

SOUTH AFRICAN QUALIFICATIONS AUTHORITY

NO. 6306

13 June 2025

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 of Registration
60/1.2/0090	2025/01/21	LINTIRAL	Tablet	Biotech Laboratories (Pty) Ltd	EACH TABLET CONTAINS METHYLPHENIDATE HYDROCHLORIDE 10,0 mg	Annexure A
58/21.13/0002.001	2025/01/21	LIRAGLUTIDE 6 mg/ml CIPLA	Injection	Cipla Medpro (Pty) Ltd	EACH 1,0 ml SOLUTION CONTAINS LIRAGLUTIDE 6,0 mg	Annexure A
58/21.13/0001	2025/01/21	GIUPTRA	Injection	Cipla Medpro (Pty) Ltd	EACH 1,0 ml SOLUTION CONTAINS LIRAGLUTIDE 6,0 mg	Annexure A
57/2.5/0848	2025/01/21	ETHOSUXIMIDE MC PHARMA	Syrup	MC Pharma (Pty) Ltd	EACH 5,0 ml SYRUP CONTAINS ETHOSUXIMIDE 250,0 mg	Annexure A
57/10.3/0362	2025/01/21	MUCOLOG	Tablet	Adcock Ingram Limited	EACH TABLET CONTAINS ACETYLCYSTEINE 600,0 mg	Annexure A
57/12.2/0188	2025/01/21	ZOLPIDEM XR 12,5 ADCO	Tablet	Adcock Ingram Limited	EACH TABLET CONTAINS ZOLPIDEM TARTRATE 12,5 mg	Annexure A
53/20.2.2/0383	2025/01/21	FUNGIKEM	Capsule	Ascend Laboratories (Pty) Ltd	EACH CAPSULE CONTAINS ITRACONAZOLE 100,0 mg	Annexure A
53/20.2.2/0384.383	2025/01/21	MYNOSCEND	Capsule	Ascend Laboratories (Pty) Ltd	EACH CAPSULE CONTAINS ITRACONAZOLE 100,0 mg	Annexure A
53/20.2.2/0385.383	2025/01/21	ITRACONAZOLE 100 ASCEND	Capsule	Ascend Laboratories (Pty) Ltd	EACH CAPSULE CONTAINS ITRACONAZOLE 100,0 mg	Annexure A
55/20.2.8/0440	2025/01/21	RIAMILOVIR 250 PHARMACENTRIX	Capsule	Pharmacentrix (Pty) Ltd	EACH CAPSULE CONTAINS RIAMILOVIR SODIUM DIHYDRATE 250,0 mg	Annexure A
56/26/0441	2025/01/21	EQUITUZ	Infusion	Equity Pharmaceutical (Pty) Ltd	EACH VIAL CONTAINS TRASTUZUMAB 440,0 mg	Annexure A
56/4/0765	2025/01/21	DEXVICA	Injection	Equity Pharmaceutical (Pty) Ltd	EACH 1,0 ml SOLUTION CONTAINS LEVOBUPIVACAINE HYDROCHLORIDE MONOHYDRATE EQUIVALENT TO LEVOBUPIVACAINE 5,0 mg	Annexure A
56/11.10/1062	2025/01/25	DORPIZOL 10 mg/ml	Oral Solution	Key Oncologics (Pty) Ltd	EACH 1,0 ml SOLUTION CONTAINS TINCTURE FROM <i>Papaver somniferum</i> L., SUCCUS SICCUS (OPIUM, RAW) EQUIVALENT TO MORPHINE 10,0 mg	Annexure A
56/8.2/1093	2025/01/21	RIVAHET 2,5	Tablet	Hetero Drugs South Africa (Pty) Ltd	EACH TABLET CONTAINS RIVAROXABAN 2,5 mg	Annexure A
56/8.2/1094	2025/01/21	RIVAHET 10	Tablet	Hetero Drugs South Africa (Pty) Ltd	EACH TABLET CONTAINS RIVAROXABAN 10,0 mg	Annexure A
56/8.2/1095	2025/01/21	RIVAHET 15	Tablet	Hetero Drugs South Africa (Pty) Ltd	EACH TABLET CONTAINS RIVAROXABAN 15,0 mg	Annexure A
56/8.2/1096	2025/01/21	RIVAHET 20	Tablet	Hetero Drugs South Africa (Pty) Ltd	EACH TABLET CONTAINS RIVAROXABAN 20,0 mg	Annexure A
56/8.2/1097.1093	2025/01/21	XARHET 2,5	Tablet	Hetero Drugs South Africa (Pty) Ltd	EACH TABLET CONTAINS RIVAROXABAN 2,5 mg	Annexure A

