Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

28 OCT 2022

FDA STATEMENT

On Diethylene glycol and Ethylene glycol - contaminated Cough and Cold Syrup Manufactured by Maiden Pharmaceuticals, Ltd.

All pharmaceutical products, especially cough and cold syrups, that use glycerine as solvent, diluent, and thickening agent, are mandatorily required to be tested for purity as raw materials when used. Diethylene glycol and ethylene glycol are cheap alternatives used by non-GMP compliant manufacturers. Both impurities have industrial applications including as anti-freeze and brake fluid agents. Only those glycerines that have passed laboratory analysis under GMP requirements are allowed to be present in pharmaceutical preparations.

Maiden Pharmaceuticals, Ltd. Haryana, India was reported by World Health Organization Medical Product Alert as the single source of the four contaminated and substandard products identified in the Gambia. The four products are **Promethazine Oral Solution, Kofexmalin Baby Cough Syrup, Makoff Baby Cough Syrup** and **Magrip N Cold Syrup.**

The Food and Drug Administration Philippines has no registered pharmaceutical products manufactured by Maiden Pharmaceuticals, Ltd. Should there be a local distributor-importer that intends to register any drug product manufactured by Maiden Pharmaceuticals, Ltd, the pharmaceutical plant facilities will be subjected to on-site foreign Good Manufacturing Practices (GMP) inspection, just like any other drug manufacturer in India that supplies and distributes pharmaceutical products in the Philippines.

DR. SAMUEL A. ZACATE
Director General

Civic Drive, Filinvest Corporate City, Alabang 1781 Muntinlupa, Philippines
Trunk Line +63 2 857 1900 Fax +63 2 807 0751
Website: www.fda.gov.ph Email: info@fda.gov.ph