



# GOVERNMENT GAZETTE

## OF THE

# REPUBLIC OF NAMIBIA

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WINDHOEK - 8 April 2011

No. 4683

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## Government Notices

### MINISTRY OF HEALTH AND SOCIAL SERVICES

No. 39

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 give notice that the medicines set out in the Schedule are registered subject to the following conditions:

- (a) the manufacture and control of the medicine 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 contained in the package insert must, on a regular basis, be updated to conform with the package insert approved by the Medical Control Council;
- (d) the holder of the certificate of registration which is 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 conditions of 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, 25 March 2011

**SCHEDULE**  
**NAMIBIA VETERINARY MEDICINES REGISTER - LOT 1**

APPLICANT	REGISTERED NAME	APPROVED NAME OF ACTIVE(S)	DOSSAGE FORM	STRENGTH/DOSE UNIT	REG. NO. NAMIBIA	REGISTRATION DATE	SCHED. STATUS
Norbrook Laboratories (Pty) Ltd	Hexasol Injection	Oxytetracycline Dihydrate, Flumixin Meglumine	Injection	Each 1,0 ml solution contains Oxytetracycline Dihydrate equiv. to Oxytetracycline 300,0 mg, Flumixin Meglumine equiv. to Flumixin 20,0 mg	05/17.1.10/0519	2005.07.20	NS2
Norbrook Laboratories (Pty) Ltd	Pyroflam Injection	Flumixin Meglumine	Injection	Each 1,0 ml solution contains Flumixin Meglumine 50,0 mg	06/2.6/0038	2006.02.08	NS2
Norbrook Laboratories (Pty) Ltd	Ultraject Injection	Procaine Penicillin	Injection	Each 1,0 ml suspension contains Procaine Penicillin 300,0 mg	06/21.2/0039	2006.02.08	NS2
Norbrook Laboratories SA (Pty) Ltd	Norotyl Injection	Tylosin	Injection	Each 1,0 ml Injection contains Tylosin 150,0 mg	10/17.1.4/0669	11/11/2010	NS2
Norbrook Laboratories SA (Pty) Ltd	Noroclav Injection	Amoxicillin Trihydrate, Potassium Clavulanate	Injection	Each 1ml suspension contains: Amoxicillin Trihydrate equiv. to Amoxicillin 140,0 mg, Potassium Clavulanate equiv. to Clavulanic Acid 35,0 mg	10/17.1.1.1/0670	11/11/2010	NS2
Norbrook Laboratories SA (Pty) Ltd	Colvasone Injection	Dexamethasone Sodium Phosphate	Injection	Each 1ml solution contains; Dexamethasone Sodium Phosphate 2,0 mg	10/3.1.1/0671	11/11/2010	NS2
Virbac RSA (Pty) Ltd	Potencil	Amoxicillin Trihydrate; Colistin Sulphate	injection	Each 100,0 ml suspension contains Amoxicillin trihydrate equivalent to Amoxicillin 10,0 g and Colistin Sulphate 25,0 million IU	10/21.1/0672	11/11/2010	NS2
Virbac RSA (Pty) Ltd	Zoletil 100	Tiletamine hydrochloride; Zolazepam hydrochloride	injectable powder in vial	Each vial contains Tiletamine hydrochloride equivalent to Tiletamine 250 mg and Zolazepam hydrochloride equivalent to Zolazepam 250 mg	10/2.1/0673	11/11/2010	NS3
Virbac RSA (Pty) Ltd	Alizine	Aglepristone	injection	Each 1,0 ml contains Aglepristone 30,0 mg	10/22.6.2/9674	11/11/2010	NS1
Cipla-Medpro (Pty) Ltd	Petcam	Meloxicam	suspension	Each 1 ml suspension contains Meloxicam BP 1,5 mg	10/3.1.2/0675	11/11/2010	NS2
Cipla-Medpro (Pty) Ltd	Omepracote	Omeprazole	oral paste	Each 6,15 g oral paste syringe contains Omeprazole 2,28 mg	10/8.4.3/0676	11/11/2010	NS2

**MINISTRY OF HEALTH AND SOCIAL SERVICES**

No. 40

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 give notice that the medicines set out in 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 Organization;
- (b) in order to assess compliance with paragraph (a), inspections and investigations may be carried out regularly by inspectors authorized in terms of sections 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**

