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.

Re- Advertisement of Ref no:. SAHPRA 047-2023. Candidates who previously applied are encouraged to reapply.

MEDICINE REGISTRATION OFFICER
NAMES AND SCHEDULING
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 072/2023

CENTRE: Pretoria

Requirements: Matric certificate and appropriate 4-year Bachelor of Pharmacy Degree and registration as a Pharmacist with South African Pharmacy Council (SAPC) at NQF level 8 as recognised by SAQA. A relevant Master's qualification will be an added advantage.

Grade 1 – 4-year Bachelor of Pharmacy Degree and registration as a Pharmacist with South African Pharmacy Council (SAPC) at NQF level 8 as recognised by SAQA plus a minimum of four (4) years of relevant experience of which one (1) in regulatory.

Grade 2 – 4-year Bachelor of Pharmacy Degree and registration as a Pharmacist with South African Pharmacy Council (SAPC) at NQF level 8 as recognised by SAQA plus a minimum of eight (8) years of relevant experience of which two (2) in regulatory.

CORE COMPETENCIES AND TECHNICAL PROFICIENCIES: 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 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. * Initiative-taking and able to work independently. * Good communication skills (written, verbal, negotiation, conflict management, presentation). * Innovative thinking, initiative, assertive and leadership qualities. * Dedication and accurate work. * Ethical behaviour. * Must be willing to travel and work irregular hours. * Customer service. * Planning and organizing skills

DUTIES: Generate evaluation report(s) for each new applications (Generics) in compliance with required template and adopted regulatory /scientific standards and submit for peer review. Following peer review process amend the report (s) accordingly to generate a list of queries to the applicant using the correct templates. Prepare report for the internal working groups and where necessary present at advisory committee for complex scientific matters. Provide quality assurance of reports and facilitate resolutions on technical matters. Generate evaluation report(s) for each new applications (Generics) in compliance with required template and adopted regulatory /scientific standards and submit for peer review. Following peer review process amend the report (s) accordingly to generate a list of queries to the applicant using the correct templates. Prepare report for the internal working groups and where necessary present at advisory committee for complex scientific matters. Provide quality assurance of reports and facilitate resolutions on technical matters.

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 for the internal working groups and where necessary present at advisory committee for complex scientific matters. Prepare query letter to the applicant. Provide quality assurance of reports and facilitate resolutions on technical matters. Participate in special projects and registration group. Lead and manage assessments peer review and discussion working group where relevant. Compile discussion documents and reports. Provide regular trainings to new internal MRO's and external evaluators. Take comprehensive notes of discussions of relevant discussions. Prepare documents for SAHPRA management/ RC meeting.

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 aren't in place. 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. Attend and support the internal and external Audit, including resolution of queries. Manage and keep records regularly of clinical trial related activities. Investigate and advise pharmaceutical industry / applicant's queries or other members of the Public. Manage resolution of the queries in area of work. Provide advice or recommend to inspectorate or regulatory compliance unit. Represent SAHPRA in the local, regional and/or global sphere. Arrange and attend Industry Task Group working groups and external stakeholder meetings.

Review the request from the applicant and prepare a report/document for Advisory Naming and Scheduling Committee. Capture the final recommendation from the Advisory Naming and Scheduling Committee. Prepare a referral letter to Advisory Clinical Committee or any other relevant advisory committee. Consolidate the reports and submit to registration committee's approval/rejection. Liaise with relevant stakeholder on the outcome of the request. Prepare a submission to Minister of Health for approval of amendments on consolidated schedule.

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.
- 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: The closing date has been extended to the 12 January 2024 at 16H00. SAHPRA apologies for any inconvenience caused.