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# Contents

# NOTIFICATION OF REGISTRATION OF MEDICINES IN TERMS OF SECTION 17 OF THE MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT 101 OF 1965)

| Registration Number | Date Registered | Product name | Dosage form | Applicant | API | Conditions of Registrations |
|---|---|---|---|---|---|---|
| 45/2.5/0938 | 2021/01/26 | CONVULEX CR 300 | TABLET | TAKEDA (PTY) LTD | EACH TABLET CONTAINS SODIUM VALPROATE 300,0 mg | Annexure A |
| 45/2.5/0947 | 2021/01/26 | CONVULEX CR 500 | TABLET | TAKEDA (PTY) LTD | EACH TABLET CONTAINS SODIUM VALPROATE 500,0 mg | Annexure A |
| 53/20.2.8/0484 | 2021/01/26 | TAFTRIMYL | TABLET | XIXIA PHARMACEUTICALS (PTY) LTD | EACH TABLET CONTAINS DOLUTEGRAVIR 50,0 mg; EMTRICITABINE 200,0 mg; TENOFOVIR ALAFENAMIDE 25,0 mg | Annexure A |
| 53/20.2.8/0485.484 | 2021/01/26 | MYLATAF | TABLET | XIXIA PHARMACEUTICALS (PTY) LTD | EACH TABLET CONTAINS DOLUTEGRAVIR 50,0 mg; EMTRICITABINE 200,0 mg; TENOFOVIR ALAFENAMIDE 25,0 mg | Annexure A |
| 53/20.2.8/0468 | 2021/01/21 | KOMYCITAF | TABLET | MYLAN (PTY) LTD | EACH TABLET CONTAINS DOLUTEGRAVIR 50,0 mg; EMTRICITABINE 200,0 mg; TENOFOVIR ALAFENAMIDE 25,0 mg | Annexure A |
| 53/20.2.8/0469.468 | 2021/01/21 | DOLTRITAF | TABLET | MYLAN (PTY) LTD | EACH TABLET CONTAINS DOLUTEGRAVIR 50,0 mg; EMTRICITABINE 200,0 mg; TENOFOVIR ALAFENAMIDE 25,0 mg | Annexure A |
| 53/30.5/0223 | 2021/01/21 | XEOMIN 50 UNITS | INJECTION | AUSTELL PHARMACEUTICALS (PTY) LTD | EACH VIAL CONTAINS BOTULINUM NEUROTOXIN TYPE A 50,0 UNITS | Annexure A |
| 53/30.5/0224 | 2021/01/21 | XEOMIN 100 UNITS | INJECTION | AUSTELL PHARMACEUTICALS (PTY) LTD | EACH VIAL CONTAINS BOTULINUM NEUROTOXIN TYPE A 100,0 UNITS | Annexure A |
| 51/13.12/0879 | 2021/01/26 | DUPIXENT | INJECTION | SANOFI-AVENTIS SOUTH AFRICA (PTY) LTD | EACH 2,0 ml SOLUTION CONTAINS DUPILUMAB 300,0 mg | Annexure A |
| 51/13.12/0880 | 2021/01/26 | DUBRANTIS | INJECTION | SANOFI-AVENTIS SOUTH AFRICA (PTY) LTD | EACH 2,0 ml SOLUTION CONTAINS DUPILUMAB 300,0 mg | Annexure A |
| 54/27/347 | 2021/02/09 | DEFKEM 125 | TABLET | ALKEM LABORATORIES (PTY) LTD | EACH DISPERSIBLE TABLET CONTAINS DEFERASIROX 125,0 mg | Annexure A |
| 54/27/348 | 2021/02/09 | DEFKEM 250 | TABLET | ALKEM LABORATORIES (PTY) LTD | EACH DISPERSIBLE TABLET CONTAINS DEFERASIROX 250,0 mg | Annexure A |
| 54/27/349 | 2021/02/09 | DEFKEM 500 | TABLET | ALKEM LABORATORIES (PTY) LTD | EACH DISPERSIBLE TABLET CONTAINS DEFERASIROX 500,0 mg | Annexure A |
| 54/27/350.347 | 2021/02/09 | DEFERASIROX 125 ALKEM | TABLET | ALKEM LABORATORIES (PTY) LTD | EACH DISPERSIBLE TABLET CONTAINS DEFERASIROX 125,0 mg | Annexure A |

