

GOVERNMENT NOTICE NO. 21 published on. 4/1/2019

THE TANZANIA FOOD, DRUGS AND COSMETICS ACT
(CAP. 219)

NOTICE

(Made under section 53(6))

THE TANZANIA FOOD, DRUGS AND COSMETICS (LIST OF REGISTERED HUMAN AND VETERINARY MEDICINAL PRODUCTS AND WITHDRAWN MEDICINAL PRODUCTS) NOTICE, 2019

Cap.219

WHEREAS section 53(6) of the TANZANIA FOOD, DRUGS AND COSMETICS ACT, requires the Director General to cause the list of registered human medicinal products to be published by Notice in the Gazette;

AND WHEREAS the Tanzania Food and Drugs Authority has approved the names under which human and veterinary medicinal products and medicinal products that have been withdrawn from the list of registered medicines, the qualitative and quantitative content of their active components, the names of the registrants, registration numbers and dosage forms as shown in the First, Second and Third Schedules to this Notice.

NOW THEREFORE the list of registered human and veterinary medicinal products and medicinal products that have been withdrawn registration the qualitative and quantitative content of their active components, the names of the registrants and the registration numbers are as follows;

Citation

1. This Notice may be cited as the Tanzania Food, Drugs and Cosmetics (List of Registered Medicines) Notice, 2018.

Notification of approval

2. The list of registered medicines are as specified in the First, Second and Third Schedules to this Notice.

*Tanzania Food, Drugs and Cosmetics (List of Registered Human and
Veterinary Medicinal Products and Withdrawn Medicinal Products)*

GN. No. 21 (Contd)

SCHEDULES

TANZANIA FOOD AND DRUGS AUTHORITY								
LIST OF REGISTERED HUMAN MEDICINAL PRODUCTS FROM 1 ST JANUARY, 2018 TO 30TH JUNE, 2018								
s	Regis- tration Num- ber	Product Name	INN Name	Dosa- ge Form	Produc- t Streng- th	Registr- ant Country	Manufactu- rer	Manuf- acture r's Count- ry
Registrant: A. Menarini Industrie Farmaceutiche Riunite S.R.L								
1	TAN 00,17 60 M01 A AMI	Fastum	Ketoprofen	Capsu- les	50 mg	ITALY	A.Menarin i Manufactu- ring Logistics and Services	ITAL Y
Registrant: Abacus Pharma Africa Limited								
2	TZ 18 H 0115	Verzepam	Diazepam	Soluti- on for injecti- on	5 mg/ml	Tanzani- a	VERVE HUMAN CARE LABORA- TORIES	INDI- A
3	TZ 18 H 0098	Expen	Benzyl Penicillin	Powd- er for soluti- on for injecti- on	5,000, 000 IU	Tanzani- a	Reyoung Pharmaceu- tical Company Limited	CHIN- A
4	TZ 18 H 0090	Cloxcin- 500	Cloxacillin Sodium	Powd- er for soluti- on for injecti- on	500 mg	Tanzani- a	Reyoung Pharmaceu- tical Company Limited	CHIN- A
5	TZ 18 H 0064	Amoxyn- 500	Amoxycillin	Capsu- les	500 mg	Tanzani- a	Reyoung Pharmaceu- tical Company Limited	CHIN- A
6	TZ 18 H 0102	Fortiwin- 4	Procaine Penicillin + Benzyl Penicillin	Powd- er for soluti- on for injecti	4 mega unit	Tanzani- a	Reyoung Pharmaceu- tical Company Limited	CHIN- A

Tanzania Food, Drugs and Cosmetics (List of Registered Human and Veterinary Medicinal Products and Withdrawn Medicinal Products)

GN. No. 21 (Contd)

				on				
Registrant: ACME Formulation Private Limited								
7	TZ 18 H 0114	Orni - Flox	Ofloxacin + Ornidazole	Table ts	200 + 500 mg	INDIA	ACME FORMUL ATION PRIVATE LIMITED	INDI A
Registrant: Ajanta Pharma Limited								
8	TZ 18 H 0015	Rosucho l - 10	Rosuvastatin Calcium	Table ts	10 mg	INDIA	Ajanta Pharma Limited	INDI A
9	TAN 09,08 5 P01B AJA	Artefan	Artemether + Lumefantrine	Table ts	20 mg + 120 mg	INDIA	Ajanta Pharma Limited	INDI A
10	TZ 18 H 0014	Rosucho l - 20	Rosuvastatin	Table ts	20 mg	INDIA	Ajanta Pharma Limited	INDI A
Registrant: Amoun Pharmaceutical Industries Company S. A. E								
11	TAN 00,24 73 M03 B AMO	Roysan	Tizanidine	Table ts	4 mg	EGYPT	Amoun Pharmaceu tical Industries Company	EGYP T
12	TAN 00,24 75 A11A AMO	Haema Caps	Ferrous fumerate equivalent to Iron BP + Folic Acid BP + Cyanocobalam in USP + Ascorbic Acid USP + Zinc Sulphate BP	Capsu les, hard	75 mg + 350 mg + 5 mg + 25 mg + 10 mg + 50 mg + 2 mg + 25 mg + 15 mg + 75 mg + 2 mg + 400 IU + 200 mg + 45 mg	EGYPT	Amoun Pharmaceu tical Industries Company	EGYP T

Tanzania Food, Drugs and Cosmetics (List of Registered Human and Veterinary Medicinal Products and Withdrawn Medicinal Products)

GN. No. 21 (Contd)

					+ 15 mg			
13	TAN 00,2473 M03 B AMO	Roysan	Tizanidine	Tablets	4 mg	EGYPT	Amoun Pharmaceutical Industries Company	EGYPT
Registrant: Artemis Life Sciences								
14	TZ 18 H 0097	ERTI 250	Erythromycin Stearate eq to Erythromycin	Tablets	250 mg	U.A.E	S Kant Healthcare Limited	INDIA
Registrant: Astellas Pharma Proprietary Limited								
15	TZ 18 H 0117	Mycamine 100	Micafungin	Solution For Infusion	100 mg	SOUTH AFRICA	Astellas Pharma Tech Co. Ltd.	IRELAND
16	TZ 18 H 0126	Mycamine 50	Micafungin	Solution For Infusion	50 mg	SOUTH AFRICA	Astellas Pharma Tech Co. Ltd.	IRELAND
Registrant: Astra Lifecare (India) Private Limited								
19	TZ 18 H 0003	Aspiclox	Ampicillin + Cloxacillin	Capsules	250 + 250 mg	INDIA	Astra Lifecare (India) Private Limited	INDIA
20	TZ 18 H 0021	Karvid 12.5	Carvedilol	Tablets	12.5 mg	INDIA	Astra lifecare (India) Private Limited	INDIA
21	TZ 18 H 0020	Karvid 6.25	Carvedilol EP/BP	Tablets	6.25 mg	INDIA	Astra Lifecare (India) Private Limited	INDIA

Tanzania Food, Drugs and Cosmetics (List of Registered Human and Veterinary Medicinal Products and Withdrawn Medicinal Products)

GN. No. 21 (Contd)

