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 EVALUATOR LEVEL 3 - ADVANCED – CER (CLINICAL)
Ref No.: SAHPRA 022/2020 (Part-time)

CENTRE: Remote

REQUIREMENTS: PharmD (Clinical), MBCHB, Clinicians, Clinical Pharmacologist. •At least 8 years post qualification experience. •Detailed knowledge of one or more areas of regulatory activity. •Evaluate novel or complex APIs; peer review evaluations; mentor lower level evaluators. Working knowledge of document management and workflow management software is an added bonus as well as the knowledge of CTD and eCTD software applications.

COMPETENCIES/SKILLS: •Knowledge of technical aspects for evaluation of safety and efficacy of medicines. •Sound working knowledge of computer software packages. **Ability to:** •evaluate scientific evidence of the safety and efficacy of medicines application, •interpret results of clinical studies and make clinical practice and labelling recommendations, •mentor a team of evaluators and develop them from a technical standpoint, •communicate fluently in English with both written and verbal communication. •Clinical content knowledge of the therapeutic area under evaluation. •Understanding of clinical study design principles and impact on study results. •Able to understand the clinical content knowledge of the therapeutic area under evaluation. •Plans proactively and communicates potential roadblocks to Portfolio Coordinator timeously.

DUTIES: Assess and evaluate the clinical safety and efficacy of applications for the registration of medicines: •Reviews and evaluates the applicant reports relating to clinical studies submitted in support of the labelling of NCE and generic medicines. • Review clinical data to support labelling of medicines for regulatory purposes. • Consistently update the application manager and assigned peer reviewer on the progress of the application. • Prepares a comprehensive summary of the data reviewed and submits conclusions for approval by the peer reviewer. •Assess the labelling in terms of the assessed data. •Provide input into report results for the technical committee when evaluation result differs to that of the peer reviewer. •Engages in technical conversations with the applicant should the Portfolio Coordinator deem it necessary. •Other responsibilities as identified by the clinical backlog divisional lead. **Technical oversight of the assessment and evaluation of the safety and efficacy of applications for the registration of medicines:** •Provide guidance to primary evaluators whist they conduct reviews. •Reviews primary evaluator's reports relating to evaluation of clinical studies submitted in support of NCEs and generic drugs. •Consistently update the

application manager on applicant information. •Provide input into review results for the technical committee should the review provide a different outcome to that of the primary evaluator. •Provide input into report results for the technical committee. **Risk Management and Audit:** •Standard operating procedures and guidelines must be adhered to. •Assesses applicant responses to queries on applications for registration of medicines. •Attend relevant training as may be necessary to support your function.

INSTRUCTIONS TO APPLICANTS: All applications must:

- Be submitted with a covering letter clearly reflecting the name of the position, name and date of the publication (candidates must use the **post reference numbers**), 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, Tel: +27 71 605 1508. Email: setlola.molepo@sahpra.org.za (**DO NOT SEND APPLICATIONS TO THIS EMAIL ADDRESS).**

CLOSING DATE: 29 May 2020 at 16H00.