GOVERNMENT GAZETTE

OF THE

REPUBLIC OF NAMIBIA

N$2.00 WINDHOEK - 21 April 2011 No. 4695

CONTENTS

Page

Government Notice

MINISTRY OF HEALTH AND SOCIAL SERVICES

No. 47 2011

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 make know that the medicines set out in Part I of the Schedule have been registered

(a) in terms of that Act ;and

(b) subject to the conditions set out in Part II of the Schedule.

J. GAESEB
REGISTRAR OF MEDICINES Windhoek, 5 April 2011

SCHEDULE

PART I

S/N	APPLICANT	PROPRIETARY NAME	APPROVED NAME OF ACTIVE(S)	DOSAGE FORM	STRENGTH/DOSE UNIT	REGIST. NO.	REG. DATE	SCHED. STATUS
1	Pharmacare Ltd	Intelence	Etravirine	tablet	Each tablet contains etravirine 100,0 mg	11/20.2.8/0001	2/10/2011	NS2
2	Pharmacare Ltd	Prezista 600 mg	Darunavir	film-coated tablet	Each film-coated tablet contains Darunavir ethanolate 650,45 mg equivalent to Darunavir 600,0 mg	11/20.2.8/0002	2/10/2011	NS2
3	Pharmacare Ltd	Aspen Epirubicin 50 mg / 25 ml	Epirubicin hydrochloride	injection	Each 25,0 ml solution contains Epirubicin Hydrochloride 50,0 mg	11/26/0003	2/10/2011	NS2
4	Pharmacare Ltd	Aspen Epirubicin 200 mg / 100 ml	Epirubicin hydrochloride	injection	Each 100,0 ml solution contains Epirubicin Hydrochloride 200,0 mg	11/26/0004	2/10/2011	NS2
5	Pharmacare Ltd	Zefurime 250 mg	Cefuroxime axetil	tablet	Each tablet contains Cefuroxime 250 mg (as Cefuroxime axetil)	1 1/20.1.1/00005	2/10/2011	NS2
6	Pharmacare Ltd	Zefurime 500 mg	Cefuroxime axetil	tablet	Each tablet contains 500 mg cefuroxime (as cefuroxime axetil	11/20.1.1/0006	2/10/2011	NS2
7	Pharmacare Ltd	Aspelone	Prednisolone Sodium Phosphate	liquid	Each 5,0 ml liquid contains Prednisolone Sodium Phosphate equivalent to Prednisolone 15,0 mg	11/21.5.1/0007	2/10/2011	NS2
8	GlaxoSmithKline South Africa (Pty) Ltd	Grand-Pa Advance	Paracetamol	tablet	Each tablet contains Paracetamol 500 mg	11/2.8/0008	2/10/2011	NS1
9	GlaxoSmithKline South Africa (Pty) Ltd	Paramed	Paracetamol	tablet	Each tablet contains Paracetamol 500 mg	11/2.8/0009	2/10/2011	NS1
10	GlaxoSmithKline South Africa (Pty) Ltd	Corsodyl Mouthwash Mint	Chlorhexidine gluconate	solution	Each 10 ml contains Chlorhexidine Gluconate 20,0 mg	11/16.4/0010	2/10/2011	NS1
11	Novartis South Africa (Pty) Ltd	Galvus 50 mg	Vildagliptin	tablet	Each tablet contains Vildagliptin 50 mg	11/21.2/0011	2/10/2011	NS2

