

DR. STEPHEN K. OPUNI

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Dear Healthcare Professional,

**REPORTING INCIDENTS OF THERAPEUTIC INEFFECTIVENESS AS ADVERSE EVENTS**

The Food and Drugs Authority (FDA) has since January 2012 received reports of **therapeutic ineffectiveness** some of which have resulted in fatal outcomes. However, reports have indicated that there are increasing numbers of similar cases that are not reported by healthcare professionals to the FDA.

Investigations into the reports received by the FDA revealed that some of the products:

1. Contain impurities at levels higher than Pharmacopeia standards.
2. Contain no Active Pharmaceutical Ingredient (API) or lower levels of API than the Pharmacopeia standards.
3. Are not registered by the Food and Drugs Authority

The FDA will like to encourage all healthcare professionals to closely monitor patients under their care and report any suspected incidents of therapeutic failure to the FDA using the Adverse Reaction reporting form.

The World Health Organization Programme for International Monitoring has noted that therapeutic ineffectiveness is an important reportable adverse event in pharmacovigilance.

All adverse drug reactions including therapeutic ineffectiveness should be reported to the National Pharmacovigilance Centre, FDA or through the Institutional Contact Person(s) in your facilities.

The National Pharmacovigilance Centre can be contacted on mobile: **024 4310 297** or e-mail: [drug.safety@fdaghana.gov.gh](mailto:drug.safety@fdaghana.gov.gh).

You may also download the Adverse Drug Reaction reporting form on the FDA website, [www.fdaghana.gov.gh](http://www.fdaghana.gov.gh).

For further enquiries, complaints and reports of adverse reaction to any other medicinal product, contact the FDA through the following address.

**Postal address:** The Chief Executive  
Food and Drugs Authority  
P. O. Box CT2783  
Cantonments, Accra

**Telephone:** 0302 235100 / 0302 233200  
**Mobile:** 0244 310 297  
**Fax:** 0302 229794

Yours faithfully,

**DR. STEPHEN K. OPUNI**  
**CHIEF EXECUTIVE**