

**Alteplase (Actilyse<sup>®</sup>)**

**No. 87/04**

**Boehringer Ingelheim**

*New indication: Treatment of acute ischaemic stroke.*

## **Summary of Recommendation**

8 February, 2004

The Scottish Medicines Consortium (SMC) has completed its assessment of the above product and advises NHS Boards and ADTCs on its use in NHS Scotland. The recommendation is summarised as follows:

**Advice:** following a full submission

Alteplase (rt-PA) (Actilyse) is accepted for restricted use within NHS Scotland for the treatment of acute ischaemic stroke.

Alteplase is licensed in the UK for the early treatment of acute ischaemic stroke, but there are potentially fatal risks incurred in using this treatment. The use of alteplase is therefore confined to specialist centres with adequate resources and appropriate expertise. It is associated with an increased risk of intracerebral haemorrhage including fatal haemorrhage and must be used strictly in accordance with detailed protocols specifying the availability of appropriate expertise and resources, including computerised tomography or magnetic resonance imaging in order to exclude haemorrhagic stroke. Treatment centres must participate in the post-marketing surveillance study SITS-MOST (Safe Implementation of Thrombolysis in Stroke Monitoring Study) designed to determine whether alteplase is as safe and beneficial in routine clinical practice as has been shown in the clinical trial setting.

Further details of SITS-MOST are available from [www.acutestroke.org](http://www.acutestroke.org)

**Professor David H Lawson**  
**Chairman**