

## Notice Information: - 3rd Party Publications 14 June 2013

### Part 1. Product Information

- a) Title: PRAC recommends restricting the use of codeine when used for pain relief in children
- b) Product Name/Type: Codeine-containing medicines when used for the management of pain in children

### Part 2. Problem/Issue

- a) Problem/Issue:
- The European Medicines Agency's Pharmacovigilance Risk Assessment Committee ( PRAC ) has recommended a series of measures to address safety concerns with codeine-containing medicines when used for the management of pain in children. This follows the PRAC's review of reports of children who developed serious adverse effects or died after taking codeine for pain relief. Most of the cases occurred after surgical removal of the tonsils or adenoids for obstructive sleep apnoea (frequent interruption of breathing during sleep).
- The PRAC recommendation will now be considered by the Coordination Group for Mutual Recognition and Decentralised Procedures - Human (CMDh) at its meeting on 24-26 June 2013.
- Patients who have any questions should speak to their doctor or pharmacist.

### Part 3. Enquiries

- a) All enquiries should be made to: For full EMA statement please refer to link below:
- PRAC recommends restricting the use of codeine when used for pain relief in children