Registrant: AstraZeneca United Kingdom Limited								
22	TAN 00,2294 A02B AST	Nexium	Esomeprazole Magnesium	Tablets	20mg	UNITED KINGDOM	AstraZeneca AB.	SWE DEN
23	TAN 00,2293 A02B AST	Nexium	Esomeprazole	Tablets	40mg	UNITED KINGDOM	AstraZeneca AB.	SWE DEN
Registrant: ATCO Laboratories Limited								
24	TZ 18 H 0009	Proloxin	Ciprofloxacin Hydrochloride	Ear/Eye Drops	3 mg/ml	PAKISTAN	ATCO Laboratories Limited	PAKISTAN
Registrant: Aurobindo Pharma Limited								
25	TZ13 H046	Drox 250	Cefadroxil	Powder for Oral suspension	250mg /5ml	INDIA	Aurobindo Pharma Limited	INDIA
26	TZ 18 H 0103	Glimesure 4	Glimepiride	Tablets	4 mg	INDIA	Aurobindo Pharma Limited	INDIA
27	TZ 18 H 0031	Glimesure 2	Glimepiride	Tablets	2 mg	INDIA	Aurobindo Pharma Limited	INDIA
28	TZ 18 H 0030	Glimesure 3	Glimepiride	Tablets	3 mg	INDIA	Aurobindo Pharma Limited	INDIA
Registrant: Auronext Pharma Private Limited								
29	TZ 18 H 0096	Ertapik	Ertapenem Monosodium	Powder for solution for injection	1 g	INDIA	Auronext Pharma Private Limited	INDIA
30	TZ 18 H 0096	Ertapik	Ertapenem Monosodium	Powder for solution for injection	1 g	INDIA	Auronext Pharma Private Limited	INDIA
Registrant: Bafna Pharmaceuticals Limited								
31	TZ 18 H 0049	Rosufast - 20	Rosuvastatin	Tablet, Film-	20 mg	INDIA	Bafna Pharmaceuticals	INDIA

Tanzania Food, Drugs and Cosmetics (List of Registered Human and Veterinary Medicinal Products and Withdrawn Medicinal Products)

GN. No. 21 (Contd)

				coated			Limited	
Registrant: Beta Pharmaceuticals Limited								
32	TAN 00,1357 A02A BET	Paracetamol	Paracetamol	Solution	120 mg/5ml	UNITED KINGDOM	Bell Sons & Company (Drugists) Limited	UNITED KINGDOM
Registrant: Bharat Serums and Vaccines Limited								
33	TZ 18 H 0018	Endoprost	Carboprost Tromethamine	Injection	125 mcg	INDIA	Bharat Serums and Vaccines Limited	INDIA
34	TZ 18 H 0017	Endoprost	Carboprost Tromethamine	Injection	250 mcg	INDIA	Bharat Serums and Vaccines Limited	INDIA
Registrant: Brookes Pharma Private Limited								
35	TZ13 H161	Oxoferin	Tetrachlorodecaxide	Solution	1.037 mg	PAKISTAN	Brookes Pharmaceuticals Laboratories (Pakistan) Limited	PAKISTAN
Registrant: Cadila Healthcare Limited								
36	TZ 18 H 0120	Zolan 5	Zolmitriptan	Tablets	5 mg	INDIA	Cadila Healthcare Limited	INDIA
37	TZ 18 H 0055	TRAMAZAC P	Tramadol + Paracetamol	Tablet, Film-coated	37.5/325 mg	INDIA	Cadila Healthcare Limited	INDIA
38	TAN 00,645 C01C CAH	Catenol	Atenolol	Tablets	50 mg	INDIA	Cadila Healthcare Limited	INDIA
Registrant: Cadila Pharmaceuticals Limited								
39	TZ13 H043	Teli 80	Telmisartan	Tablets	80mg	INDIA	Cadila Pharmaceuticals Limited	INDIA

Tanzania Food, Drugs and Cosmetics (List of Registered Human and Veterinary Medicinal Products and Withdrawn Medicinal Products)

GN. No. 21 (Contd)

40	TZ13 H042	Teli 40	Telmisartan	Tablets	40mg	INDIA	Cadila Pharmaceuticals Limited	INDIA
41	TZ13 H073	Teli H	Telmisartan and Hydrochlorothiazide	Tablets	40mg + 12.5mg	INDIA	Cadila Pharmaceuticals Limited	INDIA
Registrant: Cipla Limited								
42	TZ18 H0094	Dolutegravir Sodium	Dolutegravir Sodium	Tablets	50 mg	INDIA	Cipla Limited	INDIA
43	TZ18 H0101	Foracort 400 inhaler	Formoterol + Budesonide	Aerosol Inhaler	6 + 400 mcg/dose	INDIA	Cipla Limited	INDIA
44	TZ13 H030	Efavir 600	Efavirenz	Tablets	600mg	INDIA	Cipla Limited	INDIA
45	TZ18 H0042	Caspogin 70	Caspofungin	Powder for solution for injection	70 mg	INDIA	Cipla Limited (Unit IX)	INDIA
Registrant: Cosmos Limited								
46	TAN00,1380 D01A COS	Nycostat	Nystatin	Suspension, Oral	10000 IU/ml	KENYA	Cosmos Limited	KENYA
47	TAN00,2316 N02B COS	Painotab	Caffeine + Paracetamol	Capsules	30 mg + 650 mg	KENYA	Cosmos Limited	KENYA
48	TAN00,1378 N03A COS	Phenobarbital	Phenobarbital	Tablets	30 mg	KENYA	Cosmos Limited	KENYA
49	TAN00,1382 C06A COS	Salbut	Salbutamol	Tablets	4 mg	KENYA	Cosmos Limited	KENYA
Registrant: Dawa Limited								
50	TZ18 H0125	Oracef	Cefalexin Monohydrate	Capsules, hard	250 mg	KENYA	Dawa Limited	KENYA

Tanzania Food, Drugs and Cosmetics (List of Registered Human and Veterinary Medicinal Products and Withdrawn Medicinal Products)

GN. No. 21 (Contd)

Registrant: Elys Chemical Industries Limited								
51	TAN 00,17 95 D01A ELY	Fungista t	Miconazole	Cream	2 %w/w	KENYA	Elys Chemical Industries Limited	KENYA
52	TAN 00,17 97 C03C ELY	Frusemide	Frusemide	Tablets	40 mg	KENYA	Elys Chemical Industries Limited	KENYA
53	TAN 00,18 00 R05A ELY	Cold Flu	Caffeine + Chlorpheniramine + Paracetamol + Phenylephrine	Capsules	400 mg + 30 mg + 4 mg + 5 mg	KENYA	Elys Chemical Industries Limited	KENYA
54	TAN 00,17 94 A03B ELY	Bukol	Hyoscine	Tablets	10 mg	KENYA	Elys Chemical Industries Limited	KENYA
55	TAN 00,23 29 A02A ELY	Alugel	Oxethazaine BP + Dried Aluminium Hydroxide USP + Magnesium Hydrochloride USP	Suspension, Oral	250 mg/5ml + 120 mg/5ml	KENYA	Elys Chemical Industries Limited	KENYA
56	TAN 00,17 96 D07A ELY	Elyvate	Betamethasone	Cream	0.1 %w/w	KENYA	Elys Chemical Industries Limited	KENYA
57	TAN 00,17 78 D07A ELY	Elycort	Hydrocortisone	Cream	1 % w/w	KENYA	Elys Chemical Industries Limited	KENYA
58	TAN 00,14 00 P02X ELY	Alprim	Sulfamethoxazole+Trimethoprim	Tablets	400 mg + 80 mg	KENYA	Elys Chemical Industries Limited	KENYA
59	TAN 00,13 98 J03B ELY	Alprim	Sulfamethoxazole+Trimethoprim	Suspension, Oral	200 mg/5ml + 40 mg/5ml	KENYA	Elys Chemical Industries Limited	KENYA

Tanzania Food, Drugs and Cosmetics (List of Registered Human and Veterinary Medicinal Products and Withdrawn Medicinal Products)

GN. No. 21 (Contd)

