

NATIONAL



AUTHORITY

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CIRCULAR NO. 23

Dear Healthcare provider,

SUSPENSION OF REGISTRATION OF PRODUCTS FROM THE DRUG REGISTER

Background

NDA is mandated to ensure that the population of Uganda has access to safe, effective and quality drugs.

We received market complaints on quality of different pharmaceutical products. Some of the complaints were related to the occurrence of serious adverse events whereas other products had critical quality defects posing a risk to public health. Further investigations revealed that the manufacturing facilities of some of these drugs did not comply with Good Manufacturing Practices (GMP) requirements.

The National Drug Authority Board then decided to suspend and recall **All Parenteral (Injectable) products** manufactured by the facilities which were found to operate at unacceptable levels of GMP requirements. These include;

NO.	MANUFACTURER	NAME OF DRUG	GENERIC NAME OF DRUG
1	JIANGSU PENGYAO PHARMACEUTICALS CO. LTD -NO. 10 CHAQUAN ROAD YIXING CITY JIANGSU PROVINCE, CHINA	R-ETHER	ARTEMETHER 80MG/ML
		GMYCIN-80	GENTAMYCIN SULPHATE 80MG/2ML
		FALCIMAX-600	QUININE DIHYDROCHLORIDE 600MG/2ML
		ARTEMETHER INJECTION	ARTEMETHER 80MG/ML
		QUININE DIHYDROCHLORIDE INJECTION	QUININE DIHYDROCHLORIDE 600MG/2ML
		DICLOMAX-75	DICLOFENAC SODIUM 75MG/ML
2	ANHUI CHENGSHI MEDICINE MANUFACTURE CO. LTD-INDUSTRIAL AREA, BENGBU CITY, ANHUI PROVINCE, CHINA	GENTAMYCIN INJECTION	GENTAMYCIN 80MG/2ML
		ARTEMETHER INJECTION	ARTEMETHER 80MG/ML
		VITAMIN B INJECTION	VIT B1 + VIT B2 + VIT B6 + NICOTINAMIDE + CALCIUM DEXTROPANTOTHENATE
		DICLOFENAC SODIUM	DICLOFENAC 75MG/3ML

HEAD OFFICE

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OUR MISSION

Promoting and protecting public health
through the effective regulation of human
and animal medicines and healthcare
products

REGIONAL OFFICES

Central Region, Nakawa - Tel: +256 312 261 548,
Western Nile Region, Arua - Tel: +256 414 671 033,
South western Region, Mbarara - Tel: +256 414 671 034,
South Eastern Region, Jinja - Tel/Fax: +256 434122 176,
Eastern Region, Tororo -Tel: +256 454 445 195,
Western Region, Hoima - Tel/Fax +256 465 440 688,
Northern Region, Lira - Tel/Fax +256 414 671 032

CONTINUATION SHEET

3	SHANDONG XIER KANGTAI PHARMACEUTICAL CO. LTD-PRIVATE ECONOMY ZONE, YANZHOU DISTRICT, SHANDONG, CHINA PR	CELLTRIAXON	CEFTRIAXONE 1GM
		EXPEN	BENZYL PENICILLIN 1MU
		PROCILIN	FORTIFIED PROCAINE BENZYL PENICILLIN 4MU

NOTE: The names of drugs in the table above apply only to those drugs manufactured by the suspended manufacturing facilities.

Advise to Health workers.

1. Do not purchase any Injectable products manufactured by the companies in the table above. The license holders of these products have been instructed to recall the affected products and halt any importation.
2. Quarantine and return all of the affected products to their suppliers
3. To Report to NDA any adverse drugs reactions associated with similar products or any other product defects. Reports can be sent to any NDA office or by email to druginfo@nda.or.ug or calling 0414-255665 or by sending a message on WhatsApp to 0791415555

Thank you for your continued cooperation.



Helen Byomire Ndagije
DIRECTOR PRODUCT SAFETY

Copy: Director Health Services, Clinical Services, Ministry of Health
 Director Product Assessment and Registration
 Director, Inspectorate and Enforcement

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OUR MISSION

To ensure access to quality, safe and Efficacious human and veterinary medicines And other healthcare products through the Regulation and control of their production, Importation, distribution and use.

REGIONAL OFFICES

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