



GOVERNMENT GAZETTE

OF THE

REPUBLIC OF NAMIBIA

N\$7.20

WINDHOEK - 4 August 2020

No. 7296

CONTENTS

Page

GOVERNMENT NOTICES

No. 179	Cancellation of certain medicines: Medicines and Related Substances Control Act, 2003	1
No. 180	Registration of certain medicines: Medicines and Related Substances Control Act, 2003	7

Government Notices

MINISTRY OF HEALTH AND SOCIAL SERVICES

No. 179

2020

CANCELLATION OF CERTAIN MEDICINES: MEDICINES AND RELATED SUBSTANCES CONTROL ACT, 2003

In terms of section 23(a) of the Medicines and Related Substances Control Act, 2003 (Act No. 13 of 2003), I give notice that the medicines set out in the Schedule have been cancelled in terms of that Act.

J. GAESEB
REGISTRAR OF MEDICINES

Windhoek, 22 July 2020

SCHEDULE

S/N	Applicant	Registered Name	Approved name of active(s)	Registration Number
1	GlaxoSmithKline South Africa (Pty) Ltd	Amoxil S	Amoxicillin trihydrate	90/20.1.2/001574
2	GlaxoSmithKline South Africa (Pty) Ltd	Amoxil SF	Amoxicillin trihydrate	90/20.1.2/001575
3	GlaxoSmithKline South Africa (Pty) Ltd	Augmentin S	Amoxicillin + Clavulanate Potassium	90/20.1.2/001581
4	GlaxoSmithKline South Africa (Pty) Ltd	Augmentin SF	Amoxicillin + Clavulanate Potassium	90/20.1.2/001582
5	GlaxoSmithKline South Africa (Pty) Ltd	Beclforte Inhaler	Beclomethasone dipropionate	90/21.5.1/00565
6	GlaxoSmithKline South Africa (Pty) Ltd	Beconase Aqueous Nasal Spray	Beclomethasone dipropionate	90/21.5.1/00566
7	GlaxoSmithKline South Africa (Pty) Ltd	Becotide 50 Inhaler	Beclomethasone dipropionate	90/21.5.1/00568
8	GlaxoSmithKline South Africa (Pty) Ltd	Becotide 100 Inhaler	Beclomethasone dipropionate	90/21.5.1/00567
9	GlaxoSmithKline South Africa (Pty) Ltd	Brevoxyl cream	Benzoyl Peroxide	08/13.12/0210
10	GlaxoSmithKline South Africa (Pty) Ltd	Cirus tablets	Cetirizine Dihydrochloride, Pseudoephedrine Hydrochloride	08/5.7.1/0006
11	GlaxoSmithKline South Africa (Pty) Ltd	Cutivate ointment	Fluticasone Propionate	04/13.4.1/0859
12	GlaxoSmithKline South Africa (Pty) Ltd	Dermovate cream	Clobetasol propionate	90/13.4.1/00571
13	GlaxoSmithKline South Africa (Pty) Ltd	Dermovate ointment	Clobetasol propionate	90/13.4.1/00572
14	GlaxoSmithKline South Africa (Pty) Ltd	Dermovate Scalp Application	Clobetasol propionate	90/13.4.1/00573
15	GlaxoSmithKline South Africa (Pty) Ltd	Elantan capsule 50mg	Isosorbide Mononitrate	04/7.1.4/0689
16	GlaxoSmithKline South Africa (Pty) Ltd	Eumovate ointment		90/13.4.1/00574
17	GlaxoSmithKline South Africa (Pty) Ltd	Imigran injection	Sumatriptan	04/7.3/0941
18	GlaxoSmithKline South Africa (Pty) Ltd	Imigran 20mg Nasal spray	Sumatriptan	04/7.3/0871
19	GlaxoSmithKline South Africa (Pty) Ltd	Imigran 50mg tablets	Sumatriptan	04/7.3/0872
20	GlaxoSmithKline South Africa (Pty) Ltd	Imigran 100mg tablets	Sumatriptan	04/7.3/0873
21	GlaxoSmithKline South Africa (Pty) Ltd	Lamictin P25 tablets	Lamotrigine	04/2.5/0862
22	GlaxoSmithKline South Africa (Pty) Ltd	Lamictin P200	Lamotrigine	04/2.5/0865
23	GlaxoSmithKline South Africa (Pty) Ltd	Mencevax ACW135Y	Polysaccharides A, C, W 135 and Y (Freeze-dried preparation of purified polysaccharides from Nisseria Meningitidis)	04/30.1/0882
24	GlaxoSmithKline South Africa (Pty) Ltd	Nootropoli 400mg capsules	Piracetam	90/1.1/001634
25	GlaxoSmithKline South Africa (Pty) Ltd	Nootropoli 800mg capsules	Piracetam	90/1.1/001635

