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

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REGULATIONS

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

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THE TANZANIA MEDICINES AND MEDICAL DEVICES (FEES AND CHARGES) REGULATIONS, 2021

ARRANGEMENT OF REGULATIONS

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PART I
PRELIMINARY PROVISIONS

Citation

1. These Regulations may be cited as the Tanzania Medicines and Medical Devices (Fees and Charges) Regulations, 2021.

Application

2. These Regulations shall apply in charging fees for regulatory activities, non-regulated and regulated products to include medicines, medical devices, diagnostics, laboratory equipment, blood and blood products, medical gases, antiseptics, disinfectants, tobacco products and other related medical products and health technologies in Mainland Tanzania.

Interpretation

3. In these Regulations, unless the context otherwise requires-

Cap. 219

"Act" means the Tanzania Medicines and Medical Devices Act;

"accreditation" means the formal recognition of a laboratory by the Authority in relation to the competence of the laboratory to conform to specified standards;

"alteration or variation fee" means a fee paid by a marketing authorisation holder in relation to alteration to be made regarding product composition, formulation, packaging, labelling or any other changes relating to alteration made to a registered product;

"animal biological specimens" means any material drawn from animals such as blood, urine, tissues, organs, saliva, spinal fluid, hair, nail clippings, or any other material of animal origin;

"annual retention fee" means a fee paid by the marketing authorisation holder for the purpose of retaining a registered product in the register of the Authority;

"antiseptic" means a product that inactivates, reduces, prevents or arrests growth of microorganisms with the inherent intent to mitigate or prevent disease on the skin or mucous membrane;

"biocidal products" means antiseptics or disinfectants;

"ceiling price" means a price set by the Authority for a medicinal product in accordance with the pricing formula provided for under these Regulations;

"cost including freight" means the amount of free on board cost plus freight charges and insurance premiums;

"commercial samples" means samples submitted by the customer for testing purposes which do not form part of marketing authorisation application;

"customer" means a person who receives laboratory services offered by the Authority;

"disinfectant" means an antimicrobial agent capable of destroying pathogenic and potentially pathogenic microorganisms on environmental surfaces and inanimate objects;

"disposal" means the process of donating samples fit for human consumption or rendering unfit samples or laboratory wastes such that they are harmless;

"domestic products" means products manufactured by facilities located within Mainland Tanzania;

"donation" means medicines, medical devices and diagnostics supplied by donor agencies recognised by the Authority but excluding medicines, medical devices and diagnostics supplied through vertical programmes;

"fees" means any charge made or levied in connection to services rendered by the Authority;

"freight on board or free on board or its acronym FoB" means a value of regulated product to be imported into mainland Tanzania;

GN. No. 295

"good manufacturing practices or its acronym GMP" means practices as described in Tanzania Medicines and Medical Devices (Good Manufacturing Practices) Regulations;

"imported products" means products manufactured outside Mainland Tanzania;

"innovator product" means the product that was first authorised worldwide for marketing (normally as a patented product) on the basis of the documentation of its efficacy, safety and quality, according to requirements at the time of authorisation;

"large scale enterprise" means an enterprise with capital investment exceeding eight hundred million shillings;

Caps. 287 and 288

"local government authority" means a district authority or an urban authority established by the Local Government (District Authorities) Act or the Local Government (Urban Authorities) Act;

"manufacturer" means a person or firm that is engaged in the manufacture of a product regulated under the Act;

"manufacturing" means all operations involved in the product preparation, processing, compounding, formulating, filling, refining, transformation, packing and labelling of product regulated under the Act;

"marketing authorisation holder" means a company, firm or organisation that has been granted a marketing authorisation which allows the holder to market a product regulated under the Act;

"medical supplies" means items that used for curative, prosthetic or medical care in the health facilities;

"medium scale enterprise" means an enterprise with capital investment of not less than two hundred million but not exceeding eight hundred million shillings;

"method validation or verification" means an action of proving and documenting that any procedure, process, equipment, activity or system will, with a high degree of assurance, lead to the expected results;

"Minister" means the Minister responsible for health;

"non-medical products" means all products that do not meet the definition of a medicine, medical device or diagnostics as set out in these Regulations;

"non-regulated products" means products other than regulated products;

GN. No. 412 of 2018

"orphan medicine" means a medicinal product designated as such under the terms and conditions set out in the Tanzania Medicines and Medical Devices (Orphan Medicines) Regulations;

"pre-licensing or registration inspection" means inspection carried out on premises to verify compliance with set requirements prior to granting of a license or permit or registration certificate;

"product carrier" means any box, detachable compartment, tank or container, receptacle, or any other arrangement in which a product may be carried in;

"product dealer" means a product manufacturer, packer, importer, exporter, distributor, seller or any other dealer in any product business to which the Act applies;

"quality management system" means coordinated activities, processes and procedures focused on ensuring quality and consistently meeting customer requirements including enhancing their satisfaction;

"registration certificate" means a certificate issued by the Authority in respect of a registered product or premises;

"regulated products" means medicines, medical devices, diagnostics, laboratory equipment, blood and blood products, medical gases, antiseptics, disinfectants and other related medical products and health technologies;

"sample" means a portion of a material or product collected for testing according to a defined sampling procedure;

"sampling" means operations designed to obtain a representative portion of a material or product, based on an appropriate statistical approach for a defined purpose to include acceptance of consignments or batch release;

