



GOVERNMENT GAZETTE

OF THE

REPUBLIC OF NAMIBIA

N\$2.80

WINDHOEK - 19 November 2007

No. 3937

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Government Notice

MINISTRY OF HEALTH AND SOCIAL SERVICES

No. 211 2007

REGISTRATION OF CERTAIN MEDICINES: MEDICINES AND RELATED SUBSTANCES CONTROL ACT, 1965

In terms of section 17 of the Medicines and Related Substances Control Act, 1965 (Act No. 101 of 1965), I withdraw Government Notice No. 138 of 1 August 2007 and give notice that the medicines set out in the Schedule have been registered in terms of the 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), inspections and investigations may be carried out regularly by inspectors authorized in terms of section 26 of the Act;
- (c) The information in the package insert must regularly be updated to conform to the package insert approved by the Council;

- (d) The holder of the certificate of registration which is referred to in section 15(4) of the Act, must comply with the Act;
- (e) The registration of medicine is subject to regular review regarding its quality, safety and efficacy, and the council may, when necessary, vary the registration of the medicine;
- (f) The first two production batches must be validated in accordance with the detailed process validation protocol which was submitted at the time of the application for registration;
- (g) A validation report must be submitted to the council within one month from the date of completion of the validation referred to in paragraph (f); and
- (h) The council may review the registration dossier at such intervals as it may determine.

MR. J #GAESEB
REGISTRAR OF MEDICINES

Windhoek, 1 November 2007

SCHEDULE

S/N	APPLICANT	REGISTERED NAME	APPROVED NAME OF ACTIVE(S)	DOSSAGE FORM	STRENGTH/DOSE UNIT	NAM. REG. NO
1	Merck Sharp & Dohle Interphanna	Rota Teq	Combination	Oral Solution	Each 2ml dose contains human-bovine rotavirus reassortants GI 2.2 x 10 ⁶ Infectious Units, G2 2.8 x 10 ⁷ Infectious Units, G3 2.2 x 10 ⁶ Infectious Units, G4 2.0 x 10 ⁷ Infectious Units, PI 2.3 x 10 ⁶ Infectious Units	07/30.1/0015
2	GlaxoSmithKline SA (Pty) Ltd	Rotarix	Combination	Lyophilized Powder	Each 1,0 ml dose contains Live attenuated Human Rotavirus RIX4414 Strain - not less than 10 ⁶ CCID ₅₀	07/30.1/0016
3	GlaxoSmithKline SA (Pty) Ltd	Duosyn	Lamivudine, Zidovudine	Tablets	Each tablet contains Lamivudine 150,0 mg, Zidovudine 300,0 mg	07/20.2.8/0017
4	GlaxoSmithKline SA (Pty) Ltd	Heptovir	Lamivudine	Tablets	Each tablet contains Lamivudine 150,0 mg	07/20.2.8/0018
5	Phannaicare Limited (Pty) Ltd	Capastat Ig Injection	Capreomycin Sulphate	Injection	Each 1 Oml vial contains Capreomycin Sulphate equiv. to Capreomycin 1,0 g	07/20.1.1/0019
6	Merck Sharp & Dohle Interphanna	Gardasil	Combination	Injection	Each 0.5ml dose contains approximately 20 µg of HPV 6 L1 protein, 40 µg of HPV 11 L1 protein, 40 µg of HPV 16 L1 Protein, and 20 µg of HPV 18 L1 protein	07/30.1/0020
7	Bristol-Myers Squibb (Pty) Ltd	Perfalgan 0,5 g Solution for Injection	Paracetamol	Solution for Injection	Each 50 ml solution for Infusion contains Paracetamol 0,5 g	07/2.7/0021
8	Bristol-Myers Squibb (Pty) Ltd	Perfalgan 1,0 g Solution for Injection	Paracetamol	Solution for Injection	Each 100 ml solution for Infusion contains Paracetamol 1,0 g	07/2.7/0022

