EXECUTIVE INSTRUMENT

E. I. 167

INSTRUCTIONS FOR THE RESTRICTION OF IMPORTATION, MANUFACTURE AND REGISTRATION OF CODEINE-CONTAINING COUGH SYRUPS INSTRUMENT, 2018

WHEREAS the Republic of Ghana subscribes to the World Health Organisation objective of attainment by all people of the highest possible level of physical, mental and social well-being and not merely the absence of disease or infirmity;

WHEREAS the Food and Drugs Authority convened an emergency meeting of the Ministry of Health Standing Technical Advisory Committee on Safety of Medicines with consumer representatives and the media, which discussed issues relating to the abuse of Tramadol and codeine-containing cough syrups, and proposed measures to combat the menace;

WHEREAS the Committee reviewed the available data and discussed the subject extensively in respect of the magnitude of the problem; the registration status and classification; the indications for use by the Ministry of Health; the importation and supply chain; the distribution channel; stakeholder engagement; rehabilitation and other drugs or substances of abuse and made recommendations;

WHEREAS the Minister for Health is satisfied with the work of the Committee and finds the recommendations made acceptable;

WHEREAS a press statement has been issued due to the security threats that the effects of the misuse of these opioids posed to the public;

WHEREAS the Minister for Health is further satisfied that restrictions imposed on the importation, manufacture and registration of codeine-containing cough syrups will not affect health outcomes adversely in the Republic of Ghana since the alternative ingredients and strengths listed in the Standard Treatment Guidelines of the Republic of Ghana (7th Edition, 2017) exhibit similar activities compared with the restricted ingredient, but have a lower potential for addiction; and

WHEREAS the Ministry of Health is committed to providing information to healthcare professionals and the general public about the restriction of the importation, manufacture and registration of codeine-containing cough syrups and to indicating available alternatives registered for use in the Republic of Ghana;

NOW THEREFORE, in exercise of the power conferred on the Minister for Health by section 116 of the Public Health Act, 2012 (Act 851) this Instrument is made this 22nd day of August, 2018.

Ban of codeine-containing cough syrups

1. (1) All registration and market authorisation covering codeine-containing cough syrups, including Diphex with codeine cough syrup, Benylin with codeine cough syrup and Actifed dry cough and cold syrup, is revoked.

(2) A person shall not manufacture, import or offer for sale codeine-containing cough syrups, including Diphex with codeine cough syrup, Benylin with codeine cough syrup and Actifed dry cough and cold syrup.

(3) There shall not be a renewal of registration for Diphex with codeine cough syrup, Benylin with codeine cough syrup and Actifed dry cough and cold syrup.

(4) An application for the registration of Diphex with codeine cough syrup, Benylin with codeine cough syrup and Actifed dry cough and cold syrup, pending with the Food and Drugs Authority before the coming into force of this Executive Instrument, shall not be processed and market authorisation shall not be issued in respect of the application.

(5) All other approved dosage forms and strengths of codeine registered by the Food and Drugs Authority for other indications in adults and children shall be re-classified as "Controlled Drugs" and dispensed only upon proof of a valid prescription and a record of prescriptions kept.

(6) All other approved dosage forms and strengths of codeine registered by the Food and Drugs Authority for distribution, dispensing and use shall be re-classified as "Prescription Only Medicines" and maintained as such.

HON. KWAKU AGYEMAN-MANU (MP)
Minister for Health

Date of *Gazette* notification: 26th September, 2018.