"small scale enterprise" means an enterprise with capital investment exceeding five million shillings but less than two hundred million shillings;

"specifications" means a list of tests, references to analytical procedures and appropriate acceptance criteria, which are numerical limits, ranges, or other criteria for the tests described;

"tobacco product" means tobacco leaves, extracts of tobacco

leaves, cigarettes, cigars, cigarius, handrolling tobacco and includes other smoking tobacco products such as, pipe tobacco and any chewing tobacco which is manufactured whole or partly from tobacco or any substance used as substitute of tobacco; and

"vertical programmes" means national disease control programmes for malaria, human immunodeficiency virus and acquired immunodeficiency syndrome, tuberculosis and leprosy, immunisation, neglected tropical diseases and any other programme for diseases of public health importance recognised by the Authority.

PART II
FEES AND CHARGES

Fees and charges

4.-(1) Any person who intends to conduct business related to products regulated under the Act, shall pay fees and charges as specified in the First Schedule of these Regulations.

(2) A person may submit commercial samples for laboratory analysis and pay fees and charges as prescribed in the Second Schedule to these Regulations.

(3) A person may submit samples of non-regulated products for laboratory analysis and pay fees and charges as prescribed in the Third Schedule to these Regulations.

(4) Other services to be offered by the Authority shall be charged fees as prescribed in the Fourth Schedule to these Regulations.

(5) Fees and charges shall be paid in Tanzanian shillings or US$ equivalent to the amount of Tanzanian shillings or any convertible currency equal to the amount payable in Tanzanian shillings on the date of payment.

(6) The Minister may upon advice of the Director General, change or vary any fees and charges in force at any time.

(7) Failure to pay in time the fees and charges in force shall attract a penalty of fifteen percent of the total amount payable.

Appropriation of fees and

5.-(1) Fees and charges paid under these Regulations

charges

shall be collected and appropriated by the Authority.

(2) Fees and charges payable under these Regulations shall not be refundable.

(3) The Authority may, where satisfied that the declared value do not reflect the actual cost which were to be used to calculate FoB, reject the importation approval or uplift the value of consignment to the cost that would be the valued amount of the product or consignment.

Payment by order of court

6.-(1) When an order of the court requires a person to pay for fees and charges retrospectively for any regulated product or services, such pay shall include the calculated fifteen percent of the total amount ought to have been paid prior to the court order.

(2) The FoB charges shall be paid before importation of the respective consignment declared by the importer.

Fees and charges prescribed by other regulations

7.-(1) Any other regulations made under the Act for which fees and charges are prescribed, shall be deemed to have been part of these Regulations.

(2) A person who shall be charged to pay fees and charges under any other regulations made under the Act, shall be deemed to have complied with these Regulations and shall have the same legal effect as payment made under these Regulations.

Fees for GMP inspection and quality audits

8.-(1) Fees paid for Good Manufacturing Practice inspections or quality audits shall be determined and charged based on the manufacturing sites.

(2) The Authority shall charge additional fees not exceeding twenty five percent for each additional production line or block.

Fees for promotional materials

9.-(1) Promotional materials with medical claims shall be charged fees as prescribed in the First Schedule to these Regulations.

(2) Subject to subregulation (1), promotional materials that have no medical claims shall not be charged.

Fees for

10.-(1) Tobacco products shall be charged fees as

tobacco products

prescribed in the First Schedule to these Regulations.

(2) For the purpose of this regulation, tobacco products shall include cigarettes, cigars, hand-rolled tobacco, pipe tobacco, chewing tobacco and any other smoking tobacco.

PART III
GENERAL PROVISIONS

Offence and penalty

11. Any person who-

(a) contravenes or fails to comply with these Regulations;

(b) aid another person to commit an offence,

commits an offence and shall, on conviction, be liable to the penalty prescribed under the Act.

Compounding of offences

12.-(1) The Director General, Inspector or any other authorised person may, subject to and in accordance with the provisions of these Regulations, and upon being satisfied that a person has committed an offence against these Regulations, compound such offence by accepting from such person a sum of money in respect of which the offence has been committed.

(2) The sum of money payable under subregulation (1) shall be two third of the maximum amount of the fine for the offence as prescribed in the Act.

(3) The power conferred by this section shall be exercised where a person admits that he has committed an offence and agrees in writing in the form prescribed in the Fifth Schedule to these Regulations to the offence being dealt with under this regulation.

(4) The Director General or officer exercising powers under this regulation shall give to the person from whom he receives any sum of money under subregulation (2) a receipt which shall be in a prescribed form.

(5) Any sum of money received under this regulation shall be paid to the Authority.

(6) If any proceedings are brought against any person for an offence against these Regulations, it shall be a good defense if such person proves that the offence with which he

is charged has been compounded under this regulation.

Revocation and saving provision GN. No. 464 of 2015

13. (1) The Tanzania Food, Drugs and Cosmetics (Fees and Charges) Regulations, 2015 are hereby revoked.

(2) All fees, charges, orders or actions made under the revoked Regulations in regulation 9 shall be deemed to have been made under these Regulations.

