



GOVERNMENT GAZETTE

OF THE

REPUBLIC OF NAMIBIA

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Government Notices

MINISTRY OF HEALTH AND SOCIAL SERVICES

No. 209 2009

NOTICE OF APPOINTMENT OF MEMBERS OF NAMIBIA MEDICINES REGULATORY COUNCIL: MEDICINES AND RELATED SUBSTANCES CONTROL ACT, 2003

Under subsection (4) of section 3 of the Medicines and Related Substances Control Act, 2003 (Act No. 13 of 2003), I give notice that I have under subsection (1) of that section, appointed the following persons as members of the Namibia Medicines Regulatory Council for a period of three years commencing on 17 August 2009 and terminating on 16 August 2012.

1. Dr A. Marais
2. Ms T. K. Angula
3. Ms R. De Waal
4. Dr M. R. Diekmann
5. Dr N. Hamata,
6. Dr R. Hassel,
7. Dr K. T. Kafidi,
8. Ms U. Katjipuka,
9. Dr I. Katjitaë,
10. Ms K. Mutirua,

11. Ms D. J. Tjipura,
12. Ms H. K. Undjombala,

R. KAMWI
MINISTER OF HEALTH AND SOCIAL SERVICES

MINISTRY OF HEALTH AND SOCIAL SERVICES

No. 210

2009

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

In terms of section 23 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), inspections and investigations may be carried out regularly by inspectors authorized in terms of section 35 of the Act;
- (c) the information in the package insert must regularly be updated to conform with the package insert approved by the Council;
- (d) the holder of the certificate of registration, referred to in section 19(7) 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, as it considers 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 the Council may determine.

J. GAESEB
REGISTRAR OF MEDICINES

**NOTIFICATION OF REGISTRATION OF CERTAIN MEDICINES
SCHEDULE**

S/N	APPLICANT	REGISTERED NAME	APPROVED NAME OF ACTIVE(S)	DOSSAGE FORM	STRENGTH/DOSE UNIT	REGIST. NO. NAMIBIA	REGISTRATION DATE
1	GlaxoSmithKline SA(Pty) Ltd	Avamys Nasal Spray	Fluticasone Furoate	Nasal Spray	Each metered spray contains Fluticasone Furoate 27,5 µg	09/21.5.1/0001	29/9/2009
2	Janssen Pharmaceutica (Pty) Ltd	Lyrinel 5 mg	Oxybutynin Hydrochloride	Tablets	Each prolonged-release tablet contains Oxybutynin Hydrochloride 5,0 mg	09/5.4/0002	29/9/2009
3	Janssen Pharmaceutica (Pty) Ltd	Lyrinel 10 mg	Oxybutynin Hydrochloride	Tablets	Each prolonged-release tablet contains Oxybutynin Hydrochloride 10,0 mg	09/5.4/0003	29/9/2009
4	Janssen Pharmaceutica (Pty) Ltd	Lyrinel 15 mg	Oxybutynin Hydrochloride	Tablets	Each prolonged-release tablet contains Oxybutynin Hydrochloride 15,0 mg	09/5.4/0004	29/9/2009
5	Astellas Pharma (Pty) Ltd	Protopic 0.03% Ointment	Tacrolimus Monohydrate	Ointment	Each 1 g Ointment contains Tacrolimus Monohydrate equiv. to Tacrolimus 0,3 mg	09/13/0005	29/9/2009
6	Astellas Pharma (Pty) Ltd	Protopic 0,1% Ointment	Tacrolimus Monohydrate	Ointment	Each 1 g ointment contains Tacrolimus Monohydrate equiv. to Tacrolimus 1,0 mg	09/13/0006	29/9/2009
7	Sandoz South Africa (Pty) Ltd	Curam 625 Disp Tablet	Amoxicillin Trihydrate; Potassium Clavulanate	Tablets	Each tablet contains Amoxicillin Trihydrate equiv. to Amoxicillin 500,0 mg; Potassium Clavulanate equiv. to Clavulanic Acid 125,0 mg	09/20.1.2/0007	29/9/2009
8	Sandoz South Africa (Pty) Ltd	Sandoz Co-Amoxyclav 625 Disp Tablet	Amoxicillin Trihydrate; Potassium Clavulanate	Tablets	Each tablet contains Amoxicillin Trihydrate equiv. to Amoxicillin 500,0 mg; Potassium Clavulanate equiv. to Clavulanic Acid 125,0 mg	09/20.1.2/0008	29/9/2009
9	Sandoz South Africa (Pty) Ltd	Rokef 0,5 g	Ceftriaxone Sodium	Injection	Each vial contains Ceftriaxone Sodium equiv. to Ceftriaxone 0,5 g	09/20.1.1/0009	29/9/2009
10	Sandoz South Africa (Pty) Ltd	Rokef 1,0 g	Ceftriaxone Sodium	Injection	Each vial contains Ceftriaxone Sodium equiv. to Ceftriaxone 1,0 g	09/20.1.1/0010	29/9/2009
11	Sandoz South Africa (Pty) Ltd	Rokef 2.0 g	Ceftriaxone Sodium	Injection	Each vial contains Ceftriaxone Sodium equiv. to Ceftriaxone 2.0 g	09/20.1.1/0011	29/9/2009

