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:
HEALTH PRODUCTS AUTHORISATION: RENEWALS X6
SALARY: R 657 376.00 – R834 199.00 per annum. **(TOTAL COST TO COMPANY)**
(Grade 1 – Grade 2) Market related salary will be determined by the years of experience obtained post qualification and community service.
Ref No.: SAHPRA 063/2023

CENTRE: Pretoria

REQUIREMENTS: • Matric certificate and appropriate 4-year Bachelor of Pharmacy Degree and registration as a Pharmacist with South African Pharmacy Council (SAPC) or / Honours Degree in Chemistry or equivalent related qualification at NQF level 8 as recognised by SAQA.

Grade 1 – 4-year Bachelor of Pharmacy Degree NQF or Honours Degree in Chemistry or equivalent related qualification at NQF level 8 as recognised by SAQA plus a minimum of five (5) of experience in regulatory. Knowledge of technical evaluation of quality, safety and efficacy aspects of medicines.

Grade 2 - 4-year Bachelor of Pharmacy Degree NQF level 8 as recognised by SAQA and registration as a Pharmacist with South African Pharmacy Council (SAPC) and minimum of three (3) years' experience in regulatory or Honours Degree in Chemistry or equivalent related qualification at NQF level 8 as recognised by SAQA plus a minimum of ten (10) years of experience in regulatory). Knowledge of technical evaluation of quality, safety and efficacy aspects of medicines.

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 requirements for medicine Product Quality Reviews, the associated technical aspects of manufacturing and relevant Good Manufacturing Practices, as per SAHPRA GMP. * Knowledge of technical aspects for evaluation of quality and efficacy of bioequivalence of medicines. * Comprehensive knowledge and understanding of relevant legislation, guidelines, protocols, standard operating procedures, and work instructions as outlined by regulatory authorities. * Good planning, organizational and interpersonal skills. * Self-motivated and able to work independently. * Decision making informed by technical expertise. * Good communication skills (written, verbal, negotiation, conflict management, presentation). * Innovative thinking, initiative, assertive and leadership qualities. * Dedication and accurate work. * Ability to manage a variety of cross-functional team members. * Ethical

behaviour. * Computer skills (knowledge of MS Office). * Must be willing to travel and work irregular hours. * Customer service. *A valid driver's licence.

DUTIES: • **Evaluation and peer-reviewing of renewal applications**: * Evaluate and generate evaluation report(s) for renewal applications (Generics) in compliance with required template and adopted regulatory and scientific standards as per GMP PIC/s guidelines, EMA renewal guidelines etc and submit for peer review. * Peer review evaluation reports, in compliance with good review practice and draft peer reviewed report. * Request QA, expert advice or send to technical committee meeting if necessary and submit signed report for filing and further processing. * Following peer review process, amend the report (s) accordingly to generate a list of queries to the applicant using the correct templates. * Prepare reports or memos for the internal working groups. * Prepare query letter to the applicant. * Prepare a basis of approval or rejection. * Provide quality assurance of reports and facilitate resolutions on technical matters.

• **Evaluate applicant responses of renewal applications:** * Evaluate and generate second (and subsequent) evaluation report (s) for each response application and submit for peer review in compliance with required template and adopted regulatory /scientific standards and submit for peer review. * Peer review other evaluators response reports, according to the required template and adopted regulatory/scientific standards. * Prepare report and record outcomes for the internal working groups, technical meetings or committee meeting. * Prepare query letter to the applicant. * Prepare a basis of approval or rejection.* Provide quality assurance of reports and facilitate resolutions on technical matters.

• **Technical screening of renewal applications:** * Generate technical screening evaluation report(s) for each application and submit for peer review. * Following peer review process, amend the technical screening report (s) accordingly to generate a list of queries to the applicant using the correct templates. * Peer-review technical screening report (s) done by other reviewers.* Prepare screening query / screening rejection letter to the applicant. * Provide quality assurance of reports and facilitate resolutions on technical matters.

• **Develop and update guidelines, SOPs, and templates:** * Review existing guidelines, SOPs and templates and update when necessary. * Provide training on guidelines, SOPs, and templates. * Create new guidelines, SOPs, and templates where SOPs are not in place. * Provide regular work-plans and output to the unit manager (qualitative and quantitative report). * Perform any other related duty as requested by manager/senior manager.

• **Participate in technical working groups or special projects and provide support to the unit as well as to the Advisory Committees:** * Participate in special projects as necessary based on technical and operational needs of the unit. * Lead and manage assessments peer review and discussion working group where relevant. * Compile discussion documents and reports. * Take comprehensive notes of discussions of relevant discussions.

• **Risk Management and Audit:** * SOPs and guidelines must be adhered to. * Create and maintain data bases. * Use the most current templates and guidelines. * Provide and attend relevant training as may be necessary. * Align with QMS requirements. * Align with ICH/VICH, WHO and international standards and use the most current SAHPRA templates and guidelines.

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: 18 December 2023 at 16H00.