



GOVERNMENT GAZETTE

OF THE

REPUBLIC OF NAMIBIA

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WINDHOEK - 31 July 2012

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Government Notices

MINISTRY OF HEALTH AND SOCIAL SERVICES

No. 186

2012

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

In term of section 23 of the Medicines and Related Substances Control Act, 2003 (Act No. 13 of 2003), I give notice of the cancellation of registration of the medicines set out in the Schedule below.

J. GAESEB
REGISTRAR OF MEDICINES

Windhoek, 9 July 2012

SCHEDULE

S/N	HOLDER OF CERTIFICATE OF REGISTRATION	PROPRIETARY NAME OF MEDICINE	REGISTRATION NO.
1	Bayer Schering Pharma	Fludara	04/26/1437
2	Bristol-Myers Squibb (Pty) Ltd	Videx 25 mg tablets	04/20.2.8/1096
3	Bristol-Myers Squibb (Pty) Ltd	Videx 50 mg tablets	04/20.2.8/1097

4	Bristol-Myers Squibb (Pty) Ltd	Videx 100 mg tablets	04/20.2.8/1098
5	Bristol-Myers Squibb (Pty) Ltd	Videx 150 mg tablets	04/20.2.8/1099
6	Bristol-Myers Squibb (Pty) Ltd	Videx Paediatric Powder	04/20.2.8/0130
7	Bristol-Myers Squibb (Pty) Ltd	Zerit 20mg Capsules	04/20.2.8/1100
8	Bristol-Myers Squibb (Pty) Ltd	Zerit 30mg Capsules	04/20.2.8/1101
9	Bristol-Myers Squibb (Pty) Ltd	Zerit 40mg Capsules	04/20.2.8/1102
10	Bristol-Myers Squibb (Pty) Ltd	Zerit 1mg/ml Powder	04/20.2.8/1156
11	Janssen Pharmaceutica (Pty) Ltd	Acnidazol	90/23.12/00606
12	Janssen Pharmaceutica (Pty) Ltd	Acneclear Cream	04/13.12/0238
13	Janssen Pharmaceutica (Pty) Ltd	Tramal Suppositories	04/2.9/0262
14	Janssen Pharmaceutica (Pty) Ltd	Ortho-Est	04/21.8.1/0276
15	Janssen Pharmaceutica (Pty) Ltd	Eporex 2000/ml	04/30.4/0233
16	Janssen Pharmaceutica (Pty) Ltd	Reminyl 8mg	04/5.3/0285
17	Janssen Pharmaceutica (Pty) Ltd	Reminyl 4mg	04/5.3/0287
18	Janssen Pharmaceutica (Pty) Ltd	Reminyl 12mg	04/5.3/0291
19	Janssen Pharmaceutica (Pty) Ltd	Tinset 1mg/ml	04/5.7.1/0288
20	Ingelheim Pharmaceuticals (Pty) Ltd	Mobic 15mg Suppository	04/3.1/1615
21	GlaxoSmithKline S.A (Pty) Ltd	Infanrix DTPa HB	04/30.1/0892
22	Bristol-Myers Squibb (Pty) Ltd	Videx EC 250 mg	06/20.2.8/0284
23	Bristol-Myers Squibb (Pty) Ltd	Videx EC 400 mg	06/20.2.8/0285
24	Bristol-Myers Squibb (Pty) Ltd	Reyalaz 150 mg	06/20.2.6/0202
25	Bristol-Myers Squibb (Pty) Ltd	Reyalaz 200 mg	06/20.2/0203
26	Pharmacare Limited	Distalgesic Tablets	04/2.8/0220
27	Bayer Schering Pharma	Noctamid Tablets	90/2.2/019
28	Bayer Schering Pharma	Primobolan S	90/21.6/022
29	Eli Lilly (SA) (Pty) Limited	Xigris 20 mg	04/8/0667

MINISTRY OF HEALTH AND SOCIAL SERVICES

No. 187

2012

EXCLUSION OF CERTAIN MEDICINES FROM OPERATION OF CERTAIN REGULATIONS: MEDICINES AND RELATED SUBSTANCES CONTROL ACT, 2003

In terms of section 45(1) of the Medicines and Related Substances Act, 2003 (Act No. 13 of 2003), after consultation with the Namibia Medicines Regulatory Council, I exclude the medicines referred to in Schedule 0, 1, 2, 3 and 4 of Government Notice No. 180 of 25 July 2008 from the operation of the following regulations, published under Government Notice No. 178 of 25 July 2008, for a period of 20 months from the date of publication of this notice:

- (a) 11(1)(b) and (l);
- (b) 12(1)(a) and (w);
- (c) 13(1)(a) and (j);
- (d) 14(1)(c) and (1); and
- (e) 15(1)(a) and (n).

R.N. KAMWI
MINISTER OF HEALTH AND SOCIAL SERVICES

Windhoek, 7 July 2012

MINISTRY OF HEALTH AND SOCIAL SERVICES

No. 188

2012

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 current Good Manufacturing Practices as required by the World Health Organisation;
- (b) in order to assess compliance with paragraph (a) inspections and investigations may be carried out regularly by inspectors authorised in terms of section 35 of the Act;
- (c) the information in the package insert must, on a regular basis, be updated to conform with the package insert approved by the Council;
- (d) the holder of the certificate of registration which is referred to in subsection (7) of section 19 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 (e) ; and
- (h) the Council may review the registration dossier at such intervals as the Council may determine.

