The South African Health Products Regulatory Authority (SAHPRA), is the National Medicines Regulatory Authority established in terms of the ***Medicines and Related Substances Act, 1965, (Act No. 101 of 1965) as amended*****,** to provide for the monitoring, evaluation, regulation, investigation, inspection, registration and control of medicines, scheduled substances, clinical trials and medical devices, and related matters in the public interest.

MEDICINES REGISTRATION OFFICER: GR 3
(Clinical Evaluations: Post-registration)
Ref No.: SAHPRA 025/2021

CENTRE: Pretoria

REQUIREMENTS: • Appropriate 4-year Bachelor of Pharmacy Degree and registration as a Pharmacist with the South African Pharmacy Council (SAPC). A relevant NQF 9 qualification in the health sciences will be an added advantage.
Experience: • A minimum of 8 years practicing as a pharmacist and at least one-year regulatory experience.

COMPETENCIES, KNOWLEDGE AND SKILLS: * Knowledge and application of the Medicines and Related Substances Control Act 101 of 1965, as amended, and its related Regulations and guidelines, with respect to the regulation of medicines in terms of quality, safety, and efficacy. * A solid understanding of the pharmaceutical regulatory environment. * Team management * Computer literacy (MS Office packages). * Supervisory skills. * Good planning, organisational and interpersonal skills/qualities. * Good communication skills (written and verbal). * Innovative thinking, initiative, and leadership qualities. * Dedication and accurate work. * Knowledge of database management will be advantageous. * Ability to work well under pressure. * Ability to work in a team. * Must be willing to travel and work irregular hours. *A valid driver's licence.

DUTIES: Evaluation of Variation Applications: * Evaluation and finalization of type I variation applications. * Evaluations of Type II variation applications. * Assess submissions for compliance with variation amendment guideline. * Prepare an evaluation report. * Evaluation of pharmacovigilance referrals. * Evaluation of USRN submission for compliance with the USRN guideline where applicable. * Prepare query letter to applicants. * Prepare recommendations to applicants wherein there are minor errors on the professional information and PIL. **Technical Validation / Screening of Variation Applications and Responses:** * Ensure priority medicines and urgent applications/responses are screened and identified as such for rapid processing e.g., TB, ONC, ARV, HORMONES, USRN. * Attend to queries from previous and/or current screening cycle. * Ensure that the outcome is captured by Evaluation Coordinator (EC) on the database and a rejection/approval letter sent out to the applicant. * Conduct thorough screening of variation applications for evaluation. * Prepare a screening outcome report

and communicate outcome to the EC. **Evaluation of Responses to Variations:** * Assess submissions for compliance with variation amendment guideline. ***** Evaluation of clinical responses from applicants. * Prepare clinical report for SAHPRA (approved PI) documents. * Prepare query letter to applicants. * Prepare recommendation to applicant wherein there are minor errors on the professional information and PIL. **Timeous Execution of Recommendations:** * Preparation of recommendation for pharmacovigilance referral outcome. * Execution of evaluation Clinical Committee recommendations. * Capturing of ACC Committee recommendations. * Ensure the correctness of ACC recommendations before communication to the applicants within 5 working days.

INSTRUCTIONS TO APPLICANTS: All applications must:

- Be submitted with a covering letter clearly reflecting the **name of the position and post reference number**, be signed, accompanied by a comprehensive CV, the names of 3 referees and recently certified copies of ID and qualification/s.
- Applications without the afore mentioned will not be considered. Should you be in possession of a foreign qualification, it must be accompanied by an evaluation certificate from the South African Qualification Authority (SAQA).
- A separate application must be completed for each post. SAHPRA will not be liable where applicants use incorrect or no reference number on their applications.
- Applications must be submitted by email to **recruitment@sahpra.org.za,** including the required certified documentation as indicated. **DO NOT MAKE ENQUIRIES TO THIS ADDRESS.**
- No late applications will be accepted. CVs will not be returned. Applications, which are received after the closing date, will not be considered.
- Further communication will be limited to shortlisted candidates. If you have not received a response from SAHPRA within 3 months of the closing date, please consider your application as unsuccessful.
- It will be expected of candidates to be available for selection interviews on a date, time and place as determined by SAHPRA.

Applicants must note that further checks will be conducted once they are shortlisted and that their appointment is subject to positive outcomes on these checks, which include security clearance, qualification verification, criminal records, credit records, citizenship status and previous employment.
SAHPRA is guided by the principles of Employment Equity. Candidates with disabilities are encouraged to apply and an indication in this regard will be appreciated. SAHPRA reserves the right to fill or not to fill the vacant post/s.

Enquiries: Ms S. Molepo, Email: setlola.molepo@sahpra.org.za (**DO NOT SEND APPLICATIONS TO THIS EMAIL ADDRESS).**

CLOSING DATE: 09 July 2021 at 16H00.