DEPARTMENT OF HEALTH

NO. R. 2079 **13 May 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
56/30.2/0002	2022/01/25	COMINARTY	INJECTION	PFIZER LABORATORIES (PTY) LTD	EACH 0,3 ml DOSE CONTAINS COVID-19 MRNA VACCINE 30,0 ug	Annexure A
53/20.2.8/0232	2022/01/25	PIFELTRO	TABLET	MSD (PTY) LTD	EACH TABLET CONTAINS DORAVIRINE 100,0 mg	Annexure C
56/30.2/0795	2022/01/31	COVID-19 VACCINE MC PHARMA	INJECTION	MC PHARMA (PTY) LTD	EACH 0,5 ml DOSE CONTAINS SARS-COV-2 VACCINE (VERO CELL) INACTIVATED 6,5 U	Annexure B
55/18.5/0207	2022/02/01	UNITRO 50	CAPSULES	AUROGEN SOUTH AFRICA (PTY) LTD	EACH CAPSULE CONTAINS NITROFURANTOIN 50,0 mg	Annexure C
55/18.5/0208	2022/02/01	UNITRO 100	CAPSULES	AUROGEN SOUTH AFRICA (PTY) LTD	EACH CAPSULE CONTAINS NITROFURANTOIN 100,0 mg	Annexure C
55/18.5/0209.207	2022/02/01	ZOCZEN 50	CAPSULES	AUROGEN SOUTH AFRICA (PTY) LTD	EACH CAPSULE CONTAINS NITROFURANTOIN 50,0 mg	Annexure C
55/18.5/0210.208	2022/02/01	ZOCZEN 100	CAPSULES	AUROGEN SOUTH AFRICA (PTY) LTD	EACH CAPSULE CONTAINS NITROFURANTOIN 100,0 mg	Annexure C
55/18.5/0211.207	2022/02/01	MACRIXTIR 50	CAPSULES	AUROGEN SOUTH AFRICA (PTY) LTD	EACH CAPSULE CONTAINS NITROFURANTOIN 50,0 mg	Annexure C
55/18.5/0212.208	2022/02/01	MACRIXTIR 100	CAPSULES	AUROGEN SOUTH AFRICA (PTY) LTD	EACH CAPSULE CONTAINS NITROFURANTOIN 100,0 mg	Annexure C
55/11.5/0446	2022/01/25	LEBALAX 5 mg	SUPPOSITORY	LEBASI PHARMACEUTICALS (PTY) LTD	EACH SUPPOSITORY CONTAINS BISACODYL 5,0 mg	Annexure C
55/11.5/0447	2022/01/25	LEBALAX 10 mg	SUPPOSITORY	LEBASI PHARMACEUTICALS (PTY) LTD	ACH SUPPOSITORY CONTAINS BISACODYL 10,0 mg	Annexure C
55/1.2/0307	2022/01/25	DULOXETINE DR 30 TEVA	CAPSULES	TEVA PHARMACEUTICALS (PTY) LTD	EACH CAPSULE CONTAINS DULOXETINE HYDROCHLORIDE EQUIVALENT TO DULOXETINE 30,0 mg	Annexure C
55/1.2/0308	2022/01/25	DULOXETINE DR 60 TEVA	CAPSULES	TEVA PHARMACEUTICALS (PTY) LTD	EACH CAPSULE CONTAINS DULOXETINE HYDROCHLORIDE EQUIVALENT TO DULOXETINE 60,0 mg	Annexure C
21/17.1.4/05	2022/02/15	DRAXXIN PLUS 100 mg/ml & 120 mg/ml	SOLUTION	ZOETIS SOUTH AFRICA (PTY) LTD	EACH 1,0 ml SOLUTION CONTAINS KETOPROFEN 120,0 mg & TULATHROMYCIN 100,0 mg	Annexure C
20/17.1.4/08	2022/02/15	TULAVEN	INJECTION	CEVA ANIMAL HEALTH (PTY) LTD	EACH 1,0 ml SOLUTION CONTAINS TULATHROMYCIN 100,0 mg	Annexure C
54/32.16/0811	2022/02/22	TALOMUNE 0,5 mg	CAPSULES	STRIDES PHARMA SA (PTY) LTD	EACH CAPSULE CONTAINS TACROLIMUS 0,5 mg	Annexure C
54/32.16/0812	2022/02/22	TALOMUNE 1 mg	CAPSULES	STRIDES PHARMA SA (PTY) LTD	EACH CAPSULE CONTAINS TACROLIMUS 1,0 mg	Annexure C
54/32.16/0813	2022/02/22	TALOMUNE 5 mg	CAPSULES	STRIDES PHARMA SA (PTY) LTD	EACH CAPSULE CONTAINS TACROLIMUS 5,0 mg	Annexure C
54/32.16/0814.811	2022/02/22	GRAFOLIN 0,5 mg	CAPSULES	STRIDES PHARMA SA (PTY) LTD	EACH CAPSULE CONTAINS TACROLIMUS 0,5 mg	Annexure C
54/32.16/0815.812	2022/02/22	GRAFOLIN 1 mg	CAPSULES	STRIDES PHARMA SA (PTY) LTD	EACH CAPSULE CONTAINS TACROLIMUS 1,0 mg	Annexure C
54/32.16/0816.813	2022/02/22	GRAFOLIN 5 mg	CAPSULES	STRIDES PHARMA SA (PTY) LTD	EACH CAPSULE CONTAINS TACROLIMUS 5,0 mg	Annexure C
54/21.12/0880	2022/02/22	BICALUTAMIDE 150 ACCORD	TABLET	ACCORD HEALTHCARE (PTY) LTD	EACH TABLET CONTAINS BICALUTAMIDE 150,0 mg	Annexure C

