NOTICE TO IMPORTERS AND MANUFACTURERS OF PHARMACEUTICAL, FOOD AND COSMETIC PRODUCTS

Following recent reports of the death of over 60 and 99 children in the Gambia and Indonesia respectively, from acute kidney injury suspected to have been caused by Diethylene Glycol (DEG) and Ethylene Glycol (EG) impurities found in pharmaceutical syrup formulations, the Food and Drugs Authority (FDA) on 20th October 2022 in a letter to manufacturers of pharmaceutical, food and cosmetic products gave directives on the importation of Glycerin and Propylene Glycol.

Further to those directives, the FDA wishes to direct with immediate effect that:

1. All batches of imported Glycerin and Propylene Glycol raw materials should be accompanied by a certificate of analysis that have test and limit for Diethylene Glycol (DEG) and Ethylene Glycol (EG) as per the recognized official compendia.

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2. All batches of imported Glycerin and Propylene Glycol shall be released under detention, sampled at the port of entry and tested for the presence of DEG and EG at USP-Ghana Quality Control Laboratory at the cost of the importer.

3. Only tested and released Glycerin and Propylene Glycol imported raw materials shall be used in formulating products to be put on the market.

4. For all batches of finished pharmaceutical products (FPP) imported into the country that have Glycerin and Propylene Glycol as excipients, the manufacturers are required to submit documentary proof of the FPP manufacturer's control of DEG and EG in the excipients used for the FPP.

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5. In the absence of proof of the control of DEG and EG in the excipients as indicated above, the FPP shall be sampled at the port of entry and tested for the presence of DEG and EG at USP-Ghana Quality Control Laboratory at the cost of the importer.

6. Only FPP that meet the above requirements would be allowed onto the market.

Importers, manufacturers, and other stakeholders are to take note of this and comply accordingly.

Chief Executive Officer
Food and Drugs Authority

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