All correspondence should be addressed to the Director General

In reply, please quote .....

ZAMBIA MEDICINES REGULATORY AUTHORITY

PUBLIC NOTICE

Date: 14th July, 2023

To: Distributors, Wholesalers, Retailers, Health Facilities, Healthcare Professionals, General Public

MEDICAL PRODUCT ALERT:
RECALL OF ALL MEDICINES MANUFACTURED BY GLUMEX PHARMACEUTICALS MANUFACTURING PRIVATE LIMITED, INDIA FROM THE ZAMBIAN MARKET

The Zambia Medicines Regulatory Authority (ZAMRA) is a statutory body established under an Act of Parliament, the Medicines and Allied Substances Act No. 3 of 2013 of the laws of Zambia. The main mandate of ZAMRA is to regulate, and control the manufacture, importation, storage, distribution, supply, sale and use of medicines and allied substances for human and animal use for public health protection.

The Authority wishes to notify healthcare professionals and the general public that it has **revoked Marketing Authorisations (MAs)** for all medicines and allied substances manufactured by **Glumex Pharmaceuticals Manufacturing Private Limited, India** (*See attached list for ease of reference*). This revocation of the MAs is as a result of failure by the facility to comply with the World Health Organisation's current Good Manufacturing Practices (cGMP) Guidelines. Based on this, the quality, safety and efficacy of products from this manufacturer is not guaranteed.

Therefore, as a result of the revocation of MAs, no products manufactured by Glumex Pharmaceuticals Manufacturing Private Limited, India will be allowed in Zambia. The revocation of the MAs will remain in force until such a time the Authority determines otherwise.

In view of the above, all health facilities, pharmaceutical outlets and members of the public in possession of any product manufactured by Glumex Pharmaceuticals Manufacturing Private Limited, India are advised to stop distribution, dispensing or using these products and return them to their supplier for replacement with better quality assured products. Importers of these products have been directed to initiate the withdraw of these products from the market and plan for their safe disposal.

The Authority has heightened its post market surveillance activities for these products and will closely monitor the withdraw process to ensure that the products are completely removed from circulation in the interest of public health.

Should the public need further clarification, please do not hesitate to contact the undersigned.

Makomani Siyanga (Mr)
DIRECTOR-GENERAL

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Off Kenneth Kaunda International Airport Road
P.O. Box 31890, Lusaka, ZAMBIA
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E-mail: pharmacy@zamra.co.zm

Report Adverse Reactions to:
Pharmacovigilance Unit, Lusaka
Tel: +260 211 432 356
E-mail:npvu@zamra.co.zm
Website: www.zamra.co.zm

ZAMBIA MEDICINES REGULATORY AUTHORITY

List of products withdrawn from the market

S/N	Name of Product(s)	Application No.	Marketing Authorisation No.
1.	C.P. Mex Syrup	2331/03	169/003
2.	Eryomycin Syrup	2332/03	169/002
3.	Glucain Tablets	2333/03	169/004
4.	Pharmadar Tablets	2334/03	169/001
5.	Gluvit Syrup	2511/04	169/008
6.	Biovit-Z-Syrup	2512/04	169/006
7.	Cold Care Tablets	2513/04	169/007
8.	Pharmadar Suspension	2514/04	169/005
9.	Lopamet Capsules	3660/05	169/010
10.	Apectin Tablets	3661/05	169/011
11.	Clopin Syrup	3662/05	169/012
12.	Cephamex Syrup	3663/05	169/013
13.	Flucomex Capsules	3664/05	169/014
14.	Eromycin Tablets	3665/05	169/015
15.	Ketomex Tablets	3676/05	169/009
16.	Ebut Capsules	4124/06	169/028
17.	Paracetamol Tablets	4537/07	169/021
18.	Nalidixic Acid Oral Suspension	4539/07	169/023
19.	Pyridoxine Tablets	4540/07	169/022
20.	Methyldopa Tablets	4567/07	169/018
21.	Amizide Tablets	4568/07	169/017
22.	Zovex Tablets	4569/07	169/019
23.	Ketomex Suspension	4570/07	169/016
24.	Aminophylline Tablets	4705/07	169/024
25.	Apectine Syrup	4706/07	169/027
26.	Glibenclamide Tablets	4707/07	169/025
27.	Viengray Tablets	4708/07	169/026
28.	Carbamex 200mg Tablets	4538/07	169/020