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: GR 2 (Licensing)
(DPSA Equivalent Level OSD TCE: GR 2)
Ref No.: SAHPRA 037/2021

CENTRE: Pretoria

REQUIREMENTS: • Appropriate 4-year Bachelor of Pharmacy Degree and registration as a Pharmacist with the South African Pharmacy Council (SAPC) Proof of registration as a Pharmacist must be submitted with your application. • Regulatory and pharmaceutical 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, with respect to the regulation of medicines in terms of quality, safety, efficacy and performance. * Knowledge of technical aspects for evaluation. * Information evaluation. * Technical and scientific aspects of medicine regulation. * Comprehensive knowledge and understanding of relevant legislation, protocols, standard operating procedures and work instructions. * Evaluation guidelines as prescribed by the relevant regulatory authorities. * Computer literacy (MS Office packages with emphasis on above basic Ms Excel). * Good planning, organisational and interpersonal skills/qualities. * Communication skills (verbal, written, negotiation, conflict management, presentation). * Self-motivated and able to work independently. * Decision making. * Objectivity. * Resilience. * Dedication and accurate work. * Knowledge of database management will be advantageous. * Ability to work well under pressure. * Assertiveness * Ability to work in a team. * Ethical behaviour. * Customer service. * Coordination skills. * Time management. * Good telephone etiquette. * Must be willing to work irregular hours, e.g., after-hours meetings and stakeholder engagements.

DUTIES: • **Technical Evaluation of Licence Applications submitted for the granting of the following categories of licences to determine the level of compliance with the provision of the Act and its regulations, principles of GMP and GWP and applicable guidelines: *** New licence applications to manufacture medicines and scheduled substances, * New licence applications to cultivate cannabis for the purposes of producing a scheduled substance and * New Licence applications to act as a wholesaler and distributor of medicine and scheduled substances. • **Technical evaluation for the re-granting of the above categories of licences**. • **Ensuring applicable databases and registers are updated**. • **Ensure implementation and maintenance of the Licensing Unit's QMS:** * Ensuring that applicable Guidelines and SOPs are implemented, periodically reviewed and updated within defined review periods as per the SAHPRA QMS requirements. * Ensuring that non-conformances are investigated, CAPAs identified and implemented as per the SAHPRA QMS

requirements. * Contribute significantly towards the Licensing Unit's preparation and in the pending WHO benchmarking assessment of the Licensing Unit. * Contribute significantly towards the Licensing Unit in its efforts to obtaining ISO 9001:2015 accreditation. • **Ensuring Performance and Finance Reports are accurately submitted within defined timelines as per applicable guidelines.** • **Being responsive to queries from the public on licensing processes:** * Ensuring advice communicated to the public is accurate and is within the provisions of the Act, Regulations and SAHPRA guidelines. • **Honouring meeting appointments with SAHPRA stakeholders.**

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 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: 1 October 2021 at 16H00.