S/N	Applicant	Registered Name	Approved name of active(s)	Registration Number
26	GlaxoSmithKline South Africa (Pty) Ltd	Zantac 150mg tablets	Ranitidine hydrochloride	90/11.4.3/00592
27	GlaxoSmithKline South Africa (Pty) Ltd	Zantac 300mg tablets	Ranitidine hydrochloride	90/11.4.3/00593
28	GlaxoSmithKline South Africa (Pty) Ltd	Zelitrex 250mg	Valaciclovir	04/20.2.8/0913
29	Pharmacare Limited t/a Aspen Pharmacare	Alvercol Granules	Alverine citrate	05/11.5/0439
30	Novartis South Africa (Pty) Limited	Voltaren 12.5mg	Diclofenac	90/3.1/00731
31	Sanofi-Aventis South Africa (Pty) Ltd	Amaryl M 1mg/250mg	Glimepiride+Metformin	10/21.2/0580
32	Sanofi-Aventis South Africa (Pty) Ltd	Arava 100mg	Leflunomide	04/3.1/1451
33	Sanofi-Aventis South Africa (Pty) Ltd	Arelix 3mg	Piretanide	90/18.1/001509
34	Sanofi-Aventis South Africa (Pty) Ltd	Arelix 6mg	Piretanide	90/18.1/001510
35	Sanofi-Aventis South Africa (Pty) Ltd	Anthisan injection	Mepyramine maleate	14/5.7/0353
36	Sanofi-Aventis South Africa (Pty) Ltd	Anthisan 50mg tablets	Mepyramine maleate	14/5.7/0354
37	Sanofi-Aventis South Africa (Pty) Ltd	Anthisan elixir 25mg/5ml	Mepyramine maleate	14/5.7/0357
38	Sanofi-Aventis South Africa (Pty) Ltd	Analgen SA tablets	Aluminium Acetylsalicylate, Paracetamol, Chlorphenoxamine HCl, Codeine Phosphate, Caffeine, Phenobarbitone	14/2.8/0355
39	Sanofi-Aventis South Africa (Pty) Ltd	Benzamycin	Erythromycin-Benzoyl peroxide	04/13.12/1455
40	Sanofi-Aventis South Africa (Pty) Ltd	Bi-Profenid 150mg tablets	Ketoprofen	10/3.1/0157
41	Sanofi-Aventis South Africa (Pty) Ltd	Bronchicough	Tincture Cimicifugae, Tincture Pimpinellae, Tincture Quebracho, Ephedrine Hydrochloride, Eucalyptus Oil, Tincture Grindeliae, Tincture Primulae, Tincture Thymi	90/10.1/00300
42	Sanofi-Aventis South Africa (Pty) Ltd	Bronchiflu syrup	Mepyramine Maleate, Menthol, Ammonium Chloride, Paracetamol, Phenylpropanolamine HCl, Alcohol 95%	14/5.8/0348
43	Sanofi-Aventis South Africa (Pty) Ltd	Claforan 1g vial	Cefotaxime	90/20.1.1/00302
44	Sanofi-Aventis South Africa (Pty) Ltd	Claforan 500mg vial	Cefotaxime	90/20.1.1/00303
45	Sanofi-Aventis South Africa (Pty) Ltd	Clopidogrel 75mg	Clopidogrel	10/8.2/0021
46	Sanofi-Aventis South Africa (Pty) Ltd	Clopidogrel-Winthrop 75mg	Clopidogrel	10/8.2/0221
47	Sanofi-Aventis South Africa (Pty) Ltd	Colchicine Houde 1mg	Colchicine	01 1001653
48	Mirren (Pty) Ltd	Streptase 1 500 000IU	Streptokinase	11/31/0042
49	Sanofi-Aventis South Africa (Pty) Ltd	Cordarone X100	Amiodarone	05/6.2/0007

