GOVERNMENT GAZETTE

OF THE

REPUBLIC OF NAMIBIA

N$6.00 WINDHOEK - 21 May 2019 No. 6910

CONTENTS

Page

Government Notices

MINISTRY OF HEALTH AND SOCIAL SERVICES

No. 127 2019

NOTIFICATION OF 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), an inspection or investigation may be carried out regularly by an inspector authorised in terms of sections 35 of the Medicines and Related Substances Control Act, 2003;

(c) the information contained in the medicine package insert must, on a regular basis, be updated to conform with the package insert approved by the Namibia Medicines Regulatory Council so as to provide accurate information to the user of the medicines;

(d) the holder of the certificate of registration must comply with the provisions of the Medicines and Related Substances Control Act, 2003;

(e) the registration of medicine is subject to regular review regarding its quality, safety and efficacy and the Namibia Medicines Regulatory 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 Namibia Medicines Regulatory Council within 30 days from the date of completion of the validation referred to in paragraph (f); and

(h) the Namibia Medicines Regulatory Council may review the registration dossier and determine the intervals when such review takes place.

J. GAESEB
REGISTRAR OF MEDICINES Windhoek, 8 May 2019

SCHEDULE

S/n	Applicant	Proprietary name	Approved name of active(s)	Dosage form	Strength/dose unit	Registration Number	Registration Date	Scheduling Status
1	Guerbet South Africa (Pty) Ltd	Optiray 300 - 30 ml	Loversol	Injection	Each 30ml contains 636mg/ml loversol equivalent to 300mg/ml organically bound iodine	19/28/0001	21/02/2019	NS2
2	Guerbet South Africa (Pty) Ltd	Optiray 300 - 50 ml	Loversol	Injection	Each 50ml contains 636mg/ml loversol equivalent to 300mg/ml organically bound iodine	19/28/0002	21/02/2019	NS2
3	Guerbet South Africa (Pty) Ltd	Optiray 300 - 75 ml	Loversol	Injection	Each 75ml contains 636mg/ml loversol equivalent to 300mg/ml organically bound iodine	19/28/0003	21/02/2019	NS2
4	Guerbet South Africa (Pty) Ltd	Optiray 300 - 100 ml	Loversol	Injection	Each 100 ml contains 636mg/ml loversol equivalent to 300mg/ml organically bound iodine	19/28/0004	21/02/2019	NS2
5	Guerbet South Africa (Pty) Ltd	Optiray 300 - 125 ml	Loversol	Injection	Each 125ml contains 636mg/ml loversol equivalent to 300mg/ml organically bound iodine	19/28/0005	21/02/2019	NS2
6	Guerbet South Africa (Pty) Ltd	Optiray 300 - 500 ml	Loversol	Injection	Each 500ml contains 636mg/ml loversol equivalent to 300mg/ml organically bound iodine	19/28/0006	21/02/2019	NS2
7	Guerbet South Africa (Pty) Ltd	Optiray 350 - 50 ml	Loversol	Injection	Each 50ml contains 741mg/ml loversol equivalent to 3500mg/ml organically bound iodine	19/28/0007	21/02/2019	NS2
8	Guerbet South Africa (Pty) Ltd	Optiray 350 - 75 ml	Loversol	Injection	Each 75ml contains 741mg/ml loversol equivalent to 3500mg/ml organically bound iodine	19/28/0008	21/02/2019	NS2
9	Guerbet South Africa (Pty) Ltd	Optiray 350 - 100 ml	Loversol	Injection	Each 100ml contains 741mg/ml loversol equivalent to 3500mg/ml organically bound iodine	19/28/0009	21/02/2019	NS2
10	Guerbet South Africa (Pty) Ltd	Optiray 350 - 125 ml	Loversol	Injection	Each 125ml contains 741mg/ml loversol equivalent to 3500mg/ml organically bound iodine	19/28/0010	21/02/2019	NS2

