

EXPRESSION OF INTEREST SOLICITATION FOR EVALUATION 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.

One of the critical priorities of SAHPRA, since its launch, has been the clearance of its backlog of new medicine registration and variation applications and to prevent the development of backlog in the Business as Usual (BAU) stream. This document provides an overview of desired skillsets and how to submit your expression of interest to become one of the SAHPRA evaluators and/or a member of the advisory committee.

POSITION DETAILS

SAHPRA is specifically requesting submission of curriculum vitae by persons with experience in the disciplines of: pharmaceutical chemistry/organic chemistry, pharmaceuticals and pharmaceutical development, bioequivalence, biological medicines, toxicology & medicine safety, biomedical & clinical engineering, biotechnology, virology & microbiology complementary, African traditional medicines, veterinary, clinical and clinical trials, vigilance, medical device, good practices (Good Manufacturing Practice, Good Clinical Practice and other good practices), radiation control and legal related to health products. CVs will be considered for potential appointment as external expert evaluators and or a member of the advisory committee.

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

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 of technical aspects for evaluation of quality and bioequivalence of health products
- Extensive knowledge of technical aspects for inspection of sites for Good Manufacturing Practices (GMP) and other good practices
- Extensive knowledge and application of the Medicines and Related Substance Control Act, 101 of 1965 and related regulations or the Hazardous Substances Act (Act 15 of 1973) 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

Applicable Skills

- Ability to evaluate scientific evidence of the safety and efficacy of medicinal products
- Ability to understand the clinical content knowledge of therapeutic areas under evaluation
- Understanding of bio statistical principles of medical research
- Understanding of clinical study design principles and impact on study results
- Understanding of the pharmacology of chemicals under evaluation
- Ability to interpret results of clinical studies and make clinical practice and labelling recommendations

Please note: candidates need not possess all of the above knowledge and skills to express interest. SAHPRA is compiling CVs for a variety of evaluator positions that require select knowledge and skills from the more comprehensive list above.

Competencies

- Ability to communicate fluently in English with both written and verbal communication
- Manages 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 roadblocks

Relevant Qualifications

- Appropriate degree in medicine/pharmacy/pharmaceutical science and natural sciences.

INSTRUCTIONS TO INTERESTED PARTIES

Interested persons should:

- Submit a comprehensive CV and qualification/s as well as a cover letter expressing your area of interest and motivation by email addressed to **Ms Shirona Naidoo**, and copied to **Ms Portia Nkambule** using the following contact details:
- Deadline: 21 February 2020

Email - shirona.naidoo@sahpra.org.za

and copy portia.nkambule@sahpra.org.za

Enquiries: Further communication will be limited to candidates with appropriate skillsets

Ms Shirona Naidoo - shirona.naidoo@sahpra.org.za.

This solicitation of interest remains open until further notice.

DR BOITUMELO SEMETE-MAKOKOTLELA

SAHPRA CEO