PUBLIC NOTICE

FDA/CSD/CPE/PNS/24/008

SAFETY ALERT ON ILLEGAL SALE OF SUBSTANDARD AND FALSIFIED COLAMAR (ARTEMETHER/ LUMEFANTERINE 20/120 MG) ORAL SUSPENSION

Accra: August 15, 2024 -The Food and Drugs Authority (FDA) is notifying healthcare professionals and the public of falsified and substandard anti-malarial medicine, **Colamar (Artemether/Lumefantrine 20/120 mg)** for Oral Suspension circulating on Nigerian Market.

The details of the substandard and falsified product is provided below:

Product Name : **Colamar 20/120 Powder for Oral Suspension**
Stated Active Ingredients : **Artemether 20mg/Lumefantrine 120 mg**
Batch Number : **ALD2424**
Manufacturing date : **02/2024**
Expiry date : **01/2027**
Stated NRN : **B4-4065**
Name of Manufacturer : **Archy Pharm. Nig Ltd., Nigeria**

A report by the National Agency for Food and Drug Administration and Control (NAFDAC), Nigeria indicated that the product has a fake NAFDAC Registration Number (NRN).

Colamar Powder for Oral Suspension is not registered by the Food and Drugs Authority for use in Ghana

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If found on the Ghanaian Market; its importation and distribution would be illegal and in contravention of the Sec 118 of the Public Health Act, 2012 Act 851.

Importers, distributors, retailers, and consumers are advised to remain vigilant throughout the supply chain to prevent the importation, distribution, sale, and use of unregistered, substandard, and falsified products. All medical products must be obtained from authorized/licensed suppliers and their authenticity and physical condition carefully checked.

Anyone in possession of the above-mentioned product is advised to discontinue sale or use and submit stock to the nearest FDA office. The FDA is encouraging healthcare professionals and the public to report availability of the Colamar Suspension on the Ghanaian market to FDA through the hotline 0551112224/5.

Adverse reactions to Colamar suspension and all other products including lack of efficacy, medication error, and substandard and falsified medical products are to be reported to the FDA through the following:

1. Download and complete the Med Safety App (Google Play Store or App Store)
2. Complete and submit the report online at http:/adr.fdaghana.gov.gh/
3. Download and complete the Adverse Reaction (AR) Reporting

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Form (http://www.fdaghana.gov.gh/operational -guide.php).
4. Community Pharmacies Designated as Patient Safety Centers

Photographs of the product is attached

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Photo of falsified product.

Signed
Chief Executive Officer
Food and Drugs Authority

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