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Dear Healthcare Professional,

**RESTRICTIONS ON THE USE OF CODEINE AS AN ANALGESIC IN CHILDREN
AND ADOLESCENTS**

The National Pharmacovigilance Centre at the Food and Drugs Authority (FDA) is writing to inform healthcare professionals about restrictions on the use of codeine in the following:

- Analgesia in children and adolescents.
- Cough medication in children less than 12 years.
- Breastfeeding women.

This follows a review of safety information regarding the use of codeine as analgesia in certain children and adolescents after tonsillectomy and/or adenoidectomy (surgery to remove the tonsils and/or adenoids) by the US Food and Drugs Administration and Pharmacovigilance Risk Assessment Committee (PRAC) of the European Medicines Agency (EMA). The agencies investigated reports of serious and fatal respiratory depression in children after taking codeine for pain relief which occurred after surgical removal of tonsils or adenoids for obstructive sleep apnoea. Some of the children who experienced these reactions showed evidence of being “ultra rapid metabolizers” of codeine which led to high levels of morphine in the blood that caused toxic effects such as respiratory depression. Codeine is converted into morphine (which is responsible for its pharmacological effects) by the cytochrome P450 enzyme CYP2D6.

The decision by the US FDA and PRAC were presented to the FDA’s Technical Advisory Committee for Safety and the Committee has recommended the following risk minimization measures to ensure that only children for whom the benefits outweighs the risks are given codeine:

- 1. Use of codeine is contraindicated in patients younger than 18 years of age for pain relief following tonsillectomy and/or adenoidectomy for Obstructive Sleep Apnoea Syndrome (OSAS) and in those known to be CYP2D6 ultra-rapid metabolisers.**

2. Codeine-containing medicines should only be used to treat acute moderate pain in children above 12 years of age, and only if it cannot be relieved by other pain killers such as paracetamol and ibuprofen.
3. Cough medications containing codeine are no longer recommended for use in children less than 12 years of age.
4. The use of codeine is contraindicated in breastfeeding women due to an increased risk for the child if the mother is an ultra-rapid metaboliser.
5. Information should be given to parents and caregivers on how to recognise the signs of morphine toxicity, and advice should be given to stop giving the child codeine and to seek medical attention immediately if their child is showing these signs or symptoms.
6. Symptoms of codeine toxicity include: reduced levels of consciousness; lack of appetite; somnolence; constipation; respiratory depression; ‘pin-point’ pupils; or nausea and vomiting

The Food and Drugs Authority has not received any reports of serious and fatal respiratory depression in children taking codeine for pain relief or any other indication. Healthcare professionals are therefore encouraged to report any adverse drug reactions to the National Pharmacovigilance Centre, Food and Drugs Authority by completing the “**Blue Form**” or call **024 431 0297** or send e-mail to drug.safety@fdaghana.gov.gh.

For further enquiries contact the National Pharmacovigilance Centre, FDA through the following address:

Postal address: The Chief Executive
Food and Drugs Authority
P. O. Box CT2783
Cantonments
Accra.

Telephone: 024 431 0297 / 0302 233200
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Yours faithfully,

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CHIEF EXECUTIVE