The South African Health Products Regulatory Authority (SAHPRA) is the National Medicines Regulatory Authority established in terms of the ***Medicines and Related Substances Act, 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: PHARMACOVIGILANCE

SALARY: R 700 105.00 – R 888 422.00 per annum (TOTAL COST TO COMPANY)

(Grade 1 – Grade 2) Market-related salary will be determined by the years of experience obtained post qualification, Internship and Community Service in line with governing frameworks.

Ref No.: SAHPRA 07/2025

CENTRE: PRETORIA

REQUIREMENTS: Matric certificate and appropriate four-year degree in Pharmacy at NQF Level 8 as recognised by the South African Qualifications Authority (SAQA) and registration with a Professional Body (South African Pharmacy Council). A relevant Master's degree will be an added advantage. A valid driver's licence.

EXPERIENCE:

Grade 1 – A minimum of two (2) years of Pharmacovigilance experience post internship and Community Service. Regulatory experience will be an added advantage.

Grade 2 –A minimum of five (5) years of Pharmacovigilance experience post internship and Community Service.

COMPETENCIES, KNOWLEDGE, AND SKILLS: 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. Basic knowledge of the medicines regulatory framework, policies, and process. Knowledge and understanding of clinical pharmacology. Basic understanding of medicine registration and harmonisation.

- Excellent interpersonal and communication skills (written and verbal)
- Critical thinking
- Ability to exercise good judgment and solve problems quickly and effectively.
- Computer skills.
- Solution orientated.
- Ability to work under pressure.
- Ability to maintain high levels of confidentiality.
- Interpersonal skills.

- Change management.
- Knowledge management.
- Service delivery innovation.
- Problem solving and analysis.
- Client orientation and customer focus.
- Proactive stakeholder management.
- Situational adaptability.
- Collaboration.

DUTIES: **Operational Management:** Responsible for the accurate and timeous assessment of safety documents received, and performance as per the defined processes. Preparing comprehensive reports for various purposes (e.g., regulatory submissions, advisory committees, internal communication). Preparing accurate, timely, and well-documented reports that meet regulatory requirements. Documenting decision-making processes and justifications. Writing clear, concise, and evidence-based reports. Producing scientific peer-reviewed evaluation reports. Provide technical and administrative support to committees. Engaging stakeholders relating to regulatory matters. Manage product review systems. Processing applications received for approval. **Support the AEFI management:** Conduct case management and causality assessments for AEFI cases for all registered vaccines. Establish integrated procedures and processes for monitoring, reporting and assessment of vaccine-related safety concerns. Train healthcare professionals in the provinces on AEFI management, causality assessment and AEFI reporting procedures and tools. Review, update and implement updated procedures and processes for the management of registered vaccines. **Support Pharmacovigilance (PVC) and National Immunisation Safety Expert Committee (NISEC):** Support the PVC/NISEC both technically and administratively. Coordinate all PVC/NISEC meetings and minutes thereof. Allocate case files for clinical assessment to both pharmacovigilance technical officers and NISEC members. Update AEFI cases on reports management system as per the NISEC causality assessment outcome. Prepare and provide monthly reports/statics on AEFI cases. Ensure case closure and provision of feedback to the provinces. Prepare and communicate all regulatory decisions as per the meeting discussions. **Coordinate and support provinces on vaccines and therapeutics safety reporting and case management:** Support and strengthen linkages with provincial Departments of Health (DoH) to facilitate SAHPRA decentralised pharmacovigilance activities. Implement procedures and strengthen coordination with provincial and district-level DoH staff to improve AEFI and ADR reporting and case management activities. Develop/update reporting procedures for both AEFIs and therapeutics ADRs and co-ordinate finalisation. Strengthen provincial safety committees and linkages to SAHPRA. **Training and outreach:** Co-ordinate and implement trainings for healthcare professionals in both private and private sectors. Co-ordinate medicine safety awareness webinars and workshops. Work closely with provinces and stakeholders for planning and implementation of outreach programmes for both healthcare professionals and the public. **Benefit-Risk Evaluation:** Critically assess Risk Management Plans (RMP)/Periodic Benefit-risk Evaluation Reports (PBRER)/Periodic Safety Update Reports (PSUR)/Summary of Benefit-Risk Evaluation reports/Safety signals as submitted by applicants or received from any other stakeholder. Write clear, concise, and evidence-based reports. Produce scientific peer-reviewed scientific reports for discussion. Timeous preparation and submission of assessment reports to ensure compliance with targets and timelines. Prepare and publish safety-related communications timeously. **ICSR Management:** Processing and management of ADR/ADE reports received. Clinical assessment of serious adverse reaction reports. Co-ordinate and participate in causality assessment meetings of serious cases and cases of public interest. Conduct signal detection/assessment and necessary investigation. **Financial Management:** Collating, compiling, and submitting accurate reports in a timely manner to satisfy statutory and business requirements as well as be able to communicate key financial messages to stakeholders with clarity

and consistency. Provide general advice on all related financial matters to all relevant colleagues involved, directly or indirectly, in the financial circuit. Monitors and maintains all required financial records for compliance and audit to all agreed requirements. Collate financial data and reports for analysis and to facilitate decision making. **Governance, Compliance and Risk:** Achieve and maintain process quality. Adherence with the OHSA to ensure a safe and healthy working environment. Ensure adherence to all process quality assurance requirements. Assist with Performance Reporting within the predetermined timeline. Identify and record operational risks and consult with the Unit Manager. Mitigate risks within operational control. Resolve the operational risks effectively and timeously. Filing of evaluation reports under respective product folders. Assisting with the compliance of the Quality Management System requirements of the unit. Identify and record operational risks and consult with Unit Manager. Development and maintenance of guiding principles (SOPs, guidelines, policies, etc.) to ensure consistency, efficiency and alignment of PV processes. Identify and implement new approaches to improve and to maintain consistency, efficiency and alignment of PV processes. Update policy documents to improve and maintain high levels of operational efficiency and effectiveness. **People Management:** Self-management. Manage own Performance and Individual Development Plan. Living the SAHPRA values. Sharing knowledge with and informal coaching peers (as applicable).

INSTRUCTIONS TO APPLICANTS: (HOW TO APPLY): Interested applicants who meet the above requirements should forward their applications accompanied by a signed cover 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 three (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 might 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 complies with the provisions of the Protection of Personal Information Act (POPIA), 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 B. Rakgotho, email: bafedile.rakgotho@sahpra.org.za
(APPLICATIONS SENT TO THESE EMAIL ADDRESSES WILL NOT BE CONSIDERED FOR THE RECRUITMENT PROCESS). The closing date is 21 February 2025 at 16:00.