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| 54/27/351.348 | 2021/02/09 | DEFERASIROX 250 ALKEM | TABLET | ALKEM LABORATORIES (PTY) LTD | EACH DISPERSIBLE TABLET CONTAINS DEFERASIROX 250,0 mg | Annexure A |
| 54/27/352.349 | 2021/02/09 | DEFERASIROX 500 ALKEM | TABLET | ALKEM LABORATORIES (PTY) LTD | EACH DISPERSIBLE TABLET CONTAINS DEFERASIROX 500,0 mg | Annexure A |
| 54/17.1/0866 | 2021/02/09 | MERAXT 10 mg/ml | INJECTION | KAHMA BIOTECH (PTY) LTD | EACH 5,0 ml CONTAINS ROCURONIUM BROMIDE 50,0 mg | Annexure A |
| 55/20.2.8/0333 | 2021/02/09 | XOFLUZA 20 mg | TABLET | ROCHE PRODUCTS (PTY) LTD | EACH TABLET CONTAINS BALOXAVIR MARBOXIL 20,0 mg | Annexure A |
| 55/20.2.8/0334 | 2021/02/09 | XOFLUZA 40 mg | TABLET | ROCHE PRODUCTS (PTY) LTD | EACH TABLET CONTAINS BALOXAVIR MARBOXIL 40,0 mg | Annexure A |
| 55/8.2/0053 | 2021/02/09 | ZYQUIS 2,5 | TABLET | ZYDUS HEALTHCARE SA (PTY) LTD | EACH TABLET CONTAINS APIXABAN 2,5 mg | Annexure A |
| 55/8.2/0054 | 2021/02/09 | ZYQUIS 5 | TABLET | ZYDUS HEALTHCARE SA (PTY) LTD | EACH TABLET CONTAINS APIXABAN 5 mg | Annexure A |
| 55/8.2/0055.053 | 2021/02/09 | APIXABAN 2,5 ZYDUS | TABLET | ZYDUS HEALTHCARE SA (PTY) LTD | EACH TABLET CONTAINS APIXABAN 2,5 mg | Annexure A |
| 55/8.2/0056.054 | 2021/02/09 | APIXABAN 5 ZYDUS | TABLET | ZYDUS HEALTHCARE SA (PTY) LTD | EACH TABLET CONTAINS APIXABAN 5 mg | Annexure A |
| 55/20.2.8/0111 | 2021/02/09 | VIRLAM | TABLET | PHARMA DYNAMICS (PTY) LTD | EACH TABLET CONTAINS LAMIVUDINE 300,0 mg AND TENOFOVIR DISOPROXIL FUMARATE 300,0 mg | Annexure A |
| 54/21.5.1/0111.109 | 2021/02/16 | SEREFLO DPI 50/100 | INHALATION | CIPLA MEDPRO (PTY) LTD | EACH BLISTER CONTAINS SALMETEROL XINAFOATE 50,0 ug AND FLUTICASONE PROPIONATE 100,0 ug | Annexure A |
| 54/21.5.1/0112.110 | 2021/02/16 | SEREFLO DPI 50/250 | INHALATION | CIPLA MEDPRO (PTY) LTD | EACH BLISTER CONTAINS SALMETEROL XINAFOATE 50,0 ug AND FLUTICASONE PROPIONATE 250,0 ug | Annexure A |
| 55/16.5/0135 | 2021/02/16 | CEPACOL ANTI-INFLAMMATORY MOUTHWASH | SOLUTION | ADCOCK INGRAM LIMITED | EACH 15,0 ml SOLUTION CONTAINS BENZYDAMINE HYDROCHLORIDE 22,5 mg | Annexure A |
| 18/21/02 | 2021/02/23 | ATOPICA 100 mg/ML ORAL SOLUTION FOR CATS AND DOGS | SOLUTION | ELI LILLY SA (PTY) LTD | EACH 1,0 ml SOLUTION CONTAINS CICLOSPORIN 100,0 mg | Annexure A |
| 53/5.3/0046 | 2021/02/23 | DONECEPT ODT 5 | TABLET | CIPLA MEDPRO (PTY) LTD | EACH TABLET CONTAINS DONEPEZIL HYDROCHLORIDE 5,0 mg | Annexure A |
| 53/5.3/0047 | 2021/02/23 | DONECEPT ODT 10 | TABLET | CIPLA MEDPRO (PTY) LTD | EACH TABLET CONTAINS DONEPEZIL HYDROCHLORIDE 10,0 mg | Annexure A |
| 53/20.2.8/0184 | 2021/02/23 | ZIDOCOMB 150/300 | TABLET | iPHARMA (PTY) LTD | EACH TABLET CONTAINS LAMIVUDINE 150,0 mg AND ZIDOVUDINE 300,0 mg | Annexure A |
| 53/34/0489 | 2021/02/23 | EVERZOR 2,5 | TABLET | ADCOCK INGRAM LIMITED | EACH TABLET CONTAINS EVEROLIMUS 2,5 mg | Annexure A |
| 53/34/0490 | 2021/02/23 | EVERZOR 5 | TABLET | ADCOCK INGRAM LIMITED | EACH TABLET CONTAINS EVEROLIMUS 5 mg | Annexure A |
| 53/34/0491 | 2021/02/23 | EVERZOR 10 | TABLET | ADCOCK INGRAM LIMITED | EACH TABLET CONTAINS EVEROLIMUS 10 mg | Annexure A |

