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: R657 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 018/2024
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 or an MBChB degree and registration as a Medical Officer with the Health Professional Council of South Africa (HPCSA) at NQF level 8 as recognised by SAQA. A relevant Master's qualification at NQF level 9 as recognised by SAQA will be an added advantage. Valid driver's license.

EXPERIENCE:
Grade 1 – 4-year Bachelor of Pharmacy Degree and registration as a Pharmacist with South African Pharmacy Council (SAPC) or / an MBChB degree and registration as a Medical Officer with the Health Professional Council of South Africa (HPCSA) at NQF level 8 as recognised by SAQA plus a minimum of three (3) years of clinical 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) or / an MBChB degree and registration as a Medical Officer with the Health Professional Council of South Africa (HPCSA) at NQF level 8 as recognised by SAQA plus a minimum of six (6) years of clinical experience of which two (2) in regulatory.

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 and understanding of the legal and regulatory framework governing the review process, locally and internationally. An understanding of the medicine's discovery process and the pharmaceutical regulatory environment. Technical proficiency in regulatory review practices, pharmacokinetics, pharmacodynamics, bioavailability/bioequivalence,

clinical study data analysis and review for safety, efficacy, and quality. 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. Must be willing to travel and work irregular hours. Ability to work well under pressure. Collaborative skills. Knowledge of quality management systems. Organisational awareness. Good decision-making and critical analytical skills.

DUTIES: **Evaluation of Variation Applications (Reviewing a broad range of applications as a primary peer reviewer):** Assess, analyse, and provide recommendations for minor safety amendments (Type Iain and Type IB) applications, including the applicant's responses to safety concerns raised by either the applicants or the Authority. *Identify key issues, and critically evaluate scientific data (i.e., pharmacokinetic, bioavailability, and bioequivalence data, in vitro (pre-clinical) and in vivo clinical studies of a medicine with different endpoints) from multiple sources. *Provide recommendations for major safety and/or efficacy amendments for simpler and complex molecules. *Conducting a comprehensive review to ensure that the risk profile of each medicinal product is regularly updated to incorporate new information and that risk criteria are modified based on new statistical data on hazards, possible damages to manage their impact on clinical practice and public health. *Review and summarise relevant information from clinical trials for product information documents to ensure that the product information contains accurate claims on product effectiveness, and safety as well as adequate directions for product use. *Consult other experts, act as a mentor, and provide guidance on assessments to other reviewers by conducting a critical review of their reports. *Ensure timeous reviews of applications. **Conducts evidence-informed practice:** Identifies the parts of a scientific publication and the general purpose of each part. Searches published literature using key terms to find articles on specific subjects related to the application undergoing review. Summarises the essential message and purpose of published materials, such as scientific publications, reports, or guidelines. Utilises the full range of reference and resource materials in this area. **Makes or recommends regulatory decisions:** Generate detailed scientific evaluation reports in line with the good review practice guide, ICH guidelines, SAHPRA guidelines and other relevant international standards for internal peer review and where necessary, for presentation to the Advisory Clinical Committee. Prepare evaluation outcome (recommendations/queries/approval/non-approval) to be communicated to the external stakeholder. **Technical Validation / Screening of Variation Applications and Responses:** Ensure priority medicines and urgent applications/responses are screened and identified as such for rapid processing as per the priority review policy. Attend to queries from previous and/or current screening cycle. Ensure that the outcome is captured on the database and that a rejection/approval letter is sent out to the applicant. Conduct thorough technical screening of variation applications for evaluation i.e., ensuring references submitted to support the proposed amendments are appropriate and complete. Assess submissions for compliance with the local regulatory requirements as stipulated in the variation addendum and other clinical guidelines**.** Direct the implementation of different regulatory pathways based on reliance, collaboration, and recognition. Prepare a screening outcome report and to be communicated to the external stakeholders. **Evaluation of Responses to Variations:** Assess submissions for compliance with the Variation addendum and other clinical guidelines. Primary and peer review of responses with clinical data for simpler molecules. Prepare a critical clinical response evaluation report after the review of the safety and/or efficacy data from clinical studies, published literature sources, reliance

decisions of other regulatory authorities, or review of documented signals. Prepare evaluation outcome (recommendations/queries/approval/non-approval) and communicate outcome to the applicant. **Audit and Risk Management:** Ensure an unqualified risk and internal audit opinion for Clinical Post-Registrations by submitting monthly POEs and updating the risk register monthly. Continuously respond to the needs and expectations of the industry, external evaluators, and Internal queries within a period of 1 week. Adherence to SOPs and SAHPRA, ICH, EMA and other relevant guidelines. Develop, review, and improve the accuracy of databases to enable revenue recognition by the finance unit. Respond to relevant queries timeously. Attend relevant training as may be necessary. **Implement internal communication and provide regulatory support through stakeholder management:** Liaising with management, legal and communications departments for advice to clarify established SAHPRA systems and methodologies. Provides comments, inputs and advice on international standards and guidance documents, representing the interest of SAHPRA at national, regional, and international levels. Provides regulatory support and guidance to industry and other stakeholders of the Authority. *Provides support to management in the operation of the department/unit. Participate in special projects and Pre- and Post-registration working groups as required and engage in technical scientific discussions on ongoing applications under review. Prepare discussion documents, including agendas, minutes and action items, and reports where required. Preparation of recommendations for pharmacovigilance referral outcome. Capturing and Execution of Advisory Clinical Committee recommendations. Participate in international scientific regulatory forums and discussion groups including ICH or WHO, as relevant and when nominated. Provide regular work-plans and output to the manager. Perform any other related duty as requested by the manager/senior manager.

INSTRUCTIONS TO APPLICANTS (HOW TO APPLY): Interested applicants who meet the above requirements should forward their applications accompanied by signed covering letter attached to the comprehensive CV with the names and email addresses of three (3) referees clearly reflecting the **name of the position and post reference number**, 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. **All shortlisted candidates will be subjected to a technical exercise that intends to test relevant knowledge, skill and technical elements of the job.**
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.

Interested persons who meet the above-stated qualifications should forward their applications which should consist of a cover letter, detailed Curriculum Vitae, copies of qualification(s) and Identity Document. ONLY shortlisted candidates will be required to submit certified copies of qualifications and other related documents on or before the day of the interview following communication from Human Resources.

SAHPRA comply with the provisions of Protection of Personal Information Act (POPIA); Act No. 4 of 2013. We will use your personal information provided to us for the purpose of recruitment only and more specifically for the purpose of the position/vacancy you have applied for. In the event your application was unsuccessful, SAHPRA will retain your personal information for internal audit purposes as required by policies.

Applications should be submitted through the SAHPRA Website Online Portal: **SAHPRA website (**https://www.sahpra.org.za**) – About Us – Vacancies**.

Enquiries: Ms S. Molepo, Email: setlola.molepo@sahpra.org.za **(APPLICATIONS SENT TO THIS EMAIL ADDRESS WILL NOT BE CONSIDERED FOR THE RECRUITMENT PROCESS). The closing date is 28 June 2024 at 16H00.**