

GOVERNMENT NOTICES • GOEWERMENSKENNISGEWINGS

DEPARTMENT OF HEALTH

NO. R. 3829

1 September 2023

NOTIFICATION OF REGISTRATION OF MEDICINES IN TERMS OF SECTION 17 OF THE MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT 101 OF 1965) AS AMENDED						
Registration Number	Registration Date	Product Name	Dosage Form	Applicant Name	Ingredients	Conditions for Registration
55/8.2/0143.140	2023/04/04	AXOLITA 10 mg	Tablet	Pharma Dynamics (Pty) Ltd	EACH TABLET CONTAINS RIVAROXABAN 10,0 mg	Annexure A
55/8.2/0144.141	2023/04/04	AXOLITA 15 mg	Tablet	Pharma Dynamics (Pty) Ltd	EACH TABLET CONTAINS RIVAROXABAN 15,0 mg	Annexure A
55/8.2/0145.142	2023/04/04	AXOLITA 20 mg	Tablet	Pharma Dynamics (Pty) Ltd	EACH TABLET CONTAINS RIVAROXABAN 20,0 mg	Annexure A
55/3.3/0784	2023/04/04	COLNOVA 0,5	Tablet	Novagen Pharma (Pty) Ltd	EACH TABLET CONTAINS COLCHICINE 0,5 mg	Annexure A
56/7.1.3/1177	2023/04/04	COVENAP 10 mg	Tablet	Austell Pharmaceuticals (Pty) Ltd	EACH TABLET CONTAINS ENALAPRIL MALEATE 10,0 mg	Annexure A
56/7.1.3/1176	2023/04/04	COVENAP 5 mg	Tablet	Austell Pharmaceuticals (Pty) Ltd	EACH TABLET CONTAINS ENALAPRIL MALEATE 5,0 mg	Annexure A
55/21.1/0514.513	2023/04/04	INSULIN ASPART 100 units/ml SANOFI	Injection	Sanofi-Aventis South Africa (Pty) Ltd	EACH 1,0 ml SOLUTION CONTAINS INSULIN ASPART 100,0 units	Annexure A
54/10.2.1/0627	2023/04/04	LEVALBUTEROL 0,31 mg/3 ml CIPLA	Inhalation	Cipla Medpro (Pty) Ltd	EACH 3,0 ml SOLUTION CONTAINS LEVALBUTEROL HYDROCHLORIDE EQUIVALENT TO LEVALBUTEROL 0,31 mg	Annexure A
54/10.2.1/0628	2023/04/04	LEVALBUTEROL 0,63 mg/3 ml CIPLA	Inhalation	Cipla Medpro (Pty) Ltd	EACH 3,0 ml SOLUTION CONTAINS LEVALBUTEROL HYDROCHLORIDE EQUIVALENT TO LEVALBUTEROL 0,63 mg	Annexure A
54/10.2.1/0629	2023/04/04	LEVALBUTEROL 1,25 mg/3 ml CIPLA	Inhalation	Cipla Medpro (Pty) Ltd	EACH 3,0 ml SOLUTION CONTAINS LEVALBUTEROL HYDROCHLORIDE EQUIVALENT TO LEVALBUTEROL 1,25 mg	Annexure A
55/8.2/0716.715	2023/04/04	RABOVIX 10 mg	Tablet	Viatrix Healthcare (Pty) Ltd	EACH TABLET CONTAINS RIVAROXABAN 10,0 mg	Annexure A
55/8.2/0715	2023/04/04	REXARAV 10 mg	Tablet	Viatrix Healthcare (Pty) Ltd	EACH TABLET CONTAINS RIVAROXABAN 10,0 mg	Annexure A
54/10.2.1/0630.627	2023/04/04	SILEA 0,31 mg/3ml	Inhalation	Cipla Medpro (Pty) Ltd	EACH 3,0 ml SOLUTION CONTAINS LEVALBUTEROL HYDROCHLORIDE EQUIVALENT TO LEVALBUTEROL 0,31 mg	Annexure A
54/10.2.1/0631.628	2023/04/04	SILEA 0,63 mg/3 ml	Inhalation	Cipla Medpro (Pty) Ltd	EACH 3,0 ml SOLUTION CONTAINS LEVALBUTEROL HYDROCHLORIDE EQUIVALENT TO LEVALBUTEROL 0,63 mg	Annexure A
54/10.2.1/0632.629	2023/04/04	SILEA 1,25 mg/3ml	Inhalation	Cipla Medpro (Pty) Ltd	EACH 3,0 ml SOLUTION CONTAINS LEVALBUTEROL HYDROCHLORIDE EQUIVALENT TO LEVALBUTEROL 1,25 mg	Annexure A
54/15.3/0408	2023/04/04	TOBROFT	Eye Drops	Austell Pharmaceuticals (Pty) Ltd	EACH 1,0 ml SUSPENSION CONTAINS DEXAMETHASONE 1,0 mg TOBRAMYCIN 3,0 mg	Annexure A

