Supporting Health Initiatives
a division of Wits Health Consortium (Pty) Ltd

TERMS OF REFERENCE

CONSULTANCY TO SUPPORT THE SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY'S REGISTRATION RENEWALS WORKSTREAM TO ENABLE SAHPRA TO ATTAIN WORLD HEALTH ORGANIZATION MATURITY LEVEL THREE FOR REGULATION OF MEDICINES.

INTRODUCTION

In 2022, the South African Health Products Regulatory Authority (SAHPRA) was the second National Regulatory Authority (NRA) on the African continent to attain the World Health Organization's maturity level (ML3) for an agency able to regulate vaccines produced in its country, with the Lot Release regulatory function scoring a maturity level of 4 (operating at an advanced performance level, with continual improvement).

As part of the WHO's ongoing benchmarking of SAHPRA in terms of medicine regulation, the successful implementation of a renewals process for product registrations is pivotal to the South African regulator obtaining ML 3 for medicines.

RENEWALS PROCESS IMPLEMENTATION

To comply with the legal provisions as set out in the Medicines and Related Substances Act (Act 101 of 1965), as amended, which requires re-registration or renewal of all currently authorised orthodox medicinal products every 5 years, SAHPRA has implemented a process via a dedicated workstream, to renew the validity of currently registered orthodox medicinal product registrations.

By successfully implementing this process, SAHPRA will ensure that it complies with the relevant legal provisions, while enabling it to adhere to the requirements as set out by the WHO in its Global Benchmarking Tool (GBT), under the Marketing Authorization (MA) indicator. It is SAHPRA's intention to comply with WHO Review Practice and the requirements contained in the WHO Guidelines, thereby achieving its goal of attaining ML3 NRA for both vaccines and medicines. This milestone is of particular importance to the regulator and industry alike, as it may allow for regulators from other countries and/or regions to rely on SAHPRA's regulatory decisions regarding products authorized, thereby facilitating shorter timelines for registrations in other markets. Especially, within the SADC region, this will of benefit.

To effect the operationalisation of the renewals process, a dedicated, self-contained unit has been created to handle the receipt of the applications, the screening activities, as well as the renewal-focused review process and completion thereof with the issuance of a registration renewal certificate. The recruitment of key incumbents has commenced; however, within the current 2023-2024 SAHPRA budget, no provision has been made for a manager to provide oversight and report back to the SAHPRA Executive and Board in terms of the operationalisation of the Renewals workstream.

To aid the successful implementation of the registration renewals process, the Bill & Melinda Gates Foundation is offering to support a contracted individual to fill the role of Renewals Manager for one year, after which SAHPRA intends to retain this as a permanent position on its organogram. This individual will be contracted and remunerated via Supporting Health Initiatives, a Division of Wits Health Consortium and will provide implementation oversight of the renewals workstream.

OBJECTIVES OF THE CONSULTANCY

The objectives of the consultancy, with respect to the Renewals Manager, shall be: -

- To provide end-to-end oversight, coordination, and leadership of the medicine's renewals process.
- To actively engage with units/programmes in SAHPRA on the implementation of the workstream, in terms of further optimisation of the process with input into guidelines, standard operating procedures and other working documents.
- To oversee recruitment of staff required and manage the team for the optimal functioning of the unit, together with ensuring training and orientation requirements for the Renewals Medicines Regulatory Officers (MROs) and other staff are fulfilled.
- To regularly provide feedback to internal (SAHPRA Executive & Board) and external (the World Health Organization, the pharmaceutical industry and BMGF) stakeholders regarding the operationalisation of the Renewals unit.
- To strategically align with global best practices to ensure a streamlined registration renewals process.

SCOPE

The consultancy will be limited to activities related to the Renewals unit in the Health Products Authorisation (HPA) Programme and will report directly to the SAHPRA Chief Operating Officer (COO). The contracted individual will focus on implementation and optimisation of the operations within this unit and will regularly update all stakeholders in terms of progress.

EXPECTED DELIVERABLES

- Ensuring an operational Renewals unit capacitated with the required staff, adequately skilled to enable fulfilment of its mandate of renewal of product registrations within 120 business days.
- Develop strategy, an annual performance plan, operational plans and budget for renewals aligned with organisational needs and ensuring the most effective utilisation of resources.
- Timely reporting to the SAHPRA Executive in terms of the Renewals unit's monthly, quarterly, and annual achievement of its Key Performance Indicators (KPIs).
- Timely submission of revenue line listings and supporting evidence to ensure financial accountability of the unit.
- Ensuring unit attains and maintains an unqualified overall Auditor General audit outcome, as well as compliant internal SAHPRA audits.
- Managing performance of Renewals unit staff in accordance with SAHPRA's HR policy.
- Oversee performance assessments of any external evaluators.
- Oversee the development, implementation and maintenance of regulations, guidelines, policies and procedures pertaining to renewals of medicines, to ensure alignment with international and national protocols, legislations and other legal requirements.
- Liaise with representatives from industry and international regulators, and other relevant stakeholders to ensure appropriate and correct information and establishment of productive and relevant relationships.
- Obtain positive feedback from stakeholders engaged via surveys and other mechanisms.

- Performing quality assurance of evaluations and sign of query letters/approvals/certificate reviews.

DURATION AND LOCATION

- One (1) year fixed term contract with Supporting Health Initiatives a Division of Wits Health Consortium.
- Based at the SAHPRA office in Pretoria, working according to SAHPRA's current hybrid working policy.

SAHPRA may to retain the position of Renewals Manager and the consultant may apply for the position according to SAHPRA's recruitment process.

REQUIREMENTS AND QUALIFICATIONS

The consultant shall possess the following qualifications: -

- A degree in pharmacy or pharmaceutical sciences.
- A master's degree in pharmacy, strategic management or project management would be advantageous.
- At least 10 years' experience within the medicines regulatory sphere.
- Excellent report writing and presentation skills.
- Excellent people-management abilities.
- Able to manage conflict and work under pressure.
- Experience in the execution of projects funded by development partners will be an added advantage.
- Sound and in-depth knowledge of the Medicines and Related Substances Act 101, 1965 as amended and the regulations pertaining to the Act.
- Sound knowledge of regulatory scientific and technical requirements (to assess the quality, safety and efficacy aspects of medicines).