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| 53/34/0492.489 | 2021/02/23 | EVEROLIMUS 2,5 ADCO | TABLET | ADCOCK INGRAM LIMITED | EACH TABLET CONTAINS EVEROLIMUS 2,5 mg | Annexure A |
| 53/34/0493.490 | 2021/02/23 | EVEROLIMUS 5 ADCO | TABLET | ADCOCK INGRAM LIMITED | EACH TABLET CONTAINS EVEROLIMUS 5 mg | Annexure A |
| 53/34/0494.491 | 2021/02/23 | EVEROLIMUS 10 ADCO | TABLET | ADCOCK INGRAM LIMITED | EACH TABLET CONTAINS EVEROLIMUS 10 mg | Annexure A |
| 53/30.1/0502 | 2021/02/23 | REMIFLIX | INFUSION | CIPLA MEDPRO (PTY) LTD | EACH VIAL CONTAINS INFLIXIMAB 100,0 mg | Annexure A |
| 53/30.3/0726 | 2021/02/23 | NUWIQ 250 IU | INJECTION | OCTAPHARMA SOUTH AFRICA (PTY) LTD | EACH VIAL CONTAINS HUMAN COAGULATION FACTOR VIII (rDNA) SIMOCTOCOG ALFA 250 IU | Annexure A |
| 53/30.3/0727 | 2021/02/23 | NUWIQ 500 IU | INJECTION | OCTAPHARMA SOUTH AFRICA (PTY) LTD | EACH VIAL CONTAINS HUMAN COAGULATION FACTOR VIII (rDNA) SIMOCTOCOG ALFA 500 IU | Annexure A |
| 53/30.3/0728 | 2021/02/23 | NUWIQ 1 000 IU | INJECTION | OCTAPHARMA SOUTH AFRICA (PTY) LTD | EACH VIAL CONTAINS HUMAN COAGULATION FACTOR VIII (rDNA) SIMOCTOCOG ALFA 1 000 IU | Annexure A |
| 53/30.3/0729 | 2021/02/23 | NUWIQ 2 000 IU | INJECTION | OCTAPHARMA SOUTH AFRICA (PTY) LTD | EACH VIAL CONTAINS HUMAN COAGULATION FACTOR VIII (rDNA) SIMOCTOCOG ALFA 2 000 IU | Annexure A |
| 54/30.1/0001 | 2021/02/23 | IMFINZI 120 mg | SOLUTION | ASTRAZENECA PHARMACEUTICALS (PTY) LTD | EACH 2,4 ml CONTAINS DURVALUMAB 120,0 mg | Annexure A |
| 54/30.1/0002 | 2021/02/23 | IMFINZI 500 mg | SOLUTION | ASTRAZENECA PHARMACEUTICALS (PTY) LTD | EACH 10,0 ml CONTAINS DURVALUMAB 500,0 mg | Annexure A |
| 54/30.1/0003.001 | 2021/02/23 | FIDURSI 120 mg | SOLUTION | ASTRAZENECA PHARMACEUTICALS (PTY) LTD | EACH 2,4 ml CONTAINS DURVALUMAB 120,0 mg | Annexure A |
| 54/30.1/0004.002 | 2021/02/23 | FIDURSI 500 mg | SOLUTION | ASTRAZENECA PHARMACEUTICALS (PTY) LTD | EACH 10,0 ml CONTAINS DURVALUMAB 500,0 mg | Annexure A |
| 54/7.5/0137 | 2021/02/23 | EZIMVA 10/10 | TABLET | ALKEM LABORATORIES (PTY) LTD | EACH TABLET CONTAINS EZETIMIBE 10,0 mg AND SIMVASTATIN 10 mg | Annexure A |
| 54/7.5/0138 | 2021/02/23 | EZIMVA 10/20 | TABLET | ALKEM LABORATORIES (PTY) LTD | EACH TABLET CONTAINS EZETIMIBE 10,0 mg AND SIMVASTATIN 20 mg | Annexure A |
| 54/7.5/0139 | 2021/02/23 | EZIMVA 10/40 | TABLET | ALKEM LABORATORIES (PTY) LTD | EACH TABLET CONTAINS EZETIMIBE 10,0 mg AND SIMVASTATIN 40 mg | Annexure A |
| 54/7.5/0140 | 2021/02/23 | EZIMVA 10/80 | TABLET | ALKEM LABORATORIES (PTY) LTD | EACH TABLET CONTAINS EZETIMIBE 10,0 mg AND SIMVASTATIN 80 mg | Annexure A |
| 54/7.5/0141.137 | 2021/02/23 | EZETIMIBE SIMVASTATIN ALKEM 10 mg/10 mg | TABLET | ALKEM LABORATORIES (PTY) LTD | EACH TABLET CONTAINS EZETIMIBE 10,0 mg AND SIMVASTATIN 10 mg | Annexure A |
| 54/7.5/0142.138 | 2021/02/23 | EZETIMIBE SIMVASTATIN ALKEM 10 mg/20 mg | TABLET | ALKEM LABORATORIES (PTY) LTD | EACH TABLET CONTAINS EZETIMIBE 10,0 mg AND SIMVASTATIN 20 mg | Annexure A |
| 54/7.5/0143.139 | 2021/02/23 | EZETIMIBE SIMVASTATIN ALKEM 10 mg/40 mg | TABLET | ALKEM LABORATORIES (PTY) LTD | EACH TABLET CONTAINS EZETIMIBE 10,0 mg AND SIMVASTATIN 40 mg | Annexure A |
| 54/7.5/0144.140 | 2021/02/23 | EZETIMIBE SIMVASTATIN ALKEM 10 mg/80 mg | TABLET | ALKEM LABORATORIES (PTY) LTD | EACH TABLET CONTAINS EZETIMIBE 10,0 mg AND SIMVASTATIN 80 mg | Annexure A |
| 54/30.1/0765 | 2021/02/23 | FASENRA 30 mg | SOLUTION | ASTRAZENECA PHARMACEUTICALS (PTY) LTD | EACH 1,0 ml SOLUTION CONTAINS BENRALIZUMAB 30,0 mg | Annexure A |