Windhoek, 25 March 2011

**SCHEDULE**  
**MEDICINES REGISTER UP-DATE LOT 17**

S/N	APPLICANT	PROPRIETARY NAME	APPROVED NAME OF ACTIVE(S)	DOSAGE FORM	STRENGTH/DOSE UNIT	REGIST. NO. NAMIBIA	REGISTRATION DATE	SCHED. STATUS
1	Sanofi Aventis South Africa (Pty) Ltd	Stilnox MR 12,5	Zolpidem Tartrate	tablet	Each tablet contains Zolpidem Tartrate 12,5 mg	10/2.2./0582	11/11/2010	NS3
2	Equity Pharmaceuticals (Pty) Ltd	Equity - Pilocarpine 2% Eye Drops	Pilocarpine hydrochloride	eye drops	Each ml solution contains pilocarpine hydrochloride 20 mg	10/15.4/0583	11/11/2010	NS2
3	Equity Pharmaceuticals (Pty) Ltd	Paradote	Acetylcysteine	solution for infusion	Each ml solution contains acetylcysteine 200,0 mg	10/10.2.2./0584	11/11/2010	NS1
4	Inova Pharmaceuticals (Pty) Ltd	Migril Tablets	Ergotamine tartrate; Cyclizine hydrochloride; Caffeine hydrate	tablet	Each tablet contains Ergotamine Tartrate EP 2.0mg, Cyclizine hydrochloride BP 50,0mg and Caffeine BP equivalent to Caffeine hydrate BP 100,0 mg	10/7.3./0585	11/11/2010	NS1
5	AstraZeneca Pharmaceuticals (Pty) Ltd	Seroquel 25	Quetiapine fumarate	tablet	Each tablet contains Quetiapine fumarate equivalent to Quetiapine 25,0 mg	10/2.6.5/0586	11/11/2010	NS3
6	AstraZeneca Pharmaceuticals (Pty) Ltd	Seroquel 100	Quetiapine fumarate	tablet	Each tablet contains Quetiapine fumarate equivalent to Quetiapine 100,0 mg	10/2.6.5/0587	11/11/2010	NS3
7	AstraZeneca Pharmaceuticals (Pty) Ltd	Seroquel 200	Quetiapine fumarate	tablet	Each tablet contains Quetiapine fumarate equivalent to Quetiapine 200,0 mg	10/2.6.5/0588	11/11/2010	NS3
8	AstraZeneca Pharmaceuticals (Pty) Ltd	Seroquel 300	Quetiapine fumarate	tablet	Each tablet contains Quetiapine fumarate equivalent to Quetiapine 300,0 mg	10/2.6.5/0589	11/11/2010	NS3
9	Aurobindo Pharma (Pty) Ltd	Soniren 200 mg Capsules	Didanosine	capsule	Each capsule contains Didanosine 200,0 mg	10/20.2.8./0590	11/11/2010	NS2
10	Aurobindo Pharma (Pty) Ltd	Soniren 250 mg Capsules	Didanosine	capsule	Each capsule contains Didanosine 250,0 mg	10/20.2.8./0591	11/11/2010	NS2
11	Aurobindo Pharma (Pty) Ltd	Soniren 400 mg Capsules	Didanosine	capsule	Each capsule contains Didanosine 400,0 mg	10/20.2.8./0592	11/11/2010	NS2
12	Aurobindo Pharma (Pty) Ltd	Auro-zolpidem 5 mg	Zolpidem tartrate	tablet	Each tablet contains Zolpidem tartrate 5 mg	10/2.2./0593	11/11/2010	NS3

