Malta, 22 November 2007

Circular No. P19/2007

Dear Healthcare Professional,

Re: Suspension of the Marketing Authorisation of Aprotinin-containing medicines for systemic use

Following the recent suspension of aprotinin-containing medicines for systemic use in Germany on 5 November 2007 as a result on newly available interim results from the BART clinical trial showing increased mortality for patients receiving aprotinin, the European Medicines Agency (EMEA) has concluded that the risks of these medicines are greater than their benefits and has recommended the suspension of their marketing authorizations. The only aprotinin-containing medicine was systemic use currently licensed for marketing in Malta is Trasylol®. The Medicines Authority has participated in these discussions held at the EMEA and is in agreement with the actions described in the attached **press release** and **Q & A document** issued by the EMEA. The Medicines Authority will notify healthcare providers and patients in a timely fashion of the outcome of the Article 31 referral that has now been triggered off 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.

Medicines Authority
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