European Medicines Agency
Press office

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PRESS RELEASE

Wyeth withdraws its application to extend the marketing authorisation for Tygacil

The European Medicines Agency (EMEA) has been formally notified by Wyeth Europa Ltd of its decision to withdraw its application to extend the marketing authorisation for the medicinal product Tygacil (tigecycline) to include a new indication.

Tygacil was first authorised in the European Union in April 2006. It is currently authorised for complicated skin and soft-tissue infections and complicated intra-abdominal infections.

On 3 August 2007, Wyeth submitted an application to extend the currently authorised indications for Tygacil to include treatment of community-acquired pneumonia. At the time of the withdrawal, the application was under review by the Agency's Committee for Medicinal Products for Human Use (CHMP).

In its official letter, the company stated that the withdrawal of the application was based on the CHMP's opinion that the data provided do not allow the Committee to conclude a positive benefit-risk balance in community-acquired pneumonia at this time.

Tygacil continues to be authorised in the currently approved indications.

More information about Tygacil and the state of the scientific assessment at the time of withdrawal of the new indication will be made available in a question-and-answer document that will be published on the EMEA website after the next meeting of the CHMP on 27-30 May 2008.

--ENDS--

NOTES

1. Withdrawal of an application does not prejudice the possibility of a company making a new application at a later stage.
2. More information about Tygacil is available in the European Public Assessment Report (EPAR): http://www.emea.europa.eu/humandocs/Humans/EPAR/tygacil/tygacil.htm.
3. This press release, together with other information about the work of the EMEA, can be found on the EMEA website: http://www.emea.europa.eu

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