

Statement of Advice:

**decitabine (Dacogen®) 50 mg powder for concentrate for solution
for infusion (No: 846/12)**

Janssen-Cilag Ltd

07 December 2012

ADVICE: in the absence of a submission from the holder of the marketing authorisation

decitabine (Dacogen®) is not recommended for use within NHS Scotland.

Indication under review: Treatment of adult patients aged 65 years and above with newly diagnosed de novo or secondary acute myeloid leukaemia (AML), according to the World Health Organisation (WHO) classification, who are not candidates for standard induction chemotherapy.

The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.

Advice context:

No part of this advice may be used without the whole of the advice being quoted in full.

This advice represents the view of the Scottish Medicines Consortium. It is provided to inform the considerations of Area Drug & Therapeutics Committees and NHS Boards in Scotland in determining medicines for local use or local formulary inclusion. This advice does not override the individual responsibility of health professionals to make decisions in the exercise of their clinical judgement in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

**Chairman,
Scottish Medicines Consortium**