



Food and Drugs Authority

Head Office
P. O. Box CT 2783,
Cantonments, Accra-Ghana
Tel: (+233-302)233200, 235100
Fax: (+233-302)229794, 225502
Email: fda@fdaghana.govgh

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Dear Healthcare Professional,

SUSPENSION OF MARKETING AUTHORIZATION FOR CODEINE-CONTAINING COUGH SYRUPS

In accordance with the recommendation by the Technical Advisory Committee on Safety of Medicines (TAC-SM), the Governing Board of the Food and Drugs Authority (FDA) and subsequent directive by the Hon. Minister of Health; the FDA has with immediate effect suspend the registration, importation and the manufacture of codeine-containing cough syrups (CCS).

This decision was arrived at following reports of widespread abuse of CCS and based on the underlisted reasons:

1. Codeine has no greater antitussive (cough suppressant) activity compared with dextromethorphan.
2. Dextromethorphan, the alternative ingredient listed in the Standard Treatment Guidelines of Ghana (7th Edition, 2017), exhibits similar antitussive (cough suppressant) activity compared with codeine but has a lower addictive potential.
3. Codeine has a much greater side effect profile compared to dextromethorphan.
4. There are a number of products both locally manufactured and imported containing dextromethorphan registered by the FDA which could be used in place of CCS.

As an alternative for codeine, the FDA has registered a number of products containing dextromethorphan which are recommended for the management of symptoms of dry cough in adults.

The FDA will like to advice healthcare professionals to educate patients on the possible side effect of all medicines and also report these to the FDA by completing the Adverse Reaction Reporting Form or online using the link <http://adr.fdaghana.gov.gh/> or call 024 431 0297 or send an email to drug.safety@fdaghana.gov.gh.

Yours faithfully,

Signed

DELESE A. A. DARKO (MRS)
CHIEF EXECUTIVE OFFICER