J. GAESEB
REGISTRAR OF MEDICINES

Windhoek, 9 July 2012

SCHEDULE

	APPLICANT	REGISTERED NAME	APPROVED NAME OF ACTIVE	DOSAGE FORM	STRENGTH/DOSE UNIT	REG. NUMBER	REG. DATE	SCHEDULED STATUS
1	Adcock Ingram Limited	Adco-Meloxicam 7.5	Meloxicam	Tablet	Each tablet contains Meloxicam 7,5 mg	12/3.1/0001	01.03.2012	NS 2
2	Adcock Ingram Limited	Adco-Meloxicam 15	Meloxicam	Tablet	Each tablet contains Meloxicam 15,0 mg	12/3.1/0002	01.03.2012	NS 2
3	GlaxoSmithKline South Africa(Pty)Ltd	Paxil 20	Paroxetine Hydrochloride	Tablet	Each tablet contains Paroxetine hydrochloride equivalent to Paroxetine 20,0 mg	12/1.2/0003	01.03.2012	NS 3
4	Bodene (Pty) Ltd	Hyoscine butylbromide Fresenius 20 mg/ml	Hyoscine Butylbromide	Injection	Each 1.0 ml solution contains Hyoscine Butylbromide 20,0 mg	12/11.2/0004	01.03.2012	NS 2
5	Adcock Ingram Limited	Stresam	Etifoxine Hydrochloride	Capsule	Each capsule contains Etifoxine hydrochloride Butylbromide 50,0mg	12/2.6/0005	01.03.2012	NS 3
6	Bayer (Pty) Ltd	Xarelto 15	Rivaroxaban	Tablet	Each film-coated tablet contains Rivaroxaban 15,0 mg	12/8.2/0006	01.03.2012	NS 2
7	Bayer(Pty) Ltd	Xarelto 20	Rivaroxaban	Tablet	Each film-coated tablet contains Rivaroxaban 20,0 mg	12/8.2/0007	01.03.2012	NS 2
8	Biotech Laboratories (Pty) Ltd	Penilente L.A 2,4 MU	Benzathine Benzyl-Penicillin	Injection	Each vial of 8ml suspension buffered Benzathine Benzyl-Penicillin equivalent to Benzathine Benzyl-Penicillin 2,400,000 IU	12/20.1.2/0008	01.03.2012	NS2
9	Biotech Laboratories(Pty) Ltd	Pentlente L.A 1,2 MU	Benzathine Benzyl-Penicillin	Injection	Each vial of 4ml suspension contains Buffered Benzathine Benzyl-Penicillin equiv to Benzathine Benzyl-Penicillin 1,200,000 IU	12/20.1.2/0009	01.03.2012	NS2
10	Biotech Laboratories (Pty) Ltd	Bio-Atenolol 50	Atenolol	Tablet	Each tablet contains Atenolol 50mg	12/5.2/0010	01.03.2012	NS 2
11	Biotech Laboratories (Pty) Ltd	Bio- Cimetidine 200mg	Cimetidine	Tablet	Each film-coated tablet contains Cimetidine 200,0 mg	12/11.4.3/0011	01.03.2012	NS 2

APPLICANT	REGISTERED NAME	APPROVED NAME OF ACTIVE	DOSAGE FORM	STRENGTH/DOSE UNIT	REG. NUMBER	REG. DATE	SCHEDULED STATUS
Biotech Laboratories (Pty) Ltd	Bio-Cimetidine 400 mg	Cimetidine	Tablet	Each Film coated tablet contains Cimetidine 400,0 mg	12/11.4.3/0012	01.03.2012	NS 2
Biotech Laboratories (Pty) Ltd	Bio-Sulpiride 200	Sulpiride	Tablet	Each tablet contains Sulpiride 200,0 mg	12/2.6.5/0013	01.03.2012	NS 3
Be-Tabs Pharmaceuticals (Pty)Ltd	Betapropfen 400 FC	Ibuprofen	Tablet	Each film coated tablet contains Ibuprofen 400	12/3.1/0014	01.03.2012	NS 2
Be-Tabs Pharmaceuticals (Pty) Ltd	Bedoral 30	Ketorolac Tromethamine	Injection	Each 1 ml ampoule contains Ketorolac Tramethamine 30,0 mg	12/2.7/0015	01.03.2012	NS 2
PharmAfrica (Pty)Ltd	Tranic	Tranexamic Acid	Tablet	Each Tablet contains Tranexamic Acid 500 mg	12/8.1/0016	01.03.2012	NS 2
Astrazeneca Pharmaceuticals (Pty)Ltd	Nexiam 10 mg Sachets	Esomeprazole	Sachet	Each Sachet contains Esomeprazole 10,0 mg	12/11.4.3/0017	01.03.2012	NS 2
Pharmacare Limited	Tellerge Tablets 180	Fexofenadine Hydrochloride	Tablet	Each Tablet contains Fexofenadine Hydrochloride 120 mg	12/5.7.1/0018	01.03.2012	NS 1
Pharmacare Limited	Tellerge Tablets 120	Fexofenadine Hydrochloride	Tablet	Each tablet contains Fexofenadine Hydrochloride 120 mg	12/5.7.1/0019	01.03.2012	NS 1
Novartis (SA) (Pty) Ltd	Migroben 80 Tablet	Valsartan	Tablet	Each tablet contains Valsartan 800mg	12/7.1.3/0020	01.03.2012	NS 2
Novartis (SA) (Pty)Ltd	Microben 80 Tablet	Valsartan	Tablet	Each Tablet contains Valsartan 160,0 mg	12/7.1/0021	01.03.2012	NS 2
Novartis (SA) (Pty)Ltd	Zomevek 80 Tablet	Valsartan	Tablet	Each tablet contains Valsartan 80,0 mg	12/7.1.3/0022	01.03.2012	NS 2
Novartis (SA) (Pty)Ltd	Zomevek 160 Tablet	Valsartan	Tablet	Each Tablet contains Valsartan 160 mg	12/7.1.3/0023	01.03.2012	NS 2
Novartis (SA) (Pty)Ltd	Co-Migroben 80 Tablet	Valsartan, Hydrochlorothiazide	Tablet	Each tablet contains Valsartan 80,0 mg Hydrochlorothiazide 12,5 mg	12/7.1.3/0024	01.03.2012	NS 2
Novartis (SA) (Pty)Ltd	Co-Migroben 160 Tablet	Valsartan, Hydrochlorothiazide	Tablet	Each Tablet contains Valsartan 160,0 mg Hydrochlorothiazide 12,5 mg	12/7.1.3/0025	01.03.2012	NS 2
Novartis (SA) (Pty)Ltd	Co-Migroben 160 Plus	Valsartan, Hydrochlorothiazide	Tablet	Each tablet contains Valsartan 160,0 mg, Hydrochlorothiazide 25,0 mg	12/7.1.3/0026	01.03.2012	NS 2
Novartis (SA) (Pty)Ltd	Co-Zamevek 80 Tablets	Valsartan, Hydrochlorothiazide	Tablet	Each tablet contains Valsartan 80,0 mg, Hydrochlorothiazide 12,5 mg	12/7.1.3/0027	01.03.2012	NS 2
Novartis (SA) (Pty)Ltd	Co-Zomevek 160 Plus tablets	Valsartan, Hydrochlorothiazide	Tablet	Each Tablet contains Valsartan 160,0mg, Hydrochlorothiazide 12,5 mg	12/7.1.3/0028	01.03.2012	NS 2

