

## DEVELOPMENT OF THE SADC MRH FINANCIAL SUSTAINABILITY PLAN

The Southern African Development Community Medical Products Regulators Forum (SADC MRF) with support from the Bill & Melinda Gates Foundation is seeking a consultant(s) to develop a Financial Sustainability Plan that will provide a set of recommendations covering well-considered solutions, processes, activities, and commercial models that will ensure the continuous and effective ownership, operation, revenue collection maintenance and overall, financially sustainable management of the programme under the SADC MRF for a minimum period of ten years.

### Background

The Southern African Development Community (SADC) Medical Products Regulatory Harmonization (MRH) Programme has received financing from the Bill & Melinda Gates Foundation to support the development of a Sustainability Plan. This procurement will be managed by Supporting Health Initiatives (SHI), a Division of Wits Health Consortium Pty Ltd (WHC) for and on behalf of the SADC Medical Products Regulators Forum (SADC MRF).

WHC is a wholly owned company of the University of the Witwatersrand, Johannesburg. Structured on a divisional basis with entities operating as divisions; the primary role of WHC is to provide a Shared Service Centre for the governance, legal framework, human resource, financial/grant management for these entities.

Supporting Health Initiatives, a division of WHC, (SHI) has developed a strong track record of delivering on assignments in Africa. SHI's operations and business teams have demonstrated capacity to quickly align with partners, distribute funds, and oversee implementation. SHI has been instrumental in the successful backlog clearance of National Regulatory Authorities as well as provision of support to achieve WHO ML3.

### Description of the SADC MRH Programme

The SADC MRH programme was established in May 2011 by the SADC Secretariat with support from the African Medicines Regulatory Harmonization (AMRH) Consortium. The SADC Protocol on Health, established in 1999, through Article 29, outlines the initial mandate for member states to 'cooperate and assist one another in the harmonisation of procedures of pharmaceuticals, quality assurance, and registration' (SADC, 1999). This mandate was primarily focused on the harmonisation of medicine registration and was subsequently updated in 2016 to include other regulatory functions.

The SADC MRH builds on the ZAZIBONA<sup>1</sup> collaborative medicines registration initiative founded by four countries, namely Zambia, Zimbabwe, Botswana, and Namibia, with technical support from the World Health Organisation (WHO) to address the varying regulatory capacities of National Medicines Regulatory Authorities (NMRA). In 2014, the ZAZIBONA initiative was formally endorsed and adopted by the SADC Ministers of Health. Since then, the initiative has grown, and all 16 SADC member states are now participating either as active participants, non-active participants or observers based on their internal capacity to conduct assessments and current Good Manufacturing Practice (cGMP) inspections. Since its inception, the SADC MRH project has convened 45 joint assessment sessions and assessed over 330 products in its 10 years of operation. Participating regulatory authorities have reported that participating in the initiative has increased their capacity to conduct assessments and good manufacturing practice inspections. The initiative has achieved shorter timelines for the approval of medicines resulting in increased availability of quality-assured medicines for patients in the SADC region.

## Problem statement

In the current organisational structure, the Heads of Agencies constitute the SADC Medicines Regulators Forum (MRF) which serves as the governing body for the initiative, and they report to the SADC Health Ministers. The SADC MRF has terms of reference (TOR) that define its mandate, membership, and responsibilities.

The Forum endorsed a governance model that retains one NMRA as the coordinating entity, referred to as the Implementing Agency (IA). The role of the IA is to ensure the effective and efficient day-to-day running of the affairs of the Forum, in accordance with the strategic direction established by the Forum and within the agreed policies, procedures and budget. The main workstreams, namely the joint assessments and joint inspections, each have a coordinator who liaises with the SADC MRH programme coordinator. The IA seconds these coordinators to maintain linkages at national level, country focal persons are tasked with the responsibility of overseeing the workflow in those countries that actively contribute to the work streams. The IA has been volunteering resources to support implementation of the SADC MRH. Considering the opportunity cost to the execution of its own national mandate, and recognising the need to institutionalise the IA, the Forum has developed specific terms of reference for the IA, and to initiate the sustainability of the IA model through the provision of a management fee.

SADC MRH has to date been funded by development partners, and the World Health Organisation (WHO) that has been both a technical and funding partner. By mutual agreement, member states' contributions have also been significant, coming in the form of coverage of conferencing costs for the joint assessment sessions, inspectors, and Heads of Agencies meetings. Joint inspections, conducted on a cost recovery basis, have yielded a surplus that accumulates over time and has

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<sup>1</sup> ZAZIBONA was derived from the first two letters of the four founding countries i.e., Zambia, Zimbabwe, Botswana, and Namibia (13). The name ZAZIBONA has been maintained even though the initiative has grown to more than just the four founding countries because it has a special meaning in one of the local languages in Zambia (Nyanja) which is 'to look to the future' (13)

allowed the initiative the flexibility of bridging costs for the core activities where development partner funding was not available. The reliance on funding partners is a huge risk as funding interests shift over time. To hedge itself, and to ensure sustainability, the Forum has resolved to ensure cost recovery from all workstreams. A pilot to initiate cost recovery from the product evaluations in similar manner to the cost recovery from GMP site inspections has been initiated.