S/N	APPLICANT	REGISTERED NAME	APPROVED NAME OF ACTIVE(S)	DOSSAGE FORM	STRENGTH/DOSE UNIT	NAM. REG. NO
9	Allergan Pharmaceuticals (Pty) Ltd	Refresh Liquigel	Sodium Carboxymethylcellulose	Eye Drops	Each 1ml solution contains Sodium carboxymethylcellulose 10,0 mg	07/15.4/0023
10	Ranbaxy (S.A.) (Pty) Ltd	Cepodem 100	Cefpodoxime Proxetil	Tablets	Each Film coated Tablet contains Cefpodoxime Proxetil equiv. to Cefpodoxime 100,0 mg	07/20.1.1/0024
11	Ranbaxy (S.A.) (Pty) Ltd	Cepodem 200	Cefpodoxime Proxetil	Tablets	Each Film coated Tablet contains Cefpodosime Proxetil equiv. to Cefpodoxime 200,0 mg	07/20.1.1/0025
12	Ranbaxy (S.A.) (Pty) Ltd	Cepodem Suspension 40mg/5ml	Cefpodoxime Proxetil	Suspension	Each 5 ml suspension contains Cefpodoxime Proxetil equiv. to Cefpodoxime 40,0 mg	07/20.1.1/0026
13	Ranbaxy (S.A.) (Pty) Ltd	Ran-Citalopram 10	Citalopram	Tablets	Each tablet contains Citalopram Hydrobromide equiv. to Citalopram 10,0 mg	07/1.210027
14	Ranbaxy (S.A.) (Pty) Ltd	Ran-Citalopram 20	Citalopram	Tablets	Each tablet contains Citalopram Hydrobromide equiv. to Citalopram 20,0 mg	07/t2/0028
15	Ranbaxy (S.A.) (Pty) Ltd	Ran-Citalopram 40	Citalopram	Tablets	Each tablet contains Citalopram Hydrobromide equiv. to Citalopram 40,0 mg	07/12/0029
16	Ranbaxy (S.A.) (Pty) Ltd	Flucoric 200	Fluconazole	Capsule	Each capsule contains Fluconazole 200,0 mg	07/20.2.2/0030
17	Ranbaxy (S.A.) (Pty) Ltd	Flucoric 150	Fluconazole	Capsule	Each capsule contains Fluconazole 150,0 mg	07/20.2.2/0031
18	Ranbaxy (S.A.) (Pty) Ltd	Flucoric 100	Fluconazole	Capsule	Each capsule contains Fluconazole 100,0 mg	07/20.2.2/0032
19	Ranbaxy (S.A.) (Pty) Ltd	Flucoric 50	Fluconazole	Capsule	Each capsule contains Fluconazole 50,0 mg	07/20.2.2/0033
20	Ranbaxy (S.A.) (Pty) Ltd	Ran-Lansoprazole 15	Lansoprazole	Capsule	Each capsule contains Lansoprazole 15,0 mg	07/11.4.3/0034

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21	Ranbaxy (S.A.) (Pty) Ltd	Ran-Lansoprazole 30	Lansoprazole	Capsule	Each capsule contains Lansoprazole 30,0 tug	07/11.4.3/0035
22	Ranbaxy (S.A.) (Pty) Ltd	Laura 10 Tablets	Loratadine	Tablets	Each tablet contains Loratadine 10,0 mg	07/5.7.1/0036
23	Ranbaxy (S.A.) (Pty) Ltd	Ran-Ramipril 10	Ramipril	Capsule	Each capsule contains Ramipril 10,0 trig	07/7.1.3/0037
24	Aurobindo Phanna (Pty) Ltd	Auro-Stavudine Capsules 30 mg	Stavudine	Capsule	Each capsule contains Stavudine 30,0 mg	07/20.2.8/0038
25	Aurobindo Phanna (Pty) Ltd	Auro-Stavudine Capsules 40 mg	Stavudine	Capsule	Each capsule contains Stavudine 40,0 mg	07/20.2.8/0039
26	Cipla Life Sciences (Pty) Ltd	Stavir 30	Stavudine	Capsule	Each capsule contains Stavudine 30,0 mg	07/20.2.8/0040
27	Cipla Life Sciences (Pty) Ltd	Stavir 40	Stavudine	Capsule	Each capsule contains Stavudine 40,0 mg	07/20.2.8/0041
28	Pfizer Laboratories (Pty) Ltd	Nicorette Mint 4 tug (Gum)	Nicotine	Gum	Each gum contains Nicotine 4,0 mg	07/34/0042
29	Pfizer Laboratories (Pty) Ltd	Nicorette Mint 2 mg (Gum)	Nicotine	Gum	Each gum contains Nicotine 2,0 mg	07/34/0043
30	Pfizer Laboratories (Pty) Ltd	Nicorette 2 mg (Gum)	Nicotine	Gum	Each gum contains Nicotine 2,0 mg	07/34/0044
31	Pfizer Laboratories (Pty) Ltd	Nicorette 4 mg (Gum)	Nicotine	Gum	Each gum contains Nicotine 4,0 mg	07/34/0045
32	Phanna Dynamics (Pty) Ltd	Klarizon 250	Clarithromycin	Tablets	Each tablet contains Clarithromycin 250,0 mg	07/20.1.1/0046
33	Phanna Dynamics (Pty) Ltd	Klarizon 500	Clarithromycin	Tablets	Each tablet contains Clarithromycin 500,0 mg	07/20.1.1/0047

