EUROPEAN MEDICINES AGENCY
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Questions and answers

Withdrawal of the marketing authorisation application for VeraSeal (human fibrinogen / human thrombin)

On 29 September 2015, Instituto Grifols S.A. officially notified the Committee for Medicinal Products for Human Use (CHMP) that it wishes to withdraw its application for marketing authorisation of VeraSeal, which was intended to help stop bleeding during vascular (blood vessel) surgery when standard surgical methods for controlling bleeding are insufficient.

What is VeraSeal?

VeraSeal is a medicine that contains the active substances human fibrinogen and human thrombin. It was to be available as two separate solutions that are mixed together to prepare a sealant that is applied to the surface of blood vessels.

What was VeraSeal expected to be used for?

VeraSeal was expected to be used to help stop bleeding during vascular surgery when standard surgical methods for controlling bleeding are insufficient.

How is VeraSeal expected to work?

The active substances in VeraSeal, human fibrinogen and human thrombin, are natural proteins in the blood and are obtained from blood donors. When applied to a moist surface, the thrombin is activated and cuts fibrinogen up into smaller units called fibrin. The fibrin then aggregates (sticks together) and forms fibrin clots on the surface of blood vessels. This helps prevent bleeding and seals the blood vessels.

What did the company present to support its application?

The applicant presented data from one main study involving 167 patients who underwent vascular surgery. In this study, bleeding during surgery was managed either by applying VeraSeal or by

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applying manual pressure (a standard way of stopping bleeding during surgery). The main measure of effectiveness was the ability to stop bleeding during a 10-minute observation period, after applying the method to stop the bleeding.

How far into the evaluation was the application when it was withdrawn?

The application was withdrawn after the CHMP had evaluated the documentation provided by the company and formulated lists of questions. After the CHMP had assessed the company's responses to the last round of questions, there were still some unresolved issues.

What was the recommendation of the CHMP at that time?

Based on the review of the data and the company's response to the CHMP lists of questions, at the time of the withdrawal the CHMP had concerns and was of the provisional opinion that VeraSeal could not have been approved to help stop bleeding during vascular surgery.

The Committee was concerned that the main study had not been carried out in accordance with the guidelines for Good Clinical Practice (GCP). Findings from a GCP inspection of the study sites raised serious questions about the data from the main study submitted in support of the application. Therefore, at the time of the withdrawal, the CHMP was of the opinion that the company had not provided enough data to support the application for VeraSeal.

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

In its letter notifying the Agency of the withdrawal of the applications, the company stated that the withdrawal was due to not being able to gather the additional data required by the CHMP, including data from three ongoing clinical studies with the product, within the available timeframe.

The withdrawal letter is available here.

What consequences does this withdrawal have for patients in clinical trials or compassionate use programmes?

The company informed the CHMP that there are currently no ongoing compassionate use programmes for VeraSeal. There are no consequences for patients in the three ongoing clinical trials. If you are in a clinical trial and need more information about your treatment, contact the doctor who is giving it to you.