DEPARTMENT OF HEALTH

NO. R. 2382 **19 August 2022**

ANNEXURE A

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	API ingredients	Conditions of Registration
53/1.2/0732	2022/04/06	SPRAVATO	NASAL SPRAY	JANSSEN PHARMACEUTICA (PTY) LTD	EACH NASAL SPRAY DEVICE CONTAINS ESKETAMINE HYDROCHLORIDE EQUIVALENT TO ESKETAMINE 28,0 mg	Annexure A
54/3.1/0187	2022/04/06	RINVOQ	TABLET	ABBVIE (PTY) LTD	EACH TABLET CONTAINS UPADACITINIB 15,0 mg	Annexure A
55/20.2.8/0077	2022/04/06	QULAM-CO	TABLET	MACLEODS PHARMACEUTICALS SA (PTY) LTD	EACH TABLET CONTAINS ABACAVIR 600,0 mg LAMIVUDINE 300,0 mg	Annexure A
55/20.2.8/0078.077	2022/04/06	VIRULATE	TABLET	MACLEODS PHARMACEUTICALS SA (PTY) LTD	EACH TABLET CONTAINS ABACAVIR 600,0 mg LAMIVUDINE 300,0 mg	Annexure A
55/26/0347	2022/04/06	VEXFAN	INFUSION	EUROLAB (PTY) LTD	EACH 1,0 ml SOLUTION CONTAINS BUSULFAN 6,0 mg	Annexure A
55/7.5/0381	2022/04/06	NOVABE	TABLET	NOVAGEN PHARMA (PTY) LTD	EACH TABLET CONTAINS EZETIMIBE 10,0 mg	Annexure A
55/2.5/0538	2022/04/06	RUBILIM CR 200	TABLET	RUBY PHARMACEUTICALS (PTY) LTD	EACH TABLET CONTAINS SODIUM VALPROATE 200,0 mg	Annexure A
55/2.5/0539	2022/04/06	RUBILIM CR 300	TABLET	RUBY PHARMACEUTICALS (PTY) LTD	EACH TABLET CONTAINS SODIUM VALPROATE 300,0 mg	Annexure A
55/2.5/0540	2022/04/06	RUBILIM CR 500	TABLET	RUBY PHARMACEUTICALS (PTY) LTD	EACH TABLET CONTAINS SODIUM VALPROATE 500,0 mg	Annexure A
55/8.2/0009	2022/04/19	CRUSIA 20	INJECTION	ADCOCK INGRAM LIMITED	EACH 0,2 ml SOLUTION CONTAINS ENOXAPARIN SODIUM 20,0 mg	Annexure A
55/8.2/0010	2022/04/19	CRUSIA 40	INJECTION	ADCOCK INGRAM LIMITED	EACH 0,4 ml SOLUTION CONTAINS ENOXAPARIN SODIUM 40,0 mg	Annexure A
55/8.2/0011	2022/04/19	CRUSIA 60	INJECTION	ADCOCK INGRAM LIMITED	EACH 0,6 ml SOLUTION CONTAINS ENOXAPARIN SODIUM 60,0 mg	Annexure A
55/8.2/0012	2022/04/19	CRUSIA 80	INJECTION	ADCOCK INGRAM LIMITED	EACH 0,8 ml SOLUTION CONTAINS ENOXAPARIN SODIUM 80,0 mg	Annexure A
55/8.2/0013	2022/04/19	CRUSIA 100	INJECTION	ADCOCK INGRAM LIMITED	EACH 1,0 ml SOLUTION CONTAINS ENOXAPARIN SODIUM 100,0 mg	Annexure A
55/20.2.8/0255	2022/04/19	MYLAMBA	TABLET	MYLAN (PTY) LTD	EACH TABLET CONTAINS ABACAVIR 600,0 mg LAMIVUDINE 300,0 mg	Annexure A
55/30.2/0457	2022/04/19	PCV-10 CIPLA	INJECTION	CIPLA MEDPRO (PTY) LTD	EACH 0,5 ml SUSPENSION CONTAINS STREPTOCOCCUS PNEUMONIAE WITH 10 SEROTYPES 2,0 ug	Annexure A
55/18.8/0462	2022/04/19	JARINA PLUS	TABLET	BAYER (PTY) LTD	EACH TABLET CONTAINS DROSPIRENONE 3,0 mg ETHINYLESTRADIOL 0,03 mg LEVOMEFOLATE CALCIUM 0,451 mg	Annexure A