56/8.2/1098.1094	2025/01/21	XARHET 10	Tablet	Hetero Drugs South Africa (Pty) Ltd	EACH TABLET CONTAINS RIVAROXABAN 10,0 mg	Annexure A
56/8.2/1099.1095	2025/01/21	XARHET 15	Tablet	Hetero Drugs South Africa (Pty) Ltd	EACH TABLET CONTAINS RIVAROXABAN 15,0 mg	Annexure A
56/8.2/1100.1096	2025/01/21	XARHET 20	Tablet	Hetero Drugs South Africa (Pty) Ltd	EACH TABLET CONTAINS RIVAROXABAN 20,0 mg	Annexure A
56/8.2/1101.1093	2025/01/21	RIVAROXABAN 2,5 HETERO	Tablet	Hetero Drugs South Africa (Pty) Ltd	EACH TABLET CONTAINS RIVAROXABAN 2,5 mg	Annexure A
56/8.2/1102.1094	2025/01/21	RIVAROXABAN 10 HETERO	Tablet	Hetero Drugs South Africa (Pty) Ltd	EACH TABLET CONTAINS RIVAROXABAN 10,0 mg	Annexure A
56/8.2/1103.1095	2025/01/21	RIVAROXABAN 15 HETERO	Tablet	Hetero Drugs South Africa (Pty) Ltd	EACH TABLET CONTAINS RIVAROXABAN 15,0 mg	Annexure A
56/8.2/1104.1096	2025/01/21	RIVAROXABAN 20 HETERO	Tablet	Hetero Drugs South Africa (Pty) Ltd	EACH TABLET CONTAINS RIVAROXABAN 20,0 mg	Annexure A
56/20.2.8/1110	2025/01/21	MAKTEGIR 50 mg	Tablet	Macleods Pharmaceuticals SA (Pty) Ltd	EACH TABLET CONTAINS DOLUTEGRAVIR SODIUM EQUIVALENT TO DOLUTEGRAVIR 50,0 mg	Annexure A
56/20.2.8/1111.1110	2025/01/21	SYROMAK 50 mg	Tablet	Macleods Pharmaceuticals SA (Pty) Ltd	EACH TABLET CONTAINS DOLUTEGRAVIR SODIUM EQUIVALENT TO DOLUTEGRAVIR 50,0 mg	Annexure A
56/21.12/1131	2025/01/21	CARBIMAZOLE 5 UNIMED	Tablet	Unimed Healthcare (Pty) Ltd	EACH TABLET CONTAINS CARBIMAZOLE 5,0 mg	Annexure A
56/21.12/1132	2025/01/21	CARBIMAZOLE 20 UNIMED	Tablet	Unimed Healthcare (Pty) Ltd	EACH TABLET CONTAINS CARBIMAZOLE 20,0 mg	Annexure A
56/21.12/1133.1131	2025/01/21	CARBIFORA 5	Tablet	Unimed Healthcare (Pty) Ltd	EACH TABLET CONTAINS CARBIMAZOLE 5,0 mg	Annexure A
56/21.12/1134.1132	2025/01/21	CARBIFORA 20	Tablet	Unimed Healthcare (Pty) Ltd	EACH TABLET CONTAINS CARBIMAZOLE 20,0 mg	Annexure A
57/21.2/0009	2025/01/21	ZITAGLUC 25	Tablet	Ranbaxy Pharmaceutical (Pty) Ltd	EACH TABLET CONTAINS SITAGLIPTIN FUMARATE EQUIVALENT TO SITAGLIPTIN 25,0 mg	Annexure A
57/21.2/0010	2025/01/21	ZITAGLUC 50	Tablet	Ranbaxy Pharmaceutical (Pty) Ltd	EACH TABLET CONTAINS SITAGLIPTIN FUMARATE EQUIVALENT TO SITAGLIPTIN 50,0 mg	Annexure A
57/21.2/0011	2025/01/21	ZITAGLUC 100	Tablet	Ranbaxy Pharmaceutical (Pty) Ltd	EACH TABLET CONTAINS SITAGLIPTIN FUMARATE EQUIVALENT TO SITAGLIPTIN 100,0 mg	Annexure A
57/21.2/0012.009	2025/01/21	SITAGLIPTIN 25 RAN	Tablet	Ranbaxy Pharmaceutical (Pty) Ltd	EACH TABLET CONTAINS SITAGLIPTIN FUMARATE EQUIVALENT TO SITAGLIPTIN 25,0 mg	Annexure A
57/21.2/0013.010	2025/01/21	SITAGLIPTIN 50 RAN	Tablet	Ranbaxy Pharmaceutical (Pty) Ltd	EACH TABLET CONTAINS SITAGLIPTIN FUMARATE EQUIVALENT TO SITAGLIPTIN 50,0 mg	Annexure A
57/21.2/0014.011	2025/01/25	SITAGLIPTIN 100 RAN	Tablet	Ranbaxy Pharmaceuticals (Pty) Ltd	EACH TABLET CONTAINS SITAGLIPTIN FUMARATE EQUIVALENT TO SITAGLIPTIN 100,0 mg	Annexure A
53/13.4.1/0397	2025/01/29	GLENOSOL CREAM	Cream	Glenmark Pharmaceuticals South Africa (Pty) Ltd	EACH 1,0 g CREAM CONTAINS CLOBETASOL PROPIONATE USP 0,5 mg	Annexure A
56/11.10/0764	2025/01/29	GANATON 50 mg	Tablet	Abbott Laboratories S.A. (Pty) Ltd	EACH TABLET CONTAINS ITOPRIDE HYDROCHLORIDE 50,0 mg	Annexure A
57/5.7.1/0019	2025/01/29	ACTINCYPRO	Tablet	Pharmarec Limited	EACH TABLET CONTAINS CYPROHEPTADINE HYDROCHLORIDE 4,0 mg	Annexure A
57/5.7.1/0168	2025/01/29	AVARINEX SYRUP	Syrup	Innovata Pharmaceuticals	EACH 5,0 ml SYRUP CONTAINS DESLORATADINE 2,5 mg	Annexure A
58/20.1.1/0041	2025/01/29	SERESTIP	Capsule	Austell Pharmaceuticals (Pty) Ltd	EACH CAPSULE CONTAINS CYCLOSERINE 250,0 mg	Annexure A

57/26/0023	2025/01/29	IMTURAS 100 mg	Tablet	Alturas Healthcare (Pty) Ltd	EACH TABLET CONTAINS IMATINIB MESILATE 100,0 mg	Annexure A
57/26/0024	2025/01/29	IMTURAS 400 mg	Tablet	Alturas Healthcare (Pty) Ltd	EACH TABLET CONTAINS IMATINIB MESILATE 400,0 mg	Annexure A
56/13.4.1/0417	2025/02/04	CLONETA STRA	Shampoo	ASTRAL PHARMA (PTY) LTD	EACH 1,0 mg SHAMPOO CONTAINS CLOBETASOL PROPIONATE 0,5 mg	Annexure A
56/26/0466	2025/02/04	BEVACIZUMAB 100 EQUITY	Infusion	Equity Pharmaceutical (Pty) Ltd	EACH VIAL CONTAINS BEVACIZUMAB 100,0 mg	Annexure A
56/26/0467	2025/02/04	BEVACIZUMAB 400 EQUITY	Infusion	Equity Pharmaceutical (Pty) Ltd	EACH VIAL CONTAINS BEVACIZUMAB 400,0 mg	Annexure A
56/15.4/0843	2025/02/04	MICOGLOMA CO	Eye Drops	Adcock Ingram Limited	EACH 1,0 ml SOLUTION CONTAINS DORZOLAMIDE HYDROCHLORIDE EQUIVALENT TO DORZOLAMIDE 20,0 mg TIMOLOL MALEATE EQUIVALENT TO TIMOLOL 5,0 mg	Annexure A
56/15.4/0844.843	2025/02/04	DORZOLAMIDE CO ADCO	Eye Drops	Adcock Ingram Limited	EACH 1,0 ml SOLUTION CONTAINS DORZOLAMIDE HYDROCHLORIDE EQUIVALENT TO DORZOLAMIDE 20,0 mg TIMOLOL MALEATE EQUIVALENT TO TIMOLOL 5,0 mg	Annexure A
56/10.22/0911	2025/02/04	MONTEFLO 4 mg ORAL GRANULES	Granules	Trinity Pharma (Pty) Ltd	EACH SACHET CONTAINS MONTELUKAST 4,0 mg	Annexure A
56/7.3/1126	2025/02/04	MEDERIZAN 5	Tablet	Trinity Pharma (Pty) Ltd	EACH TABLET CONTAINS RIZATRIPTAN BENZOATE EQUIVALENT TO RIZATRIPTAN 5, 0 mg	Annexure A
56/7.3/1127	2025/02/04	MEDERIZAN 10	Tablet	Trinity Pharma (Pty) Ltd	EACH TABLET CONTAINS RIZATRIPTAN BENZOATE EQUIVALENT TO RIZATRIPTAN 10, 0 mg	Annexure A
56/2.10/1154	2025/02/04	SPASIFEN	Tablet	Trinity Pharma (Pty) Ltd	EACH TABLET CONTAINS BACLOFEN 10,0 mg	Annexure A
57/5.7.1/0028	2025/02/04	RUALIDINE 10	Tablet	Strides Pharma (SA) (Pty) Ltd	EACH TABLET CONTAINS RUPATADINE FUMARATE EQUIVALENT TO RUPATADINE 10,0 mg	Annexure A
57/20.2.2/0035	2025/02/04	ORAMICO GEL	Gel	LeBasi Pharmaceuticals (Pty) Ltd	EACH 1,0 g GEL CONTAINS MICONAZOLE 20,0 mg	Annexure A
57/26/0132	2025/02/04	LEDAGA	Gel	Key Oncologics (Pty) Ltd	EACH 1,0 g GEL CONTAINS CHLORMETHINE HYDROCHLORIDE EQUIVALENT TO CHLORMETHINE 160,0 µg	Annexure A
57/20.1.1/0156	2025/02/04	CYCLOSERINE 250 mg PD	Capsule	Pharma Dynamics (Pty) Ltd	EACH CAPSULE CONTAINS CYCLOSERINE 250,0 mg	Annexure A
57/2.10/0182	2025/02/04	FENOZYD	Tablet	Zydus Healthcare (Pty) Ltd	EACH TABLET CONTAINS BACLOFEN 10,0 mg	Annexure A
57/30.5/0287	2025/02/04	COLUMVI 2,5 mg/2,5 ml	Infusion	Roche Products (Pty) Ltd	EACH VIAL CONTAINS GLOFITAMAB 2,5 mg	Annexure A
57/30.5/0288	2025/02/04	COLUMVI 10 mg/10 ml	Infusion	Roche Products (Pty) Ltd	EACH VIAL CONTAINS GLOFITAMAB 10,0 mg	Annexure A
60/2.8/0127	2025/02/04	IBUCETAPRO TABLETS	Tablet	Adcock Ingram Limited	EACH TABLET CONTAINS IBUPROFEN 400,0 mg PARACETAMOL 325,0 mg	Annexure A
55/26/0397	2025/02/11	DASATINIB 20 EUROLAB	Tablet	Eurolab (Pty) Ltd	EACH TABLET CONTAINS DASATINIB 20,0 mg	Annexure A
55/26/0398	2025/02/11	DASATINIB 50 EUROLAB	Tablet	Eurolab (Pty) Ltd	EACH TABLET CONTAINS DASATINIB 50,0 mg	Annexure A
55/26/0399	2025/02/11	DASATINIB 70 EUROLAB	Tablet	Eurolab (Pty) Ltd	EACH TABLET CONTAINS DASATINIB 70,0 mg	Annexure A
55/26/0400	2025/02/11	DASATINIB 80 EUROLAB	Tablet	Eurolab (Pty) Ltd	EACH TABLET CONTAINS DASATINIB 80,0 mg	Annexure A
55/26/0401	2025/02/11	DASATINIB 100 EUROLAB	Tablet	Eurolab (Pty) Ltd	EACH TABLET CONTAINS DASATINIB 100,0 mg	Annexure A
55/32.16/0737	2025/02/11	ESSENTIALE 300	Capsule	Sanofi-Aventis South Africa (Pty) Ltd	EACH CAPSULE CONTAINS PHOSPHOLIPIDS FROM SOYBEANS 300,0 mg	Annexure A