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34	Boehringer Ingelheim (Pty) Ltd	Atrovent 20 HFA	Ipratropium Bromide	Metered dose inhaler	Each 50 µl metered dose (puff) contains Ipratropium Bromide 21 µg equiv. to Ipratropium Bromide Anhydrous 20 µg	07/10.2.1/0048
35	Bristol-Myers Squibb (Pty) Ltd	Baraclude Oral Solution	Entecavir	Oral Solution	Each 1 ml solution contains Entecavir 0,05 mg	07/20.2.8/0049
36	Bristol-Myers Squibb (Pty) Ltd	Baraclude 1 mg Tablets	Entecavir	Tablets	Each tablet contains Entecavir 1,0 mg	07/20.2.8/0050
37	Bristol-Myers Squibb (Pty) Ltd	Baraclude 0,5 mg Tablets	Entecavir	Tablets	Each tablet contains Entecavir 0,5 mg	07/20.2.8/0051
38	Pfizer Laboratories (Pty) Ltd	Nicorette Patch 5 mg	Nicotine	Transdermal Patch	Each 10 square cm patch contains Nicotine 8,3 mg	07/34/0052
39	Pfizer Laboratories (Pty) Ltd	Nicorette Patch 10 mg	Nicotine	Transdermal Patch	Each 20 square cm patch contains Nicotine 16,6 mg	07/34/0053
40	Pfizer Laboratories (Pty) Ltd	Nicorette Patch 15 mg	Nicotine	Transdermal Patch	Each 30 square cm patch contains Nicotine 24,9 mg	07/34/0054
41	Wyeth (Pty) Ltd	Tazocin 4 EF	Piperacillin, Tazobactam	Powder for Injection	Each vial contains Piperacillin Sodium equiv. to Piperacillin 4,0 g and Tazobactam Sodium equiv. to Tazobactam 0,5 g	07/20.1.2/0055
42	Soflens (Pty) Ltd	Minims Dexamethasone Sodium Phosphate 0,1%	Dexamethasone Sodium Phosphate	Single Dose Eye Drops	Each 0,5 ml solution contains Dexamethasone Sodium Phosphate 0,0005 g	07/15.4/0056
43	Soflens (Pty) Ltd	Minims Atropine Sulphate 1%	Atropine Sulphate	Single Dose Eye Drops	Each 0,5 ml solution contains Atropine Sulphate 5,0 mg	07/15.4/0057
44	Soflens (Pty) Ltd	Minims Oxybuprocaine Hydrochloride 0,4%	Oxybuprocaine Hydrochloride	Single Dose Eye Drops	Each 0,5 ml solution contains Oxybuprocaine Hydrochloride 2,0 mg	07/15.4/0058