APPLICANT	REGISTERED NAME	APPROVED NAME OF ACTIVE	DOSAGE FORM	STRENGTH/DOSE UNIT	REG. NUMBER	REG. DATE	SCHEDULED STATUS
29 Novartis (SA) (Pty)Ltd	Co-Zomevek 160 tablets	Valsartan, Hydrochlorothiazide	Tablet	Each tablet contains Valsartan 160,0 mg, Hydrochlorothiazide 25,0 mg	12/7.1.3/0029	01.03.2012	NS 2
30 Novartis (SA)(Pty) Ltd	Tasigna 200mg	Nilotinib Hydrochloride	Capsule	Each capsule contains Nilotinib Hydrochloride Monohydrate equivalent to Nilotinib base 200mg	12/26/0030	01.03.2012	NS 2
31 Merck S.A (Pty)Ltd	Fixime Tablets	Cefixime	Tablet	Each coated tablet contains Cefixime 400 mg	12/20.1.1/0031	01.03.2012	NS 2
32 MSD(Pty)Ltd	Zocer 10 mg tablets	Simvastatin	Tablets	Each film-coated tablet contains simvastatin 10,0 mg	12/7.5/0032	01.03.2012	NS 2
33 MSD (Pty) Ltd	Zocer 20 mg tablets	Simvastatin	Tablets	Each film-coated tablet contains Simvastatin 20,0 mg	12/7.5/0033	01.03.2012	NS2
34 Pharma Dynamics (Pty) Ltd	Actamax 5	Risedronic Sodium Hemipentahydrate	Tablets	Each film-coated tablet contains Risedronic Sodium Hemipentahydrate equivalent to Risedronate Sodium 5,0 mg	12/7.5/0034	01.03.2010	NS2
35 Pharma Dynamics (Pty) Ltd	Actamax 35	Risedronic Sodium Hemipentahydrate	Tablets	Each film-coated tablet contains Risedronic Sodium Hemipentahydrate equivalent to Risedronate Sodium 35,0 mg	12/3.2/0035	01.03.2012	NS2
36 Alcon Laboratories (SA) (Pty) Ltd	Tobradex Eye Suspension	Dexamethasone, Tobramycin	Ophthalmic Suspension	Each 1ml suspension contains Dexamethasone 1,0 mg, Tobramycin 3,0 mg	12/15.3/0036	01.03.2012	NS2
37 Alcon Laboratories (SA) (Pty) Ltd	Iodipine 1% Unit Dose	Apraclonidine Hydrochloride	Ophthalmic Solution	Each 1 ml solution contains Apraclonidine Hydrochloride equiv. to Apraclonidine 10,0 mg	12/15.4/0037	01.03.2012	NS2
38 Alcon Laboratories (SA) (Pty) Ltd	Tobralax Eye Ointment	Dexamethasone, Tobramycin	Ophthalmic Ointment	Each g ointment contains Dexamethasone 1,0 mg, Tobramycin 3,0 mg	12/15.3/0038	01.03.2012	NS2
39 MSD (Pty) Ltd	Cancidas 70 mg	Caspofungin Acetate	Powder for Infusion	Each vial contains: caspofungin Acetate equivalent to Caspofungin 70,0 mg	12/20.2.2/0039	01.03.2012	NS2
40 MSD (Pty) Ltd	Cancidas 50 mg	Caspofungin Acetate	Powder for Infusion	Each vial contains: caspofungin Acetate equivalent to Caspofungin 50,0 mg	12/20.2.2/0040	01.03.2012	NS2
41 Activo Health (Pty) Ltd	Acti-Tran 0,5 mg Capsules	Trandolapril	Capsule	Each capsule contains Trandolapril 0,5 mg	12/7.1.3/0041	01.03.2012	NS2