55/21.8.2/0463	2022/04/19	ELOINE PLUS	TABLET	BAYER (PTY) LTD	EACH TABLET CONTAINS DROSPIRENONE 3,0 mg ETHINYLESTRADIOL 0,02 mg LEVOMEFOLATE CALCIUM 0,451 mg	Annexure A
53/20.2.8/0310	2022/04/26	NEFORIM	TABLET	STRIDES PHARMA SA (PTY) LTD	EACH TABLET CONTAINS DOLUTEGRAVIR SODIUM 50,0 mg LAMIVUDINE 300,0 mg TENOFOVIR DISOPROXIL FUMARATE 300,0 mg	Annexure A
53/20.2.8/0311.310	2022/04/26	LENDOFIL	TABLET	STRIDES PHARMA SA (PTY) LTD	EACH TABLET CONTAINS DOLUTEGRAVIR SODIUM 50,0 mg LAMIVUDINE 300,0 mg TENOFOVIR DISOPROXIL FUMARATE 300,0 mg	Annexure A
53/20.2.8/0312.310	2022/04/26	VIDAVIR	TABLET	STRIDES PHARMA SA (PTY) LTD	EACH TABLET CONTAINS DOLUTEGRAVIR SODIUM 50,0 mg LAMIVUDINE 300,0 mg TENOFOVIR DISOPROXIL FUMARATE 300,0 mg	Annexure A
54/8.1/0223	2022/04/26	TRANEXAMIC INJECTION PHARMA-Q	INJECTION	PHARMA-Q HOLDINGS (PTY) LTD	EACH AMPOULE OR VIAL CONTAINS TRANEXAMIC ACID 1 000,0 mg	Annexure A
55/7.5/0468	2022/04/26	APOTRIGON 40/160 mg	CAPSULES	AUSTELL PHARMACEUTICALS (PTY) LTD	EACH CAPSULE CONTAINS FENOFIBRATE 160,0 mg PRAVASTATIN SODIUM 40,0 mg	Annexure A
54/20.2.8/0051	2022/05/03	ZATELANZ	TABLET	MYLAN (PTY) LTD	EACH TABLET CONTAINS EFAVIRENZ 400,0 mg LAMIVUDINE 300,0 mg TENOFOVIR DISOPROXIL FUMARATE 300,0 mg	Annexure A
54/20.2.8/0052.051	2022/05/03	MYLONZA 300/300/400	TABLET	MYLAN (PTY) LTD	EACH TABLET CONTAINS EFAVIRENZ 400,0 mg LAMIVUDINE 300,0 mg TENOFOVIR DISOPROXIL FUMARATE 300,0 mg	Annexure A
56/20.2.8/0131	2022/04/29	TIVICAY 5 mg	TABLET	GLAXOSMITHKLINE SOUTH AFRICA (PTY) LTD	EACH TABLET CONTAINS DOLUTEGRAVIR 5,0 mg	Annexure A
20/11.3/20	2022/05/10	LUTALYSE 12,5 mg/ml INJECTION	INJECTION	ZOETIS SOUTH AFRICA (PTY) LTD	EACH 1,0 ml SOLUTION CONTAINS DINOPROST TROMETHAMINE EQUIVALENT TO DINOPROST 12,5 mg	Annexure A
55/20.1.1/0357	2022/05/10	MONURIL	GRANULES	ADCOCK INGRAM LIMITED	EACH SACHET CONTAINS FOSFOMYCIN TROMETAMOL EQUIVALENT TO FOSFOMYCIN 3,0 g	Annexure A
55/20.1.1/0358	2022/05/10	FOSFOMYCIN ADCO	GRANULES	ADCOCK INGRAM LIMITED	EACH SACHET CONTAINS FOSFOMYCIN TROMETAMOL EQUIVALENT TO FOSFOMYCIN 3,0 g	Annexure A
56/3.1/0127	2022/05/10	NOXPAIN RAPID	TABLET	ACINO PHARMA (PTY) LTD	EACH TABLET CONTAINS LORNOXICAM 8,0 mg	Annexure A
56/18/0136	2022/05/10	BLADURIL	TABLET	ADCOCK INGRAM LIMITED	EACH TABLET CONTAINS FLAVOXATE HYDROCHLORIDE 200,0 mg	Annexure A
55/30.1/0444	2022/05/17	PHESGO FDC 1200	INJECTION	ROCHE PRODUCTS (PTY) LTD	EACH VIAL CONTAINS PERTUZUMAB 1 200,00 mg TRASTUZUMAB 600,0 mg	Annexure A
55/30.1/0445	2022/05/17	PHESGO FDC 600	INJECTION	ROCHE PRODUCTS (PTY) LTD	EACH VIAL CONTAINS PERTUZUMAB 600,00 mg TRASTUZUMAB 600,0 mg	Annexure A
55/26/0256	2022/05/17	ABEVMY 100 mg	INFUSION	MYLAN (PTY) LTD	EACH VIAL CONTAINS BEVACIZUMAB 100,0 mg	Annexure A
55/26/0257	2022/05/17	ABEVMY 400 mg	INFUSION	MYLAN (PTY) LTD	EACH VIAL CONTAINS BEVACIZUMAB 400,0 mg	Annexure A