55/32.16/0738	2025/02/11	ESSENTIALE 600	Capsule	Sanofi-Aventis South Africa (Pty) Ltd	EACH CAPSULE CONTAINS PHOSPHOLIPIDS FROM SOYBEANS 600,0 mg	Annexure A
56/15.1/0706	2025/02/11	MOXIFLOXACIN EYE DROPS ASCENDIS	Eye Drops	Ascendis Pharma (Pty) Ltd	EACH 1,0 ml SOLUTION CONTAINS MOXIFLOXACIN HYDROCHLORIDE EQUIVALENT TO MOXIFLOXACIN 5,0 mg	Annexure A
56/15.4/0845	2025/02/11	ICOBIMIL	Eye Drops	Adcock Ingram Limited	EACH 1,0 ml SOLUTION CONTAINS BIMATOPROST 0,3 mg TIMOLOL MALEATE EQUIVALENT TO TIMOLOL 5,0 mg	Annexure A
56/15.4/0846.845	2025/02/11	BIMATOPROST CO ADCO	Eye Drops	Adcock Ingram Limited	EACH 1,0 ml SOLUTION CONTAINS BIMATOPROST 0,3 mg TIMOLOL MALEATE EQUIVALENT TO TIMOLOL 5,0 mg	Annexure A
56/34/1031	2025/02/11	MYCOPHENOLATE 250 ASCENDIS	Capsule	Ascendis Pharma (Pty) Ltd	EACH CAPSULE CONTAINS MYCOPHENOLATE MOFETIL 250,0 mg	Annexure A
56/21.12/1216	2025/02/11	FINASTERIDE 1 mg ASCEND	Tablet	Ascend Laboratories (Pty) Ltd	EACH TABLET CONTAINS FINASTERIDE 1,0 mg	Annexure A
56/21.12/1217	2025/02/11	FINASTERIDE 5 mg ASCEND	Tablet	Ascend Laboratories (Pty) Ltd	EACH TABLET CONTAINS FINASTERIDE 5,0 mg	Annexure A
57/5.4/0076	2025/02/11	PLACOGY 1 mg/5 ml VIAL	Injection	Hetero Drugs South Africa (Pty) Ltd	EACH 5,0 ml SOLUTION CONTAINS GLYCOPYRRROLATE 1,0 mg	Annexure A
57/5.4/0077	2025/02/11	PLACOGY 4 mg/20 ml VIAL	Injection	Hetero Drugs South Africa (Pty) Ltd	EACH 20,0 ml SOLUTION CONTAINS GLYCOPYRRROLATE 4,0 mg	Annexure A
57/5.4/0078.076	2025/02/11	GLYOPY 1 mg/5 ml VIAL	Injection	Hetero Drugs South Africa (Pty) Ltd	EACH 5,0 ml SOLUTION CONTAINS GLYCOPYRRROLATE 1,0 mg	Annexure A
57/5.4/0079.077	2025/02/11	GLYOPY 4 mg/20 ml VIAL	Injection	Hetero Drugs South Africa (Pty) Ltd	EACH 20,0 ml SOLUTION CONTAINS GLYCOPYRRROLATE 4,0 mg	Annexure A
57/20.3/0092	2025/02/11	LORBRENA 25 mg	Tablet	Pfizer Laboratories (Pty) Ltd	EACH TABLET CONTAINS LORLATINIB 25,0 mg	Annexure A
57/20.3/0093	2025/02/11	LORBRENA 100 mg	Tablet	Pfizer Laboratories (Pty) Ltd	EACH TABLET CONTAINS LORLATINIB 100,0 mg	Annexure A
57/20.3/0094.092	2025/02/11	LORLATINIB 25 mg PFIZER	Tablet	Pfizer Laboratories (Pty) Ltd	EACH TABLET CONTAINS LORLATINIB 25,0 mg	Annexure A
57/20.3/0095.093	2025/02/11	LORLATINIB 100 mg PFIZER	Tablet	Pfizer Laboratories (Pty) Ltd	EACH TABLET CONTAINS LORLATINIB 100,0 mg	Annexure A
57/5.7.2/0152	2025/02/11	FEPRIP	Infusion	Hetero Drugs South Africa (Pty) Ltd	EACH VIAL CONTAINS FOSAPREPITANT DIMEGLUMINE EQUIVALENT TO FOSAPREPITANT 150,0 mg	Annexure A
57/5.7.2/0153.152	2025/02/11	FOSAPREPITANT HETERO	Infusion	Hetero Drugs South Africa (Pty) Ltd	EACH VIAL CONTAINS FOSAPREPITANT DIMEGLUMINE EQUIVALENT TO FOSAPREPITANT 150,0 mg	Annexure A
57/20.2/0330	2025/02/11	PLASULCA 50 mg	Infusion	Pharmacare Limited	EACH VIAL CONTAINS MICAFUNGIN SODIUM EQUIVALENT TO MICAFUNGIN 50,0 mg	Annexure A
57/20.2.2/0331	2025/02/11	PLASULCA 100 mg	Infusion	Pharmacare Limited	EACH VIAL CONTAINS MICAFUNGIN SODIUM EQUIVALENT TO MICAFUNGIN 100,0 mg	Annexure A
590253	2025/02/11	VILDAMET 50/850	Tablet	Innovata Pharmaceuticals	EACH TABLET CONTAINS VILDAGLIPTIN 50,0 mg METFORMIN HYDROCHLORIDE 850,0 mg	Annexure A
59/21.2/0254	2025/02/11	VILDAMET 50/1 000	Tablet	Innovata Pharmaceuticals	EACH TABLET CONTAINS VILDAGLIPTIN 50,0 mg METFORMIN HYDROCHLORIDE 1 000,0 mg	Annexure A
58/21.013/0223	2025/02/11	WEGOVY 0,25 mg	Injection	Novo Nordisk (Pty) Ltd	EACH DOSE CONTAINS SEMAGLUTIDE 0,25 mg	Annexure A
58/21.013/0224	2025/02/11	WEGOVY 0,5 mg	Injection	Novo Nordisk (Pty) Ltd	EACH DOSE CONTAINS SEMAGLUTIDE 0,5 mg	Annexure A
58/21.013/0225	2025/02/11	WEGOVY 1 mg	Injection	Novo Nordisk (Pty) Ltd	EACH DOSE CONTAINS SEMAGLUTIDE 1 mg	Annexure A
58/21.013/0226	2025/02/11	WEGOVY 1,7 mg	Injection	Novo Nordisk (Pty) Ltd	EACH DOSE CONTAINS SEMAGLUTIDE 1,7 mg	Annexure A
58/21.013/0227	2025/02/11	WEGOVY 2,4 mg	Injection	Novo Nordisk (Pty) Ltd	EACH DOSE CONTAINS SEMAGLUTIDE 2,4 mg	Annexure A