In order to consolidate the gains and improve the effectiveness and efficiency of the SADC MRH initiative, a SADC MRH Strategic Plan: 2023 – 2027 has been developed with the support of the SADC Support Towards Industrialization and the Productive Sectors (SIPS) Programme. The strategic plan serves as a roadmap that builds on the successes of the existing initiatives and further galvanize Member States to align around a singular objective of establishing and implementing a system of regulatory harmonisation for health products in the SADC region. The strategic pillars of the plan focus on strengthening policy and legislation, human resource, processes, governance, technology, finance, and sustainability of the SADC MRH initiative. The overall budget for the implementation of the strategic plan over the five-year period is estimated at USD 4 022 550.

The strategic plan has prioritised the need for a review of the current governance structure and operating model. Further, the plan proposes the development and implementation of a revenue generation model incorporating the concept of a fee-for-service by scaling up the uptake and usage of the regional route for medicines registration and GMP Inspections. In light of the above, the SADC MRF is commissioning a consultancy to develop a financial sustainability plan for SADC MRH.

### **Purpose of the consultancy**

1. To identify the regional programme's financial (capital) needs that are required to ensure its continued function and maintain sustainable and optimum levels of efficiency;
2. To create a concrete financial sustainability plan for the regional programme's operations that will enable the SADC region to meet these needs over time. The plan, in addition to defining the requirements, shall also propose and define mechanisms to raise the needed funds with a comprehensive set of options.
3. To propose an implementation plan in the form of a roadmap with timelines with clear financial and operational timelines.

### **Deliverables**

A detailed financial plan for the SADC MRH Programme which clearly identifies the financial requirements, the resources available, funding gaps, potential funding sources and amounts, fundraising plan and stakeholder alignment strategy to support implementation of the financial plan, with a view to longer term sustainability and reduced dependence on donor funding.

**Deliverable 1:** Inception report within 7 days of accepting the contract, which shall include a work plan outlining the approach, methodology and timelines for the assignment. The assignment will be virtual and excludes travel. The consultant(s) is also expected to identify any risks to completing the assignment and mitigating measures that can be applied.

**Deliverable 2:** Funding landscape analysis for the region

*Activity 1:* Review current budget and financial projections for the SADC MRH Programme.

*Activity 2:* Create detailed financial maps and flows based on SADC MRF's current strategy.

*Activity 3:* Understand SADC MRH financial sourcing landscape: key players, funding envelopes, and restrictions.

*Activity 4:* Define financial gaps over the next few years based on the strategic plans.

*Activity 5:* Leverage international best practices to develop an optimal revenue model for the SADC MRH Programme.

**Deliverable 3:** Develop long-term financing strategy and action plan for the SADC MRH Programme

*Activity 1:* Develop a comprehensive set of options for increasing funding flow including effectively leveraging current funding and other current and potential sources. This shall include core stakeholder engagement.

*Activity 2:* Create a financial cost and revenue model anchored on existing cost recovery activities and other revenue drivers to estimate the potential for the various models and shortlist the most promising models.

*Activity 3:* Make a presentation to the SADC MRF on the proposed implementation plan.

**All deliverables shall be provided in a clear written report.**

**Profiles and skills required of the consultant or consultancy team:**

- Previous experience in financial analysis and forecasting, preferably in the health field.
- Proven experience in conducting assignments of a similar nature.
- Results-oriented with good interpersonal skills.
- A working knowledge of medical products regulation and public health and how regional cooperation groupings work is desirable and will be an added advantage.
- Fluency in written and spoken English. Knowledge of either French and/or Portuguese will be an added advantage.

## Timeline

The level of effort required for this assignment is **15-20 working days**. The assignment will commence on 1 July 2024 and must be completed by 30 August 2024.

Applications must be submitted no later than **midnight SAST Friday 21st June 2024**.

## Applications must include the following:

- Full Curriculum Vitae of applicant(s).
- A Proposed Pricing Schedule for the assignment, based on the level of effort for the assignment and linked to the deliverables.
- Detailed portfolio of evidence of previous experience related to the assignment.

Applications must be submitted to [SHIproposals@witshealth.co.za](mailto:SHIproposals@witshealth.co.za) and copied to [coordinator@zazibona.com](mailto:coordinator@zazibona.com)

Email subject title of submission to clearly state: **Development of the SADC MRH Financial Sustainability Plan**

**Non-compliance with the above instructions will result in disqualification.**