GOVERNMENT GAZETTE

OF THE

REPUBLIC OF NAMIBIA

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Government Notice

MINISTRY OF HEALTH AND SOCIAL SERVICES

No. 193 2006

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

In terms of section 17 of the Medicines and Related Substances Control Act, 1965 (Act No. 101 of 1965), the registrar gives notice that the medicines set out in the Schedule have been registered in terms of that Act.

The conditions subject to which the medicines are registered are stipulated under the note to that Schedule.

SCHEDULE

NAMIBIAN MEDICINES REGISTER UPDATE OCTOBER 2006							
S/N	**APPLICANT**	**REGISTERED NAME**	**APPROVED NAME OF ACTIVE COMPONENT(S)**	**DOSSAGE FORM**	**STRENGTH/DOSE UNIT**	**REG. NO. IN (SECTION 15 OF ACT NO. 101 OF 1965)**	**REGIS-TRATION DATE**
1	Bristol-Myers Squibb (Pty) Limited	Videx EC 250mg	Didanosine	Capsule	Each capsule contains Didanosine 250,0 mg	06/20.2.8/0284	10/11/2006
2	Bristol-Myers Squibb (Pty) Limited	Videx EC 400mg	Didanosine	Capsule	Each capsule contains Didanosine 400,0 mg	06/20.2.8/0285	10/11/2006
3	Cipla-Medpro (Pty) Ltd	Beclate 50 HFA	Beclomethasone Dipropionate	Inhaler	Each actuation delivers Beclomethasone Dipropionate 50,0µg	06/21.51/0286	10/11/2006
4	Cipla-Medpro (Pty) Ltd	Beclate 100 HFA	Beclomethasone Dipropionate	Inhaler	Each actuation delivers Beclomethasone Dipropionate 100,0 µg	06/21.5.1/0287	10/11/2006
5	Cipla-Medpro (Pty) Ltd	Beclate 200 HFA	Beclomethasone Dipropionate	Inhaler	Each actuation delivers Beclomethasone Dipropionate 200,0 µg	06/21.5.1/0288	10/11/2006
6	Cipla-Medpro (Pty) Ltd	Beclate 250 HFA	Beclomethasone Dipropionate	Inhaler	Each actuation delivers Beclomethasone Dipropionate 250,0 µg	06/21.5 1/0289	10/11/2006
7	Cipla-Medpro (Pty) Ltd	Depramil 40	Citalopram Hydrobromide	Tablet	Each tablet contains Citalopram Hydrobromide equiv. to Citalopram 40,0 mg	06/1.2/0290	10/11/2006
8	Cipla-Medpro (Pty) Ltd	Doximal	Doxycycline Hydrochloride	Tablet	Each tablet contains Doxycycline Hydrochloride equiv. to Doxycycline 100,0 mg	06/20.1.1/0291	10/11/2006
9	Cipla-Medpro (Pty) Ltd	Duolin Respules	Ipratropium Bromide, Salbutamol Sulphate	Solution	Each 2,5 ml solution contains Ipratropium Bromide 0,5 mg, Salbutamol Sulphate equiv. to Salbutamol 2,5 mg	06/10.2.1/0292	10/11/2006
10	Cipla-Medpro (Pty) Ltd	Medaspor Topical Cream	Clotrimazole	Cream	Each 1g cream contains Clotrimazole 10,0 mg	06/20.2.2/0293	10/11/2006