60	TAN 00,19 75 R03A ELY	Ventosal	Salbutamol	Tablets	4 mg	KENYA	Elys Chemical Industries Limited	KENYA
61	TAN 00,18 01 D07A ELY	Elyvate	Betamethasone	Cream	01 % w/w	KENYA	Elys Chemical Industries Limited	KENYA
62	TAN 00,17 84 N02B ELY	Elymol	Paracetamol	Tablets	500 mg	KENYA	Elys Chemical Industries Limited	KENYA
63	TAN 00,17 80 H02A ELY	Prednisolone	Prednisolone	Tablets	5 mg	KENYA	Elys Chemical Industries Limited	KENYA
64	TAN 00,19 76 D04A ELY	CIPI-M	Chlorpheniramine	Tablets	4 mg	KENYA	Elys Chemical Industries Limited	KENYA
65	TAN 00,13 99 A07A ELY	Lyfe	Glucose Anhydrous BP + Sodium Chloride BP + Potassium Chloride BP + Sodium Citrate Dihydrate BP	Powder for Oral solution	135 g + 26 g + 15 g + 29 g	KENYA	Elys Chemical Industries Limited	KENYA
66	TAN 00,17 93 D07X ELY	Elyclob G	Beclomethasone + Clotrimazole + Gentamycin	Cream	0.025 % w/w + 1 %w/w + 0.2 % w/w	KENYA	Elys Chemical Industries Limited	KENYA
67	TAN 00,17 91 M01 A ELY	Ibufen	Ibuprofen	Tablets	200 mg	KENYA	Elys Chemical Industries Limited	KENYA
68	TAN 00,19 71 A11E ELY	Vitamin B Complex	Thiamine + Riboflavine + Nicotinamide	Tablets	11 mg + 115 mg + 165 mg	KENYA	Elys Chemical Industries Limited	KENYA

Tanzania Food, Drugs and Cosmetics (List of Registered Human and Veterinary Medicinal Products and Withdrawn Medicinal Products)

GN. No. 21 (Contd)

69	TAN 00,15 84 J01F ELY	Elocin dry syrup	Erythromycin	Syrup	125mg /5 ml	KENY A	Elys Chemical Industries Limited	KEN YA
70	TAN 00,17 77 P01X ELY	Elyzole	Albendazole	Table ts	200 mg	KENY A	Elys Chemical Industries Limited	KEN YA
71	TAN 00,17 86 P01A ELY	Elogyl	Metronidazole	Table ts	200 mg	KENY A	Elys Chemical Industries Limited	KEN YA
72	TAN 00,17 83 P02X ELY	Elyzole	Albendazole	Suspe nion, Oral	200 mg/5m l	KENY A	ELYS CHEMIC AL INDUSTR IES LTD	KEN YA
73	TAN 00,19 73 P02X ELY	Vumtrex	Levamisole	Table ts	40 mg	KENY A	Elys Chemical Industries Limited	KEN YA
74	TAN 00,17 98 J01F ELY	Elocin	Erythromycin	Table ts	25 mg	KENY A	Elys Chemical Industries Limited	KEN YA
Registrant: Emcure Pharmaceutical Limited								
75	TZ 18 H 0050	Instgra	Dolutegravir Sodium	Table t, Film- coate d	50 mg	INDIA	Emcure Pharmaceu ticals Limited	INDI A
76	TAN 00,25 59 A11J HAR	Caloshel l	Calcium + Cholecalciferol	Table ts	1250 mg + 250 IU	INDIA	Emcure Pharmaceu ticals Limited	INDI A
77	TAN 00,25 55 B03A EMC	Orofer	Iron (III) Hydroxide Polymatose Complex	Syrup	50 mg/5m l	INDIA	Emcure Pharmaceu ticals Limited	INDI A

Tanzania Food, Drugs and Cosmetics (List of Registered Human and Veterinary Medicinal Products and Withdrawn Medicinal Products)

GN. No. 21 (Contd)

Registrant: Esapharma s.r.l.								
78	TZ 18 H 0129	Oranvate Gel	Clobetasol Propionate	Gel	0.5 mg/g	ITALY	Esapharma s.r.l.	ITALY
79	TZ 18 H 0109	Lemonvate Cream	Clobetasol Propionate	Gel	0.5 mg/g	ITALY	Esapharma s.r.l.	ITALY
Registrant: Eva Pharma for Pharmaceuticals and Medical Appliances								
80	TZ 18 H 0065	Virecta 100 mg	Sildenafil Citrate	Tablets	100mg	EGYPT	Eva Pharma for Pharmaceuticals and Medical Appliances	EGYPT
Registrant: F.Hoffman-La Roche Limited								
81	TZ 18 H 0111	Mabthera SC	Rituximab	Injection	1600 mg	SWITZERLAND	F.Hoffman-La Roche Ltd.	SWITZERLAND
82	TZ 18 H 0112	Mabthera SC	Rituximab	Injection	1400 mg	Tanzania	F.Hoffman-La Roche Limited	SWITZERLAND
83	TAN 08,00 6 N04B F.H	Dormicum	Midazolam	Solution for injection	50mg/ 10ml	SWITZERLAND	Galenical Bulk Production	FRANCE
84	TZ13 H064	Herceptin	Trastuzumab	Powder	150mg	SWITZERLAND	F.Hoffman-La Roche Limited	SWITZERLAND
85	TAN 08,00 7 N04B F.H	Dormicum	Midazolam	Solution for injection	15mg/ 3ml	SWITZERLAND	CENEXI S.A.S	FRANCE
Registrant: FDC Limited								
86	TAN 00,14 10 S01A FDC	Pyricort	Dexamethasone + Gentamycin	Eye Drops	0.3%w/v + 0.1%w/v	INDIA	FDC Limited	INDIA
87	TZ 18 H 0107	Latanoprost Eye Drops	Latanoprost	Solution	0.005 %w/v	INDIA	FDC Limited	INDIA
88	TZ 18 H 0107	Latanoprost Eye Drops	Latanoprost	Solution	0.005 %w/v	INDIA	FDC Limited	INDIA
Registrant: Galentic Pharma (India) Private Limited								

Tanzania Food, Drugs and Cosmetics (List of Registered Human and Veterinary Medicinal Products and Withdrawn Medicinal Products)

GN. No. 21 (Contd)

89	TAN 00,41 06 S01D GAL	Netravir eye ointment	Acyclovir	Oint ment	30 mg/g	INDIA	Galentic Pharma (India) Pvt, Ltd.	INDI A
Registrant: Getz Pharma Private Limited								
90	TZ 18 H 0047	SOLIFE N	Solifenacin Succinate	Table ts	5 mg	PAKIS TAN	Getz Pharma Private Limited	PAKI STAN
Registrant: GlaxoSmithKline Pharmaceutical Kenya Limited								
91	TAN 00,10 77 D07A GLA	Betnovat e cream	Betamethasone	Crea m	0.1 %w/w	KENY A	GlaxoSmit hKline Operations (UK) Limited	UNIT ED KING DOM
92	TAN 08,05 9 J01D GSK	Proxima	Cefuroxime	Suspe nsion, Oral	125 mg/5ml	KENY A	GlaxoSmit hKline Operations (UK) Limited	UNIT ED KING DOM
93	TAN 08,05 9 J01D GSK	Proxima	Cefuroxime	Suspe nsion, Oral	125 mg/5ml	KENY A	GlaxoSmit hKline Operations (UK) Limited	UNIT ED KING DOM
94	TAN 08,05 8 J01D GSK	Proxima	Cefuroxime	Suspe nsion, Oral	250 mg/ml	KENY A	GlaxoSmit hKline Operations (UK) Limited	UNIT ED KING DOM
95	TAN 00,34 8 J01C SKB	Augment in	Amoxicillin + Clavulanate	Table ts	500 mg + 125 mg	KENY A	GlaxoSmit hKline Limited	UNIT ED KING DOM
Registrant: Glenmark Pharmaceuticals Limited								
96	TZ13 H071	Ibicar	Beclomethason e	Inhale r	200Mc g	INDIA	Glenmark Pharmaceu ticals Limited	INDI A
Registrant: Guilin Pharmaceutical Shanghai Co. Limited								
97	TZ 18 H 0104	Gucefor	Cefuroxime Sodium	Powd er for soluti on for injection	750 mg	CHINA	Reyoung Pharmaceu tical Company Limited	CHIN A

Tanzania Food, Drugs and Cosmetics (List of Registered Human and Veterinary Medicinal Products and Withdrawn Medicinal Products)

GN. No. 21 (Contd)

