DR. STEPHEN K. OPUNI

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Dear Healthcare Professional,

DICLOFENAC AND RISK OF CARDIOVASCULAR EVENTS (HEART ATTACK AND STROKE)

The National Pharmacovigilance Centre at the Food and Drugs Authority (FDA) is writing to inform healthcare professionals that a recent publication[1] has suggested an increased risk of cardiovascular events such as heart attack and stroke with the use of Diclofenac; these events are similar to those elicited by COX-2 inhibitors. This applies particularly when Diclofenac is given systemically (by means such as capsules, tablets and injections) at a **high dose (150 mg daily)** and for **long-term treatment**.

The FDA's Technical Advisory Committee on Safety has reviewed the publication in the Lancet and actions by other regulatory authorities. The Committee concluded that although the benefits of Diclofenac still outweigh the risks, the following cautions should be taken by healthcare professionals when prescribing and dispensing systemic Diclofenac preparations:

1. **Give the lowest effective dose and for the shortest period of time to minimize the risks of arterial thromboembolic events (blood clots in the arteries).**
2. **Carefully consider patients with underlying medical conditions that will increase the risk of these events (hypertension, hyperlipidaemia, diabetes, ischaemic heart disease and smoking)**
3. **Avoid in patients with serious underlying heart or circulatory conditions, such as heart failure, heart disease, circulatory** problems or a previous heart attack or stroke.

[1] http://dx.doi.org/10.1016/S0140-6736(13)60900-9

The Food and Drugs Authority has registered Diclofenac under different brand names (refer to the registered product list on the Food and Drugs Authority's website at: http://www.fdaghana.gov.gh/pdfs/Quick%20links/DRUG%20REGISTER%20MARCH%2021%202011.pdf

Diclofenac is indicated for pain and inflammation in rheumatic disease (including juvenile idiopathic arthritis) and other musculoskeletal disorders; acute gout and postoperative pain and registered with the following category of distribution: 25mg as over-the-counter; 50mg as pharmacist initiated and 100mg as prescription only medicine. These should therefore be taken into account when prescribing and dispensing this product.

The Food and Drugs Authority has not received any report relating to cardiovascular events (heart attack and stroke) to the use of Diclofenac. Healthcare professionals, however, are encouraged to report any adverse drug reactions to Diclofenac and any other medication to the National Pharmacovigilance Centre, Food and Drugs Authority by completing the blue adverse reaction reporting form or call **024 431 0297** or send e-mail to, **drug.safety@fdaghana.gov.gh**.

For further enquiries 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
Fax: 0302 229794

Yours faithfully,

DR. STEPHEN K. OPUNI
CHIEF EXECUTIVE