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| 54/30.1/0766.765 | 2021/02/23 | ARLISPO 30 mg | SOLUTION | ASTRAZENECA PHARMACEUTICALS (PTY) LTD | EACH 1,0 ml SOLUTION CONTAINS BENRALIZUMAB 30,0 mg | Annexure A |
| 15/3.1.2.1/09 | 2021/03/02 | METACAM 0,5 mg ORAL SUSPENSION FOR CATS | SOLUTION | BOEHRINGER INGELHEIM ANIMAL HEALTH SA (PTY) LTD | EACH 1,0 ml SOLUTION CONTAINS MELOXICAM 0,5 mg | Annexure A |
| 20/5.3.2/12 | 2021/03/02 | SEMINTRA 10 mg/ml | SOLUTION | BOEHRINGER INGELHEIM ANIMAL HEALTH SA (PTY) LTD | EACH 1,0 ml SOLUTION CONTAINS TELMISARTAN 10,0 mg | Annexure A |
| 53/20.1.2/0464 | 2021/03/02 | CO-AMOXYCLAV BD AUSTELL | TABLET | AUSTELL PHARMACEUTICALS (PTY) LTD | EACH TABLET CONTAINS AMOXICILLIN TRIHYDRATE 875,0 mg AND POTASSIUM CLAVULANATE 125,0 mg | Annexure A |
| 53/20.1.2/0465 | 2021/03/02 | CO-AMOXYCLAV BD CAMOX | TABLET | AUSTELL PHARMACEUTICALS (PTY) LTD | EACH TABLET CONTAINS AMOXICILLIN TRIHYDRATE 875,0 mg AND POTASSIUM CLAVULANATE 125,0 mg | Annexure A |
| 53/20.1.2/0466 | 2021/03/02 | AVUTAN 1 000 BD | TABLET | AUSTELL PHARMACEUTICALS (PTY) LTD | EACH TABLET CONTAINS AMOXICILLIN TRIHYDRATE 875,0 mg AND POTASSIUM CLAVULANATE 125,0 mg | Annexure A |
| 53/22.1.4/0677 | 2021/03/02 | ZODORAY 1 ug | CAPSULE | STRIDES PHARMA SA (PTY) LTD | EACH CAPSULE CONTAINS ALFACALCIDOL 1,0 ug | Annexure A |
| 53/22.1.4/0678 | 2021/03/02 | ZODORAY 0,5 ug | CAPSULE | STRIDES PHARMA SA (PTY) LTD | EACH CAPSULE CONTAINS ALFACALCIDOL 0,5 ug | Annexure A |
| 53/22.1.4/0679 | 2021/03/02 | ZODORAY 0,25 ug | CAPSULE | STRIDES PHARMA SA (PTY) LTD | EACH CAPSULE CONTAINS ALFACALCIDOL 0,25 ug | Annexure A |
| 53/22.1.4/0680.677 | 2021/03/02 | CALCILOS 1 ug | CAPSULE | STRIDES PHARMA SA (PTY) LTD | EACH CAPSULE CONTAINS ALFACALCIDOL 1,0 ug | Annexure A |
| 53/22.1.4/0681.678 | 2021/03/02 | CALCILOS 0,5 ug | CAPSULE | STRIDES PHARMA SA (PTY) LTD | EACH CAPSULE CONTAINS ALFACALCIDOL 0,5 ug | Annexure A |
| 53/22.1.4/0682.679 | 2021/03/02 | CALCILOS 0,25 ug | CAPSULE | STRIDES PHARMA SA (PTY) LTD | EACH CAPSULE CONTAINS ALFACALCIDOL 0,25 ug | Annexure A |
| 54/34/0425 | 2021/03/02 | OCTREOTIDE TEVA 10 mg | INJECTION | TEVA PHARMACEUTICALS (PTY) LTD | EACH VIAL CONTAINS OCTREOTIDE ACETATE 10,0 mg | Annexure A |
| 54/34/0426 | 2021/03/02 | OCTREOTIDE TEVA 20 mg | INJECTION | TEVA PHARMACEUTICALS (PTY) LTD | EACH VIAL CONTAINS OCTREOTIDE ACETATE 20,0 mg | Annexure A |
| 54/34/0427 | 2021/03/02 | OCTREOTIDE TEVA 30 mg | INJECTION | TEVA PHARMACEUTICALS (PTY) LTD | EACH VIAL CONTAINS OCTREOTIDE ACETATE 30,0 mg | Annexure A |
| 15/3.1.2.2/05 | 2021/03/09 | INFLACAM 330 mg/SACHET | GRANULES | VIRBAC RSA (PTY) LTD | EACH SACHET CONTAINS MELOXICAM 330,0 mg | Annexure A |
| 17/17.1.4/06 | 2021/03/09 | DRAXXIN 25 | INJECTION | ZOETIS SOUTH AFRICA (PTY) LTD | EACH 1,0 ml SOLUTION CONTAINS TULATHROMYCIN 25,0 mg | Annexure A |
| 54/26/0265 | 2021/03/09 | TANICEP 500 | TABLET | HETERO DRUGS SOUTH AFRICA (PTY) LTD | EACH TABLET CONTAINS CAPECITABINE 500,0 mg | Annexure A |
| 54/26/0266.265 | 2021/03/09 | BINECAP 500 | TABLET | HETERO DRUGS SOUTH AFRICA (PTY) LTD | EACH TABLET CONTAINS CAPECITABINE 500,0 mg | Annexure A |

