PHARMACY BOARD OF SIERRA LEONE

MINISTRY OF HEALTH AND SANITATION

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Our Ref.....

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CONTAMINATED PAEDIATRIC MEDICINES IDENTIFIED IN THE GAMBIA

The Pharmacy Board of Sierra Leone (PBSL) wishes to inform the general public that it has received a medical product alert from the World Health Organization (WHO) referring to four(4) substandard products identified in the Gambia and reported to WHO in September 2022.

These products are deemed out of specification as they have failed to meet quality standards and specifications.

Product name	Promethazine oral solution	Kofexmalin baby cough syrup	Makoff baby cough syrup	Maxgrip n cold syrup
Reported active ingredient	Promethazine	Pheniramine maleate, ammonium chloride, menthol	Chlorpheniramine maleate, phenylephrine HBR, Dextromethorphan syrup	Paracetamol phenylephrine HCL, Chlorpheniramine Maleate
Stated manufacturer	MAIDEN PHARMACEUTICAL LIMITED (Haryana, India)	MAIDEN PHARMACEUTICALS LIMITED (Haryana, India)	MAIDEN PHARMACEUTICALS (Haryana,India)	MAIDEN PHARMACEUTICALS LIMITED ((Haryana, India)
Lot number	ML21-202	ML21-199	ML21-203	ML21-198
Manufacturing date	DEC-21	DEC-21	DEC-21	DEC-21
Expiry date	NOV-24	NOV-24	NOV-24	NOV-24

The above products have, after laboratory analysis found to contain unacceptable amounts of diethylene glycol (DEG) and ethylene glycol(EG) as contaminants that are toxic to humans as they can cause vomiting, diarrhoea, acute kidney injury, altered mental state, and may lead to death when consumed.

In light of the above, the Pharmacy Board of Sierra Leone would like to assure the general public of the following:

1. **Pharmacy Board has done extensive surveillance of the pharmaceutical market in Sierra Leone over the past few days and has not found any of these products**
2. **None of the above products are currently registered by PBSL, including the manufacturer Maiden Pharmaceuticals, India**
3. **PBSL has a robust quality risk management and quality control analyses system that evaluates and test every syrup for the said contaminants viz DEG and EG since 2008 before they are approved for marketing in Sierra Leone**
4. **PBSL conducts risk-based routine post-marketing surveillance on all products that have received Marketing Authorization in Sierra Leone to ascertain their continued quality, effectiveness and safety.**
5. **PBSL will continue its post-market surveillance activities at the borders and across the country to promptly detect and remove from the market any of the said products peradventure they enter the Sierra Leone market.**

We want to continue to encourage the public to be on the lookout for all substandard and falsified medical products as well as individuals (peddlers and hawkers) and premises without the legal mandate to sell medicines and other medical products to the general public.

For more enquiries and to report substandard and falsified medical products,kindly reach out to PBSL on **099117117 or 073994830.**

Dr. James P. Komeh
ACTING REGISTRAR

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