55/21.1/0513	2023/04/04	TRUVELOG	Injection	Sanofi-Aventis South Africa (Pty) Ltd	EACH 1,0 ml SOLUTION CONTAINS INSULIN ASPART 100,0 units	Annexure A
54/1.2/0557	2023/04/04	VORTIOXETINE 10 mg UNICHEM	Tablet	Unichem SA (Pty) Ltd	EACH TABLET CONTAINS VORTIOXETINE HYDROBROMIDE EQUIVALENT TO VORTIOXETINE 10,0 mg	Annexure A
54/1.2/0558	2023/04/04	VORTIOXETINE 20 mg UNICHEM	Tablet	Unichem SA (Pty) Ltd	EACH TABLET CONTAINS VORTIOXETINE HYDROBROMIDE EQUIVALENT TO VORTIOXETINE 20,0 mg	Annexure A
54/1.2/0556	2023/04/04	VORTIOXETINE 5 mg UNICHEM	Tablet	Unichem SA (Pty) Ltd	EACH TABLET CONTAINS VORTIOXETINE HYDROBROMIDE EQUIVALENT TO VORTIOXETINE 5,0 mg	Annexure A
54/15.3/0409.408	2023/04/04	XAMFLAM	Eye Drops	Austell Pharmaceuticals (Pty) Ltd	EACH 1,0 ml SUSPENSION CONTAINS DEXAMETHASONE 1,0 mg TOBRAMYCIN 3,0 mg	Annexure A
55/8.2/0140	2023/04/04	XAROBAN 10 mg	Tablet	Pharma Dynamics (Pty) Ltd	EACH TABLET CONTAINS RIVAROXABAN 10,0 mg	Annexure A
55/8.2/0141	2023/04/04	XAROBAN 15 mg	Tablet	Pharma Dynamics (Pty) Ltd	EACH TABLET CONTAINS RIVAROXABAN 15,0 mg	Annexure A
55/8.2/0142	2023/04/04	XAROBAN 20 mg	Tablet	Pharma Dynamics (Pty) Ltd	EACH TABLET CONTAINS RIVAROXABAN 20,0 mg	Annexure A
55/8.2/0717.715	2023/04/04	XAVIAT 10 mg	Tablet	Viatrix Healthcare (Pty) Ltd	EACH TABLET CONTAINS RIVAROXABAN 10,0 mg	Annexure A
55/11.10/0503	2023/04/11	ACEMISO	Tablet	Ruby Pharmaceuticals (Pty) Ltd	EACH TABLET CONTAINS MISOPROSTOL 200,0 ug	Annexure A
54/21.2/0465	2023/04/11	FORTESE XR 500	Tablet	ALKEM LABORATORIES (PTY) LTD	EACH TABLET CONTAINS METFORMIN HYDROCHLORIDE 500,0 mg	Annexure A
54/21.2/0466	2023/04/11	FORTESE XR 750	Tablet	ALKEM LABORATORIES (PTY) LTD	EACH TABLET CONTAINS METFORMIN HYDROCHLORIDE 750,0 mg	Annexure A
54/15.4/0388	2023/04/11	LOBIMOPT	Eye Drops	Trinity Pharma (Pty) Ltd	EACH 1,0 ml SOLUTION CONTAINS TIMOLOL MALEATE EQUIVALENT TO TIMOLOL 5,0 mg BIMATOPROST 3,0 mg	Annexure A
54/21.2/0467.465	2023/04/11	METFORMIN XR 500 ALKEM	Tablet	ALKEM LABORATORIES (PTY) LTD	EACH TABLET CONTAINS METFORMIN HYDROCHLORIDE 500,0mg	Annexure A
54/21.2/0468.466	2023/04/11	METFORMIN XR 750 ALKEM	Tablet	ALKEM LABORATORIES (PTY) LTD	EACH TABLET CONTAINS METFORMIN HYDROCHLORIDE 750,0 mg	Annexure A
54/15.4/0390.388	2023/04/11	TIMATEAR	Eye Drops	Trinity Pharma (Pty) Ltd	EACH 1,0 ml SOLUTION CONTAINS TIMOLOL MALEATE EQUIVALENT TO TIMOLOL 5,0 mg BIMATOPROST 3,0 mg	Annexure A
54/15.4/0389.388	2023/04/11	TIMPROMAT	Eye Drops	Trinity Pharma (Pty) Ltd	EACH 1,0 ml SOLUTION CONTAINS TIMOLOL MALEATE EQUIVALENT TO TIMOLOL 5,0 mg BIMATOPROST 3,0 mg	Annexure A
56/2.6.5/0059	2023/04/18	AMPERI 5 mg/ml	Injection	LeBasi Pharmaceuticals (Pty) Ltd	EACH 1,0 ml SOLUTION CONTAINS HALOPERIDOL 5,0 mg	Annexure A
55/8.2/0492.489	2023/04/18	AZIRIV 10	Tablet	Ruby Pharmaceuticals (Pty) Ltd	EACH TABLET CONTAINS RIVAROXABAN 10,0 mg	Annexure A
55/8.2/0493.490	2023/04/18	AZIRIV 15	Tablet	Ruby Pharmaceuticals (Pty) Ltd	EACH TABLET CONTAINS RIVAROXABAN 15,0 mg	Annexure A
55/8.2/0494.491	2023/04/18	AZIRIV 20	Tablet	Ruby Pharmaceuticals (Pty) Ltd	EACH TABLET CONTAINS RIVAROXABAN 20,0 mg	Annexure A

55/32.16/0351	2023/04/18	BYDUREON BCISE	Injection	AstraZeneca Pharmaceuticals (Pty) Ltd	EACH DOSE CONTAINS EXENATIDE 2,0 mg	Annexure A
56/21.8.2/0340	2023/04/18	DIENOGEST 2 mg DYNA	Tablet	Pharma Dynamics (Pty) Ltd	EACH TABLET CONTAINS DIENOGEST 2,0 mg	Annexure A
55/26/0558	2023/04/18	MELPISPAL 50	Injection	Ruby Pharmaceuticals (Pty) Ltd	EACH VIAL CONTAINS MELPHALAN HYDROCHLORIDE 50,0 mg	Annexure A
56/34/0213	2023/04/18	MODULFIN 0,5 mg	Capsule	Accord Healthcare (Pty) Ltd	EACH CAPSULE CONTAINS FINGOLIMOD HYDROCHLORIDE EQUIVALENT TO FINGOLIMOD 0,5 mg	Annexure A
55/7.2/0361	2023/04/18	PHENPRESSOR 10 mg/ml	Injection	KAHMA BIOTECH (Pty) Ltd	EACH 1,0 ml SOLUTION CONTAINS PHENYLEPHRINE HYDROCHLORIDE 10,0 mg	Annexure A
55/8.2/0489	2023/04/18	RUBAROX 10	Tablet	Ruby Pharmaceuticals (Pty) Ltd	EACH TABLET CONTAINS RIVAROXABAN 10,0 mg	Annexure A
55/8.2/0490	2023/04/18	RUBAROX 15	Tablet	Ruby Pharmaceuticals (Pty) Ltd	EACH TABLET CONTAINS RIVAROXABAN 15,0 mg	Annexure A
55/8.2/0491	2023/04/18	RUBAROX 20	Tablet	Ruby Pharmaceuticals (Pty) Ltd	EACH TABLET CONTAINS RIVAROXABAN 20,0 mg	Annexure A
55/21.5.1/0730	2023/04/18	SERHALE 50/100	Inhalation	Innovata Pharmaceuticals	EACH DOSE CONTAINS SALMETEROL XINAFOATE EQUIVALENT TO SALMETEROL 50,0 ug FLUTICASON PROPRIONATE 100,0 ug	Annexure A
55/21.5.1/0731	2023/04/18	SERHALE 50/250	Inhalation	Innovata Pharmaceuticals	EACH DOSE CONTAINS SALMETEROL XINAFOATE EQUIVALENT TO SALMETEROL 50,0 ug FLUTICASON PROPRIONATE 250,0 ug	Annexure A
55/21.5.1/0732	2023/04/18	SERHALE 50/500	Inhalation	Innovata Pharmaceuticals	EACH DOSE CONTAINS SALMETEROL XINAFOATE EQUIVALENT TO SALMETEROL 50,0 ug FLUTICASON PROPRIONATE 500,0 ug	Annexure A
57/20.2.3/0155	2023/04/18	UKUZID 300 mg	Tablet	Pharma Dynamics (Pty) Ltd	EACH TABLET CONTAINS ISONIAZID 300,0 mg	Annexure A
55/2.6.5/0263	2023/04/18	QLANTRIS XR 50 mg	Tablet	Viatrix Healthcare (Pty) Ltd	EACH TABLET CONTAINS QUETIAPINE FUMARATE EQUIVALENT TO QUETIAPINE 50,0 mg	Annexure A
55/2.6.5/0264	2023/04/18	QLANTRIS XR 150 mg	Tablet	Viatrix Healthcare (Pty) Ltd	EACH TABLET CONTAINS QUETIAPINE FUMARATE EQUIVALENT TO QUETIAPINE 150,0 mg	Annexure A
55/2.6.5/0265	2023/04/18	QLANTRIS XR 200 mg	Tablet	Viatrix Healthcare (Pty) Ltd	EACH TABLET CONTAINS QUETIAPINE FUMARATE EQUIVALENT TO QUETIAPINE 200,0 mg	Annexure A
55/2.6.5/0266	2023/04/18	QLANTRIS XR 300 mg	Tablet	Viatrix Healthcare (Pty) Ltd	EACH TABLET CONTAINS QUETIAPINE FUMARATE EQUIVALENT TO QUETIAPINE 300,0 mg	Annexure A
55/2.6.5/0267	2023/04/18	QLANTRIS XR 400 mg	Tablet	Viatrix Healthcare (Pty) Ltd	EACH TABLET CONTAINS QUETIAPINE FUMARATE EQUIVALENT TO QUETIAPINE 400,0 mg	Annexure A
56/26/0040	2023/04/25	BORTEZOMIB EQUITY	Injection	Equity Pharmaceutical (Pty) Ltd	EACH VIAL CONTAINS BORTEZOMIB 3,5 mg	Annexure A
54/20.2.3/0237	2023/04/25	CLOFAZIMINE TABLETS 100 mg	Tablet	Macleods Pharmaceuticals SA (Pty) Ltd	EACH TABLET CONTAINS CLOFAZIMINE 100,0 mg	Annexure A
54/20.2.3/0236	2023/04/25	CLOFAZIMINE TABLETS 50 mg	Tablet	Macleods Pharmaceuticals SA (Pty) Ltd	EACH TABLET CONTAINS CLOFAZIMINE 50,0 mg	Annexure A
55/26/0171	2023/04/25	COCITRED	Infusion	Aurogen South Africa (Pty) Ltd	EACH VIAL CONTAINS DECITABINE 50,0 mg	Annexure A
53/20.1.1/0715	2023/04/25	CYTAGIL IV	Infusion	Pharma Dynamics (Pty) Ltd	EACH VIAL CONTAINS TIGECYCLINE 50,0 mg	Annexure A