13	Aurobindo Pharma (Pty) Ltd	Auro-zolpidem 10 mg	Zolpidem tartrate	tablet	Each tablet contains Zolpidem tartrate 10 mg	10/2.2/0594	11/11/2010	NS3
14	Aurobindo Pharma (Pty) Ltd	Auro-Emtricitabine/Tenofovir 200/300 mg Tablets	Tenofovir disoproxil fumarate; Emtricitabine	tablet	Each tablet contains Emtricitabine 200,0 mg, Tenofovir disoproxil fumarate 300,0 mg	10/20.2.8/0595	11/11/2010	NS2
15	Aurobindo Pharma (Pty) Ltd	Vireno 300 mg Tablets	Tenofovir disoproxil fumarate	tablet	Each tablet contains Tenofovir disoproxil fumarate 300,0 mg	10/20.2.8/0596	11/11/2010	NS2
16	Aurobindo Pharma (Pty) Ltd	Auro-Cefotaxime 250 mg Injection	Cefotaxime Sodium	injection	Each vial contains Cefotaxime sodium equivalent to Cefotaxime 250,0 mg	10/20.1.1/597	11/11/2010	NS2
17	Aurobindo Pharma (Pty) Ltd	Auro-Cefotaxime 500 mg Injection	Cefotaxime Sodium	injection	Each vial contains Cefotaxime sodium equivalent to Cefotaxime 500,0 mg	10/20.1.1/0598	11/11/2010	NS2
18	Aurobindo Pharma (Pty) Ltd	Auro-Cefotaxime 1000 mg Injection	Cefotaxime Sodium	injection	Each vial contains Cefotaxime sodium equivalent to Cefotaxime 1000,0 mg	10/20.1.1/0599	11/11/2010	NS2
19	Aurobindo Pharma (Pty) Ltd	Auro-Cefotaxime 2000 mg Injection	Cefotaxime Sodium	injection	Each vial contains Cefotaxime sodium equivalent to Cefotaxime 2000,0 mg	10/20.1.1/0600	11/11/2010	NS2
20	Janssen Pharmaceutica (Pty) Ltd	Reminyl CR 8 mg	Galantamine hydrobromide	prolonged release capsule	Each prolonged release capsule contains Galantamine hydrobromide equivalent to Galantamine base 8,0 mg	10/5.3/0601	11/11/2010	NS2
21	Janssen Pharmaceutica (Pty) Ltd	Reminyl CR 16 mg	Galantamine hydrobromide	prolonged release capsule	Each prolonged release capsule contains Galantamine hydrobromide equivalent to Galantamine base 16,0 mg	10/5.3/0602	11/11/2010	NS2
22	Janssen Pharmaceutica (Pty) Ltd	Reminyl CR 24 mg	Galantamine hydrobromide	prolonged release capsule	Each prolonged release capsule contains Galantamine hydrobromide equivalent to Galantamine base 24,0 mg	10/5.3/0603	11/11/2010	NS2
23	Ingelheim Pharmaceuticals (Pty) Ltd	Mucoxgin Peppermint	Ambroxol hydrochloride	lozenge	Each lozenge contains Ambroxol hydrochloride 20,0 mg	10/10.1/0604	11/11/2010	NS1
24	Ranbaxy (SA) (Pty) Ltd	Oncomam	Anastrozole	Tablet	Each film-coated tablet contains Anastrozole 1,0 mg	10/21.12/0605	11/11/2010	NS2
25	Macleods Pharmaceuticals Ltd	Ecox	Ethambutol Hydrochloride	Tablet	Each film-coated tablet contains Ethambutol hydrochloride 100 mg	10/20.2.2/0606	11/11/2010	NS2
26	Macleods Pharmaceuticals Ltd	Macox E	Rifampicin BP, Isoniazid BP, Ethambutol Hydrochloride	Tablet	Each film-coated tablet contains Rifampicin BP 150 mg, Isoniazid BP 75 mg and Ethambutol hydrochloride BP 275 mg	10/20.2.2/0607	11/11/2010	NS2
27	Cipla Medpro (Pty) Ltd	Medpro Simvastatin 10	Simvastatin	Tablet	Each film-coated tablet contains Simvastatin 10 mg	10/7.5/0608	11/11/2010	NS2

