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Withdrawal of application for the marketing authorisation of Garsun (artesunate)

B & O Pharm withdrew its application for a marketing authorisation of Garsun, intended for the treatment of severe malaria caused by *Plasmodium falciparum*.

The company withdrew the application on 8 December 2022.

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

Garsun was developed as a medicine for treating adults and children with severe malaria caused by the parasite *Plasmodium falciparum*.

Garsun contains the active substance artesunate and was to be given as an injection into a vein.

Garsun was designated an 'orphan medicine' (a medicine used in rare diseases) on 28 July 2015 for the treatment of malaria. Further information on the orphan designation can be found on the Agency's website: ema.europa.eu/medicines/human/orphan-designations/eu3151521.

How does Garsun work?

The active substance in Garsun, artesunate, is a derivative of the naturally occurring substance artemisinin. Its exact mode of action is not fully understood, but once it has entered blood cells infected by the malaria parasite, the medicine is thought to form toxic substances called 'free radicals' that kill the parasite.

What did the company present to support its application?

The company presented results from two main studies involving almost 7,000 patients with severe malaria caused by *Plasmodium falciparum* in countries where malaria is endemic. The studies compared Garsun with quinine, a standard medicine for severe malaria, and investigated how well both medicines were able to prevent death from severe malaria.

The patients in these studies also received treatments with additional medicines.

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How far into the evaluation was the application when it was withdrawn?

The application was withdrawn after the European Medicines Agency had evaluated the information from the company and prepared questions for the company.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

At the time of the withdrawal, the Agency was waiting for confirmation that one of the manufacturing sites was compliant with good manufacturing practice (GMP).

In addition, EMA had asked the company to provide further information to justify its application, as another orphan medicine with the same active substance was already authorised in the EU. (Generally, when one orphan medicine is authorised, it can be protected from competition from similar medicines.)

Therefore, at the time of the withdrawal, the Agency's opinion was that the medicine could not have been approved.

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 after it had revised its business strategy.

Does this withdrawal affect patients in clinical trials?

The company informed the Agency that there are no ongoing clinical trials with Garsun.