11	Cipla-Medpro (Pty) Ltd	Osteobon 70	Alendronate Sodium	Tablet	Each tablet contains Alendronate Sodium equiv. to Alendronic Acid 70,0 mg	06/3.2/0294	10/11/2006
12	Cipla-Medpro (Pty) Ltd	Simcard 40	Simvastain	Tablet	Each tablet contains Simvastain 40,0 mg	06/7.5/0295	10/11/2006
13	Cipla-Medpro (Pty) Ltd	Simcard 80	Simvastain	Tablet	Each tablet contains Simvastain 80,0 mg	06/7.5/0296	10/11/2006
14	Cipla-Medpro (Pty) Ltd	Laxette	Lactulose	Solution	Each 5ml solution contains Lactulose 3,3 g	06/11.5/0297	10/11/2006
15	Ranbaxy (S.A.) (Pty) Ltd	Nafin 250	Terbinafine Hydrochloride	Tablet	Each tablet contains Terbinafine Hydrochloride equivalent to Terbinafine 250,0 mg	06/20.2.2/0298	10/11/2006
16	Cipla-Medpro (Pty) Ltd	Venlor XR 37.5	Venlafaxine Hydrochloride	Capsule	Each capsule contains Venlafaxine Hydrochloride equivalent to Venlafaxine 37,5 mg	06/1.2/0299	10/11/2006
17	Cipla-Medpro (Pty) Ltd	Venlor XR 75	Venlafaxine Hydrochloride	Capsule	Each capsule contains Venlafaxine Hydrochloride equivalent to Venlafaxine 75,0 mg	06/1.2/0300	10/11/2006
18	Cipla-Medpro (Pty) Ltd	Venlor XR 150	Venlafaxine Hydrochloride	Capsule	Each capsule contains Venlafaxine Hydrochloride equivalent to Venlafaxine 150,0 mg	06/1.2/0301	10/11/2006
19	Cipla-Medpro (Pty) Ltd	Coxflam 7,5	Meloxicam	Tablet	Each tablet contains Meloxicam 7,5 mg	06/3.1/0302	10/11/2006
20	Cipla-Medpro (Pty) Ltd	Coxflam 15	Meloxicam	Tablet	Each tablet contains Meloxicam 15,0 mg	06/3.1/0303	10/11/2006
21	Cipla-Medpro (Pty) Ltd	Olexar 2,5	Olanzepine	Tablet	Each tablet contains Olanzepine 2,5 mg	06/2.6.5/0304	10/11/2006
22	Cipla-Medpro (Pty) Ltd	Olexar 5	Olanzepine	Tablet	Each tablet contains Olanzepine 5,0 mg	06/2.6.5/0305	10/11/2006
23	Cipla-Medpro (Pty) Ltd	Olexar 10	Olanzepine	Tablet	Each tablet contains Olanzepine 10,0 mg	06/2.6.5/0306	10/11/2006

24	Cipla-Medpro (Pty) Ltd	Ipvent Respules	Ipratropium Bromide	Inhaler	Each 2,0 ml Solution contains Ipratropium Bromide 0,50 mg	06/10.2.1/0307	10/11/2006
25	Cipla-Medpro (Pty) Ltd	Serdep-50	Sertraline Hydrochloride	Tablet	Each tablet contains Sertraline Hydrochloride equivalent to Sertraline 50,0 mg	06/1.2/0308	10/11/2006
26	AstraZeneca Pharmaceuticals (Pty) Ltd	Atacand 8 mg	Candesartan Cilexetil	Tablet	Each tablet contains: Candesartan Cilexetil 8,0 mg	06/7.1.3/0309	10/11/2006
27	AstraZeneca Pharmaceuticals (Py) Ltd	Symbicord Turbuhaler	Formoterol Fumarate Dihydrate, Budesonide	Inhaler	Each delivered dose contains: Formoterol Fumarate Dihydrate 9,0 mcg. Budesonide 320,0 mcg	06/21.5.1/0310	10/11/2006
28	Pharmaplan (Pty) Ltd	Cyprene-35 ED	Cyproterone Acetate, Ethynyestradiol	Tablet	Each active tablet contains Cyproterone Acetate 2,0 mg, Ethynyestradiol 0,035 mg	06/21.8.2/0311	10/11/2006
29	Pharmaplan (Pty) Ltd	Sun Pharma Sterile Water for Injection	Water for Injection	Injection	Each ampoules contains water for injection 2,0 ml	06/34/0312	10/11/2006
30	Pharmaplan (Pty) Ltd	Muscoron	Vecuronium Bromide	Injection	Each Ampoule contains Vecuronium Bromide 4,0 mg	06/17.1/0313	10/11/2006
31	Pharmaplan (Pty) Ltd	Dolotram Capsules	Tramadol Hydrochloride	Capsule	Each Capsule contains Tramadol Hydrochloride 50,0mg	06/2.9/0314	10/11/2006
32	Pharmaplan (Pty) Ltd	Flutinol	Fluoxetine Hydrochloride	Capsule	Each capsule contains Fluoxetine Hydrochloride equivalent to Fluoxetene 20,0 mg	06/1.2/0315	10/11/2006
33	Pfizer Laboratories (Pty) Ltd	Ultreon	Azithromycin Dihydrate	Tablet	Each tablet contains Azithromycin Dihydrate equivalent to Azithromycin 500,0 mg	06/20.1.1/0316	10/11/2006
34	Cipla-Medpro (Pty) Ltd	Glygard	Gliclazide	Tablet	Each tablet contains Gliglazide 80,0 mg	06/21.2/0317	10/11/2006

