



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.gov.gh

FDA/CPE/PRE/18/0010

17th September 2018

The News Editor

Dear Sir/Madam

PUBLIC ALERT – PRODUCT RECALL

HYDROCORTISONE INJECTION B.P. 100MG

The Food and Drugs Authority wishes to alert all health care professionals and consumers, not to distribute, supply, use or purchase any Hydrocortisone Injection B.P 100mg labelled as follows:

Product name: Hydrocortisone Sodium Succinate Injection B.P 100mg
Batch number: 5AE01007
Expiry Date: 09/2018
Manufacturer: Ambica Pharma Sales, India.

FDA laboratory analysis of the product found that there was a lack of **uniformity of content and related concerns, which makes it unfit and unsafe for purpose.**

The Authority has commenced the process of immediate withdrawal of the product from health facilities and pharmaceutical suppliers that may have stocks, and hereby directs all such facilities to immediately check their medical supplies, quarantine any affected product, labelled as above, and return them to the suppliers or the Food and Drugs Authority.

The FDA assures the general public that it will continue to do all within its mandate to ensure the safety and efficacy of all products found in the Ghanaian market.

Health care professionals and suppliers of pharmaceutical products are encouraged to obtain any medications they administer or provide to consumers/the general public, from reliable sources that adhere to proper quality standards.

The FDA urges the general public and health care professionals to report all adverse reactions, quality problems or any practice suspected to be against public health and safety to any of the following contacts:

Hotlines: 0299802932, 0299802933.

 0206973065  fdaghana  Food and Drugs Authority, Ghana

 www.fdaghana.gov.gh

Signed

DELESE A. A. DARKO (MRS)

Chief Executive Officer