



Food and Drugs Authority

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FDA/SMC/SMD/VGU/18/0395

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Dear Healthcare Professional,

FOLLOW-UP: SUSPENSION OF MARKETING AUTHORIZATION FOR CODEINE-CONTAINING COUGH SYRUPS

This is a follow up to the Food and Drugs Authority's Dear Healthcare Professional (DHCP) letter reference number FDA/SMC/SMD/VGU/18/0293 and dated 17th July 2018¹ regarding the suspension of marketing authorization for codeine-containing cough syrups.

The FDA wishes to inform you that the Hon. Minister of Health on 22nd August 2018 issued an Executive Instrument, E.I 167 on the suspension, registration, importation and the manufacture of codeine- containing cough syrups. The E.I can be accessed on the FDA website on the link below:

<https://fdaghana.gov.gh/images/stories/pdfs/News%20&%20Events/EXECUTIVE%20INSTRUMENT%20167.pdf>

In view of this suspension the FDA has taken stock of available CCS up to manufacturing and warehouse levels and monitoring the use of the product.

The FDA has given a phase-out period for the use of the current stock and the underlisted should be strictly adhered to during the period.

- CCS should be prescribed only when necessary.
- CCS should be dispensed only on valid prescription and record of the prescription kept at the pharmacy.

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.

¹ <https://fdaghana.gov.gh/images/stories/pdfs/Dear%20Helthcare%20Prof/2018/18-293-SUSPENSION%20OF%20MAH%20FOR%20CCCS-SIGNED0001.pdf>

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,

Singed

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