



EXPRESSION OF INTEREST TO SERVE IN THE AFRICAN TRADITIONAL MEDICINES WORKING GROUP OF THE SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY

BACKGROUND

The South African Health Products Regulatory Authority (SAHPRA) is an entity created and tasked with the responsibility of regulating all health products, both of human and animal use, including clinical trials, complementary medicines, medical devices and *in vitro* diagnostics. SAHPRA has the added responsibility of overseeing radiation control as mandated by the Medicines and Related Substances Act, 1965 (Act 101 of 1965 as amended) as well as the Hazardous Substances Act, 1973 (Act No 15 of 1973). 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.

SAHPRA, as part of its mandate, will begin considering appropriate mechanisms of regulating proprietary (final finished products for commercialisation) African Traditional Medicines (ATMs). These mechanisms must be centred around the development of an appropriate framework which recognises the philosophical, historical and traditional use of such medicines within the regulatory context of South African legislation. The consideration of quality, safety and efficacy of proprietary ATMs, as a form of medicine as defined, is included within the legislative mandate of the SAHPRA.

This document provides an overview of desired skillsets for persons required by SAHPRA who will be considered to serve in the African Traditional Medicines Working Group to support SAHPRA in considering and developing the regulatory approach for ATMs and make recommendations to the SAHPRA Chief Executive Officer (CEO).

Requirements

SAHPRA requests the submission of curriculum vitae (CVs) by persons with experience and expertise in:

1. the regulatory practices of medicines in general;
2. clinical investigation or application of ATMs;
3. practice and use of ATMs;
4. quality or safety criteria that pertain to ATMs or related medicines;
5. the review of and knowledge of research associated with ATMs, including but not limited to, clinical evidence, clinical trials, evaluation of evidence, clinical knowledge and may relate to any medical field or speciality;
6. various requirements and aspects of quality associated with the manufacture, production, sale or retail of ATMs; or
7. legal matters related to health products.

Competencies

- Ability to communicate fluently in English in terms of both written and verbal professional communication;
- Manage time efficiently through efficient work and effective prioritisation;
- Willingness to receive feedback, dedicated to learning and, striving to continuously improve; and
- Plans proactively and communicates potential challenges together with proposed solutions effectively and coherently.

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Candidates must hold the necessary tools of trade including the capacity to undertake the requisite work with all reference points available, internet connection and ability to be involved in regular teleconferences as may be required.

Please note:

- This expression of interest is not intended to regulate the African Traditional Medicine Practice and what happens in the Traditional Health Practitioners space, but to develop a framework that will be used to regulate final finished products for commercialisation
- Candidates need to possess knowledge and skills to express interest which should be clearly indicated by the CV and accompanying cover letter.
- Interested individuals should submit CVs and explicitly indicate in the cover letter their area of expertise, past experience and nature of the qualification(s) which makes them eligible for such consideration.
- SAHPRA will consider all submissions to serve in or act as part of the Working Group and reserves the right to make any such appointment as determined to be necessary or applicable, for any duration of time, at its own discretion.
- International experts will be considered
- The term of the Working Group will be twelve (12) months

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: mukona.mphidi@sahpra.org.za)
- Further communication will be limited to nominated candidates with appropriate skillsets.
- Closing date: **Friday, 11 September 2020 at 16h00.**

Enquiries: Ms Mukona Mphidi mukona.mphidi@sahpra.org.za
Dr Kaizer Thembo Kaizer.thembo@sahpra.org.za

DR BOITUMELO SEMETE-MAKOKOTLELA
SAHPRA CEO