12	Cipla Medpro (Pty) Ltd	Falcimom Kit (Adults)	Amodiaquine, Artesunate	Tablets	Each Kit contains 12 tablets of Amodiaquine Hydrochloride 200,0, 12 tablets of Artesunate 50,0 mg	09/20.2.6/0012	29/9/2009
13	Cipla Medpro (Pty) Ltd	Falcimom Kit (Adolescents)	Amodiaquine, Artesunate	Tablets	Each Kit contains 6 tablets of Amodiaquine Hydrochloride 200,0 6 tablets of Artesunate 50,0 mg	09/20.2.6/0013	29/9/2009
14	Cipla Medpro (Pty) Ltd	Falcimom Kit (Children)	Amodiaquine, Artesunate	Tablets	Each Kit contains one tablets of Amodiaquine Hydrochloride 200,0 one tablets of Artesunate 50,0 mg	09/20.2.6/0014	29/9/2009
15	Cipla Medpro (Pty) Ltd	Efavir 600	Efavirenz	Tablets	Each film coated tablet contains Efavirenz 600,0 mg	09/20.2.8/0015	29/9/2009
16	Cipla Medpro (Pty) Ltd	Fexo 120	Fexofenadine Hydrochloride	Tablet	Each tablet contains Fexofenadine Hydrochloride 120,0 mg	09/5.7.1/0016	29/9/2009
17	Cipla Medpro (Pty) Ltd	Fexo 180	Fexofenadine Hydrochloride	Tablet	Each tablet contains Fexofenadine Hydrochloride 180,0 mg	09/5.7.1/0017	29/9/2009
18	Cipla Medpro (Pty) Ltd	Cipla-Warfarin 1mg	Warfarin Sodium Clathrate	Tablet	Each tablet contains Warfarin Sodium Clathrate equivalent to Warfarin Sodium 1,0 mg	09/8.2/0018	29/9/2009
19	Cipla Medpro (Pty) Ltd	Cipla-Warfarin 3mg	Warfarin Sodium Clathrate	Tablet	Each tablet contains Warfarin Sodium Clathrate equivalent to Warfarin Sodium 3,0 mg	09/8.2/0019	29/9/2009
20	Cipla Medpro (Pty) Ltd	Cipla-Warfarin 5mg	Warfarin Sodium Clathrate	Tablet	Each tablet contains Warfarin Sodium Clathrate equivalent to Warfarin Sodium 5,0 mg	09/8.2/0020	29/9/2009
21	Cipla Medpro (Pty) Ltd	Depramil-S 20	Escitalopram Oxalate	Tablet	Each film coated tablet contains Escitalopram Oxalate 20,0 mg	09/1.2/0021	29/9/2009
22	Cipla Medpro (Pty) Ltd	Depramil-S 10	Escitalopram Oxalate	Tablet	Each film coated tablet contains Escitalopram Oxalate 10,0 mg	09/1.2/0022	29/9/2009
23	Cipla Medpro (Pty) Ltd	Depramil-S 5	Escitalopram Oxalate	Tablet	Each film coated tablet contains Escitalopram Oxalate 5,0 mg	09/1.2/0023	29/9/2009
24	Cipla Medpro (Pty) Ltd	Tavalox 750	Levofloxacin Hemihydrate	Tablet	Each tablet contains Levofloxacin Hemihydrate equivalent to Levofloxacin 750,0 mg	09/20.1.1/0024	29/9/2009