SCHEDULES

FIRST SCHEDULE

(Made under regulation 4(1))

FEES AND CHARGES FOR REGULATED PRODUCTS

S/N	SERVICE	CURRENCY	FEE
	MEDICINES		
	Marketing Authorisation of Human and Veterinary Medicines (Domestic)		
1.	New or renewal application	TZS	1,000,000
2.	Variation – Major	TZS	200,000
3.	Variation – Minor	TZS	100,000
	Marketing Authorisation of Human, Veterinary Medicines and Biological Products (Imported)		
4.	New or renewal application – Non-biologicals	USD	2,000
5.	New or renewal application – Biologicals	USD	3,000
6.	Retention	USD	300
7.	Variation – Major	USD	1,000
8.	Variation – Minor	USD	300
9.	Fast track registration	USD	Double the respective fee
	Pricing of innovator medicinal products		
10.	New or renewal application for pricing	USD	200
	MEDICAL DEVICES		
	Marketing Authorisation of Medical Devices (Domestic)		
11.	Class A for notification (Non –Registrable)	TZS	50,000
12.	Class A (Registrable)	TZS	100,000
13.	Class B	TZS	200,000
14.	Class C	TZS	500,000
15.	Class D	TZS	500,000
16.	Variation – Major	TZS	150,000
17.	Variation – Minor	TZS	100,000
	Marketing Authorisation of Medical Devices (Imported)		
18.	Class A for notification (Non –Registrable)	USD	100
19.	Class A (Registrable)	USD	500
20.	Class B	USD	2,500
21.	Class C	USD	2,500
22.	Class D	USD	2,500
23.	Spare parts and Accessories	USD	500
24.	Variation – Major	USD	300
25.	Variation – Minor	USD	150
26.	Retention (Registered devices)	USD	200
27.	Retention (Notified devices)	USD	50
	DIAGNOSTICS		
	Marketing Authorisation of Diagnostics (Domestic)		
28.	Class A for notification (Non –Registrable)	TZS	50,000
29.	Class A (Registrable)	TZS	100,000

S/N	SERVICE	CURRENCY	FEE
30.	Class B	TZS	200,000
31.	Class C	TZS	500,000
32.	Class D	TZS	500,000
33.	Variation – Major	TZS	150,000
34.	Variation – Minor	TZS	100,000
	Marketing Authorisation of Diagnostics (Imported)		
35.	Class A for notification (Non –Registrable)	USD	100
36.	Class A (Registrable)	USD	300
37.	Class B	USD	1,000
38.	Class C	USD	1,500
39.	Class D	USD	2,000
40.	Variation – Major	USD	500
41.	Variation – Minor	USD	200
42.	Retention (Registered diagnostics)	USD	200
43.	Retention (Notified diagnostics)	USD	50
	Performance Evaluation Tests (Diagnostics)		
44.	Haematology Analyzer	USD	3,000
45.	Clinical Chemistry Analyzer	USD	3,500
46.	Molecular Analyzer	USD	5,300
47.	Chemi-luminescent Analyzer	USD	5,300
48.	Chromatography Analyzer	USD	4,800
49.	Molecular Analyzer- Sequencer	USD	5,300
50.	Diagnostic Tests (Laboratory and Field)	USD	3,000
51.	Staining Reagents, Media and Discs	USD	1,000
52.	Bacteriological Analyzer	USD	4,800
53.	Others	USD	3,000
	ANTISEPTICS AND DISINFECTANTS		
	Marketing Authorisation of Antiseptics and Disinfectants (Domestic)		
54.	New or renewal application	TZS	100,000
55.	Registration fees for antiseptics and disinfectants manufactured by small and medium enterprises	TZS	50,000
	Marketing Authorisation of Antiseptics and Disinfectants (Imported)		
56.	New or renewal application	USD	300
57.	Variation	USD	100
58.	Retention	USD	80
	TOBACCO PRODUCTS		
	Marketing Authorisation of tobacco products (Domestic)		
59.	New or renewal application	TZS	300,000
60.	Variation – Major	TZS	100,000
61.	Variation – Minor	TZS	50,000
	Marketing Authorisation of tobacco products (Imported)		
62.	New or renewal application	USD	300
63.	Variation – Major	USD	100
64.	Variation – Minor	USD	50
	CLINICAL TRIALS		
65.	Application to conduct clinical trials	USD	3,000
66.	Amendment-Major	USD	500
67.	Amendment-Minor	USD	300
68.	Fast track	USD	Double authorisation fee

