REPUBLIC OF LIBERIA
LIBERIA MEDICINES & HEALTH PRODUCTS REGULATORY AUTHORITY (LMHRA)
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LMHRA Declares 'Failed Pharmaceutical Product', (Para Clear Paracetamol Suspension) Which Contains Toxic Substance Ethylene Glycol

-Warns Against the Sale of the Medicinal Product

(Monrovia-June 19, 2023): The Managing Director of the Liberia Medicines and Health Products Regulatory Authority (LMHRA), Dr. Keturah C. Smith-Chineh, has disclosed that the Authority has declared "FAIL" about 256 cartons of "Paracetamol Oral Suspension125mg/5ml known as Para Clear Suspension, with batch number L220008." These 256 cartons were quarantined ~~since~~ last year, after~~—~~ a failed physical inspection at Quality Control Lab since October 2022.

Para Clear Paracetamol syrup, was manufactured in India, by a pharmaceutical company known as "Curis Life Sciences PVT. Ltd.

According to her during a called press conference June 12, 2023, the failed pharmaceutical product was manufactured for the effective relief of body pains~~headaches, backaches,~~ and fever.

Dr. Smith-Chineh said~~,~~ the samples were taken to National Agency for Food and Drug Administration and Control (NAFDAC) by the LMHRA Quality Control Lab team for confirmatory analytical testing and the quality analysis was paid for. The lab result returned FAIL. ~~The decision to stop the product from entering the market was followed by another failed test conducted in Nigeria~~

Therefore, Managing Director Smith-Chineh disclosed that due to the above, the Authority has revoked, with immediate effect, the manufacturer's license, as well as marketing authorization of all

products registered by the Company. The LMHRA's Managing Director further intimated that the medicinal product, which is toxic, will be disposed of accordingly.

~~She further informed the public that an investigation conducted by the World Health Organization (WHO) also revealed that the Para Clear medical product poses threats to the lives of children similar to the Gambian scenario.~~

"This product came into the country last year September, it was tested in our Quality Control Laboratory and was rendered failed. As part of the procedures we carry on at the LMHRA, if a product is rendered failed, the importer has the right to ask for Third-party testing, ~~in order~~ to have a transparent process. And this is also in line with international best practice," Dr. Smith-Chineh noted.

Accordingly, the LMHRA Managing Director, emphasized that third-party testing of failed products must be conducted in World Health Organization (WHO) prequalified or ISO/IEC 17025 accredited Laboratories. Therefore, for the West African region, the Ghana Food and Drugs Authority (FDA) and the National Agency for Food and Drug Administration and Control (NAFDAC), are the two Accredited ISO/IEC 17025 Quality Control labs recommended. Consequently, the samples of the paracetamol oral suspension were sent to NAFDAC on April 18, 2023.

LMHRA Managing Director Smith-Chineh also disclosed that last week, Friday, June 9, 2023, the results of the failed medicinal (Para Clear Paracetamol Suspension ~~with Batch number L220008)~~ were sent back to Liberia from Nigeria; and it was reported that the product failed due to the fact it has Ethylene Glycol, a substance she said is considered highly toxic and leads to acute renal impairment (kidney failure). The product also failed the requirement for acute oral toxicity.

Therefore, while investigations are ongoing, Dr. Smith-Chineh is encouraging the public to report to the Authority, if the above-mentioned failed medicinal product is seen anywhere on the Liberian market. As part of LMHRA's policy that all syrups (including anti-malaria, anti-hypertensive, and anti-diabetics) must be quarantined pending analytical results from the laboratory, she assured the public that the 256 cartons of the quarantined product are still intact and will be destroyed (incinerated) subsequently.

Managing Director Smith-Chineh has further warned the public not to consume any of these products~~,~~ because they are not fit for human consumption.

~~According to scientific researchers, Ethylene glycol is an organic compound with the formula (CH_2OH_2). It is mainly used as a raw material in the manufacture of polyester fibers, paints, and brake fluid as an anti-freeze formulations. It is an odorless, colorless, flammable, viscous liquid. The~~ ~~r~~Repeated exposure to ethylene glycol may lead to~~:~~ irritation of the throat, mild headache, ~~backache, loss~~and loss of consciousness, acute renal impairment, and death.

Meanwhile, Managing Director Smith-Chineh is calling on the public to report to the regulatory authority all illegal entry and offloading of ~~the~~ pharmaceutical products, due to the fact the country has several porous border points and the Authority's regional staff are constrained.

The public is encouraged to reach the LMHRA on its hotlines at: **5054 or 0880140555 or 0770140555.**