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45	Soflens (Pty) Ltd	Minims Lidocaine and Fluorescein	Lignocaine, Fluorescein	Single Dose Eye Drops	Each 0,5 ml solution contains Lignocaine Hydrochloride 20,0 mg; Fluorescein Sodium 1,25 mg	07/15.4/0059
46	Soflens (Pty) Ltd	Minims Pilocarpine 2%	Pilocarpine Nitrate	Single Dose Eye Drops	Each 0,5 ml solution contains Pilocarpine Nitrate 10,0 mg	07/15.4/0060
47	Soflens (Pty) Ltd	Minims Pilocarpine 4%	Pilocarpine Nitrate	Single Dose Eye Drops	Each 0,5 ml solution contains Pilocarpine Nitrate 20,0 mg	07/15.4/0061
48	Allergan Pharmaceuticals (Pty) Ltd	Acular	Ketorolac Tromethamine	Eye Drops	Each 1ml solution contains Ketorolac Tromethamine 5,0 mg	07/15.4/0062
49	Hoffmann-La Roche Ltd	Bonviva Solution for Injection 3mg/3ml	Ibandronic Acid Monosodium	Injection	Each pre-filled syringe contains Ibandronic Acid Monosodium Monohydrate equiv. to Ibandronic Acid 3,0 mg	07/3.2/0063
50	Hoffmann-La Roche Ltd	Xeloda 500 mg Tablets	Capecitabine	Tablets	Each film-coated tablet contains Capecitabine 500,0 mg	07/26/0064
51	Hoffmann-La Roche Ltd	Mabthera 100 mg	Rituximab	solution for infusion	Each single-use 10ml vial contains Rituximab 100,0 mg	07/26/0065
52	Hoffmann-La Roche Ltd	Mabthera 500 mg	Rituximab	Concentrate for solution for infusion	Each single-use 50ml vial contains Rituximab 500,0 mg	07/26/0066
53	Hoffmann-La Roche Ltd	Xeloda 150 mg Tablets	Capecitabine	Tablets	Each film-coated tablet contains Capecitabine 150,0 mg	07/26/0067
54	Hoffmann-La Roche Ltd	Avastin 100	Bevacizumab	Concentrate for solution for infusion	Each 4 ml single use vial contains Bevacizumab 100,0 mg	07/26/0068
55	Hoffmann-La Roche Ltd	Avastin 400	Bevacizumab	Concentrate for solution for infusion	Each 16 ml single use vial contains Bevacizumab 400,0 mg	07/26/0069

S/N	APPLICANT	REGISTERED NAME	APPROVED NAME OF ACTIVE(S)	DOSSAGE FORM	STRENGTH/DOSE UNIT	NAM. REG. NO
56	Teemed Phanna (Pty) Ltd	Scanlux 370 mg/ml	Iopamidol	Injection	Each lml solution contains Iopamidol 755 mg equiv. to Iodine 370,0 mg	07/28/0070
57	Teemed Phanna (Pty) Ltd	Scanlux 300 mg/ml	Iopamidol	Injection	Each lml solution contains Iopamidol 612 mg equiv. to Iodine 300,0 mg	07/28/0071
58	Teemed Pharioia (Pty) Ltd	Baritop 100	Barium Sulphate	Suspension	Each 100 ml suspension contains microfinned Barium Sulphate 100,0 g	07/28/0072
59	Be-Tabs Pharmaceuticals (Pty) Ltd	B-Block 50	Atenolol	Tablet	Each tablet contains Atenolol 50.0 mg	07/5.2/0073
60	Be-Tabs Pharmaceuticals (Pty) Ltd	B-Block 100	Atenolol	Tablet	Each tablet contains Atenolol 100.0 mg	07/5.2/0074
61	Be-Tabs Pharmaceuticals (Pty) Ltd	Lorfast Tablets	Loratadine	Tablet	Each tablet contains Loratadine 10.0 mg	07/5.7.1/0075
62	Be-Tabs Pharmaceuticals (Pty) Ltd	Nozer	Omeprazole	Capsule	Each tablet contains Omeprazole 20.0 mg	07/11.4.3/0076
63	Be-Tabs Pharmaceuticals (Pty) Ltd	Ranit 150	Ranitidine Hydrochloride	Tablet	Each tablet contains Ranitidine Hydrochloride equiv. to Ranitidine 150,0 mg	07/11.4.3/0077
64	Be-Tabs Pharmaceuticals (Pty) Ltd	Ranit 300	Ranitidine Hydrochloride	Tablet	Each tablet contains Ranitidine Hydrochloride equiv. to Ranitidine 300,0 mg	07/11.4.3/0078
65	Be-Tabs Pharmaceuticals (Pty) Ltd	Be-Tabs Naproxene 250	Naproxen	Tablets	Each tablet contains Naproxen 250.0 mg	07/3.1/0079