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| 54/26/0267.265 | 2021/03/09 | CAPTERO 500 | TABLET | HETERO DRUGS SOUTH AFRICA (PTY) LTD | EACH TABLET CONTAINS CAPECITABINE 500,0 mg | Annexure A |
| 54.20.2.8/0407 | 2021/03/16 | DOVIPSA | TABLET | GLAXOSMITHKLINE SOUTH AFRICA (PTY) LTD | EACH TABLET CONTAINS DOLUTEGRAVIR 50,0 mg AND LAMIVUDINE 300,0 mg | Annexure A |
| 54/1.2/0589 | 2021/03/16 | DULOXETINE MR 30 UNICORN | CAPSULE | UNICORN PHARMACEUTICALS (PTY) LTD | EACH CAPSULE CONTAINS DULOXETINE HYDROCHLORIDE 30,0 mg | Annexure A |
| 54/1.2/0590 | 2021/03/16 | DULOXETINE MR 60 UNICORN | CAPSULE | UNICORN PHARMACEUTICALS (PTY) LTD | EACH CAPSULE CONTAINS DULOXETINE HYDROCHLORIDE 60,0 mg | Annexure A |
| 54/20.2.3/0655 | 2021/03/16 | PRETOMANID MYLAN | TABLET | MYLAN (PTY) LTD | EACH TABLET CONTAINS PRETOMANID 200,0 mg | Annexure A |
| 54/20.2.3/0656.655 | 2021/03/16 | MYPRETO | TABLET | MYLAN (PTY) LTD | EACH TABLET CONTAINS PRETOMANID 200,0 mg | Annexure A |
| 54/20.2.3/0657.655 | 2021/03/16 | PRETAMYL | TABLET | MYLAN (PTY) LTD | EACH TABLET CONTAINS PRETOMANID 200,0 mg | Annexure A |
| 54/20.2.8/0377 | 2021/03/30 | RITOVAZ | TABLET | RANBAXY PHARMACEUTICALS (PTY) LTD | EACH TABLET CONTAINS ATAZANAVIR 300,0 mg AND RITONAVIR 100,0 mg | Annexure A |
| 55/26/0297 | 2021/03/30 | IMBRUVICA 140 | TABLET | JANSSEN PHARMACEUTICA (PTY) LTD | EACH TABLET CONTAINS IBRUTINIB 140,0 mg | Annexure A |
| 55/26/0298 | 2021/03/30 | IMBRUVICA 280 | TABLET | JANSSEN PHARMACEUTICA (PTY) LTD | EACH TABLET CONTAINS IBRUTINIB 280,0 mg | Annexure A |
| 55/26/0299 | 2021/03/30 | IMBRUVICA 420 | TABLET | JANSSEN PHARMACEUTICA (PTY) LTD | EACH TABLET CONTAINS IBRUTINIB 420,0 mg | Annexure A |
| 55/26/0300 | 2021/03/30 | IMBRUVICA 560 | TABLET | JANSSEN PHARMACEUTICA (PTY) LTD | EACH TABLET CONTAINS IBRUTINIB 560,0 mg | Annexure A |
| 53/21.2/0227 | 2021/03/30 | METFORMIN TEVA ER 500 | TABLET | TEVA PHARMACEUTICALS (PTY) LTD | EACH TABLET CONTAINS METFORMIN HYDROCHLORIDE 500,0 mg | Annexure A |
| 53/21.2/0228 | 2021/03/30 | METFORMIN TEVA ER 750 | TABLET | TEVA PHARMACEUTICALS (PTY) LTD | EACH TABLET CONTAINS METFORMIN HYDROCHLORIDE 750,0 mg | Annexure A |
| 53/21.2/0229 | 2021/03/30 | METFORMIN TEVA ER 1 000 | TABLET | TEVA PHARMACEUTICALS (PTY) LTD | EACH TABLET CONTAINS METFORMIN HYDROCHLORIDE 1 000,0 mg | Annexure A |
| 54/34/0338 | 2021/03/30 | FINGOLIMOD ALKEM | CAPSULE | ALKEM LABORATORIES (PTY) LTD | EACH CAPSULE CONTAINS FINGOLIMOD 0,5 mg | Annexure A |
| 54/34/0339.338 | 2021/03/30 | FINKEM | CAPSULE | ALKEM LABORATORIES (PTY) LTD | EACH CAPSULE CONTAINS FINGOLIMOD 0,5 mg | Annexure A |
| 55/30.5/0849 | 2021/03/30 | JANSSEN COVID-19 VACCINE | INJECTION | JANSSEN PHARMACEUTICA (PTY) LTD | EACH 0,5 ml DOSE CONTAINS Ad26.COV2.S, RECOMBINANT 5 x $10^{10}$ VIRUS PARTICLES | Annexure B |

## ANNEXURE A

### CONDITIONS OF REGISTRATIONS

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.

## ANNEXURE B

### CONDITIONS OF REGISTRATION

1. That the vaccine be supplied in accordance with the NDoH Covid -19 vaccination plan.
2. The applicant shall ensure that the medicine is manufactured and controlled in terms of current Good Manufacturing Practices as determined by SAHPRA.
3. 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.
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 product may be advertised to the professions only.
7. The submitted PI and PIL is in global format and has been provisionally accepted, however the PI and PIL should be aligned with the South African labelling requirements and be compliant with the requirements of the Legal Metrology Act, 2014. This update should be provided within 12 months from the date of approval.
8. Risk Management Plan: The reporting of suspected adverse effects should be according to SAHPRA guidelines and in line with the applicant's risk management plan (RMP). The applicant should submit a RMP that addresses the South African Pharmacovigilance Procedures and South African specific COVID-19 risks. This RMP should be submitted within 90 days from the date of regulatory approval, these should include:
   - epidemiology of COVID-19 in South Africa,
   - persons living with HIV,
   - persons with tuberculosis,
   - and the efficacy of the vaccine in populations exposed to SARS-CoV-2 variants, particularly 501Y.V2.

   The RMP should also have a protocol indicating how breakthrough infections will be detected, investigated and reported.