56/8.2/0815	2025/02/18	IVENOXIN 20	Injection	Kahma Biotech (Pty) Ltd	EACH 0,2 ml SOLUTION CONTAINS ENOXAPARIN SODIUM 20,0 mg	Annexure A
56/8.2/0816	2025/02/18	IVENOXIN 40	Injection	Kahma Biotech (Pty) Ltd	EACH 0,4 ml SOLUTION CONTAINS ENOXAPARIN SODIUM 40,0 mg	Annexure A
56/8.2/0817	2025/02/18	IVENOXIN 60	Injection	Kahma Biotech (Pty) Ltd	EACH 0,6 ml SOLUTION CONTAINS ENOXAPARIN SODIUM 60,0 mg	Annexure A
56/8.2/0818	2025/02/18	IVENOXIN 80	Injection	Kahma Biotech (Pty) Ltd	EACH 0,8 ml SOLUTION CONTAINS ENOXAPARIN SODIUM 80,0 mg	Annexure A
56/8.2/0819	2025/02/18	IVENOXIN 100	Injection	Kahma Biotech (Pty) Ltd	EACH 10,0 ml SOLUTION CONTAINS ENOXAPARIN SODIUM 100,0 mg	Annexure A
57/18.1/0344	2025/02/18	SPIROIUB FC 25 mg	Tablet	Jubilant Pharma SA (Pty) Ltd	EACH TABLET CONTAINS SPIRONOLACTONE 25,0 mg	Annexure A
57/18.1/0345	2025/02/18	SPIROIUB FC 100 mg	Tablet	Jubilant Pharma SA (Pty) Ltd	EACH TABLET CONTAINS SPIRONOLACTONE 100,0 mg	Annexure A
57/18.1/0346.344	2025/02/18	JUBACTONE FC 25 mg	Tablet	Jubilant Pharma SA (Pty) Ltd	EACH TABLET CONTAINS SPIRONOLACTONE 25,0 mg	Annexure A
57/18.1/0347.345	2025/02/18	JUBACTONE FC 100 mg	Tablet	Jubilant Pharma SA (Pty) Ltd	EACH TABLET CONTAINS SPIRONOLACTONE 100,0 mg	Annexure A
57/20.1.1/0421	2025/02/18	TIPERABEX 4 g/0,5 g	Infusion	Abex Pharmaceutica (Pty) Ltd	EACH VIAL CONTAINS PIPERACILLIN SODIUM EQUIVALENT TO PIPERACILLIN 4,0 g TAZOBACTAM SODIUM EQUIVALENT TO TAZOBACTAM 0,5 g	Annexure A
57/8.3/0484	2025/02/18	TEVIFER 100	Injection	Teva Pharmaceuticals (Pty) Ltd	EACH 2,0 ml SOLUTION CONTAINS FERRIC CARBOXYMALTOSE EQUIVALENT TO IRON 100,0 mg	Annexure A
56/18.6/1006	2025/02/18	DINOTILIS	Pessary	Austell Pharmaceuticals (Pty) Ltd	EACH PESSARY CONTAINS ESTIROL 0,03 mg	Annexure A
60/34/0353	2025/02/18	SOBRIXA 8,0 mg	Tablet	Adcock Ingram Critical Care (Pty) Ltd	EACH TABLET CONTAINS BUPRENORPHINE HYDROCHLORIDE EQUIVALENT TO BUPRENORPHINE 8,0 mg	Annexure A
600/34/0352	2025/02/18	SOBRIXA 2,0 mg	Tablet	Adcock Ingram Critical Care (Pty) Ltd	EACH TABLET CONTAINS BUPRENORPHINE HYDROCHLORIDE EQUIVALENT TO BUPRENORPHINE 2,0 mg	Annexure A
60/34/0351	2025/02/18	SOBRIXA 0,4 mg	Tablet	Adcock Ingram Critical Care (Pty) Ltd	EACH TABLET CONTAINS BUPRENORPHINE HYDROCHLORIDE EQUIVALENT TO BUPRENORPHINE 0,4 mg	Annexure A
59/7.1.3/0798	2025/02/18	EXNATAM 5/1,25/5 mg	Tablet	Servier Laboratories South Africa (Pty) Ltd	EACH TABLET CONTAINS PERINDOPRIL ARGININE 5,0 mg INDAPAMIDE 1,25 mg AMLODIPINE BESILATE EQUIVALENT TO AMLODIPINE 5,0 mg	Annexure A
59/7.1.3/0799	2025/02/18	EXNATAM 5/1,25/10 mg	Tablet	Servier Laboratories South Africa (Pty) Ltd	EACH TABLET CONTAINS PERINDOPRIL ARGININE 5,0 mg INDAPAMIDE 1,25 mg AMLODIPINE BESILATE EQUIVALENT TO AMLODIPINE 10,0 mg	Annexure A
59/7.1.3/0800	2025/02/18	EXNATAM 10/2,5/5 mg	Tablet	Servier Laboratories South Africa (Pty) Ltd	EACH TABLET CONTAINS PERINDOPRIL ARGININE 10,0 mg INDAPAMIDE 2,5 mg AMLODIPINE BESILATE EQUIVALENT TO AMLODIPINE 5,0 mg	Annexure A
59/7.1.3/0801	2025/02/18	EXNATAM 10/2,5/10 mg	Tablet	Servier Laboratories South Africa (Pty) Ltd	EACH TABLET CONTAINS PERINDOPRIL ARGININE 10,0 mg INDAPAMIDE 2,5 mg AMLODIPINE BESILATE EQUIVALENT TO AMLODIPINE 10,0 mg	Annexure A
59/5.7.1/0767	2025/02/18	DESLOTAZ	Tablet	Ranbaxy Pharmaceutical (Pty) Ltd	EACH TABLET CONTAINS DESLORATADINE 5,0 mg	Annexure A