S/N	SERVICE	CURRENCY	FEE
	GMP INSPECTION AND QUALITY AUDIT		
	GMP inspection and Quality Audit fee for medicines and medical device facilities per block (Foreign)		
69.	East Africa	USD	4,000
70.	Southern Africa Development Community (SADC) Countries	USD	4,500
71.	Rest of Africa	USD	5,000
72.	Asia	USD	6,000
73.	Europe	USD	6,500
74.	America	USD	7,500
75.	Australia and New Zealand	USD	7,500
	PROMOTIONAL MATERIALS		
	Evaluation and Approval of Promotional Materials		
	Medicinal Products		
76.	Promotional materials – Domestic	TZS	100,000
77.	Abbreviated advert – Domestic	TZS	50,000
78.	Promotional materials – Foreign	USD	100
79.	Abbreviated advert – Foreign	USD	50
	Tobacco Products		
80.	Annual enforcement fee for manufacturers, importers and wholesalers	TZS	500,000
	PERMITS		
81.	Trade fair permit-Foreign company	USD	200
82.	Change of Local Technical Representative	USD	2,000
83.	Large Pharmaceutical manufacturers	TZS	700,000
84.	Medium Pharmaceutical manufacturers	TZS	500,000
85.	Small Pharmaceutical manufacturers	TZS	300,000
86.	Large Medical Devices, Diagnostics and Medical Gases Manufacturers	TZS	700,000
87.	Medium Medical Devices, Diagnostics and Medical Gases Manufacturers	TZS	500,000
88.	Small Medical Devices, Diagnostics and Medical Gases Manufacturers	TZS	300,000
89.	Large Biocidal Manufacturers	TZS	500,000
90.	Medium Biocidal Manufacturers	TZS	300,000
91.	Small Biocidal Manufacturers	TZS	100,000
92.	Large Tobacco Product Manufacturers	TZS	500,000
93.	Medium Tobacco Product Manufacturers	TZS	300,000
94.	Pharmaceutical Importers	TZS	300,000
95.	Importing Warehouses	TZS	300,000
96.	Wholesale Veterinary Outlets	TZS	300,000
97.	Wholesale Medical Device Outlets	TZS	300,000
98.	Retail Medical Device Outlets	TZS	100,000
99.	Medical Device and Diagnostic Warehouses	TZS	300,000
100.	Disposal charge on value of condemned products	TZS	25%
101.	Inspection of consignments at owners premises	TZS	100,000
	IMPORTATION FEES		
102.	Medicinal Products	FoB	2%
103.	Medical devices and diagnostics	FoB	2%
104.	Antiseptics and disinfectants	FoB	2%

S/N	SERVICE	CURRENCY	FEE
105.	Donated medicines, medical devices and diagnostics	FoB	0.25%
106.	Medical laboratory equipment	FoB	2%
107.	Accessories and spare parts for medical devices, diagnostics and medical laboratory equipment	FoB	0.50%

SECOND SCHEDULE

(Made under regulation 4(2))

LABORATORY COMMERCIAL SAMPLES ANALYSIS

S/N	PARAMETERS	FEES in TZS
	MEDICINES	
	Tablets, Capsules and Sachets	
1.	Physical examination	10,000
	Identification tests	
2.	by UV/VIS Spectrophotometer	150,000
3.	by HPLC for each API	1,000,000
4.	by FTIR	230,000
5.	by TLC	300,000
6.	by Colour reaction	180,000
7.	by Melting point	70,000
8.	by Optical rotation	70,000
	Assay	
9.	by UV/VIS Spectrophotometer	400,000
10.	by HPLC for each API	1,500,000
11.	by Titration	500,000
12.	Bioassay	400,000
	Dissolution	
13.	by UV/VIS Spectrophotometer	300,000
14.	by HPLC for each API	1,600,000
	Uniformity of dosage unit	
15.	Content Uniformity by UV/VIS Spectrophotometer	740,000
16.	Content Uniformity by HPLC for each API	3,000,000
17.	by Weight Variation	60,000
	Related Substances or impurities	
18.	by HPLC (limit)	1,200,000
19.	by HPLC for each API	1,500,000
20.	by TLC	800,000
21.	by TLC (limit)	150,000
	Residual solvents	

S/N	PARAMETERS	FEES in TZS
22.	by GC/MS	1,500,000
	Moisture Content	
23.	by Loss on drying	160,000
24.	by KF	1,000,000
25.	by direct titration	1,000,000
26.	by distillation	130,000
	Other tests	
27.	Disintegration	80,000
28.	Hardness	20,000
29.	Friability	60,000
30.	Sulphated Ash	530,000
31.	Heavy metals by for each heavy metal by MPAES	100,000
32.	Fineness of dispersion (dispersible tablets)	80,000
	Microbiological Tests	
33.	Total Aerial Microbial Count	390,000
34.	Yeast/Mould Count	330,000
35.	*Escherichia coli*	280,000
36.	*Pseudomonas aeruginosa*	280,000
37.	Salmonella	350,000
38.	*Staphylococcus aureus*	350,000
	Syrups, Suspensions, Solutions and Powder or Granules for Suspension	
39.	Physical examination	10,000
	Identification	
40.	by UV/VIS Spectrophotometer	150,000
41.	by HPLC for each API	1,000,000
42.	by FTIR	240,000
43.	by TLC	400,000
44.	by Colour reaction	180,000
45.	by Optical rotation	70,000
	Assay	
46.	by UV/VIS Spectrophotometer	400,000
47.	by HPLC for each API	1,500,000
48.	by Titration	500,000
49.	Bioassay	400,000
	Uniformity of dosage unit	
50.	Content Uniformity by UV/VIS Spectrophotometer	750,000
51.	Content Uniformity by HPLC for each API	3,000,000
52.	by Weight Variation	60,000
	Related Substances or impurities	
53.	by HPLC (limit)	1,200,000
54.	by HPLC for each API	1,500,000