9. The applicant should provide Periodic Safety Update Reports as per the SAHPRA guidelines. The applicant should submit the first PSUR within 6 months of registration. The applicant shall conform to all pharmacovigilance activities specified in the updated RMP that has been accepted by SAHPRA.
10. The applicant must inform SAHPRA of any correspondence pertaining to the quality, safety and efficacy of the vaccine that is submitted to, or is a response to, queries raised by the EMA or other African Regulatory Authorities.
11. The applicant must inform SAHPRA on the company's response, as they become available, to the list of recommendations included in the CHMP Assessment Report dated 11 March 2021.
12. The applicant must promptly provide to SAHPRA any further data from studies, recommendations or guidance that is generated by them, or which otherwise come into their possession, which is relevant to the risk / benefit profile of the product and/or is relevant to the conditions of use.
13. All vaccine lots (imported and locally manufactured) destined for the South African market is subject to lot release by the South African National Control Laboratory. General guidance for lot release is provided in the Lot Release Guideline for COVID –19 Vaccines available on the SAHPRA website.
14. The applicant is to submit the latest product quality review for the vaccine as it becomes available.
15. Shelf life and stability:

    a.) Module 3.2.S: Active Substance

    A provisional 24-months shelf life is approved for the Active substance for storage at -80 (-5/+10) °C to -50 (+/-10) °C in sterile (gamma irradiated) 10 L polycarbonate bottles, each fitted with a silicone stopper assembly and polycarbonate dip tube. Applicant must inform SAHPRA if an out-of-specification is observed for any shelf-life parameter of the 7 batches currently on stability.

    Stability data updates must be submitted on a 6-monthly basis until the 24 months provisional shelf life for the active substance has been confirmed.

    b.) Module 3.2.P: Final Product

    A provisional 24-months shelf life for the product filled into Type I glass vials with grey chlorobutyl rubber stoppers and sealed with aluminium flip-off seals for storage at -25°C to -15°C, with a 3 months storage period at 2 to 8 °C during its long-term shelf life after which it must be discarded, is approved. Applicant must submit stability data on batches that are currently in the ongoing stability program and must inform the SAHPRA if an out-of-specification is observed for any of the batches on long term stability.

    Stability data updates must be submitted on a 6-monthly basis until the 24 months provisional shelf life for the final product has been confirmed.
16. As the rolling submissions were not aligned with the ZA CTD format requirements, the applicant is required to provide an update of the product submission to ZA CTD format. This is subject to review within12 months of the conditional registration

## DEPARTMENT OF JUSTICE AND CONSTITUTIONAL DEVELOPMENT

**NO. R. 680** **6 August 2021**

### LEGAL AID SOUTH AFRICA ACT, 2014: AMENDMENT OF REGULATIONS

The Minister of Justice and Correctional Services has, under section 23(1) of the Legal Aid South Africa Act, 2014 (Act No. 39 of 2014), after receipt of recommendations of the Board of Directors of Legal Aid South Africa, made the regulations in the Schedule.

### SCHEDULE

**Definitions**

**1.** In this Schedule, the "Regulations" means the regulations published under Government Notice No. R. 745 of 26 July 2017, as amended by Government Notice No. R. 498 of 29 March 2019.

**Amendment of regulation 9 of Regulations**

**2.** Regulation 9 of the Regulations is hereby amended—

(*a*) by the substitution in subregulation (1) for the words preceding paragraph (*a*) of the following words:

"(1) Legal Aid South Africa may grant legal aid to a litigant in any civil matter, with or without a waiting period, where—"; and

(*b*) by the addition after subregulation (5) of the following subregulation:

"(6) In the event that a waiting period referred to in subregulation (1) is applied, Legal Aid South Africa must prioritise civil matters which have a significant impact on clients' lives, including, but not limited to, the following matters:

(*a*) Civil proceedings involving children;
(*b*) evictions;
(*c*) social security matters;
(*d*) educational matters: and
(*e*) income related matters, such as employment or dismissals, pension and related funds and maintenance.".

**Amendment of regulation 11 of Regulations**

**3.** Regulation 11 of the Regulations is hereby amended by the substitution for subregulation (3) of the following subregulation:

"(3) Subject to regulation 23(8), legal aid may not be granted for any action that can be brought in a small claims court in terms of the Small Claims Courts Act, 1984 (Act No. 61 of 1984): Provided that Legal Aid South Africa may grant legal aid for a claim that exceeds the monetary jurisdiction of the small claims court by more than 50 percent.".

**Amendment of regulation 13 of Regulations**

**4.** Regulation 13 of the Regulations is hereby amended—

(*a*) by the substitution for subregulation (1) of the following subregulation:

"(1) In a maintenance case in terms of the Maintenance Act, 1998 (Act No. 99 of 1998), a domestic violence case in terms of the Domestic Violence Act, 1998 (Act No. 116 of 1998), or a matter brought in terms of the Protection from Harassment Act, 2011 (Act No. 17 of 2011), Legal Aid South Africa may grant legal aid to a legal aid applicant for an initial consultation to advise him or her on his or her rights, the procedure he or she can follow and his or her prospects of success."; and

(*b*) by the substitution for subregulation (2) of the following subregulation:

"(2) Legal aid may be granted for legal representation in a court hearing for matters referred to in subregulation (1), if—

*(a)* in the opinion of Legal Aid South Africa, the legal aid applicant's claim or defence has good prospects of success; and

*(b)* the—

(i) opposing party is represented by a legal practitioner or is a legal practitioner; or

(ii) the legal aid applicant is over 60 years of age or disabled.".

**Amendment of regulation 14 of Regulations**

**5.** Regulation 14 of the Regulations is hereby amended by the substitution in subregulation (1) for paragraph (*c*) of the following paragraph:

"(*c*) assistance to enforce an award by the Commission for Conciliation, Mediation and Arbitration established in terms of the Labour Relations Act, 1995, where the Commission for Conciliation, Mediation and Arbitration has already instructed a sheriff at its own cost and a sheriff has been unable to successfully execute, except where there is no prospect of recovery.".

