treatment of HSDD (<u>hypoactive sexual desire disorder</u>)," the administration added.

Besides the inconclusive results, the FDA noted the drug in some patients caused side effects including depression and dizziness.

The US Reproductive Health Drugs Advisory Committee also said that the efficacy and safety of flibanserin had not been determined.

Boehringer Ingelheim has been researching flibanserin as a treatment for post-menopausal HSDD in women since the popular Viagra for men hit the market in 1998.

The potential market for a libido booster for women has been estimated by some analysts at around two billion dollars.

Flibanserin belongs to a family of anti-depressants that acts on the body's level of serotonin, a molecule that plays a role in mood changes.

Boehringer Ingelheim said that "the company continues to believe in the value that flibanserin would have for women suffering with HSDD, a significant and recognised medical condition which impacts the lives of many women around the world."

"The decision was not made lightly, considering the advanced stage of development," board chairman Andreas Barner was quoted as saying.

"We remain convinced of the positive benefit-risk ratio of flibanserin for <u>women</u> suffering with HSDD."

Boehringer Ingelheim said it would reallocate resources to other areas, such as stroke prevention, diabetes and cancer.



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