35	Cipla-Medpro (Pty) Ltd	Gelumen	Combination	Suspension	Each 10 ml suspension contains; Dicyclomine Hydrochloride 5,0 mg, Compressed Aluminium Hydroxide Gel equivalent to Dried Aluminium Hydroxide Gel 400,0 mg, Magnesium Oxide 200,0 mg	06/11.4.2/0318	10/11/2006
36	Ferring (Pty) Limited	Menogon	Combination	Injection	Each ampoule with powder for solution for injection contains, Menotrophin (Human Menopousal Gonadotropin. HMG corresponding to 75 IU FSH (folicle stimulating hormone) and 75 IU LH (Lutenizing Hormone)	06/21.10/0319	10/11/2006
37	Zydus Healthcare SA (Pty) Ltd	R-Loc Injection	Ranitidine Hydrochloride	Injection	Each 2,0 ml Ampoule contains, Ranitidine Hydrochloride equivalent to Ranitidine 50,0 mg	06/11.4.3/0320	10/11/2006
38	Hoffmann-La Roche Ltd	Tamiflu 12 mg/ml Powder for Oral Suspension	Oseltamivir Phosphate	Suspension	Each l ml suspension contains Oseltamivir Phosphate equivalent to Oseltamivir 12,0 mg	06/20.2.8/0321	10/11/2006
39	Hoffmann-La Roche Ltd	Tamiflu Capsules	Oseltamivir Phosphate	Capsule	Each capsule contains Oseltamivir Phosphate equivalent to Oseltamivir 75,0 mg	06/20.2.8/0322	10/11/2006
40	Abbott Laboratories (Pty) Ltd	Aluvia	Lopinavir. Ritonavir	Tablet	Each film-coated tablet contains Lopinavir 250,0 mg Ritonavir 50,0 mg	06/20.2.8/0323	10/11/2006
41	Aurobindo Pharma (Pty) Ltd	Auro-Zidovudine tablets 300 mg	Zidovudine	Tablet	Each tablet contains Zidoxudine 300,0 mg	06/20.2.8/0324	10/11/2006
42	Aurobindo Pharma (Pty) Ltd	Auro-Lamivudine tablets 150 mg	Lamivudine	Tablet	Each tablet contains Lamivudine 150,0 mg	06/20.2.8/0325	10/11/2006
43	Aurobindo Pharma (Pty) Ltd	Auro-Nevirapine Tablets 200 mg	Nevirapine	Tablet	Each tablet contains Nevirapine 200,0 mg	06/20.2.8/0326	10/11/2006

