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) (AMENDMENT) REGULATIONS, 2024

Citation GN. No. 686 of 2021	**1.** These Regulations may be cited as the Tanzania Medicines and Medical Devices (Fees and Charges) (Amendment) Regulations, 2024 and shall be read as one with the Tanzania Medicines and Medical Devices (Fees and Charges) Regulations, 2021.
Amendment of regulation 3	**2.** -(1) The principal Regulations are amended in regulation 3 by adding at the end of the definition of "annual retention fee" the words "and facilitating post marketing surveillance of medical products circulating on the Tanzanian market".
	(2) The principal Regulations are amended in regulation 3 by adding new definitions as follows: - "abbreviated advert" means advertisement which is exempted from the requirement to include prescribing information for the advertised product; "bioequivalence" means the absence of a significant difference in the bioavailability between two pharmaceutically equivalent products under similar conditions in an appropriately designed study; "biosimilar" means a biological medicine highly similar to another already approved biological medicine or reference medicine; "class A" means low risk medical devices or diagnostics including laboratory equipment; "class B" means low to moderate risk medical devices or diagnostics; "class C" means moderate to high risk medical devices or diagnostics; "class D" means high risk medical devices or diagnostics; "good storage and distribution practices" means the part of quality assurance that ensures the quality , safety and efficacy or performance of a regulated product is maintained throughout the supply chain until when it reaches the patient; "good clinical and laboratory practice" means a set of standards that provides guidance on implementing good clinical practice or its acronym

	"GCP" and good laboratory practice or its acronym "GLP" principles; "good clinical practice" means an ethical and scientific quality standard for designing, conducting ,performing, monitoring, auditing, recording analyzing and reporting clinical trials that involve the participation of human beings; "good laboratory practice" means a quality system that covers the organizational process and the conditions under which non-clinical laboratory studies are planned, performed , monitored, recorded, archives and reported; "hemovigilance" means a set of organized surveillance procedures relating to serious adverse or unexpected events or reactions in donors or recipients and epidemiological follow up of donors; "incineration" means the waste treatment process that involves combustion of substances contained in waste materials; "incinerator" means a furnace or apparatus for burning waste at high temperature; "ISO 13485" means an international standard setting the minimum requirements to be met by organizations involved in the design, production, installation and servicing of medical devices and related products; "major variations" mean changes that could have major effects on the overall quality, safety and efficacy or performance of a regulated product; "marketing authorization or registration" means an official approval of a regulated product to be marketed or distributed in Tanzania; "medical gases" means any gas that is intended for therapeutic use for; a. treatment and prevention of diseases; b. performing diagnostic tests; c. calibration machines used for making diagnostic test; and d. restoration, correction and modification of physiological functions in human beings. and includes oxygen, medical air, nitric oxide and mixtures of helium, oxygen and carbon monoxide. "minor variations" mean changes that may have minor effects on the overall quality, safety and efficacy or performance of a regulated product; "notification" "pharmacovigilance" means the science and activities relating to detection, assessment, understanding and prevention of adverse events or any other possible related medicine problems and shall have the same

	meaning to medical devices and diagnostics; "post marketing surveillance" means the monitoring of regulated products including tobacco products once they reach the market after marketing authorization or registration; "positive list of items" means the list of pharmaceutical items produced or manufactured by local pharmaceutical industries with quantity enough to meet the country need; "promotional materials" means any representation concerning the attributes of the product conveyed by any means whatever the purpose of encouraging the usage of the product; "quality audit" means inspection of medical devices and diagnostics manufacturing facilities for the purpose of establishing compliance to ISO 13485; "register" means official list of products registered or authorized to be marketed in Tanzania Mainland and gazette in the government gazette; "retention" means an act of retaining a regulated product on the register and subsequent enforcement activities including post marketing surveillance and vigilance; "risk management" means a set of activities and interventions designed to identify, characterize, prevent or minimize risks relating to regulated products, including the assessment of the effectiveness of those interventions; and "social media" means a digital technology that allows the sharing of ideas and information including texts and visual through visual networks and communities.
Amendment of regulation 9	**3.** The principal Regulations are amended by adding sub regulation 3 with the words "subject to sub regulation (1) promotional materials advertised online and social media shall be charged fees as prescribed in these Regulations".
Deletion and substitution of Schedules	**4.** The principal Regulations are amended by deleting the First, Second, Third, Fourth and Fifth Schedule and substituting for them the following: -

