EXECUTIVE INSTRUMENT

E. I. 168

INSTRUCTIONS FOR THE CONTROL OF THE IMPORTATION, MANUFACTURE AND SALE OF TRAMADOL AND TRAMADOL-CONTAINING PRODUCTS 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 the control of the importation, manufacture and sale of Tramadol and Tramadol-containing products 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 controlled 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 control of the importation, manufacture and sale of Tramadol and Tramadol-containing products 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.

Control of manufacture, importation and sale of Tramadol and Tramadol-containing products

1. (1) A person shall not manufacture, import or offer for sale Tramadol or a Tramadol-containing product with a dosage form and strength above that which is registered by the Food and Drugs Authority.

(2) Subparagraph (1) does not apply to

(a) Tramadol tablets, capsules and injectables with 50mg and 100mg and 50mg/1 ml to 2ml dosage and strength;

(b) fixed-dose combination products containing 37.5mg or 50mg of Tramadol; and

(c) 325mg or 500mg of paracetamol.

(3) All dosage forms and strengths of registered Tramadol and Tramadol-containing products shall be dispensed as "Prescription Only Medicines".

(4) All dosage forms and strengths of registered Tramadol and Tramadol-containing products shall not be prescribed and dispensed at health facilities below the level of District Hospitals.

(5) Despite subparagraph (1), the Food and Drugs Authority may register Tramadol and Tramadol-containing products with higher dosage forms where the Minister is satisfied that the Tramadol and Tramadol-containing products will address and improve the health needs of the country.

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

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