EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Press release

Marvel LifeSciences Ltd withdraws its marketing authorisation applications for Solumarv, Isomarv and Combimarv (human insulin)

The European Medicines Agency has been formally notified by Marvel LifeSciences Ltd of its decision to withdraw its applications for centralised marketing authorisations for the medicines Solumarv, Isomarv and Combimarv (human insulin), all 100 IU/ml solution for injection. They were intended to be used for the treatment of patients with diabetes mellitus who require insulin for the maintenance of glucose homeostasis.

The medicines were developed as 'biosimilar' medicines. This means that they are similar to a biological medicine already authorised in the European Union that contains the same active substance (also known as the 'reference medicine'), Humulin S.

The applications for the marketing authorisation for Solumarv, Isomarv and Combimarv were submitted to the Agency on 5 December 2011. At the time of the withdrawal, all three medicines were under review by the Agency's Committee for Medicinal Products for Human Use (CHMP).

In its official letter, the company stated that, "the decision to withdraw is in order to have sufficient time to repeat and submit bioequivalence T1D [type 1 diabetes] PK/PD [pharmacokinetic/pharmacodynamic] data on each clamp study in order to comply with the planned new insulin guideline …, at a validated CRO [contract research organization]."

More information about Solumarv, Isomarv and Combimarv 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 Agency's website after the CHMP meeting of 10-13 December 2012.

Notes

1. This press release, together with all related documents, is available on the Agency's website.

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2. Withdrawal of an application does not prejudice the possibility of a company making a new application at a later stage.

3. A question-and-answer document on biosimilar medicines can be found here: http://www.ema.europa.eu/docs/en_GB/document_library/Medicine_QA/2009/12/WC500020062.pdf

4. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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