GOVERNMENT GAZETTE

OF THE

REPUBLIC OF NAMIBIA

N$6.60 WINDHOEK - 18 November 2019 No. 7052

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NOTIFICATION OF CANCELLATION 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 registration of the medicines set out in the Schedule is cancelled.

J. GAESEB
REGISTRAR OF MEDICINES Windhoek, 4 November 2019

SCHEDULE

S/N	Applicant	Registered Name	Approved name of active(s)	Registration Number
1	GlaxoSmithKline South Africa (Pty) Ltd	Hiberix	Haemophilus influenza type b capsular polysaccharide (PRP) conjugated to tetanus toxoid	04/30.1/0891
2	Adcock Ingram Limited	Fucidin H Ointment	Fucidin	14/13.4.1/0491
3	Adcock Ingram Limited	Dovonex Scalp Solution	Calcipotriol Hydrate	05/13.9.1/0148
4	Soflens (Pty) Ltd	Minims Pilocarpine 4%	Pilocarpine	07/15.4/0061
5	Abbvie (Pty) Ltd	Synagis 100mg Lyophilised powder for solution	Palivizumab	11/30.2/0048
6	Abbvie (Pty) Ltd	Synagis 50mg Lyophilised powder for solution	Palivizumab	11/30.2/0047
7	MSD (Pty) Ltd	Stocrin 50	Efavirenz	10/20.2.8/0159
8	MSD (Pty) Ltd	Stocrin 200	Efavirenz	10/20.2.8/0160
9	Bayer (Pty) Ltd	Progynova 1mg	Oestradiol valerate	90/21.8.1/023
10	Bayer (Pty) Ltd	Progynova 2mg	Oestradiol valerate	14/21.8.1/0369

MINISTRY OF HEALTH AND SOCIAL SERVICES

No. 354 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 medicine set out in the Schedule have been registered in terms of that Act, subject to the following conditions:

(a) the applicant must ensure that the medicine is manufactured and controlled in terms of current good manufacturing practices as determined by the Namibia Medicines Regulatory Council (hereafter referred to as "the Council");

(b) inspections or investigations may be carried out regularly by an inspector authorised in terms of sections 35 of the Act, in order to assess compliance with existing good manufacturing practices;

(c) the applicant must ensure that the information contained in the medicine package insert is regularly updated so as to provide accurate information to the user of the medicine;

(d) the applicant must comply with the provisions of the Medicines and Related Substances Control Act, 2003 (Act No. 13 of 2003);

(e) the registration of medicine is subject to regular review by the Council regarding its quality, safety and efficacy and the Council may vary the registration of the medicine, as it considers necessary;

(f) the applicant must validate the first two production batches in terms of the detailed process validation protocol which was submitted at the time of the application for registration and that validation report must be submitted to the Council within 30 days from the date of completion of the validation; and

(g) the Council may review the registration dossier and may determine the intervals when the reviews will take place.

J. GAESEB
REGISTRAR OF MEDICINES Windhoek, 4 November 2019

SCHEDULE

S/N	Applicant	Proprietary name	Approved name of active(s)	Dosage form	Species	Registration Number	Registration Date	Scheduling status
1	Ceva Animal Health (Pty) Ltd	Prid Delta	Each intra-vaginal device contains 1,55 g Progesterone	Intra-vaginal device	Cattle	V19/11.2.3/1444	25/07/2019	NS2

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MINISTRY OF HEALTH AND SOCIAL SERVICES

No. 355 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 medicine set out in the Schedule have been registered in terms of that Act, subject to the following conditions:

(a) the applicant must ensure that the medicine is manufactured and controlled in terms of current good manufacturing practices as determined by the Namibia Medicines Regulatory Council (hereafter referred to as "the Council");

(b) inspections or investigations may be carried out regularly by an inspector authorised in terms of sections 35 of the Act, in order to assess compliance with existing good manufacturing practices;

(c) the applicant must ensure that the information contained in the medicine package insert is regularly updated so as to provide accurate information to the user of the medicine;

(d) the applicant must comply with the provisions of the Medicines and Related Substances Control Act, 2003 (Act No. 13 of 2003);

(e) the registration of medicine is subject to regular review by the Council regarding its quality, safety and efficacy and the Council may vary the registration of the medicine, as it considers necessary;

(f) the applicant must validate the first two production batches in terms of the detailed process validation protocol which was submitted at the time of the application for registration and that validation report must be submitted to the Council within 30 days from the date of completion of the validation; and

(g) the Council may review the registration dossier and may determine the intervals when the reviews will take place.

