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Withdrawal of application for the marketing authorisation of Abylqis (*Arachis hypogaea* extract)

DBV Technologies withdrew its application for a marketing authorisation of Abylqis for the treatment of peanut allergies.

The company withdrew the application on 17 December 2021.

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

Abylqis was developed as a medicine to treat children with peanut allergies.

Abylqis contains *Arachis hypogaea* extract and was to be available as a skin patch.

How does Abylqis work?

Abylqis contains an extract from peanuts (*Arachis hypogaea*). The medicine is used to expose patients with allergies to peanuts to controlled doses of the allergen (the substance they are allergic to) to get the body's immune system used to the substance.

What did the company present to support its application?

The company presented results from a main study involving 356 children 4 to 11 years old with peanut allergies, where Abylqis was compared with placebo (a dummy treatment). The main measure of effectiveness was the number of children who, after treatment, could tolerate a much larger amount of peanut protein without having an allergic reaction.

How far into the evaluation was the application when it was withdrawn?

The application was withdrawn after the European Medicines Agency had evaluated the information from the company and prepared questions for the company. The company had not responded to the last round of questions at the time of the withdrawal.

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What did the Agency recommend at that time?

Based on the review of the data, at the time of the withdrawal, the Agency had some concerns and its provisional opinion was that Abylqis could not have been authorised for the treatment of peanut allergies.

The Agency considered that the results of the study were not sufficient to establish the effectiveness of the medicine, with results showing a small reduction in the sensitivity to peanuts and an increased risk of allergic reactions related to the medicine. Therefore, at the time of the withdrawal, the Agency's opinion was that the benefits of Abylqis did not outweigh its risks.

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 its withdrawal was based on feedback it received indicating that the data from the main study were not sufficient to address the Agency's concerns and that a new main study would be initiated.

Does this withdrawal affect patients in clinical trials?

The company informed the Agency that there are no consequences for patients in clinical trials using Abylqis.

If your child is in a clinical trial and you need more information about their treatment, speak with their clinical trial doctor.