S/N	APPLICANT	PROPRIETARY NAME	APPROVED NAME OF ACTIVE(S)	DOSAGE FORM	STRENGTH/DOSE UNIT	REGIST. NO.	REG. DATE	SCHED. STATUS
12	Abbott Laboratories SA (Pty) Ltd	Norvir 100 mg Tablets	Ritonavir	tablet	Each film-coated tablet contains Ritonavir 100 mg	11/20.2.8/0012	2/10/2011	NS2
13	Ingelheim Pharmaceuticals (Pty) Ltd	Pradaxa 150 mg	Dabigatran Etexilate	capsule	Each capsule contains Dabigatran Etexilate Mesilate 172.95 equiv. to Dabigatran Etexilate 150,0 mg	11/8.2/0013	2/10/2011	NS2
14	Janssen Pharmaceutica (Pty) Ltd	Trisporal	Itraconazole	capsule	Each capsule contains Itraconazole 100,0 mg	11/20.2.2/0014	2/10/2011	NS2
15	Pharmachemie (Pty) Ltd	PCH-Paclitaxel 30	Paclitaxel	concentrate for infusion	Each 5,0 ml solution contains Paclitaxel 30,0 mg	11/26/0015	2/10/2011	NS2
16	Pharmachemie (Pty) Ltd	PCH-Paclitaxel 100	Paclitaxel	concentrate for infusion	Each 16.7 ml solution contains Paclitaxel 100,0 mg	11/26/0016	2/10/2011	NS2
17	Pharmachemie (Pty) Ltd	PCH-Paclitaxel 300	Paclitaxel	concentrate for infusion	Each 50,0 ml solution contains Paclitaxel 300,0 mg	11/26/0017	2/10/2011	NS2
18	Teva Pharmaceuti-cals (Pty) Ltd	Abitrexate 1 g	Methotrexate	injection	Each 10 ml solution contains Methotrexate 1,0g	11/26/0018	2/10/2011	NS2
19	Pharmachemie (Pty) Ltd	Blenamax 15 U	Bleomycin Sulphate	injection	Each vial contains Bleomycin Sulphate equivalent to Bleomycin 15,0 U	11/26/0019	2/10/2011	NS2
20	Pharmachemie (Pty) Ltd	Platosin 10 mg/ 10 ml	Cisplatin	injection	Each 10,0 ml vial contains Cisplatin 10,0 mg	11/26/0020	2/10/2011	NS2
21	Pharmachemie (Pty) Ltd	Platosin 50 mg/50 ml	Cisplatin	injection	Each 50,0 ml vial contains Cisplatin 50,0 mg	11/26/0021	2/10/2011	NS2
22	GlaxoSmithKline South Africa (Pty) Ltd	Aropax CR 12,5	Paroxetine Hydrochloride	tablet	Each tablet contains Paroxetine Hydrochloride equivalent to Paroxetine 12,5 mg	11/1.2/0022	2/10/2011	NS3
23	GlaxoSmithKline South Africa (Pty) Ltd	Aropax CR 25	Paroxetine Hydrochloride	tablet	Each tablet contains Paroxetine Hydrochloride equivalent to Paroxetine 25,0 mg	11/1.2/0023	2/10/2011	NS3

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24	Reckitt Benckiser Pharmaceuticals (Pty) Ltd	Gaviscon Plus Liquid	Sodium Alginate; Sodium Bicarbonate; Calcium Carbonate	suspension	Each 10,0 ml contains Sodium Alginate 500 mg, Calcium Carbonate 325 mg and Sodium Bicarbonate 213 mg	11/11.10/0024	2/10/2011	NS1
25	Reckitt Benckiser Pharmaceuticals (Pty) Ltd	Gaviscon Coolmint Liquid	Sodium Alginate	suspension	Each 10,0 ml suspension contains Sodium Alginate 500,0 mg	11/11.10/0025	2/10/2011	NS1
26	Reckitt Benckiser Pharmaceuticals (Pty) Ltd	Disprin Melts	Aspirin	tablet	Each tablet contains Aspirin 300,0 mg	11/2.8/0026	2/10/2011	NS1
27	Ranbaxy (SA) (Pty) Ltd	Esroc	Rocuronium Bromide	injection	Each 5 ml vial contains Rocuronium Bromide 50,0 mg	11/17.1/0027	2/10/2011	NS2
28	Ingelheim Pharmaceuticals (Pty) Ltd	Twynsta 40/5 mg tablet	Telmisartan, Amlodipine Besylate	tablet	Each tablet contains Telmisartan 40,0 mg and Amlodipine Besylate equivalent to Amlodipine base 5,0 mg	11/7.1.3/0028	2/10/2011	NS2
29	Ingelheim Pharmaceuticals (Pty) Ltd	Twynsta 40/10 mg tablet	Telmisartan, Amlodipine Besylate	tablet	Each tablet contains Telmisartan 40,0 mg and Amlodipine Besylate equivalent to Amlodipine base 10,0 mg	11/7.1.3/0029	2/10/2011	NS2
30	Ingelheim Pharmaceuticals (Pty) Ltd	Twynsta 80/5 mg tablet	Telmisartan, Amlodipine Besylate	tablet	Each tablet contains Telmisartan 80,0 mg and Amlodipine Besylate equivalent to Amlodipine base 5,0 mg	11/7.1.3/0030	2/10/2011	NS2
31	Ingelheim Pharmaceuticals (Pty) Ltd	Twynsta 80/10 mg tablet	Telmisartan; Amlodipine Besylate	tablet	Each tablet contains Telmisartan 80,0 mg and Amlodipine Besylate equivalent to Amlodipine base 10,0 mg	11/7.1.3/0031	2/10/2011	NS2
32	Ferring (Pty) Ltd	Gonapeptyl Depot Powder	Triptorelin	powder for injection	Each vial contains Triptorelin 3,75 mg	11/21.10/0032	2/10/2011	NS2
33	Erongo Agencies (Pty) Ltd	Foliron	Ferrous Fumarate; Folic Acid	film-coated tablet	Each film-coated tablet contains Ferrous Fumarate BP 310 mg (equivalent to 100 mg ferrous iron) and Folic Acid 0,35 mg	11/8.3/0033	2/10/2011	NS2

