



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Questions and answers

Withdrawal of the marketing authorisation application for SecreFlo (secretin human)

On 15 August 2012, Repligen Europe Limited officially notified the Committee for Medicinal Products for Human Use (CHMP) that it wishes to withdraw its application for a marketing authorisation for SecreFlo, intended for use in the detection of duct abnormalities in the pancreas.

What is SecreFlo?

SecreFlo is a medicine that contains the active substance secretin human. It was to be available as a solution for injection.

What was SecreFlo expected to be used for?

SecreFlo was expected to be used in patients undergoing magnetic resonance imaging (MRI, a type of scan where images of the internal organs are taken) to obtain a clearer image of their pancreas. It was to be used in patients with known or suspected pancreatitis (inflammation of the pancreas) so that abnormalities in the small ducts within the pancreas can be seen more clearly.

Being able to see abnormalities in the pancreatic ducts is important for making decisions on how to treat these patients.

How is SecreFlo expected to work?

The active substance in SecreFlo is a copy of human secretin, a natural hormone that stimulates the pancreas to secrete fluids into the small intestine. The medicine's use in visualising the pancreatic ducts is based on its action of stimulating fluid secretion, which causes the ducts in the pancreas to widen significantly and therefore appear more clearly in a scan.

SecreFlo was to be injected into a patient's vein just before undergoing a MRI scan.

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What did the company present to support its application?

The company presented data from one main study, which involved 270 patients with a history of acute pancreatitis who had MRI scans with or without previous SecreFlo injections. Images from the scans were read by expert radiologists without prior knowledge of the patients' condition and the results were compared with what was already known from other tests.

The main measures of effectiveness were based on the sensitivity of the scans (how well they detected abnormalities in the ducts) and their specificity (how well normal ducts were identified as normal).

How far into the evaluation was the application when it was withdrawn?

The application was withdrawn at 'day 120'. This means that the CHMP had evaluated the initial documentation provided by the company and formulated a list of questions. The company had not yet responded to the questions at the time of the withdrawal.

What was the recommendation of the CHMP at that time?

At the time of the withdrawal, the CHMP had some concerns and was of the provisional opinion that SecreFlo could not have been approved.

The Committee was concerned that there may not have been adequate safeguards to ensure that the final readings of the scans were not biased. The scans had had to be read a second time after initial readings were deemed unreliable.

Another concern was the fact that patients in the study (patients with a history of acute pancreatitis) were not representative of patients for whom the medicine was intended (patients with known or suspected pancreatitis). The CHMP also noted that the clinical relevance of the study results was unclear.

What were the reasons given by the company for withdrawing the application?

In its letter notifying the Agency of the withdrawal of application, the company stated that the withdrawal was based on the fact that the concerns raised by the CHMP could not be addressed in the available timeframe.

The withdrawal letter is available [here](#).

What consequences does this withdrawal have for patients in clinical trials?

The company informed the CHMP that there were no ongoing clinical trials with SecreFlo at the time of the withdrawal.