98	TZ 18 H 0048	Zathenza	Benzathine Penicillin	Powder for solution for injection	2.4 MIU	CHINA	Reyoung Pharmaceutical Company Limited	CHINA
Registrant: Guilin Pharmaceuticals Company Limited								
99	TZ 18 H 0004	G - Cospe	Sulfadoxine + Pyrimethamine	Tablets	500 + 25 mg		GUILIN PHARMACEUTICAL COMPANY Limited	CHINA
Registrant: Hastand Export Marketing Private Limited								
100	TAN 00,21 2 D07C AUR	Betacort N	Betamethasone + Neomycin	Cream	0064 %w/w + 05 % w/w	INDIA	Aurochem Pharmaceuticals (I) Pvt. Limited	INDIA
Registrant: Hebei Oriental Pharma Import and Export Corporation								
101	TZ 18 H 0085	Baceftri	Ceftriaxone Sodium	Powder for solution for injection	1 g	CHINA	Reyoung Pharmaceutical Company Limited	CHINA
102	TZ 18 H 0084	BA- WATER	Sterilized Water for Injection	Solution	5 ml	CHINA	Shijiazhuang No.4 Pharmaceutical Co. Limited	CHINA
103	TZ 18 H 0083	BA- WATER	Sterilized Water for Injection	Injection	10 ml	CHINA	Shijiazhuang No.4 Pharmaceutical Co. Limited	CHINA
104	TZ 18 H 0082	Ba-DNS	Glucose + Sodium Chloride	Injection	0.9 + 5 %	CHINA	Shijiazhuang No.4 Pharmaceutical Co. Limited	CHINA
Registrant: Hetero Laboratories Limited								
105	TZ 18 H 0072	Alzer 5	Donepezil Hydrochloride	Tablets	5 mg	INDIA	Hetero Labs Limited (UNIT V)	INDIA
106	TZ 18 H 0091	Darunavir	Darunavir	Tablets	400 mg	INDIA	Hetero Labs Limited	INDIA

Tanzania Food, Drugs and Cosmetics (List of Registered Human and Veterinary Medicinal Products and Withdrawn Medicinal Products)

GN. No. 21 (Contd)

Registrant: Hetero Labs Limited								
107	TZ 18 H 0093	Dolutegravir	Dolutegravir Sodium	Tablets	50 mg	INDIA	Hetero Labs Limited	INDIA
Registrant: Hovid Bhd								
108	TZ13 H041	Pengesic SR Tablet	Tramadol Hydrochloride	Tablets	100mg	MALAYSIA	Hovid Bhd	MALAYSIA
Registrant: Immacule Lifesciences Private Limited								
109	TZ 18 H 0010	Imreb	Rabeprazole	Lyophilized Injection	20 mg	INDIA	Immacule Lifesciences Private Limited	INDIA
Registrant: Indchemie Health Specialities Private Limited								
110	TZ 18 H 0011	Zenoxim - 500	Cefuroxime Axetil	Tablets	500 mg	INDIA	Alkem Laboratories Limited	INDIA
Registrant: Indi Pharma Private Limited								
111	TAN 07,311 J01F IND	Clinicin	Clindamycin	Gel	1% w/v	INDIA	Indi Pharma Private Limited	INDIA
Registrant: Indoco Remedies Limited								
112	TAN 00,2457 D01A IND	Cloben	Beclomethasone + Clotrimazole	Cream	0.025 % w/w + 1 %w/w	INDIA	Indoco Remedies Limited (Plant I)	INDIA
113	TZ13 H154	ATM 200	Azithromycin	Suspension, Oral	200 mg/5 ml	INDIA	Indoco Remedies Limited	INDIA
114	TAN 00,2344 A04A IND	Nosic	Doxylamine + Pyridoxine	Tablets	10 mg + 10 mg	INDIA	Indoco Remedies Limited (Plant I)	INDIA
115	TAN 00,2349 M01A IND	Flamar-mx	Diclofenac + Chlorzoxazone + Paracetamol	Tablets	50 mg + 250 mg + 325 mg	INDIA	Indoco Remedies Limited (Plant I)	INDIA
116	TZ 18 H 0113	Metcheck 850	Metformin Hydrochloride	Tablets	850 mg	INDIA	Indoco Remedies Limited	INDIA

Tanzania Food, Drugs and Cosmetics (List of Registered Human and Veterinary Medicinal Products and Withdrawn Medicinal Products)

GN. No. 21 (Contd)

117	TZ13 H054	Flamgen	Methyl Salicylate + Mephensin + Methyl Nicotinate	Cream	8% w/w + 5% w/w + 1% w/w + 2% w/w	INDIA	Indoco Remedies Limited (Plant I)	INDIA
Registrant: Intas Pharmaceuticals Limited								
118	TZ 18 H 0061	Rovas 5	Rosuvastatin	Tablets	5 mg	INDIA	Intas Pharmaceuticals Limited	INDIA
119	TZ 18 H 0060	Rovas 10	Rosuvastatin	Tablets	10 mg	INDIA	Intas Pharmaceuticals Limited	INDIA
120	TZ13 H020	Sartel-40H	Telmisartan and Hydrochlorothiazide	Tablets	40/12.5 mg	INDIA	Intas Pharmaceuticals Limited	INDIA
121	TZ 18 H 0059	Rovas 20	Rosuvastatin	Tablet, Film-coated	20 mg	INDIA	Intas Pharmaceuticals LIMITED	INDIA
122	TAN 00,21 54 A02B INT	Heligo kit	Clarithromycin + Lansoprazole + Tinidazole	Tablets	250 mg + 30 mg + 500 mg	INDIA	Intas Pharmaceuticals Limited	INDIA
Registrant: IPCA Laboratories Limited								
123	TZ 18 H 0008	Rapiclav 250 DT	Amoxicillin and Clavulanate Potassium	Tablets	250 + 62.5 mg	INDIA	IPCA Laboratories Limited	INDIA
124	TZ13 H025	Lumerax 80/480	Artemether and lumefantrine	Tablets	80mg + 480mg	INDIA	IPCA Laboratories Limited	INDIA
Registrant: Laboratories and Allied Limited								
125	TAN 00,41 28 J01H LAB	Kemoxyl	Amoxicillin trihydrate	Powder for Oral solution	125 mg/5ml	KENYA	Laboratories and Allied Limited	KENYA
126	TAN 00,41 29	Letrax	Levamisole	Tablets	40 mg	KENYA	Laboratories and Allied	KENYA

Tanzania Food, Drugs and Cosmetics (List of Registered Human and Veterinary Medicinal Products and Withdrawn Medicinal Products)

GN. No. 21 (Contd)

	P02X LAB						Limited	
1 2 7	TAN 00,26 20 P02X PHD	Natoa	Mebendazole	Suspe nsion, Oral	100 mg/5m l	KENY A	Laboratori es and Allied Limited	KEN YA
1 2 8	TZ13 H072	Ferrollic - LF Tablets	Albendazole	Table ts	200mg + 0.40m g	KENY A	Laboratori es and Allied Limited	KEN YA
Registrant: Lincoln Pharmaceuticals Limited								
1 2 9	TAN 00,20 01 N02B LIN	Vivian	Diclofenac	Table ts	50 mg	INDIA	Lincoln Pharmaceu ticals Limited	INDI A
1 3 0	TAN 00,20 00 J03C LIN	Dermofu lvin	Griseofulvin	Table ts	500 mg	INDIA	Lincoln Pharmaceu ticals Limited	INDI A
1 3 1	TZ 18 H 0119	TINI- 500	Tinidazole	Table ts	500 mg	INDIA	Lincoln Pharmaceu ticals Limited	INDI A
1 3 2	TZ 18 H 0108	LCT Kit	Lansoprazole 30mg + Tinidazole 500mg + Clarithromycin 250mg	Table ts	30 + 250 + 500 mg	INDIA	Lincoln Pharmaceu ticals Ltd	INDI A
1 3 3	TZ 18 H 0127	VAST- 10	Atorvastatin Calcium	Table ts	10 mg	INDIA	Lincoln Pharmaceu ticals Limited	INDI A
1 3 4	TAN 00,19 98 D01A LIN	Clotrilin V	Clotrimazole	Crea m	2 %w/w	INDIA	Lincoln Pharmaceu ticals Limited	INDI A
1 3 5	TZ 18 H 0025	VAST- 20	Atorvastatin Calcium	Table ts	20 mg	INDIA	Lincoln Pharmaceu ticals Limited	INDI A
1 3 6	TAN 00,19 99 J01A	Teterous	Tetracycline	Capsu les	250 mg	INDIA	Lincoln Pharmaceu ticals Limited	INDI A