25	Cipla Medpro (Pty) Ltd	Tavaloxx 500	Levofloxacin Hemihydrate	Tablet	Each tablet contains Levofloxacin Hemihydrate equivalent to Levofloxacin 500,0 mg	09/20.1.1/0025	29/9/2009
26	Cipla Medpro (Pty) Ltd	Tavaloxx 250	Levofloxacin Hemihydrate	Tablet	Each tablet contains Levofloxacin Hemihydrate equivalent to Levofloxacin 250,0 mg	09/20.1.1/0026	29/9/2009
27	Cipla Medpro (Pty) Ltd	Lamikit-ELS 40	Lamivudine, Stavudine, Efavirenz	Tablet	Lamivir-S 40: Each tablet contains Lamivudine 150,0 mg and Stavudine 40,0 mg, Efavir 600: Each film coated tablet contains Efavirenz 600,0 mg	09/20.2.8/0027	29/9/2009
28	Cipla Medpro (Pty) Ltd	Lamikit-ELS 30	Lamivudine, Stavudine, Efavirenz	Tablet	Lamivir-S 40: Each tablet contains Lamivudine 150,0 mg and Stavudine 30,0 mg, Efavir 600: Each film coated tablet contains Efavirenz 600,0 mg	09/20.2.8/0028	29/9/2009
29	Cipla Medpro (Pty) Ltd	Efakit	Efavirenz, Abacavir, Lamivudine	Tablet	Efavir 600: Each film coated tablet contains Efavirenz 600,0 mg. Cipla-Abacavir 300: Each film-coated tablet contains Abacavir sulphate equiv. to abacavir 300,0 mg. Cipla-Lamivudine 300: Each film-coated tablet contains Lamivudine 300,0 mg	09/20.2.8/0029	29/9/2009
30	Cipla Medpro (Pty) Ltd	Lamivir S 30	Stavudine, Lamivudine	Tablet	Each tablet contains Stavudine 30,0 mg, Lamivudine 150,0 mg	09/20.2.8/0030	29/9/2009
31	Cipla Medpro (Pty) Ltd	Piramax 200	Topiramate	Tablet	Each film coated tablet contains Topiramate 200,0 mg	09/2.5/0031	29/9/2009
32	Cipla Medpro (Pty) Ltd	Piramax 100	Topiramate	Tablet	Each film coated tablet contains Topiramate 100,0 mg	09/2.5/0032	29/9/2009
33	Cipla Medpro (Pty) Ltd	Piramax 25	Topiramate	Tablet	Each film coated tablet contains Topiramate 25,0 mg	09/2.5/0033	29/9/2009
34	Ranbaxy (S.A.) (Pty) Ltd	Ran-Alendronate 70	Sodium Alendronate	Tablet	Each tablet contains Sodium Alendronate Anhydrous equiv. to Alendronic Acid 70,0 mg	09/3.2/0034	29/9/2009

