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Withdrawal of application for the marketing authorisation of Zemdri (plazomicin)

Cipla Europe NV withdrew its application for a marketing authorisation of Zemdri for the treatment of complicated urinary tract infection.

The company withdrew the application on 16 June 2020.

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

Zemdri was developed as an antibiotic medicine for use in adults with complicated (difficult-to-treat) infections of the urinary tract, including infections of the kidneys (pyelonephritis), when the standard recommended treatments cannot be given.

Zemdri contains the active substance plazomicin and was to be available as a concentrate to make up a solution for infusion (drip) into a vein.

How does Zemdri work?

The active substance in Zemdri, plazomicin, is one of a group of antibiotics called aminoglycosides that work by blocking the production of proteins that certain bacteria need to build their cell walls. This damages the bacteria and eventually kills them. Plazomicin is active against strains of bacteria that are resistant to some other aminoglycosides.

What did the company present to support its application?

The effectiveness of Zemdri in treating complicated urinary tract infections was compared against infusion of another antibiotic, meropenem, both followed by antibiotic treatment by mouth as appropriate, in a main study involving 609 patients. The company also presented supporting data on the use of Zemdri in infections that had spread to the bloodstream and in patients with pneumonia.

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How far into the evaluation was the application when it was withdrawn?

The application was withdrawn after the European Medicines Agency had evaluated the information supplied by the company and prepared questions for the company. After the Agency had assessed the company's responses to the last round of questions, there were still some unresolved issues.

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 still had some concerns and its provisional opinion was that Zemdri could not have been authorised for the treatment of complicated urinary tract infections. The Agency was concerned that the choice of method for sterilising the medicine had not been fully justified, and considered that further work to determine the feasibility of an additional sterilisation step should be undertaken. Therefore, at the time of the withdrawal, the Agency's opinion was that the benefits of Zemdri 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 was withdrawing its application for commercial reasons.

Does this withdrawal affect patients in clinical trials?

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

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