SAHPRA
South African
Health Products
Regulatory Authority

SAHPRA Head Office
Building A
Loftus Park
2nd Floor
Kirkness Road
Arcadia
0083

CALL FOR EXPRESSION OF INTEREST

BIOLOGICAL MEDICINES EXTERNAL EVALUATORS

The South African Health Products Regulatory Authority (SAHPRA) hereby invite expression of interest for candidates to serve as External Evaluators for Biological Medicines Evaluation (inclusive of Quality and Clinical safety and efficacy data).

SAHPRA is a Schedule 3A Public Entity established in terms of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965) to oversee the regulation of medicines, medical devices, and in vitro diagnostics (IVDs) intended for human and animal use; the licensing of manufacturers, wholesalers and distributors of medicines, medical devices and IVDs; and the conduct of clinical trials.

REQUIREMENTS

The External Evaluators are appointed in terms of section 3 (5) of the Medicine's Act, as amended to assist the Authority in carrying out its functions. These fully qualified external evaluators are crucial to supplementing the skills and experience of the Authority in the area of Biological Medicines Evaluation.Expression of interest is required for experts who are already familiar with the ICH, SAHPRA and other recognised relevant international requirements for biological medicines as well as eCTD dossier reviews for both new biological medicines registrations and variations such that they are able to commence with immediate effect.

Expression of interest is required in the following disciplines:

- **Six (6)** external evaluators for the Biologicals Medicines Committee

Experience in biological medicines regulations and understanding of new registration, variations, and comparability requirements, individuals should possess expertise in:

- Interpretation and implementation of relevant ICH guidelines, SAHPRA and other recognised relevant international requirements.
- Familiarity with SAHPRA regulations and procedures for biological medicine registration and post-marketing activities.
- Understanding of comparability requirements for biological medicines, including analytical comparability, non-clinical comparability, and clinical comparability assessments to support changes in manufacturing processes, formulations, or specifications.
- Experience in regulatory affairs, particularly in the assessment of biological medicines
- Understanding of International requirements for biological medicines

Experience and knowledge in the following will be an added advantage:

- Viral Safety Evaluation of Biotechnology Products Derived from Cell Lines of Human or Animal Origin.
- Analysis of the Expression Construct in Cells Used for Production of rDNA-Derived Protein Products.
- Testing of Biotechnological/Biological Products.
- Derivation and Characterisation of Cell Substrates Used for Production of Biotechnological/Biological Products.
- Reviewers who have review experience in National regulatory authorities (minimum 2 years in biological medicines reviews),

EXCLUSIONS:

Where such person is conflicted in terms of SAHPRA Policy on Management of Conflict of Interest (GOV02).
is disqualified under the Relevant Act applicable to his or her profession from practising as such.

- has been found guilty of improper or disgraceful conduct at an inquiry held under ambit of the relevant Act.
- is a patient as defined in section 1 of the Mental Health Care Act, 2002 (Act No. 17 of 2002).
- has been convicted of an offence in respect whereof he or she was sentenced to imprisonment without the option of a fine or in the case of fraud.
- does not meet the minimum requirements.

RELEVANT QUALIFICATIONS

Appropriate degree in biological sciences /pharmacy/pharmaceutical sciences, or other relevant sciences**.**

Registration with the statutory regulatory board/council relating to his/her profession where applicable is recommended.
Applicant must be in good standing with the regulatory board/ council with which he/ she is registered where applicable.

TERM OF OFFICE

The term of service for external evaluators is three (3) years effective from date of appointment and may be appointed for a further extension of term(s).

PROCEDURE

- A comprehensive CV, qualification/s and a motivation expressing area of expertise must be submitted **online at** https://apply.sahpra.org.za:6006/
- Only documents in pdf must be uploaded.
- Further communication will be limited to candidates with appropriate skill sets.
- Closing date for applications is **Friday, 14 June 2024 at 16h30. No late applications will be accepted.**

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