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FDA/CSD/CPE/PRS/25/003

FDA RESPONDS TO BBC AFRICA EYE INVESTIGATION: WHO IS FLOODING WEST AFRICA WITH OPIOIDS?

Accra, February 26, 2025: The Food and Drugs Authority (FDA) has taken note of the recent BBC Africa Eye investigative report exposing the alleged exportation of unapproved drugs containing tapentadol, a powerful opioid, and carisoprodol by Indian pharmaceutical company Aveo Pharmaceuticals, through Westfin International, to West Africa, particularly Côte d'Ivoire, Nigeria, and Ghana.

Is the FDA Aware of These Products?

The FDA categorically states that it has not registered tapentadol or carisoprodol as single-ingredient products, nor has it approved Tafradol, a fixed-dose combination of both substances, for any medical condition. Additionally,

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the FDA's Centre for Import and Export Control (CIEC) has not received or processed an import permit application for Tafradol or similar brands, as such products are unauthorized for use in Ghana.

During the BBC investigation, the FDA was contacted and unequivocally confirmed that these drugs are unapproved and illegal for importation. This exposé reinforces the Authority's longstanding enforcement efforts against the illegal importation of unregistered drugs and substances of abuse, including Tramadol, Trafanol, Tarapamol, and Tramaking. Through rigorous surveillance, the FDA has imposed fines, seized illicit drugs, and ensured their safe disposal.

Tapentadol is an opioid with a high potential for addiction,

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leading to psychological dependence. Abuse can cause drowsiness, lethargy, respiratory collapse, and even death. Carisoprodol, used in some countries for musculoskeletal pain management, also carries addiction risks and can cause drowsiness, concentration difficulties, and confusion. Despite ongoing enforcement, recent FDA operations have identified the continued presence of various Tramadol brands, including Trafanol, Tarapamol, and Tramaking, in Tamale and other parts of Ghana.

What Actions Has the FDA Taken?

On December 18, 2023, a container (MRKU 9648934) declared for transit to Nemin, Niger, was found to contain 181 cartons of Royal 225mg (Tapentadol and Carisoprodol),

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51 cartons of Timaking 120mg (Tapentadol and Carisoprodol), and 90 cartons of Tafradol 120mg. These were seized and disposed of following a court order dated January 16, 2025, with destruction completed on February 21, 2025.

In May 2024, a joint operation involving the FDA, National Security, Narcotics Control Commission, Ghana Revenue Authority (Customs Division), Bureau of National Investigations, and other agencies intercepted 376 cartons of Tramadol Hydrochloride 225mg (Tramaking 225mg) concealed among 50 cartons of laboratory coverall suits. These were safely disposed of in October 2024.

Through sustained surveillance, the FDA has confiscated approximately 287,011 units of Tramadol in varying

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strengths from 50mg to 225mg, 8,576 units of Trafadol, and 2,053 units of Tramaking at different border posts, over-the-counter medicine sellers (OTCMS), and from hawkers. None of the confiscated products had manufacturer details indicated on them.

Additionally, the FDA, in collaboration with state agencies, including the Ghana Revenue Authority (Customs Division), Narcotics Control Commission, National Investigation Bureau, Port Health, Ghana Standards Authority, Ghana Police Service, National Security, Pharmacy Council, Local Government, Environmental Protection Agency, and the media, has conducted multiple safe disposals of confiscated Tramadol and other opioids. Perpetrators of these illegal activities face strict regulatory

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sanctions, including administrative fines and prosecution. Currently, the FDA is prosecuting six Over-the-Counter Medicine Sellers for the illegal sale and distribution of Tramadol and other opioids.

Does the FDA Know Samos Pharma and Aveo Pharmaceuticals?

Samos Pharma, mentioned in the BBC report, is a registered importer of injections and eye drops manufactured by FDA-inspected Indian companies, none of which is Aveo Pharmaceuticals. However, records from 2022 and 2023 indicate that Westfin International Private Limited and Aveo Pharmaceuticals were exporters of these products to Samos Pharma.

Aveo Pharmaceuticals Pvt. Ltd. was granted a Good

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Manufacturing Practices (GMP) certificate in September 2024 following an inspection in April 2024. The company was in the process of contract manufacturing for Masters Pharmaceutical Limited, based in Kumasi, which had applied for the registration of six products.

However, in light of the BBC Africa Eye findings on Aveo Pharmaceuticals' involvement in the illegal manufacturing and distribution of opioid products, the FDA has directed Samos Pharma to immediately cease using Westfin International Private Limited and Aveo Pharmaceuticals as exporters. Similarly, the Authority has suspended the processing of Masters Pharmaceutical Limited's application using Aveo Pharmaceuticals as a contract manufacturer with immediate effect and has also

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suspended Aveo Pharmaceuticals' GMP certificate.

FDA's Continued Regulatory Interventions

The FDA has long implemented stringent measures to combat opioid abuse. In 2018, based on the FDA's advice, the Minister of Health issued Executive Instruments E.I. 167 and E.I. 168. Executive Instrument 167 banned the manufacture and sale of codeine-containing cough syrup, while Executive Instrument 168 reclassified Tramadol as a controlled substance, restricting its manufacture, sale, and distribution despite its absence from international control lists. Executive Instrument 168 established strict import, manufacturing, and sales controls, mandating that Tramadol be available only by prescription to mitigate abuse.

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The FDA assures the public that it is actively working with key stakeholders to investigate the issues raised in the BBC Africa Eye report and remains resolute in its mission to protect public health and ensure the safety of all regulated products in Ghana

For all inquiries and concerns, please reach out to us through the contacts below..

Signed
Chief Executive Officer
Food and Drugs Authority

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