55/26/0173.171	2023/04/25	DARBECT	Infusion	Aurogen South Africa (Pty) Ltd	EACH VIAL CONTAINS DECITABINE 50,0 mg	Annexure A
55/21.8.2/0725	2023/04/25	DIENOGESE 2 mg PHARMC	Tablet	Pharmacorp (Pty) Ltd	EACH TABLET CONTAINS DIENOGESE 2,0 mg	Annexure A
53/20.1.1/0716.715	2023/04/25	GATICIL IV	Infusion	Pharma Dynamics (Pty) Ltd	EACH VIAL CONTAINS TIGECYCLINE 50,0 mg	Annexure A
53/7.1.3/0156	2023/04/25	LOSARTAN CO 100/12,5 AUSTELL	Tablet	Austell Pharmaceuticals (Pty) Ltd	EACH TABLET CONTAINS LOSARTAN POTASSIUM 100,0 mg HYDROCHLOROTHAZIDE 12,5 mg	Annexure A
53/7.1.3/0157	2023/04/25	LOSARTAN CO 100/25 AUSTELL	Tablet	Austell Pharmaceuticals (Pty) Ltd	EACH TABLET CONTAINS LOSARTAN POTASSIUM 100,0 mg HYDROCHLOROTHAZIDE 25,0 mg	Annexure A
53/7.1.3/0155	2023/04/25	LOSARTAN CO 50/12,5 AUSTELL	Tablet	Austell Pharmaceuticals (Pty) Ltd	EACH TABLET CONTAINS LOSARTAN POTASSIUM 50,0 mg HYDROCHLOROTHAZIDE 12,5 mg	Annexure A
54/7.1.5/0035	2023/04/25	STENDRIL 100	Tablet	Ruby Pharmaceuticals (Pty) Ltd	EACH TABLET CONTAINS SILDENAFIL CITRATE EQUIVALENT TO SILDENAFIL 100,0 mg	Annexure A
54/7.1.5/0826	2023/04/25	STENDRIL 25	Tablet	Ruby Pharmaceuticals (Pty) Ltd	EACH TABLET CONTAINS SILDENAFIL CITRATE EQUIVALENT TO SILDENAFIL 25,0 mg	Annexure A
54/7.1.5/0034	2023/04/25	STENDRIL 50	Tablet	Ruby Pharmaceuticals (Pty) Ltd	EACH TABLET CONTAINS SILDENAFIL CITRATE EQUIVALENT TO SILDENAFIL 50,0 mg	Annexure A
55/26/0172.171	2023/04/25	TOCENAR	Infusion	Aurogen South Africa (Pty) Ltd	EACH VIAL CONTAINS DECITABINE 50,0 mg	Annexure A
54/20.2.3/0239.237	2023/04/25	TUBRAMAK 100 mg	Tablet	Macleods Pharmaceuticals SA (Pty) Ltd	EACH TABLET CONTAINS CLOFAZIMINE 100,0 mg	Annexure A
54/20.2.3/0238.236	2023/04/25	TUBRAMAK 50 mg	Tablet	Macleods Pharmaceuticals SA (Pty) Ltd	EACH TABLET CONTAINS CLOFAZIMINE 50,0 mg	Annexure A
53/20.2.8/0106	2023/04/25	VIRONETO	Tablet	Strides Pharma (SA) (Pty) Ltd	EACH TABLET CONTAINS TENOFOVIR DISOPROXIL FUMARATE 300,0 mg	Annexure A
55/21.12/0112	2023/05/02	ABIZISTA 250 mg	Tablet	Eurolab (Pty) Ltd	EACH TABLET CONTAINS ABIRATERONE ACETATE 250,0 mg	Annexure A
55/21.12/0113	2023/05/02	ABIZISTA 500 mg	Tablet	Eurolab (Pty) Ltd	EACH TABLET CONTAINS ABIRATERONE ACETATE 500,0 mg	Annexure A
53/5.7.1/0331.330	2023/05/02	ALLERBAS ALLERGY 10 mg TABLETS	Tablet	Adcock Ingram Limited	EACH TABLET CONTAINS EBASTINE 10,0 mg	Annexure A
53/5.7.1/0330	2023/05/02	EBASTINE 10 mg ADCO	Tablet	Adcock Ingram Limited	EACH TABLET CONTAINS EBASTINE 10,0 mg	Annexure A
57/20.2.3/0157	2023/05/02	FRIPNIT PLUS	Tablet	Pharma Dynamics (Pty) Ltd	EACH TABLET CONTAINS RIFAPENTINE 300,0 mg ISONIAZID 300,0 mg	Annexure A
55/2.5/0553	2023/05/02	NAVILIZE 100 mg/ml (10 ml)	Injection	KAHMA BIOTECH (Pty) Ltd	EACH 1,0 ml SOLUTION CONTAINS SODIUM VALPROATE 100,0 mg	Annexure A
55/2.5/0551	2023/05/02	NAVILIZE 100 mg/ml (3 ml)	Injection	KAHMA BIOTECH (Pty) Ltd	EACH 1,0 ml SOLUTION CONTAINS SODIUM VALPROATE 100,0 mg	Annexure A
55/2.5/0552	2023/05/02	NAVILIZE 100 mg/ml (4 ml)	Injection	KAHMA BIOTECH (Pty) Ltd	EACH 1,0 ml SOLUTION CONTAINS SODIUM VALPROATE 100,0 mg	Annexure A
53/11.5/0673	2023/05/02	PHOLIPEG	Oral Solution	Strides Pharma (SA) (Pty) Ltd	EACH SACHET CONTAINS MACROGOL 3350 13,125 g POTASSIUM CHLORIDE 0,0466 g SODIUM BICARBONATE 0,1785 g SODIUM CHLORIDE 0,3507 g	Annexure A

