

THE UNITED REPUBLIC OF TANZANIA

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SUBSIDIARY LEGISLATION

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THE TANZANIA MEDICINES AND MEDICAL DEVICES ACT,
(CAP. 219)

REGULATIONS

(Made under section 122(1)(t) and (z))

THE TANZANIA MEDICINES AND MEDICAL DEVICES (LABORATORY ANALYSIS OF
MEDICAL AND NON-MEDICAL PRODUCTS) (AMENDMENT) REGULATIONS, 2022

Citation

1. These Regulations may be cited as the Tanzania Medicines and Medical Devices (Laboratory Analysis of Medical and Non-Medical Products) (Amendment) Regulations, 2022 and shall be read as one with the Tanzania Medicines and Medical Devices (Laboratory Analysis of Medical and Non-Medical Products) Regulations, 2021 hereinafter referred as the “principal Regulations”.

GN. No.
685 of 2021

Amendment of
regulation 2

2. The principal Regulations are amended by deleting regulation 2 and substituting for it the following:
“Application 2. These Regulations shall apply in the laboratory analysis of medical and related products in the Mainland Tanzania.”.

Amendment of
regulation 21

3. The principal Regulations are amended in regulation 21(2) by deleting the words “specified under the

Fifth and Sixth Schedule to these Regulations” and substituting for them the words “or conformity subject to regulation 17”.

Amendment of regulation 22

4. The principal Regulations are amended in regulation 22 by deleting subregulation (2) and substituting for it the following:

“(2) Subject to subregulation (1), where analysed samples have been found to comply with specifications, the Authority may dispose the samples by-

- (a) donating to the public institutions or health facilities upon both parties signing the handing over note with detailed information of the samples donated including, the quantity, value, generic name and reasons thereby;
- (b) in case of samples analysed upon request by the owner for export or any other commercial purpose, return and handover to the owner; and
- (c) for samples that were analysed as result of violation of the Act, conduct destruction in accordance with the disposal regulations.”.

Amendment of regulation 33

5. The principal Regulations are amended in regulation 33 by inserting the words “under these Regulations” immediately after the word “offence” appearing in paragraph (e).

Amendment of regulation 62

6. The principal Regulations are amended in regulation 62 by adding immediately after subregulation (3) the following:

“(4) The Minister shall, within thirty days from the date of the decision under subregulation (3), give notice of the decision made to the Appellant.”.

Amendment of
First Schedule

7. The principal Regulations are amended in the First Schedule by deleting reference to “regulation 56” in the enabling phrase appearing immediately after the heading “FORM NO. 5” and substituting for it a reference to “regulation 55”.

Dodoma,
30th December, 2022

UMMY A. MWALIMU,
Minister of Health