28	Cipla Medpro (Pty) Ltd	Medpro Simvastatin 20	Simvastatin	Tablet	Each film-coated tablet contains Simvastatin 20 mg	10/7.5/0609	11/11/2010	NS2
29	Pharma Dynamics (Pty) Ltd	Pearinda Plus 2	Perindopril tert-butylamine; Indapamide	tablet	Each tablet contains Perindopril tert-butylamine salt 2,0 mg and Indapamide 0.625 mg	10/7.1.3/0610	11/11/2010	NS2
30	Pharma Dynamics (Pty) Ltd	Pearinda Plus 4	perindopril tert-butylamine; indapamide	tablet	Each tablet contains Perindopril tert-butylamine salt 4,0 mg and Indapamide 1.25 mg	10/7.1.3/0611	11/11/2010	NS2
31	Ranbaxy (SA) (Pty) Ltd	Exeran	Exemestane	tablet	Each film-coated tablet contains Exemestane 25,0 mg	10/21.12/0612	11/11/2010	NS2
32	Roche Products (Pty) Ltd	Pegasys 135	Peginterferon alfa-2a	injection	Each syringe of 0,5 ml solution contains Peginterferon alfa-2a 135 micrograms	10/26/0613	11/11/2010	NS2
33	Roche Products (Pty) Ltd	Pegasys 180	Peginterferon alfa-2a	injection	Each syringe of 0,5 ml solution contains Peginterferon alfa-2a 180 micrograms	10/26/0614	11/11/2010	NS2
34	Roche Products (Pty) Ltd	Herceptin	Trastuzumab	powder for solution for infusion	Each multidose vial contains Trastuzumab 440,0 mg	10/26/0615	11/11/2010	NS2
35	Macleods Pharmaceuticals Ltd	Streptomac - 1	Streptomycin sulphate	Injection	Each vial contains Streptomycin sulphate equivalent to Streptomycin 1 g	10/20.2.2/0616	11/11/2010	NS2
36	Macleods Pharmaceuticals Ltd	Tenomac 50	Atenolol	Tablet	Each film-coated tablet contains atenolol 50 mg	10/5.2/0617	11/11/2010	NS2
37	Macleods Pharmaceuticals Ltd	Cefolac 200	Cefixime Trihydrate	Tablet	Each film-coated tablet contains Cefixime Trihydrate 250 mg	10/20.1.1/0618	11/11/2010	NS2
38	Pharmacare Limited	Adaphen 10	Methylphenidate hydrochloride	tablet	Each tablet contains Methylphenidate Hydrochloride 10,0 mg	10/1.2/0619	11/11/2010	NS4
39	Pharmacare Limited	Altosec 40 mg/10 ml	Omeprazole	injection	Each vial contains Omeprazole 40,0 mg	10/11.4.3/0620	11/11/2010	NS2
40	Pharmacare Limited	Aspen Gentamicin Injection 80 mg/2 ml	Gentamicin sulphate	injection	Each 2 ml solution contains Gentamicin sulphate equivalent to Gentamicin 80 mg	10/20.1.1/0621	11/11/2010	NS2
41	Pharmacare Limited	Aspen Granisetron 2 mg	Granisetron hydrochloride	tablet	Each tablet contains granisetron hydrochloride equivalent to Granisetron 2,0 mg	10/5.7.2/0622	11/11/2010	NS2