Tanzania Food, Drugs and Cosmetics (List of Registered Human and Veterinary Medicinal Products and Withdrawn Medicinal Products)

GN. No. 21 (Contd)

	LIN							
1 3 7	TZ 18 H 0052	Timolin	Timolol Maleate	Ophth almic Soluti on	0.5 %w/v	INDIA	Lincoln Parenteral Limited	INDI A
1 3 8	TAN 00,41 36 J03C LIN	Norzole	Norfloxacin + Tinidazole	Table ts	400 mg + 600 mg	INDIA	Lincoln Pharmaceu ticals Limited	INDI A
1 3 9	TZ 18 H 0051	Binafin	Terbinafine Hydrochloride	Crea m	1%	INDIA	Lincoln Pharmaceu ticals Limited	INDI A
1 4 0	TZ 18 H 0106	KLARO -500	Clarithromycin	Table ts	500 mg	INDIA	Lincoln Pharmaceu ticals Limited	INDI A
Registrant: M.J. Biopharm Private Limited								
1 4 1	TZ13 H053	Azyth	Azithromycin Dihydrate	Capsu les, hard	250 mg	INDIA	M.J Biopharm Limited	INDI A
1 4 2	TZ 18 H 0128	Teico- 1000	Cefepime	Powd er for soluti on for injecti on	1000m g	INDIA	M.J Biopharm Limited	INDI A
1 4 3	TZ 18 H 0066	Teico- 500	Cefepime	Powd er for soluti on for injecti on	500mg	INDIA	M.J Biopharm Limited	INDI A
Registrant: Macleods Pharmaceuticals Limited								
1 4 4	TZ 18 H 0056	Isoniazid	Isoniazid	Table ts	300 mg	INDIA	Macleods Pharmaceu ticals Limited	INDI A
1 4 5	TZ 18 H 0038	Febumac 80	Febuxostat	Table ts	80 mg	INDIA	Macleods Pharmaceu ticals Limited	INDI A
Registrant: Medley Pharmaceuticals Limited								

Tanzania Food, Drugs and Cosmetics (List of Registered Human and Veterinary Medicinal Products and Withdrawn Medicinal Products)

GN. No. 21 (Contd)

146	TZ13 H013	Motinorm	Domperidone	Syrup	5 mg/5ml	INDIA	Medley Pharmaceuticals Limited	INDIA
Registrant: Medopharm Private Limited								
147	TZ18 H0089	Cledomox 625		Tablet, Film-coated	500 + 125 mg	INDIA	Medopharm Private Limited	INDIA
Registrant: Mega Lifesciences (Australia) Proprietary Company Limited								
148	TZ13 H045	Ligabab 150	Pregabalin	Capsules	150mg	AUSTRALIA	MSN Laboratories Private Limited (Formulations Division),	INDIA
149	TZ13 H044	Ligabab 75	Pregabalin	Capsules	75mg	AUSTRALIA	MSN Laboratories Private Limited (Formulations Division),	INDIA
150	TZ18 H0012	PANFOR SR-1000	Metformin Hydrochloride	Tablets	1000 mg	AUSTRALIA	Inventia Healthcare Private Limited	INDIA
151	TZ13 H100	CILZEC	Telmisartan	Tablets	80mg	AUSTRALIA	MSN Laboratories Private Limited (Formulations division)	INDIA
152	TZ13 H111	Cilzec Plus	Telmisartan	Tablets	40mg/12.5mg	AUSTRALIA	MSN Laboratories Private Limited (Formulations division)	INDIA

Tanzania Food, Drugs and Cosmetics (List of Registered Human and Veterinary Medicinal Products and Withdrawn Medicinal Products)

GN. No. 21 (Contd)

153	TZ13 H110	Kipel 5	Montelukast	Tablets	5mg	AUSTRALIA	MSN Laboratories Private Limited (Formulations division)	INDIA
154	TZ13 H109	Kipel 4	Montelukast	Tablets, Chewable	4 mg	AUSTRALIA	MSN Laboratories Private Limited (Formulations division)	INDIA
Registrant: Mega Lifesciences Public Company Limited								

*Tanzania Food, Drugs and Cosmetics (List of Registered Human and
Veterinary Medicinal Products and Withdrawn Medicinal Products)*

Gn. No. 21 (Contd)

155	TZ13 H004	Prenatal	Multivitamins and trace elements	Capsu les, soft	Vitami n A Palmit ate 4,000. 00 IU, Vitami n D ₃ 400.00 IU, Vitami n B ₁ (Thia mine Mono nitrate) 2.00 mg, Vitami n B ₂ (Ribof lavin) 2.00 mg, Niacin amide 10.00 mg, Vitami n B ₆ (Pyrid oxine Hydro chlorid e) 2.00 mg, Calciu m Pantot henate 2.00 mg, Folic Acid 0.25 mg, Vitami n C (Ascor bic Acid)	THAIL AND	Mega Lifescienc es Public Company Limited	THAI LAN D
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*Tanzania Food, Drugs and Cosmetics (List of Registered Human and
Veterinary Medicinal Products and Withdrawn Medicinal Products)*

Gn. No. 21 (Contd)

				37.50 mg, Vitami n B ₁₂ 2.00 mcg, Calciu m (as carbon ate) 100.00 mg, Vitami n E (Toco pheryl Acetat e) 1.00 IU, Iron (as Ferrou s Sulpha te) 20.00 mg, Coppe r (as Coppe r Sulpha te) 0.5 mg, Iodine (as Potassi um Iodide) 0.05 mg, Magne sium (as Magne sium Sulpha te) 1.00 mg,			
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*Tanzania Food, Drugs and Cosmetics (List of Registered Human and
Veterinary Medicinal Products and Withdrawn Medicinal Products)*

GN. No. 21 (Contd)

					Manga nese (as Manga nese Sulpha te) 0.10 mg, Potassi um (as Potassi um Sulpha te) 1.00 mg, Potassi um iodine 0.05m g, Zinc (as Zinc Sulpha te) monoh ydrate 0.15 mg			
Registrant: Merck Proprietary Limited								
1 5 6	TZ13 H177	Glucoph age	Metformin Hydrochloride	Table ts	1000 mg	SOUT H AFRIC A	Merck Sante s.a.s.	FRAN CE
1 5 7	TZ13 H137	Glucoph age	Metformin Hydrochloride	Table ts	500 mg	SOUT H AFRIC A	Merck Sante s.a.s.	FRAN CE
Registrant: Moraf Pharmaceuticals LTD								

Tanzania Food, Drugs and Cosmetics (List of Registered Human and Veterinary Medicinal Products and Withdrawn Medicinal Products)

GN. No. 21 (Contd)

158	TZ 18 H 0028	AMLOB ERG 10	Amlodipine Besylate	Tablets	10 mg	Tanzania	THE MADRAS PHARMACEUTICALS	INDIA
159	TZ 18 H 0027	AMLOB ERG 5	Amlodipine Besylate	Tablets	5 mg	Tanzania	THE MADRAS PHARMACEUTICALS	INDIA
Registrant: MSD (Pty) Limited								
160	TAN 00,25 56 R06A ESS	Aerius	Desloratadine	Tablets	5 mg	SOUTH AFRICA	Schering Plough Laboratories N.V	BELGIUM
161	TZ 18 H 0118	Singulair 4 mg	Montelukast Sodium	Granules	4 mg	SOUTH AFRICA	MSD (Pty) Limited	SOUTH AFRICA
Registrant: MSN Laboratories Private Limited (Formulations division)								
162	TZ 18 H 0026	Dapoxetine 60	Dapoxetine Hydrochloride	Tablets	60 mg	INDIA	MSN Laboratories Private Limited (Formulations Division),	INDIA
163	TZ13 H181	Breathezy 10	Montelukast	Tablets	10mg	INDIA	MSN Laboratories Private Limited (Formulations Division),	INDIA
164	TZ13 H117	Pregasafe	Pregabalin	Capsules	75 mg	INDIA	MSN Laboratories Private Limited (Formulations Division),	INDIA
Registrant: Mylan Laboratories Limited								

