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 038-2023. Candidates who previously applied are encouraged to reapply.

MEDICINES REGISTRATION OFFICER – PHARMACOVIGILANCE

(FIXED TERM CONTRACT POSITION: 24 MONTHS)

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 070/2023

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. • A postgraduate qualification in relevant Science or equivalent is an added advantage.

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 of which two (2) year must be in pharmacovigilance. Training in pharmacovigilance. • Knowledge and application of the Medicines and Related Substances Act (Act 101 of 1965) as amended and its Regulations. • Knowledge of quality, safety, and efficacy aspects of medicines. • Knowledge of medicines registration with respect to safety and efficacy of medicines. • Experience in drafting medical industry communications and articles.

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 of which one (1) year must be in pharmacovigilance 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 of which three (3) years must be in pharmacovigilance. Training in pharmacovigilance. • Knowledge and application of the Medicines and Related Substances Act (Act 101 of 1965) as amended and its Regulations. • Knowledge of quality, safety, and efficacy aspects of medicines. • Knowledge of medicines registration with respect to safety and efficacy of medicines. • Experience in drafting medical industry communications and articles.

COMPETENCIES, KNOWLEDGE AND SKILLS: * Comprehensive and sound knowledge of all relevant legislation, protocols, regulations, and guidelines pertaining to the Medicines and Related Substances Act, Act 101 of 1965. * Good verbal and numerical reasoning skills to allow analysis and interpretation of written and numerical data. * Delivery of service objectives with professional excellence and efficiency. * Ability to make effective decisions by using evidence and knowledge to support accurate, expert decisions and advice while carefully considering the implications of such a decision. * Good planning and organisational skills. * Ability to work unsupervised for long periods of time. * Promoting a more proactive, service oriented and performance-based management culture. * Good, effective communication skills (verbal, written, conflict management and resolution). * Ability to meet tight deadlines and manage multiple, often competing priorities. * Ability to work within a team environment. * Ethical behaviour and adherence to the SAHPRA Code of Conduct. * Proficient knowledge of MS Office. *A valid Driver's License.

DUTIES: • Individual case safety reports management: * Processing of adverse drug events reports. * Clinical case assessment of adverse drug reaction reports and feedback provision to reporters. * Signal detection and management. * Reporter follow-up and system update. **• Benefit-Risk assessment:** * Investigate and review medicines safety concerns and prepare review reports for peer review and/or Pharmacovigilance Technical Advisory Committee discussions. * Peer review technical reports. * Technical support to the Pharmacovigilance Technical Advisory Committee. * Publication of safety regulatory decisions made by the Authority. **• Medicine Safety Communication:** * Draft, finalise and communicate safety communication documents (DHCPL, Newsletter, Articles, MSAs, Media Queries, Press release) as per the guiding principles. **• PV stakeholder management:** * Identify key stakeholder for engagements. * Arrange/participate in the stakeholder engagements. * Record/Minute the discussions and action plans. * Ensure implementation and follow-up of resolutions. **• Promote PV awareness and outreach:** * Develop a quarterly PV awareness and outreach plan. * Develop/update PV training materials. * Train healthcare professionals and the public on pharmacovigilance. * Coordinate medicine safety webinars. **• 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 maintain high levels of operational efficiency and effectiveness. * Update policy documents in line with international standards to improve and maintain high levels of operational efficiency and effectiveness. * Development and maintenance of guiding principles (SOPs, guidelines, policies, etc.) to ensure consistency, efficiency and alignment of PV processes.

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.