**Amendment of regulation 15 of Regulations**

**6.** Regulation 15 of the Regulations is hereby amended by the substitution for subregulation (2) of the following subregulation:

"(2) Legal Aid South Africa may not grant legal aid for the following matters:

*(a)* A divorce appeal;

*(b)* a divorce action if the legal aid applicant married a foreigner to enable that foreigner to obtain South African citizenship; and

*(c)* a divorce action where there is—

(i) no allegation of domestic abuse;

(ii) no child, including a disabled or intellectually challenged child;

(iii) no immovable property as part of the joint estate;

(iv) no pension interest as part of the joint assets; or

(v) any other substantial benefit in the joint estate.".

**Amendment of regulation 23 of Regulations**

**7.** Regulation 23 of the Regulations is hereby amended by the substitution for subregulation (8) of the following subregulation:

"(8) Legal aid may be granted to a child for a monetary claim that falls within the small claims court monetary jurisdiction where it is required to protect the best interests of that child and if substantial injustice would otherwise result.".

**Amendment of regulation 27 of Regulations**

**8.** Regulation 27 of the Regulations is hereby amended by the addition after subregulation (6) of the following subregulation:

"(7) The amounts contemplated in subregulations (2), (3), (4), (5) and (6) will increase annually on 1 April on the basis of the Consumer Price Index, rounded off to the next 100.".

**Amendment of regulation 31 of Regulations**

**9.** Regulation 31 of the Regulations is hereby amended—

(*a*) by the substitution for subregulation (1) of the following subregulation:

"(1) If a legal aid applicant does not qualify for legal aid in terms of the means test, Legal Aid South Africa may provide partially subsidised legal aid and require from the legal aid applicant to contribute to the cost of the legal aid.";

(*b*) by the substitution in subregulation (2) for the full stop at the end of paragraph *(c)* of the expression "; and"; and

*(c)* by the addition in subregulation (2) after paragraph (*c*) of the following paragraph:

"(*d*) whether the requirements of regulation 9(1) are met, in civil matters.".

**Amendment of regulation 32 of Regulations**

**10.** Regulation 32 of the Regulations is hereby amended—

(*a*) by the substitution in subregulation (1) for paragraphs (*b*) and (*c*) of the following paragraphs:

"(*b*) cessation of the criminal trial;

(*c*) the accused is convicted and sentenced to direct imprisonment; or"; and

(*b*) by the addition after paragraph (*c*) of the following paragraph:

"(*d*) the finalisation of a civil matter,".

**TSEBISO YA MMUSO**
**LEFAPHA LA TOKA LE NTSHETSOPELE YA MOLAOTHEO**

**THUSO YA MOLAO AFRIKA BORWA, 2014 (MOLAO 39 WA 2014): MELAO**

Letona la Toka le Ditshebeletso tsa Tlhabollo ya batshwaruwa le entse melao Shejuleng ka tlasa karolo 23(1) ya Thuso ya Molao Afrika Borwa, 2014 (Molao 39 wa 2014), ka mora ho fumana dikgothaletso tsa Balaodi ba Lekgotla.

**SHEJULE**

**Ditlhaloso**

**1.** Shejuleng sena, "Melao" e hlalosa melao e phatlaladitsweng ka tlasa Tsebiso ya Mmuso Palo. R. 745 ya la 26 Phupu 2017, jwalo ka ha e lokisitswe ka Tsebiso ya Mmuso ya Palo. R. 498 ya la 29 Hlakubele 2019.

**Tokiso ya molao 9 ho Melao**

**2.** Molao 9 ho Melao o lokisitswe—

(*a*) ka phetolo ho molawana (1) bakeng la mantswe a etelletseng pele temana *(a)* ya mantswe a latelang:

"(1) Thuso ya Molao Afrika Borwa e ka nehelana ka thusa ya molao ho motletlebi nyeweng e nngwe le e nngwe ya baahi, ka, kapa ntle le nako ya kemo, moo—"; le

(*b*) ka ho kenngwa ka mora molawana (5) ya molawana o latelang:

"(6) Ha ho ka etsahala hore nako ya ho ema e hlalositsweng molawaneng (1) e kenngwe tshebetsong, Thuso ya Molao Afrika Borwa e tshwanetse ho nka dintlha tsa baahi tse nang le sekgahla se seholo maphelong a bathusuwa e le tsa bohlokwa, ho akga ka hare dintlha tse latelang:

(*a*) Dinyewe tsa baahi tse akgang bana;
(*b*) ho ntshwa;
(*c*) dintlha tsa tshireletso ya baahi;
(*d*) dintlha tsa thuto: le
(*e*) dintlha tsa lekeno, jwalo ka mosebetsi kapa ho lelekwa, phenshene le ditjhelete tse amehang le tlhokome.".

**Tokiso ya molao 11 ho Melao**

**3.** Molao 11 ho Melao e lokisitswe ka phetolo molawaneng (3) ho melao e latelang:

"(3) Ho ipapisitswe le molao 23(8), thuso ya molao e ka se nehelwe bakeng la ketso e nngwe le e nngwe e ka tliswang lekgotleng la ditleleimi tse nyane ho latela *Small Claims Courts Act, 1984 (Act No. 61 of 1984)*: Ha feela Thuso ya Molao Afrika Borwa e ka nehelana ka thuso ya molao bakeng la tleleimi e fetang matla a tjhelete ya lekgotla la dinyewe la ditleleimi tse nyane ka diperesente tse fetang 50.".

