

From the Chief Medical Officer  
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Department of  
**Health, Social Services  
and Public Safety**

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AN ROINN

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**HSS(MD)28/2007**

To: Medical Directors of HSC Trusts  
*for cascade to clinical directors, surgeons  
& anaesthetists*  
Directors of Public Health HSS Boards

Your Ref:  
Our Ref: HSS(MD)28/2007  
Date: 6 November 2007

Dear Colleague

## **APROTININ - SUSPENSION OF MARKETING DUE TO SAFETY CONCERNS**

Please see the attached communication from Professor Gordon Duff, Chairman, Commission on Human Medicines regarding the use of Aprotinin in the prevention of major blood loss during coronary artery bypass graft surgery in patients at high risk of bleeding. A clinical trial (the BART trial) has been terminated as data suggest that Aprotinin may be associated with an increased risk of death compared with tranexamic acid and aminocaproic acid. Marketing of Aprotinin has therefore been suspended as a precautionary decision until full trial data are available.

In particular, please note the following:

### **New advice on practice**

**Aprotinin should only be used after careful consideration in individual cases where, for example, the risk of blood loss during surgery is considered to be particularly high (e.g. redo CABG surgery), where there is no suitable alternative, and only when the likely benefits outweigh any risks to individual patients.**

A full regulatory review of the balance of risks and benefits of aprotinin is underway. The outcome of this depends on availability of data from the BART study and this may take at least 3 months. The Commission on Human Medicines (CHM) will be considering the current position at its meeting this week.

Any further advice will be issued as soon as available. For further information please contact the Medicines and Healthcare products Regulatory Agency (MHRA) at 020 7084 2000 ([www.mhra.gov.uk](http://www.mhra.gov.uk))

