STATUTORY INSTRUMENTS
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STATUTORY INSTRUMENTS

2025 No. 74

The National Drug Policy and Authority (Fees) (Amendment) Regulations, 2025

(Under section 61 of the National Drug Policy and Authority Act, Cap. 198)

IN EXERCISE of the powers conferred upon the Minister responsible for health by section 61 of the National Drug Policy and Authority Act, and on the advice of the National Drug Authority, these Regulations are made, this 1st day of October, 2025.

1. Citation

These Regulations may be cited as the National Drug Policy and Authority (Fees) (Amendment) Regulations, 2025.

2. Amendment of S.I. No. 67 of 2025

The Schedule to the National Drug Policy and Authority (Fees) Regulations, 2025 is amended—

(a) in Part 1, item 3 (f) by substituting "(f) Notification of amendment of application for imported drugs" with, "(f) Notification of amendment of application for locally manufactured drugs";

(b) in Part 5—

(i) item 3 by substituting "3. Fees for the manufacture of bulk sterile and non-sterile pharmaceutical products" with, "3. Fees for the manufacture of bulk and intermediate sterile and non-sterile pharmaceutical products";

(ii) item 3 (b) by substituting "(b) Licence to manufacture bulk products" with "(b) Licence to manufacture bulk or intermediate products";

(iii) item 3 (c) by substituting "(c) Licence to conduct quality control testing activities for bulk sterile and non-sterile pharmaceutical products" with "(c) Licence to conduct quality control activities for sterile and non-sterile pharmaceutical products";

(c) in Part 6—

(i) paragraph (c) by substituting "(c) Verification of consignment of donations and grants imported for projects and programmes of commercial organisations and Government Ministries, departments and institutions" with, "(c) Verification of consignment of registered drugs other than drugs specified in paragraphs (f) and (p) and verification of consignment of registered drugs imported for donation or as a grant or for a project or programme of a Government Ministry, department or institution";

(ii) by inserting immediately after paragraph (f) the following—

"(fa)	Verification of consignment of imported drugs from a country which is not a Partner State of the East African Community where the consignment comprises drugs in paragraph (f) and where the importation is for a project or programme of a Government Ministry, department or institution	15% of FOB price"

(iii) paragraph (h) by substituting the fee with "15% of FOB price";

(iv) paragraph (o) by substituting the word "primary" with the word "secondary"; and

(d) in Part 7—

(i) by substituting for item 1, the following—

"1. Examination of drugs by the Authority in the course of performance of its functions (except cannabis and imported herbal drugs)

	Test	**Fees per batch**
(a)	Testing of samples of local drug products (three batches) for purpose of registration; single ingredient—	
	(i)) where the Authority provides the inputs	5,700,000/=
	(ii)) where the manufacturer provides the inputs	1,900,000/=
(b)	Testing of samples of local drug products for purposes of registration; for any additional ingredient	1,900,000/=

(c)	Testing of samples of local drug products (three batches) for purpose of registration, where the samples are manufactured after failure of test in paragraph (a) or (b), respectively	USD$ 6,000
(d)	Testing of samples of imported drug products (three batches) for purpose of registration; single ingredient	22,800,000/=
(e)	Testing of samples of imported drug products for purposes of registration; for any additional ingredient	5,700,000/=
(f)	Testing of local drug products after registration	USD$ 300
(g)	Testing of imported drug products after registration	USD$ 1,500
(h)	Re-testing of sample of drug product at the request of owner, manufacturer, importer or any other person	$10,000
(i)	Testing of drug product by the Authority in laboratory not owned by the Authority	Cost for testing + 10% of the cost

(ii) by substituting for item 4 D, the following)—

D. Other services	
Test for product classification	USD$ 100

HON. DR. ACENG JANE RUTH OCERO
Minister of Health.