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Questions and answers

Withdrawal of the marketing authorisation application for Ertapenem Hospira (ertapenem)

On 13 September 2016, Hospira UK Limited officially notified the Committee for Medicinal Products for Human Use (CHMP) that it wishes to withdraw its application for a marketing authorisation for Ertapenem Hospira, for the treatment of certain infections and for the prevention of infection in colorectal surgery.

What is Ertapenem Hospira?

Ertapenem Hospira is an antibiotic medicine that contains the active substance ertapenem. It was to be available as a vial containing a powder which is dissolved before use to make up a solution for infusion (drip) into a vein.

Ertapenem Hospira was developed as a 'generic medicine'. This means that Ertapenem Hospira was intended to be similar to a 'reference medicine' already authorised in the European Union called Invanz. For more information on generic medicines, see the question-and-answer document here.

What was Ertapenem Hospira expected to be used for?

Ertapenem Hospira was expected to be used in adults and children aged over 3 months to treat the following infections, if caused by bacteria likely to be killed by ertapenem:

- infections in the abdomen;
- community-acquired pneumonia (infection of the lungs caught away from hospital);
- gynaecological infections;
- foot infections in diabetes patients.

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Ertapenem Hospira was also expected to be used to prevent infection at the site of colorectal surgery (surgery in the lower part of the bowel, including the rectum and anus).

How does Ertapenem Hospira work?

Ertapenem Hospira is expected to work in the same way as the reference medicine, Invanz. The active substance in Ertapenem Hospira and Invanz, ertapenem, belongs to a group of antibiotics known as 'carbapenems'. Ertapenem attaches to certain proteins on the surface of the bacteria cells. This upsets the essential functions that keep the cells alive, and kills the bacteria. Ertapenem can work on a range of different bacteria.

What did the company present to support its application?

Because Ertapenem Hospira was developed as a generic medicine, the company presented the results of studies to show the quality of the medicine. No further studies were carried out because Ertapenem Hospira is a generic medicine that is given by infusion and contains the same active substance as the reference medicine, Invanz.

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 Ertapenem Hospira could not have been approved for the treatment of infections and for the prevention of infection in colorectal surgery.

The CHMP had concerns about the choice of the starting materials for making the active substance, the process used to manufacture the medicine, the method for testing the purity of the medicine and the medicine's shelf life. At the time of the withdrawal, the CHMP was of the opinion that the company had not addressed its concerns and the quality of Ertapenem Hospira had not been demonstrated.

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 the withdrawal of the application is based on commercial reasons following an evaluation of the current market situation.

The withdrawal letter is available here.