S/N	Applicant	Registered Name	Approved name of active(s)	Registration Number
50	Sanofi-Aventis South Africa (Pty) Ltd	Granocyte 34	Lenograstim 33.6 MIU	04/30.4/1638
51	Sanofi-Aventis South Africa (Pty) Ltd	Eglovely 50mg	Sulpiride	90/2.6.5/001514
52	Sanofi-Aventis South Africa (Pty) Ltd	Eglovely Elixir	Sulpiride	90/2.6.5/001515
53	Sanofi-Aventis South Africa (Pty) Ltd	Eglovely forte	Sulpiride	90/2.6.5/001516
54	Sanofi-Aventis South Africa (Pty) Ltd	Eglovely injection	Sulpiride	90/2.6.5/001517
55	Sanofi-Aventis South Africa (Pty) Ltd	Endoxan 1g	Cyclophosphamide	03 1002384
56	Sanofi-Aventis South Africa (Pty) Ltd	Endoxan 200mg	Cyclophosphamide	14/26/0427
57	Sanofi-Aventis South Africa (Pty) Ltd	Endoxan 50mg	Cyclophosphamide	03 1002385
58	Sanofi-Aventis South Africa (Pty) Ltd	Endoxan 500mg	Cyclophosphamide	03 1002383
59	Sanofi-Aventis South Africa (Pty) Ltd	Essaven	Escin+Phospholipids+Rutosides	02 1000640
60	Sanofi-Aventis South Africa (Pty) Ltd	Gardenal sodium 200mg/ml	Phenobarbital	03 1001894
61	Sanofi-Aventis South Africa (Pty) Ltd	Holoxan 500mg	Ifosfamide	90/26/00313
62	Sanofi-Aventis South Africa (Pty) Ltd	Holoxan 1g	Ifosfamide	04/26/1639
63	Sanofi-Aventis South Africa (Pty) Ltd	Holoxan 2g	Ifosfamide	90/26/00312
64	Sanofi-Aventis South Africa (Pty) Ltd	Intropin 40mg/ml	Dopamine	90/6.1/001521
65	Sanofi-Aventis South Africa (Pty) Ltd	Lanzor 30mg	Lansoprazole	04/11.4.3/0377
66	Sanofi-Aventis South Africa (Pty) Ltd	Lanzor 15mg	Lansoprazole	04/11.4.3/0376
67	Sanofi-Aventis South Africa (Pty) Ltd	Largactil 2ml	Chlorpromazine HCl	14/2.7.1/0358
68	Sanofi-Aventis South Africa (Pty) Ltd	Largactil 5ml	Chlorpromazine HCl	14/2.7.1/0461
69	Sanofi-Aventis South Africa (Pty) Ltd	Lasix 250mg/25ml	Furosemide	14/18.1/0360
70	Sanofi-Aventis South Africa (Pty) Ltd	Zamanon	Dolasetron mesilate	04/5.7.2/1460
71	Sanofi-Aventis South Africa (Pty) Ltd	Mimiric	Benzbromarone	90/3.3/001522
72	Sanofi-Aventis South Africa (Pty) Ltd	Narcan	Naloxone HCl	90/1.4/001523
73	Sanofi-Aventis South Africa (Pty) Ltd	Narcan Neonatal injection	Naloxone HCl	90/1.4/001524
74	Sanofi-Aventis South Africa (Pty) Ltd	Nomopain tablets	Paracetamol, Codeine Phosphate, Doxylamine Succinate, Caffeine	04/2.8/1641
75	Sanofi-Aventis South Africa (Pty) Ltd	Orucote suppository	Ketoprofen	90/3.1/0328
76	Sanofi-Aventis South Africa (Pty) Ltd	Plavix	Clopidogrel	05/8.2/0240

