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.

MEDICINES REGISTRATION OFFICER
CLINICAL EVALUATION MANAGEMENT: SECTION 21 UNIT
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 073/2023

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 / an MBChB degree and registration as a Medical Officer with the Health Professional Council of South Africa (HPCSA). A postgraduate qualification in pharmacology or related will be an added advantage.

Grade 1 – 4-year Bachelor of Pharmacy Degree and registration as a Pharmacist with South African Pharmacy Council (SAPC) or / an MBChB degree and registration as a Medical Officer with the Health Professional Council of South Africa (HPCSA). Minimum of four (4) years experience in the hospital setting or clinical research setting (post community service) of which one (1) year in regulatory.

Grade 2 – 4-year Bachelor of Pharmacy Degree and registration as a Pharmacist with South African Pharmacy Council (SAPC) or / an MBChB degree and registration as a Medical Officer with the Health Professional Council of South Africa (HPCSA). Minimum of eight (8) years of experience in the hospital setting or clinical research setting (post community service) of which two (2) years in regulatory.

CORE COMPETENCIES AND TECHNICAL PROFICIENCIES: *Sound and in-depth knowledge of the Medicines and Related Substances Act 101, 1965 as amended and the regulations pertaining to the Act. *Sound knowledge of regulatory scientific and technical requirement (in terms of quality, safety and efficacy aspect). *Good 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. *A solid understanding of application procedures. *Section 21 application technical evaluation skills. *Planning and organising skills. *Performance measurement skills. *Self-motivated and able to work independently. *Team management. *Competent in problem solving and team building. *Decision making. *Objectivity. *Prepared to travel and work irregular hours. *Drive and self-management skills. *Resilience. *Communication skills (verbal, written, negotiation, conflict management, presentation). *Interpersonal skills. *Assertiveness. *Ethical behaviour. *Customer service. *Knowledge of MS Office. *A valid driver's license.

DUTIES: OUTPUT 1: Technical screening of section 21 applications. Evaluation of Section 21 applications based on review of data from multiple sources. Research Section 21 applications for new unregistered medicines. Liaise with experts (internal and external) on high-priority applications. Attend to and review written Section 21 queries, e.g., procedural, new products, monitor Section 21 email inbox. Compile Section 21 agenda documents for presentation at Clinical Trials Committee meeting or SAHPRA internal discussions. Prepare minutes of the CTC meeting pertaining to Section 21 resolutions. Prepare letter/s to relevant stakeholders communicating CTC meeting resolutions or expert discussion on Section 21 issues. Liaise with experts on high-priority applications.

OUTPUT 2: 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. Draft policy documents as pertains to section 21 authorizations (SOPs, guidelines, legislation amendments). Contribute to optimal submission of proof of payment source document (section 21 applications) to the Finance unit.

OUTPUT 3: Supervise admin staff in the Section 21 unit. Play an active role with stakeholder engagement, awareness and outreach programs (e.g., applicants, pharmaceutical industry, NDoH, etc.).

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: **18 December 2023 at 16H00.**