53/11.5/0674.673	2023/05/02	PHYGLETON	Oral Solution	Strides Pharma (SA) (Pty) Ltd	EACH SACHET CONTAINS MACROGOL 3350 13,125 g POTASSIUM CHLORIDE 0,0466 g SODIUM BICARBONATE 0,1785 g SODIUM CHLORIDE 0,3507 g	Annexure A
56/26/0453	2023/05/02	RIBEND 100	Infusion	Innovata Pharmaceuticals	EACH VIAL CONTAINS BENDAMUSTINE HYDROCHLORIDE 100,0 mg	Annexure A
56/26/0452	2023/05/02	RIBEND 25	Infusion	Innovata Pharmaceuticals	EACH VIAL CONTAINS BENDAMUSTINE HYDROCHLORIDE 25,0 mg	Annexure A
56/20.2.8/0482	2023/05/02	TRIETA	Tablet	Cipla Medpro (Pty) Ltd	EACH TABLET CONTAINS EFAVIRENZ 400,0 mg LAMIVUDINE 300,0 mg TENOFOVIR DISOPROXIL EQUIVALENT TO TENOFOVIR DISOPROXIL 245,0 mg	Annexure A
56/20.2.8/0483.482	2023/05/02	TRILEF	Tablet	Cipla Medpro (Pty) Ltd	EACH TABLET CONTAINS EFAVIRENZ 400,0 mg LAMIVUDINE 300,0 mg TENOFOVIR DISOPROXIL EQUIVALENT TO TENOFOVIR DISOPROXIL 245,0 mg	Annexure A
55/7.5/0453	2023/05/02	CREVAS 15 mg	Tablet	Pharma Dynamics (Pty) Ltd	EACH TABLET CONTAINS ROSUVASTATIN CALCIUM EQUIVALENT TO ROSUVASTATIN 15,0 mg	Annexure A
55/7.5/0454	2023/05/02	CREVAS 30 mg	Tablet	Pharma Dynamics (Pty) Ltd	EACH TABLET CONTAINS ROSUVASTATIN CALCIUM EQUIVALENT TO ROSUVASTATIN 30,0 mg	Annexure A
56/26/0923	2023/05/09	CYCLOCORD 1 g	Injection	Accord Healthcare (Pty) Ltd	EACH VIAL CONTAINS CYCLOPHOSPHAMIDE MONOHYDRATE 1,0 g	Annexure A
56/26/0922	2023/05/09	CYCLOCORD 500 mg	Injection	Accord Healthcare (Pty) Ltd	EACH VIAL CONTAINS CYCLOPHOSPHAMIDE MONOHYDRATE 500,0 mg	Annexure A
55/7.5/0407	2023/05/09	LIPOCOMB 10 mg/10 mg	Capsule	Servier Laboratories South Africa (Pty) Ltd	EACH CAPSULE CONTAINS ROSUVASTATIN ZINC 10,0 mg EZETIMIBE 10,0 mg	Annexure A
55/7.5/0408	2023/05/09	LIPOCOMB 20 mg/10 mg	Capsule	Servier Laboratories South Africa (Pty) Ltd	EACH CAPSULE CONTAINS ROSUVASTATIN ZINC 20,0 mg EZETIMIBE 10,0 mg	Annexure A
55/34/0899	2023/05/09	TEMADEX 200	Injection	Teva Pharmaceuticals (Pty) Ltd	EACH 2,0 ml VIAL CONTAINS SUGAMMADEX SODIUM EQUIVALENT TO SUGAMMADEX 200,0 mg	Annexure A
55/34/0900	2023/05/09	TEMADEX 500	Injection	Teva Pharmaceuticals (Pty) Ltd	EACH 2,0 ml VIAL CONTAINS SUGAMMADEX SODIUM EQUIVALENT TO SUGAMMADEX 500,0 mg	Annexure A
55/20.1.1/0750	2023/05/09	TIGECYCLINE ADCO	Infusion	Adcock Ingram Limited	EACH VIAL CONTAINS TIGECYCLINE 50,0 mg	Annexure A
53/20.1.2/0153	2023/05/16	AMOXICILLIN 250 PORTFOLIO	Capsule	Portfolio Laboratories (Pty) Ltd	EACH CAPSULE CONTAINS AMOXICILLIN TRIHYDRATE EQUIVALENT TO AMOXICILLIN 250,0 mg	Annexure A
53/20.1.2/0154	2023/05/16	AMOXICILLIN 500 PORTFOLIO	Capsule	Portfolio Laboratories (Pty) Ltd	EACH CAPSULE CONTAINS AMOXICILLIN TRIHYDRATE EQUIVALENT TO AMOXICILLIN 500,0 mg	Annexure A
54/15.1/0202	2023/05/16	AVOXA EYE DROPS	Eye Drops	Austell Pharmaceuticals (Pty) Ltd	EACH 1,0 ml SOLUTION CONTAINS MOXIFLOXACIN HYDROCHLORIDE EQUIVALENT TO MOXIFLOXACIN 5,0 mg	Annexure A
55/1.2/0106	2023/05/16	BRIVOR 10 mg	Tablet	Pharma Dynamics (Pty) Ltd	EACH TABLET CONTAINS VORTIOXETINE HYDROBROMIDE EQUIVALENT TO VORTIOXETINE 10,0 mg	Annexure A