42	Pharmacare Limited	Aspen Lansoprazole 15	Lansoprazole	capsule	Each capsule contains Lansoprazole 15,0 mg	10/11.4.3/0623	11/11/2010	NS2
43	Pharmacare Limited	Augmaxcil Injection	Amoxicillin sodium; Potassium clavulanate	injection	Each vial contains Amoxicillin sodium equivalent to Amoxicillin 1000,0 mg and Potassium clavulanate equivalent to Clavulanic Acid 200,0 mg	10/20.1.2/0624	11/11/2010	NS2
44	Pharmacare Limited	Ban Pain Syrup	Codeine phosphate; Paracetamol; Promethazine hydrochloride	syrup	Each 5 ml syrup contains Codeine phosphate 5 mg, Paracetamol 120 mg and Promethazine hydrochloride 6,5 mg	10/2.8/0625	11/11/2010	NS1
45	Pharmacare Limited	Clindaspen 300 mg	Clindamycin Phosphate	injection	Each 1,0 ml solution contains Clindamycin phosphate equivalent to Clindamycin 150,0 mg	10/20.1.1/0626	11/11/2010	NS2
46	Pharmacare Limited	Clindaspen 600 mg	clindamycin phosphate	injection	Each 1,0 ml solution contains Clindamycin phosphate equivalent to Clindamycin 150,0 mg	10/20.1.1/0627	11/11/2010	NS2
47	Pharmacare Limited	Ibumol Banana	Paracetamol; Ibuprofen	suspension	Each 10,0 ml suspension contains Paracetamol 250,0 mg and Ibuprofen 200,0 mg	10/2.8/0628	11/11/2010	NS1
48	Pharmacare Limited	Mybucod	Ibuprofen; Paracetamol; Codeine Phosphate	tablet	Each tablet contains Ibuprofen 200,0 mg, Paracetamol 350,0 mg and Codeine Phosphate 10,0 mg	10/2.8/0629	11/11/2010	NS1
49	Pharmacare Limited	AP Methylpred	Methylprednisolone Sodium Succinate	injection	Each 8,0 ml solution contains Methylprednisolone Sodium Succinate equivalent to Methylprednisolone 500,0 mg	10/21.5.1/0630	11/11/2010	NS2
50	Pharmacare Limited	Aspen Efavirenz 200 mg	Efavirenz	tablet	Each tablet contains Efavirenz 200 mg	10/20.2.8/0631	11/11/2010	NS2
51	Pharmacare Limited	Aspen Efavirenz 600 mg	Efavirenz	tablet	Each tablet contains Efavirenz 600 mg	10/20.2.8/0632	11/11/2010	NS2
52	Pharmacare Limited	A-Lennon Furosemide Injection 20 mg/2 ml	Furosemide	injection	Each 2 ml injection contains Furosemide 20,0 mg	10/18.1/0633	11/11/2010	NS2
53	Pharmacare Limited	Almadin 5 mg	Amlodipine Besylate	tablet	Each tablet contains Amlodipine Besylate equivalent to Amlodipine 5,0 mg	10/7.1/0634	11/11/2010	NS2
54	Ranbaxy (SA) (Pty) Ltd	Reskit 0,5	Risperidone	tablet	Each tablet contains Risperidone 0,5 mg	10/2.6.5/0635	11/11/2010	NS3
55	Ranbaxy (SA) (Pty) Ltd	Reskit 1	Risperidone	tablet	Each tablet contains Risperidone 1,0 mg	10/2.6.5/0636	11/11/2010	NS3



56	Ranbaxy (SA) (Pty) Ltd	Reskit 2	Risperidone	tablet	Each tablet contains Risperidone 2,0 mg	10/2.6.5/0637	11/11/2010	NS3
57	Ranbaxy (SA) (Pty) Ltd	Sonke-Didanosine 250	Didanosine	capsule	Each capsule contains Didanosine 250,0 mg	10/20/2.8/0638	11/11/2010	NS2
58	Ranbaxy (SA) (Pty) Ltd	Sonke-Didanosine 400	Didanosine	capsule	Each capsule contains Didanosine 400,0 mg	10/20.2.8/0639	11/11/2010	NS2
59	Ranbaxy (SA) (Pty) Ltd	Diolo 80	Valsartan	film-coated tablet	Each film-coated tablet contains Valsartan 80,0 mg	10/7.1.3/0640	11/11/2010	NS2
60	Ranbaxy (SA) (Pty) Ltd	Diolo 160	Valsartan	film-coated tablet	Each film-coated tablet contains Valsartan 160,0 mg	10/7.1.3/0641	11/11/2010	NS2
61	Ingelheim Pharmaceuticals (Pty) Ltd	Pexola ER 0,375 mg	Pramipexole Dihydrochloride Monohydrate	extended release tablet	Each extended release tablet contains Pramipexole Dihydrochloride Monohydrate 0,375 mg	10/5.4.1/0642	11/11/2010	NS2
62	Ingelheim Pharmaceuticals (Pty) Ltd	Pexola ER 0,75 mg	Pramipexole Dihydrochloride Monohydrate	extended release tablet	Each extended release tablet contains Pramipexole Dihydrochloride Monohydrate 0,75 mg	10/5.4.1/0643	11/11/2010	NS2
63	Ingelheim Pharmaceuticals (Pty) Ltd	Pexola ER 1,5 mg	Pramipexole Dihydrochloride Monohydrate	extended release tablet	Each extended release tablet contains Pramipexole Dihydrochloride Monohydrate 1,5 mg	10/5.4.1/0644	11/11/2010	NS2
64	Ingelheim Pharmaceuticals (Pty) Ltd	Pexola ER 3,0 mg	Pramipexole Dihydrochloride Monohydrate	extended release tablet	Each extended release tablet contains Pramipexole Dihydrochloride Monohydrate 3,0 mg	10/5.4.1/0645	11/11/2010	NS2
65	Ingelheim Pharmaceuticals (Pty) Ltd	Pexola ER 4,5 mg	Pramipexole Dihydrochloride Monohydrate	extended release tablet	Each extended release tablet contains Pramipexole Dihydrochloride Monohydrate 4,5 mg	10/5.4.1/0646	11/11/2010	NS2
66	Adcock Ingram Limited	Adco Efavirenz 50 mg	Efavirenz	capsule	Each capsule contains Efavirenz 50,0 mg	10/20.2.8/0647	11/11/2010	NS2

