15 September 2017
EMA/589782/2017
EMEA/H/C/4419

Questions and answers

Withdrawal of the marketing authorisation application for Tigecycline Accord (tigecycline)

On 12 September 2017, Accord Healthcare Limited officially notified the Committee for Medicinal Products for Human Use (CHMP) that it wishes to withdraw its application for a marketing authorisation for Tigecycline Accord, for the treatment of certain complicated infections.

What is Tigecycline Accord?

Tigecycline Accord is an antibiotic medicine that contains the active substance tigecycline. It was to be available as a powder to make a solution for infusion (drip) into a vein.

Tigecycline Accord was developed as a 'generic medicine'. This means that Tigecycline Accord contains the same active substance and was intended to work in the same way as a 'reference medicine' already authorised in the European Union called Tygacil. For more information on generic medicines, see the question-and-answer document here.

What was Tigecycline Accord expected to be used for?

Tigecycline Accord was expected to be used to treat adults and children older than 8 years with complicated infections of the skin and soft tissue (the tissue below the skin), except foot infections in people with diabetes. It was also intended to treat complicated infections in the abdomen (belly). 'Complicated' means that the infection is difficult to treat. It was intended for use only when other antibiotics were not suitable.

How does Tigecycline Accord work?

The active substance in Tigecycline Accord and Tygacil, tigecycline, is one of a group of antibiotics called 'glycylcyclines'. It works against the bacteria that cause infections by blocking the bacteria's ribosomes, the parts of the cell where new proteins are made. Because the medicine blocks the production of new proteins, the bacteria cannot multiply and they eventually die.

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What did the company present to support its application?

Studies on the benefits and risks of the active substance in the approved uses have already been carried out with the reference medicine, Tygacil, and did not need to be repeated for Tigecycline Accord.

As for every medicine, the company also provided studies on the quality of Tigecycline Accord. There was no need for 'bioequivalence' studies to investigate whether Tigecycline Accord is absorbed similarly to the reference medicine to produce the same level of the active substance in the blood. This is because Tigecycline Accord is given by infusion into a vein, so the active substance is delivered straight into the bloodstream.

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

The application was withdrawn after the CHMP had evaluated the initial documentation provided by the company and formulated a list of questions. The company had not yet responded to the questions at the time of the withdrawal.

What was the recommendation of the CHMP at that time?

Based on the review of the data, at the time of the withdrawal, the CHMP had some concerns and was of the provisional opinion that Tigecycline Accord could not have been approved to treat complicated infections.

The CHMP's main concern was lack of compliance with Good Manufacturing Practice (GMP) by the manufacturing site for the medicine's active substance.

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 was withdrawing the medicine for marketing reasons because of the issues at the manufacturing site.

The withdrawal letter is available here.

What consequences does this withdrawal have for patients in clinical trials?

The company informed the CHMP that there are no consequences for patients currently included in clinical trials using Tigecycline Accord.

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