S/N	PARAMETERS	FEES in TZS
55.	by TLC	800,000
56.	by TLC(limit)	140,000
57.	Deliverable volume	60,000
	Residual solvents	
58.	by GC/MS	1,500,000
	Moisture Content	
59.	by Loss on drying	160,000
60.	by KF	1,000,000
61.	by direct titration	1,000,000
62.	by distillation	130,000
	Microbiological Tests	
63.	Total Aerial Microbial Count	390,000
64.	Yeast/Mould Count	330,000
65.	*Escherichia coli*	280,000
66.	*Pseudomonas aeruginosa*	280,000
67.	Salmonella	350,000
68.	*Staphylococcus aureus*	350,000
	Other Tests	
69.	Sulphated Ash	530,000
70.	Heavy metals by for each heavy metal by MPAES	100,000
71.	pH	20,000
72.	Weight /mL	55,000
73.	Sulphated Ash	530,000
	Injectables (Large & Small Volumes) and Dry powders for injection	
74.	Physical examination	10,000
75.	Assay	
76.	by UV/VIS Spectrophotometer	400,000
77.	by HPLC for each API	1,500,000
78.	by MPAES	1,200,000
79.	by Optical Rotation	70,000
80.	by Titration	500,000
81.	Bioassay	400,000
	Identification	
82.	by UV/VIS Spectrophotometer	150,000
83.	by HPLC for each API	1,000,000
84.	by FTIR	240,000
85.	by TLC	400,000
86.	by Colour reaction	180,000
87.	by Optical rotation	70,000
	Moisture Content	
88.	by Loss on drying	160,000
89.	by KF	1,000,000

S/N	PARAMETERS	FEES in TZS
90.	by direct titration	1,000,000
91.	by distillation	120,000
92.	pH	20,000
	Related Substances or impurities	
93.	by HPLC (limit)	1,200,000
94.	by HPLC for each API	1,500,000
95.	by TLC	800,000
96.	by TLC (limit)	140,000
	Residual solvents	
97.	by GC/MS	1,500,000
	Uniformity of dosage unit	
98.	Content Uniformity by UV/VIS Spectrophotometer	700,000
99.	Content Uniformity by HPLC	2,900,000
100.	by Weight Variation	60,000
	Other Tests	
101.	Limit test in Heavy metals for each heavy metal by MPAES	100,000
102.	Sulphated Ashes	530,000
103.	Deliverable volume	60,000
104.	Clarity of solution	60,000
105.	Particulate Matter	60,000
106.	Colour of solution	800,000
107.	Extractable volume	50,000
	Sterility	
108.	by filtration	320,000
109.	by closed system	350,000
110.	Bacterial endotoxins	350,000
	External Preparations	
	Creams, Ointments, Gels and Lotions (Sterile and Non-Sterile)	
111.	Physical examination	10,000
	Assay	
112.	by UV/VIS Spectrophotometer	400,000
113.	by HPLC for each API	1,400,000
114.	by Titration	520,000
115.	Bioassay	400,000
	Identification	
116.	by UV/VIS Spectrophotometer	150,000
117.	by HPLC for each API	1,000,000
118.	by FTIR	240,000
119.	by TLC	400,000
120.	by Colour reaction	180,000
	Uniformity of dosage unit	
121.	by UV/VIS Spectrophotometer	750,000

S/N	PARAMETERS	FEES in TZS
122.	by HPLC for each API	3,000,000
123.	by Weight Variation	60,000
	Water content	
124.	by KF	1,000,000
125.	by distillation	120,000
	Limit of other impurities	
126.	Limit test in Heavy metals for each heavy metal by MPAES	100,000
127.	Sulphated Ash	530,000
	Microbiological Tests	
128.	Total Aerial Microbial Count	390,000
129.	Yeast/Mould Count	330,000
	Inhalers and Aerosols	
130.	Physical examination	10,000
	Identification	
131.	by UV/VIS Spectrophotometer	150,000
132.	by HPLC for each API	1,000,000
133.	by FTIR	230,000
134.	by TLC	300,000
135.	by Colour reaction	180,000
136.	by Optical rotation	70,000
	Assay	
137.	by UV/VIS Spectrophotometer	400,000
138.	by HPLC for each API	1,500,000
139.	by Titration	400,000
	Uniformity of delivered dose	
140.	by determination of contents	1,450,000
141.	Deposition of the Emitted dose	1,450,000
	Related Substances or impurities	
142.	by HPLC for each API	1,200,000
143.	by HPLC (limit)	1,500,000
144.	by TLC	800,000
145.	by TLC(limit)	140,000
	Moisture Content	
146.	by Loss on drying	160,000
147.	by KF	1,000,000
148.	by direct titration	1,000,000
149.	by distillation	120,000
	Leak test	
150.	Direct measurement	60,000

S/N	PARAMETERS	FEES in TZS
	Other Tests	
151.	Sulphated Ash	530,000
152.	Heavy metals for each metal by MPAES	100,000
	Microbiological Tests	
153.	Total Aerial Microbial Count	390,000
154.	Yeast/Mould Count	330,000
	Eye, Nose and Ear drops	
155.	Physical examination	10,000
	Assay	
156.	by UV/VIS Spectrophotometer	400,000
157.	by HPLC for each API	1,000,000
158.	by Titration	500,000
159.	Bioassay	400,000
	Identification	
160.	by UV/VIS Spectrophotometer	150,000
161.	by HPLC for each API	1,000,000
162.	by FTIR	240,000
163.	by TLC	400,000
164.	by Colour reaction	180,000
165.	by Optical rotation	70,000
	Water Content	
166.	by KF	1,000,000
167.	by direct titration	1,000,000
168.	by distillation	130,000
169.	pH	20,000
	Related Substances or impurities	
170.	by HPLC	1,200,000
171.	by HPLC (limit)	1,500,000
172.	by TLC	800,000
173.	by TLC(limit)	140,000
	Uniformity of dosage unit	
174.	Content Uniformity by UV/VIS	730,000
175.	Content Uniformity by HPLC	2,900,000
176.	by Weight Variation	60,000
	Other Tests	
177.	Limit test in Heavy metals	200,000
178.	Sulphate Ash	530,000
179.	Leakage	60,000
180.	Metal particles	60,000
	Sterility	
181.	by filtration	320,000
182.	by closed system	350,000