	APPLICANT	REGISTERED NAME	APPROVED NAME OF ACTIVE	DOSAGE FORM	STRENGTH/DOSE UNIT	REG. NUMBER	REG. DATE	SCHEDULED STATUS
42	Activo Health (Pty) Ltd	Acti-Tran 2 mg Capsules	Trandolapril	Capsule	Each capsule contains Trandolapril 2,0 mg	12/7.1.3/0042	01.03.2012	NS2
43	Activo Health (Pty) Ltd	Acti-Tran 4 mg Capsules	Trandolapril	Capsule	Each capsule contains Trandolapril 4,0 mg	12/7.1.3/0043	01.03.2012	NS2
44	Adcock Ingram Limited	Adco - Covospor Vaginal	Clotrimazole	Vaginal cream	Each 1 g of cream contains clotrimazole 10 mg	12/20.2.2/0044	01.03.2012	NS1
45	Adcock Ingram Limited	Adco Lamivudine and Zidovudine 150/300	Lamivudine, Zidovudine	Tablets	Each tablet contains Lamivudine 150,0 mg, Zidovudine 300,0 mg	12/20.2.8/0045	01.03.2012	NS2
46	Winthrop Pharmaceuticals (Pty) Ltd	Levofloxacin Winthrop I.V. 250	Levofloxacin hemihydrate	Injection	Each 50 ml vial solution for infusion contains Levofloxacin hemihydrate equivalent to Levofloxacin 250 mg	12/20.1.1/0046	01.03.2012	NS2
47	Winthrop Pharmaceuticals (Pty) Ltd	Levofloxacin Winthrop I.V. 500	Levofloxacin hemihydrate	Injection	Each 100 ml vial solution for infusion contains Levofloxacin hemihydrate equivalent to Levofloxacin 500 mg	12/20.1.1/0047	01.03.2012	NS2
48	GlaxoSmithKline South Africa (Pty) Ltd	Med-Lemon Wet Cough Syrup	Guaiphenesin	Syrup	Each 10 ml syrup contains Guaiphenesin 100 mg	12/10.1/0048	01.03.2012	NS0
49	GlaxoSmithKline South Africa (Pty) Ltd	Med-Lemon Hot Medication with Vitamin-C	Combination	Powder / sachet	Each sachet contains aspirin 800 mg, caffeine anhydrous 50 mg, ascorbic acid 45 mg and menthol polvaromans 14,40 mg	12/5.8/0049	01.03.2012	NS0
50	GlaxoSmithKline South Africa (Pty) Ltd	Med-Lemon Flu & Congestion Hot Medication with Vitamin C	Combination	Powder / sachet	Each sachet contains Phenylephrine HCl 10,0 mg, Paracetamol 600,0 mg, Ascorbic acid 40,0 mg	12/5.8/0050	01.03.2012	NS1
51	GlaxoSmithKline South Africa (Pty) Ltd	Eno Active Fruit Salt - Apple	Combination	Powder / sachet	Each 5,0 g dose contains sodium bicarbonate 2,32g ; anhydrous citric acid 2,18 g and sodium carbonate 0,50g	12/11.4/0051	01.03.2010	NS0
52	GlaxoSmithKline South Africa (Pty) Ltd	Eno Active Fruit Salt - Lemon	Combination	Powder / sachet	Each 5,0 g contains sodium bicarbonate 2,29g; anhydrous citric acid 2,16 g and sodium carbonate 0,50 mg	12/11.4/0052	01.03.2012	NS0

APPLICANT	REGISTERED NAME	APPROVED NAME OF ACTIVE	DOSAGE FORM	STRENGTH/DOSE UNIT	REG. NUMBER	REG. DATE	SCHEDULED STATUS
GlaxoSmithKline South Africa (Pty) Ltd	Eno Active Fruit Salt - Orange	Combination	Powder / sachet	Each 5,0 g dose contains sodium bicarbonate 2,29 g, anhydrous citric acid 2,16 g and sodium carbonate 0,50 g	12/11.4/0053	01.03.2012	NS0
GlaxoSmithKline South Africa (Pty) Ltd	Eno Active Fruit Salt - Regular	Combination	Powder / sachet	Each 5,0 g dose contains sodium bicarbonate 2,29 g, anhydrous citric acid 2,16 g and sodium carbonate 0,50 g	12/11.4/0054	01.03.2012	NS0
Adcock Ingram Limited	Adco-Quinaretic 10/12,5	Quinapril Hydrochloride / Hydrochlorothiazide	Tablet	Each tablet contains Quinapril Hydrochloride equiv. to Quinapril 10,0 mg, Hydrochlorothiazide 12,5 mg	12/7.1.3/0055	01.03.2012	NS2
Adcock Ingram Limited	Dilinct Dry Cough Syrup	Dextromethorphan Hydrobromide	Syrup	Each 5 ml syrup contains Dextromethorphan Hydrobromide 15,0 mg	12/10.1/0056	01.03.2012	NS1
Pfizer Laboratories (Pty) Ltd	Advil Liqui-Gels	Ibuprofen	Capsule	Each capsule contains Ibuprofen 200,0 mg	12/2.7/0057	01.03.2012	NS1
Pharma Dynamics (Pty) Ltd	Dyna Cefpodoxime 100 mg	Cefpodoxime Proxetil	Tablets	Each tablet contains: Cefpodoxime Proxetil equiv. to Cefpodoxime 100,0 mg	12/20.1.1/0058	01.03.2012	NS2
abbott Laboratories SA (Pty) Ltd	PreceDEX	Dexmedetomidine	Concentrate for Infusion	Each 1 ml solution contains Dexmedetomidine 100 µg	12/2.9/0059	01.03.2012	NS3
Cipla-Medpro (Pty) Ltd	Cipla-Irinotecan 100mg/5ml	Irinotecan	Solution for Infusion	Each 1ml solution contains; Irinotecan Hydrochloride Trihydrate 20,0 mg	12/26/0060	01.03.2012	NS2
Cipla-Medpro (Pty) Ltd	Cipla-Irinotecan 40mg/2ml	Irinotecan	Solution for Infusion	Each 1ml solution contains; Irinotecan Hydrochloride Trihydrate 20,0 mg	12/26/0061	01.03.2012	NS2
Cipla-Medpro (Pty) Ltd	Bicadex	Bicalutamide	Tablet	Each film coated tablet contains Bicalutamide 50,0 mg	12/21.12/0062	01.03.2012	NS2
Sandoz SA (Pty) Ltd	Sandoz Alendronate 70	Sodium Alendronate	Tablet	Each tablet contains Alendronate sodium equiv. to Alendronic Acid 70,0 mg	12/3.2/0063	01.03.2012	NS2
Sandoz SA (Pty) Ltd	Ostomir 70	Sodium Alendronate	Tablet	Each tablet contains Alendronate sodium equivalent to Alendronic Acid 70,0 mg	12/3.2/0064	01.03.2012	NS2