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 - non-biologicals	TZS	1,000,000
2.	New or renewal application - biologicals	TZS	3,000,000
3.	Variation – Major	TZS	200,000
4.	Variation – Minor	TZS	100,000
	Marketing Authorisation of Human, Veterinary Medicines and Biological Products (Imported)		
5.	New or renewal application – non-biologicals	USD	2,000
6.	New or renewal application – biologicals	USD	3,000
7.	Retention	USD	300
8.	Variation – Major	USD	1,000
9.	Variation – Minor	USD	300
10	Fast track registration	USD	Double the respective fee
	Pricing of innovator medicinal products		
11	New or renewal application for pricing	USD	200
	MEDICAL DEVICES		
	Marketing Authorisation of Medical Devices (Domestic)		
12	New or renewal Class A for notification (Non – Registrable)	TZS	50,000
13	New or renewal medical laboratory equipment	TZS	50,000
14	New or renewal Class A (Registrable)	TZS	100,000
15	New or renewal Class B	TZS	200,000
16	New or renewal Class C	TZS	500,000
17	New or renewal Class D	TZS	500,000
18	Variation – Major	TZS	150,000
19	Variation – Minor	TZS	100,000
	Marketing Authorisation of Medical Devices (Imported)		
20	New or renewal Class A for notification (Non – Registrable)	USD	50
21	New or renewal medical laboratory equipment	USD	50
22	New or renewal Class A (Registrable)	USD	500
23	New or renewal Class B	USD	2,500
24	New or renewal Class C	USD	2,500
25	New or renewal Class D	USD	2,500
26	Variation – Major	USD	250
27	Variation – Minor	USD	150
28	Retention (Registered devices)	USD	200
29	Retention (Notified devices)	USD	30
	DIAGNOSTICS		
	Marketing Authorisation of Diagnostics (Domestic)		
30	New or renewal Class A for notification (Non – Registrable)	TZS	50,000
31	New or renewal Class A (Registrable)	TZS	100,000

S/N	SERVICE	CURRENCY	FEE
32.	New or renewal Class B	TZS	200,000
33.	New or renewal Class C	TZS	500,000
34.	New or renewal Class D	TZS	500,000
35.	Variation – Major	TZS	150,000
36.	Variation – Minor	TZS	100,000
	Marketing Authorisation of Diagnostics (Imported)		
37.	New or renewal Class A for notification (Non – Registrable)	USD	50
38.	New or renewal Class A (Registrable)	USD	300
39.	New or renewal Class B	USD	1,000
40.	New or renewal Class C	USD	1,500
41.	New or renewal Class D	USD	2,000
42.	Variation – Major	USD	400
43.	Variation – Minor	USD	200
44.	Retention (Registered diagnostics)	USD	200
45.	Retention (Notified diagnostics)	USD	30
	Performance Evaluation Tests (Diagnostics)		
46.	Haematology Analyzer	USD	2000
47.	Clinical Chemistry Analyzer	USD	2500
48.	Molecular Analyzer	USD	4500
49.	Chemi-luminescent Analyzer	USD	4500
50.	Chromatography Analyzer	USD	3800
51.	Molecular Analyzer- Sequencer	USD	4500
52.	Diagnostic Tests (Laboratory and Field)	USD	2000
