



## **Fentanyl citrate (Breakyl<sup>®</sup>)**

**for the management of breakthrough pain in opioid  
tolerant adult patients with cancer**

**Meda Pharmaceuticals Ltd**

**September 2011**

### **Statement of Advice**

**ADVICE:** in the absence of a submission from the holder of the marketing authorisation, fentanyl citrate (Breakyl<sup>®</sup>) cannot be endorsed for use within NHS Wales for the management of breakthrough pain in opioid tolerant adult patients with cancer.

#### **Advice context:**

The All Wales Medicines Strategy Group (AWMSG) takes into account the National Institute for Health and Clinical Excellence (NICE) future work programme when considering whether a product will be appraised. To avoid duplication of effort, AWMSG would not normally consider undertaking an appraisal if NICE intend to publish final advice for the same product within twelve months of the projected Form B submission date. AWMSG advice is interim to that of NICE, should NICE subsequently publish guidance.

The above medicine cannot be endorsed for use within NHS Wales as an appraisal by NICE or AWMSG has not been undertaken. The medicine should NOT be prescribed routinely within NHS Wales for the indication stated above.

In the absence of guidance issued by NICE or AWMSG, clinicians should continue to exercise their clinical judgement when providing care for an individual patient. This should be in consultation with the patient and/or guardian or carer, based on the best available evidence.

This statement will be removed on receipt of a submission (i.e. the full submission [Forms A and B] or limited submission [Forms A and C]) or when final NICE guidance becomes available.