55/18.6/0091	2022/02/22	FLUOMIZIN VAGINAL TABLET	TABLET	ADCOCK INGRAM LIMITED	EACH TABLET CONTAINS DEQUALINIUM CHLORIDE 10,0 mg	Annexure C
55/18.8/0034	2022/02/28	VISAFEM	TABLET	ADCOCK INGRAM LIMITED	EACH TABLET CONTAINS DIENOGEST 2,0 mg	Annexure C
55/18.8/0035.034	2022/02/28	DIENOGEST ADCO	TABLET	ADCOCK INGRAM LIMITED	EACH TABLET CONTAINS DIENOGEST 2,0 mg	Annexure C
53/32.16/0183	2022/03/01	ALECENSA	CAPSULES	ROCHE PRODUCTS (PTY) LTD	EACH CAPSULE CONTAINS ALECTINIB HYDROCHLORIDE EQUIVALENT TO ALECTINIB 150,0 mg	Annexure C
54/20.2.3/0160	2022/03/08	SOLONEX CO	TABLET	MACLEODS PHARMACEUTICALS SA (PTY) LTD	EACH TABLET CONTAINS ISONIAZID 300,0 mg RIFAPENTINE 300,0 mg	Annexure C
54/20.2.3/0161.160	2022/03/08	INOZI-CO	TABLET	MACLEODS PHARMACEUTICALS SA (PTY) LTD	EACH TABLET CONTAINS ISONIAZID 300,0 mg RIFAPENTINE 300,0 mg	Annexure C
55/20.2.8/0786	2022/03/08	DAPIRING	VAGINAL RING	LEBASI PHARMACEUTICALS (PTY) LTD	EACH VAGINAL RING CONTAINS DAPIVIRINE 25,0 mg	Annexure C
55/21.12/0321	2022/03/15	NUBEQA	TABLET	BAYER (PTY) LTD	EACH TABLET CONTAINS DAROLUTAMIDE 300,0 mg	Annexure C
54/21.12/0825	2022/03/15	ABIKEM	TABLET	ASCEND LABORATORIES (PTY) LTD	EACH TABLET CONTAINS ABIRATERONE 250,0 mg	Annexure C
56/21.12/0606	2022/03/15	FREXIVO	INJECTION	ASTRAZENECA PHARMACEUTICALS (PTY) LTD	EACH 5,0 ml SOLUTION CONTAINS FULVESTRANT 250,0 mg	Annexure C
55/1.2/0580	2022/03/15	VORTIOXETINE 5 mg LUNDBECK	TABLET	H. LUNDBECK (PTY) LTD	EACH TABLET CONTAINS VORTIOXETINE HYDROBROMIDE EQUIVALENT TO VORTIOXETINE 5,0 mg	Annexure C
55/1.2/0581	2022/03/15	VORTIOXETINE 10 mg LUNDBECK	TABLET	H. LUNDBECK (PTY) LTD	EACH TABLET CONTAINS VORTIOXETINE HYDROBROMIDE EQUIVALENT TO VORTIOXETINE 10,0 mg	Annexure C
55/1.2/0582	2022/03/15	VORTIOXETINE 15 mg LUNDBECK	TABLET	H. LUNDBECK (PTY) LTD	EACH TABLET CONTAINS VORTIOXETINE HYDROBROMIDE EQUIVALENT TO VORTIOXETINE 15,0 mg	Annexure C
55/1.2/0583	2022/03/15	VORTIOXETINE 20 mg LUNDBECK	TABLET	H. LUNDBECK (PTY) LTD	EACH TABLET CONTAINS VORTIOXETINE HYDROBROMIDE EQUIVALENT TO VORTIOXETINE 20,0 mg	Annexure C
20/17.1.3/17	2022/03/29	PARAFOR 70 mg/g	POWDER	HUVEPHARMA SOUTH AFRICA (PTY) LTD	EACH 1,0 g POWDER CONTAINS PAROMOMYCIN SULFATE EQUIVALENT TO PAROMOMYCIN 70,0 mg	Annexure C
53/7.1/0521	2022/03/29	DAPINELAT 30	TABLET	BIOTECH LABORATORIES (PTY) LTD	EACH TABLET CONTAINS NIFEDIPINE 30,0 mg	Annexure C
53/7.1/0522	2022/03/29	DAPINELAT 60	TABLET	BIOTECH LABORATORIES (PTY) LTD	EACH TABLET CONTAINS NIFEDIPINE 60,0 mg	Annexure C
56/8.1/0497	2022/03/29	TRANMENXIO IV	INJECTION	BIOTECH LABORATORIES (PTY) LTD	EACH AMPOULE CONTAINS TRANEXAMIC ACID 500,0 mg	Annexure C
56/21.2/0607	2022/03/29	DUFORZIG 5	TABLET	ASTRAZENECA PHARMACEUTICALS (PTY) LTD	EACH TABLET CONTAINS DAPAGLIFLOZIN PROPRANEDIOL EQUIVALENT TO DAPAGLIFLOZIN 5,0 mg	Annexure C
56/21.2/0608	2022/03/29	DUFORZIG 10	TABLET	ASTRAZENECA PHARMACEUTICALS (PTY) LTD	EACH TABLET CONTAINS DAPAGLIFLOZIN PROPRANEDIOL EQUIVALENT TO DAPAGLIFLOZIN 10,0 mg	Annexure C