53.	Staining Reagents, Media and Discs	USD	1000
54.	Bacteriological Analyzer	USD	3800
55.	Performance verification for selected diagnostics	USD	3000
	ANTISEPTICS AND DISINFECTANTS		
	Marketing Authorisation of Antiseptics and Disinfectants (Domestic)		
56.	New or renewal application	TZS	100,000
57.	Registration fees for antiseptics and disinfectants manufactured by small and medium enterprises	TZS	50,000
	Marketing Authorisation of Antiseptics and Disinfectants (Imported)		
58.	New or renewal application	USD	300
59.	Variation	USD	100
60.	Retention	USD	50
	TOBACCO PRODUCTS		
	Post marketing surveillance of tobacco products		
61.	Inspection, sample collection and laboratory analysis for harmful ingredients (per product)	TZS	300,000
	CLINICAL TRIALS		
62.	Application to conduct clinical trials	USD	3,000
63.	Amendment-Major	USD	500
64.	Amendment-Minor	USD	300
65.	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)		
66.	East Africa	USD	4,000
67.	Southern Africa Development Community (SADC) Countries	USD	4,500
68.	Rest of Africa	USD	5,000
69.	Asia	USD	6,000
70.	Europe	USD	6,500
71.	America	USD	7,500
72.	Australia and New Zealand	USD	7,500
	PROMOTIONAL MATERIALS		
	Evaluation and Approval of Promotional Materials for Medicines, Medical Devices and Diagnostics		
73.	Promotional materials – Domestic	TZS	100,000
74.	Promotional materials – Foreign	USD	100
75.	Abbreviated advert – Foreign	USD	50
76.	Online and social media adverts	TZS	200,000
	PERMITS		
77.	Trade fair permit-Foreign company	USD	200
78.	Change of Local Technical Representative	USD	1,800
79.	Large Pharmaceutical manufacturers	TZS	700,000
80.	Medium Pharmaceutical manufacturers	TZS	500,000
81.	Small Pharmaceutical manufacturers	TZS	300,000
82.	Large Medical Devices, Diagnostics and Medical Gases Manufacturers	TZS	700,000
83.	Medium Medical Devices, Diagnostics and Medical Gases Manufacturers	TZS	500,000
84.	Small Medical Devices, Diagnostics and Medical Gases Manufacturers	TZS	300,000
85.	Large Biocidal Manufacturers	TZS	500,000
86.	Medium Biocidal Manufacturers	TZS	300,000
87.	Small Biocidal Manufacturers	TZS	100,000
88.	Pharmaceutical Importers	TZS	300,000
89.	Importing Warehouses	TZS	300,000
90.	Wholesale Veterinary Outlets	TZS	300,000
91.	Wholesale Medical Device Outlets	TZS	300,000
92.	Retail Medical Device Outlets	TZS	100,000
93.	Medical Device and Diagnostic Warehouses	TZS	300,000
94.	Disposal charge on value of condemned products	TZS	25%
95.	Incineration (per kg)	TZS	2,000
96.	Inspection of consignments at owners premises	TZS	100,000
	IMPORTATION FEES		
97.	Medicinal Products	FoB	2%
98.	Medical devices and diagnostics	FoB	2%
99.	Antiseptics and disinfectants	FoB	2%

