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# Withdrawal of application for the marketing authorisation of Rayoqta (abicipar pegol)

Allergan Pharmaceuticals International Limited withdrew its application for a marketing authorisation of Rayoqta for the treatment of age-related macular degeneration.

The company withdrew the application on 17 July 2020.

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

Rayoqta was developed as a medicine to treat adults with the 'wet' form of age-related macular degeneration (AMD), a disease which affects the central part of the retina (called the macula) at the back of the eye and causes gradual loss of vision.

Rayoqta contains the active substance abicipar pegol and was to be available as a solution for injection into the eye.

## How does Rayoqta work?

In patients with wet AMD, too much of a protein called vascular endothelial growth factor A (VEGF-A) in the eye causes blood vessels under the macula to grow abnormally and swell up, which can cause loss of vision.

The active substance in Rayoqta, abicipar pegol, attaches to VEGF-A in the eye and stops its activity. This was expected to stop the growth of new abnormal blood vessels and so stabilise or even improve vision.

## What did the company present to support its application?

The company presented the results of 2 main studies in a total of almost 1,900 patients with wet AMD who had not been treated before. The studies compared Rayoqta with ranibizumab (a medicine for AMD) and looked at the number of patients who maintained vision (defined as losing fewer than 15 letters in a standard eye test) after the first year of treatment. The studies tested Rayoqta given at 8- and 12-weekly intervals.

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## How far into the evaluation was the application when it was withdrawn?

The application was withdrawn after that the European Medicines Agency had evaluated the information from the company and prepared questions for the company.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.

## 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 Rayoqta could not have been authorised for the treatment of wet AMD.

The Agency considered that Rayoqta had not consistently been shown to be as effective as ranibizumab at maintaining vision. In addition, the Agency had concerns about the safety profile of the medicine and considered that measures were needed to manage the risks. In particular, inflammation inside the eye, which may have an impact on vision, was more frequent in patients treated with Rayoqta than in those treated with ranibizumab. The Agency considered that further investigation was needed to reduce the severity of this side effect and possibly eliminate it.

Therefore, at the time of the withdrawal, the Agency's opinion was that the benefits of Rayoqta 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 it withdrew its application because the concerns raised could not be resolved within the available time frame.

## Does this withdrawal affect patients in clinical trials or compassionate use programmes?

The company informed the Agency that the withdrawal will have no consequences on patients as there are no ongoing clinical trials or compassionate use programmes ongoing with the medicine.