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.

MEDICINES CONTROL OFFICER: REGULATORY COMPLIANCE

(FIXED TERM CONTRACT: UNTIL 30 SEPTEMBER 2025)

SALARY: R700 105.00 – R888 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 and community service in line with governing frameworks

Ref No.: SAHPRA 24/2025

CENTRE: Pretoria

REQUIREMENTS: Matric certificate and appropriate four-year Bachelor of Pharmacy degree and registration as a Pharmacist with the South African Pharmacy Council (SAPC) at NQF level 8 as recognised by the South African Qualifications Authority (SAQA). A relevant Master's qualification at NQF level 9 as recognised by SAQA will be an added advantage. Valid driver's licence.

EXPERIENCE

Grade 1: Four-year Bachelor of Pharmacy degree and registration as a Pharmacist with the SAPC at NQF level 8 as recognised by SAQA plus a minimum of three (3) years' experience as a practising pharmacist post community service, of which two (2) should be in pharmaceutical regulatory environment.

Grade 2: Four-year Bachelor of Pharmacy degree and registration as a Pharmacist the SAPC at NQF level 8 as recognised by SAQA plus a minimum of five (5) years' experience as a practising pharmacist post community service, of which three (3) should be in pharmaceutical regulatory environment.

COMPETENCIES, KNOWLEDGE AND SKILLS

*A solid understanding of application procedures. *Medicines Act as Amended and its Regulations. *Consolidated Schedules. *Planning and organisational skills. *Interpersonal skills. *Investigation skills. *Computer skills and knowledge of MS Office. *Drive and self-management skills. *Communication skills. *Report writing. *Resilience. *Assertiveness. *Ethical behaviour. *Ability to work under pressure and irregular hours. *Professionalism. *Ethical conduct and adherence to the SAHPRA Code of Conduct. *Integrity.

DUTIES: Investigation of compliance / non-compliance and reporting: Investigate matters related to the contravention of the Medicines Act (medical device establishments, pharmacies, complementary medicine establishments, ports of entry, illegal establishments, etc. Investigate complaints relating to the advertising of medicines (control of promotional, marketing, and advertising activities). Allocated post-marketing surveillance of advertising cases. Issuing of authorisations for samples, reference standards, etc relating to import, export. Processing of applications for donations. Processing of applications for Section 36. Coordinate, review applications for destruction of scheduled medicines/substances, medical devices, and IVDs. Cooperation and collaborations with stakeholders locally and abroad. Review applications and compile possession permits for manufacturing and research. Detention/seizure of non-compliant products. Coordinate and schedule allocated investigations with the team inspector as per allocation. Investigate and attend to industry /applicant queries. Conduct joint inspection/s with law enforcement agencies (e.g. BMA, SARS, HPCSA, SAVC, SAPS & SAPC). Perform all activities according to relevant SOPs.

Responsible for overall Product Quality defects/ Complaints activities requiring Alerts and Recalls actions (Substandard/Falsified medical products): Identify activities relating to Product Quality defects, specifically those requiring alerts. Apply the SOP for alerts/recalls timely. Ensure that management is updated. Ensure that appropriate communication is prepared for approval. Ensure that draft information for internal and external stakeholders is available for review and approval. Ensure that Applicants comply with the conditions of alerts/recalls. Update the website notifications. Prepare a monthly report for the manager. Write an annual report for alerts/recalls. Provide feedback to relevant SAHPRA unit/s where applicable.

Inspection and reporting: Inspect allocated sites (e.g. Cannabis sites, pharmacies, wholesalers – site can be based on the complaint received). Reports to be completed within 30 working days from the inspection date. Help review the SOP for Investigations and conduct inspections in accordance with SOP. Participate in risk and audit enquiries (internal and external audits). Compile reports and resolutions for the Licensing Unit or referral unit applicable. Ensure the reports comply with QMS

approved formats.

Lodge criminal cases with the authorities and appear in court when subpoenaed: Where criminal offenses are identified, open criminal cases with the South African Police Services (SAPS) and write affidavits/statements. Attend to court as per subpoena. Assist SAPS/National Prosecuting Authority with writing affidavits for crimes relating to contravention of the Medicines Act.

Strengthen Cooperation with stakeholders (training, information sharing): Participate in Border Management Authority, South African Revenue Services, SAPS, Health Professions Council for South Africa and SAPC as aligned with Memoranda of Understanding (MoUs). Attend meetings, conferences and briefings with stakeholders, including workshops and training overseas. Support the initiatives of stakeholders which are relating to contravention of the Medicines Act. Support the Communication Unit's queries relating to media. Training of stakeholders. Consult with internal core business and support units whenever applicable (Manager, Senior Manager, Executive Management, Advisory Committees, Complementary Medicines, Medical Device Unit, Section 21, Names and Scheduling, Veterinary, Biological). Foster cooperation and collaboration with relevant SAHPRA units to enhance appropriate regulatory outcomes on matters. Foster cooperation and collaboration with statutory bodies, industry associations, activist organisations and media. Attend operations quarterly with law enforcement agencies.

Reporting: Participate in risk and audit queries relating to your focal area. Submit and present performance reports on your focal area monthly. Comply with QMS requirements for a clean audit. Review SOP and Guidelines for alerts, recalls and withdrawals as required.

INSTRUCTIONS TO APPLICANTS (HOW TO APPLY):

- Interested persons who meet the above-stated requirements should submit their application, clearly state the position name and post reference number, including a signed cover letter, clearly state the position name and post reference number, detailed Curriculum Vitae (CV) with the names and email addresses of three (3) referees, copies of required qualifications (including matric) 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.
- Should you have a foreign qualification, your application must be accompanied by an evaluation certificate (report) from the South African Qualifications Authority (SAQA).
- Incomplete applications or applications without the aforementioned documents or information will not be considered.
- No late applications will be accepted. Any submissions received after the specified date and time will not be considered, and CVs will not be returned.
- **Due to the larger number of responses anticipated, communication will be limited to short-listed candidates only. Applicants who have not been contacted within three (3) months after the closing date should consider that their application to be unsuccessful.**

- Shortlisted candidates will be expected to attend selection interviews at a date, time, and location as specified by SAHPRA.
- Applicants should note that pre-suitability checks will be conducted after they have been shortlisted. Their appointment is subject to positive outcomes from these checks, which include security clearance, verification of qualifications, criminal records, credit checks, citizenship status, and work experience.
- SAHPRA is committed to being an equal opportunity employer. When filling vacant positions, the entity will consider the principles outlined in Section 195(1)(i) of the Constitution of the Republic of South Africa, Act 101 of 1996, and the Employment Equity Act, 55 of 1998. Applicants with disabilities are encouraged to apply and indicate their disability status, which will be appreciated.
- SAHPRA reserves the right not to make any appointment(s) to the advertised post(s).
- SAHPRA adheres to the provisions of the Protection of Personal Information Act (POPIA), 4 of 2013. CVs will not be returned, as the personal information you provide will be used solely for recruitment purposes, specifically for the position or vacancy you have applied for. If your application is unsuccessful, your personal information will be retained for internal audit purposes.
- Applications should be submitted through the SAHPRA Website Online Portal: https://www.sahpra.org.za/vacancies.
- **For enquiries:** Please contact Mr Itumeleng Mosenyi, HR Business Partner, via email at itumeleng.mosenyi@sahpra.org.za**. NOTE: APPLICATIONS SUBMITTED TO THIS EMAIL ADDRESS WILL NOT BE CONSIDERED AS PART OF THE RECRUITMENT PROCESS.**
- **The closing date is 24 May 2025 at 16:00.**