S/N	Applicant	Registered Name	Approved name of active(s)	Registration Number
77	Sanofi-Aventis South Africa (Pty) Ltd	Proctosedyl Ointment	Cinchocaine hydrochloride+hydrocortisone	14/13.4.1/0464
78	Sanofi-Aventis South Africa (Pty) Ltd	Proctosedyl Suppositories	Cinchocaine hydrochloride+hydrocortisone	14/13.4.1/0465
79	Sanofi-Aventis South Africa (Pty) Ltd	Profenid Gel	Ketoprofen	10/20.11/0095
80	Sanofi-Aventis South Africa (Pty) Ltd	Quinoderm	Benzoyl peroxide, potassium hydroxyquinoline sulphate	14/13.11/0325
81	Sanofi-Aventis South Africa (Pty) Ltd	Ramiwin	Ramipril	06/7.1.3/0189
82	Sanofi-Aventis South Africa (Pty) Ltd	Rifa four E-200	Rifampicin, Isoniazid, Pyrazinamide, Ethambutol	04/20.2.2/0381
83	Sanofi-Aventis South Africa (Pty) Ltd	Rifinah	Rifampicin, Isoniazid	04/20.2.3/1457
84	Sanofi-Aventis South Africa (Pty) Ltd	Rifinah 150mg tablet	Rifampicin, Isoniazid	04/20.2.3/1645
85	Sanofi-Aventis South Africa (Pty) Ltd	Rifinah Junior 60/30	Rifampicin, Isoniazid	04/20.2.3/1644
86	Sanofi-Aventis South Africa (Pty) Ltd	Rulide	Roxithromycin	90/20.1.1/00335
87	Sanofi-Aventis South Africa (Pty) Ltd	Sectral 25mg	Acebutolol	05/5.2/0406
88	Sanofi-Aventis South Africa (Pty) Ltd	Sectral 100mg	Acebutolol	90/5.2/00340
89	Sanofi-Aventis South Africa (Pty) Ltd	Sectral 200mg	Acebutolol	90/5.2/00341
90	Sanofi-Aventis South Africa (Pty) Ltd	Sectral 400mg	Acebutolol	90/5.2/00342
91	Sanofi-Aventis South Africa (Pty) Ltd	Sofratulle pieces	Impregnated gauze	14/14.2/0361
92	Sanofi-Aventis South Africa (Pty) Ltd	Surmontil 50mg	Trimipramine maleate	90/1.2/00346
93	Sanofi-Aventis South Africa (Pty) Ltd	Tarivid 200mg	Ofloxacin	04/20.1.1/0382
94	Sanofi-Aventis South Africa (Pty) Ltd	Tarivid 400mg	Ofloxacin	04/20.1.1/0383
95	Sanofi-Aventis South Africa (Pty) Ltd	Tarivid IV 200mg	Ofloxacin	04/20.1.1/1458
96	Sanofi-Aventis South Africa (Pty) Ltd	Tavan SP-54	Sodium Pentosan	03 1001989
97	Sanofi-Aventis South Africa (Pty) Ltd	Tavanic IV 250mg	Levofloxacin	04/20.1.1/1649
98	Sanofi-Aventis South Africa (Pty) Ltd	Tavanic IV 500mg	Levofloxacin	04/20.1.1/0384
100	Sanofi-Aventis South Africa (Pty) Ltd	Tavanic 500mg tablet	Levofloxacin	04/20.1.1/1459
101	Sanofi-Aventis South Africa (Pty) Ltd	Tavanic 250mg Tablet	Levofloxacin	04/20.1.1/1209
102	Sanofi-Aventis South Africa (Pty) Ltd	Trental	Pentoxifylline	90/8/00348
103	Sanofi-Aventis South Africa (Pty) Ltd	Tridil 25mg	Glyceryl trinitrate	90/7.1.3/001528
104	Sanofi-Aventis South Africa (Pty) Ltd	Tridil 50mg	Glyceryl trinitrate	90/7.1.3/001529
105	Sanofi-Aventis South Africa (Pty) Ltd	Tridomose	Gestrinone	90/21.12/00349

S/N	Applicant	Registered Name	Approved name of active(s)	Registration Number
106	Sanofi-Aventis South Africa (Pty) Ltd	Tritace	Ramipril	04/7.1.3/1389
107	Sanofi-Aventis South Africa (Pty) Ltd	Uromitexan	Mesna	90/18/00351
108	Sanofi-Aventis South Africa (Pty) Ltd	Virobis cream	Moroxydine Hydrochloride, Cetrimide, Diphenhydramine HCL	14/20.2.6/0346
109	Sanofi-Aventis South Africa (Pty) Ltd	Virobis tablets	Moroxydine Hydrochloride, Atropine Methonitrate, Scopolamine Methonitrate	14/20.2.8/0431
110	P&G South African Trading (Pty) Ltd	Iliadin tablets	Paracetamol, Caffeine and Bromopheniramine	10/5.8/0650
111	Merck (Pty) Ltd	Besobrial tablets	Acamprosate Calcium	04/9/0575
112	Janssen Pharmaceutica	Sinamax Cold and Flu Caplets	Ibuprofen, Pseudoephedrine HCl	04/5.8/0290
113	Janssen Pharmaceutica	Risperdal 4mg tablets	Risperidone	04/2.6.5/0256
114	Pharmaplan (Pty) Ltd	Cardiject 250	Dobutamine	08/6.1/0002
115	Novo Nordisk	NovoNorm 0.5mg	Repaglinide	05/21.2/0411
116	Novo Nordisk	NovoNorm 1.0mg	Repaglinide	05/21.2/0412
117	Novo Nordisk	NovoNorm 2.0mg	Repaglinide	05/21.2/0413
118	AstraZeneca Pharmaceuticals (Pty) Ltd	Vimovo 500/20mg	Naproxen and Esomeprazole	13/3.1/0207
119	Roche Products (Pty) Ltd	Konakion MM PAED 2mg/2ml	PHYTOMENADIONE	10/22/0654
120	Roche Products (Pty) Ltd	Konakion MM 10mg/1ml	PHYTOMENADIONE	10/22/0655
121	Pfizer Laboratories (Pty) Ltd	Prevenar 7	Streptococcus Pneumoniae (4, 9V, 14, 18C, 19F and 23F)	06/30.1/0094

MINISTRY OF HEALTH AND SOCIAL SERVICES

No. 180

2020

**REGISTRATION OF CERTAIN MEDICINES:
MEDICINES AND RELATED SUBSTANCES CONTROL ACT, 2003**

In terms of section 23(a) of the Medicines and Related Substances Control Act, 2003 (Act No. 13 of 2003), I give notice that the medicines set out in the Schedule have been registered in terms of that Act, subject to the following conditions:

- (a) The manufacture and control of the medicines must be in accordance with the existing good manufacturing practices as required by the World Health Organization;
- (b) In order to assess compliance with paragraph (a) above, inspections and investigations may be carried out regularly by inspectors authorised in terms of sections 35 of the Act to undertake such inspections and investigations;
- (c) Every manufacturer of a medicine must, with the approval of the Namibia Medicines Regulatory Council, ensure that the information contained in the medicine package insert is regularly updated and varied so as to provide accurate information to the user of the medicine;
- (d) The holder of the certificate of registration referred to in section 19(4) of the Act must comply with the provisions of the Act;
- (e) The registration of medicine is subject to regular review regarding its quality, safety and efficacy and the Namibia Medicines Regulatory Council may if necessary, vary the registration of the medicine;
- (f) The first two production batches must be validated in accordance with the detailed validation process which was submitted at the time of the application for registration;
- (g) A validation report must be submitted to the Namibia Medicines Regulatory Council within 30 days from the date of completion of the validation process referred to in paragraph (f); and
- (h) The Namibia Medicines Regulatory Council may review the registration dossier and may determine the intervals when such review will take place.

J. GAESEB
REGISTRAR OF MEDICINES

Windhoek, 22 July 2020

SCHEDULE

S/N	Applicant	Proprietary Name	Approved Name Of Active(S)	Dosage Form	Strength/Dose Unit	Registration Number	Registration Date	Scheduling Status
1	Alcon Laboratories (SA) (Pty) Ltd	Viscoat	Sodium hyaluronate and Sodium chondroitin sulphate	Ophthalmic Viscosurgical Device	Each ml contains: Sodium hyaluronate 30mg and Sodium chondroitin sulphate 40mg	20/32.2/0001	09.04.2020	NS2
2	Alcon Laboratories (SA) (Pty) Ltd	Duovisc	Sodium hyaluronate and Sodium chondroitin sulphate	Ophthalmic Viscosurgical Device	VISCOAT - Each ml contains: Sodium hyaluronate 30mg and Sodium chondroitin sulphate 40mg PROVISC - Each ml contains: Sodium hyaluronate 10mg	20/32.2/0002	09.04.2020	NS2
3	Alcon Laboratories (SA) (Pty) Ltd	Provisc	Sodium hyaluronate	Ophthalmic Viscosurgical Device	Each ml contains: Sodium hyaluronate 10mg	20/32.2/0003	09.04.2020	NS2
4	Eli Lilly (SA) (Pty) Ltd	Cyramza 100	Ramucirumab	Concentrate for Solution for Infusion	Each ml contains: Ramucirumab 10mg	20/26/0004	09.04.2020	NS2
5	Eli Lilly (SA) (Pty) Ltd	Cyramza 500	Ramucirumab	Concentrate for Solution for Infusion	Each ml contains: Ramucirumab 10mg	20/26/0005	09.04.2020	NS2
6	Janssen Pharmaceutica (Pty) Ltd	Imbruvica	Ibrutinib	Capsule	Each capsule contains: Ibrutinib 140mg	20/26/0006	09.04.2020	NS2
7	Pharmacare Limited t/a Aspen Pharmacare	Emla 5%	Lidocaine & Prilocaine	Cream	Each 1g cream contains: Lidocaine 25mg and Prilocaine 25mg	20/4/0007	09.04.2020	NS1
8	Cipla Medpro (Pty) Ltd	Ultipot	Potassium chloride	Slow release film-coated tablet	Each Slow Release Film-Coated Tablet contains: 600mg Potassium chloride equivalent to 315mg potassium (8 mmol / 8 meq K+)	20/24/0008	09.04.2020	NS1
9	AstraZeneca Pharmaceuticals (Pty) Ltd	Forxiga 5mg	Dapagliflozin propanediol	Film-coated tablet	Each film-coated tablet contains: Dapagliflozin Propanediol equivalent to Dapagliflozin 5mg	20/21.2/0009	09.04.2020	NS2
10	AstraZeneca Pharmaceuticals (Pty) Ltd	Forxiga 10mg	Dapagliflozin propanediol	Film-coated tablet	Each film-coated tablet contains: Dapagliflozin Propanediol Dapagliflozin 10mg	20/21.2/0010	09.04.2020	NS2
11	Biotech Laboratories (Pty) Ltd	Loratadine 10 biotech	Loratadine	Tablet	Each tablet contains: Loratadine 10mg	20/5.7.1/0011	09.04.2020	NS1