S/N	SERVICE	CURRENCY	FEE
100	Donated medicines, medical devices and diagnostics	FoB	0.25%
101	Medical laboratory equipment	FoB	2%
102	Large medical equipment	FoB	1%
103	Large and small volume parenterals or infusions and positive list items imported from countries outside the East African Community territory	FoB	20%

SECOND SCHEDULE

(Made under regulation 4(2))

LABORATORY COMMERCIAL SAMPLES ANALYSIS

S/N	PARAMETERS	FEE (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	FEE
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
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
	Assay	
75.	by UV/VIS Spectrophotometer	400,000
76.	by HPLC for each API	1,500,000
77.	by MPAES	1,200,000
78.	by Optical Rotation	70,000
79.	by Titration	500,000
80.	Bioassay	400,000
	Identification	
81.	by UV/VIS Spectrophotometer	150,000
82.	by HPLC for each API	1,000,000
83.	by FTIR	240,000
84.	by TLC	400,000
85.	by Colour reaction	180,000
86.	by Optical rotation	70,000
	Moisture Content	
87.	by Loss on drying	160,000
88.	by KF	1,000,000

S/N	PARAMETERS	FEE
89.	by direct titration	1,000,000
90.	by distillation	120,000
91.	pH	20,000
	Related Substances or impurities	
92.	by HPLC (limit)	1,200,000
93.	by HPLC for each API	1,500,000
94.	by TLC	800,000
95.	by TLC (limit)	140,000
	Residual solvents	
96.	by GC/MS	1,500,000
	Uniformity of dosage unit	
97.	Content Uniformity by UV/VIS Spectrophotometer	700,000
98.	Content Uniformity by HPLC	2,900,000
99.	by Weight Variation	60,000
	Other Tests	
100.	Limit test in Heavy metals for each heavy metal by MPAES	100,000
101.	Sulphated Ashes	530,000
102.	Deliverable volume	60,000
103.	Clarity of solution	60,000
104.	Particulate Matter	60,000
105.	Colour of solution	800,000
106.	Extractable volume	50,000
	Sterility	
107.	by filtration	320,000
108.	by closed system	350,000
109.	Bacterial endotoxins	350,000
110.	Identification by PCR/ Sequencing	600,000
111.	Potency by ELISA/PCR/Tissue culture technique	600,000
112.	Detection of Bile-Torelant Gram Negative Bacteria	330000
113.	Detection of Burkholderia cepacia	280000
114.	Total combined Yeasts and Moulds count	330000
115.	Detection of Clostridia	280000
116.	Detection of Candida albicans	280000
117.	Detection of Enterobactericeae	330000
118.	Mycoplasma detection by PCR Technique	600,000
119.	Identification and Purification of Adeno virus Vector by- Sequence/or western blott	600,000
120.	mRNA sequence for SARS Cov-2 Virus by Genome sequence	600,000
121.	Identification of SARS Cov-2 virus by PCR	600,000
122.	Identification of DNA/RNA by PCR	600,000
123.	Quantification of genotype (DNA/RNA)	1,000,000
124.	Infectivity and antigen	1,000,000
	Creams, Ointments, Gels and Lotions (Sterile and Non-Sterile)	
125.	Physical examination	10,000
	Assay	
126.	by UV/VIS Spectrophotometer	400,000
127.	by HPLC for each API	1,400,000
128.	by Titration	520,000
129.	Bioassay	400,000
	Identification	
130.	by UV/VIS Spectrophotometer	150,000
131.	by HPLC for each API	1,000,000
132.	by FTIR	240,000
133.	by TLC	400,000
134.	by Colour reaction	180,000
	Uniformity of dosage unit	
135.	by UV/VIS Spectrophotometer	750,000

S/N	PARAMETERS	FEE
136.	by HPLC for each API	3,000,000
137.	by Weight Variation	60,000
	Water content	
138.	by KF	1,000,000
139.	by distillation	120,000
	Limit of other impurities	
140.	Limit test in Heavy metals for each heavy metal by MPAES	100,000
141.	Sulphated Ash	530,000
142.	**Microbiological Tests**	
143.	Total Aerial Microbial Count	390,000
144.	Yeast/Mould Count	330,000
	Inhalers and Aerosols	
145.	Physical examination	10,000
	Identification	
146.	by UV/VIS Spectrophotometer	150,000
147.	by HPLC for each API	1,000,000
148.	by FTIR	230,000
149.	by TLC	300,000
150.	by Colour reaction	180,000
151.	by Optical rotation	70,000
	Assay	
152.	by UV/VIS Spectrophotometer	400,000
153.	by HPLC for each API	1,500,000
154.	by Titration	400,000
	Uniformity of delivered dose	
155.	by determination of contents	1,450,000
156.	Deposition of the Emitted dose	1,450,000
	Related Substances or impurities	
157.	by HPLC for each API	1,200,000
158.	by HPLC (limit)	1,500,000
159.	by TLC	800,000
160.	by TLC(limit)	140,000
	Moisture Content	
161.	by Loss on drying	160,000
162.	by KF	1,000,000
163.	by direct titration	1,000,000
164.	by distillation	120,000
	Leak test	
165.	Direct measurement	60,000

