European Medicines Agency
Press office

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PRESS RELEASE
Marvel LifeSciences Ltd withdraws its marketing authorisation applications for Insulin Human Rapid Marvel, Insulin Human Long Marvel and Insulin Human 30/70 Mix Marvel

The European Medicines Agency (EMEA) has been formally notified by Marvel LifeSciences Ltd of its decision to withdraw its applications for a centralised marketing authorisation for the medicines Insulin Human Rapid Marvel, Insulin Human Long Marvel and Insulin Human 30/70 Mix Marvel.

These medicines were expected to be used for the treatment of patients with diabetes mellitus who require insulin for the maintenance of glucose homeostasis and for the initial control of diabetes mellitus and diabetes mellitus in pregnancy.

The applications for marketing authorisation of the three insulins were made as applications for similar biological medicinal products, claiming that the medicines are biologically similar to a reference medicine already authorised in the European Union (Humulin, from Eli Lilly). The applications were submitted to the EMEA on 2 March 2007. At the time of the withdrawal, they were 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 three applications was based on the decision of the CHMP not to grant an extension to the timeframe given to them to respond to a list of questions. This request was in addition to an earlier extension of three months that had been granted by the CHMP.

More information about Insulin Human Rapid Marvel, Insulin Human Long Marvel and Insulin Human 30/70 Mix Marvel 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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