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 2
(Pharmaceutical Evaluations: Quality Post-registration)
(DPSA Equivalent Level OSD TCE: GR 2 = R692 433 p/a)
Ref No.: SAHPRA 033/2021

CENTRE: Pretoria

REQUIREMENTS: • Appropriate 4-year Bachelor of Pharmacy Degree and registration as a Pharmacist with the South African Pharmacy Council (SAPC) Proof of registration as a Pharmacist must be submitted with your application. • Regulatory experience will be an added advantage.

COMPETENCIES, KNOWLEDGE AND SKILLS: * Knowledge and application of the Medicines and Related Substances Control Act 101 of 1965, as amended, and its related Regulations, with respect to the regulation of medicines in terms of quality, safety, and efficacy. * Knowledge of technical aspects for evaluation. * Information evaluation. * Technical and scientific aspects of medicine regulation. * Comprehensive knowledge and understanding of relevant legislation, protocols, standard operating procedures and work instructions. * Evaluation guidelines as prescribed by the relevant regulatory authorities. * Computer literacy (MS Office packages). * Good planning, organisational and interpersonal skills/qualities. * Communication skills (verbal, written, negotiation, conflict management, presentation). * Self-motivated and able to work independently. * Decision making. * Objectivity. * Resilience. * Dedication and accurate work. * Interpersonal skills. * Knowledge of database management will be advantageous. * Ability to work well under pressure. * Assertiveness * Ability to work in a team. * Ethical behaviour. * Customer service. * Must be willing to travel and work irregular hours. *A valid driver's licence. * Coordination skills. * Time management. * Good telephone etiquette.

DUTIES: • **Evaluation of generic applications and peer-reviewing of generic applications: *** Evaluation of Type I and II quality variation applications. * Prepare an evaluation report. * Peer-review reports done by other reviewers. * Prepare second evaluation report. * Prepare query or approval or rejection letter to the applicant. • **Technical screen and evaluate the quality and efficacy (bio-equivalence) aspects of the quality variation applications for the registered medicines:** * Generate screening/evaluation report for each application. * Send report to second evaluator for peer review. • **Evaluate applicant responses and variations for the registered medicines:** * Evaluate the quality and efficacy (bio-equivalence) aspects of responses and variations for the registered medicines. ***** Generate evaluation report. * Prepare report for the internal peer review and where necessary present at advisory committee. • **Risk Management and Audit:** * SOP and Guidelines must

be adhered to. * Create and maintain data bases. * Respond to relevant queries timeously. * Respond to applicants' questions pertaining to recommendations and any other related concerns. * Provide and attend relevant training as may be necessary. • **Develop and update guidelines, SOPs:** * Review existing SOPs and update when necessary. * Create new SOPs where relevant. * Provide regular work-plans and output to the unit manager (qualitative and quantities report). * Perform any other related duty as requested by manager/senior manager.

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: 17 September 2021 at 16H00.