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34	Sanofi - Aventis South Africa (Pty) Ltd	Intanza 15	Haemagglutinin Influenza A H3N2; H1N1 strain inactivated and Influenza B Strain inactivated	Suspension for injection	Each 0,1 ml contains Hemagglutinin Influenza virus A (H3N2) strain inactivated 15μg, H1N1 inactivated strain 15μg and B strain inactivated 15μg	11/30.1/0034	2/10/2011	NS1
35	Sanofi - Aventis South Africa (Pty) Ltd	Intanza 9	Haemagglutinin Influenza A H3N2; H1N1 strain inactivated and Influenza B strain inactivated	Suspension for injection	Each 0,1 ml contains Hemagglutinin Influenza virus A (H3N2) strain inactivated 9μg, H1N1 inactivated strain 9μg and B strain inactivated 9μg	11/30.1/0035	2/10/2011	NS1
36	Smith & Nephew Pharmaceuticals (Pty) Ltd	Bactrazine Cream	Silver Sulphadiazine	cream	Each gram of cream contains Silver Sulphadiazine 0,01 g	11/14.2/0036	2/10/2011	NS1
37	Oshakati Pharmacy	Beriglobin P2 ml	Human Immunoglobulin	injection	Each 2 ml solution for injection contains Human Immunoglobulin 320 mg	11/30.2/0037	2/10/2011	NS2
38	Oshakati Pharmacy	Beriglobin P 5 ml	Human Immunoglobulin	injection	Each 5 ml solution for injection contains Human Immunoglobulin 800 mg	11/30.2/0038	2/10/2011	NS2
39	Oshakati Pharmacy	Tensopyn	paracetamol, codeine phosphate; caffeine anhydrous; doxylamine succinate	tablet	Each tablet contains Paracetamol 450 mg, Codeine Phosphate 10 mg, Caffeine Anhydrous 30 mg and Doxylamine Succinate 5 mg	11/2.9/0039	2/10/2011	NS1
40	Oshakati Pharmacy	Tensopyn Effervescent	caffeine; codeine phosphate; doxylamine succinate; paracetamol	tablet	Each tablet contains Paracetamol 450 mg, Doxylamine succinate 5 mg, Caffeine Anhydrous 50 mg and Codeine Phosphate 10 mg	11/2.8/0040	2/10/2011	NS1
41	Oshakati Pharmacy	Streptase 750000 IU	Streptokinase	injection	Each vial contains Streptokinase 750,000 IU	11/31/0041	2/10/2011	NS2

S/N	APPLICANT	PROPRIETARY NAME	APPROVED NAME OF ACTIVE(S)	DOSAGE FORM	STRENGTH/DOSE UNIT	REGIST. NO.	REG. DATE	SCHED. STATUS
42	Oshakati Pharmacy	Streptase 1500000 IU	Streptokinase	injection	Each vial contains Streptokinase 1,500,000 IU	11/31/0042	2/10/2011	NS2
43	GlaxoSmithKline South Africa (Pty) Ltd	Calpol Paediatric Suspension	Paracetamol	suspension	Each 5 ml suspension contains Paracetamol 120 mg	11/2.7/0043	2/10/2011	NS1
44	Specpharm (Pty) Ltd	Spec Teicoplanin 200	Teicoplanin	powder for injection	Each vial contains lyophilised Teicoplanin 200 mg	11/20.1.1/0044	2/10/2011	NS2
45	Specpharm (Pty) Ltd	Spec Teicoplanin 400	Teicoplanin	powder for injection	Each vial contains lyophilised Teicoplanin 400 mg	11/20.1.1/0045	2/10/2011	NS2
46	Pharma Dynamics (Pty) Ltd	Osteonate 70 mg	Monosodium Alendronate Trihydrate	tablet	Each tablet contains Monosodium Alendronate Trihydrate equivalent to Alendronic Acid 70,0 mg	11/3.2/0046	2/10/2011	NS2

PART II

The Medicines set out in Part I of the Schedule have been registered subject to the following conditions:

1. The manufacture and control of the medicines must comply with the requirements of the Current Good Manufacturing Practices as required by the World Health Organization.

2. 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.

3. The information contained in the package insert must be updated regularly to conform to the package insert that has been approved by the Namibia Medicines Regulatory Council.

4. The holder of the certificate of registration, referred to in section 19(7) of the Act, must comply with the Act.

5. The Namibian Medicines Regulatory Council must regularly review the registration of medicine in terms of quality, of safety and efficacy and the Council may, should it consider necessary vary the registration the medicine.

6. The first two production batches of the medicines must be validated in accordance with the detailed process validation protocol which was submitted at the time of the application for registration.

7. A validation report must be submitted to the Council within one month from the date of completion of the validation referred to in paragraph (6).

8. The Council may review the registration dossier at such intervals considered necessary by the Council.

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