56/21.2/0609.607	2022/03/29	KEDGEO 5	TABLET	ASTRAZENECA PHARMACEUTICALS (PTY) LTD	EACH TABLET CONTAINS DAPAGLIFLOZIN PROPRANEDIOL EQUIVALENT TO DAPAGLIFLOZIN 5,0 mg	Annexure C
56/21.2/0610.608	2022/03/29	KEDGEO 10	TABLET	ASTRAZENECA PHARMACEUTICALS (PTY) LTD	EACH TABLET CONTAINS DAPAGLIFLOZIN PROPRANEDIOL EQUIVALENT TO DAPAGLIFLOZIN 10,0 mg	Annexure C
56/21.2/0611.607	2022/03/29	TAPLEO 5	TABLET	ASTRAZENECA PHARMACEUTICALS (PTY) LTD	EACH TABLET CONTAINS DAPAGLIFLOZIN PROPRANEDIOL EQUIVALENT TO DAPAGLIFLOZIN 5,0 mg	Annexure C
56/21.2/0612.608	2022/03/29	TAPLEO 10	TABLET	ASTRAZENECA PHARMACEUTICALS (PTY) LTD	EACH TABLET CONTAINS DAPAGLIFLOZIN PROPRANEDIOL EQUIVALENT TO DAPAGLIFLOZIN 10,0 mg	Annexure C
55/26/0390	2022/03/29	CALQUENCE	CAPSULES	ASTRAZENECA PHARMACEUTICALS (PTY) LTD	EACH CAPSULE CONTAINS ACALABRUTINIB 100,0 mg	Annexure C
55/8.2/0311	2022/03/29	RIVAR 10	TABLET	INNOVATA PHARMACEUTICALS (PTY) LTD	EACH TABLET CONTAINS RIVAROXABAN 10,0 mg	Annexure C
55/8.2/0312	2022/03/29	RIVAR 15	TABLET	INNOVATA PHARMACEUTICALS (PTY) LTD	EACH TABLET CONTAINS RIVAROXABAN 15,0 mg	Annexure C
55/8.2/0313	2022/03/29	RIVAR 20	TABLET	INNOVATA PHARMACEUTICALS (PTY) LTD	EACH TABLET CONTAINS RIVAROXABAN 20,0 mg	Annexure C
55/8.2/0314.311	2022/03/29	RAVELTO 10	TABLET	INNOVATA PHARMACEUTICALS (PTY) LTD	EACH TABLET CONTAINS RIVAROXABAN 10,0 mg	Annexure C
55/8.2/0315.311	2022/03/29	RAVELTO 15	TABLET	INNOVATA PHARMACEUTICALS (PTY) LTD	EACH TABLET CONTAINS RIVAROXABAN 15,0 mg	Annexure C
55/8.2/0316.313	2022/03/29	RAVELTO 20	TABLET	INNOVATA PHARMACEUTICALS (PTY) LTD	EACH TABLET CONTAINS RIVAROXABAN 20,0 mg	Annexure C