	APPLICANT	REGISTERED NAME	APPROVED NAME OF ACTIVE	DOSAGE FORM	STRENGTH/DOSE UNIT	REG. NUMBER	REG. DATE	SCHEDULED STATUS
65	Sandoz SA (Pty) Ltd	Ibupain	Combination	Capsule	Each capsule contains: Ibuprofen 200,0 mg, Paracetamol 250,0 mg	12/2.8/0065	01.03.2012	NS1
66	Ingelheim Pharmaceuticals (Pty) Ltd	Micace 5 mg	Ramipril	Tablet	Each uncoated tablet contains Ramipril 5,0 mg	12/7.1.3/0066	01.03.2012	NS2
67	Ingelheim Pharmaceuticals (Pty) Ltd	Micace 10 mg	Ramipril	Tablet	Each uncoated tablet contains Ramipril 10,0 mg	12/3.2/0067	01.03.2012	NS2
68	Pharmacare Limited	Risonel 35	Risedronate Sodium	Tablet	Each film-coated tablet contains Risedronic Sodium Hemipentahydrate equivalent to Risedronate Sodium 35,0 mg	12/3.2/0068	01.03.2012	NS2
69	Pharmacare Limited	Risonel 5	Risedronate Sodium	Tablet	Each film-coated tablet contains Risedronic Sodium Hemipentahydrate equivalent to Risedronate Sodium 5,0 mg	12/3.2/0069	01.03.2012	NS2
70	Pharma Dynamics (Pty) Ltd	Zartan Co 50/12,5	Losartan Potassium, Hydrochlorothiazide	Tablet	Each tablet contains Losartan Potassium equivalent to Losartan 50 mg and Hydrochlorothiazide 12,5 mg	12/7.1.3/0070	01.03.2012	NS2
71	Pharma Dynamics (Pty) Ltd	Zartan Co 100/25	Losartan Potassium, Hydrochlorothiazide	Tablet	Each tablet contains Losartan Potassium equivalent to losartan 100 mg and Hydrochlorothiazide 25 mg	12/7.1.3/0071	01.03.2012	NS2
72	Sandoz SA (Pty) Ltd	Migrex 100	Sumatriptan	Tablet	Each tablet contains Sumatriptan Succinate equivalent to Sumatriptan 100,0 mg	12/7.3/0072	01.03.2012	NS2
73	Sandoz SA (Pty) Ltd	Migrex 50	Sumatriptan	Tablet	Each tablet contains Sumatriptan Succinate equivalent to Sumatriptan 50,0 mg	12/7.3/0073	01.03.2012	NS2
74	Sandoz SA (Pty) Ltd	Sandoz K600	Potassium Chloride	Tablet	Each sugar coated tablet contains Potassium Chloride 600,0 mg	12/24/0074	01.03.2012	NS1
75	Sandoz SA (Pty) Ltd	Sandoz Ceftriaxone 2,0 g	Ceftriaxone Sodium	Injection	Each vial contains Ceftriaxone Sodium equivalent to Ceftriaxone 2,0 g	12/20.1.1/0075	01.03.2012	NS2
76	Sandoz SA (Pty) Ltd	Sandoz Ceftriaxone 1,0 g	Ceftriaxone Sodium	Injection	Each vial contains Ceftriaxone Sodium equivalent to Ceftriaxone 1,0 g	12/20.1.1/0076	01.03.2012	NS2
77	Sandoz SA (Pty) Ltd	Sandoz Ceftriaxone 0,5 g	Ceftriaxone Sodium	Injection	Each vial contains Ceftriaxone Sodium equivalent to Ceftriaxone 0,5 g	12/20.1.1/0077	01.03.2012	NS2
78	AstraZeneca Pharmaceuticals (Pty) Ltd	Atacand 32 mg	Candesartan Cilexetil	Tablet	Each tablet contains Candesartan Cilexetil 32,0 mg	12/7.1.3/0078	01.03.2012	NS2

