

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: VIGILANCE GR 2
Ref No.: SAHPRA 013/2022

CENTRE: Pretoria

REQUIREMENTS: • Appropriate 4-year Bachelor of Pharmacy Degree and registration as a Pharmacist with the South African Pharmacy Council (SAPC).

Experience: • Training and experience in pharmacovigilance.

COMPETENCIES (KNOWLEDGE, SKILLS & ABILITIES): * 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. * An understanding of the ADR/ADE reporting process. * Working knowledge in pharmacology and data management. * Computer literacy and MS Windows computer skills, Excel and database applications. * Good report writing and presentation skills. * Good planning, organisational and skills. * Good verbal and written communication skills. * Ability to work independently and in a team. * Pay attention to details.

DUTIES: • **Collection, management and assessment of suspected Adverse Drug Reactions:** * Technical screening, Capturing, Uploading and committing of ADR/ADE reports. * Participate/Perform in causality assessment on serious cases and cases of interest. * Technical screening, Perform signal detection and conduct investigations. * Prepare review report for discussions at Peer Review/Pharmacovigilance Advisory Committee/Management. • **Health Products Evaluation and Risk Management:** * Investigate safety concerns and prepare review report for peer-review. * Peer-review reports done by other reviewers. * Attend, present and participate in peer-review and Pharmacovigilance Advisory Committee discussions. * Minute Peer-Review/Pharmacovigilance Advisory Committee discussions and recommendations. * Execute Peer-review/PAC recommendations. • **Partnerships, Collaboration & Communication:** * Prepare and attend Industry engagements and other Regulatory Forums. * Respond to stakeholder queries timeously. * Review and facilitate the finalisation and publication of DHCPs, Media Release, MSA & Newsletters. •

Vigilance Awareness, Promotion and Training: * Plan vigilance awareness and promotion campaigns among HCPs and the public. * Training of HCPs and students on vigilance scope. * Develop vigilance training material/information tool. * Present and exhibit at medical/pharmaceutical conferences/workshops/etc. • **Vigilance Quality System:** * Identify and Implement new approaches to improve efficiency of function. * Identify and implement new approaches aligned with international medicine regulatory best practice. * Vigilance regulatory processes and practices are standardised with policies and procedures. * Maintain and update safety issue record spreadsheet and POEs for audit purposes.

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 of 3 referees and recently certified copies of ID and qualification/s.
- Applications without the afore mentioned 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: 11 March 2022 at 16H00.