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66	Be-Tabs Pharmaceuticals (Pty) Ltd	Betaxime-250	Cefuroxime Sodium	Powder for Injection	Each vial contains Cefuroxime Sodium equiv. to Cefuroxime 250.0 mg	07/20.1.1/0080
67	Be-Tabs Pharmaceuticals(Pty) Ltd	Betaxime-750	Cefuroxime Sodium	Powder for Injection	Each vial contains Cefuroxime Sodium equiv. to Cefuroxime 750.0 mg	07/20.1.1/0081
68	Be-Tabs Pharmaceuticals (Pty) Ltd	Triaxiphin 1 G	Ceftriaxone Sodium	Powder for Injection	Each vial contains Ceftriaxone Sodium equiv. to Ceftriaxone 1.0 g	07/20.1.1/0082
69	Be-Tabs Pharmaceuticals (Pty) Ltd	Triaxiphin 500 mg	Ceftriaxone Sodium	Powder for Injection	Each vial contains Ceftriaxone Sodium equiv. to Ceftriaxone 500.0 mg	07/20.1.1/0083
70	Astellas Pharma (Pty) Ltd	Vesicare 5 mg	Solifenacin Succinate	Tablets	Each film-coated tablet contains Solifenacin Succinate 5.0 mg	07/5.4/0084
71	Ferring (Pty) Ltd	Menopur	Menotrophin (Human Menopausal Gonadotrophin)	Powder for Injection	Each vial contains Menotrophin equiv. to FSH 75 IU and LH 75 IU	07/21.10/0085
72	UCB (SA) (Pty) Ltd	Kepra Oral Solution 100 mg/ml	Levetiracetam	Oral Solution	Each lml solution contains Levetiracetam 100.0 mg	07/2.5/0086
73	MSD (Pty) Ltd	Invanz	Ertapenem Sodium	Injection	Each vial contains Ertapenem Sodium equiv. to Ertapenem 1.0 g	07/20.1.1/0087
74	Phannaplan (Pty) Ltd	Epleptin 400	Gabapentin	Capsule	Each capsule contains Gabapentin 400.0 mg	07/2.5/0088
75	Pharmaplan (Pty) Ltd	Epleptin 300	Gabapentin	Capsule	Each capsule contains Gabapentin 300.0 mg	07/2.5/0089
76	Phannaplan (Pty) Ltd	Epleptin 100	Gabapentin	Capsule	Each capsule contains Gabapentin 100.0 mg	07/2.5/0090
77	Janssen Pharmaceutica (Pty) Ltd	Prezista 300 mg Tablets	Darunavir Ethanolate	Tablets	Each film-coated tablet contains Darunavir Ethanolate equiv. to Danmavir 300.0 mg	07/20.2.8/0091

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78	Ingelheim Pharmaceuticals(Pty) Ltd	Inflammiide 400 Novolizer	Budesonide	Inhaler	Each metered dose (10,9 mg powder) contains Budesonide 400 Ng.	07/21.5.1/0092
79	Pfizer Laboratories (Pty) Ltd	Nicorette Microtab 2 mg	Nicotine	Tablet	Each tablet contains Nicotine B-Cyclodextrin equiv. to Nicotine 2.0 mg	07/34/0093
80	Genop Healthcare (Pty) Ltd	Trans-Ver-Sal	Salicylic Acid	Patch	Each 1,0 g contains salicylic Acid 150.0 mg	07/13.8/0094
81	Generix International SA (Pty) Ltd	Tamsul 0,4 SR	Tamsulosin Hydrochloride	Capsule	Each sustained release capsule contains Tamsulosin Hydrochloride 0.4 mg	07/34/0095
82	Genedx International SA (Pty) Ltd	Parkilyne	Selegiline Hydrochloride	Tablets	Each tablet contains Selegiline Hydrochloride 5.0 mg	07/5.4.1/0096
83	Eli Lilly (S.A.) (Pty) Ltd	Alimta 500 mg	Pemetrexed Disodium	Infusion	Each vial contains Pemetrexed Disodium equiv. to Pemetrexed 500.0 mg	07/26/0097
84	Pharma Dynamics (Pty) Ltd	Lancap 15	Lansoprazole	Capsules	Each capsule contains Lansoprazole 15.0 mg	07/11.4.3/0098
85	Phanna Dynamics (Pty) Ltd	Lancap 30	Lansoprazole	Capsules	Each capsule contains Lansoprazole 30.0 mg	07/11.4.3/0099
86	Pfizer Laboratories (Pty) Ltd	Zitluomax One	Azithromycin Extended Release	Oral Suspension	Each bottle contains Azithromycin Dihydrate equiv. to Azithromycin base 2,0 g	07120.1.110100
87	GlaxoSmithKline South Africa (Pty) Ltd	Infrinix hexa	Combination	Vaccine	Each 0,5 ml dose contains; Diphtheria toxoid nlt 30,0 in, Tetanus Toxoid nit 40,0 in, Pertusis Toxoid 25,0 µg; Pertactin 8,0 µg, Filamentous Hemagglutinin 25,0 µg, Recombinant HBsAG 10,0 µg, Polio Virus Type 1 Mahoney strain 40 du, Polio Virus type 2 MEF-1 strain 8,0 du, Polio Virus type 3 saukett strain 32,0 du, Haemophilus Influenza type B: PRP 10 µg, T 20,0 - 40,0 µg	07/30.1/0101