55/26/0258.256	2022/05/17	BEVACIZUMAB 100 mg MYLAN	INFUSION	MYLAN (PTY) LTD	EACH VIAL CONTAINS BEVACIZUMAB 100,0 mg	Annexure A
55/26/0259.257	2022/05/17	BEVACIZUMAB 400 mg MYLAN	INFUSION	MYLAN (PTY) LTD	EACH VIAL CONTAINS BEVACIZUMAB 400,0 mg	Annexure A
55/26/0260.256	2022/05/17	BEVAMYL 100 mg	INFUSION	MYLAN (PTY) LTD	EACH VIAL CONTAINS BEVACIZUMAB 100,0 mg	Annexure A
55/26/0261.257	2022/05/17	BEVAMYL 400 mg	INFUSION	MYLAN (PTY) LTD	EACH VIAL CONTAINS BEVACIZUMAB 400,0 mg	Annexure A
54/32.16/0737	2022/05/17	TERIFLUNOMIDE 14 TEVA	TABLET	TEVA PHARMACEUTICALS (PTY) LTD	EACH TABLET CONTAINS TERIFLUNOMIDE 14,0 mg	Annexure A
53/7.1.3/0631	2022/05/17	UPTRAVI 200 ug	TABLET	JANSSEN PHARMACEUTICA (PTY) LTD	EACH TABLET CONTAINS SELEXIPAG 200,0 ug	Annexure A
53/7.1.3/0632	2022/05/17	UPTRAVI 400 ug	TABLET	JANSSEN PHARMACEUTICA (PTY) LTD	EACH TABLET CONTAINS SELEXIPAG 400,0 ug	Annexure A
53/7.1.3/0633	2022/05/17	UPTRAVI 600 ug	TABLET	JANSSEN PHARMACEUTICA (PTY) LTD	EACH TABLET CONTAINS SELEXIPAG 600,0 ug	Annexure A
53/7.1.3/0634	2022/05/17	UPTRAVI 800 ug	TABLET	JANSSEN PHARMACEUTICA (PTY) LTD	EACH TABLET CONTAINS SELEXIPAG 800,0 ug	Annexure A
53/7.1.3/0635	2022/05/17	UPTRAVI 1 000 ug	TABLET	JANSSEN PHARMACEUTICA (PTY) LTD	EACH TABLET CONTAINS SELEXIPAG 1 000,0 ug	Annexure A
53/7.1.3/0636	2022/05/17	UPTRAVI 1 200 ug	TABLET	JANSSEN PHARMACEUTICA (PTY) LTD	EACH TABLET CONTAINS SELEXIPAG 1 200,0 ug	Annexure A
53/7.1.3/0637	2022/05/17	UPTRAVI 1 400 ug	TABLET	JANSSEN PHARMACEUTICA (PTY) LTD	EACH TABLET CONTAINS SELEXIPAG 1 400,0 ug	Annexure A
53/7.1.3/0638	2022/05/17	UPTRAVI 1 600 ug	TABLET	JANSSEN PHARMACEUTICA (PTY) LTD	EACH TABLET CONTAINS SELEXIPAG 1 600,0 ug	Annexure A
54/7.1.3/0817	2022/05/17	HYDININ 25 mg	TABLET	STRIDES PHARMA SA (PTY) LTD	EACH TABLET CONTAINS HYDRALAZINE HYDROCHLORIDE 25,0 mg	Annexure A
54/7.1.3/0818	2022/05/17	HYDININ 50 mg	TABLET	STRIDES PHARMA SA (PTY) LTD	EACH TABLET CONTAINS HYDRALAZINE HYDROCHLORIDE 50,0 mg	Annexure A
54/7.1.3/0819	2022/05/17	HYDININ 100 mg	TABLET	STRIDES PHARMA SA (PTY) LTD	EACH TABLET CONTAINS HYDRALAZINE HYDROCHLORIDE 100,0 mg	Annexure A
54/7.1.3/0820.817	2022/05/17	TRINLANIN 25 mg	TABLET	STRIDES PHARMA SA (PTY) LTD	EACH TABLET CONTAINS HYDRALAZINE HYDROCHLORIDE 25,0 mg	Annexure A
54/7.1.3/0821.818	2022/05/17	TRINLANIN 50 mg	TABLET	STRIDES PHARMA SA (PTY) LTD	EACH TABLET CONTAINS HYDRALAZINE HYDROCHLORIDE 50,0 mg	Annexure A
54/7.1.3/0822.819	2022/05/17	TRINLANIN 100 mg	TABLET	STRIDES PHARMA SA (PTY) LTD	EACH TABLET CONTAINS HYDRALAZINE HYDROCHLORIDE 100,0 mg	Annexure A
54/1.2/0026	2022/05/24	BUPYRA XL 150	TABLET	TEVA PHARMACEUTICALS (PTY) LTD	EACH TABLET CONTAINS BUPROPION 150,0 mg	Annexure A
54/1.2/0533	2022/05/24	BUPYRA XL 300	TABLET	TEVA PHARMACEUTICALS (PTY) LTD	EACH TABLET CONTAINS BUPROPION 300,0 mg	Annexure A
54/20.1.1/0203	2022/05/24	TIASEP	INFUSION	ABEX PHARMACEUTICA (PTY) LTD	EACH VIAL CONTAINS CILASTATIN SODIUM EQUIVALENT TO CILASTATIN 500,0 mg IMIPENEM 500,0 mg	Annexure A

54/20.1.1/0204.203	2022/05/24	CILNEM	INFUSION	ABEX PHARMACEUTICA (PTY) LTD	EACH VIAL CONTAINS CILASTATIN SODIUM EQUIVALENT TO CILASTATIN 500,0 mg IMIPENEM 500,0 mg	Annexure A
55/20.2.8/0388	2022/05/24	QUADRIMUNE	GRANULES	CIPLA MEDPRO (PTY) LTD	EACH CAPSULE OF GRANULES CONTAINS ABACAVIR 30,0 mg LAMIVUDINE 15,0 mg LOPINAVIR 40,0 mg RITONAVIR 10,0 mg	Annexure A
55/20.2.8/0389.388	2022/05/24	CUATRO	GRANULES	CIPLA MEDPRO (PTY) LTD	EACH CAPSULE OF GRANULES CONTAINS ABACAVIR 30,0 mg LAMIVUDINE 15,0 mg LOPINAVIR 40,0 mg RITONAVIR 10,0 mg	Annexure A
56/5.11/0094	2022/05/24	CHOLSTYQ	INJECTION	UMSEBE HEALTHCARE	EACH 1,0 ml SOLUTION CONTAINS GLYCOPYRRONIUM BROMIDE 0,5 mg NEOSTIGMINE METHYLSULPHATE 2,5 mg	Annexure A
56/30.2/0647	2022/05/24	COVID-19 VACCINE LHC	INJECTION	LHC PHARMACEUTICALS (PTY) LTD	EACH 0,5 ml DOSE CONTAINS SARS-COV-2 (INACTIVATED) ANTIGEN 4,0 ug	Annexure B
55/26/0428	2022/05/31	SPACAN 40	INFUSION	RUBY PHARMACEUTICALS (PTY) LTD	EACH VIAL CONTAINS IRINOTECAN HYDROCHLORIDE 40,0 mg	Annexure A
19/3.1.2.2/18	2022/05/31	INFLACAM 0,5 mg/ml	SUSPENSION	VIRBAC RSA (PTY) LTD	EACH 1,0 ml SUSPENSION CONTAINS MELOXICAM 0,5 mg	Annexure A
54/1.2/0506	2022/05/31	XIROV 5	TABLET	ALKEM LABORATORIES (PTY) LTD	EACH TABLET CONTAINS VORTIOXETINE HYDROBROMIDE EQUIVALENT TO VORTIOXETINE 5,0 mg	Annexure A
54/1.2/0507	2022/05/31	XIROV 10	TABLET	ALKEM LABORATORIES (PTY) LTD	EACH TABLET CONTAINS VORTIOXETINE HYDROBROMIDE EQUIVALENT TO VORTIOXETINE 10,0 mg	Annexure A
54/1.2/0508	2022/05/31	XIROV 15	TABLET	ALKEM LABORATORIES (PTY) LTD	EACH TABLET CONTAINS VORTIOXETINE HYDROBROMIDE EQUIVALENT TO VORTIOXETINE 15,0 mg	Annexure A
54/1.2/0509	2022/05/31	XIROV 20	TABLET	ALKEM LABORATORIES (PTY) LTD	EACH TABLET CONTAINS VORTIOXETINE HYDROBROMIDE EQUIVALENT TO VORTIOXETINE 20,0 mg	Annexure A
54/1.2/0510.506	2022/05/31	VORTIOXETINE 5 mg ALKEM	TABLET	ALKEM LABORATORIES (PTY) LTD	EACH TABLET CONTAINS VORTIOXETINE HYDROBROMIDE EQUIVALENT TO VORTIOXETINE 5,0 mg	Annexure A
54/1.2/0511.507	2022/05/31	VORTIOXETINE 10 mg ALKEM	TABLET	ALKEM LABORATORIES (PTY) LTD	EACH TABLET CONTAINS VORTIOXETINE HYDROBROMIDE EQUIVALENT TO VORTIOXETINE 10,0 mg	Annexure A
54/1.2/0512.508	2022/05/31	VORTIOXETINE 15 mg ALKEM	TABLET	ALKEM LABORATORIES (PTY) LTD	EACH TABLET CONTAINS VORTIOXETINE HYDROBROMIDE EQUIVALENT TO VORTIOXETINE 15,0 mg	Annexure A
54/1.2/0513.509	2022/05/31	VORTIOXETINE 20 mg ALKEM	TABLET	ALKEM LABORATORIES (PTY) LTD	EACH TABLET CONTAINS VORTIOXETINE HYDROBROMIDE EQUIVALENT TO VORTIOXETINE 20,0 mg	Annexure A
54/32.11/0832	2022/05/31	PRISMASOL 2 mmol/l SOLUTION	SOLUTION	BAXTER HEALTHCARE SA (PTY) LTD	EACH 1 000,0 ml SOLUTION CONTAINS CALCIUM 1,75 mmol CHLORIDE 111,5 mmol GLUCOSE 6,1 mmol MAGNESIUM 0,5 mmol POTASSIUM 2,0 mmol SODIUM	Annexure A