**Tokiso ya molao 13 ho Melao**

**4.** Molao 13 ho Melao o lokisitswe—

(*a*) ka phetolo bakeng la molawana (1) ya molawana o latelang:

"(1) Nyeweng ya tlhokomelo ho latela *Maintenance Act, 1998 (Act No. 99 of 1998)*, nyeweng ya dikgoka tsa ka lapeng ho latela *Domestic Violence Act, 1998 (Act No. 116 of 1998)*, kapa ntlha e tlesitsweng ho latela *Protection from Harassment Act, 2011 (Act No. 17 of 2011)*, Thuso ya Molao Afrika Borwa e ka nehelana ka thuso ya molao ho mokopi wa thuso ya molao bakeng la kopano ya pele ho ka mo eletsa ka ditokelo tsa hae, tsamaiso eo a tshwanetseng ho e latela le kgonahalo ya hae ya tlholo."; le

(*b*) ka phetolo bakeng la molawana (2) ho molawana o latelang:

"(2) Thuso ya molao e ka nehelwa bakeng la kemedi ya molao ho mamelweng ha lekgotla la dinyewe ho dintlha tse hlalositsweng ho molawana (1), e bang—

*(a)* ho ya ka mohopolo wa Thuso ya Molao Afrika Borwa, tleleimi kapa boitshireletso ba mokopi wa thuso ya molao e na le kgonahalo e ntle ya tlholo;

*(b)* le—

(i) ya kgahlano ya emetsweng ke mosebeletsi wa molao kapa e le mosebeletsi wa molao;

(ii) mokopi wa thuso ya molao a le dilemo tse ka hodimo ho dilemo tse 60 kapa a na le boqhwala.".

**Tokiso ya molao 14 ho Melao**

**5.** Molao 14 ya Melao e fetotswe ka phetolo ho molawana (1) bakeng la temana *(c)* ka temana e latelang:

"(*c*) thuso bakeng la ho kenya tshebetsong sephetho sa Khomishene ya Poelano le Bonamodi e theuweng ho latela Molao wa Basebetsi wa 1995, moo Khomishene ya Poelano le Bonamodi e seng e laetse sherifi ka ditjeho tsa yona mme sherifi e sa kgona ho ka atleha tshebetsong ya hae, ntle le moo ho senang kgonahalo ya phumaneho.".

**Tokiso ya molao 15 ho Melao**

**6.** Molao 15 ho Melao e lokisitswe ka phetolo bakeng la molawana (2) wa molawana o latelang:

"(2) Thuso ya Molao Afrika Borwa e ka se nehelane ka thuso ya molao bakeng la dintlha tse latelang:

*(a)* boipiletso tlhalanong;

*(b)* nyewe ya tlhalano e bang mokopi wa thuso ya molao a nyalane le molata hore molata eo a fumane boahi ba Afrika Borwa; le

*(c)* tlhalano moo—

(i) ho senang tlhekefetso ya ka lapeng;

(ii) ho senang ngwana, ho akga ngwana wa seqhwala kapa ya nang le bothata ba kelelle;

(iii) ho senang thepa e sa sutheng e le karolo ya thepa ya kopanelo;

(iv) ho senang kgahleho ya phenshene e le karolo ya kopanelo ya thepa; kapa

(v) kuno e nngwe le enngwe e kgolo kopanelong ya thepa.".

**Tokiso ya molao 23 ho Melao**

**7.** Molao 23 ho Melao o lokisitswe ka phetolo bakeng la molawana (8) ho molawana o latelang:

"(8) Thuso ya molao e ka nehelwa ho ngwana bakeng la tleleimi ya tjhelete e welang ka tlasa matla a tjhelete a lekgotla la dinyewe la ditleleimi tse nyane moo ho hlokahalang ho sireletsa dikgahleho tsa ngwana eo mme toka e ka be e sa phethahala.".

**Tokiso ya molao 27 ho Melao**

**8.** Molao 27 o lokisitswe ka ho kenngwa ha molawana o latelang ka mora molawana (6):

"(7) Palo e hlalositsweng molawaneng (2), (3), (4), (5) le (6) e tla eketseha selemo le selemo ka la 1 Mmesa ka lebaka la Tshupane ya Theko ya Bareki, e akareditsweng ho 100 le latelang.".

**Tokiso ya molao 31 ho Melao**

**9.** Molao 31 ho Melao e lokisitswe—

(*a*) ka phetolo bakeng la molawana (1) wa molawana o latelang:

"(1) E bang mokopi wa thuso ya molao a sa dumellesehe ho ka thuswa ho latela teko e etswang, Thuso ya Molao Afrika Borwa e ka nehelana ka thuso e sa fellang ya molao mme e kope mokopi wa thuso ya molao ho kaba le seabo ditjehong tsa thuso ya molao.";

(*b*) ka phetolo ho molawana (2) bakeng la kgutlo qetellong ya temana *(c)* ho polelwana "; le"; le

*(c)* ka ho kenngwa ha molawana (2) ka mora temana *(c)* ka temana e latelang:

"(*d*) hore na ditlhoko tsa molao 9(1) di fihletswe, dinyeweng tsa baahi.".

**Tokiso ya molao 32 ho Melao**

**10.** Molao 32 ho Melao e lokisitswe—

(*a*) ka phetolo ho molawana (1) bakeng la temana *(b)* le *(c)* tsa ditemana tse latelang:

"(*b*) ho fediswa ha nyewe ya tlolo ya molao;

(*c*) moqosuwa o ahlotswe aba a kwallwa; kapa"; le

(*b*) ka ho kenngwa ka mora temana (*c*) ya temana e latelang:

"(*d*) phethelo nyeweng tsa baahi,".