	APPLICANT	REGISTERED NAME	APPROVED NAME OF ACTIVE	DOSAGE FORM	STRENGTH/DOSE UNIT	REG. NUMBER	REG. DATE	SCHEDULED STATUS
79	AstraZeneca Pharmaceuticals (Pty) Ltd	Atacand Plus 32 /12.5	Candesartan Cilexetil, Hydrochlorothiazide	Tablet	Each tablet contains Candesartan Cilexetil 32.0 mg, Hydrochlorothiazide 12.5 mg	12/7.1.3/0079	01.03.2012	NS2
80	AstraZeneca Pharmaceuticals (Pty) Ltd	Atacand Plus 32 /25	Candesartan Cilexetil, Hydrochlorothiazide	Tablet	Each tablet contains Candesartan Cilexetil 32.0 mg, Hydrochlorothiazide 25 mg	12/7.1.3/0080	01.03.2012	NS2
81	Adcock Ingram Limited	Adco-Abacavir	Abacavir Sulphate	Tablet	Each tablet contains Abacavir sulphate equivalent to Abacavir 300,0 mg	12/20.2.8/0081	01.03.2012	NS2
82	Adcock Ingram Limited	Adco-Emtevir	Amtricitabine, Tenofovir disoproxil Fumarate	Tablet	Each tablet contains Emtricitabine 200,0 mg, Tenofovir Disoproxil Fumarate 300,0 mg	12/20.2.8/0082	01.03.2012	NS2
83	Pharmacare Limited	Nitepax Suspension	Noscapine	Suspension	Each 5 ml suspension contains noscapine resin complex equivalent to Noscapine 25 mg	12/10.1/0083	01.03.2012	NS1
84	Ranbaxy (S.A.) (Pty) Ltd	Casprost 150	Bicalutamide	Tablet	Each film-coated tablet contains Bicalutamide 150,0 mg	12/21.12/0084	01.03.2012	NS2
85	Ranbaxy (S.A.) (Pty) Ltd	Casprost 50	Bicalutamide	Tablet	Each film-coated tablet contains Bicalutamide 50,0 mg	12/21.12/0085	01.03.2012	NS2
86	Ranbaxy (S.A.) (Pty) Ltd	Ran-Pravastatin 40	Pravastatin Sodium	Tablet	Each tablet contains Pravastatin Sodium 40,0 mg	12/7.5/0086	01.03.2012	NS2
87	Ranbaxy (S.A.) (Pty) Ltd	Ran-Pravastatin 20	Pravastatin Sodium	Tablet	Each tablet contains Pravastatin Sodium 20,0 mg	12/7.5/0087	01.03.2012	NS2
88	Ranbaxy (S.A.) (Pty) Ltd	Ran-Pravastatin 10	Pravastatin Sodium	Tablet	Each tablet contains Pravastatin Sodium 10,0 mg	12/7.5/0088	01.03.2012	NS2
89	Sandoz SA (Pty) Ltd	Tramahexal SR 100	Tramadol Hydrochloride	Tablet	Each modified release tablet contains Tramadol Hydrochloride 100,0 mg	12/2.9/0089	01.03.2012	NS3
90	Sandoz SA (Pty) Ltd	Tramahexal SR 150	Tramadol Hydrochloride	Tablet	Each modified release tablet contains Tramadol Hydrochloride 150,0 mg	12/2.9/0090	01.03.2012	NS3
91	Sandoz SA (Pty) Ltd	Tramahexal SR 200	Tramadol Hydrochloride	Tablet	Each modified release tablet contains Tramadol Hydrochloride 200,0 mg	12/2.9/0091	01.03.2012	NS3

