

eplerenone (Inspra)

(No: 136/04)

Pfizer Limited

Summary of Advice

13 December 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 advice is summarised as follows:

Advice: following a full submission.

Eplerenone (Inspra[®]) is accepted for restricted use within NHS Scotland in addition to standard therapy, to reduce the risk of cardiovascular mortality and morbidity after recent myocardial infarction (MI) in stable patients with left ventricular dysfunction (left ventricular ejection fraction $\leq 40\%$) and clinical evidence of heart failure

Its use should be restricted to patients who cannot tolerate spironolactone due to sex hormone mediated adverse effects. Eplerenone is the second aldosterone antagonist marketed in the UK. It reduces all-cause mortality and cardiovascular-related mortality and hospitalisation in patients with heart failure post-MI. However, there are no data on its clinical and cost effectiveness in this population compared to the other aldosterone antagonist marketed in the UK, which also reduces mortality and morbidity in patients with heart failure and is considerably cheaper.

The licence holder has indicated their decision to resubmit.

Professor David H Lawson
Chairman