

NEW FEES AND CHARGES FOR MEDICINES, COSMETICS AND MEDICAL DEVICES – With Effect From: 01/10/2011

	SERVICE	COST
1.	Application to conduct clinical trials	USD 3,000
2.	Fast track for clinical trial application	Double the cost of registration and analysis fee
3.	Amendments for major changes in clinical trials	USD 200
4.	Amendments for minor changes in clinical trials	USD 100
5.	Retention fee on imported medical devices	Class A- USD 25 Class B- USD 40 Class C- USD 60 Class D- USD100
6.	Screening for application for registration of medical devices:	Foreign USD 50 Locally manufactured Class A- TZS 15, 000 Class B, C & D TZS 30,000
7.	Application fee for registration of foreign medical devices	Class A-USD 50 Class B -USD 500 Class C- USD 750 Class D USD 1,000
8.	Registration fees for locally manufactured Medical Devices	Class B TZS 300,000 Class C TZS 400,000 Class D-TZS 600,000
9.	Retention fee on locally manufactured medical devices	Class A- USD10 Class B- USD20

	SERVICE	COST
		Class C- USD30 Class D- USD50
10.	Annual dealers permit Medical Devices	Retail distributor TZS 60,000 Wholesale distributors TZS 130,000 Manufacturer Medium TZS 200,000 Large TZS 300,000
11	Registration of medicinal products	Locally manufactured medicinal products TZS 600,000 Variation TZS 60,000 Retention TZS 100,000 Duplicate Certificate TZS 30,000 Both old and new foreign medicinal products USD 1,250 Variation USD 200 (major) and USD 100 (minor) Retention USD 200 Duplicate Certificate USD 30
12	Fast track for medicinal products registration	Double the cost of registration
13	Registration of Antiseptics, disinfectants and medicated soaps	Locally manufactured TZS 130,000 Retention TZS 60,000 Duplicate Certificate TZS 30,000 Imported disinfectants to be charged as follows: Evaluation USD 300 Retention USD 100

	SERVICE	COST
		Duplicate Certificate USD 30
14	Registration of cosmetics	Locally manufactured USD 45 Duplicate Certificate TZS 20,000/=
		Imported cosmetics to be charged as follows: Evaluation USD75 Duplicate Certificate USD 30-
15	GMP Inspection within specified period of product registration	(a)Local pharmaceutical facilities - 150,000/= per year (b)Overseas pharmaceutical facilities - East Africa – USD 3,000 - Africa USD 4,500 - Far East and Asia/India USD 6,000 - Europe and America USD 6,500
16	Annual dealer permit	Wholesale Pharmacy – TZS 200,000/=- Pharmaceutical manufacturers (a) Small TZS 120,000/=
		(b) Medium TZS 350,000/=
		(c) Large TZS 500,000/=
17	Annual dealers permits	Wholesalers' cosmetics outlets TZS 120,000/= Retail cosmetic outlets TZS 60,000/= Small Cosmetics manufacturers TZS 75,000/= Medium cosmetics manufactures TZS 200,000/= Large cosmetics manufactures TZS- 300,000/=
18	Medical representatives Certificate	Local Companies: TZS 100,000 for each company represented Foreign Companies: USD 500 Person Representative

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		- Local – TZS 100,000 - Foreigner – USD 500
19	Certificate of Pharmaceutical Product (CPP)	- TZS 20,000/=
20	Disposal Certificate	- TZS 30,000
21	Export Permit for all regulated product	- TZS 20,000/=
22	Permit for Psychotropic and Narcotics drugs	- TZS 20,000/=

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