European Medicines Agency
Press office

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PRESS RELEASE
Guerbet withdraws its marketing authorisation application for Sinerem

The European Medicines Agency (EMEA) has been formally notified by Guerbet of its decision to withdraw its application for a centralised marketing authorisation for the medicine Sinerem (superparamagnetic iron oxide nanoparticles stabilised with dextran and sodium citrate).

Sinerem was expected to be used for the characterisation of lymph nodes visualised with magnetic resonance imaging in the evaluation of primary tumour spread in pelvic cancers.

The application for marketing authorisation for Sinerem was submitted to the EMEA on 26 of October 2006. At the time of the withdrawal, it 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 Sinerem was based on the information that the CHMP considered that the main study used to evaluate the benefit-risk profile of the medicine had failed to statistically demonstrate the efficacy of Sinerem.

More information about Sinerem and the state of the scientific assessment at the time of withdrawal will be made available in a question-and-answer document. This document, together with the withdrawal letter from the company, will be published on the EMEA website shortly.

-- ENDS --

Notes:

1. Withdrawal of an application does not prejudice the possibility of a company making a new application at a later stage.
2. This press release, together with other information on the work of the EMEA, can be found on the EMEA website: www.emea.europa.eu

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