55/8.2/0317.311	2022/03/29	VARIXA 10	TABLET	INNOVATA PHARMACEUTICALS (PTY) LTD	EACH TABLET CONTAINS RIVAROXABAN 10,0 mg	Annexure C
55/8.2/0318.312	2022/03/29	VARIXA 15	TABLET	INNOVATA PHARMACEUTICALS (PTY) LTD	EACH TABLET CONTAINS RIVAROXABAN 15,0 mg	Annexure C
55/8.2/0319.313	2022/03/29	VARIXA 20	TABLET	INNOVATA PHARMACEUTICALS (PTY) LTD	EACH TABLET CONTAINS RIVAROXABAN 20,0 mg	Annexure C
20/17.1.4/16	2022/03/29	TILMOVET 300 mg/ml	INJECTION	HUVEPHARMA SOUTH AFRICA (PTY) LTD	EACH 1,0 ml SOLUTION CONTAINS TILMICOSIN 300,0 mg	Annexure C
54/1.2/0681	2022/03/29	VEIKIRIN 10	TABLET	STRIDES PHARMA SA (PTY) LTD	EACH TABLET CONTAINS AMITRIPTYLINE HCl 10,0 mg	Annexure C
54/1.2/0682	2022/03/29	VEIKIRIN 25	TABLET	STRIDES PHARMA SA (PTY) LTD	EACH TABLET CONTAINS AMITRIPTYLINE HCl 25,0 mg	Annexure C
54/1.2/0683	2022/03/29	VEIKIRIN 50	TABLET	STRIDES PHARMA SA (PTY) LTD	EACH TABLET CONTAINS AMITRIPTYLINE HCl 50,0 mg	Annexure C
54/1.2/0684.681	2022/03/29	AMDERIP 10	TABLET	STRIDES PHARMA SA (PTY) LTD	EACH TABLET CONTAINS AMITRIPTYLINE HCl 10,0 mg	Annexure C
54/1.2/0685.682	2022/03/29	AMDERIP 25	TABLET	STRIDES PHARMA SA (PTY) LTD	EACH TABLET CONTAINS AMITRIPTYLINE HCl 25,0 mg	Annexure C
54/1.2/0686.683	2022/03/29	AMDERIP 50	TABLET	STRIDES PHARMA SA (PTY) LTD	EACH TABLET CONTAINS AMITRIPTYLINE HCl 50,0 mg	Annexure C
55/17.1/0102	2022/03/29	IMMAROC	INJECTION	RUBY PHARMACEUTICALS (PTY) LTD	EACH VIAL CONTAINS ROCURONIUM BROMIDE 50,0 mg	Annexure C
55/8.1/0127	2022/03/29	IMMATRA	INJECTION	RUBY PHARMACEUTICALS (PTY) LTD	EACH 1,0 ml SOLUTION CONTAINS TRANEXAMIC ACID 100,0 mg	Annexure C
55/8.1/0128.127	2022/03/29	RUBINEX	INJECTION	RUBY PHARMACEUTICALS (PTY) LTD	EACH 1,0 ml SOLUTION CONTAINS TRANEXAMIC ACID 100,0 mg	Annexure C

