



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.

**MEDICAL OFFICER: SECTION 21
(DPSA Equivalent Level SR 11 (Non-OSD TCE) – R744 255)
Ref No.: SAHPRA 026/2022**

CENTRE: Pretoria

REQUIREMENTS: A qualification in one of the following from a recognised tertiary institution: • MBChB (Certification of active Registration with the HPCSA as an independent practitioner is required). • Master of Pharmacy (MPharm). • Master of Clinical Pharmacy (M.Clin.Pharm). • Pharm.D.

Experience: • Previous experience in a clinical or regulatory research (non-patient facing) environment will be advantageous.

CORE COMPETENCIES AND TECHNICAL PROFICIENCIES: * Comprehensive and sound knowledge of all relevant legislation, protocols, regulations, and guidelines pertaining to the Medicines and Related Substances Act 101 of 1965. * Sound knowledge of the regulatory requirements of the use of an unregistered medicine, i.e., Section 21 of the Medicines Act and Regulation 29 of the General Medicines Regulations. * Sound knowledge of regulatory scientific and technical requirements in terms of quality, safety, and efficacy. * Comprehensive knowledge and understanding of the international regulatory clinical trials guidelines. * Proficient knowledge of MS Office (Word, Excel, PowerPoint). * Good, effective communication skills (verbal, written, conflict management and resolution). * 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. * Ability to work unsupervised for long periods of time. * Ability to work within a team environment. * Good planning and organisational skills. * Promoting a more proactive, service oriented and performance-based management culture. * Communication skills (verbal, written, negotiation, conflict management, presentation). * Ability to meet tight deadlines and manage multiple, often competing priorities. * Ethical behaviour and adherence to the SAHPRA Code of Conduct. * Prepared to travel and work irregular hours. * A valid driver's licence.

DUTIES: • Evaluation of applications: * Technical screening and evaluation of Section 21 applications: ○ Process between 60-80 applications daily and 50 to 70 resubmissions daily. ○ Ensure that 85% of applications must be screened and evaluated within three (3) working days (24 working hours). ○ Risks must be identified if this target is unable to be met and corrective actions must be put in progress to mitigate these risks. * Research Section 21 applications for new unregistered medicines: ○ Carry out evidence-based research to understand the context behind the application, e.g., public health emergency, supply chain issues. * Liaise with

experts on high-priority applications. * Attend to and review written and telephonic Section 21 queries, e.g., procedural, new products and monitor the Section 21 email inbox. * Compile Section 21 agenda documents for presentation at SAHPRA internal discussions. * Prepare minutes of the SAHPRA Internal meeting pertaining to Section 21 resolutions. * Prepare letter/s to relevant stakeholders communicating meeting resolutions or expert discussion on Section 21 issues. * Present at relevant internal SAHPRA meetings and provide evidence-based recommendations. • **Monitoring and Evaluation activities:** * Conduct monitoring and evaluation of the unit's activities as per Annual performance Plan, Operational Plan, revenue-generating requirements, and risk register entries on a monthly and quarterly basis. • **Supervisory duties:** * Supervise MROs in the Section 21 unit and provide team leadership and direction on daily operational tasks and responsibilities. * Ensure that performance contracts and appraisals are conducted timeously and provide feedback to the Manager, Section 21. • **Unit Administration:** * Draft policy documents as pertains to Section 21 authorisations (SOPs, guidelines, legislation amendments). * Ensure timely and accurate submission of proof of payment source document for all Section 21 applications to the Finance unit.

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.
- 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: 13 May 2022 at 16H00.