S/N	PARAMETERS	FEE
	Other Tests	
166.	Sulphated Ash	530,000
167.	Heavy metals for each metal by MPAES	100,000
	Microbiological Tests	
168.	Total Aerial Microbial Count	390,000
169.	Yeast/Mould Count	330,000
	Eye, Nose and Ear drops	
170.	Physical examination	10,000
	Assay	
171.	by UV/VIS Spectrophotometer	400,000
172.	by HPLC for each API	1,000,000
173.	by Titration	500,000
174.	Bioassay	400,000
	Identification	
175.	by UV/VIS Spectrophotometer	150,000
176.	by HPLC for each API	1,000,000
177.	by FTIR	240,000
178.	by TLC	400,000
179.	by Colour reaction	180,000
180.	by Optical rotation	70,000
	Water Content	
181.	by KF	1,000,000
182.	by direct titration	1,000,000
183.	by distillation	130,000
184.	pH	20,000
	Related Substances or impurities	
185.	by HPLC	1,200,000
186.	by HPLC (limit)	1,500,000
187.	by TLC	800,000
188.	by TLC(limit)	140,000
	Uniformity of dosage unit	
189.	Content Uniformity by UV/VIS	730,000
190.	Content Uniformity by HPLC	2,900,000
191.	by Weight Variation	60,000
	Other Tests	
192.	Limit test in Heavy metals	200,000
193.	Sulphate Ash	530,000
194.	Leakage	60,000
195.	Metal particles	60,000
	Sterility	
196.	by filtration	320,000
197.	by closed system	350,000
	Excipients for all dosage forms	
198.	by ICP-OES	1,200,000
199.	by LC-MS/MS	1,500,000
200.	by GC-MS/MS	1,500,000
201.	by TLC	800,000
202.	by Dynamic Light Scattering	1,200,000
203.	by Classical Light Scattering	1,200,000
204.	by Light Obscuration or Extinction	1,200,000
	BIOCIDAL PRODUCTS	
	Antiseptics	
	Hand sanitizers	
205.	Alcohol content by alcohometer	10,000
206.	Alcohol content by GC/MS	100,000
207.	pH	20,000
208.	Hydrogen peroxide (as preservative) by titration	50,000
209.	Methanol limit test by GC/MS	100,000
	Methylated spirits	
210.	Alcohol content by alcohometer	10,000
211.	Alcohol content by GC/MS	100,000
	Povidone Iodine	
212.	Iodine content by titration	50,000
	Disinfectants	
	Assay by titration	50,000

213.	Assay by GC/MS	100,000
214.	Challenge test	300,000
	Raw Materials (Active Pharmaceutical Ingredients and Excipients)	
215.	Appearance/Description	20,000
	Assay	
216.	by UV/VIS Spectrophotometer	400,000
217.	Bioassay	400,000
218.	by HPLC	1,500,000
219.	by Titration	500,000
	Identification	
220.	by UV/VIS Spectrophotometer	150,000
221.	by HPLC	1,500,000
222.	by FTIR	240,000
223.	by TLC	400,000
224.	by LC/MS	1,000,000
225.	by GC/MS	1,000,000
226.	by Colour reaction	180,000
227.	by Optical rotation	70,000
228.	by Melting point	70,000
	Moisture Content	
229.	by Loss on drying	160,000
230.	by KF	1,000,000
231.	by Direct titration	1,000,000
232.	by Distillation	130,000
	Related Substances or impurities	
233.	by HPLC (limit)	1,200,000
234.	by HPLC	1,500,00
235.	by TLC	800,000
236.	by TLC (limit)	140,000
	Residual solvents	
237.	by GC/MS	1,500,000
	Other Tests	
238.	Heavy metals by limits test	200,000
239.	Sulphated Ash	530,000
	Microbiological Tests	
240.	Total Aerial Microbial Count	390,000
241.	Yeast/Mould Count	330,000
242.	Escherichia coli	280,000
243.	Pseudomonas aeruginosa	280,000
244.	Salmonella	360,000
245.	Staphylococcus aureus	360,000
	TOBACCO PRODUCTS	
246.	Nicotine by GC/MS	1,500,000
247.	Ammonia by HPLC	1,000,000
248.	Humectants by GC/MS	1,500,000
249.	Tar, nicotine, carbon monoxide by GC/MS and IR (Non dispersive)	1,200,000
250.	TSNAs by LC/MS/MS	2,000,000
251.	Benzol-alphapyrene by GC/MS	1,000,000
252.	Benzene and 1,3 butadiene by GC/MS	1,000,000
253.	Carbonyls by HPLC – Diode Array Detector	1,500,000
254.	Hydrogen cyanide by Continuous Flow Calorimeter	400,000
255.	Nitrogen oxide by Chemiluminescence Nitrogen Oxide Analyzer	500,000
256.	Metals by MPEAS for each metal	100,000
257.	Metals by ICP-AES	100,000
258.	Identification and quantification of pesticides by GC/MS	1,500,000
	MEDICAL DEVICES	
	Condoms (Male and Female) and Gloves	
259.	Length (mm)	50,000
260.	Width (mm)	50,000
261.	Thickness (mm)	50,000
262.	Packaging integrity	130,000
263.	Bursting pressure (kPa) and Volume (L)	500,000
264.	Visible defects	20,000
265.	Freedom from holes - Water leakage test	500,000
266.	Freedom from holes by Electrical leakage test	500,000
267.	Tensile properties	320,000
268.	Top ring diameter (mm)	50,000
269.	Top ring thickness (mm)	50,000