					140,0 mmol SODIUM BICARBONATE 32,0 mmol SODIUM LACTATE 3,0 mmol	
54/32.11/0833	2022/05/31	PRISMASOL 4 mmol/l SOLUTION	SOLUTION	BAXTER HEALTHCARE SA (PTY) LTD	EACH 1 000,0 ml SOLUTION CONTAINS CALCIUM 1,75 mmol CHLORIDE 113,5 mmol GLUCOSE 6,1 mmol MAGNESIUM 0,5 mmol POTASSIUM 4,0 mmol SODIUM 140,0 mmol SODIUM BICARBONATE 32,0 mmol SODIUM LACTATE 3,0 mmol	Annexure A
55/26/0429	2022/05/31	SPACAN 100	INFUSION	RUBY PHARMACEUTICALS (PTY) LTD	EACH VIAL CONTAINS IRINOTECAN HYDROCHLORIDE 100,0 mg	Annexure A
55/26/0430	2022/05/31	SPACAN 300	INFUSION	RUBY PHARMACEUTICALS (PTY) LTD	EACH VIAL CONTAINS IRINOTECAN HYDROCHLORIDE 300,0 mg	Annexure A
55/26/0431	2022/05/31	SPACAN 500	INFUSION	RUBY PHARMACEUTICALS (PTY) LTD	EACH VIAL CONTAINS IRINOTECAN HYDROCHLORIDE 500,0 mg	Annexure A
55/20.2.3/0304	2022/05/31	DUOPIC 150/75	TABLET	ADCOCK INGRAM LIMITED	EACH TABLET CONTAINS ISONIAZID 75,0 mg RIFAMPICIN 150,0 mg	Annexure A
55/26/0362	2022/05/31	INOTRIX 40 mg/2 ml	INFUSION	AUROGEN SOUTH AFRICA (PTY) LTD	EACH 2,0 ml SOLUTION CONTAINS IRINOTECAN HYDROCHLORIDE 40,0 mg	Annexure A
55/26/0363	2022/05/31	INOTRIX 100 mg/5 ml	INFUSION	AUROGEN SOUTH AFRICA (PTY) LTD	EACH 5,0 ml SOLUTION CONTAINS IRINOTECAN HYDROCHLORIDE 100,0 mg	Annexure A
55/26/0364	2022/05/31	INOTRIX 300 mg/15 ml	INFUSION	AUROGEN SOUTH AFRICA (PTY) LTD	EACH 15,0 ml SOLUTION CONTAINS IRINOTECAN HYDROCHLORIDE 300,0 mg	Annexure A
55/26/0365.362	2022/05/31	TRINAXID 40 mg/2 ml	INFUSION	AUROGEN SOUTH AFRICA (PTY) LTD	EACH 2,0 ml SOLUTION CONTAINS IRINOTECAN HYDROCHLORIDE 40,0 mg	Annexure A
55/26/0366.363	2022/05/31	TRINAXID 100 mg/5 ml	INFUSION	AUROGEN SOUTH AFRICA (PTY) LTD	EACH 5,0 ml SOLUTION CONTAINS IRINOTECAN HYDROCHLORIDE 100,0 mg	Annexure A
55/26/0367.364	2022/05/31	TRINAXID 300 mg/15 ml	INFUSION	AUROGEN SOUTH AFRICA (PTY) LTD	EACH 15,0 ml SOLUTION CONTAINS IRINOTECAN HYDROCHLORIDE 300,0 mg	Annexure A
56/26/0286	2022/05/31	REDDITUX 100	INFUSION	DR REDDY'S LABORATORIES (PTY) LTD	EACH VIAL CONTAINS RITUXIMAB 100,0 mg	Annexure A
56/26/0287.286	2022/05/31	REDDITUX 500	INFUSION	DR REDDY'S LABORATORIES (PTY) LTD	EACH VIAL CONTAINS RITUXIMAB 500,0 mg	Annexure A
53/1.2/0028	2022/06/07	ATTENTUS 10 mg	CAPSULES	AUROGEN SOUTH AFRICA (PTY) LTD	EACH CAPSULE CONTAINS ATOMOXETINE HYDROCHLORIDE EQUIVALENT TO ATOMOXETINE 10,0 mg	Annexure A
53/1.2/0029	2022/06/07	ATTENTUS 18 mg	CAPSULES	AUROGEN SOUTH AFRICA (PTY) LTD	EACH CAPSULE CONTAINS ATOMOXETINE HYDROCHLORIDE EQUIVALENT TO ATOMOXETINE 18,0 mg	Annexure A
53/1.2/0030	2022/06/07	ATTENTUS 25 mg	CAPSULES	AUROGEN SOUTH AFRICA (PTY) LTD	EACH CAPSULE CONTAINS ATOMOXETINE HYDROCHLORIDE EQUIVALENT TO ATOMOXETINE 25,0 mg	Annexure A
53/1.2/0031	2022/06/07	ATTENTUS 40 mg	CAPSULES	AUROGEN SOUTH AFRICA (PTY) LTD	EACH CAPSULE CONTAINS ATOMOXETINE HYDROCHLORIDE EQUIVALENT TO ATOMOXETINE 40,0 mg	Annexure A