55/1.2/0107	2023/05/16	BRIVOR 20 mg	Tablet	Pharma Dynamics (Pty) Ltd	EACH TABLET CONTAINS VORTIOXETINE HYDROBROMIDE EQUIVALENT TO VORTIOXETINE 20,0 mg	Annexure A
55/1.2/0105	2023/05/16	BRIVOR 5 mg	Tablet	Pharma Dynamics (Pty) Ltd	EACH TABLET CONTAINS VORTIOXETINE HYDROBROMIDE EQUIVALENT TO VORTIOXETINE 5,0 mg	Annexure A
57/5.7.1/0264	2023/05/16	DAZIT SYRUP	Oral Solution	Ranbaxy Pharmaceutical (Pty) Ltd	EACH 5,0 ml SOLUTION CONTAINS DESLORATADINE 2,5 mg	Annexure A
56/20.2.8/0886.883	2023/05/16	DUNARID 400	Tablet	Hetero Drugs South Africa (Pty) Ltd	EACH TABLET CONTAINS DARUNAVIR 400,0 mg	Annexure A
56/20.2.8/0888.885	2023/05/16	DUNARID 800	Tablet	Hetero Drugs South Africa (Pty) Ltd	EACH TABLET CONTAINS DARUNAVIR 800,0 mg	Annexure A
53/20.1.1/0575.574	2023/05/16	FORURI	Oral Solution	Abex Pharmaceutica (Pty) Ltd	EACH SACHET CONTAINS FOSFOMYCIN TROMETAMOL EQUIVALENT TO FOSFOMYCIN 3,0 g	Annexure A
54/3.1/0039	2023/05/16	LEXIB 100	Capsule	Ruby Pharmaceuticals (Pty) Ltd	EACH CAPSULE CONTAINS CELECOXIB 100,0 mg	Annexure A
54/3.1/0040	2023/05/16	LEXIB 200	Capsule	Ruby Pharmaceuticals (Pty) Ltd	EACH CAPSULE CONTAINS CELECOXIB 200,0 mg	Annexure A
53/20.1.1/0574	2023/05/16	UTICIDE	Oral Solution	Abex Pharmaceutica (Pty) Ltd	EACH SACHET CONTAINS FOSFOMYCIN TROMETAMOL EQUIVALENT TO FOSFOMYCIN 3,0 g	Annexure A
55/34/0103	2023/05/16	VERSUDX	Injection	Pharmcare Limited û Woodmead	EACH 1,0 ml SOLUTION CONTAINS SUGAMMADEX OCTASODIUM 100,0 mg	Annexure A
55/1.2/0109.106	2023/05/16	VORTIOXETINE 10 mg DYNA	Tablet	Pharma Dynamics (Pty) Ltd	EACH TABLET CONTAINS VORTIOXETINE HYDROBROMIDE EQUIVALENT TO VORTIOXETINE 10,0 mg	Annexure A
55/1.2/0110.107	2023/05/16	VORTIOXETINE 20 mg DYNA	Tablet	Pharma Dynamics (Pty) Ltd	EACH TABLET CONTAINS VORTIOXETINE HYDROBROMIDE EQUIVALENT TO VORTIOXETINE 20,0 mg	Annexure A
55/1.2/0108.105	2023/05/16	VORTIOXETINE 5 mg DYNA	Tablet	Pharma Dynamics (Pty) Ltd	EACH TABLET CONTAINS VORTIOXETINE HYDROBROMIDE EQUIVALENT TO VORTIOXETINE 5,0 mg	Annexure A
56/20.2.8/0883	2023/05/16	VUNAD 400	Tablet	Hetero Drugs South Africa (Pty) Ltd	EACH TABLET CONTAINS DARUNAVIR 400,0 mg	Annexure A
56/20.2.8/0885	2023/05/16	VUNAD 800	Tablet	Hetero Drugs South Africa (Pty) Ltd	EACH TABLET CONTAINS DARUNAVIR 800,0 mg	Annexure A
55/19/0705	2023/05/16	OXYTOCIN 10 IU/ml COSPHARM	Injection	Cospharm Investments (Pty) Ltd	EACH 1,0 ml SOLUTION CONTAINS OXYTOCIN 10,0 IU	Annexure A
55/5.4/0554	2023/05/16	SOLIFENACIN 5 mg UNICHEM	Tablet	Unichem SA (Pty) Ltd	EACH TABLET CONTAINS SOLIFENACIN SUCCINATE EQUIVALENT TO SOLIFENACIN 5,0 mg	Annexure A
55/5.4/0555	2023/05/16	SOLIFENACIN 10 mg UNICHEM	Tablet	Unichem SA (Pty) Ltd	EACH TABLET CONTAINS SOLIFENACIN SUCCINATE EQUIVALENT TO SOLIFENACIN 10,0 mg	Annexure A
55/5.7.1/0712	2023/05/23	ALLERWAY MELTAWAY 5	Tablet	Dr Reddy's Laboratories (Pty) Ltd	EACH TABLET CONTAINS LEVOCETIRIZINE DIHYDROCHLORIDE 0,5 mg	Annexure A

55/2.11/0517.515	2023/05/23	CABREXXA 0,5	Tablet	Abex Pharmaceutica (Pty) Ltd	EACH TABLET CONTAINS VARENICLINE TARTRATE EQUIVALENT TO VARENICLINE 0,5 mg	Annexure A
55/2.11/0518.516	2023/05/23	CABREXXA 1	Tablet	Abex Pharmaceutica (Pty) Ltd	EACH TABLET CONTAINS VARENICLINE TARTRATE EQUIVALENT TO VARENICLINE 1,0 mg	Annexure A
56/20.1.1/0105	2023/05/23	CLINDAMYCIN EQUITY	Capsule	Equity Pharmaceutical (Pty) Ltd	EACH CAPSULE CONTAINS CLINDAMYCIN HYDROCHLORIDE EQUIVALENT TO CLINDAMYCIN 150,0 mg	Annexure A
55/7.1.3/0413	2023/05/23	ENPRESIL CO	Tablet	Unicorn Pharmaceuticals (Pty) Ltd	EACH TABLET CONTAINS ENALAPRIL MALEATE 20,0 mg HYDROCHLOROTHAZIDE 12,5 mg	Annexure A
54/20.1.1/0076	2023/05/23	EURINIC 3 g	Oral Solution	Austell Pharmaceuticals (Pty) Ltd	EACH SACHET CONTAINS FOSFOMYCIN TROMETAMOL EQUIVALENT TO FOSFOMYCIN 3,0 g	Annexure A
54/20.1.1/0078.076	2023/05/23	FOSFOMYCIN 3 g AUSTELL	Oral Solution	Austell Pharmaceuticals (Pty) Ltd	EACH SACHET CONTAINS FOSFOMYCIN TROMETAMOL EQUIVALENT TO FOSFOMYCIN 3,0 g	Annexure A
54/20.1.1/0077.076	2023/05/23	FOSFOMYCIN 3 g CAMOX	Oral Solution	Austell Pharmaceuticals (Pty) Ltd	EACH SACHET CONTAINS FOSFOMYCIN TROMETAMOL EQUIVALENT TO FOSFOMYCIN 3,0 g	Annexure A
55/30.2/0426	2023/05/23	MEASLES RUBELLA CIPLA	Injection	Cipla Medpro (Pty) Ltd	EACH 0,5 ml DOSE CONTAINS MEASLES VIRUS (EDMONSTON ZAGREB STRAIN) NLT 1 000,0 CCID50 RUBELLA VIRUS (WISTAR RA27/3) NLT 1 000,0 CCID50	Annexure A
55/20.2.2/0667	2023/05/23	MICAFUNGIN 100 mg ADCO	Infusion	Adcock Ingram Critical Care (Pty) Ltd	EACH VIAL CONTAINS MICAFUNGIN SODIUM EQUIVALENT TO MICAFUNGIN 100,0 mg	Annexure A
55/20.2.2/0666	2023/05/23	MICAFUNGIN 50mg ADCO	Infusion	Adcock Ingram Critical Care (Pty) Ltd	EACH VIAL CONTAINS MICAFUNGIN SODIUM EQUIVALENT TO MICAFUNGIN 50,0 mg	Annexure A
55/2.11/0515	2023/05/23	NIKABEX 0,5	Tablet	Abex Pharmaceutica (Pty) Ltd	EACH TABLET CONTAINS VARENICLINE TARTRATE EQUIVALENT TO VARENICLINE 0,5 mg	Annexure A
55/2.11/0516	2023/05/23	NIKABEX 1	Tablet	Abex Pharmaceutica (Pty) Ltd	EACH TABLET CONTAINS VARENICLINE TARTRATE EQUIVALENT TO VARENICLINE 1,0 mg	Annexure A
56/26/0575	2023/05/23	ROZLYTREK 100 mg	Capsule	Roche Products (Pty) Ltd	EACH CAPSULE CONTAINS ENTRECTINIB 100,0 mg	Annexure A
56/26/0576	2023/05/23	ROZLYTREK 200 mg	Capsule	Roche Products (Pty) Ltd	EACH CAPSULE CONTAINS ENTRECTINIB 200,0 mg	Annexure A
54/20.1.2/0009	2023/05/30	ACTIMENTIN 600 BD	Suspension	Activo Health (Pty) Ltd	EACH 5,0 ml SUSPENSION CONTAINS AMOXICILLIN TRIHYDRATE EQUIVALENT TO AMOXICILIN 600,0 mg CLAVULANATE TRIHYDRATE EQUIVALENT TO CALVULANIC ACID 42,9 mg	Annexure A
54/1.2/0431	2023/05/30	ATEROCON LA 10 mg	Capsule	Austell Pharmaceuticals (Pty) Ltd	EACH CAPSULE METHYLPHENIDATE HYDROCHLORIDE 10,0 mg	Annexure A
54/1.2/0432	2023/05/30	ATEROCON LA 20 mg	Capsule	Austell Pharmaceuticals (Pty) Ltd	EACH CAPSULE CONTAINS METHYLPHENIDATE HYDROCHLORIDE 20,0 mg	Annexure A
54/1.2/0433	2023/05/30	ATEROCON LA 30 mg	Capsule	Austell Pharmaceuticals (Pty) Ltd	EACH CAPSULE CONTAINS METHYLPHENIDATE HYDROCHLORIDE 30,0 mg	Annexure A
54/1.2/0434	2023/05/30	ATEROCON LA 40 mg	Capsule	Austell Pharmaceuticals (Pty) Ltd	EACH CAPSULE CONTAINS METHYLPHENIDATE HYDROCHLORIDE 40,0 mg	Annexure A