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88	Biogaran South Africa (Pty) Ltd	Prexum 5 mg	Perindopril Arginine	Tablets	Each tablet contains Perindopril Arginine 5,0 mg	07/7.1.3/0102
89	Biogaran South Africa (Pty) Ltd	Prexum 10 mg	Perindopril Arginine	Tablets	Each tablet contains Perindopril Arginine 10,0 mg	07/7.1.3/0103
90	Novartis South Africa (Pty) Ltd	Tareg 80	Valsartan	Tablets	Each film- coated tablet contains Valsartan 80,0 mg	07/7.1.3/0104 Novartis South Africa (Pty)
91	Novartis South Africa (Pty) Ltd	Tareg 160	Valsartan	Tablets	Each film- coated tablet contains Valsartan 160,0 mg	07/7.1.3/0105
92	Novartis South Africa (Pty) Ltd	Tareg 40	Valsartan	Tablets	Each film- coated tablet contains Valsartan 40,0 mg	07/7.1.3/0106
93	Novartis South Africa (Pty) Ltd	Co-Tareg 80	Valsartan Hydrochlorothiazide	Tablets	Each tablet contains Valsartan 80,0 mg, Hydrochlorothiazide 12,5 t ug	07/7.1.3/0107
94	Novartis South Africa (Pty) Ltd	Co-Tareg 160	Valsartan Hydrochlorothiazide	Tablets	Each tablet contains Valsartan 160,0 mg, Hydrochlorothiazide 12.5 mg	07/7.1.3/0108
95	Novartis South Africa (Pty) Ltd	Co-Tareg 160 Plus	Valsartan Hydrochlorothiazide	Tablets	Each tablet contains Valsartan 160,0 mg, Hydrochlorothiazide 25,0 mg	07/7.1.3/0109
96	Novartis South Africa (Pty) Ltd	Co-Diovan 160 Plus	Valsartan Hydrochlorothiazide	Tablets	Each tablet contains Valsartan 160,0 mg, Hydrochlorothiazide 25,0 mg	07/7.1.3/0110
97	Sandoz SA (Pty) Ltd	Sandoz Levofloxacin 250	Levofloxacin Hemihydrate	Tablets	Each tablet contains Levofloxacin Hemilhydrate equiv. to Levofloxacin 250,0 mg	07/20.1.1/0111
98	Sandoz SA (Pty) Ltd	Sandoz Levofloxacin 500	Levofloxacin Hemihydrate	Tablets	Each tablet contains Levofloxacin Hemihydrate equiv. to Levofloxacin 500,0 mg	0/20.1.1/0112
99	Sandoz SA (Pty) Ltd	Sandoz Azithromycin 500	Azithromycin Monohydrate	Tablets	Each tablet contains Azithromycin Monohydrate equiv. to Azithromycin 500,0 mg	07/20.1.1/0113