67	Sanofi Aventis South Africa (Pty) Ltd	Menactra	Meningococcal Serogroup A, C, Y and W-135 polysaccharide; Diphtheria toxoid conjugate protein carrier	solution for injection	Each 0.5 ml contains Meningococcal Serogroup A, C, Y and W-135 4 mcg, Diphtheria Toxoid Conjugate Protein carrier approx. 48 mcg	10/30.1/0648	11/11/2010	NS1
68	Pfizer Laboratories (Pty) Ltd	Dimetapp Paediatric Elixir	Brompheniramine maleate; Pseudoephedrine	elixir	Each 5 ml elixir contains Brompheniramine maleate 1 mg and Pseudoephedrine HCl 15 mg	10/5.8/0649	11/11/2010	NS1
69	Merck (Pty) Ltd	Iliadin Tablets	Paracetamol; Caffeine and Brompheniramine	tablet	Each tablet contains Paracetamol 325 mg, Caffeine 30 mg and Brompheniramine Maleate 3 mg	10/5.8/0650	11/11/2010	NS1
70	GlaxoSmithKline South Africa (Pty) Ltd	Priorix Tetra	Measles, Mumps, Rubella and Varicella vaccine	suspension for injection	Each dose after reconstitution contains live attenuated Measles virus, NLT 103.0 CCID50, live attenuated Mumps virus NLT 104.4 CCID50, live attenuated Rubella virus NLT 103.0 CCID50 and live attenuated Varicella virus NLT 103.3 PFU	10/30.1/0651	11/11/2010	NS1
71	Winthrop Pharmaceuticals (Pty) Ltd	Oxaliwin 50 mg/10 ml RTU	Oxaliplatin	solution for infusion	Each vial contains 10 ml of solution equivalent Oxaliplatin 50 mg	10/26/0652	11/11/2010	NS2
72	Winthrop Pharmaceuticals (Pty) Ltd	Oxaliwin 100 mg/20 ml RTU	Oxaliplatin	solution for infusion	Each vial contains 10 ml of solution equivalent Oxaliplatin 100 mg	10/26/0653	11/11/2010	NS2
73	Roche Products (Pty) Ltd	Konaktion MM Paediatric	Phytomenadione	solution for injection	Each 0.2ml ampoule contains Phytomenadion (Vit. K1) 2 mg	10/22/0654	11/11/2010	NS1
74	Roche Products (Pty) Ltd	Konaktion MM	phytomenadione	solution for injection	Each ampoule contains phytomenadione in a mixed micelles vehicle of glycocholic acid and lecithin 10.0 mg	10/22/0655	11/11/2010	NS1
75	Roche Products (Pty) Ltd	Copegus 200	Ribavirin	tablet	Each tablet contains Ribavirin 200,0 mg	10/20.2.8/0656	11/11/2010	NS2
76	Serum Institute of India Ltd	Tetanus Toxoid Vaccine Adsorbed	Adsorbed tetanus toxoid	injection	Each single 0.5 ml human dose contains Adsorbed Tetanus Toxoid $\geq 5$ Lf ( $\geq 40$ IU)	10/30.1/0657	11/11/2010	NS1