58/10.2.2/0186	2025/02/18	FLEMKLEER 200	Tablet	Dezzo Trading 392 (Pty) Ltd	EACH TABLET CONTAINS ACETYLCYSTEINE 200,0 mg	Annexure A
57/8.3/0486	2025/02/18	TEVIFER 1 000	Injection	Teva Pharmaceuticals (Pty) Ltd	EACH 20,0 ml SOLUTION CONTAINS FERRIC CARBOXYMALTOSE EQUIVALENT TO IRON 1 000,0 mg	Annexure A
57/8.3/0485	2025/02/18	TEVIFER 500	Injection	Teva Pharmaceuticals (Pty) Ltd	EACH 10,0 ml SOLUTION CONTAINS FERRIC CARBOXYMALTOSE EQUIVALENT TO IRON 500,0 mg	Annexure A
56/14.2/0749	2025/02/25	SILVABLAZE OTC	Cream	Biotech Laboratories (Pty) Ltd	EACH 1,0 g CREAM CONTAINS SILVER SULFADIAZINE 10,0 mg	Annexure A
56/2.7/0926	2025/02/25	BRUFEN 400 mg RAPID	Capsule	Abbott Laboratories S.A. (Pty) Ltd	EACH CAPSULE CONTAINS IBUPROFEN 400,0 mg	Annexure A
56/3.3/1019	2025/02/25	BEXACOS 100 mg	Tablet	Hetero Drugs South Africa (Pty) Ltd	EACH TABLET CONTAINS ALLOPURINOL 100,0 mg	Annexure A
56/3.3/1020	2025/02/25	BEXACOS 300 mg	Tablet	Hetero Drugs South Africa (Pty) Ltd	EACH TABLET CONTAINS ALLOPURINOL 300,0 mg	Annexure A
56/3.3/1021.1019	2025/02/25	APRIGOUT 100	Tablet	Hetero Drugs South Africa (Pty) Ltd	EACH TABLET CONTAINS ALLOPURINOL 100,0 mg	Annexure A
56/3.3/1022.1020	2025/02/25	APRIGOUT 300	Tablet	Hetero Drugs South Africa (Pty) Ltd	EACH TABLET CONTAINS ALLOPURINOL 300,0 mg	Annexure A
56/3.3/1023.1019	2025/02/25	ZYRECOS 100 mg	Tablet	Hetero Drugs South Africa (Pty) Ltd	EACH TABLET CONTAINS ALLOPURINOL 100,0 mg	Annexure A
56/3.3/1024.1020	2025/02/25	ZYRECOS 300 mg	Tablet	Hetero Drugs South Africa (Pty) Ltd	EACH TABLET CONTAINS ALLOPURINOL 300,0 mg	Annexure A
57/2.7/0260	2025/02/25	TEPAMIN	Injection	Hetero Drugs South Africa (Pty) Ltd	EACH 100,0 ml SOLUTION CONTAINS ACETAMINOPHEN 1 000,0 mg	Annexure A
60/2.8/0374	2025/02/25	PANADO EXTRA TABLETS	Tablet	Adcock Ingram Limited	EACH TABLET CONTAINS ASPIRIN 400,0 mg PARACETAMOL 100,0 mg CAFFEINE 30,0 mg	Annexure A
21/17.1.4/31	2025/02/11	TULATHROMYCIN 25 mg/ml HUVE	Injection	Huvepharma South Africa (Pty) Ltd	TULATHROMYCIN 25,0 mg	Annexure A
53/20.1.6/0558	2025/03/11	CLINDAMYCIN 1 % m/m FOAMGLENMARK	Foam	Glenmark Pharmaceuticals South Africa (Pty) Ltd	EACH 1,0 g OF FOAM CONTAINS CLINDAMYCIN PHOSPHATE 10,0 mg	Annexure A
54/26/0879	2025/03/11	METHOTREXATE 2,5 mg TABLETS ACCORD	Tablet	Accord Healthcare (Pty) Ltd	EACH TABLET CONTAINS METHOTREXATE DISODIUM EQUIVALENT TO METHOTREXATE 2,5 mg	Annexure A
56/11.2/0268	2025/03/11	BUTYRONEX 20	Injection	LeBasi Pharmaceuticals (Pty) Ltd	EACH 1,0 ml VIAL CONTAINS HYOSCINE BUTYLBROMIDE 20,0 mg	Annexure A
56/21.5/0500	2025/03/11	DUOASMA DPI 50/100	Inhalation	Glenmark Pharmaceuticals South Africa (Pty) Ltd	EACH DOSE CONTAINS SALMETEROL XINAFOATE EQUIVALENT TO SALMETEROL 50,0 µg FLUTICASONE PROPIONATE 100,0 µg	Annexure A
56/21.5.1/0500	2025/03/11	DOUASMA DPI 50/250	Inhalation	Glenmark Pharmaceuticals South Africa (Pty) Ltd	EACH DOSE CONTAINS SALMETEROL XINAFOATE EQUIVALENT TO SALMETEROL 50,0 µg FLUTICASONE PROPIONATE 250,0 µg	Annexure A
56/21.5.1/0502	2025/03/11	DUOASMA DPI 50/100	Inhalation	Glenmark Pharmaceuticals South Africa (Pty) Ltd	EACH DOSE CONTAINS SALMETEROL XINAFOATE EQUIVALENT TO SALMETEROL 50,0 µg FLUTICASONE PROPIONATE 500,0 µg	Annexure A
56/14.2/0750	2025/03/11	SILVOBLAZE	Cream	Biotech Laboratories (Pty) Ltd	EACH 1,0 g CREAM CONTAINS SILVER SULFADIAZINE 10,0 mg	Annexure A