44	Aurobindo Pharma (Pty) Ltd	Auro-Lamizido	Lamivudine, Zidovudine	Tablet	Each tablet contain Lamivudine 150,0 mg, Zidovudine 300,0 mg	06/20.2.8/0327	10/11/2006
45	Pharmaplan (Pty) Ltd	Zofer 4 mg Injection	Ondansetron Hydrochloride	Injection	Each ampoule contains Ondansetron Hydrochloride equivalent to Ondansetron 4,0 mg	06/5.10/0328	10/11/2006
46	Pharmaplan (Pty) Ltd	Zofer 8 mg Injection	Ondansetron Hydrochloride	Injection	Each ampoule contains Ondansetron Hydrochloride equivalent to Ondansetron 8,0 mg	06/5.10/0329	10/11/2006
47	Pharmaplan (Pty) Ltd	Zofer 4 mg Tablets	Ondansetron Hydrochloride	Tablet	Each tablet contains Ondansetron Hydrochloride equivalent to Ondansetron 4,0 mg	06/5.10/0330	10/11/2006
48	Pharmaplan (Pty) Ltd	Zofer 8 mg Tablets	Ondansetron Hydrochloride	Tablet	Each tablet contains Ondansetron Hydrochloride equivalent to Ondansetron 8,0 mg	06/5.10/0331	10/11/2006
49	Pharmaplan (Pty) Ltd	Pantocid 40 mg Injection	Pantoprazole Sodium	Injection	Each ampoule contains Pantoprazole Sodium equivalent to Pantoprazole 40,0 mg	06/11.4.3/0332	10/11/2006
50	Wyeth South Africa (Pty) Ltd	Preparation H Supposistories	Yeast Cell Extract, Shark Liver Oil	Suppository	Each suppository contains; Yeast Cell Extract 23,0 mg, Shark Liver Oil 69,0 mg	06/14.1/0333	10/11/2006
51	Merck Generics RSA (Pty) Ltd	Merck-Simvastatin 10mg	Simvastatin	Tablet	Each tablet contains Simvastatin 10,0 mg	06/7.5/0334	10/11/2006
52	Merck Generics RSA (Pty) Ltd	Merck-Simvastatin 20mg	Simvastatin	Tablet	Each tablet contains Simvastatin 20,0 mg	06/7.5/0335	10/11/2006
53	Merck Generics RSA (Pty) Ltd	Merck-Simvastatin 40mg	Simvastatin	Tablet	Each tablet contains Simvastatin 40,0 mg	06/7.5/0336	10/11/2006
54	Hetero Drugs	Zidolam	Lamivudine. Zidovudine	Tablet	Each tablet contains Lamivudine 150,0 mg. Zidovudine 300,0 mg	06/20.2.8/0337	10/11/2006
55	Hetero Drugs	Heptavir 150	Lamivudine	Tablet	Each tablet contains Lamivudine 150,0 mg	06/20.2.8/0338	10/11/2006
56	Hetero Drugs	Stag-40	Stavudine	Tablet	Each tablet contains stavudine 40,0 mg	06/20.2.8/0339	10/11/2006

Note:

The above medicines are registered subject to the following conditions:

(a) the manufacture of medicine and the control of medicine must be done in accordance with current good manufacturing practices as required by the World Health Organisation;

(b) in order to assess compliance with paragraph (a), investigations and inspections may be carried out by inspectors, authorized in terms of section 26 of the Medicines and Related Substances Control Act, 1965 (Act No. 101 of 1965), at such reasonable times as the council may consider necessary;

(c) every manufacturer of medicine must, with the approval of the 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 provisions of the Medicines and Related Substances Control Act, 1965 (Act No. 101 of 1965), apply to every manufacturer of medicine registered in terms of section 15 of the Medicines and Related Substances Control Act, 1965 (Act No. 101 of 1965);

(e) the quality, safety and therapeutic efficacy of the registered medicine will be reviewed on a regular basis, and if necessary the registration of such medicine varied;

(f) the first two production batches must be fully validated in terms of the detailed process validation protocol submitted at the time of application for registration;

(g) a validation report must be submitted within one month from the date of completion of the validation process referred to in paragraph (f); and

(h) the council may review the registration dossier at such intervals as may be determined by the council.

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