S/N	PARAMETERS	FEES in TZS
	BIOCIDAL PRODUCTS	
	Antiseptics	
	Hand sanitisers	
183.	Alcohol content by alcohometer	10,000
184.	Alcohol content by GC/MS	100,000
185.	pH	20,000
186.	Hydrogen peroxide (as preservative) by titration	50,000
187.	Methanol limit test by GC/MS	100,000
	Methylated spirits	
188.	Alcohol content by alcohometer	10,000
189.	Alcohol content by GC/MS	100,000
	Povidone Iodine	
190.	Iodine content by titration	50,000
	Disinfectants	
191.	Assay by titration	50,000
192.	Assay by GC/MS	100,000
193.	Challenge test	300,000
	Raw Materials (Active Pharmaceutical Ingredients and Excipients)	
194.	Appearance/Description	20,000
	Assay	
195.	by UV/VIS Spectrophotometer	400,000
196.	Bioassay	400,000
197.	by HPLC	1,500,000
198.	by Titration	500,000
	Identification	
199.	by UV/VIS Spectrophotometer	150,000
200.	by HPLC	1,500,000
201.	by FTIR	240,000
202.	by TLC	400,000
203.	by LC/MS	1,000,000
204.	by GC/MS	1,000,000
205.	by Colour reaction	180,000
206.	by Optical rotation	70,000
207.	by Melting point	70,000
	Moisture Content	
208.	by Loss on drying	160,000
209.	by KF	1,000,000
210.	by Direct titration	1,000,000
211.	by Distillation	130,000
	Related Substances or impurities	
212.	by HPLC (limit)	1,200,000
213.	by HPLC	1,500,00

S/N	PARAMETERS	FEES in TZS
		0
214.	by TLC	800,000
215.	by TLC (limit)	140,000
	Residual solvents	
216.	by GC/MS	1,500,000
	Other Tests	
217.	Heavy metals by limits test	200,000
218.	Sulphated Ash	530,000
	Microbiological Tests	
219.	Total Aerial Microbial Count	390,000
220.	Yeast/Mould Count	330,000
221.	*Escherichia coli*	280,000
222.	*Pseudomonas aeruginosa*	280,000
223.	Salmonella	360,000
224.	*Staphylococcus aureus*	360,000
	TOBACCO PRODUCTS	
225.	Nicotine by GC/MS	1,500,000
226.	Ammonia by HPLC	1,000,000
227.	Humectants by GC/MS	1,500,000
228.	Tar, nicotine, carbon monoxide by GC/MS and IR (Non dispersive)	1,200,000
229.	TSNAs by LC/MS/MS	2,000,000
230.	Benzol-alphapyrene by GC/MS	1,000,000
231.	Benzene and 1,3 butadiene by GC/MS	1,000,000
232.	Carbonyls by HPLC – Diode Array Detector	1,500,000
233.	Hydrogen cyanide by Continuous Flow Calorimeter	400,000
234.	Nitrogen oxide by Chemiluminescence Nitrogen Oxide Analyzer	500,000
235.	Metals by MPEAS for each metal	100,000
236.	Metals by ICP-AES	100,000
	MEDICAL DEVICES	
	Condoms (Male and Female) and Gloves	
237.	Length (mm)	50,000
238.	Width (mm)	50,000
239.	Thickness (mm)	50,000
240.	Packaging integrity	130,000
241.	Bursting Pressure (kPa) and Volume (L)	500,000
242.	Visible Defects	20,000
243.	Freedom from holes - Water leakage test	500,000
244.	Freedom from holes by Electrical leakage test	500,000
245.	Tensile properties	320,000
246.	Top ring diameter (mm)	50,000

S/N	PARAMETERS	FEES in TZS
247.	Top ring thickness (mm)	50,000
248.	Inner ring height (mm)	50,000
249.	Inner ring thickness (mm)	50,000
250.	Inner ring external diameter (mm)	50,000
251.	Lubricant Quantity (mg)	150,000
	Diapers and sanitary pads	
252.	Absorbance capacity	80,000
253.	Absorbance rate (s)	80,000
254.	pH	20,000
255.	Moisture content	130,000
256.	Water soluble extract	60,000
257.	Fluorescence	150,000
258.	Flushability	300,000
259.	Water soluble colouring matter	60,000
	Absorbent cotton and gauze	
260.	Sinking time (s)	80,000
261.	Water holding capacity (g)	80,000
262.	pH	20,000
263.	Foreign fibres	100,000
264.	Fluorescence	150,000
265.	Neps	100,000
266.	Ether soluble substance	60,000
267.	Extractible colouring matter	200,000
268.	Surface-active substances	60,000
269.	Water soluble substances	60,000
270.	Loss on drying	130,000
271.	Sulphated ash	500,000
272.	Thread count	60,000
273.	Minimum breakable load	50,000
	Plaster of Paris and Zinc Oxide	
274.	Percentage of $CaSO_4.½H_2O$	500,000
275.	Percentage of ZnO	500,000
276.	Adhesiveness	230,000
	Sutures	
277.	Length	50,000
278.	Diameter	50,000
279.	Tensile strength	320,000
280.	Needle attachment	100,000
281.	Identification tests	100,000
282.	Heavy Metals per element by MPAES	100,000
283.	pH	20,000
284.	Sterility	350,000
	Syringes, needle, cannula and infusion set	
285.	Syringe separation force	230,000
286.	Syringe Liquid Leakage	230,000
287.	Air Leakage Past syringe Piston	230,000
288.	Test for forces required to operate piston	100,000
289.	Freedom from air and liquid leakage	230,000