53/1.2/0032	2022/06/07	ATTENTUS 60 mg	CAPSULES	AUROGEN SOUTH AFRICA (PTY) LTD	EACH CAPSULE CONTAINS ATOMOXETINE HYDROCHLORIDE EQUIVALENT TO ATOMOXETINE 60,0 mg	Annexure A
53/1.2/0033/028	2022/06/07	PELLEGO 10 mg	CAPSULES	AUROGEN SOUTH AFRICA (PTY) LTD	EACH CAPSULE CONTAINS ATOMOXETINE HYDROCHLORIDE EQUIVALENT TO ATOMOXETINE 10,0 mg	Annexure A
53/1.2/0034.029	2022/06/07	PELLEGO 18 mg	CAPSULES	AUROGEN SOUTH AFRICA (PTY) LTD	EACH CAPSULE CONTAINS ATOMOXETINE HYDROCHLORIDE EQUIVALENT TO ATOMOXETINE 18,0 mg	Annexure A
53/1.2/0035.030	2022/06/07	PELLEGO 25 mg	CAPSULES	AUROGEN SOUTH AFRICA (PTY) LTD	EACH CAPSULE CONTAINS ATOMOXETINE HYDROCHLORIDE EQUIVALENT TO ATOMOXETINE 25,0 mg	Annexure A
53/1.2/0036.031	2022/06/07	PELLEGO 40 mg	CAPSULES	AUROGEN SOUTH AFRICA (PTY) LTD	EACH CAPSULE CONTAINS ATOMOXETINE HYDROCHLORIDE EQUIVALENT TO ATOMOXETINE 40,0 mg	Annexure A
53/1.2/0037.032	2022/06/07	PELLEGO 60 mg	CAPSULES	AUROGEN SOUTH AFRICA (PTY) LTD	EACH CAPSULE CONTAINS ATOMOXETINE HYDROCHLORIDE EQUIVALENT TO ATOMOXETINE 60,0 mg	Annexure A
53/1.2/0038.028	2022/06/07	STRADENT 10 mg	CAPSULES	AUROGEN SOUTH AFRICA (PTY) LTD	EACH CAPSULE CONTAINS ATOMOXETINE HYDROCHLORIDE EQUIVALENT TO ATOMOXETINE 10,0 mg	Annexure A
53/1.2/0039.029	2022/06/07	STRADENT 18 mg	CAPSULES	AUROGEN SOUTH AFRICA (PTY) LTD	EACH CAPSULE CONTAINS ATOMOXETINE HYDROCHLORIDE EQUIVALENT TO ATOMOXETINE 18,0 mg	Annexure A
53/1.2/0040.030	2022/06/07	STRADENT 25 mg	CAPSULES	AUROGEN SOUTH AFRICA (PTY) LTD	EACH CAPSULE CONTAINS ATOMOXETINE HYDROCHLORIDE EQUIVALENT TO ATOMOXETINE 25,0 mg	Annexure A
53/1.2/0041.031	2022/06/07	STRADENT 40 mg	CAPSULES	AUROGEN SOUTH AFRICA (PTY) LTD	EACH CAPSULE CONTAINS ATOMOXETINE HYDROCHLORIDE EQUIVALENT TO ATOMOXETINE 40,0 mg	Annexure A
53/1.2/0042.032	2022/06/07	STRADENT 60 mg	CAPSULES	AUROGEN SOUTH AFRICA (PTY) LTD	EACH CAPSULE CONTAINS ATOMOXETINE HYDROCHLORIDE EQUIVALENT TO ATOMOXETINE 60,0 mg	Annexure A
55/7.1.3/0889	2022/06/07	HYDININ 10 mg	TABLET	STRIDES PHARMA SA (PTY) LTD	EACH TABLET CONTAINS HYDRALAZINE HYDROCHLORIDE 10,0 mg	Annexure A
55/7.1.3/0890.889	2022/06/07	TRINRALIN 10 mg	TABLET	STRIDES PHARMA SA (PTY) LTD	EACH TABLET CONTAINS HYDRALAZINE HYDROCHLORIDE 10,0 mg	Annexure A
55/20.2.2/0236	2022/06/07	CASFIN 50	INFUSION	KAHMA BIOTECH (PTY) LTD	EACH VIAL CONTAINS CASPOFUNGIN ACETATE 50,0 mg	Annexure A
55/20.2.2/0237	2022/06/07	CASFIN 70	INFUSION	KAHMA BIOTECH (PTY) LTD	EACH VIAL CONTAINS CASPOFUNGIN ACETATE 70,0 mg	Annexure A
55/2.5/0281	2022/06/07	DIACOMIT 250 CAPSULE	CAPSULES	EQUITY PHARMACEUTICALS (PTY) LTD	EACH CAPSULE CONTAINS STIRIPENTOL 250,0 mg	Annexure A
55/2.5/0282	2022/06/07	DIACOMIT 500 CAPSULE	CAPSULES	EQUITY PHARMACEUTICALS (PTY) LTD	EACH CAPSULE CONTAINS STIRIPENTOL 500,0 mg	Annexure A

