

## **Press release of EMA in English**

### **PRAC recommends restrictions on the use of codeine for cough and cold in children**

EMA's Pharmacovigilance Risk Assessment Committee (PRAC) has recommended restrictions on the use of codeine-containing medicines for cough and cold in children because of the risk of serious side effects with these medicines, including the risk of breathing problems.

The PRAC recommended specifically that:

- Codeine should be contraindicated in children below 12 years. This means it must not be used in this patient group.
- Use of codeine for cough and cold is not recommended in children and adolescents between 12 and 18 years who have problems with breathing.
- All liquid codeine medicines should be available in child-resistant containers to avoid accidental ingestion.

The effects of codeine are due to its conversion into morphine in the body. Some people convert codeine to morphine at a faster rate than normal, resulting in high levels of morphine in their blood. High levels of morphine can lead to serious effects, such as breathing difficulties.

Read more on the following hyperlink:

[http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Codeine\\_containing\\_medicinal\\_products\\_for\\_the\\_treatment\\_of\\_cough\\_and\\_cold\\_in\\_paediatric\\_patients/human\\_referral\\_prac\\_000039.jsp&mid=WC0b01ac05805c516f](http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Codeine_containing_medicinal_products_for_the_treatment_of_cough_and_cold_in_paediatric_patients/human_referral_prac_000039.jsp&mid=WC0b01ac05805c516f)