270.	Inner ring height (mm)	50,000
271.	Inner ring thickness (mm)	50,000
272.	Inner ring external diameter (mm)	50,000
273.	Lubricant Quantity (mg)	150,000
	Diapers and sanitary pads	
274.	Absorbance capacity	80,000
275.	Absorbance rate (s)	80,000
276.	pH	20,000
277.	Moisture content	130,000
278.	Water soluble extract	60,000
279.	Fluorescence	150,000
280.	Flushability	300,000
281.	Water soluble colouring matter	60,000
282.	Moisture content	25,000
283.	Water soluble extract	50,000
284.	Fluorescent brighteners	25,000
285.	Migration of colour	50,000
	Absorbent cotton and gauze	
286.	Sinking time (s)	80,000
287.	Water holding capacity (g)	80,000
288.	pH	20,000
289.	Foreign fibres	100,000
290.	Fluorescence	150,000
291.	Neps	100,000
292.	Ether soluble substance	60,000
293.	Extractible colouring matter	200,000
294.	Surface-active substances	60,000
295.	Water soluble substances	60,000
296.	Loss on drying	130,000
297.	Sulphated ash	500,000
298.	Thread count	60,000
299.	Minimum breakable load	50,000
300.	Ash content	100,000
301.	Fibre analysis	100,000
302.	Flame Test	50,000
303.	Length	50,000
304.	Width	50,000
305.	Fluorescent brighteners	25,000
	Plaster of Paris and Zinc Oxide	
306.	Percentage of $CaSO_4.½H_2O$	500,000
307.	Percentage of ZnO	500,000
308.	Adhesiveness	230,000
	Sutures	
309.	Length	50,000
310.	Diameter	50,000
311.	Tensile strength	320,000
312.	Needle attachment	100,000
313.	Identification tests	100,000
314.	Heavy Metals per element by MPAES	100,000
315.	pH	20,000
316.	Sterility	350,000
	Syringes, needle, cannula and infusion set	
317.	Syringe separation force	230,000
318.	Syringe Liquid Leakage	230,000
319.	Air Leakage Past syringe Piston	230,000
320.	Test for forces required to operate piston	100,000
321.	Freedom from air and liquid leakage	230,000
322.	Dead space	80,000
323.	Quantity of silicone	150,000
324.	Fit of plunger/stopper in barrel	50,000
325.	Acidity or alkalinity	20,000
326.	Extractible metals	60,000
327.	Container closure integrity	100,000
328.	Drug-container integrity	100,000
329.	Flow rate through needle	60,000
330.	Penetration force and drag force	50,000

331.	Needle bonding strength	50,000
332.	Corrosion resistance	100,000
333.	Peak tensile force	60,000
	Surgical Blades	
334.	Angle (□)	100,000
335.	Hole distance (d)	100,000
336.	Hole diameter (e)	100,000
337.	Sharpness	200,000
338.	Determination of Fitting Dimension	200,000
	Microscopes	
339.	Performance verification	1,000,000
	Face Masks – Medical and N95 Masks	
340.	Air Permeability	100,000
341.	Bacterial filtration efficiency %	320,000
342.	Splash resistance	250,000
343.	Bacterial cleanliness	300,000
344.	Contamination with any virus including SARS CoV-2	300,000
345.	Physical Test	100,000
346.	Splash resistance	100,000
	IUDs - Copper-bearing intrauterine devices	
347.	Dimensions	80,000
348.	Tensile force	320,000
349.	Visco-elastic property (memory test)	50,000
350.	Barium sulfate content	150,000
351.	Sterility	350,000
	Orthopedic implants and accessories	
352.	Particulate contamination	100,000
353.	Organic contaminants	60,000
354.	Inorganic contaminants	60,000
355.	Bio burden	350,000
356.	Bacterial endotoxins	350,000
	Surgical adhesive plaster and bandage	
357.	Zinc oxide content	150,000
358.	Tensile strength	320,000
359.	Weight of adhesive mass	50,000
360.	Adhesive property –adhesive strength	50,000
361.	Sterility	350,000
362.	Peel test/ peeling force	50,000
363.	Elongation across fabric width	80,000
	Blood bags	
364.	Volume of anticoagulant	50,000
365.	Resistance to leakage	100,000
366.	Permanence of labelling	100,000
	DIAGNOSTICS	
	Widal test kit	
367.	Sensitivity vs serodiagnosis of typhoid by ELISA/PCR	1,000,000
368.	Specificity (false positive or negative)	1,000,000
	HIV test kit	
369.	Sensitivity test	650,000
370.	Specificity test	650,000
	Hepatitis test kit	
371.	Sensitivity test	650,000
372.	Specificity test	650,000
	Blood grouping reagents	
373.	Specificity-Test for IgM and IgG red blood cells heterospecific antibodies	1,000,000
374.	Potency - anti-IgG potency by chequerboard titration studies	1,000,000
375.	Test for unwanted positive reactions	1,000,000