	APPLICANT	REGISTERED NAME	APPROVED NAME OF ACTIVE	DOSAGE FORM	STRENGTH/DOSE UNIT	REG. NUMBER	REG. DATE	SCHEDULED STATUS
92	Sandoz SA (Pty) Ltd	Cefu-Hexal 250	Cefuroxime Axetil	Tablet	Each film-coated tablet contains Cefuroxime Axetil equivalent to Cefuroxime 250,0 mg	12/20.1.1/0092	01.03.2012	NS2
93	Sandoz SA (Pty) Ltd	Cefu-Hexal 500	Cefuroxime Axetil	Tablet	Each film-coated tablet contains Cefuroxime Axetil equivalent to Cefuroxime 250,0 mg	12/20.1.1/0093	01.03.2012	NS2
94	Sandoz SA (Pty) Ltd	Terbane 250	Terbinafine Hydrochloride	Tablet	Each tablet contains Terbinafine Hydrochloride equivalent to Terbinafine 250,0 mg	12/20.2.2/0094	01.03.2012	NS2
95	Adcock Ingram Limited	Gripion Cold and Flu Tablets	Combination	Tablet	Each tablet contains; Phenylephrine Hydrochloride 5,0 mg, Chlorpheniramine Maleate 2,0 mg, Paracetamol 150,0 mg, Caffein Anhydrous 15,0 mg	12/5.8/0095	01.03.2012	NS1
96	Pfizer Laboratories (Pty) Ltd	Champix 0.5	Varenicline Tartrate	Tablet	Each tablet contains Varenicline Tartrate equivalent to Varenicline 0,5 mg	12/34/0096	01.03.2012	NS 2
97	Pfizer Laboratories (Pty) Ltd	Champix 1.0	Varenicline Tartrate	Tablet	Each tablet contains Varenicline Tartrate equivalent to Varenicline 1.0 mg	12/34/0097	01.03.2012	NS 2
98	Pfizer Laboratories (Pty) Ltd	Advil-Liqui-Gels 400	Ibuprofen	Capsule	Each liquid-gel capsule contains Ibuprofen 400,0 mg	12/2.7/0098	01.03.2012	NS 1
99	PharmAfrica (Pty) Ltd	Oculet	Providone	Eye drops	Each 1ml solution contains Povidone 20,0 mg	12/15.4/0099	01.03.2012	NS 0
100	Milani Laboratories (India) (Pty) Ltd	ML-Cotri Suspension	Sulphamethoxale, Trimethoprim	Suspension	Each 5 ml suspension contains Sulphamethoxazole 220,0 mg, Trimethoprim 40,0 mg	12/20.2/0100	26.04.2012	NS 2
101	Milani Laboratories (India) (Pty) Ltd	Milmaleate Tablets	Chlorpheniramine Maleate	Tablets	Each uncoated tablet contains Chlorpheniramine Maleate 4,0 mg	12/5.7/0101	26.04.2012	NS 1
102	Milani Laboratories (India) Pty Ltd	Metro Forte Suspension	Metronidazole Benzoate	Suspension	Each 5ml suspension contains Metronidazole Benzoate equivalent to Metronidazole 200,0 mg	12/20.2.6/0102	26.04.2012	NS 2
103	Milani Laboratories (India) Pty Ltd	Metronidazole Tablets BP 400 mg	Metronidazole	Tablets	Each sugar coated tablet contains Metronidazole BP 400,0 mg	12/20.2.6/103	26.04.2012	NS 2
104	Milani Laboratories (India) Pty Ltd	Cloxacillin Capsules USP 250 mg	Cloxacillin Sodium	Capsules	Each capsule contains Cloxacillin 250,0 mg	12/20.1.2/104	26.04.2012	NS 2

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Milan Laboratories (India) Pty Ltd	Bertrim-480	Sulphamethoxazole, Trimethoprim	Tablets	Each tablet contains Sulphamethoxazole 400,0 mg, Trimethoprim 80,0 mg	12/20.2/0105	26.04.2012	NS 2
Milan Laboratories (India) Pty Ltd	Phenoxyethylpenicillin Oral Solution 250 mg/ 5ml	Phenoxyethylpenicillin Potassium	Powder for reconstitution	Each 5 ml of reconstituted solution contains Phenoxyethylpenicillin Potassium BP equivalent to Phenoxyethylpenicillin 250,0 mg	12/20.1.2/0106	26.04.2012	NS 2
Milan Laboratories (India) Pty Ltd	Phenoxyethylpenicillin oral Solution 125 mg/ 5ml	Phenoxyethylpenicillin Potassium	Powder for reconstitution	Each 5 ml of reconstituted solution contains Phenoxyethylpenicillin Potassium BP equivalent to Phenoxyethylpenicillin 125,0 mg	12/20.1.2/0107	26.04.2012	NS 2
Cipla-Mepro (Pty) Ltd	Odimmune	Efavirenz, Emtricitabine, Tenofovir Disoproxil Fumarate	Tablets	Each tablet contains Efavirenz 600,0 mg, Emtricitabine 200,0 mg, Tenofovir Disoproxil Fumarate 300,0 mg	12/20.2.8/0108	26.04.2012	NS2
Oshakati Pharmacy	Tensopyn Paediatric Syrup	Paracetamol, Codeine Phosphate	Syrup	Each 5ml syrup contains; Paracetamol 150,0 mg, Codeine Phosphate 4,0 mg	12/21.2/0109	26.04.2012	NS 1
Pharma Dynamics (Pty) Ltd	Dyna Gliclazide SR 30 mg	Gliclazide	Tablets	Each modified release tablet contains Gliclazide 30,0 mg	12/21.2/0110	26.04.2012	NS 2
Cipla-Medpro (Pty) Ltd	Cipla-Paclitaxel 100 mg/ 16.7 ml	Paclitaxel	Injection	Each single dose vial (16.7) ml contains Paclitaxel 100,0 mg	12/26/0111	26.04.2012	NS2
Cipla-Medpro (Pty) Ltd	Cipla- Paclitaxel 30 mg/ 15 ml	Paclitaxel	Injection	Each single dose vial (5ml) contains Paclitaxel 30,0 mg	12/26/0112	26.04.2012	NS 2
Cipla-Medpro (Pty) Ltd	Cipla-Paclitaxel 300mg/ 50 mg	Paclitaxel	Injection	Each single dose vial (50 ml) contains Paclitaxel 300,0 mg	12/26/0113	26.04.2012	NS 2
Cipla-Medpro (Pty) Ltd	Alkafizz Effervescent Granules	Combination	Granules	Each medicine measure (4g) contains; Sodium Citrate 0.613 g, Sodium bicarbonate 1,716 g, Citric Acid Anhydrous 0,702 g, Tartaric Acid 0.858 g	12/18.3/0114	26.04.2012	NS 0
Cipla- Medpro (Pty) Ltd	Cipla Docetaxel 80	Docetaxel Trihydrate	Injection	Each vial contains Docetaxel Trihydrate equivalent to Docetaxel (anhydrous) 80,0 mg	12/26/0115	26.04.2012	NS 2
Cipla-Medpro (Pty) Ltd	Solvent for Cipla Docetaxel 80	Ethanol 13,0 % m/v	Injection	Each vial contains Ethanol 13,0%	12/32.2/0116	26.04.2012	NS 1