Tanzania Food, Drugs and Cosmetics (List of Registered Human and Veterinary Medicinal Products and Withdrawn Medicinal Products)

GN. No. 21 (Contd)

165	TAN 08,013 J05A MAT	Lopinavir/Ritonavir	Lopinavir + Ritonavir	Tablets	200mg + 150mg	INDIA	Mylan Laboratories Limited	INDIA
166	TAN 08,012 J05A MAT	Abacavir Sulphate	Abacavir Sulfate	Tablets	300mg	INDIA	Mylan Laboratories Limited	INDIA
167	TAN 08,009 J05A MAT	Tenofovir Disoproxil Fumarate/Emtricitabine	Tenofovir + Emtricitabine	Tablets	300mg + 200mg	INDIA	Mylan Laboratories Limited	INDIA
168	TAN 08,016 J05A MAT	Nevirapine	Nevirapine	Tablets	200mg	INDIA	Mylan Laboratories Limited	INDIA
169	TAN 08,011 J05A MAT	Tenofovir Disoproxil Fumarate	Tenofovir Disoproxil Fumarate	Tablets	300mg	INDIA	Mylan Laboratories Limited	INDIA
170	TAN 08,010 J05A MAT	Tenofovir Disoproxil Fumarate/Lamivudine	Tenofovir Disoproxil Fumarate + Lamivudine	Tablets	300mg + 300mg	INDIA	Mylan Laboratories Limited	INDIA
Registrant: Napp Pharmaceuticals limited								
171	TZ 18 H 0100	Flutiform	Formoterol and fluticasone	Inhaler	250/10 mcg	UNITED KINGDOM	Fisons Limited	UNITED KINGDOM
Registrant: Naprod Life Sciences Pvt Limited.								
172	TZ13 H019	4 - Epeedo - 50	Epirubicin	Lyophilized Injection	50 mg	INDIA	Naprod Life Sciences Private Limited	INDIA
Registrant: Nectar Lifesciences Limited								

Tanzania Food, Drugs and Cosmetics (List of Registered Human and Veterinary Medicinal Products and Withdrawn Medicinal Products)

GN. No. 21 (Contd)

173	TZ 18 H 0013	FIXINE CT 400	Cefixime	Tablets	100 mg/5ml	INDIA	Nectar Lifesciences Limited - UNIT VI	INDIA
Registrant: Novo Nordisk Production S.A.S								
174	TZ 18 H 0131	Human Insulin - Insultard	Human Insulin	Suspension for injection	100 IU/ml	FRANCE	Novo Nordisk A/S	DENMARK
175	TZ 18 H 0130	Human Insulin - Actrapid	Human Insulin	Suspension for injection	100 IU/ml	FRANCE	Novo Nordisk A/S	DENMARK
176	TZ 18 H 0135	Human Insulin - NovoRapid FlexPen	Insulin aspart	Solution for injection	100 units/ml	FRANCE	Novo Nordisk A/S	DENMARK
177	TZ 18 H 0134	NovoMix 30 FlexPen	Insulin aspart	Suspension for injection	100 units/ml	FRANCE	Novo Nordisk A/S	DENMARK
178	TZ 18 H 0133	Human Insulin - Mixtard 30	Human Insulin	Suspension for injection	100 IU/ml	FRANCE	Novo Nordisk A/S	DENMARK
179	TZ 18 H 0132	Human Insulin - Levemir Flexpen	Insulin Detemir	Solution for injection	100 IU/ml	FRANCE	Novo Nordisk A/S	DENMARK
Registrant: Octapharma AG								
180	TZ 18 H 0079	Albunorm 20	Albumin	Solution for injection	200 g/L	SWITZERLAND	Octapharma Productionsgesellschaft Deutschland mbH	GERMANY
Registrant: Panacea Biotec Limited								
181	TZ13 H114	Livoluk	Lactulose	Solution, Oral	10 g	INDIA	Panacea Biotech Limited	INDIA
Registrant: Pfizer Laboratories Limited								

Tanzania Food, Drugs and Cosmetics (List of Registered Human and Veterinary Medicinal Products and Withdrawn Medicinal Products)

GN. No. 21 (Contd)

182	TAN 00,930 B04A WAR	Lipitor	Atorvastatin	Tablets	10mg	KENYA	Pfizer manufacturing Deutschland GmbH	GERMANY
Registrant: Pharmed Limited								
183	TZ 18 H 0123	Synezze	Cetirizine hydrochloride	Solution	5 mg/5ml	Tanzania	Aurochem Laboratories India Private Limited	INDIA
184	TZ 18 H 0123	Synezze	Cetirizine hydrochloride	Solution	5 mg/5ml	Tanzania	Aurochem Laboratories India Private Limited	INDIA
Registrant: Reckitt Benckiser Healthcare UK Limited								
185	TZ 18 H 0039	Nurofen Cold & Flu	Ibuprofen + Pseudoephedrine	Tablets	230 mg	UNITED KINGDOM	Reckitt Benckiser Healthcare International Limited	UNITED KINGDOM
186	TZ 18 H 0037	nurofen	Ibuprofen	Capsules, soft	400 mg	UNITED KINGDOM	Reckitt Benckiser Healthcare International Limited	UNITED KINGDOM
187	TZ 18 H 0032	nurofen	Ibuprofen	Tablets	400 mg	UNITED KINGDOM	Reckitt Benckiser Healthcare International Limited	UNITED KINGDOM
Registrant: Remedica Limited								
188	TAN 00,2632 G04B REM	Alopron	Allopurinol	Tablets	300 mg	CYPRUS	Remedica Limited	CYPRUS
Registrant: Rena Exports								
189	TZ 18 H 0122	Triaf - Inj 1g	Ceftriaxone	Powder for solution for injection	1 g	INDIA	REYOUNG PHARMACEUTICAL CO., LIMITED	CHINA

Tanzania Food, Drugs and Cosmetics (List of Registered Human and Veterinary Medicinal Products and Withdrawn Medicinal Products)

GN. No. 21 (Contd)

Registrant: Riva Pharma S.A.E								
190	TAN 00,2637 J01C RIP	Rivaclox	Ampicillin + Cloxacillin	Suspension, Oral	125 mg/5ml + 125 mg/5ml	EGYPT	Riva Pharma S.A.E	EGYPT
Registrant: Rotexmedica GmbH Arzneimittelwerk								
191	TZ13 H065	Oxytocin	Oxytocin	Solution for injection	5 Units / ml	GERMANY	Rotexmedica GmbH Arzneimittelwerk	GERMANY
Registrant: S K Age Exports								
192	TAN 00,9621 J01K SKT	Ciprokan t	Ciprofloxacin Hydrochloride	Tablets	500 mg	INDIA	S Kant Healthcare Limited	INDIA
193	TAN 08,0230 C01C S K	Propranolol	Propranolol	Tablets	40 mg	INDIA	S Kant Healthcare Limited	INDIA
194	TZ 18 H 0002	MYGRA	Sildenafil Citrate	Tablets	100 mg	INDIA	S Kant Healthcare Limited	INDIA
195	TAN 08,1059 J03C S K	SilverKant	Silver Sulfadiazine	Cream	1.0%w/w	INDIA	S Kant Healthcare Limited	INDIA
Registrant: Salama Pharmaceuticals Limited								
196	TZ 18 H 0046	Panacid 40	Pantoprazole sodium	Tablet, Enteric Coated	40 mg	Tanzania	ACME Formulation Private Limited	INDIA
197	TZ 18 H 0086	CEFIPY M	Cefipime	Powder for solution for injection	1 g	Tanzania	REYOUNG PHARMACEUTICAL CO., LIMITED	CHINA
198	TZ 18 H 0074	BSV-HUMOG 75 HP	Menotropins	Injection	75 IU	Tanzania	Bharat Serums and Vaccines Limited	INDIA