S/N	Applicant	Proprietary Name	Approved Name Of Active(S)	Dosage Form	Strength/Dose Unit	Registration Number	Registration Date	Scheduling Status
12	Doré Pharmaceuticals (Pty) Ltd	Ibuprofen-Doré 400mg	Ibuprofen	Tablet	Each tablet contains: Ibuprofen 400mg	20/2.8/0012	09.04.2020	NS1/NS2
13	Doré Pharmaceuticals (Pty) Ltd	Metformin-Doré 500mg tablets	Metformin	Tablet	Each tablet contains: Metformin 500mg	20/21.2/0013	09.04.2020	NS2
14	Jubilant Generics Limited	Levojob 500	Levofloxacin hemihydrate	Film-coated tablet	Each film-coated tablet contains: Levofloxacin hemihydrate 512.460mg corresponding to Levofloxacin 500mg	20/20.1.1/0014	09.04.2020	NS2
15	Jubilant Generics Limited	Levojob 250	Levofloxacin hemihydrate	Film-coated tablet	Each film-coated tablet contains: Levofloxacin hemihydrate 256.230mg corresponding to Levofloxacin 250mg	20/20.1.1/0015	09.04.2020	NS2
16	Jubilant Generics Limited	Jubazi 250	Azithromycin dihydrate	Film-coated tablet	Each film-coated tablets contains Azithromycin dihydrate Ph. Eur. 262.02mg equivalent to Azithromycin 250mg	20/20.1.1/0016	09.04.2020	NS2
17	Jubilant Generics Limited	Jubazi 500	Azithromycin dihydrate	Film-coated tablet	Each film-coated tablets contains Azithromycin dihydrate Ph. Eur. 524.04mg equivalent to Azithromycin 500mg	20/20.1.1/0017	09.04.2020	NS2
18	Namax Pharmaceutical (Pty) Ltd	Sevoflurane Usp inhalation anesthetic liquid 250ml	Sevoflurane	Volatile liquid for inhalation	Each bottle contains: Sevoflurane 250ml	20/2.1/0018	09.04.2020	NS3
19	Aurobindo Pharma (Pty) Ltd	Dolin 5mg	Escitalopram oxalate	Tablet	Each film-coated tablet contains: Escitalopram oxalate equivalent to escitalopram 5mg.	20/1.2/0019	09.04.2020	NS3
20	Aurobindo Pharma (Pty) Ltd	Dolin 10mg	Escitalopram oxalate	Tablet	Each film-coated tablet contains: Escitalopram oxalate equivalent to 10mg escitalopram.	20/1.2/0020	09.04.2020	NS3
21	Aurobindo Pharma (Pty) Ltd	Dolin 20mg	Escitalopram oxalate	Tablet	Each film-coated tablet contains: Escitalopram oxalate equivalent to 20mg Escitalopram	20/1.2/0021	09.04.2020	NS3
22	Litha Pharma (Pty) Ltd	Hibor 2500iu/0.2ml	Bemiparin sodium	Solution for injection	Each 0,2ml contains: 60mg Bemiparin (low-molecular weight heparin, sodium salt) equivalent to 2500 IU (anti Factor Xa *) [equivalent to 25 000 i. u. (anti F-Xa) permil]	20/8.2/0022	09.04.2020	NS2
23	Litha Pharma (Pty) Ltd	Hibor 3500iu/0.2ml	Bemiparin sodium	Solution for injection	Each 0,2ml contains: 60mg Bemiparin (low-molecular weight heparin, sodium salt) equivalent to 3500 IU (anti Factor Xa *) [equivalent to 25 000 i. u. (anti F-Xa) permil]	20/8.2/0023	09.04.2020	NS2

