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 X2 (PEM: Post-registration)
DPSA Equivalent Level OSD TCE: GR 1-3
Ref No.: SAHPRA 040/2020

CENTRE: Pretoria

REQUIREMENTS: • Appropriate 4-year Bachelor of Pharmacy Degree. • Regulatory experience will be an added advantage.

COMPETENCIES, KNOWLEDGE AND SKILLS: * Knowledge and application of the Medicines and Related Substances Act (101 of 1965) as amended and its related Regulations and Guidelines. * Knowledge of technical aspects for evaluation of quality and efficacy (bioequivalence) of medicines. * Computer literacy and sound working knowledge of computer software packages. * Technical and scientific aspects of medicine regulation. * Evaluation guidelines as prescribed by the relevant regulatory authorities. * Planning and organisational skills. * Leadership skills. * Coordination skills. * Written and verbal communication skills. * Diversity management. * Time management. * Good telephone etiquette. * Supervisory skills.

DUTIES: • Assess, and peer review new applications for the registration of medicines: * Technical screen and evaluate the quality and efficacy (bio-equivalence) aspects of new applications for the registration of medicines. * Generate screening/evaluation report for each application. * Send report to second evaluator for peer review. * Present report to the peer review process and advisory committee. * Minute discussions and amend report accordingly to generate a recommendation. **• Evaluate applicant responses and variations for registration/approval of medicines:** * Evaluate the quality and efficacy (bio-equivalence) aspects of responses and variations for the registration/approval of medicines. * Generate evaluation report. * Prepare report for the internal peer review and where necessary present at advisory committee. * Peruse peer review report/feedback and minute committee discussions and amend report accordingly to generate queries/questions**. • Form part of technical working groups or special projects and also provide support to the Advisory Committees:** * Participate in special projects or registration group. * Lead and manage assessments peer review and discussion working group where relevant. * Compile discussion documents and reports. * Take comprehensive notes of discussions of relevant discussions. * Prepare documents for SAHPRA management/ RC meeting. **• Risk Management and Audit:** * SOP and Guidelines must be adhered to. * Create and maintain data bases. * Respond to relevant queries timeously. * Respond to applicants' questions pertaining to recommendations and any other related concerns. * Provide and attend relevant training as may be necessary. **• Develop and update guidelines, SOPs:** * Review existing SOPs and

update when necessary. * Create new SOPs where relevant. • Provide regular work-plans and output to the unit manager (qualitative and quantities report). • Perform any other related duty as requested by manager/senior manager.

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 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: 09 October 2020 at 16H00.