54/1.2/0435	2023/05/30	ATEROCON LA 60 mg	Capsule	Austell Pharmaceuticals (Pty) Ltd	EACH CAPSULE CONTAINS METHYLPHENIDATE HYDROCHLORIDE 60,0 mg	Annexure A
56/2.2/0389	2023/05/30	CADIATEV	Tablet	Teva Pharmaceuticals (Pty) Ltd	EACH TABLET CONTAINS MELATONIN 2,0 mg	Annexure A
53/32.2/0386	2023/05/30	DEPROL 180	Tablet	ALKEM LABORATORIES (PTY) LTD	EACH TABLET CONTAINS MYCOPHENOLATE SODIUM EQUIVALENT TO MYCOPHENOLIC ACID 180,0 mg	Annexure A
53/32.2/0387	2023/05/30	DEPROL 360	Tablet	ALKEM LABORATORIES (PTY) LTD	EACH TABLET CONTAINS MYCOPHENOLATE SODIUM EQUIVALENT TO MYCOPHENOLIC ACID 180,0 mg	Annexure A
56/21.12/0699.699	2023/05/30	FENDEXAM	Tablet	Aurogen South Africa (Pty) Ltd	EACH TABLET CONTAINS TAMOXIFEN CITRATE EQUIVALENT TO TAMOXIFEN 20,0 mg	Annexure A
53/32.2/0388.386	2023/05/30	LESOR 180	Tablet	ALKEM LABORATORIES (PTY) LTD	EACH TABLET CONTAINS MYCOPHENOLATE SODIUM EQUIVALENT TO MYCOPHENOLIC ACID 180,0 mg	Annexure A
53/32.2/0389.387	2023/05/30	LESOR 360	Tablet	ALKEM LABORATORIES (PTY) LTD	EACH TABLET CONTAINS MYCOPHENOLATE SODIUM EQUIVALENT TO MYCOPHENOLIC ACID 360,0 mg	Annexure A
55/26/0846	2023/05/30	MERCAPTOPURINE EQUITY	Tablet	Equity Pharmaceutical (Pty) Ltd	EACH TABLET CONTAINS MERCAPTOPURINE 50,0 mg	Annexure A
55/21.7/0727	2023/05/30	TESTAFORTE	Cream	Pharmacorp (Pty) Ltd	EACH 1,0 ml CREAM CONTAINS TESTOSTERONE 50,0 mg	Annexure A
53/32.2/0390.386	2023/05/30	TRANSWELL 180	Tablet	ALKEM LABORATORIES (PTY) LTD	EACH TABLET CONTAINS MYCOPHENOLATE SODIUM EQUIVALENT TO MYCOPHENOLIC ACID 180,0 mg	Annexure A
53/32.2/0391.387	2023/05/30	TRANSWELL 360	Tablet	ALKEM LABORATORIES (PTY) LTD	EACH TABLET CONTAINS MYCOPHENOLATE SODIUM EQUIVALENT TO MYCOPHENOLIC ACID 360,0 mg	Annexure A
56/21.12/0698	2023/05/30	TREMOFID	Tablet	Aurogen South Africa (Pty) Ltd	EACH TABLET CONTAINS TAMOXIFEN CITRATE EQUIVALENT TO TAMOXIFEN 20,0 mg	Annexure A
55/21.12/0760	2023/06/06	ACEGYNE	Tablet	Ruby Pharmaceuticals (Pty) Ltd	EACH TABLET CONTAINS MISOPROSTOL 200,0 mg	Annexure A
55/21.12/0761.760	2023/06/06	ACEMIFE	Tablet	Ruby Pharmaceuticals (Pty) Ltd	EACH TABLET CONTAINS MISOPROSTOL 200,0 mg	Annexure A
55/6.2/0465	2023/06/06	AMIODARONE 30 mg/ml PREFILLED SYRINGE ACCORD	Injection	Accord Healthcare (Pty) Ltd	EACH 1,0 ml SOLUTION CONTAINS AMIODARONE 30,0 mg	Annexure A
55/13.1/0755	2023/06/06	CHLORHEXIDINE GLUCONATE HANDRUB ADCO	Solution	Adcock Ingram Critical Care (Pty) Ltd	EACH SOLUTION CONTAINS CHLORHEXIDINE GLUCONATE 0,5% w/v	Annexure A
53/26/0177	2023/06/06	PROTECADE 1 mg	Injection	Adcock Ingram Critical Care (Pty) Ltd	EACH VIAL CONTAINS BORTEZOMIB 1,0 mg	Annexure A
53/26/0178	2023/06/06	PROTECADE 3,5 mg	Injection	Adcock Ingram Critical Care (Pty) Ltd	EACH VIAL CONTAINS BORTEZOMIB 3,5 mg	Annexure A
56/7.2/0060	2023/06/06	RUSAIN 10 mg/ml	Injection	LeBasi Pharmaceuticals (Pty) Ltd	EACH 1,0 ml SOLUTION CONTAINS PHENYLEPHRINE HYDROCHLORIDE 10, 0 mg	Annexure A
56/26/0386	2023/06/06	VIZIMPRO 15 mg	Tablet	Pfizer Laboratories (Pty) Ltd	EACH TABLET CONTAINS DACOMITINIB 15,0 mg	Annexure A
56/26/0387	2023/06/06	VIZIMPRO 30 mg	Tablet	Pfizer Laboratories (Pty) Ltd	EACH TABLET CONTAINS DACOMITINIB 30,0 mg	Annexure A
56/26/0388	2023/06/06	VIZIMPRO 45 mg	Tablet	Pfizer Laboratories (Pty) Ltd	EACH TABLET CONTAINS DACOMITINIB 45,0 mg	Annexure A
55/10.3/0685	2023/06/13	ACC 200 POWDER FOR ORAL SOLUTION	Solution	Sandoz South Africa (Pty) Ltd	EACH SACHET CONTAINS ACETYCYSTEINE 200,0 mg	Annexure A