Annexure A

CONDITIONS OF REGISTRATION FOR COVID-19 VACCINE

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. 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 of concern that are prevalent.

    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 EMA CHMP Assessment Reports.

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. To provide update on outcome of data integrity investigation.

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 shelf life of 6 months is approved for BNT162b2 drug substance when stored at -20 ± 5 °C in an Ethylene Vinyl Acetate (EVA) containers. Applicant must inform SAHPRA if an out-of-specification is observed for any shelf-life parameter of the batches currently on long-term stability.

b.) Module 3.2.P: Final Product

Unopened vials:

Frozen vial 9: A shelf life of 9 months is approved for BNT162b2 final product when stored at -90 °C to -60 °C in a 2 ml glass vials, with rubber stopper and aluminium flip off cap.

Within the 9-month shelf life, unopened vials may be stored and transported at -25 °C to -15 °C for a single period of up to 2 weeks and can be returned to -90 °C to -60 °C. When stored frozen at -90 °C to -60 °C, 195-vial packs of the vaccine can be thawed at 2 °C to 8 °C for 3 hours or individual vials can be thawed at room temperature (up to 30 °C) for 30 minutes.

Applicant must submit stability data on commercial process validation batches that are currently in the ongoing stability program and must inform the SAHPRA if an out-of-specification is observed for any of these batches or any other batch on long term stability.

Thawed vial: A shelf-life of 1 month is approved for thawed vial when stored at 2 °C to 8 °C, within the 9-month shelf-life

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 a consolidated ZA CTD format. This is subject to review within12 months of the conditional registration.

17. Module 4 and 5: Applicant must submit the final study reports of all ongoing studies.

Annexure B

CONDITIONS OF REGISTRATION OF COVID-19 VACCINES

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. 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 6 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 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 any

     dominant 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.
9. 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.

10. The applicant must immediately 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 Medical Products Administration of China. The information and data of future quality developments should be submitted to SAHPRA on a 6 monthly basis or as it becomes available.

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 Lot Release Guideline for COVID –19 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. A shelf-life of 12 months for the final product in vials (0,5 ml per vial), stored at 2-8 °C, is assigned, with final product being prepared from bulk product stored at 2- 8 °C for a maximum period of 6 months.

15. 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 a consolidated ZA CTD format. This is subject to review within 12 months of the conditional registration.

Annexure C

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.