35	Ranbaxy (S.A.) (Pty) Ltd	Ran-Alendronate 10	Sodium Alendronate	Tablet	Each tablet contains Sodium Alendronate Anhydrous equiv. to Alendronic Acid 10,0 mg	09/3.2/0035	29/9/2009
36	Ranbaxy (S.A.) (Pty) Ltd	Sonke-Lastad 30	Lamivudine, Stavudine	Tablet	Each tablet contains Lamivudine 150 mg and Stavudine 30 mg	09/20.2.8/0036	29/9/2009
37	Ranbaxy (S.A.) (Pty) Ltd	Sonke-Lastad 40	Lamivudine, Stavudine	Tablet	Each tablet contains Lamivudine 150 mg and Stavudine 40 mg	09/20.2.8/0037	29/9/2009
38	Ranbaxy (S.A.) (Pty) Ltd	Sonke-Didanosine 100	Didanosine	Tablet	Each chewable / dispersible tablet contains Didanosine 100,0 mg	09/20.2.8/0038	29/9/2009
39	Ranbaxy (S.A.) (Pty) Ltd	Sonke-Didanosine 50	Didanosine	Tablet	Each chewable / dispersible tablet contains Didanosine 50,0 mg	09/20.2.8/0039	29/9/2009
40	Ranbaxy (S.A.) (Pty) Ltd	Sonke-Didanosine 25	Didanosine	Tablet	Each chewable / dispersible tablet contains Didanosine 25,0 mg	09/20.2.8/0040	29/9/2009
41	Ranbaxy (S.A.) (Pty) Ltd	Sonke-Indinavir 400	Indinavir Sulphate	Capsule	Each capsule contains Indinavir Sulphate equiv. to Indinavir 400,0 mg	09/20.2.8/0041	29/9/2009
42	Ranbaxy (S.A.) (Pty) Ltd	Sonke-Abacclamizid	Abacavir Sulphate, Lamivudine, Zidovudine	Tablet	Each film-coated tablet contains Abacavir Sulphate equiv. to Abacavir 300,0 mg, Lamivudine 150,0 mg and Zidovudine 300,0 mg	09/20.2.8/0042	29/9/2009
43	Ranbaxy (S.A.) (Pty) Ltd	Migo 100	Sumatriptan Succinate	Tablet	Each tablet contains Sumatriptan Succinate equiv. to Sumatriptan 100,0 mg	09/7.3/0043	29/9/2009
44	Ranbaxy (S.A.) (Pty) Ltd	Migo 50	Sumatriptan Succinate	Tablet	Each tablet contains Sumatriptan Succinate equiv. to Sumatriptan 50,0 mg	09/7.3/0044	29/9/2009
45	Ranbaxy (S.A.) (Pty) Ltd	Sonke-Laminestav 30	Lamivudine, Nevirapine, Stavudine	Tablet	Each tablet contains Lamivudine 150 mg, Nevirapine 200 mg and Stavudine 30 mg	09/20.2.8/0045	29/9/2009
46	Ranbaxy (S.A.) (Pty) Ltd	Sonke-Laminestav 40	Lamivudine, Nevirapine, Stavudine	Tablet	Each tablet contains Lamivudine 150 mg, Nevirapine 200 mg and Stavudine 40 mg	09/20.2.8/0046	29/9/2009
47	Aurobindo Pharma (Pty) Ltd	Auro-Zidovudine Oral Solution 50mg/5ml	Zidovudine	Oral Solution	Each 5ml solution contains Zidovudine 50,0 mg	09/20.2.8/0047	29/9/2009

48	Aurobindo Pharma (Pty) Ltd	Auro-Efavirenz Tablets 600mg	Efavirenz	Tablets	Each tablet contains Efavirenz 600,0 mg	09/20.2.8/0048	29/9/2009
49	Aurobindo Pharma (Pty) Ltd	Auro-Nevirapine Oral Suspension 50mg/5ml	Nevirapine	Suspension	Each 5ml suspension contains Nevirapine 50,0 mg	09/20.2.8/0049	29/9/2009
50	Aurobindo Pharma (Pty) Ltd	Auro-Lamivudine Oral Solution 10mg/ml	Lamivudine	Oral Solution	Each 1 ml solution contains Lamivudine 10,0 mg	09/20.2.8/0050	29/9/2009
51	Aurobindo Pharma (Pty) Ltd	Auro-Lamistav 30	Stavudine, Lamivudine	Tablets	Each tablet contains Stavudine 30,0 mg, Lamivudine 150,0 mg	09/20.2.8/0051	29/9/2009
52	Aurobindo Pharma (Pty) Ltd	Auro-Lamistav 40	Stavudine, Lamivudine	Tablets	Each tablet contains Stavudine 40,0 mg, Lamivudine 150,0 mg	09/20.2.8/0052	29/9/2009
53	Aurobindo Pharma (Pty) Ltd	Auro-Zilavirenz	Lamivudine, Zidovudine, Efavirenz	Tablets	Each Lamivudine / Zidovudine tablet contains Lamivudine 150,0 mg and Zidovudine 300,0 mg. Each Efavirenz tablet contains Efavirenz 600,0 mg	09/20.2.8/0053	29/9/2009
54	Aurobindo Pharma (Pty) Ltd	Auro-Efavirenz Capsules 200mg	Efavirenz	Capsules	Each capsule contains Efavirenz 200,0 mg	09/20.2.8/0054	29/9/2009
55	Aurobindo Pharma (Pty) Ltd	Auro-Efavirenz Capsules 100mg	Efavirenz	Capsules	Each capsule contains Efavirenz 100,0 mg	09/20.2.8/0055	29/9/2009
56	Aurobindo Pharma (Pty) Ltd	Auro-Efavirenz Capsules 50mg	Efavirenz	Capsules	Each capsule contains Efavirenz 50,0 mg	09/20.2.8/0056	29/9/2009
57	Aurobindo Pharma (Pty) Ltd	Auro-Abacavir Sulfate Oral Solution 20 mg/ml	Abacavir Sulphate	Oral Solution	Each 1 ml solution contains Abacavir Sulphate 20,0 mg	09/20.2.8/0057	29/9/2009
58	Aurobindo Pharma (Pty) Ltd	Auro-Abacavir Sulfate Tablets 300 mg	Abacavir Sulphate	Tablet	Each tablet contains Abacavir Sulfate 300,0 mg	09/20.2.8/0058	29/9/2009
59	Aurobindo Pharma (Pty) Ltd	Auro-Zidovudine Capsules 100 mg	Zidovudine	Capsule	Each capsule contains Zidovudine 100,0 mg	09/20.2.8/0059	29/9/2009
60	Aurobindo Pharma (Pty) Ltd	Auro-Stavudine Capsules 15 mg	Stavudine	Capsule	Each capsule contains Stavudine USP 15,0 mg	09/20.2.8/0060	29/9/2009
61	Aurobindo Pharma (Pty) Ltd	Auro-Didanosine Tablets 200 mg	Didanosine	Tablets	Each dispersible / chewable tablet contains Didanosine 200,0 mg	09/20.28/0061	29/9/2009