56/20.2.8/1001	2025/03/11	TRILATED	Tablet	Encha Health (Pty) Ltd	EACH TABLET CONTAINS DOLUTEGRAVIR SODIUM EQUIVALENT TO DOLUTEGRAVIR 50,0 mg LAMIVUDINE 300,0 mg TENOFOVIR DISOPROXIL FUMARATE EQUIVALENT TO TENOFOVIR DISOPROXIL 300,0 mg	Annexure A
56/7.5/1213	2025/03/11	TYRACHOL POWDER	Powder	Ascend Laboratories (Pty) Ltd	EACH POUCH OR SCOOP CONTAINS CHOLESTYRAMINE RESIN 4,0 g	Annexure A
57/20.1.1/0164	2025/03/11	LYMEVOR 300 mg	Capsule	Trinity Pharma (Pty) Ltd	EACH CAPSULE CONTAINS LYMECYCLINE EQUIVALENT TO TETRACYCLINE 300,0 mg	Annexure A
57/20.1.1/0165	2025/03/11	LYMEDEX 300 mg	Capsule	Trinity Pharma (Pty) Ltd	EACH CAPSULE CONTAINS LYMECYCLINE EQUIVALENT TO TETRACYCLINE 300,0 mg	Annexure A
57/11.4.3/0190	2025/03/11	PANTOCID OTC	Tablet	Ranbaxy Pharmaceutical (Pty) Ltd	EACH TABLET CONTAINS PANTOPRAZOLE SODIUM SESQUIHYDRATE EQUIVALENT TO PANTOPRAZOLE 20,0 mg	Annexure A
57/21.2/0222	2025/03/11	DAPAGLIFLOZIN 5 mg ADCO	Tablet	Adcock Ingram Limited	EACH TABLET CONTAINS DAPAGLIFLOZIN 5,0 mg	Annexure A
57/21.2/0223	2025/03/11	DAPAGLIFLOZIN 10 mg ADCO	Tablet	Adcock Ingram Limited	EACH TABLET CONTAINS DAPAGLIFLOZIN 10,0 mg	Annexure A
59/3.3/0111	2025/03/11	REDURIC 100	Tablet	Innovata Pharmaceuticals	EACH TABLET CONTAINS ALLOPURINOL 100,0 mg	Annexure A
59/3.3/0112	2025/03/11	REDURIC 300	Tablet	Innovata Pharmaceuticals	EACH TABLET CONTAINS ALLOPURINOL 300,0 mg	Annexure A
53/13.4.1/0398	2025/03/04	GLENCOSOL 0,05% m/m OINTMENT	Ointment	Glenmark Pharmaceuticals South Africa (Pty) Ltd	EACH 1,0 g OF OINTMENT CONTAINS CLOBETASOL PROPIONATE 0,5 mg	Annexure A
54/5.7.1/0174	2025/03/04	LUMONT CO	Tablet	Zydus Healthcare (Pty) Ltd	EACH TABLET CONTAINS MONTELUKAST SODIUM EQUIVALENT TO MONTELUKAST 10,0 mg LEVOCETIRIZINE DIHYDROCHLORIDE 5,0 mg	Annexure A
54/5.7.1/0175.174	2025/03/04	MONTECET	Tablet	Zydus Healthcare (Pty) Ltd	EACH TABLET CONTAINS MONTELUKAST SODIUM EQUIVALENT TO MONTELUKAST 10,0 mg LEVOCETIRIZINE DIHYDROCHLORIDE 5,0 mg	Annexure A
56/26/1064	2025/03/04	IBRANCE TABLETS 75 mg	Tablet	Pfizer Laboratories PFE (Pty) Ltd	EACH TABLET CONTAINS PALBOCICLIB 75,0 mg	Annexure A
56/26/1065	2025/03/04	IBRANCE TABLETS 100 mg	Tablet	Pfizer Laboratories (Pty) Ltd	EACH TABLET CONTAINS PALBOCICLIB 100,0 mg	Annexure A
56/26/1066	2025/03/04	IBRANCE TABLETS 125 mg	Tablet	Pfizer Laboratories (Pty) Ltd	EACH TABLET CONTAINS PALBOCICLIB 125,0 mg	Annexure A
56/26/1067.1064	2025/03/04	PALBOCICLIB 75 mg TABLETS PFIZER	Tablet	Pfizer Laboratories (Pty) Ltd	EACH TABLET CONTAINS PALBOCICLIB 75,0 mg	Annexure A
56/26/1068.1065	2025/03/04	PALBOCICLIB 100 mg TABLETS PFIZER	Tablet	Pfizer Laboratories (Pty) Ltd	EACH TABLET CONTAINS PALBOCICLIB 100,0 mg	Annexure A
56/26/1069.1066	2025/03/04	PALBOCICLIB 125 mg TABLETS PFIZER	Tablet	Pfizer Laboratories (Pty) Ltd	EACH TABLET CONTAINS PALBOCICLIB 125,0 mg	Annexure A
60/16.1/0542	2025/03/04	NASYLO	Nasal Spray	Lamar International (Pty) Ltd	EACH 1,0 ml VIAL CONTAINS XYLOMETAZOLINE HYDROCHLORIDE EQUIVALENT TO XYLOMETAZOLINE 1,0 mg	Annexure A
52/8.2/0528	2025/03/18	TICAKEM	Tablet	Ascend Laboratories (Pty) Ltd	EACH TABLET CONTAINS TICAGRELOR 90,0 mg	Annexure A
52/8.2/0529.528	2025/03/18	TICALOR	Tablet	Ascend Laboratories (Pty) Ltd	EACH TABLET CONTAINS TICAGRELOR 90,0 mg	Annexure A
52/8.2/0530.528	2025/03/18	TICAGRELOR ASCEND	Tablet	Ascend Laboratories (Pty) Ltd	EACH TABLET CONTAINS TICAGRELOR 90,0 mg	Annexure A
54/11.4.3/0268	2025/03/18	OMEHET	Capsule	Hetero Drugs South Africa (Pty) Ltd	EACH CAPSULE CONTAINS OMEPRAZOLE (FORM-B) 20,0 mg	Annexure A
54/14.4.3/0269.268	2025/03/18	FLORITEOR 20	Capsule	Hetero Drugs South Africa (Pty) Ltd	EACH CAPSULE CONTAINS OMEPRAZOLE (FORM-B) 20,0 mg	Annexure A

