

NATIONAL



AUTHORITY

Safe Drugs Save Lives

7th October 2024

1892/NDA/DIE/10/2024

PUBLIC NOTICE

CIRCULAR NO. 005/DIE/2024

MANDATORY POST SHIPMENT ANALYSIS OF DRUGS AND SELECT SURGICAL INSTRUMENTS

The National Drug Authority (NDA) was established in 1993 by the National Drug Policy and Authority Statute, which in 2000 became the National Drug Policy and Authority Act, Cap 198 of the Laws of Uganda (2000 Edition) to ensure the availability at all times, of essential, efficacious and cost-effective healthcare products to the entire population of Uganda as a means of providing satisfactory healthcare and safeguarding the appropriate use of these products.

The Authority runs a Quality Surveillance Plan aimed at monitoring the quality of drugs, surgical instruments and appliances and other healthcare products regulated by NDA. For the products earmarked for laboratory analysis, the sampling occurs at different levels of the supply chain including, the Ports of Entry, wholesalers/distributors, pharmacies and drug shops, dispensing facilities, hospitals, health centers and clinics. The selection of products for inclusion on the plan is risk-based, considering previous quality issues or complaints associated with the product, complexity of manufacturing and the volumes distributed.

As the Authority implements this plan, it is imperative that the products under mandatory sampling and analysis are communicated as a means of minimizing any disruptions that may arise. Below is a table with products targeted under this level.

Table 1: Products under Mandatory Testing

1) Male and Female Condoms	11) IV Cannulas	20) Surgical Instruments Set
2) Gloves	12) Surgical Sutures	21) Amoxicillin/Clavulanic Acid Tablets
3) Giving Sets	13) Cotton (Imported)	22) Artesunate for Injection
4) Needles and Syringes	14) Gauze (Imported)	23) Levamisole HCL & Oxytocin Suspension
5) Rapid Diagnostic Test Kits – Malaria	15) Surgical Blades	24) Albendazole Tablets – Human
6) Rapid Diagnostic Test Kits – HIV	16) Adhesive Plaster	25) Metformin API
7) Metformin FPP	17) Losartan FPP	26) Ranitidine FPP
8) Valsartan FPP	18) Paracetamol Suspensions	27) Cyclophosphamide Injection
9) Medicine kits for PUD with Lansoprazole/Omeprazole, Tinidazole and Clarithromycin	19) Oxytocin	28) Fluorouracil Injection
10) All imported herbal products		

HEAD OFFICE

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NATIONAL DRUG QUALITY CONTROL LABORATORY

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OUR MISSION

To protect and promote human and animal health through the effective regulation of drugs and healthcare products.

REGIONAL OFFICES

Central Region, Akamwesi - Tel: (+256) 414 672 734
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South Eastern Region, Jinja - Tel: (+256) 434 122 176
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Table 2: Sample Sizes

Serial No.	Product/Dosage Form	Lot/Batch Size	Sample Size (Per Batch/Lot)
1	Tablets/Capsules (Bulk Strip Packages)	N/A	100
2	Tablets/Capsules (Individual Packs)	N/A	50
3	Tablets/Capsules (Tin Packs)	N/A	1
4	Powders/Granules in Packs less than 100 grams	N/A	50
5	Powders/Granules in Packs greater than 100 grams but less than 500 grams	N/A	20
6	Powders/Granules in Packs of 500 grams or greater	N/A	10
7	Sterile Powders	N/A	50
8	Suspensions/Solutions/Emulsions - up to 100 mL	N/A	50
9	Suspensions/Solutions/Emulsions - Above 100 mL to 250 mL	N/A	20
10	Suspensions/Solutions/Emulsions - Above 250 mL to 500 mL	N/A	10
11	Suspensions/Solutions/Emulsions - Above 500 mL to 1000 mL	N/A	5
12	Suspensions/Solutions/Emulsions - Above 1000 mL	N/A	3
13	Small Volume Parenterals (up to 100mL)	N/A	50
14	Large Volume Parenterals (Above 500mL)	N/A	12
15	Adhesive Plaster	N/A	12 pcs
16	Surgical Instruments Set	N/A	2 sets
17	Surgical Blades	N/A	100 pcs
18	Gauze (Imported)	N/A	4 rolls
19	Cotton (Imported)	N/A	4 rolls
20	Surgical Sutures	N/A	60 pcs
21	IV Cannulas	N/A	200 pcs
22	Rapid Diagnostic Test Kits - Malaria	N/A	200 pcs
23	Rapid Diagnostic Test Kits - HIV	N/A	200 pcs
24	Needles and Syringes	N/A	200 pcs
25	Giving Sets	N/A	100 pcs
26	Condoms (Male and Female)	Up to 10,000	700 pcs
		10,001 – 35,000	800 pcs
		35,001 – 150,000	900 pcs
		150,001 – 500,000	1100 pcs
27	Medical Gloves	500,001 and over	700 pcs
		500,000 – 150,001	500 pcs
		150,000 -35,001	300 pcs
		35,000 – 10,001	200 pcs
		10,000 – 3,201	200 pcs
		3,200 – 1,201	200 pcs
		Up to 1200	100 pcs
		Batch Size not Indicated	700 pcs

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CONTINUATION SHEET

Fees prescribed under the National Drug Policy and Authority (Fees) Regulations, 2022 will apply where applicable.

Inquiries can be made on ndaug@nda.or.ug or delivered to NDA Tower Plot 93 Buganda Rd Kampala.



D.H.P.
David Nahamya
SECRETARY TO THE AUTHORITY

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