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Questions and answers

Withdrawal of the application for a change to the marketing authorisation for Qutenza (capsaicin)

On 14 March 2012, Astellas Pharma Europe B.V. 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 Qutenza, which would have extended its use to patients with diabetes who have peripheral neuropathic pain not caused by their diabetes.

What is Qutenza?

Qutenza is a cutaneous patch (a patch that delivers a medicine to the skin). It contains the active substance capsaicin (8%).

Qutenza has been authorised in the EU since May 2009 and is already used to treat peripheral neuropathic pain (pain that is caused by damage to the nerves in the extremities) in adults who do not have diabetes. It is used either alone or together with other painkillers.

What was Qutenza expected to be used for?

Qutenza was also expected to be used in patients with diabetes who have peripheral neuropathic pain not caused by their diabetes.

How is Qutenza expected to work?

In patients with diabetes, Qutenza is expected to work in the same way as it does in its existing indication.

The active substance in Qutenza, capsaicin, is a substance normally found in chilli peppers that is a 'selective agonist' of the 'transient receptor potential vanilloid 1' (TRPV1) receptor. This means that it stimulates the TRPV1 receptor, which is found in the nociceptors (pain receptors) in the skin. Qutenza

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contains high doses of capsaicin that are released quickly and overstimulate the TRPV1 receptors. Overstimulating the receptors makes them become 'desensitised' and no longer able to respond to the stimuli that normally cause pain in patients with peripheral neuropathic pain.

What did the company present to support its application?

No new studies were submitted to support this application. The company presented further detailed analysis of the results of some of the studies that had been submitted at time the medicine was first approved.

At the time of the initial approval, the evidence supporting the medicine's use in patients with diabetic neuropathic pain was considered insufficient and the CHMP excluded its use in all patients with diabetes. The company's analysis was intended to show that diabetic patients with peripheral neuropathic pain not caused by diabetes have as good outcomes with Qutenza as non-diabetic patients. The analysis included data on 2,073 diabetic and non-diabetic patients from six studies.

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

The application was withdrawn after 'day 90'. This means that the CHMP had evaluated the documentation provided by the company and formulated lists of questions. After the CHMP had assessed the company's responses to the questions, there were still some unresolved issues.

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 lists of questions, at the time of the withdrawal, the CHMP had some concerns and was of the provisional opinion that Qutenza could not have been approved to treat diabetic patients with non-diabetic peripheral neuropathic pain. The Committee was concerned that it would not be possible in clinical practice to distinguish patients with non-diabetic neuropathic pain from those with diabetic neuropathic pain. Patients with diabetes, but especially those with diabetic neuropathic pain, could be put at risk as Qutenza may increase their chances of developing ulcers in the foot, which could lead to serious complications.

Therefore, at the time of the withdrawal, the CHMP was of the opinion that the benefits of Qutenza in diabetic patients did not outweigh its risks.

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

In its official letter, the company stated that its decision to withdraw the application was based on the CHMP's view that the data provided do not allow the Committee to conclude on a positive benefit-risk balance.

The withdrawal letter can be found here.

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

If you are in a clinical trial and need more information about your treatment, contact the doctor who is giving it to you.

What is happening with Qutenza for the treatment of neuropathic pain in patients who do not have diabetes?

There are no consequences on the use of Qutenza in its authorised indication.

The full European Public Assessment Report for Qutenza can found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports.