

Current Trasylol® (aprotinin injection) News

Bayer has acknowledged that it mistakenly did not inform the U.S. Food and Drug Administration prior to a recent FDA Advisory Committee meeting about a retrospective observational study commissioned by the company to analyze the effects of aprotinin, aminocaproic acid and tranexamic acid in patients undergoing coronary artery bypass graft (CABG) surgery. This data was not shared immediately with the agency because it was preliminary in nature and raised significant questions on the study population, outcomes and methodology.

Bayer believes that despite the highly preliminary nature of this data, the information should have been shared with the FDA prior to the September 21st Advisory Committee meeting held to assess the safety and efficacy of Trasylol® (aprotinin injection). This was a mistake on the company's part. Bayer has since submitted a copy of the preliminary report to the FDA and has notified other regulatory authorities.

At this time, only preliminary results are available and clarifications and additional analysis of the data need to be made. Bayer is in close contact with the study author and the regulatory authorities. While we are moving swiftly, until such time as a thorough analysis and review of the data can be undertaken, final conclusions regarding the study can not be drawn.

As an observational study, patients were not assigned at random to receive various treatments, but rather had their treatment chosen by their physician as part of their standard medical care. Consequently patients receiving Trasylol may have had a higher chance of serious complications to begin with as compared to patients receiving no treatment or treatment with another drug intended to decrease bleeding. This possibility complicates the assessment of whether the available data show that Trasylol treatment, rather than other factors, increased the chance for serious kidney or heart complications.

Bayer is committed to patient safety. The company will continue to work closely with the FDA to address questions regarding this study and the overall safety and efficacy of Trasylol.

Links to Related FDA Communications

- [September 29, 2006 FDA Statement](#)
- [February 8, 2006 FDA Public Health Advisory](#)