J. GAESEB
REGISTRAR OF MEDICINES Windhoek, 4 November 2019

SCHEDULE

S/N	Applicant	Proprietary name	Approved name of active(s)	Dosage form	Species	Registration Number	Registration Date	Scheduling status
1	Ascendis Animal Health (Pty) Ltd	Deca-Sure	Purified & concentrated toxoids of Clostridium perfringens Type A, B, C & D; Clostridium septicum; Clostridium novyi Type B; Clostridium tetani; Clostridium sordelli; Integral anacultures of Clostridium chauvoei; Clostridium novyi Type D (Clostridium haemolyticum)	Vaccine: injection	Cattle, Sheep	V19/24.4.2/1443	09/05/2019	NS0

MINISTRY OF HEALTH AND SOCIAL SERVICES

No. 356 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 applicant must ensure that the medicine is manufactured and controlled in terms of the current good manufacturing practices as determined by the Namibia Medicines Regulatory Council (hereafter referred to as "the Council");

(b) inspections and investigations may be carried out regularly by inspectors authorised in terms of sections 35 of the Act, in order to assess compliance with existing good manufacturing practices;

(c) the applicant must ensure that the information contained in the medicine package insert is regularly updated so as to provide accurate information to the user of the medicine;

(d) the applicant must comply with the provisions of the Medicines and Related Substances Control Act, 2003 (Act No. 13 of 2003);

(e) the registration of medicine is subject to regular review by the Council regarding its quality, safety and efficacy and the Council may vary the registration of the medicine, as it considers necessary;

(f) the applicant must validate the first two production batches in terms of the detailed process validation protocol which was submitted at the time of the application for registration and that validation report must be submitted to the Council within 30 days from the date of completion of the validation; and

(g) the Council may review the registration dossier and may determine the intervals when the reviews will take place.

J. GAESEB
REGISTRAR OF MEDICINES Windhoek, 4 November 2019

SCHEDULE

S/N	Applicant	Proprietary name	Approved name of active(s)	Dosage form	Strength/dose unit	Registration number	Registration date	Scheduling status
1	MSN Laboratories Private Limited	Longride 60	Dapoxetine hydrochloride	Film-coated tablet	Each film-coated tablet contains Dapoxetine hydrochloride 60mg	19/1.2/0091	25.07.2019	NS3
2	MSN Laboratories Private Limited	Longride 30	Dapoxetine hydrochloride	Film-coated tablet	Each film-coated tablet contains Dapoxetine hydrochloride 30mg	19/1.2/0092	25.07.2019	NS3
3	MSN Laboratories Private Limited	Apritant IV	Fosaprepitant Dimeglumine	Lyophilised injection	Each vial contains Fosaprepitant Dimeglumine 150mg	19/5.7.2/0093	25.07.2019	NS2
4	Doré Pharmaceuticals (Pty) Ltd	Paracetamol-Doré 500mg	Paracetamol	Tablet	Each tablet contains Paracetamol 500mg	19/2.8/0094	25.07.2019	NS1
5	Serum Institute of India Pvt. Ltd	Rabivax-S	Rabies vaccine	Powder for injection	Each dose of 1 ml contains: Purified Rabies Antigen (Rabies virus Pitman-Moore Strain 3218-VERO adapted and grown on vero cells, inactivated by using b -propiolactone) not less than 2.5 IU	19/30.1/0095	25.07.2019	NS2
6	iNova Pharmaceuticals (Pty) Ltd	Norflex Gel Forte	Benzydamine hydrochloride	Gel	Each 100g contains Benzydamine hydrochloride 5g	19/2.8/0096	25.07.2019	NS2
7	Ranbaxy (SA) (Pty) Ltd	Cetizal 5	Levocetirizine dihydrochloride	Film-coated tablet	Each film-coated tablet contains Levocetirizine dihydrochloride 5mg	19/5.7.1/0097	25.07.2019	NS1
8	Mylan Pharmaceuticals Private Limited	Fulphila	Pegfilgrastim	Concentrate for solution for subcutaneous injection	Each 0.6 ml solution in a pre- filled syringe contains Pegfilgrastim 6 mg	19/32.2/0098	25.07.2019	NS2
9	Macleods Pharmaceuticals Limited	Monopas 4g	Para aminosalicylate	Powder for suspension	Each sachet contains Para Aminosalicylate 4g	19/20.2.3/0099	25.07.2019	NS2
10	MSN Laboratories Private Limited	Nuclofar	Clofarabine	Liquid injection	Each ml of concentrate contains Clofarabine 1mg	19/26/0100	25.07.2019	NS2