	Malaria rapid diagnostic kit	
376.	Sensitivity test	650,000
377.	Specificity test	650,000
	Syphilis Diagnostic Kit	
378.	Sensitivity test	650,000
379.	Specificity test	650,000
	Urine Pregnancy test Kit	
380.	Sensitivity test	650,000
381.	Specificity test	650,000

THIRD SCHEDULE

(Made under regulation 4(3))

NON-REGULATED PRODUCT SAMPLES ANALYSIS AND OTHER SERVICES

S/N	PARAMETERS	FEE
	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

S/N	PARAMETERS	FEE
	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	600,000
	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 and quantification of pesticides by GC/MS	1,500,000
17.	Identification of heavy metals by MPAES for each element	100,000
18.	Quantification of heavy metals by MPAES for each element	100,000
19.	Identification and quantification of veterinary drug residues by HPLC for each API	1,500,000
20.	Identification and quantification of veterinary drug residues by LC/MSMS for each API	2,000,000
21.	Alcohol content in alcoholic beverages by GC/MS	100,000
22.	Methanol contamination in alcoholic beverages by GC/MS	100,000
23.	Microbiological Tests	
24.	Total Aerial Microbial Count	390,000
25.	Yeast/Mould Count	330,000
26.	*Escherichia coli*	280,000
27.	*Pseudomonas aeruginosa*	280,000
28.	Salmonella spp	350,000
29.	*Staphylococcus aureus*	350,000
30.	*Bacillus cereus*	350,000
	COSMETIC SAMPLES	
31.	Identification of banned ingredients (steroids and hydroquinone) by TLC	50,000
32.	Identification and quantification of heavy metals by MPAES	100,000
	SOIL SAMPLES	
33.	Identification and quantification of soil minerals for each element by MPEAS	100,000
34.	pH	20,000
	WATER SAMPLES	
	Identification and quantification tests	
35.	Identification and quantification of minerals for each element by MPEAS	100,000
36.	Identification and quantification of drug residues by HPLC for each API	1,500,000
37.	Identification and quantification of drug residues by LC/MSMS for each API	2,000,000
38.	Identification and quantification of pesticides by GC/MS	300,000
39.	Conductivity	20,000
40.	Total dissolved solids	100,000

SN	PARAMETERS	FEE
41.	pH	20,000
	Microbiological Tests	
42.	Total Aerial Microbial Count	390,000
43.	Yeast/Mould Count	330,000
44.	*Escherichia coli*	280,000
45.	*Pseudomonas aeruginosa*	280,000
46.	Salmonella spp	350,000
47.	*Staphylococcus aureus*	350,000
48.	*Bacillus cereus*	350,000
49.	Total coliforms	350,000
	OTHER SERVICES	
50.	Purification of water per 30 Litres	40,000
51.	Sterilization of hospital garments and supplies (for each item) by steam sterilizer or autoclave	10,000
52.	Analytical method verification for each API	1,000,000
53.	Analytical method validation for each API	3,000,000
54.	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 Vigilance of medical devices and Diagnostics	500
14.	Training on Quality Management System - ISO 9001	400
15.	Training on Quality Management System - ISO17025	400
16.	Training on Quality Management System - ISO13485	400
17.	Training on Quality Management System - ISO15189	400
18.	Training on laboratory analytical techniques	800
19.	Training on analytical method development and validation	1,000
20.	Training on microbiological testing	500
ACCREDITATION SERVICES		
21.	Application for accreditation	200
22.	Resubmission of documentation for accreditation	300
23.	Extension of non-critical scope (desk review)	200
24.	Initial assessment	500
25.	Annual accreditation fee	100
26.	Scope extension (if it involves site visit)	500

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 12 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 12 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
March, 2024

Ummy A. Mwalimu
Minister for Health.