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117	Cipla-medpro (Pty) Ltd	Cipla Docetaxel 20	Docetaxel Trihydrate	Injection	Each vial contains Docetaxel Trihydrate equivalent to Docetaxel (anhydrous) 20,0 mg	12/26/0117	26.04.2012	NS 2
118	Cipla- Medpro (Pty) Ltd	Solvent for Cipla Docetaxel 20	Ethanol 13,0% m/v	Injection	Each vial contains Ethanol 13,0% m/v	12/32.2/0118	26.04.2012	NS 1
119	Roche Products (Pty) Ltd	CellCept	Mycophenolate Mofetil	Capsules	Each capsule contains Mycophenolate Mofetil 250,0 mg	12/34/0119	26.04.2012	NS 2
120	Roche Products (Pty) Ltd	CellCept 500	Mycophenolate Mofetil	Tablets	Each film-coated tablet contains Mycophenolate Mofetil 500,0 mg	12/34/0120	26.04.2012	NS 2
121	Adcock Ingram Ltd	Aco-Lamivudine 300 mg tablets	Lamivudine	Tablets	Each tablet contains Lamivudine 300,0 mg	12/20.2.8/0121	26.04.2012	NS 2
122	Janssen Pharmaceutica (Pty) Ltd	Topamax SC 15	Topiramate	Capsules	Each capsule contains Topiramate 15 mg	12/2.5/0123	26.04.2012	NS 2
123	Meyerszell Laboratories (Pty) Ltd	Covarex Cream	Miconazole Nitrate	Cream	Each 1 g cream contains Miconazole Nitrate 20,0 mg	12/13.9.2/0123	26.04.2012	NS1
124	Adcock Ingram Ltd	Adco-Mirtaron 30	Mirtazapine	Tablets	Each Tablet contains Mirtazapine 30 mg	12/1.2/0124	26.04.2012	NS 3
125	Adco Ingram Ltd	Adco Mirtaron 15	Mirtazapine	Tablets	Each Tablet contains Mirtazapine 15,0 mg	12/1.2/0125	26.04.2012	NS 3
126	Novartis SA (Pty) Ltd	Exforge 5/320	Amlodipine Besylate, Valsartan	Tablets	Each tabl contains Amlodipine Besylate equivalent to Amlodipine 5,0 mg Valsartan 320,0 mg	12/7.1.3/0126	26.04.2012	NS2
127	Novartis SA (Pty) Ltd	Exforge 10/320	Amlodipine Besylate, Valsartan	Tablets	Each tablet contains Amlodipine Besylate equivalent to Amlodipine 10,0 mg, Valsartan 320,0 mg	12/7.1.3/0127	26.04.2010	NS 2
128	Novartis SA (Pty) Ltd	Galvus Met 50/850	Vildagliptin, Metformin	Tablets	Each tablet contains Vildagliptin 50,0 mg; Metformin 850,0 mg	12/21.2/0128	26.04.2012	NS 2
129	Novartis SA (Pty) Ltd	Galvus Met 50/100	Vildagliptin, Metformin	Tablets	Each tablet contains Vildagliptin 50,0 mg; Metformin 850,0 mg	12/21.2/0129	26.04.2012	NS 2
130	Sandos SA (Pty) Ltd	Hexal-MPA 5	Medroxyprogesterone Acetate	Tablets	Each tablet contains Medroxyprogesterone Acetate 5,0 mg	12/21.8.2/0130	26.04.2012	NS 2
131	Sandos SA (Pty) Ltd	Hexal- MPA 10	Medroxyprogesterone Acetate	Tablets	Each tablet contains Medroxyprogesterone Acetate 10,0 mg	12/21.8.2/0131	26.04.2012	NS 2

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132	Sandos SA (Pty) Ltd	Fluvoxamine-Hexal 100 mg	Fluvoxamine Maleate	Tablets	Each film-coated tablet contains Fluvoxamine Maleate 100,0 mg	12/1.2/0132	26.04.2012	NS 3
133	Sandos SA (Pty) Ltd	Cetirizine-Hexal 1 mg/ ml Oral Solution	Cetirizine Dihydrochloride	Solution	Each 1 ml Oral Solution contains Cetirizine Dihydrochloride 1,0 mg	12/5.7/0133	26.04.2012	NS 1
134	Sandos SA (Pty) Ltd	Cetirizine-Hexal 10 mg	Cetirizine Dihydrochloride	Tablets	Each film coated tablet contains Cetirizine Dihydrochloride 10,0 mg	12/5.7/0134	26.04.2012	NS 1
135	Sandos SA (Pty) Ltd	BisHexal 5	Bisoprolol Fumarate	Tablets	Each film coated tablet contains Bisoprolol Fumarate 5,0 mg	12/5.2/0135	26.04.2012	NS 2
136	Sandos SA (Pty) Ltd	BisoHexal 10	Bisoprolol Fumarate	Tablets	Each film coated tablet contains Bisoprolol Fumarate 10,0 mg	12/5.2/0136	26.04.2012	NS2
137	Adcock Ingram Ltd	Nebillet 5 mg	Nebivolol Hydrochloride	Tablets	Each tablet contains Nebivolol Hydrochloride equivalent to Nebivolol 5,0 mg	12/7.1.3/0137	26.04.2012	NS 2
138	Pharma Dynamics (Pty) Ltd	Dyna Indapamide SR	Indapamide	Tablets	Each sustained release tablet contains Indapamide 1,5 mg	12/7.1/0138	26.04.2012	NS 2