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100	Sandoz SA (Pty) Ltd	Sandoz Co-Amoxyclav 0,6 g/20 ml	Amoxicillin Sodium, Potassium Clavulanate	Injection	mg. Potassium Clavulanate equiv. to Clavulanic Acid 100,0 mg mg, Potassium Clavulanate equiv. to Clavulanic Acid 100,0 mg	07/20.1.2/0114
101	Sandoz SA (Pty) Ltd	Sandoz Co-Amoxyclav 1,2 g/20 ml	Amoxicillin Sodium, Potassium Clavulanate	Injection	Each 50 ml vial contains: Amoxicillin Sodium equiv. to Amoxicillin 1000,0 mg, Potassium Clavulanate equiv. to Clavulanic Acid 200,0 mg	07/20.1.2/0115
102	Phannacia South Africa (Pty) Ltd	Accumax 40 mg	Quinapril Hydrochloride	Tablets	Each tablet contains Quinapril Hydrochloride equiv. to Quinapril 40,0 mg	07/7.1.3/0116
103	Phannacia South Africa (Pty) Ltd	Accumax 20 mg	Quinapril Hydrochloride	Tablets	Each tablet contains Quinapril Hydrochloride equiv. to Quinapril 20,0 mg	07/7.1.3/0117
104	Phannacia South Africa (Pty) Ltd	Accumax 10 mg	Quinapril Hydrochloride	Tablets	Each tablet contains Quinapril Hydrochloride equiv. to Quinapril 10,0 mg	07/7.1.3/0118
105	Phannacia South Africa (Pty) Ltd	Accumax 5 mg	Quinapril Hydrochloride	Tablets	Each tablet contains Quinapril Hydrochloride equiv. to Quinapril 5,0 mg	07/7.1.3/0119
106	Pfizer Laboratories (Pty) Ltd	Onicit	Palonosetron Hydrochloride	Injection	Each 5 ml solution for injection contains Palonosetron Hydrochloride 0,25 mg	07/5.10/0120
107	Phannacare Limited	Aspen Mometasone Cream	Mometasone Furoate	Cream	Each 1 g cream contains Mometasone Furoate 1,0 mg	07/13.4.1/0121
108	Pfizer Laboratories (Pty) Ltd Lipitor 80	Atorvastatin Calcium	Trihydrate	Tablets	Each tablet contains Atorvastatin Calcium Trihydrate equiv. to Atorvastatin 80,0 mg	07/7.5/0122
109	Phannacia South Africa (Pty) Ltd	Aspavor 40	Atorvastatin Calcium Trihydrate	Tablets	Each tablet contains Atorvastatin Calcium Trihydrate equiv. to Atorvastatin 40,0 mg	07/7.5/0123
110	Phannacia South Africa (Pty) Ltd	Aspavor 20	Atorvastatin Calcium Trihydrate	Tablets	Each tablet contains Atorvastatin Calcium Trihydrate equiv. to Atorvastatin 20,0 mg	07/7.5/0124
111	Phannacia South Africa (Pty) Ltd	Aspavor 10	Atorvastatin Calcium Trihydrate	Tablets	Each tablet contains Atorvastatin Calcium Trihydrate equiv. to Atorvastatin 10,0 mg	07/7.5/0125