55/2.5/0283	2022/06/14	DIACOMIT 250 POWDER FOR ORAL SUSPENSION	SUSPENSION	EQUITY PHARMACEUTICALS (PTY) LTD	EACH SACHET CONTAINS STIRIPENTOL 250,0 mg	Annexure A
55/2.5/0284	2022/06/14	DIACOMIT 500 POWDER FOR ORAL SUSPENSION	SUSPENSION	EQUITY PHARMACEUTICALS (PTY) LTD	EACH SACHET CONTAINS STIRIPENTOL 500,0 mg	Annexure A
54/2.5/0151	2022/06/14	SENPRAS 100	CAPSULES	STRIDES PHARMA SA (PTY) LTD	EACH CAPSULE CONTAINS GABAPENTIN 100,0 mg	Annexure A
54/2.5/0152	2022/06/14	SENPRAS 300	CAPSULES	STRIDES PHARMA SA (PTY) LTD	EACH CAPSULE CONTAINS GABAPENTIN 300,0 mg	Annexure A
54/2.5/0153	2022/06/14	SENPRAS 400	CAPSULES	STRIDES PHARMA SA (PTY) LTD	EACH CAPSULE CONTAINS GABAPENTIN 400,0 mg	Annexure A
54/2.5/0154.151	2022/06/14	PRASEN 100	CAPSULES	STRIDES PHARMA SA (PTY) LTD	EACH CAPSULE CONTAINS GABAPENTIN 100,0 mg	Annexure A
54/2.5/0155.152	2022/06/14	PRASEN 300	CAPSULES	STRIDES PHARMA SA (PTY) LTD	EACH CAPSULE CONTAINS GABAPENTIN 300,0 mg	Annexure A
54/2.5/0156.153	2022/06/14	PRASEN 400	CAPSULES	STRIDES PHARMA SA (PTY) LTD	EACH CAPSULE CONTAINS GABAPENTIN 400,0 mg	Annexure A
55/20.2.8.0139	2022/06/14	VIREMT	TABLET	PHARMA DYNAMICS (PTY) LTD	EACH TABLET CONTAINS EMTRICITABINE 200,0 mg TENOFOVIR DISOPROXIL FUMARATE 300,0 mg	Annexure A
56/20.2.8/0719	2022/06/14	SYROMAK 10 ODT	TABLET	MACLEODS PHARMACEUTICALS SA (PTY) LTD	EACH DISPERSIBLE TABLET CONTAINS DOLUTEGRAVIR SODIUM EQUIVALENT TO DOLUTEGRAVIR 10,0 mg	Annexure A
56/20.2.8/0720.719	2022/06/14	KOVASYP 10 ODT	TABLET	MACLEODS PHARMACEUTICALS SA (PTY) LTD	EACH DISPERSIBLE TABLET CONTAINS DOLUTEGRAVIR SODIUM EQUIVALENT TO DOLUTEGRAVIR 10,0 mg	Annexure A
53/8.2/0622	2022/06/14	NEBIVOPEN 2,5	TABLET	PHARMACARE LIMITED	EACH TABLET CONTAINS RIVAROXABAN 2,5 mg	Annexure A
53/8.2/0623	2022/06/14	NEBIVOPEN 10	TABLET	PHARMACARE LIMITED	EACH TABLET CONTAINS RIVAROXABAN 10,0 mg	Annexure A
53/8.2/0624	2022/06/14	NEBIVOPEN 15	TABLET	PHARMACARE LIMITED	EACH TABLET CONTAINS RIVAROXABAN 15,0 mg	Annexure A
53/8.2/0625	2022/06/14	NEBIVOPEN 20	TABLET	PHARMACARE LIMITED	EACH TABLET CONTAINS RIVAROXABAN 20,0 mg	Annexure A
55/20.2.3/0519	2022/06/14	ISONIAZID 300 mg PHARMA-Q	TABLET	PHARMA-Q (PTY) LTD	EACH TABLET CONTAINS ISONIAZID 300,0 mg	Annexure A
55/10.3/0242	2022/06/14	AMUCO 600 EFFERVESCENT	TABLET	AUSTELL PHARMACEUTICALS (PTY) LTD	EACH TABLET CONTAINS ACETYLCYSTEINE 600,0 mg	Annexure A
56/30.2/0232	2022/06/14	CORONAVAC	INJECTION	CURANTO PHARMA (PTY) LTD	EACH 0,5 ml DOSE CONTAINS INACTIVATED SARS-COV-2 VIRUS (CZ02 STRAIN) 600,0 SU	Annexure C
56/20.2.8/0018	2022/06/21	ODINSTI DISPERSIBLE TABLETS	TABLET	MYLAN (PTY) LTD	EACH DISPERSIBLE TABLET CONTAINS DOLUTEGRAVIR SODIUM EQUIVALENT TO DOLUTEGRAVIR 10,0 mg	Annexure A

