

GOVERNMENT NOTICE NO. 5 published on 6/01/2023

THE TANZANIA MEDICINES AND MEDICAL DEVICES ACT,

(CAP. 219)

REGULATIONS

(Made under section 122(1)(i))

THE TANZANIA MEDICINES AND MEDICAL DEVICES (FEES AND CHARGES)
(AMENDMENT) REGULATION, 2022

Citation

1. These Regulations may be cited as the Tanzania Medicines and Medical Devices (Fees and Charges) (Amendment) Regulations, 2022 and shall be read as one with the Tanzania Medicines and Medical Devices (Fees and Charges) Regulations, 2021 hereinafter referred to as the "principal Regulations".

GN. No.
686 of 2021

Amendment of
regulation 3

2. The principal Regulations are amended in regulation 3 by deleting the interpretation of the terms "local government authority", "innovator product", "alteration or innovation fee", "animal biological specimens", "annual retention fee", "ceiling price", "cost including freight" "freight on board or free on board or its acronym FoB", "customer", "domestic product", "donation", "non-medical products", "orphan medicine", "medical supplies", "pre-licensing or registration inspection", "product carrier", "product dealer" and "specifications".

Amendment of
First Schedule

3. The principal Regulations are amended in the First Schedule by-

(a) adding immediately after paragraph 65 the following:

"65A.	Application to conduct clinical trials (domestic)	TZS	6,000,000;
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(b) adding immediately after paragraph 66 the following:

"66A.	Amendment - Major (domestic)	TZS	2,000,000";
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(c) adding immediately after paragraph 67 the following:

"67A.	Amendment - Minor (domestic)	TZS	600,000";
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(d) adding immediately after paragraph 68 the following:

"68A.	Fast Track (domestic)	TZS	Double authorised fee".
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Dodoma,
30th December, 2022

UMMY A. MWALIMU,
Minister of Health