11	Guerbet South Africa (Pty) Ltd	Optiray 350 - 200 ml	Loversol	Injection	Each 200ml contains 741mg/ml loversol equivalent to 3500mg/ml organically bound iodine	19/28/0011	21/02/2019	NS2
12	Pharma Dynamics (Pty) Ltd	Texamer	Levocetirizine dihydrochloride	Film-coated Tablet	Each film-coated tablet contains Levocetirizine dihydrochloride 5mg	19/5.7.1/0012	21/02/2019	NS1
13	Hetero Labs Limited	Dolutegravir 50 mg Tablets	Dolutegravir Sodium	Tablet	Each tablet contains Dolutegravir Sodium equivalent to Dolutegravir 50 mg.	19/20.2.8/0013	21/02/2019	NS2
14	Pfizer Laboratories (Pty) Ltd	Celecoxib Pfizer 100	Celecoxib	Capsule	Each capsule contains Celecoxib 100mg	19/2.8/0014	21/02/2019	NS2
15	Pfizer Laboratories (Pty) Ltd	Celecoxib Pfizer 200	Celecoxib	Capsule	Each capsule contains Celecoxib 200mg	19/2.8/0015	21/02/2019	NS2
16	M/s Biological E. Limited	BE Td	Diphtheria and Tetanus Vaccine (Adsorbed, Reduced Antigen(s) Content)	Suspension for injection	Each dose of 0.5ml contains: Diphtheria Toxoid 2 Lf (≥ 2 IU), Tetanus Toxoid 8.8 Lf (≥ 20 IU), Adsorbed on Aluminium Phosphate (as AlPO4) ≥ 1.5 mg	19/30.2/0016	21/02/2019	NS1
17	Reckitt Benckiser Pharmaceuticals (Pty) Ltd	Gaviscon Liquid Aniseed	Sodium Alginate and Sodium bicarbonate	Liquid	500 mg Sodium alginate and 267 mg Sodium bicarbonate per 10mls	19/32.2/0017	21/02/2019	NS0
18	Reckitt Benckiser Pharmaceuticals (Pty) Ltd	Nurofen Express 400mg Liquid Capsules	Ibuprofen	Liquid Capsules	Each capsule contains Ibuprofen 400mg	19/2.8/0018	21/02/2019	NS1
19	Reckitt Benckiser Pharmaceuticals (Pty) Ltd	Nurofen Express 342mg Caplets	Ibuprofen	Caplets	Each caplet contains Ibuprofen 342mg	19/2.8/0019	21/02/2019	NS1
20	Reckitt Benckiser Pharmaceuticals (Pty) Ltd	Nurofen for children 200mg/5ml (Orange)	Ibuprofen	Suspension	Each 5ml contains Ibuprofen 200mg	19/2.8/0020	21/02/2019	NS1
21	Reckitt Benckiser Pharmaceuticals (Pty) Ltd	Nurofen Express 684 mg Caplets	Ibuprofen	Caplets	Each caplet contains Ibuprofen 684mg	19/2.8/0021	21/02/2019	NS2
22	Reckitt Benckiser Pharmaceuticals (Pty) Ltd	Nurofen for children 200mg/5ml (Strawberry)	Ibuprofen	Suspension	Each 5ml contains Ibuprofen 200mg	19/2.8/0022	21/02/2019	NS1

23	Aurobindo Pharma (Pty) Ltd	Zepanalz 10mg tablets	Donepezil hydrochloride	Tablets	Each tablet contains Donepezil hydrochloride 10mg	19/5.3/0023	21/02/2019	NS3
24	Aurobindo Pharma (Pty) Ltd	Zepanalz 5mg tablets	Donepezil hydrochloride	Tablets	Each tablet contains Donepezil hydrochloride 5mg	19/5.3/0024	21/02/2019	NS3
25	GlaxoSmithKline South Africa (Pty) Ltd	Polio Sabin One and Three (Oral)	Bivalent Oral Polio Vaccine	Oral Suspension	1 dose (0.1 ml) contains: Virus Polio Type 1, strain LSc, 2ab ≥106.0 CCID50, Virus Polio Type 3, strain Leon 12a, 1b ≥105.8 CCID50	19/30.2/0025	21/02/2019	NS1
26	Activo Health (Pty) Ltd	Glencet 5	Levocetirizine dihydrochloride	Film-coated Tablet	Each film-coated tablet contains Levocetirizine dihydrochloride	19/5.7.1/0026	21/02/2019	NS1
27	Cipla Quality Chemical Industries Limited	Trioday	Efavirenz, Lamivudine, Tenofovir disoproxil fumarate	Tablets	Each tablet contains Efavirenz 600mg, Lamivudine 300mg and Tenofovir disoproxil fumarate 300mg	19/20.2.8/0027	21/02/2019	NS2
28	Sanofi-Aventis South Africa (Pty) Ltd	Toujeo	Insulin glargine	Solution for injection	Each ml contains Insulin glargine 300 units (U)	19/21.1/0028	21/02/2019	NS2
29	MSD (Pty) Ltd	Bridion Solution for injection	Sugammadex	Solution for injection	Each ml contains Sugammadex 100mg	19/32.2/0029	21/02/2019	NS2
30	Biotech Laboratories (Pty) Ltd	Pyridium	Phenazopyridine hydrochloride	Tablets	Each tablet contains phenazopyridine hydrochloride equivalent to 100 mg phenazopyridine	19/32.2/0030	21/02/2019	NS1
31	Roche Products (Pty) Ltd	Ocrevus 300mg	Ocrelizumab	Injection	Each 10 ml contains Ocrelizumab 300 mg	19/30.1/0031	21/02/2019	NS2
32	Roche Products (Pty) Ltd	Perjeta	Pertuzumab	Injection	Each 14 ml contains Pertuzumab 420 mg	19/26/0032	21/02/2019	NS2
33	Roche Products (Pty) Ltd	Hemlibra® 30mg/1ml	Emicizumab	Solution for Injection	Each ml contains Emicizumab 30 mg	19/30/0033	21/02/2019	NS2
34	Roche Products (Pty) Ltd	Hemlibra® 60mg/0.4ml	Emicizumab	Solution for Injection	Each 0.4ml contains Emicizumab 60 mg	19/30.1/0034	21/02/2019	NS2
35	Roche Products (Pty) Ltd	Hemlibra® 105mg/0.7ml	Emicizumab	Solution for Injection	Each 0.7 ml contains Emicizumab 105 mg	19/30.1/0035	21/02/2019	NS2
36	Roche Products (Pty) Ltd	Hemlibra® 150mg/1ml	Emicizumab	Solution for Injection	Each ml contains Emicizumab 150 mg	19/30.1/0036	21/02/2019	NS2

