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Withdrawal of application for the marketing authorisation of Sildenafil FGK (sildenafil)

FGK Representative Service GmbH withdrew its application for a marketing authorisation of Sildenafil FGK for the treatment of adult men with erectile dysfunction.

The company withdrew the application on 19 July 2021.

What is Sildenafil FGK and what was it intended to be used for?

Sildenafil FGK was developed as a medicine to treat adult men with erectile dysfunction (sometimes called impotence), when they cannot get or keep a hard penis (erection) sufficient for satisfactory sexual activity.

Sildenafil FGK was developed as a 'hybrid medicine'. This means that Sildenafil FGK contained the same active substance as an authorised 'reference medicine', in this case Viagra, but was to be available in a different form and was to be taken in a different way. While Viagra is available as tablets to be taken by mouth and swallowed, Sildenafil FGK was to be available as a thin strip for sublingual use (to be placed under the tongue), not to be swallowed.

How does Sildenafil FGK work?

The active substance in Sildenafil FGK, sildenafil, belongs to a group of medicines called phosphodiesterase-type-5 (PDE5) inhibitors. It works by blocking the phosphodiesterase enzyme, which normally breaks down a substance known as cyclic guanosine monophosphate (cGMP). During normal sexual stimulation, cGMP is produced in the penis, where it causes the muscle in the spongy tissue of the penis (the corpora cavernosa) to relax, allowing the flow of blood into the corpora, producing the erection. By blocking the breakdown of cGMP, sildenafil restores erectile function. Sexual stimulation is still needed to produce an erection.

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What did the company present to support its application?

Studies on the benefits and risks of the active substance are not needed for a hybrid medicine because they have already been carried out with the reference medicine. As for every medicine, the company provided data on the quality of Sildenafil FGK.

The company also submitted data from a study investigating the absorption of Sildenafil FGK when placed under the tongue, compared with the absorption of the reference medicine Viagra taken by mouth as a tablet.

How far into the evaluation was the application when it was withdrawn?

The application was withdrawn after the European Medicines Agency had evaluated the information from the company and prepared questions for the company. After the Agency had assessed the company's responses to the last round of questions, there were still some unresolved issues.

What did the Agency recommend at that time?

Based on the review of the data and the company's response to the Agency's questions, at the time of the withdrawal, the Agency had some concerns and its provisional opinion was that Sildenafil FGK could not have been authorised for the treatment of erectile dysfunction.

The data submitted by the applicant did not support the sublingual use of Sildenafil FGK. The data showed that the medicine failed to completely dissolve under the tongue (even after ten minutes) in a significant proportion of men in the study and needed to be swallowed.

Therefore, at the time of the withdrawal, the Agency's opinion was that the benefits of Sildenafil FGK did not outweigh its risks based on data submitted by the applicant.

What were the reasons given by the company for withdrawing the application?

In its letter notifying the Agency of the withdrawal of the application, the company stated that the withdrawal is based on the fact that the available data were not considered sufficient to conclude on a positive benefit-risk balance for Sildenafil FGK.

Does this withdrawal affect patients in clinical trials?

The company informed the Agency that, at present, there are no ongoing trials with Sildenafil FGK.