S/N	PARAMETERS	FEES in TZS
290.	Dead space	80,000
291.	Quantity of silicone	150,000
292.	Fit of plunger/stopper in barrel	50,000
293.	Acidity or alkalinity	20,000
294.	Extractible metals	60,000
295.	Container closure integrity	100,000
296.	Drug-container integrity	100,000
297.	Flow rate through needle	60,000
298.	Penetration force and drag force	50,000
299.	Needle bonding strength	50,000
300.	Corrosion resistance	100,000
301.	Peak tensile force	60,000
	Surgical Blades	
302.	Angle (□)	100,000
303.	Hole distance (d)	100,000
304.	Hole diameter (e)	100,000
305.	Sharpness	200,000
306.	Determination of Fitting Dimension	200,000
	Microscopes	
307.	Performance verification	1,000,000
	Face masks	
	Medical and N95 Masks	
308.	Air Permeability	100,000
309.	Bacterial filtration efficiency %	320,000
310.	Splash resistance	250,000
311.	Bacterial cleanliness	300,000
312.	Contamination with SARS CoV-2 Virus	300,000
	IUDs	
	Copper-bearing intrauterine devices	
313.	Dimensions	80,000
314.	Tensile force	320,000
315.	Visco-elastic property (memory test)	50,000
316.	Barium sulfate content	150,000
317.	Sterility	350,000
	Orthopedic implants and accessories	
318.	Visual inspection	50,000
319.	Particulate contamination	100,000
320.	Organic contaminants	60,000
321.	Inorganic contaminants	60,000
322.	Bio burden	350,000
323.	Bacterial endotoxins	350,000
	Surgical adhesive plaster and bandage	
324.	Physical examination	50,000
325.	Zinc oxide content	150,000
326.	Tensile strength	320,000
327.	Weight of adhesive mass	50,000
328.	Adhesive property –adhesive strength	50,000
329.	Sterility	350,000

S/N	PARAMETERS	FEES in TZS
330.	Peel test/ peeling force	50,000
331.	Elongation across fabric width	80,000
	DIAGNOSTICS	
	Widal test kit	
332.	Sensitivity vs serodiagnosis of typhoid by ELISA/PCR	1,000,000
333.	Specificity (false positive,negatives)	1,000,000
	HIV test kit	
334.	Sensitivity test	650,000
	Blood grouping reagents	
335.	Specificity-Test for IgM and IgG red blood cells heterospecific antibodies	1,000,000
336.	Potency - anti-IgG potency by chequerboard titration studies	1,000,000
337.	Test for unwanted positive reactions	1,000,000
	Malaria rapid diagnostic kit	
338.	Sensitivity test	650,000
339.	Specificity test	650,000
	Syphilis Diagnostic Kit	
340.	Sensitivity test	650,000
341.	Specificity test	650,000
	Urine Pregnancy test Kit	
342.	Sensitivity test	650,000
343.	Specificity test	650,000

THIRD SCHEDULE

(Made under regulation 4(3))

NON-REGULATED PRODUCT SAMPLES ANALYSIS AND OTHER SERVICES

SN	PARAMETERS	FEES
	HUMAN BIOLOGICAL SAMPLES	
	Identification and quantification tests	
1.	Identification of heavy metals by MPAES for each element	100,000
2.	Quantification of heavy metals by MPAES for each element	100,000
3.	Identification and quantification of drug residues by HPLC for each API	1,500,000
4.	Identification and quantification of drug residues by LC/MSMS for each API	2,000,000
5.	Identification and quantification of drug metabolites by HPLC for each API	1,500,000
6.	Identification and quantification of drug metabolites by LC/MSMS for each API	2,000,000