54/11.4.3/0270.268	2025/03/18	OMEPRazole 20 HETERO	Capsule	Hetero Drugs South Africa (Pty) Ltd	EACH CAPSULE CONTAINS OMEPRazole (FORM-B) 20,0 mg	Annexure A
56/15.4/1049	2025/03/18	OLOPATADINE EYE DROPS FDC	Eye Drops	FDC SA (Pty) Ltd	EACH 1,0 ml SOLUTION CONTAINS OLOPATADINE HYDROCHLORIDE EQUIVALENT TO OLOPATADINE 1,0 mg	Annexure A
56/15.4/1050.1049	2025/03/18	OLOVIS	Eye Drops	FDC SA (Pty) Ltd	EACH 1,0 mg SOLUTION CONTAINS OLOPATADINE HYDROCHLORIDE EQUIVALENT TO OLOPATADINE 1,0 mg	Annexure A
56/15.4/1051.1049	2025/03/18	ZYLOPAT	Eye Drops	FDC SA (Pty) Ltd	EACH 1,0 mg SOLUTION CONTAINS OLOPATADINE HYDROCHLORIDE EQUIVALENT TO OLOPATADINE 1,0 mg	Annexure A
56/13.9.2/1212	2025/03/18	LOVACIL	Nail Lacquer	Astral Pharma (Pty) Ltd	EACH LACQUER CONTAINS AMOROLFINE HYDROCHLORIDE EQUIVALENT TO AMOROLFINE 5,0 % w/v	Annexure A
56/27/1222	2025/03/18	SIROXTRIN 125	Tablet	Trinity Pharma (Pty) Ltd	EACH TABLET CONTAINS DEFERASIROX 125,0 mg	Annexure A
56/27/1223	2025/03/18	SIROXTRIN 250	Tablet	Trinity Pharma (Pty) Ltd	EACH TABLET CONTAINS DEFERASIROX 250,0 mg	Annexure A
56/27/1224	2025/03/18	SIROXTRIN 500	Tablet	Trinity Pharma (Pty) Ltd	EACH TABLET CONTAINS DEFERASIROX 500,0 mg	Annexure A
57/21.5.1/0001	2025/03/18	BUDEFAM 0,123 mg/ml RESPULES	Nebuliser Suspension	Cipla Medpro (Pty) Ltd	EACH 1,0 ml SUSPENSION CONTAINS BUDESONIDE 0,125 mg	Annexure A
57/21.5.1/0002	2025/03/18	BUDEFAM 0,25 mg/ml RESPULES	Nebuliser Suspension	Cipla Medpro (Pty) Ltd	EACH 1,0 ml SUSPENSION CONTAINS BUDESONIDE 0,25 mg	Annexure A
56/27/1224	2025/03/18	SIROXTRIN 500	Tablet	Trinity Pharma (Pty) Ltd	EACH TABLET CONTAINS DEFERASIROX 500,0 mg	Annexure A
57/21.5.1/0003	2025/03/18	BUDEFAM 0,5 mg/ml RESPULES	Nebuliser Suspension	Cipla Medpro (Pty) Ltd	EACH 1,0 ml SUSPENSION CONTAINS BUDESONIDE 0,5 mg	Annexure A
57/21.5.1/0004.001	2025/03/18	BUDESONIDE 0,125 mg/ml RESPULES CIPLA	Nebuliser Suspension	Cipla Medpro (Pty) Ltd	EACH 1,0 ml SUSPENSION CONTAINS BUDESONIDE 0,125 mg	Annexure A
57/21.5.1/0005.002	2025/03/18	BUDESONIDE 0,25 mg/ml RESPULES CIPLA	Nebuliser Suspension	Cipla Medpro (Pty) Ltd	EACH 1,0 ml SUSPENSION CONTAINS BUDESONIDE 0,25 mg	Annexure A
57/21.5.1/0006.003	2025/03/18	BUDESONIDE 0,5 mg/ml RESPULES CIPLA	Nebuliser Suspension	Cipla Medpro (Pty) Ltd	EACH 1,0 ml SUSPENSION CONTAINS BUDESONIDE 0,5 mg	Annexure A
57/8/0016	2025/03/18	ASATRYN	Tablet	Lamar International (Pty) Ltd	EACH TABLET CONTAINS ASPIRIN 81,0 mg	Annexure A
57/7.1.3/0101	2025/03/18	CALSAR CO 5/160/12,5 mg	Tablet	Pharma Dynamics (Pty) Ltd	EACH TABLET CONTAINS AMLODIPINE BESYLATE EQUIVALENT TO AMLODIPINE 5,0 mg VALSARTAN 160,0 mg HYDROCHLOROTHIAZIDE 12,5 mg	Annexure A
57/7.1.3/0102	2025/03/18	CALSAR CO 10/160/12,5 mg	Tablet	Pharma Dynamics (Pty) Ltd	EACH TABLET CONTAINS AMLODIPINE BESYLATE EQUIVALENT TO AMLODIPINE 10,0 mg VALSARTAN 160,0 mg HYDROCHLOROTHIAZIDE 12,5 mg	Annexure A
57/7.1.3/0103	2025/03/18	CALSAR CO 5/160/25 mg	Tablet	Pharma Dynamics (Pty) Ltd	EACH TABLET CONTAINS AMLODIPINE BESYLATE EQUIVALENT TO AMLODIPINE 5,0 mg VALSARTAN 160,0 mg HYDROCHLOROTHIAZIDE 25,0 mg	Annexure A
57/7.1.3/0104	2025/03/18	CALSAR CO 10/160/25 mg	Tablet	Pharma Dynamics (Pty) Ltd	EACH TABLET CONTAINS AMLODIPINE BESYLATE EQUIVALENT TO AMLODIPINE 10,0 mg VALSARTAN 160,0 mg HYDROCHLOROTHIAZIDE 25,0 mg	Annexure A
57/7.1.3/0105	2025/03/18	CALSAR CO 10/320/25 mg	Tablet	Pharma Dynamics (Pty) Ltd	EACH TABLET CONTAINS AMLODIPINE BESYLATE EQUIVALENT TO AMLODIPINE 10,0 mg VALSARTAN 320,0 mg HYDROCHLOROTHIAZIDE 25,0 mg	Annexure A

57/26/0150	2025/03/18	PAZOTEV 200	Tablet	Teva Pharmaceuticals (Pty) Ltd	EACH TABLET CONTAINS PAZOPANIB HYDROCHLORIDE EQUIVALENT TO PAZOPANIB 200,0 mg	Annexure A
57/26/0151	2025/03/18	PAZOTEV 400	Tablet	Teva Pharmaceuticals (Pty) Ltd	EACH TABLET CONTAINS PAZOPANIB HYDROCHLORIDE EQUIVALENT TO PAZOPANIB 400,0 mg	Annexure A
57/18.10/0242	2025/03/18	FIRIALTA 10 mg	Tablet	Bayer (Pty) Ltd	EACH TABLET CONTAINS FINERENONE 10,0 mg	Annexure A
57/18.10/0243	2025/03/18	FIRIALTA 20 mg	Tablet	Bayer (Pty) Ltd	EACH TABLET CONTAINS FINERENONE 20,0 mg	Annexure A
57/18.10/02440242	2025/03/18	CYNFONERA 10 mg	Tablet	Bayer (Pty) Ltd	EACH TABLET CONTAINS FINERENONE 10,0 mg	Annexure A
57/18.10/0245.243	2025/03/18	CYNFONERA 20 mg	Tablet	Bayer (Pty) Ltd	EACH TABLET CONTAINS FINERENONE 20,0 mg	Annexure A
57/18.10/0246.242	2025/03/18	FINETIVE 10 mg	Tablet	Bayer (Pty) Ltd	EACH TABLET CONTAINS FINERENONE 10,0 mg	Annexure A
57/18.10/0427.243	2025/03/18	FINETIVE 20 mg	Tablet	Bayer (Pty) Ltd	EACH TABLET CONTAINS FINERENONE 20,0 mg	Annexure A
57/20.1.1/0266	2025/03/18	TAZOPI	Infusion	Encha Health (Pty) Ltd	EACH VIAL CONTAINS PIPERACILLIN SODIUM EQUIVALENT TO PIPERACILLIN 4,0 g TAZOBACTAM SODIUM EQUIVALENT TO TAZOBACTAM 0,5 g	Annexure A
57/30.1/0372	2025/03/18	LUNSUMIO 1 mg/1 ml	Infusion	Roche Products (Pty) Ltd	EACH VIAL CONTAINS MOSUNETUZUMAB 1,0 mg	Annexure A
57/30.1/0373	2025/03/18	LUNSUMIO 30 mg/30 ml	Infusion	Roche Products (Pty) Ltd	EACH VIAL CONTAINS MOSUNETUZUMAB 30,0 mg	Annexure A
59/26/0119	2025/03/18	AKEEGA 50 mg/500 mg	Tablet	Janssen Pharmaceutica (Pty) Ltd	EACH TABLET CONTAINS NIRAPARIB TOSYLATE MONOHYDRATE EQUIVALENT TO NIRAPARIB 50,0 mg ABIRATERONE ACETATE EQUIVALENT TO ABIRATERONE 500,0 mg	Annexure A
59/26/0120	2025/03/18	AKEEGA 100 mg/500 mg	Tablet	Janssen Pharmaceutica (Pty) Ltd	EACH TABLET CONTAINS NIRAPARIB TOSYLATE MONOHYDRATE EQUIVALENT TO NIRAPARIB 100,0 mg ABIRATERONE ACETATE EQUIVALENT TO ABIRATERONE 500,0 mg	Annexure A
46/5.8/0759	2025/03/25	MEDI SOOTHE WITH VITAMIN C - LEMON and GINGER	Powder	Pharmacare Limited	EACH SACHET CONTAINS ASPIRIN 800,0 mg CAFFEINE 50,0 mg ASORBIC ACID 45,0 mg	Annexure B
47/5.8/0323	2025/03/25	FLUEXPIN C COLD & FLU LEMON & GINGER	Powder	Pharmacare Limited	EACH SACHET CONTAINS ASPIRIN 800,0 mg CAFFEINE 50,0 mg ASORBIC ACID 45,0 mg	Annexure B
51/13.4.1/0330	2025/03/25	MACEPATAN OINTMENT	Ointment	Pharmacare Limited	EACH 1,0 g OF OINTMENT CONTAINS METHYLPREDNISOLONE ACEPONATE 1,0 mg	Annexure A
53/3.2/0225	2025/03/25	PREOVIDLEN	Tablet	Pharmacare Limited	EACH TABLET CONTAINS ALENDRONATE SODIUM TRIHYDRATE EQUIVALENT TO ALENDRONIC ACID 70,0 mg CHOLECALCIFEROL 0,14 mg	Annexure A
55/1.2/0778	2025/03/25	BUPROPION 300 ACCORD	Tablet	Accord Healthcare (Pty) Ltd	EACH TABLET CONTAINS BUPRENORPHINE HYDROCHLORIDE 300,0 mg	Annexure A
56/2.2/0729	2025/03/25	ZOLPIDEM 10 UNICORN	Tablet	Unicorn Pharmaceuticals (Pty) Ltd	EACH TABLET CONTAINS ZOLPIDEM TARTRATE EQUIVALENT TO ZOLPIDEM 10,0 mg	Annexure A
56/21.12/1105	2025/03/25	ABIRATERONE 250 SANDOZ	Tablet	Sandoz South Africa (Pty) Ltd	EACH TABLET CONTAINS ABIRATERONE ACETATE 250,0 mg	Annexure A
56/21.12/1106	2025/03/25	ABIRATERONE 500 SANDOZ	Tablet	Sandoz South Africa (Pty) Ltd	EACH TABLET CONTAINS ABIRATERONE ACETATE 500,0 mg	Annexure A
56/21.12/1107	2025/03/25	ABIRATERONE 1 000 SANDOZ	Tablet	Sandoz South Africa (Pty) Ltd	EACH TABLET CONTAINS ABIRATERONE ACETATE 1 000,0 mg	Annexure A