56/20.2.8/0019.018	2022/06/21	RISTEGRA DISPERSIBLE TABLETS	TABLET	MYLAN (PTY) LTD	EACH DISPERSIBLE TABLET CONTAINS DOLUTEGRAVIR SODIUM EQUIVALENT TO DOLUTEGRAVIR 10,0 mg	Annexure A
54/2.9/0218	2022/06/21	DEXISUN	INFUSION	RANBAXY PHARMACEUTICALS (PTY) LTD	EACH VIAL CONTAINS DEXMEDETOMIDINE HYDROCHLORIDE EQUIVALENT TO DEXMEDETOMIDINE 100,0 ug	Annexure A
55/13.4.1/0073	2022/06/28	GLENCOSOL SHAMPOO	LIQUID	GLENMARK PHARMACEUTICALS SOUTH AFRICA (PTY) LTD	EACH 1,0 g SHAMPOO CONTAINS CLOBETASOL PROPIONATE 0,5 mg	Annexure A
55/20.2.8/0341	2022/06/28	TETRI	TABLET	MYLAN (PTY) LTD	EACH TABLET CONTAINS TENOFOVIR DISOPROXIL FUMARATE 300,0 mg EMTRICITABINE 200,0 mg RILPIVIRINE 25,0 mg	Annexure A
55/20.2.8/0342.341	2022/06/28	TERESTIME	TABLET	MYLAN (PTY) LTD	EACH TABLET CONTAINS TENOFOVIR DISOPROXIL FUMARATE 300,0 mg EMTRICITABINE 200,0 mg RILPIVIRINE 25,0 mg	Annexure A
55/26/0377	2022/06/28	PEMETREXED SOLUTION 100 mg/4 ml ACCORD	INFUSION	ACCORD HEALTHCARE (PTY) LTD	EACH 4,0 ml SOLUTION CONTAINS PEMETREXED DISODIUM HEMIPENTAHYDRATE EQUIVALENT TO PEMETREXED 100,0 mg	Annexure A
55/26/0378	2022/06/28	PEMETREXED SOLUTION 500 mg/20 ml ACCORD	INFUSION	ACCORD HEALTHCARE (PTY) LTD	EACH 20,0 ml SOLUTION CONTAINS PEMETREXED DISODIUM HEMIPENTAHYDRATE EQUIVALENT TO PEMETREXED 400,0 mg	Annexure A
55/26/0379	2022/06/28	PEMETREXED SOLUTION 850 mg/34 ml ACCORD	INFUSION	ACCORD HEALTHCARE (PTY) LTD	EACH 34,0 ml SOLUTION CONTAINS PEMETREXED DISODIUM HEMIPENTAHYDRATE EQUIVALENT TO PEMETREXED 850,0 mg	Annexure A
55/26/0380	2022/06/28	PEMETREXED SOLUTION 1 000 mg/40 ml ACCORD	INFUSION	ACCORD HEALTHCARE (PTY) LTD	EACH 40,0 ml SOLUTION CONTAINS PEMETREXED DISODIUM HEMIPENTAHYDRATE EQUIVALENT TO PEMETREXED 1 000,0 mg	Annexure A
56/11.4.3/0791	2022/06/28	TUMSIGON	CAPSULES	DEZZO TRADING 392 (PTY) LTD	EACH CAPSULE CONTAINS OMEPRAZOLE 20,0 mg	Annexure A
56/11.4.3/0792.791	2022/06/28	GAZIGON	CAPSULES	DEZZO TRADING 392 (PTY) LTD	EACH CAPSULE CONTAINS OMEPRAZOLE 20,0 mg	Annexure A
56/11.4.3/0847	2022/06/28	TUMSIGON OTC	CAPSULES	DEZZO TRADING 392 (PTY) LTD	EACH CAPSULE CONTAINS OMEPRAZOLE 20,0 mg	Annexure A
56/11.4.3/0848.847	2022/06/28	GAZIGON OTC	CAPSULES	DEZZO TRADING 392 (PTY) LTD	EACH CAPSULE CONTAINS OMEPRAZOLE 20,0 mg	Annexure A
53/5.4/0052	2022/06/28	FLOLOC CHEWS 5	TABLET	CIPLA MEDPRO (PTY) LTD	EACH CHEWABLE TABLET CONTAINS SOLIFENACIN SUCCINATE 5,0 mg	Annexure A
53/5.4/0053	2022/06/28	FLOLOC CHEWS 10	TABLET	CIPLA MEDPRO (PTY) LTD	EACH CHEWABLE TABLET CONTAINS SOLIFENACIN SUCCINATE 10,0 mg	Annexure A
55/20.1.1/0156	2022/06/28	CEFALEXIN SUSPENSION 125 mg/5 ml AURO	SUSPENSION	AUROGEN SOUTH AFRICA (PTY) LTD	EACH 5,0 ml SUSPENSION CONTAINS CEPHALEXIN 125,0 mg	Annexure A
55/20.1.1/0157	2022/06/28	CEFALEXIN SUSPENSION 250 mg/5 ml AURO	SUSPENSION	AUROGEN SOUTH AFRICA (PTY) LTD	EACH 5,0 ml SUSPENSION CONTAINS CEPHALEXIN 250,0 mg	Annexure A
55/20.1.1/0158.156	2022/06/28	XENARA ORAL SUSPENSION 125 mg/5 ml	SUSPENSION	AUROGEN SOUTH AFRICA (PTY) LTD	EACH 5,0 ml SUSPENSION CONTAINS CEPHALEXIN 125,0 mg	Annexure A