11	Innovata Pharmaceuticals (Pty) Ltd	Zee 250	Azithromycin	Tablet	Each tablet contains Azithromycin 250mg	19/20.1.1/0101	25.07.2019	NS2
12	Innovata Pharmaceuticals (Pty) Ltd	Zee 500	Azithromycin	Tablet	Each tablet contains Azithromycin 500mg	19/20.1.1/0102	25.07.2019	NS2
13	Innovata Pharmaceuticals (Pty) Ltd	Avasalf 100/50	Fluticasone propionate + Salmeterol	Inhalation powder	Each actuation contains Fluticasone propionate 100mcg and Salmeterol 50mcg	19/21.5.1/0103	25.07.2019	NS2
14	Innovata Pharmaceuticals (Pty) Ltd	Avasalf 250/50	Fluticasone propionate + Salmeterol	Inhalation powder	Each actuation contains Fluticasone propionate 250mcg and Salmeterol 50mcg	19/21.5.1/0104	25.07.2019	NS2
15	Innovata Pharmaceuticals (Pty) Ltd	Avasalf 500/50	Fluticasone propionate + Salmeterol	Inhalation powder	Each actuation contains Fluticasone propionate 500mcg and Salmeterol 50mcg	19/21.5.1/0105	25.07.2019	NS2
16	Trinity Pharma (Pty) Ltd	Sildenafil Trinity 25	Sildenafil citrate	Film-coated tablet	Each film coated tablet contains sildenafil 25 mg	19/7.1.5/0106	25.07.2019	NS2
17	Trinity Pharma (Pty) Ltd	Sildenafil Trinity 50	Sildenafil citrate	Film-coated tablet	Each film coated tablet contains sildenafil 50 mg	19/7.1.5/0107	25.07.2019	NS2
18	Trinity Pharma (Pty) Ltd	Sildenafil Trinity 100	Sildenafil citrate	Film-coated tablet	Each film coated tablet contains sildenafil 100 mg	19/7.1.5/0108	25.07.2019	NS2
19	Serum Institute of India Pvt. Ltd	ROTASIIL 1 DOSE	Rotavirus vaccine, live attenuated	Freeze-dried oral vaccine	Each dose of 2.5 ml contains: Live Attenuated Bovine - Human Rotavirus Reassortant [G1, G2, G3, G4 and G9]* 105.6 FFU / Serotype	19/30.1/0109	25.07.2019	NS1
20	Serum Institute of India Pvt. Ltd	ROTASIIL 2 DOSE	Rotavirus vaccine, live attenuated	Freeze-dried oral vaccine	Each dose of 2.5 ml contains: Live Attenuated Bovine - Human Rotavirus Reassortant [G1, G2, G3, G4 and G9]* 105.6 FFU / Serotype	19/30.1/0110	25.07.2019	NS1
21	Venus Remedies Limited	Robol 10mg/5ml	Doxorubicin hydrochloride	Intravenous/ Intravesical infusion	Each ml contains Doxorubicin hydrochloride 2mg	19/26/0111	25.07.2019	NS2