Tanzania Food, Drugs and Cosmetics (List of Registered Human and Veterinary Medicinal Products and Withdrawn Medicinal Products)

GN. No. 21 (Contd)

199	TZ 18 H 0045	Tiniz 500	Tinidazole	Tablet, Film-coated	500 mg	Tanzania	ACME Formulation Private Limited	INDIA
2000	TZ 18 H 0073	HUCOG 5000 HP	Chorionic Gonadotrophin	Injection	5000 IU	Tanzania	Bharat Serums and Vaccines Limited	INDIA
2001	TZ 18 H 0054	Folix 5	Folic Acid	Tablets	5 mg	Tanzania	ACME Formulation Private Limited	INDIA
2002	TZ 18 H 0099	Fibronex 500	Tranexamic acid	Tablet, Film-coated	500 mg	Tanzania	ACME Formulation Private Limited	INDIA
2003	TZ 18 H 0053	Ramivas c 2.5	Ramipril	Capsules, hard	2.5 mg	Tanzania	ACME Formulation Private Limited	INDIA
2004	TZ 18 H 0053	Ramivas c 2.5	Ramipril	Capsules, hard	2.5 mg	Tanzania	ACME Formulation Private Limited	INDIA
2005	TZ 18 H 0024	CARDITOR-20	Atorvastatin Calcium	Tablets	20 mg	Tanzania	ACME Formulation Private Limited	INDIA
2006	TZ 18 H 0023	CARDITOR-10	Atorvastatin Calcium	Tablets	10 mg	Tanzania	ACME Formulation Private Limited	INDIA
2007	TZ 18 H 0105	Irivisc DS	Carmellose Sodium	Solution	1.0 %w/v	Tanzania	Indoco Remedies Limited (Plant II)	INDIA
2008	TZ 18 H 0124	Zyflo 10	Alfuzosin	Tablets	10 mg	Tanzania	ACME Formulation Private Limited	INDIA
2009	TZ 18 H 0088	CEROX	Cefuroxime Sodium	Solution for injection	750 mg	Tanzania	Scott Edil Advanced Research Laboratories & Education Limited	INDIA

Tanzania Food, Drugs and Cosmetics (List of Registered Human and Veterinary Medicinal Products and Withdrawn Medicinal Products)

GN. No. 21 (Contd)

210	TZ 18 H 0087	Cefipym	Cefepime	Powder for solution for injection	1000 mg	Tanzania	Scott Edil Advanced Research Laboratories & Education Limited	INDIA
Registrant: Sance Laboratories Private Limited								
211	TZ 18 H 0121	Sandox - 200	Cefpodoxime Proxetile	Tablets	200 mg	INDIA	Sance Laboratories Private Limited	INDIA
212	TZ 18 H 0043	Sanaxone - 1000	Ceftriaxone Sodium	Powder for solution for injection	1000 mg	INDIA	Sance Laboratories Private Limited	INDIA
Registrant: Sandoz GmbH								
213	TZ 18 H 0080	Amoxicillin 250mg	Amoxicillin	Tablet, Dispersible	250 mg	AUSTRIA	Sandoz GmbH, Kundl	AUSTRIA
Registrant: SERUM INSTITUTE OF INDIA LTD								
214	TAN 00,26 40 J06B SER	SII Tetanus Antitoxin	Tetanus Antitoxin	Vaccine	1500 IU/ml	INDIA	Serum Institute of India Limited	INDIA
Registrant: Shanghai Dahua Pharmaceutical Company Limited								
215	TZ 18 H 0110	LEVOP LANT	Levonorgestrel	Subdermal Implant	75 mg	CHINA	Shanghai Dahua Pharmaceutical Company Limited	CHINA
Registrant: Shayana Healthcare Private Limited								
216	TZ 18 H 0095	SHAFGRA	Sildenafil Citrate	Tablets	100 mg	INDIA	Lincoln Pharmaceuticals Limited	INDIA

Tanzania Food, Drugs and Cosmetics (List of Registered Human and Veterinary Medicinal Products and Withdrawn Medicinal Products)

GN. No. 21 (Contd)

217	TZ 18 H 0001	SHAFG RA-50	Sildenafil Citrate	Tablets	50 mg	INDIA	Lincoln Pharmaceuticals Limited	INDIA
Registrant: Square Pharmaceuticals Limited								
218	TZ 18 H 0092	Dexonex C Eye/ Ear drop	Dexamethasone + Chlorpheniramine Maleate	Ear/Eye Drops	1 + 5 mg	Bangladesh	Square Pharmaceuticals Limited	BANGLADESH
Registrant: Strides Shasun Limited								
219	TZ 18 H 0016	Nofong	Terbinafine Hydrochloride	Cream	1.0 %w/w	INDIA	The Madras Pharmaceuticals	INDIA
220	TZ 18 H 0040	Virso	Sofosbuvir	Tablets	400 mg	INDIA	Strides Shasun Limited	INDIA
Registrant: Sun Pharmaceutical Industries Limited								
221	TZ 18 H 0007	Etocox	Etoricoxib	Tablets	90 mg	INDIA	Sun Pharmaceutical Industries Limited	INDIA
222	TZ 18 H 0044	Tob DM Sterile Eye Drop	Tobramycin + Dexamethasone	Ophthalmic Suspension	1 mg	INDIA	Sun Pharmaceutical Industries Limited	INDIA
223	TZ 18 H 0006	Etocox	Etoricoxib	Tablets	60 mg	INDIA	Sun Pharmaceutical Industries Limited	INDIA
224	TZ 18 H 0005	Etocox	Etoricoxib	Tablets	120 mg	INDIA	Sun Pharmaceutical Industries Limited	INDIA
225	TAN 08,08 7 C01E SUN	Irovel	Irbesartan	Tablets	150 mg	INDIA	Sun Pharmaceutical Industries Limited	INDIA
226	TZ13 H017	Starval HCT 80 + 12.5	Valsartan + Hydrochlorothiazide	Tablets	80 mg+ 12.5 mg	INDIA	Sun Pharmaceuticals Industries Limited	INDIA
Registrant: Sunberg Life Science Private Limited								

Tanzania Food, Drugs and Cosmetics (List of Registered Human and Veterinary Medicinal Products and Withdrawn Medicinal Products)

GN. No. 21 (Contd)

2 2 7	TZ 18 H 0116	PREGA BA 75	Pregabalin	Capsu les	75 mg	INDIA	THE MADRAS PHARMA CEUTICA LS	INDI A
Registrant: Swiss Parenterals Limited								
2 2 8	TZ 18 H 0029	Clincina	Clindamycin	Soluti on for injecti on	600 mg/4ml	INDIA	Swiss Parenterals Limited	INDI A
Registrant: SYNMEDIC LABORATORIES								
2 2 9	TZ 18 H 0081	SYNAT OR 20	Atorvastatin Calcium	Table ts	20 mg	INDIA	SYNMED IC LABORA TORIES	INDI A
Registrant: TCS CO; LTD								
2 3 0	TZ 18 H 0019	Cefmdin e	Cefriaxone Sodium	Powd er for soluti on for injecti on	1.0 g	Tanzani a	FUREN PHARMA CEUTICA L GROUP COMPAN Y LIMITED.	CHIN A
Registrant: TROIKAA PHARMACEUTICALS LIMITED								
2 3 1	TZ13 H112	Troypof ol	Propofol	Emul sion for Inject ion	1%w/v	INDIA	Troikaa Pharmaceu ticals Limited	INDI A
Registrant: Unichem Laboratories Limited								
2 3 2	TZ13 H049	Corvadil	Amlodipine Besylate	Table ts	5 mg	INDIA	Unichem Laboratori es Limited	INDI A
2 3 3	TZ 18 H 0022	MPLify 20	Tadalafil	Table ts	20 mg	INDIA	Unichem Laboratori es Limited	INDI A
2 3 4	TZ13 H050	Corvadil	Amlodipine	Table ts	10 mg	INDIA	Unichem Laboratori es Limited	INDI A
Registrant: Vital Healthcare Private Limited								
2 3 5	TAN 00,24 29 R03A VIT	Vitaphyl line	Aminophylline	Inject ion	25 mg/ml	INDIA	Vital Healthcare Private Limited	INDI A