56/2.11/1193	2025/03/25	SUGAMMADEX EQUITY	Injection	Equity Pharmaceutical (Pty) Ltd	EACH 1,0 ml SOLUTION CONTAINS SUGAMMADEX 200,0 mg	Annexure A
56/2.11/1211	2025/03/25	DIREDEX	Injection	Encha Health (Pty) Ltd	EACH 2,0 ml SOLUTION CONTAINS SUGAMMADEX 200,0 mg	Annexure A
57/13.4.1/0040	2025/03/25	CLOBETASOL CREAM SHALINA	Cream	Pharmadyne Healthcare (Pty) Ltd	EACH 1,0 g CREAM CONTAINS CLOBETASOL PROPIONATE 0,5 mg	Annexure A
57/10.2.1/0042	2025/03/25	GLENISPERA 50 µg	Inhalation	Glenmark Pharmaceuticals South Africa (Pty) Ltd	EACH DOSE CONTAINS GLYCOPYRROLATE EQUIVALENT TO GLYCOPYRRONIUM 50,0 µg	Annexure A
57/2.5/0209	2025/03/25	EIZUREX 150	Tablet	Hetero Drugs South Africa (Pty) Ltd	EACH TABLET CONTAINS OXCARBAZEPINE 150,0 mg	Annexure A
57/2.5/0210	2025/03/25	EIZUREX 300	Tablet	Hetero Drugs South Africa (Pty) Ltd	EACH TABLET CONTAINS OXCARBAZEPINE 300,0 mg	Annexure A
57/2.5/0211	2025/03/25	EIZUREX 600	Tablet	Hetero Drugs South Africa (Pty) Ltd	EACH TABLET CONTAINS OXCARBAZEPINE 600,0 mg	Annexure A
57/2.5/212.209	2025/03/25	RUZECIN 150	Tablet	Hetero Drugs South Africa (Pty) Ltd	EACH TABLET CONTAINS OXCARBAZEPINE 150,0 mg	Annexure A
57/2.5/0213.210	2025/03/25	RUZEXIN 300	Tablet	Hetero Drugs South Africa (Pty) Ltd	EACH TABLET CONTAINS OXCARBAZEPINE 300,0 mg	Annexure A
57/2.5/0214.211	2025/03/25	RUZEXIN 600	Tablet	Hetero Drugs South Africa (Pty) Ltd	EACH TABLET CONTAINS OXCARBAZEPINE 600,0 mg	Annexure A
59/20.2.3/0601	2025/03/25	RIFAPENTINE/ISONIAZID 300/300 ADCO	Tablet	Adcock Ingram Limited	EACH TABLET CONTAINS RIFAPENTINE 300,0 mg ISONIAZID 300,0 mg	Annexure A
19/17.1/13	2025/03/25	TIAMULIN 100 mg/g PREMIX HUVE	Granules	Huvepharma South Africa (Pty) Ltd	EACH 1,0 g PREMIX CONTAINS TIAMULIN HYDROGEN FUMARATE 100,0 mg	Annexure A
21/17.1.6/27	2025/03/25	KARIFLOXX 100 mg/ml	Oral Solution	Biotech Laboratories (Pty) Ltd	EACH 1,0 ml SOLUTION CONTAINS ENROFLOXACIN 100,0 mg	Annexure A
23/14.3/05	2025/02/25	MOMETAMAX FORTE	Ear Drops	Intervet South Africa (Pty) Ltd	EACH 0,8 ml SUSPENSION CONTAINS GENTAMICIN SULFATE EQUIVALENT TO GENTAMICIN 6,88 mg; POSACONAZOLE 2,08 mg; MOMETASONE FUROATE MONOHYDRATE EQUIVALENT TO MOMETASONE 1,68 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/QJS document must be maintained and must be consistent with the current approved information.
57. For medicines NOT required to have a Risk Management Plan (RMP) as a condition of registration as per the latest RMP Guideline:
 - i. Registration of this medicine shall be subjected to routine pharmacovigilance and risk-minimisation activities as outlined in the latest RMP Guideline. Where specific safety concerns arise, additional pharmacovigilance and risk-minimisation activities designed to address these safety concerns may be imposed.
58. For medicines required to have an RMP as a condition of registration as per the latest RMP Guideline:
 - i. Registration of this medicine is subjected to an approved RMP for implementation as per the latest RMP Guideline. The applicant shall conform to all pharmacovigilance activities specified in the updated RMP that has been accepted by SAHPRA.

Annexure B

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.
54. The SCORE/QOS/QJS document must be maintained and must be consistent with the current approved information.
57. For medicines NOT required to have a Risk Management Plan (RMP) as a condition of registration as per the latest RMP Guideline:
 - i. Registration of this medicine shall be subjected to routine pharmacovigilance and risk-minimisation activities as outlined in the latest RMP Guideline. Where specific safety concerns arise, additional pharmacovigilance and risk-minimisation activities designed to address these safety concerns may be imposed.
58. For medicines required to have an RMP as a condition of registration as per the latest RMP Guideline:
 - i. Registration of this medicine is subjected to an approved RMP for implementation as per the latest RMP Guideline. The applicant shall conform to all pharmacovigilance activities specified in the updated RMP that has been accepted by SAHPRA.