77	Serum Institute of India Ltd	BCG Vaccine (Freeze Dried) 1 ml	live attenuated BCG	injection	Each 0.1 ml of live, attenuated BCG Vaccine contains between 1 x 10 <sup>5</sup> and 33 x 10 <sup>5</sup> C.F.U	10/30.1/0658	11/11/2010	NSI
78	Serum Institute of India Ltd	Diphtheria, Tetanus and Pertussis Vaccine Adsorbed - 10 Dose	Diphtheria toxoid, Tetanus toxoid and B. Pertussis	injection	Each single human dose (0.5 ml) contains Diphtheria Toxoid ≥ 30 IU, Tetanus Toxoid 10 Dose ≥ 40 IU and B. Pertussis ≥ 4IU	10/30.1/0659	11/11/2010	NSI
79	Serum Institute of India Ltd	Diphtheria, Tetanus, Pertussis, Hepatitis B Haemophilus influenzae type b conjugate vaccine	Diphtheria, Tetanus, Pertussis, Hepatitis B Haemophilus influenzae type b conjugate	injection	Each dose of 0.5 ml contains Diphtheria Toxoid ≥ 30 IU, Tetanus Toxoid ≥ 40 IU, Haemophilus influenzae type B.Pertussis (whole cell) ≥ 4IU, HBsAg (rDNA) ≥ 10 mcg and Purified Capsular Polysaccharide (PRP) 10 mcg	10/30.1/0660	11/11/2010	NSI
80	Serum Institute of India Ltd	Diphtheria and Tetanus Vaccine Adsorbed (Paediatric ) 10 Dose	diphtheria toxoid; tetanus toxoid	injection	Each single human dose (0.5 ml) contains Diphtheria Toxoid ≥ 30 IU and Tetanus Toxoid ≥ 40 IU	10/30.1/0661	11/11/2010	NSI
81	Serum Institute of India Ltd	Hepatitis B Vaccine (rDNA) (Adult)	purified Hepatitis B surface antigen adsorbed on Aluminium hydroxide	injection	Each dose of 1 ml contains 20 mcg of purified Hepatitis B surface antigen adsorbed on Aluminium hydroxide	10/30.1/0662	11/11/2010	NSI
82	Serum Institute of India Ltd	Measles vaccine, Live, Attenuated (Freeze Dried) 10 Dose	measles live attenuated virus particles	injection	Each single human dose when reconstituted in a volume of 0.5 ml contains not less than 1000 CCID <sub>50</sub> of live virus particles	10/30.1/0663	11/11/2010	NSI

83	Serum Institute of India Ltd	Haemophilus influenzae type b conjugate vaccine (lyophilised)	purified capsular polysaccharide; tetanus toxoid as carrier protein	injection	Each dose of 0.5 ml contains 10 mcg of Purified Capsular Polysaccharide and 19 to 33 mcg Tetanus Toxoid as carrier protein	10/30.1/0664	11/11/2010	NSI
84	Serum Institute of India Ltd	Rubella vaccine, Live, Attenuated (Freeze Dried)	live attenuated rubella virus	injection	Each single human dose when reconstituted in a volume of 0.5 ml contains not less than 1000 CCID <sub>50</sub> of Rubella virus	10/30.1/0665	11/11/2010	NSI
85	Serum Institute of India Ltd	Measles, Mumps and Rubella vaccine Live, Attenuated (Freeze Dried)	measles, mumps and rubella live attenuated virus	injection	Each single human dose when reconstituted in a volume of 0.5 ml contains not less than 1000 CCID <sub>50</sub> of Measles virus, 5000 CCID <sub>50</sub> of Mumps virus and 1000 CCID <sub>50</sub> of Rubella virus	10/30.1/0666	11/11/2010	NSI
86	Serum Institute of India Ltd	Diphtheria, Tetanus, Pertussis and Hepatitis B Vaccine Adsorbed	Diphtheria toxoid, Tetanus toxoid, Pertussis, Hepatitis B surface antigen	injection	Each single 0.5 ml human dose contains Diphtheria Toxoid $\geq$ 30 IU, Tetanus Toxoid Vaccine Adsorbed $\geq$ 40 IU, B. Pertussis (whole cell) $\geq$ 4 IU and HBsAg ( rDNA) $\geq$ 10 mcg	10/30.1/0667	11/11/2010	NSI
87	Serum Institute of India Ltd	Hepatitis B Vaccine (rDNA) (Paediatric)	purified Hepatitis B surface antigen	injection	Each dose of 0.5 ml contains 10 mcg of purified Hepatitis B surface antigen adsorbed on Aluminium hydroxide	10/30.1/0668	11/11/2010	NSI