Tanzania Food, Drugs and Cosmetics (List of Registered Human and Veterinary Medicinal Products and Withdrawn Medicinal Products)

GN. No. 21 (Contd)

Registrant: Y.S.P Industries (M) SDN. BDH								
2 3 6	TZ 18 H 0077	Poro Supposit ory	Paracetamol	Supp ositor ies	125 mg	MALA YSIA	Y.S.P Industries (M) SDN. BHD	MAL AYSI A
2 3 7	TZ 18 H 0067	Voren Plus Gel	Diclofenac Sodium	Gel	10 mg/g	MALA YSIA	Y.S.P Industries (M) SDN. BHD	MAL AYSI A
2 3 8	TZ 18 H 0078	Poro Supposit ory	Paracetamol	Supp ositor ies	250 mg	MALA YSIA	Y.S.P Industries (M) SDN. BHD	MAL AYSI A
2 3 9	TZ 18 H 0077	Poro Supposit ory	Paracetamol	Supp ositor ies	125 mg	MALA YSIA	Y.S.P Industries (M) SDN. BHD	MAL AYSI A

TANZANIA FOOD AND DRUGS AUTHORITY								
LIST OF REGISTERED VETERINARY PHARMACEUTICAL FROM 1 ST JANUARY, 2018 TO 30TH JUNE, 2018								
S/ N	Registr ation Numbe r	Product Name	INN Name	Dosage Form	Product Strength	Registr ant Countr y	Manufac turer	Manufac turer's Country
Registrant: Ashish Life Science Private Limited								
1	TZ 18 V 0001	Diminas hish Plus	Diminazen e + Phenazone	granule s for injection	2.37 g	INDIA	Ashish Life Science Private Limited	INDIA
Registrant: Bajuta International (T) Limited								
2	TZ 18 V 0004	Bacolisti n	Colistin	Water Solubl e Powde r	10%	Tanzan ia	Hebei Yuanzhe ng Pharmac eutical Co. Limited	CHINA
Registrant: Ceva Biomune (BIOMUNE COMPANY)								
3	TZ 18 V 0005	Vectorm une HVT NDV & Rispen	N/A	Live, Frozen Vaccin e	2474 + 1206 PFU	United States of Americ a	Ceva Biomune (BIOMU NE COMPA	United States of America

Tanzania Food, Drugs and Cosmetics (List of Registered Human and Veterinary Medicinal Products and Withdrawn Medicinal Products)

GN. No. 21 (Contd)

							NY)	
4	TZ 18 V 0005	Vectorm une HVT NDV & Rispons	N/A	Live, Frozen Vaccin e	2474 + 1206 PFU	United States of Americ a	Ceva Biomune (BIOMU NE COMPA NY)	United States of America
Registrant: Ceva Sante Animale								
5	TZ 18 V 0006	CEVAC CORY MUNE 7K	N/A	Emulsi on	0.5 ml	FRAN CE	Ceva Phylaxia	HUNGA RY
6	TAN 00,252 5 J01A CEV	Tenaline 20% LA	Oxytetracy cline	Solutio n for injection	20 % w/v	FRAN CE	Ceva Sante Animale	FRANC E
7	TZ 18 V 0008	Cevac CORY MUNE 4 k	N/A	suspension vaccin e	0.5 ml	FRAN CE	Ceva Phylaxia	HUNGA RY
8	TZ 18 V 0007	CEVAC VITAB RON L	N/A	live, freeze- dried vaccin e	5.5/3.3 ml	FRAN CE	Ceva Phylaxia	HUNGA RY
Registrant: Kela Laboratoria N.V								
9	TAN 00,262 4 P01X PHE	Amproli um 20%	Amprolium	Powde r for Oral solutio n	20%w/w	BELGI UM	Kela Laborato ria N.V	BELGIU M
10	TAN 00,194 9 J01K PHE	Genta 10%	Gentamicin	Solutio n for injection	100000 IU/ml	BELGI UM	Kela Laborato ria N.V	BELGIU M
11	TAN 00,258 0 J01F KEL	Tylokel 20	Tylosine Tartrate	Solutio n	200 mg/ml	BELGI UM	Kela Laborato ria N.V	BELGIU M
12	TAN 00,193 7 J01K KEL	Albenzo le 10% Suspensi on	Albendazol e	Suspension, Oral	100 mg/ml	BELGI UM	Kela Laborato ria N.V	BELGIU M

Tanzania Food, Drugs and Cosmetics (List of Registered Human and Veterinary Medicinal Products and Withdrawn Medicinal Products)

GN. No. 21 (Contd)

13	TAN 00,2583 P01X KEL	Amprolium 20%	Amprolium	Powder for Oral solution	200 mg/g	BELGIUM	Kela Laboratoria N.V	BELGIUM
14	TAN 08,071 A11A KEL	Oligovit	MULTIVI TAMIN	Emulsion for Injection	2mg/ml +01mg/ml +50,000 IU/ml +25000 IU/ml +0056mg/ml +1mg/ml +0010mg/ml +4mg/ml +10mg/ml +2mg/ml +5mg/ml +01mg/ml +01mg/ml +002mg/ml +1mg/ml +5mg/ml +5mg/ml	BELGIUM	Kela Laboratoria N.V	BELGIUM
Registrant: M.C.I Sante Animale								
15	TZ 18 V 0003	AZADIM	Diminazine diacetate	Powder for solution for injection	1050/2.36 mg/g	MOROCCO	M.C.I Sante Animale	MOROCCO
16	TZ 18 V 0002	PARANTHIC 10%	Oxfendazole	Suspension, Oral	10%	MOROCCO	M.C.I Sante Animale	MOROCCO
17	TZ 18 V 0002	PARANTHIC 10%	Oxfendazole	Suspension, Oral	10%	MOROCCO	M.C.I Sante Animale	MOROCCO
Registrant: Norbrook Kenya Limited								

Tanzania Food, Drugs and Cosmetics (List of Registered Human and Veterinary Medicinal Products and Withdrawn Medicinal Products)

Gn. No. 21 (Contd)

18	TAN 00,131 8 J01J NOR	Multijec t IMM	Neomycin + Prednisolo ne + Procaine Penicillin + Streptomyc in	Suspen sion, Oral	20 mg/g + 20 mg/g + 20 mg/g + 20 mg/g	KENY A	Norbroo k Laborato ries Limited	NORTH ERN IRELAN D
19	TAN 00,132 7 S01A NOR	Opticlox	Cloxacillin	Ointme nt	167 % w/w	KENY A	Norbroo k Laborato ries Limited	NORTH ERN IRELAN D
20	TAN 00,439 1 J01A NOR	Alamyci n LA	Oxytetracy cline	Solutio n for injection	216 %w/v	KENY A	Norbroo k Laborato ries Limited	NORTH ERN IRELAN D
21	TAN 08,080 D08A NOR	Norbroo k Milking Salve	Dichloroph en	Ointme nt	0.55%w/ w	KENY A	Norbroo k Kenya Limited	KENYA
22	TAN 00,194 5 J01A NOR	Alamyci n LA	Oxytetracy cline	Solutio n for injection	300 mg/ml	KENY A	Norbroo k Laborato ries Limited	NORTH ERN IRELAN D
23	TAN 00,132 4 J01H NOR	Noroclo x DC	Cloxacillin	Suspen sion, Oral	500mg	KENY A	Norbroo k Laborato ries Limited	NORTH ERN IRELAN D

Dar es Salaam,
....., 2018

ADAM M. FIMBO
Director General