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.

MEDICINE REGISTRATION OFFICER: CLINICAL POST-REGISTRATION EVALUATIONS
Salary: DPSA Equivalent Level SR 10 (Non-OSD TCE) – R653 613.00 p/a
Ref No.: SAHPRA 039/2022

CENTRE: Pretoria

REQUIREMENTS: ● Appropriate 4-year Bachelor of Pharmacy Degree and registration as a Pharmacist with South African Pharmacy Council (SAPC) - proof of current registration as a Pharmacist to accompany the application). ● A relevant NQF 9 qualification in the health sciences will be an added advantage.
Experience: ● A minimum of 1 year practicing as a pharmacist in a clinical environment (post community service).

CORE COMPETENCIES AND TECHNICAL PROFICIENCIES: * Knowledge and application of the Medicines and Related Substances Act (101 of 1965), as amended, and its related Regulations, with respect to the regulation of medicines in terms of quality, safety, and efficacy. * A solid understanding of the pharmaceutical regulatory environment.. * Computer literacy (MS Office packages). * Supervisory skills. * Good planning, organizational and interpersonal skills. * 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. * Good interpersonal qualities. * 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 the interim variation addendum and other clinical guidelines. * Prepare an evaluation report. * Evaluation of pharmacovigilance referrals. * Evaluation of USRN submission for compliance with the USRN guideline where applicable. * Prepare evaluation outcome (recommendations/queries/approval/non-approval) and communicate outcome to Admin/Unit manager. ● **Technical Validation / Screening of Variation Applications and Responses:** * Ensure priority medicines and urgent applications/responses are screened and identified as such for rapid processing. * Attend to queries from previous and/or current screening cycle. * Ensure that the outcome is captured 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 Manager. ● **Evaluation of Responses to Variations:** * Assess submissions for compliance with the variations addendum and other clinical guidelines. * Evaluation of clinical

responses from applicants. * Prepare clinical evaluation report. * Prepare evaluation outcome (recommendations/queries/approval/non-approval) and communicate outcome to Admin/Unit Manager. ● **Timeous Execution of Recommendations:** * Preparation of recommendation for pharmacovigilance referral outcome. * Execution of Advisory Clinical Committee recommendations. * Capturing of ACC Committee recommendations.

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 and email addresses of 3 referees and recently certified copies of ID, required qualification/s (matric included) and driver's licence where applicable.
- Applications without the aforementioned documents/information 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: 26 August 2022 at 16H00.