55/15.4/0346.345	2023/06/13	DORZOPRES		Eye Drops	Austell Pharmaceuticals (Pty) Ltd	EACH 1,0 ml SOLUTION CONTAINS DORZOLAMIDE HYDROCHLORIDE EQUIVALENT TO DORZOLAMIDE 20,0 mg	Annexure A
55/15.4/0345	2023/06/13	DORZOPT		Eye Drops	Austell Pharmaceuticals (Pty) Ltd	EACH 1,0 ml SOLUTION CONTAINS DORZOLAMIDE HYDROCHLORIDE EQUIVALENT TO DORZOLAMIDE 20,0 mg	Annexure A
55/20.2.2/0496	2023/06/13	MICAFUNGIN 100 SANDOZ		Infusion	Sandoz South Africa (Pty) Ltd	EACH VIAL CONTAINS MICAFUNGIN SODIUM EQUIVALENT TO MICAFUNGIN 100,0 mg	Annexure A
55/20.2.2/0495	2023/06/13	MICAFUNGIN 50 SANDOZ		Infusion	Sandoz South Africa (Pty) Ltd	EACH VIAL CONTAINS MICAFUNGIN SODIUM EQUIVALENT TO MICAFUNGIN 50,0 mg	Annexure A
55/34/0851	2023/06/13	PHINMO 0,5		Capsule	Dr Reddy's Laboratories (Pty) Ltd	EACH CAPSULE CONTAINS FINGOLIMOD HYDROCHLORIDE 0,5 mg	Annexure A
53/5.7.2/0449.446	2023/06/13	PREPIX 125		Capsule	Adcock Ingram Limited	EACH CAPSULE CONTAINS APREPITANT 125,0 mg	Annexure A
53/5.7.2/0448.445	2023/06/13	PREPIX 80		Capsule	Adcock Ingram Limited	EACH CAPSULE CONTAINS APREPITANT 80,0 mg	Annexure A
53/5.7.2/0450.447	2023/06/13	PREPIX COMBI PACK		Capsule	Adcock Ingram Limited	EACH BLISTER PACK CONTAINS TWO CAPSULES EACH CONTAINING APREPITANT 80,0 mg ONE CAPSULE CONTAINING APREPITANT 125,0 mg	Annexure A
20/17.1.11/01	2023/06/13	SHOTAPEN LA		Injection	Virbac RSA (Pty) Ltd	EACH 1,0 ml SUSPENSION CONTAINS BENZYL PENICILLIN BEZATHINE 73,58 mg, BENZYL PENICILLIN PROCAINE MONOHYDRATE 56,80 & DIHYDROSTREPTOMYCIN SULPHATE 164,0 mg	Annexure A
56/8.5/0108	2023/06/13	STROPEG		Injection	KAHMA BIOTECH (Pty) Ltd	EACH 0,6 ml SOLUTION CONTAINS PEGFILGRASTIM 6,0 mg	Annexure A
55/32.16/0245.244	2023/06/13	TERIFLUNOMIDE ADCO		Tablet	Adcock Ingram Limited	EACH TABLET CONTAINS TERIFLUNOMIDE 14,0 mg	Annexure A
55/32.16/0244	2023/06/13	TERITEMSO		Tablet	Adcock Ingram Limited	EACH TABLET CONTAINS TERIFLUNOMIDE 14,0 mg	Annexure A
53/5.7.2/0446	2023/06/13	VOMEND 125		Capsule	Adcock Ingram Limited	EACH CAPSULE CONTAINS APREPITANT 125,0 mg	Annexure A
53/5.7.2/0445	2023/06/13	VOMEND 80		Capsule	Adcock Ingram Limited	EACH CAPSULE CONTAINS APREPITANT 80,0 mg	Annexure A
53/5.7.2/0447	2023/06/13	VOMEND COMBI PACK		Capsule	Adcock Ingram Limited	EACH BLISTER PACK CONTAINS TWO CAPSULES EACH CONTAINING APREPITANT 80,0 mg ONE CAPSULE CONTAINING APREPITANT 125,0 mg	Annexure A
56/26/0129	2023/06/20	EGROTIB 100		Tablet	Dr Reddy's Laboratories (Pty) Ltd	EACH TABLET CONTAINS ERLOTINIB HYDROCHLORIDE EQUIVALENT TO ERLOTINIB 100,0 mg	Annexure A
56/26/0130	2023/06/20	EGROTIB 150		Tablet	Dr Reddy's Laboratories (Pty) Ltd	EACH TABLET CONTAINS ERLOTINIB HYDROCHLORIDE EQUIVALENT TO ERLOTINIB 150,0 mg	Annexure A
56/26/0128	2023/06/20	EGROTIB 25		Gel	Dr Reddy's Laboratories (Pty) Ltd	EACH TABLET CONTAINS ERLOTINIB HYDROCHLORIDE EQUIVALENT TO ERLOTINIB 25,0 mg	Annexure A

