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Questions and answers on the withdrawal of the application for a change to the marketing authorisation for Viagra

On 19 November 2008, Pfizer Limited officially notified the Committee for Medicinal Products for Human Use (CHMP) that it wishes to withdraw its application for a change to the marketing authorisation for the medicinal product Viagra 50 mg tablets. The change concerned 'switching' the classification of the medicine from 'medicinal product subject to medical prescription' to 'medicinal product *not* subject to medical prescription'.

What is Viagra?

Viagra is a medicine that contains the active substance sildenafil. It is available as tablets (25, 50 and 100 mg). Viagra is used to treat adult men with erectile dysfunction (impotence), which means that they cannot get or keep a hard penis (erection) sufficient for satisfactory sexual activity. The medicine can only be obtained with a prescription.

What was Viagra expected to be used for?

Viagra 50 mg tablets were expected to be used for the same indication, but to be available without a prescription. This would have allowed the 50 mg tablets to be available 'over-the-counter' for men with erectile dysfunction.

How does Viagra work?

The active ingredient in Viagra, 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, Viagra improves erectile function. Sexual stimulation is still needed to produce an erection.

What documentation did the company present to support its application to the CHMP?

The company presented information to support its view that Viagra 50 mg tablets were suitable to be switched to non-prescription status. This included information from previous studies looking at the medicine's safety and effectiveness, as well as information on the risks of the medicine being used incorrectly.

The company also provided details of the written information to be provided with the medicine, including the text to be printed on the outer packaging and in the Package Leaflet.

How far into the evaluation was the application when it was withdrawn?

The application was at day 145 when the company withdrew. After the CHMP had assessed the responses from the company to a list of questions, there were still some unresolved issues outstanding. The CHMP normally takes at least 60 days to adopt an opinion after it has received an application for a change to a marketing authorisation. Following the CHMP's opinion, it usually takes around six weeks for the European Commission to update the licence.

What was the recommendation of the CHMP at that time?

Based on the review of the data and the company's response to the CHMP list of questions, at the time of the withdrawal, the CHMP had some concerns and was of the provisional opinion that Viagra 50 mg tablets could not have been approved for non-prescription use.

What were the major concerns that led the CHMP to recommend the refusal of the change to the marketing authorisation?

The CHMP was concerned that Viagra 50 mg did not fulfil the criteria needed for switching its classification from prescription to non-prescription status.

Because erection problems can be a sign of an underlying disease, the Committee was concerned that switching the medicine to non-prescription use could delay or prevent the diagnosis of any underlying diseases, including coronary artery disease (obstruction of blood flow to the heart muscle).

The CHMP was also concerned that the information to be provided with the medicine was too complex, which could lead to patients using the medicine incorrectly.

In addition, the Committee was concerned that the medicine could be used outside of its approved indication, such as for recreational purposes, in particular in young people.

Therefore, at the time of the withdrawal, the CHMP was of the opinion that the benefits of Viagra 50 mg tablets as an over-the-counter treatment for erectile dysfunction did not outweigh its risks.

What were the reasons given by the company to withdraw the application?

The letter from the company notifying the EMEA of the withdrawal of the application is available [here](#).

What is happening with Viagra as a prescription-only medicine?

There are no consequences on the use of Viagra in its authorised indication as a prescription-only medicine, for which the balance of benefits and risks remains unchanged.