55/20.1.1/0159.157	2022/06/28	XENARA ORAL SUSPENSION 250 mg/5 ml	SUSPENSION	AUROGEN SOUTH AFRICA (PTY) LTD	EACH 5,0 ml SUSPENSION CONTAINS CEPHALEXIN 250,0 mg	Annexure A
55/20.1.1/0160.156	2022/06/28	CERLAZ ORAL SUSPENSION 250 mg/5 ml	SUSPENSION	AUROGEN SOUTH AFRICA (PTY) LTD	EACH 5,0 ml SUSPENSION CONTAINS CEPHALEXIN 125,0 mg	Annexure A
55/20.1.1/0161.157	2022/06/28	CERLAZ ORAL SUSPENSION 250 mg/5 ml	SUSPENSION	AUROGEN SOUTH AFRICA (PTY) LTD	EACH 5,0 ml SUSPENSION CONTAINS CEPHALEXIN 250,0 mg	Annexure A
55/32.16/0228	2022/06/28	AUBAMIDE 14 mg	TABLET	CIPLA MEDPRO (PTY) LTD	EACH TABLET CONTAINS TERIFLUNOMIDE 14,0 mg	Annexure A
09/3.1.2.2/01	2022/06/28	LOXICOM 0,5 mg/ml ORAL SUSPENSION	SUSPENSION	BIOTECH LABORATORIES (PTY) LTD	EACH 1,0 ml SUSPENSION CONTAINS MELOXICAM 0,5 mg	Annexure A
19/17.1.4/12	2022/06/28	TILMOVET 200 g/kg PREMIX	GRANULES	HUVEPHARMA SOUTH AFRICA (PTY) LTD	EACH 1,0 kg GRANULES CONTAIN TILMICOSIN 200,0 g	Annexure A
20/11.7/10	2022/06/28	LUTAGON	INJECTION	ASCENDIS ANIMAL HEALTH (PTY) LTD	EACH 1,0 ml SOLUTION CONTAINS CLOPROSTENOL SODIUM EQUIVALENT TO CLOPROSTENOL 250,0 ug	Annexure A
52/30.2/0511	2022/06/14	TETANUS AND DIPHTHERIA TOXOID BIOVAC	INJECTION	THE BIOVAC INSTITUTE	EACH 0,5 ml DOSE CONTAINS DIPHTHERIA TOXOID 2,0 IU TETANUS TOXOID 20,0 IU	Annexure A

Annexure A

CONDITIONS OF REGISTRATION

THE ACCOMPANYING REGISTRATION CERTIFICATE IS ISSUED SUBJECT TO THE FOLLOWING CONDITIONS:

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 document must be maintained and must be consistent with the current approved information.

Annexure B

CONDITIONS OF REGISTRATION FOR COVID-19 VACCINE LHC

THE ACCOMPANYING REGISTRATION CERTIFICATE IS ISSUED SUBJECT TO THE FOLLOWING CONDITIONS:

1. That the vaccine be supplied in accordance with the National Covid -19 vaccination programme.

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. 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 6 months 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 of concern that are prevalent.

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

8. The applicant should commit to 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.

9. 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 WHO or other African Regulatory Authorities.

10. The applicant must inform SAHPRA on the company's response, as they become available, to the list of recommendations included in the WHO Assessment Reports.

11. 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. To provide update on outcome of data integrity investigation.

12. All vaccine lots (imported and locally manufactured) destined for the South African market are subject to lot release by the South African National Control Laboratory. General guidance for lot release is provided in the Lot Release Guideline available on the SAHPRA website.

13. The applicant is to submit the latest product quality review for the vaccine as it becomes available.

14. Module 3.2.S: Active Substance

A 6-month shelf life is approved for the Active substance for storage at 5 ± 3 °C in 5l screw-neck borosilicate glass bottles.

15. Module 3.2.P: Final Product

PFS

A provisional 24-month shelf-life is approved for the product filled into pre-filled glass syringes with chlorobutyl rubber plunger caps and bromobutyl rubber plunges for storage at 5 ± 3 °C. The Applicant must submit stability data on batches that are currently in the ongoing stability program and must inform SAHPRA if an out-of-specification is observed for any of the batches on long term stability.

Vial

A provisional 24-month shelf-life is approved for the product filled into borosilicate glass vials with brominated butyl rubber stoppers and sealed with aluminium flip-off seals for storage at 5 ± 3 °C. The Applicant must submit stability data on batches that are currently in the ongoing stability program and must inform SAHPRA if an out-of-specification is observed for any of the batches on long term stability.

16. Stability data updates must be submitted on a 6-monthly basis until the 24-month provisional shelf life for the final product has been confirmed.

Annexure C

CONDITIONS OF REGISTRATION FOR CORONAVAC

THE ACCOMPANYING REGISTRATION CERTIFICATE IS ISSUED SUBJECT TO THE FOLLOWING CONDITIONS:

1. That the vaccine be supplied in accordance with the National Covid -19 vaccination programme.

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. 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 6 months 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 of concern that are prevalent.

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

8. The applicant should commit to 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.

9. 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 WHO or the National African Regulatory Authorities.

10. The applicant must inform SAHPRA on the company's response, as they become available, to the recommendations included in the WHO Assessment Reports.

11. 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.

12. All vaccine lots (imported and locally manufactured) destined for the South African market are subject to lot release by the South African National Control Laboratory. General guidance for lot release is provided in the Guideline for Lot Release on Human vaccines available on the SAHPRA website.

13. The applicant is to submit the latest product quality review for the vaccine as it becomes available.

14. Module 3.2.S: Active Drug Substance

A provisional shelf-life of 6 months is approved for the drug substance, inactivated SARS-CoV-2 Virus (CZ02 strain), packed in Pall Allergro™ Single Use Systems and stored at 2-8 °C.

15. Module 3.2.P: Final Product

A provisional shelf-life of 24 months is approved for the product packed in both the vial (2 ml Type 1 clear colourless glass with halogenated butyl rubber stopper and aluminium/plastic cap) and prefilled syringe (1 ml Type 1 glass barrel, plunger rod and stainless-steel needle with cap), stored at 2-8 °C, protected from light.

16. 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.