22	Venus Remedies Limited	Robol 50mg/25ml	Doxorubicin hydrochloride	Intravenous/ Intravesical infusion	Each ml contains Doxorubicin hydrochloride 2mg	19/26/0112	25.07.2019	NS2
23	MSD (Pty) Ltd	Keytruda	Pembrolizumab	Solution for infusion	Each ml contains Pembrolizumab 25mg	19/26/0113	25.07.2019	NS2
24	Takeda (Pty) Ltd	Doribax 500mg	Doripenem monohydrate	Powder for solution for infusion	Each vial contains Doripenem monohydrate 500mg	19/20.1.1/0114	25.07.2019	NS2
25	Varichem Pharmaceuticals (Pvt) Ltd	Procedyl Linctus	Codeine Phosphate, Ephedrine Hydrochloride, Promethazine Hydrochloride	Linctus	Each 5ml contains Codeine Phosphate 9 mg, Ephedrine Hydrochloride 7.2 mg and Promethazine Hydrochloride 3.6 mg	19/2.10/00115	25.07.2019	NS2
26	Doré Pharmaceuticals (Pty) Ltd	Perindopril-Doré 4mg Tablets	Perindopril erbumine	Tablet	Each tablet contains Perindopril erbumine 4mg	19/7.1.3/00116	25.07.2019	NS2
27	Strides Arcolab Limited	Artecap	Artesunate rectal capsule	Suppository	Each rectal Capsule contains Artesunate 100 mg	19/20.2.6/0117	25.07.2019	NS2
28	Laurus Labs Pvt Ltd	Tenofovir Disoproxil Fumarate 300 mg	Tenofovir Disoproxil Fumarate	Tablet	Each film-coated tablet contains Tenofovir Disoproxil Fumarate 300 mg.	19/20.2.8/0119	25.07.2019	NS2
29	Strides Arcolab Limited	Lamivudine, Zidovudine150mg / 300 mg	Lamivudine, Zidovudine	Tablet	Each film-coated tablet contains lamivudine USP 150 mg and zidovudine USP 300 mg	19/20.2.8/0120	25.07.2019	NS2
30	Macleods Pharmaceuticals Limited	Lizomac	Linezolid	Tablet	Each film-coated tablet contains linezolid 600 mg	19/20.1.1/0121	25.07.2019	NS2
31	Population Services International, South Africa	Avertiso	Misoprostol	Tablet	Each tablet contains misoprostol 200mcg	19/32.2/0122	25.07.2019	NS4
32	Cipla Medpro (Pty) Ltd	Latenef	Tenofovir Disoproxil Fumarate, Lamivudine, Efavirenz	Film-coated tablet	Each film-coated tablet contains Tenofovir Disoproxil Fumarate 300 mg, Lamivudine 300 mg and Efavirenz 600	19/20.2.8/0123	25.07.2019	NS2

33	Beximco Pharmaceiticals Limited	Pantoprazole 20mg	Pantoprazole sodium	Gastro Resistant Tablet	Each gastro-resistant tablet contains Pantoprazole sodium equivalent to Pantoprazole 20 mg	19/11.4.1/0124	25.07.2019	NS1
34	Beximco Pharmaceiticals Limited	Pantoprazole 40mg	Pantoprazole sodium	Gastro Resistant Tablet	Each gastro-resistant tablet contains Pantoprazole sodium equivalent to Pantoprazole 40 mg	19/11.4.1/0125	25.07.2019	NS2
35	Varichem Pharmaceuticals (PVT) LTD	VCs Flumed	Paracetamol, Phenylephrine HCL, Dextromethorphan HBr, Chlorpheniramine Maleate	Oral Solution	Each 5ml contais: Paracetamol 120mg, Phenylphrine HCL 2.5mg, Dextromethorphan HBr 2mg and Chlorpheniramine Maleate 0.5mg	19/5.8/0126	25.07.2019	NS1
36	Mylan Pharmaceuticals Private Limited	Ogivri	Trastuzumab	Lyophilised powder for concentrate for solution for intravenous infusion	Each vial contains Trastuzumab 440mg	19/26/0127	25.07.2019	NS2