Statement of Advice

cannabinoid oromucosal spray (Sativex ®) (No: 703/11)
Bayer plc.

4 March 2011

ADVICE: in the absence of a submission from the holder of the marketing authorisation
cannabinoid oromucosal spray (Sativex ®) is not recommended for use within NHS Scotland.

Indication under review: as an add-on treatment for symptom improvement in patients
with moderate to severe spasticity due to multiple sclerosis (MS) who have not responded
adequately to other anti-spasticity medication and who demonstrate clinically significant
improvement in spasticity related symptoms during an initial trial of therapy.

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

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