

DR. STEPHEN K. OPUNI

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Dear Healthcare Professional,

**PARACETAMOL AND THE RISK OF RARE BUT SERIOUS SKIN REACTIONS**

The National Pharmacovigilance Centre at the Food and Drugs Authority (FDA) is writing to inform healthcare professionals of rare but serious skin reactions associated with the use of paracetamol-containing products. These skin reactions, known as Stevens - Johnson Syndrome (SJS), toxic epidermal necrolysis (TEN), and acute generalized exanthematous pustulosis (AGEP), can be fatal. This follows a review by the United States Food and Drugs Administration (US FDA).

Four such cases have been reported to the National Database and the FDA's Technical Advisory Committee for Safety (TAC) evaluated this information together with the information available from the US FDA and the literature. The TAC concluded that there is a link between these severe reactions and paracetamol-containing products and has therefore cautioned healthcare professionals should be aware of the risk and consider paracetamol along with other drugs already known to have these reactions, when assessing patients with potentially drug-induced skin reactions.

Healthcare professionals should, therefore, inform patients about the following:

- Patients who develop a skin rash or reaction while using paracetamol and paracetamol-containing products should stop the drug immediately and seek medical attention.
- Anyone who has previously experienced a serious skin reaction with paracetamol-containing products should not take the drug again and should contact their health care professional to discuss alternative pain relievers/fever reducers.
- Patients are to report skin rash or reaction whilst taking Paracetamol to their healthcare professional.

Meanwhile, the Food and Drugs Authority has requested that manufacturers include a warning in the product information of paracetamol-containing products to address the risk of serious skin reactions.

Healthcare professionals are encouraged to report all such suspected cases and any other adverse drug reactions to the National Pharmacovigilance Centre by completing the “**Blue Form**” or call **024 431 0297** or send e-mail to [drug.safety@fdaghana.gov.gh](mailto:drug.safety@fdaghana.gov.gh).

For further enquiries contact the National Pharmacovigilance Centre, FDA through the following address:

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Yours faithfully,

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CHIEF EXECUTIVE