SN	PARAMETERS	FEES
	Microbiological Tests	
7.	Total Aerial Microbial Count	390,000
8.	Yeast/Mould Count	330,000
9.	*Escherichia coli*	280,000
10.	*Pseudomonas aeruginosa*	280,000
11.	Salmonella	350,000
12.	*Staphylococcus aureus*	350,000
13.	Detection and quantification of target nucleic acid per test by PCR	60,000
	FOOD SAMPLES	
	Identification and quantification tests	
14.	Identification and quantification of mycotoxins content for each mycotoxin by HPLC	250,000
15.	Identification and quantification of mycotoxins content by LC/MSMS	1,500,000
16.	Identification of heavy metals by MPAES for each element	100,000
17.	Quantification of heavy metals by MPAES for each element	100,000
18.	Identification and quantification of veterinary drug residues by HPLC for each API	1,500,000
19.	Identification and quantification of veterinary drug residues by LC/MSMS for each API	2,000,000
20.	Alcohol content in alcoholic beverages by GC/MS	100,000
21.	Methanol contamination in alcoholic beverages by GC/MS	100,000
	Microbiological Tests	
22.	Total Aerial Microbial Count	390,000
23.	Yeast/Mould Count	330,000
24.	*Escherichia coli*	280,000
25.	*Pseudomonas aeruginosa*	280,000
26.	Salmonella	350,000
27.	*Staphylococcus aureus*	350,000
28.	*Bacillus cereus*	350,000
	COSMETIC SAMPLES	
29.	Identification of banned ingredients (steroids and hydroquinone) by TLC	50,000
30.	Identification and quantification of heavy metals by MPAES	100,000
	SOIL SAMPLES	
31.	Identification and quantification of soil minerals for each element by MPEAS	100,000
32.	pH	20,000
	WATER SAMPLES	
	Identification and quantification tests	
33.	Identification and quantification of minerals for each element by MPEAS	100,000
34.	Identification and quantification of drug residues by HPLC for each API	1,500,000
35.	Identification and quantification of drug residues by LC/MSMS for each API	2,000,000
36.	Identification and quantification of pesticides by GC/MS	300,000
37.	Conductivity	20,000

SN	PARAMETERS	FEES
38.	pH	20,000
	Microbiological Tests	
39.	Total Aerial Microbial Count	390,000
40.	Yeast/Mould Count	330,000
41.	*Escherichia coli*	280,000
42.	*Pseudomonas aeruginosa*	280,000
43.	Salmonella	350,000
44.	*Staphylococcus aureus*	350,000
45.	*Bacillus cereus*	350,000
46.	Total coliforms	350,000
	OTHER SERVICES	
47.	Purification of water per 30 Litres	40,000
48.	Sterilization of hospital garments and supplies (for each item) by steam sterilizer or autoclave	10,000
49.	Analytical method verification for each API	1,000,000
50.	Analytical method validation for each API	3,000,000
51.	Analytical method development and validation for each API	10,000,000

FOURTH SCHEDULE

(Made under regulation 4(4))

TRAINING AND ACCREDITATION SERVICES

SN	TRAINING SERVICES	FEES IN USD (per person)
1.	Training on Good Regulatory Practices	500
2.	Training on compilation and assessment of quality of Active Pharmaceutical Ingredients	500
3.	Training on compilation and assessment of quality of Finished Pharmaceutical Products	500
4.	Training on compilation and assessment of bioequivalence studies data	500
5.	Training on compilation and assessment of quality of biological and biosimilar products	1,000
6.	Training on compilation and assessment of non – clinical and clinical studies data	800
7.	Training on compilation and assessment of herbal medicines	500
8.	Training on Good Manufacturing Practices	1,000
9.	Training on Good Storage and Distribution Practices	100
10.	Training on Good Clinical and Laboratory Practices	1,000
11.	Training on Pharmacovigilance and Risk Management	500

12.	Training on haemovigilance	100
13.	Training on Quality Management System - ISO 9001	400
14.	Training on Quality Management System - ISO17025	400
15.	Training on Quality Management System - ISO13485	400
16.	Training on Quality Management System - ISO15189	400
17.	Training on laboratory analytical techniques	800
18.	Training on analytical method development and validation	1,000
19.	Training on microbiological testing	500
	ACCREDITATION SERVICES	
20.	Application for accreditation	200
21.	Resubmission of documentation for accreditation	300
22.	Extension of non-critical scope (desk review)	200
23.	Initial assessment	500
24.	Annual accreditation fee	100
25.	Scope extension (if it involves site visit)	500

FIFTH SCHEDULE

(Made under regulation 12(3))

COMPOUNDING FORM

TMDA No.....
Station .....
Date .....

I, ...
(name)
of .....
(address)
do hereby admit that I have contravened section/regulation .....
(state the provision of law contravened)
by .....
(state particulars of offence)
.....
and hereby declare that rather than being prosecuted for the commission of the aforementioned offence, on my own free will, I admit that the said offence be compounded under regulation 11 of the Tanzania Medicines and Medical Devices (Fees and Charges) Regulations, 2021 by
.....
(name of officer compounding the offence)
AND I,.....
(the name and designation of officer compounding the offence
....., in exercise of the power conferred upon me by regulation 11 of the Tanzania Medicines and Medical Devices (Fees and Charges) Regulations, 2021, hereby order that.....
(name of the offender)
to pay the sum of ..... Tanzania shillings (TZS. .....) by way of compounding and that the following exhibit(s) are hereby forfeited to the Government.
(List products forfeited)
.....
.....

Dated this ..... day of ....., 20.....

.....	.....
(Signature of offender)	(Signature of officer compounding offence)
.....	.....
(witness)	(witness)

The payment of the said sum of .....Tanzania shillings has been made vide control No. ..... Dated.....which has been issued to the offender.

.....

(Signature of Officer compounding offence)

This form shall be issued in triplicate and the original copy shall be served to the offender. A duplicate copy shall be forwarded to the accountant, and the triplicate copy to the Director General.

Dodoma
6th September, 2021

DOROTHY O. GWAJIMA
Minister for Health, Community Development, Gender, Elderly and Children