S/N	APPLICANT	REGISTERED NAME	APPROVED NAME OF ACTIVE(S)	DOSSAGE FORM	STRENGTH/DOSE UNIT	NAM. REG. NO
112	Phannacia South Africa (Pty) Ltd	Lomanor 5 mg	Amlodipine Besylate	Tablets	Each tablet contains Amlodipine Besylate equiv. to Amlodipine 5,0 mg	07/7.1/0126
113	Phannacia South Africa (Pty) Ltd	Lomanor 10 mg	Amlodipine Besylate	Tablets	Each tablet contains Amlodipine Besylate equiv. to Amlodipine 10,0 mg	07/7.11/0127
114	Phannacia South Africa (Pty) Ltd	Accumax Co 20/12,5	Quinapril Hydrochloride, Hydrochlorothiazide	Tablets	Each tablet contains Quinapril Hydrochloride equiv. to Quinapril 10,0 mg Hydrochlorothiazide 12,5 mg	07/7.11/0128
115	Phannacia South Africa (Pty) Ltd	Accumax Co 20/12,5	Quinapril Hydrochloride, Hydrochlorothiazide	Tablets	Each tablet contains Quinapril Hydrochloride equiv. to Quinapril 120,0 mg.	07/7.1.3/0129
116	Bristol-Myers Squibb (Pty) Ltd	Videx 2g Powder for Oral Solution	Didanosine	Oral Solution	Each paediatric powder bottle contains Didanosine 2,0 g	07/20.2.8/0130
117	Aurobindo Pharma Limited	Stavudine Capsules 20 mg	Stavudine	Capsule	Each capsule contains Stavudine 20,0 mg	07/20.2.8/0131
118	Phannacare Limited	Q-Pril 40 mg tablets	Quinapril Hydrochloride	Tablets	Each tablet contains Quinapril Hydrochloride equiv. to Quinapril 40,0 mg	07/7.1.3/0132
119	Phannacare Limited	Q-Pril 20 mg tablets	Quinapril Hydrochloride	Tablets	Each tablet contains Quinapril Hydrochloride equiv. to Quinapril 20,0 mg	07/7.1.3/0133
120	Phannacare Limited	Q-Pril 10 mg tablets	Quinapril Hydrochloride	Tablets	Each tablet contains Quinapril Hydrochloride equiv. to Quinapril 10,0 mg	07/7.1.3/0134
121	Pharmacare Limited	Q-Pril 5 mg Tablets	Quinapril Hydrochloride	Tablets	Each tablet contains Quinapril Hydrochloride equiv. to Quinapril 5,0 mg	07/7.1.3/0135
122	Phannacare Limited	Flusin Sinus tablets	Paracetamol, Pseudoephedrine	Tablets	Each tablet contains Paracetamol 1500 mg Pseudoephedrine 30 mg	07/5.8/0136
123	Pharntacare Limited	AP Azithromycin 500 mg Tablets	Azithromycin Monohydrate	Tablets	Each Tablet contains Azithromycin Monohydrate equiv. to Azithromycin Base 500 mg	07/20.1.1/0137
124	Phannacare Limited	Lenasil 1% Cream	Terbinafine Hydrochloride	Cream	Each 1g cream contains Terbinafine Hydrochloride 10.0 mg	07/t2/0138

S/N	APPLICANT	REGISTERED NAME	APPROVED NAME OF ACTIVE(S)	DOSSAGE FORM	STRENGTH/DOSE UNIT	NAM. REG. NO
125	Pharmacare Limited	Seroloft 50 mg Tablets	Sertraline Hydrochloride	Tablets	Each tablet contains Sertraline Hydrochloride equiv. to Sertraline 50,0 mg	07/1.2/0139
126	Pharmacare Limited	Seroloft 100 mg Tablets	Sertraline Hydrochloride	Tablets	Each tablet contains Sertraline Hydrochloride equiv. to Sertraline 100,0 mg	07/1.2/0140
127	Pharmacare Limited	Mucospect Expectoant Syrup	Guaiphenesin	Syrup	Each 5 ml Sugar free, Alcohol free Syrup contains Guaiphenesin 100,0 mg	07/10.1/0141
128	Cipla Medpro (Pty) Ltd	Duovir-N	Lamivudine, Zidovudine, Nevirapine	Tablets	Each Duovir tablet contains Lamivudine 150,0 mg, Zidovudine 300,0 mg. Each Nevirapine tablet contains Nevirapine 200,0 mg	07/20.2.8/0142
129	Hexal Pharma (SA) (Pty) Ltd	Hexal Pantoprazole IV	Pantoprazole Sodium Sequihydrate	Injection	Each vial contains Pantoprazole Sodium Sequihydrate equiv. to Pantoprazole 40,0 mg	07/11.4.3/0143
130	Hexal Pharma (SA) (Pty) Ltd	Topraloc IV	Pantoprazole Sodium Sequihydrate	Injection	Each vial contains Pantoprazole Sodium Sequihydrate equiv. to Pantoprazole 40,0 mg	07/11.4.3/0144
131	Wyeth (Pty) Ltd	Minesse	Gestodene, Ethinylestradiol	Tablets	Each active tablet contains Gestodene 0.006 mg, Ethinylestradiol 0.015 mg	07/18.8/0145
132	Pharmacare Limited	Flutex Cough Mixture Honey	Guaiphenesin	Syrup	Each 5 ml of Sugar free, Alcohol free Mixture contains Guaiphenesin 100,0 mg	07/10.1/0146