DEPARTMENT OF HEALTH

NO. R. 679 **6 August 2021**

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

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

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

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

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