37	Novartis South Africa (Pty) Ltd	Jakavi 5 mg	Ruxolitinib phosphate	Film-coated Tablets	Each film-coated tablet contains 6,60 mg Ruxolitinib phosphate equivalent to 5 mg Ruxolitinib base	19/32.2/0037	21/02/2019	NS2
38	Novartis South Africa (Pty) Ltd	Jakavi 15 mg	Ruxolitinib phosphate	Film-coated Tablets	Each film-coated tablet contains 19,80 mg Ruxolitinib phosphate equivalent to 15 mg Ruxolitinib base	19/32.2/0038	21/02/2019	NS2
39	Novartis South Africa (Pty) Ltd	Jakavi 20 mg	Ruxolitinib phosphate	Film-coated Tablets	Each film-coated tablet contains 26,40 mg Ruxolitinib phosphate equivalent to 20 mg Ruxolitinib base	19/32.2/0039	21/02/2019	NS2
40	Innovata Pharmaceuticals (Pty) Ltd	Citara 250	Levetiracetam	Film-coated Tablets	Each film-coated tablet contains Levetiracetam 250mg	19/2.6/0040	21/02/2019	NS3
41	Innovata Pharmaceuticals (Pty) Ltd	Citara 500	Levetiracetam	Film-coated Tablets	Each film-coated tablet contains Levetiracetam 500mg	19/2.6/0041	21/02/2019	NS3
42	Innovata Pharmaceuticals (Pty) Ltd	Citara 750	Levetiracetam	Film-coated Tablets	Each film-coated tablet contains Levetiracetam 750mg	19/2.6/0042	21/02/2019	NS3
43	Innovata Pharmaceuticals (Pty) Ltd	Citara 1000	Levetiracetam	Film-coated Tablets	Each film-coated tablet contains Levetiracetam 1000mg	19/2.6/0043	21/02/2019	NS3
44	Fabupharm (Pty) Ltd.	Fabu-Moxifloxacin 400 mg	Moxifloxacin hydrochloride	Film-coated Tablets	Each film-coated tablet contains Moxifloxacin hydrochloride equivalent to Moxifloxacin 400 mg	19/20.1.1/0044	21/02/2019	NS2

MINISTRY OF HEALTH AND SOCIAL SERVICES

No. 128 2019

NOTIFICATION OF 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 veterinary 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 determined by the Namibia Medicines Regulatory Council;

(b) in order to assess compliance with paragraph (a), an inspection or investigation may be carried out regularly by an inspector authorised in terms of sections 35 of the Medicines and Related Substances Control Act, 2003;

(c) the information contained in the medicine package insert must, on a regular basis, be updated to conform with the package insert approved by the Namibia Medicines Regulatory Council so as to provide accurate information to the user of the medicines;

(d) the holder of the certificate of registration must comply with the provisions of the Medicines and Related Substances Control Act, 2003;

(e) the registration of medicine is subject to regular review regarding its quality, safety and efficacy and the Namibia Medicines Regulatory 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 Namibia Medicines Regulatory Council within 30 days from the date of completion of the validation referred to in paragraph (f); and

(h) the Namibia Medicines Regulatory Council may review the registration dossier and determine the intervals when such review takes place.

J. GAESEB
REGISTRAR OF MEDICINES Windhoek, 8 May 2019

SCHEDULE

S/N	Applicant	Proprietary Name	Strength/Dose Unit	Dosage Form	Species	Registration Number	Registration Date	Scheduling Status
1	Phibro Animal Health (Pty) Ltd	Aviax Plus	Semduramicin 3 g and Nicarbazin 8 g per 100 g	Oral granules	Poultry	V19/17.4.1/1440	21/02/2019	NS0
2	Intervet SA (Pty) Ltd	Bravecto Spot-on	Each ml contains Fluralaner 280 mg	Topical solution	Dogs and Cats	V19/18.3.10/1441	21/02/2019	NS0
3	Ascendis Animal Health (Pty) Ltd	Attila	Each 100 ml contains Fipronil 0.9g and Abamectin 0.5 g	Pour-on solution	Cattle	V19/18.2/1442	21/02/2019	NS0