56/3.1/0376	2023/06/20	FLAMUGO 100 g	Gel	Teva Pharmaceuticals (Pty) Ltd	EACH 1,0 g GEL CONTAINS DICLOFENAC DIETHYLAMINE EQUIVALENT TO DICLOFENAC SODIUM 10,0 mg	Annexure A
56/3.1/0377	2023/06/20	FLAMUGO 120 g	Gel	Teva Pharmaceuticals (Pty) Ltd	EACH 1,0 g GEL CONTAINS DICLOFENAC DIETHYLAMINE EQUIVALENT TO DICLOFENAC SODIUM 10,0 mg	Annexure A
56/3.1/0378	2023/06/20	FLAMUGO 150 g	Gel	Teva Pharmaceuticals (Pty) Ltd	EACH 1,0 g GEL CONTAINS DICLOFENAC DIETHYLAMINE EQUIVALENT TO DICLOFENAC SODIUM 10,0 mg	Annexure A
56/3.1/0373	2023/06/20	FLAMUGO 30 g	Gel	Teva Pharmaceuticals (Pty) Ltd	EACH 1,0 g GEL CONTAINS DICLOFENAC DIETHYLAMINE EQUIVALENT TO DICLOFENAC SODIUM 10,0 mg	Annexure A
56/3.1/0374	2023/06/20	FLAMUGO 50 g	Gel	Teva Pharmaceuticals (Pty) Ltd	EACH 1,0 g GEL CONTAINS DICLOFENAC DIETHYLAMINE EQUIVALENT TO DICLOFENAC SODIUM 10,0 mg	Annexure A
56/3.1/0375	2023/06/20	FLAMUGO 60 g	Gel	Teva Pharmaceuticals (Pty) Ltd	EACH 1,0 g GEL CONTAINS DICLOFENAC DIETHYLAMINE EQUIVALENT TO DICLOFENAC SODIUM 10,0 mg	Annexure A
53/10.2.2/0068	2023/06/20	MONTASCEND	Tablet	Ascend Laboratories (Pty) Ltd	EACH TABLET CONTAINS MONTELUKAST SODIUM EQUIVALENT TO MONTELUKAST 10,0 mg	Annexure A
53/10.2.2/0070.068	2023/06/20	MONTELUKAST 10 mg ALKEM	Tablet	Ascend Laboratories (Pty) Ltd	EACH TABLET CONTAINS MONTELUKAST SODIUM EQUIVALENT TO MONTELUKAST 10,0 mg	Annexure A
56/26/0055	2023/06/20	NATPEM 1 000	Infusion	Adcock Ingram Limited	EACH VIAL CONTAINS PEMETREXED 1 000,0 mg	Annexure A
56/26/0053	2023/06/20	NATPEM 100	Infusion	Adcock Ingram Limited	EACH VIAL CONTAINS PEMETREXED 100,0 mg	Annexure A
56/26/0054	2023/06/20	NATPEM 500	Infusion	Adcock Ingram Limited	EACH VIAL CONTAINS PEMETREXED 500,0 mg	Annexure A
53/10.2.2/0069.068	2023/06/20	TELUKEM	Tablet	Ascend Laboratories (Pty) Ltd	EACH TABLET CONTAINS MONTELUKAST SODIUM EQUIVALENT TO MONTELUKAST 10,0 mg	Annexure A
53/3.1/0017	2023/06/20	ASCEPRIB IV 400	Infusion	Ascendis Pharma (Pty) Ltd	EACH 100,0 ml SOLUTION CONTAINS IBUPROFEN 400,0 mg	Annexure A
53/3.1/0018	2023/06/20	ASCEPRIB IV 600	Infusion	Ascendis Pharma (Pty) Ltd	EACH 100,0 ml SOLUTION CONTAINS IBUPROFEN 600,0 mg	Annexure A
54/26/0081	2023/06/20	BETANUJ	Injection	Aurogen South Africa (Pty) Ltd	EACH VIAL CONTAINS BORTEZOMIB 3,5 mg	Annexure A
54/26/0082.081	2023/06/20	DEVACAD	Injection	Aurogen South Africa (Pty) Ltd	EACH VIAL CONTAINS BORTEZOMIB 3,5 mg	Annexure A
56/20.2.2/1125	2023/06/20	TERISOM	Infusion	Ranbaxy Pharmaceutical (Pty) Ltd	EACH VIAL CONTAINS AMPHOTERICIN B LIPOSOME 50,0 mg	Annexure A
54/1.2/0183.181	2023/06/27	BUPROPION 150 mg XR DYNA	Tablet	Pharma Dynamics (Pty) Ltd	EACH TABLET CONTAINS BUPROPION HYDROCHLORIDE 150,0 mg	Annexure A
54/1.2/0184.182	2023/06/27	BUPROPION 300 mg XR DYNA	Tablet	Pharma Dynamics (Pty) Ltd	EACH TABLET CONTAINS BUPROPION HYDROCHLORIDE 300,0 mg	Annexure A
56/26/0827	2023/06/27	CABXEL 60 mg/1,5 ml IV	Infusion	Hetero Drugs South Africa (Pty) Ltd	EACH 1,5 ml SOLUTION CONTAINS CABAZITAXEL 60,0 mg	Annexure A

56/26/0828.827	2023/06/27	CAPHET 60 mg/1.5 ml IV	Infusion	Hetero Drugs South Africa (Pty) Ltd	EACH 1.5 ml SOLUTION CONTAINS CABAZITAXEL 60,0 mg	Annexure A
56/32.2/0193.189	2023/06/27	POMALIDOMIDE 1 mg FORRESTER	Capsule	Forrester Pharma (Pty) Ltd	EACH CAPSULE CONTAINS POMALIDOMIDE 1,0 mg	Annexure A
56/32.2/0194.190	2023/06/27	POMALIDOMIDE 2 mg FORRESTER	Capsule	Forrester Pharma (Pty) Ltd	EACH CAPSULE CONTAINS POMALIDOMIDE 2,0 mg	Annexure A
56/32.2/0195.191	2023/06/27	POMALIDOMIDE 3 mg FORRESTER	Capsule	Forrester Pharma (Pty) Ltd	EACH CAPSULE CONTAINS POMALIDOMIDE 3,0 mg	Annexure A
56/32.2/0196.192	2023/06/27	POMALIDOMIDE 4 mg FORRESTER	Capsule	Forrester Pharma (Pty) Ltd	EACH CAPSULE CONTAINS POMALIDOMIDE 4,0 mg	Annexure A
56/32.2/0189	2023/06/27	POMYLO 1 mg	Capsule	Forrester Pharma (Pty) Ltd	EACH CAPSULE CONTAINS POMALIDOMIDE 1,0 mg	Annexure A
56/32.2/0190	2023/06/27	POMYLO 2 mg	Capsule	Forrester Pharma (Pty) Ltd	EACH CAPSULE CONTAINS POMALIDOMIDE 2,0 mg	Annexure A
56/32.2/0191	2023/06/27	POMYLO 3 mg	Capsule	Forrester Pharma (Pty) Ltd	EACH CAPSULE CONTAINS POMALIDOMIDE 3,0 mg	Annexure A
56/32.2/0192	2023/06/27	POMYLO 4 mg	Capsule	Forrester Pharma (Pty) Ltd	EACH CAPSULE CONTAINS POMALIDOMIDE 4,0 mg	Annexure A
54/1.2/0181	2023/06/27	PRODYNA 150 mg XR	Tablet	Pharma Dynamics (Pty) Ltd	EACH TABLET CONTAINS BUPROPION HYDROCHLORIDE 150,0 mg	Annexure A
54/1.2/0182	2023/06/27	PRODYNA 300 mg XR	Tablet	Pharma Dynamics (Pty) Ltd	EACH TABLET CONTAINS BUPROPION HYDROCHLORIDE 300,0 mg	Annexure A
55/2.6/0546	2023/06/27	CLOBAZAM 10 ADCO	Tablet	Adcock Ingram Limited	EACH TABLET CONTAINS CLOBAZAM 10,0 mg	Annexure A
55/2.6/0547	2023/06/27	CLOBAZAM 20 ADCO	Tablet	Adcock Ingram Limited	EACH TABLET CONTAINS CLOBAZAM 20,0 mg	Annexure A

Annexure A

1. The applicant shall ensure that the medicine is manufactured and controlled in terms of current Good Manufacturing Practices as determined by SAHPRA.
2. The manufacture of this medicine is subject to regular investigation and inspections by the inspectors appointed in terms of Section 26 of the Act, to assess compliance with current Good Manufacturing Practices.
3. The information in the professional information shall be updated on a regular basis to conform to the professional information recently approved by SAHPRA.
4. The applicant must comply with all the legal requirements of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965).
5. The registration of this medicine shall be subject to review at intervals as determined by SAHPRA regarding its quality, safety and efficacy, and the registration of this medicine may be varied subject to issues SAHPRA may deem fit.
6. The first two production batches must be fully validated in terms of the detailed process validation protocol submitted at the time of application for registration, and the validation report must be submitted within a month after completion of the validation.
7. The product may be advertised to the professions only.
54. The SCoRE/QoS/QIS document must be maintained and must be consistent with the current approved information.