European Medicines Agency
Press office

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PRESS RELEASE
European Medicines Agency recommends suspension of marketing authorisation of aprotinin-containing medicines for systemic use

The European Medicines Agency (EMEA) has recommended the suspension of the marketing authorisations of all medicinal products for systemic use containing aprotinin. Aprotinin is used to reduce blood loss and the need for blood transfusion in patients undergoing cardiopulmonary bypass in the course of coronary artery bypass graft surgery.

Following a review during its November 2007 meeting, the Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that the risks of these medicines are greater than their benefits, and that the marketing authorisations should be suspended in the Member States where the products are approved.

The CHMP recommendation follows the suspension of the aprotinin-containing medicines for systemic use in Germany on 5 November 2007. The German National Competent Authority based its decision on newly available interim results from the BART clinical trial, showing increased mortality for patients receiving aprotinin. The study was stopped and the German manufacturer, Bayer, subsequently decided to suspend the worldwide marketing of its aprotinin-containing medicinal products, Trasylol and Trasynin.

The CHMP looked at the preliminary results from the BART study as well as at the results of a number of safety observational studies. The Committee concluded that the risks of aprotinin-containing medicinal medicines for systemic use outweigh their benefits.

The CHMP also recommended that an Article 31 referral be triggered to carry out a full re-evaluation of the benefit-risk balance of aprotinin-containing products taking into account the final results of the BART study.

The CHMP opinion will now be sent to the European Commission for the adoption of a decision, applicable in all EU markets.

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Notes:
1. More information about the review is available in a separate question-and-answer-document.
2. Aprotinin-containing medicinal products are available in Europe in Austria, Belgium, Bulgaria, the Czech Republic, Cyprus, Germany, Denmark, Greece, Estonia, Finland, France, Hungary, Lithuania, Luxembourg, Latvia, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia and Sweden, under the trade names Acset, Antagosan, Antilysin Spofa, Gordox, Pantinol, Traskolan, Trasylol and Trasynin.
3. The review of aprotinin was conducted under Article 107 of the Community code relating to medicinal products for human use (Directive 2001/83/EC). This type of procedure is initiated in cases where a Member State withdraws, suspends or changes the marketing authorisation of a nationally authorised medicine as a result of the evaluation of safety data. It provides for a

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harmonised European approach because the CHMP is asked to prepare an opinion on whether or not regulatory action should be implemented throughout the European Union.

4. An article 31 referral may be initiated in specific cases where the interest of the Community is involved. The expression 'Community interest' has a broad meaning but it refers particularly to the interests of the public health in the Community, for example following concerns related to the quality, efficacy and/or safety of a medicinal product or new pharmacovigilance information.

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