S/N	Applicant	Proprietary Name	Approved Name Of Active(S)	Dosage Form	Strength/Dose Unit	Registration Number	Registration Date	Scheduling Status
24	Litha Pharma (Pty) Ltd	Hibor 5000iu/0.2ml	Bemiparin sodium	Solution for injection	Each 0,2ml contains: 60mg Bemiparin (low-molecular weight heparin, sodium salt) equivalent to 5 000 IU (anti Factor Xa *) [equivalent to 25 000 i.u. (anti F-Xa) permil]	20/8.2/0024	09.04.2020	NS2
25	Litha Pharma (Pty) Ltd	Hibor 7500iu/0.3ml	Bemiparin sodium	Solution for injection	Each 0,3ml contains: 60mg Bemiparin (low-molecular weight heparin, sodium salt) equivalent to 7500 IU (anti Factor Xa *) [equivalent to 25 000 i.u. (anti F-Xa) permil]	20/8.2/0025	09.04.2020	NS2
26	Litha Pharma (Pty) Ltd	Hibor 10 000iu/0.4ml	Bemiparin sodium	Solution for injection	Each 0,4ml contains: 60mg Bemiparin (low-molecular weight heparin, sodium salt) equivalent to 10 000 IU (anti Factor Xa *) [equivalent to 25 000 i.u. (anti F-Xa) permil]	20/8.2/0026	09.04.2020	NS2
27	Cipla Medpro (Pty) Ltd	Colchicine houde	Colchicine	Tablet	Each tablet contains: Colchicine 1mg	20/3.3/0027	09.04.2020	NS1
28	Innovata Pharmaceuticals (Pty) Ltd	Avatocin 5	Oxytocin	Liquid injection	Each vial contains: Oxytocin 5IU	20/19/0028	09.04.2020	NS2
29	SM Pharmaceuticals	Shrizine injection	Fluphenazie Decanoate	Solution for solution	Each 1ml solution contains fluphenazine decanoate 25mg.	20/2.7.1/0029	09.04.2020	NS3
30	Mylan Laboratories Limited	Komefan 140	Artemether and Lumefantrine	Tablet	Each film-coated tablet contains artemether 20mg and lumefantrine 120mg.	20/20.2.6/0030	09.04.2020	NS2
31	Mylan Laboratories Limited	Komefan 280	Artemether and Lumefantrine	Tablet	Each film-coated tablet contains artemether 40mg and lumefantrine 240mg.	20/20.2.6/0031	09.04.2020	NS2
32	Sakar Healthcare Limited	E-Dol	Tramadol Hydrochloride	Injection	Each ml contains: tramadol HCl 50mg.	20/2.9/0032	09.04.2020	NS3
33	Sakar Healthcare Limited	Frudis	Furosemide	Injection	Each 2ml contains Furosemide 20mg	20/18.1/0033	09.04.2020	NS2
34	Sakar Healthcare Limited	Ondi	Ondansetron HCl USP	Injection	Each ml contains: Ondansetron Hydrochloride USP Eq. to Ondansetron 2mg	20/5.10/0034	09.04.2020	NS2
35	Cipla Medpro (Pty) Ltd	Aripiprazole Cipla 5	Aripiprazole	Tablet	Each tablet contains: aripiprazole 5mg	20/2.6/0035	09.04.2020	NS3
36	Cipla Medpro (Pty) Ltd	Aripiprazole Cipla 10	Aripiprazole	Tablet	Each tablet contains: aripiprazole 10mg	20/2.6/0036	09.04.2020	NS3

S/N	Applicant	Proprietary Name	Approved Name Of Active(S)	Dosage Form	Strength/Dose Unit	Registration Number	Registration Date	Scheduling Status
37	Cipla Medpro (Pty) Ltd	Aripiprazole Cipla 15	Aripiprazole	Tablet	Each tablet contains: Aripiprazole 15mg	20/2.6/0037	09.04.2020	NS3
38	Cipla Medpro (Pty) Ltd	Aripiprazole Cipla 30	Aripiprazole	Tablet	Each tablet contains: Aripiprazole 30mg	20/2.6/0038	09.04.2020	NS3
39	Aurobindo Pharma (Pty) Ltd	Auro Fluconazole 50mg	Fluconazole	Capsule	Each capsule contains 50mg, 150mg and 200mg Fluconazole	20/20.2.2/0039	09.04.2020	NS2
40	Aurobindo Pharma (Pty) Ltd	Auro Fluconazole 150mg	Fluconazole	Capsule	Each capsule contains 50mg, 150mg and 200mg Fluconazole	20/20.2.2/0040	09.04.2020	NS2
41	Aurobindo Pharma (Pty) Ltd	Auro Fluconazole 200mg	Fluconazole	Capsule	Each capsule contains 50mg, 150mg and 200mg Fluconazole	20/20.2.2/0041	09.04.2020	NS2
42	Mylan Laboratories Limited	Acruptega	Dolutegravir, Lamivudine and Tenofovir Disoproxil Fumarate	Tablets	Each tablet contains: Dolutegravir 50mg, Lamivudine 300mg and Tenofovir Disoproxil Fumarate 300mg	20/20.2.8/0042	09.04.2020	NS2
43	Hetero Labs Ltd	Dolutegravir, Lamivudine and Tenofovir Disoproxil fumarate tablets 50/300/300mg	Dolutegravir, Lamivudine and Tenofovir Disoproxil Fumarate	Tablets	Each tablet contains: Dolutegravir/Lamivudine/Tenofovir Disoproxil Fumarate 50mg/300mg/300mg	20/20.2.8/0043	09.04.2020	NS2
44	Eurolab (Pty)	Doxel 20	Docetaxel equivalent to Docetaxel (anhydrous)	Solution for infusion	Each ml contains: Docetaxel 20mg	20/26/0044	09.04.2020	NS2
45	Eurolab (Pty)	Doxel 80	Docetaxel equivalent to Docetaxel (anhydrous)	Solution for infusion	Each 4ml contains: Docetaxel 80mg	20/26/0045	09.04.2020	NS2
46	Eurolab (Pty)	Doxel 140	Docetaxel equivalent to Docetaxel (anhydrous)	Solution for infusion	Each 7ml contains: Docetaxel 140mg	20/26/0046	09.04.2020	NS2
47	Mylan Laboratories Limited	Mylan Dolutegravir	Dolutegravir	Tablets	Each tablet contains: Dolutegravir 50g	20/20.2.8/0047	09.04.2020	NS2
48	Ranbaxy Pharmaceuticals (Pty) Ltd	Dolutegravir tablets 50mg	Dolutegravir	Tablets	Each tablet contains: Dolutegravir 50g	20/20.2.8/0048	09.04.2020	NS2
49	Ranbaxy Pharmaceuticals (Pty) Ltd	Coricib 30	Etoricoxib 30	Film coated tablets	Each film coated tablet contains: Etoricoxib 30mg	20/3.1/0049	09.04.2020	NS2
50	Ranbaxy Pharmaceuticals (Pty) Ltd	Coricib 60	Etoricoxib 60	Film coated tablets	Each film coated tablet contains: Etoricoxib 60mg	20/3.1/0050	09.04.2020	NS2

