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Press Office

Press release

RepliGen Europe Limited withdraws its marketing authorisation application for SecreFlo (secretin human)

The European Medicines Agency has been formally notified by RepliGen Europe Limited of its decision to withdraw its application for a centralised marketing authorisation for the medicine SecreFlo (secretin human), powder for solution for injection. SecreFlo was intended to be used with magnetic resonance imaging (MRI) to improve pancreatic duct visualization for the detection of duct abnormalities to enhance clinical decision making in adults with known or suspected pancreatitis.

The application for the marketing authorisation for SecreFlo was submitted to the Agency on 2 February 2012. At the time of the withdrawal it was under review by the Agency's Committee for Medicinal Products for Human Use (CHMP).

In its withdrawal letter, the company stated that they have decided to withdraw the application since the major objections raised by the Committee cannot be answered in the available timeframe.

More information about SecreFlo 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 17-20 September 2012.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. Withdrawal of an application does not prejudice the possibility of a company making a new application at a later stage.
3. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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