EXPRESSION OF INTEREST FOR CLINICAL EVALUATORS OF THE SAFETY AND EFFICACY OF HEALTH PRODUCTS

BACKGROUND

The South African Health Products Regulatory Authority (SAHPRA) is responsible for regulating all medicines, and medical devices in South Africa by ensuring that they meet standards of safety, efficacy and quality. SAHPRA operates in terms of the Medicines and Related Substances Act, 1965 (Act 101 of 1965), the Regulations issued in terms of that Act, and associated guidelines. SAHPRA has also been delegated the task of overseeing radiation control in South Africa. This function is governed by the Hazardous Substances Act (Act 15 of 1973) which aims to protect the public (e.g. workers, patients) against radiation used in both health settings and in industry. SAHPRA's function is therefore to promote public health and safety by ensuring that all medicines and medical devices that are available and used in the country are safe, effective and of good quality.

This document presents an overview of desired skillsets for experienced medical doctors with 5-10 years' experience to assist in the evaluation of the safety and efficacy of human medicines in the clinical pre-registrations and post-registrations focus areas of SAHPRA as consultant evaluators. Acknowledging that medicines regulatory work is not taught in our institutions of higher learning, SAHPRA undertakes to provide extensive theoretical and on-the-job training to willing candidates who show interest in medicines regulatory work.

REQUIRED TECHNICAL EXPERTISE

SAHPRA requests the submission of curriculum vitae (CV) by persons with experience in the disciplines of bioequivalence; pharmacology; clinical safety and efficacy evaluations for medicine registration purposes, clinical trials; and vigilance. CVs will be considered for potential appointment as external expert evaluators.

Interested individuals should explicitly indicate in the cover letter their area of expertise and/or interest in relation to the above disciplines.

DESIRED KNOWLEDGE & SKILLS

Applicable Knowledge

- Extensive knowledge of health products control and regulation
- Extensive knowledge of technical aspects for clinical evaluation of safety and efficacy of health products
- Extensive knowledge and application of the Medicines and Related Substance Act, 101 of 1965 (as amended) and related regulations
- Sound working knowledge of computer software packages
- Working knowledge of document management and workflow management software is desired
- Knowledge of CTD and eCTD software applications is desired but not essential.

Applicable Skills

- Ability to evaluate scientific evidence of the safety and efficacy of health products applications for registration in compliance with the Medicines and Related Substances Act, 1965 (Act 101 of 1965), as amended, as well as with the relevant guidelines.
- Demonstrated clinical knowledge and understanding of the pre-clinical and clinical content of therapeutic areas under evaluation.
- Understanding of biostatistical principles of medical research.
- Understanding of clinical study design principles and impact on study results.
- Understanding of the pharmacology of medicines/molecules under evaluation.
- Ability to interpret results of clinical studies and make clinical practice and labelling recommendations.
- Understanding of the principle of clinical epidemiology and pharmacoepidemiology.
- Experience with pharmacovigilance evaluation of medicines.

Competencies

- Ability to communicate fluently in English in terms of both written and verbal communication.
- Manage time efficiently through efficient work and effective prioritisation.

- Willingness to receive feedback, dedicated to learning and, striving to continuously improve.
- Plans proactively and communicates potential obstacles.

Relevant Qualifications

- Appropriate degree in medicine (MBCHB).

INSTRUCTIONS TO INTERESTED PARTIES

Interested persons should:

- Submit a comprehensive CV and qualification/s as well as a cover letter expressing your area of expertise and motivation by email addressed to **Ms Mukona Mphidi** (email: CEOOFFICE@sahpra.org.za).
- Further communication will be limited to nominated candidates with appropriate skillsets.
- Closing date: 31 March 2022

Enquiries: Ms Mukona Mphidi at mukona.mphidi@sahpra.org.za

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