62	Aurobindo Pharma (Pty) Ltd	Auro-Didanosine Tablets 150 mg	Didanosine	Tablets	Each dispersible / chewable tablet contains Didanosine 150,0 mg	09/20.2.8/0062	29/9/2009
63	Aurobindo Pharma (Pty) Ltd	Auro-Didanosine Tablets 100 mg	Didanosine	Tablets	Each dispersible / chewable tablet contains Didanosine 100,0 mg	09/20.2.8/0063	29/9/2009
64	Sandoz South Africa (Pty) Ltd	Risperidone Hexal 1 mg	Risperidone	Tablets	Each film coated tablets contains Risperidone 1,0 mg	09/2.6.5/0064	29/9/2009
65	Sandoz South Africa (Pty) Ltd	Risperidone Hexal 2mg	Risperidone	Tablets	Each film coated tablets contains Risperidone 2,0 mg	09/2.6.5/0065	29/9/2009
66	Sandoz South Africa (Pty) Ltd	Risperidone Hexal 3mg	Risperidone	Tablets	Each film coated tablets contains Risperidone 3,0 mg	09/2.6.5/0066	29/9/2009
67	Sandoz South Africa (Pty) Ltd	Risperidone Hexal 4mg	Risperidone	Tablets	Each film coated tablets contains Risperidone 4,0 mg	09/2.6.5/0067	29/9/2009
68	Sandoz South Africa (Pty) Ltd	Neurexal 100	Gabapentin	Capsule	Each capsule contains Gabapentin 100,0 mg	09/2.6.5/0068	29/9/2009
69	Sandoz South Africa (Pty) Ltd	Neurexal 300	Gabapentin	Capsule	Each capsule contains Gabapentin 300,0 mg	09/2.5/0069	29/9/2009
70	Sandoz South Africa (Pty) Ltd	Neurexal 400	Gabapentin	Capsule	Each capsule contains Gabapentin 400,0 mg	09/2.5/0070	29/9/2009
71	Sandoz South Africa (Pty) Ltd	Ramipril-Hexal 2,5mg Tablets	Ramipril	Tablets	Each tablet contains Ramipril 2,5 mg	09/7.1.3/0071	29/9/2009
72	Sandoz South Africa (Pty) Ltd	Ramipril-Hexal 5mg Tablets	Ramipril	Tablets	Each tablet contains Ramipril 5,0 mg	09/7.1.3/0072	29/9/2009
73	Sandoz South Africa (Pty) Ltd	Dantron 4mg/2ml	Ondansetron	Injection	Each 2ml of Solution contains Ondansetron 4,0 mg	09/5.10/0073	29/9/2009
74	Sandoz South Africa (Pty) Ltd	Dantron 8mg/4ml	Ondansetron	Injection	Each 4ml of Solution contains Ondansetron 8,0 mg	09/5.10/0074	29/9/2009