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: GR 2 (Clinical Evaluations: Post-registration) DPSA Equivalent Level OSD TCE
Ref No.: SAHPRA 035/2020

CENTRE: Pretoria

REQUIREMENTS: • Appropriate 4-year Bachelor of Pharmacy Degree. • A minimum of eight (8) years appropriate experience. • Registration as a Pharmacist.

COMPETENCIES, KNOWLEDGE AND SKILLS: * Knowledge and application of the Medicines and Related Substances Control Act 101 of 1965, as amended, and its related Regulations, with respect to the regulation of medicines in terms of quality, safety, and efficacy. * Computer literacy (MS Office packages). * Supervisory skills. * Good planning, organisational and interpersonal skills. * Good communication skills (written and verbal). * Innovative thinking, initiative, and leadership qualities. * Dedication and accurate work. * Knowledge of database management will be advantageous. * Must be willing to travel and work irregular hours. *A valid driver's licence.

DUTIES: Evaluation of generic PI/PIL applications: * Allocate generic PI/PIL applications to reviewers. * Evaluation of generic PI/PIL applications. * Follow-up with evaluators with regard to applications allocated. * Prepare a report for the Advisory Clinical Committee. * Prepare Advisory Clinical Committee documents. **Evaluation of applicants' responses:** * Evaluation of PI/PIL responses from the applicants. * Prepare committee documents for those responses that require further intervention by the committee. * Prepare in-house recommendations to applicants wherein there are minor errors on the package insert and PIL. * Allocate the response for re-evaluation by the clinical reviewers. * **Preparation of Advisory Clinical Committee documents**. * Preparation of urgent documents (including fast tracks) as requested by the, Manager, Senior Manager, the Chief Regulatory Officer and the Chairperson of committee. ***** Compile required documents for Advisory Clinical Committee recommendation. * Assist in finalization of the agenda. * Prepare, attend and participate in discussions during the meetings. * Attend to queries from committee

members. * Capturing the Advisory Clinical Committee recommendations. **Supervise the administrative staff and attending to queries addressed to the clinical unit:** * Supervise the administrative staff and all their activities in the unit to ensure the smooth running of the unit. * Ensure that the documents are distributed to committee members timeously. * Provide technical advice and information to all stakeholders. * Attend to queries from the Senior Manager, other Programmes, the legal unit and the Chief Regulatory Officer's office. **Minute Advisory Clinical Committee proceedings and execute Advisory Clinical Committee recommendations:** * Capturing the Advisory Clinical Committee minutes and recommendations. * Execution of Advisory Clinical Committee recommendations. * Ensure the correctness of Advisory Clinical Committee recommendations.

INSTRUCTIONS TO APPLICANTS: All applications must:

- Be made on Z83 forms (obtainable http://www.dpsa.gov.za/dpsa2g/documents/forms/employ.pdf or from any Government department), clearly reflecting the name of the position and the **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 form 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 or faxed applications will be accepted. CV's 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 September 2020 at 16H00.