S/N	Applicant	Proprietary Name	Approved Name Of Active(S)	Dosage Form	Strength/Dose Unit	Registration Number	Registration Date	Scheduling Status
51	Ranbaxy Pharmaceuticals (Pty) Ltd	Coricib 90	Etoricoxib 90	Film coated tablets	Each film coated tablet contains: Etoricoxib 90mg	20/3.1/0051	09.04.2020	NS2
52	Ranbaxy Pharmaceuticals (Pty) Ltd	Coricib 120	Etoricoxib 120	Film coated tablets	Each film coated tablet contains: Etoricoxib 120mg	20/3.1/0052	09.04.2020	NS2
53	Mylan Laboratories Limited	Kocitaf	Dolutegravir sodium Emtricitabine Tenofovir Alafenamie Fumarate	Tablets	Each tablet contains: Dolutegravir sodium 50mg Emtricitabine 200mg and Tenofovir Alafenamide Fumarate 25mg	20/20.2.8/0053	09.04.2020	NS2
54	Haempharma (Pty) Ltd	Apotel® max 10mg/ml	Paracetamol 10mg/ml	Solution for Infusion	Each ml contains: Paracetamol 10mg	20/2.8/0054	09.04.2020	NS2
55	Glenmark Pharmaceuticals South Africa (Pty) Ltd.	Ryaltris 0,025/0,665 % m/m nasal spray	Olopatadin, mometasone furoate	Nasal Spray	Each spray delivers: Olopatadine hydrochloride USP equivalent to Olopatadine 600 mcg and Mometasone furoate monohydrate equivalent to mometasone furoate 25 mcg	20/32.2/0055	09.04.2020	NS2
56	Emcure Pharmaceuticals Ltd.	Instgra 50	Dolutegravir	Tablets	Each tablet contains: Dolutegravir 50g	20/20.2.8/0056	09.04.2020	NS2
57	Macleods Pharmaceuticals Limited	Zidovudine oral solution Usp 50mg/5ml	Zidovudine	Oral Solution	Each 5ml solution contains: Zidovudine 50mg	20/20.2.8/0057	09.04.2020	NS2
58	Macleods Pharmaceuticals Limited	Lopinavir 100mg and ritonavir 25mg tablets	Lopinavir and Ritonavir	Film-coated Tablet	Each film coated tablet contains: Lopinavir 100mg and Ritonavir 25mg	20/20.2.8/0058	09.04.2020	NS2
59	Macleods Pharmaceuticals Limited	Tenofovir Disoproxil fumarate Usp 300mg/ Lamivudine Usp 300mg/ Efavirenz Usp 400mg	Tenofovir Disoproxil Fumarate, Lamivudine and Efavirenz	Film coated Tablet	Each tablet contains: Tenofovir Disoproxil Fumarate USP 300mg, Lamivudine USP 300mg and Efavirenz USP 400mg	20/20.2.8/0059	09.04.2020	NS2
60	Laurus Labs Limited	Dolutegravir Sodium, Lamivudine & Tenofovir Disoproxil fumarate 50/300/300mg	Dolutegravir Sodium, Lamivudine & Tenofovir Disoproxil Fumarate	Film-coated tablet	Each tablet contains: Dolutegravir sodium 50mg, lamivudine 300mg and Tenofovir disoproxil fumarate 300mg	20/20.2.8/0060	09.04.2020	NS2
61	Mylan Laboratories Limited	Contrasafe 150mg/ml	Medroxyprogesterone acetate injection 150mg/ml	Injection	Each ml of suspension contains 150mg Medroxyprogesterone acetate	20/21.8.2/0061	09.04.2020	NS2