

# Terms of reference (ToR) for the procurement of services below the EU threshold

CONFIDENTIAL

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<b>Support to SAHPRA's Organizational Transformation: Assessment and Implementation</b>	<b>Project number/ cost centre: G-011902-004/</b>
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## 0. List of abbreviations

AG	Commissioning party
AMA	African Medicines Agency
AN	Contractor
AVB	General Terms and Conditions of Contract for supplying services and work
DoH	Department of Health
DSTI	Department of Science, Technology and Innovation
EAC	East African Community
EU	European Union
FK	Expert
FKT	Expert days
GBT	Global Benchmarking Tool
KZFK	Short-term expert
MCC	Medicines Control Council
NRA	Nation Regulatory Authority
NDoH	National Department of Health
PMS	Performance Management System
RCORE	Regional Centre of Regulatory Excellence
SAHPRA	South African Health Products Regulatory Authority
SAVax	Vaccines for Africa: Roll-out and Production in South Africa
SADC	Southern African Development Community
TEI MAV+	Team Europe Initiative on Manufacturing and Access to Vaccines, Medicines, and Health Technologies
ToRs	Terms of reference
WLA	World Health Organization Listed Authority
WHO ML	World Health Organization Maturity Level

## 1. Context

The programme “Vaccines for Africa: Roll-out and Production in South Africa” (SAVax) is co-financed by the Federal Republic of Germany’s Federal Ministry for Economic Cooperation and Development (BMZ) and the European Union (EU) and implemented by GIZ. The project is part of, and contributes to, the Team Europe Initiative on Manufacturing and Access to Vaccines, Medicines, and Health Technologies (TEI MAV+) for Sub-Saharan Africa.

SAVax supports South Africa in strengthening local vaccine and pharmaceutical production and improving equitable access to safe and effective health products. The program works across the pharmaceutical value chain, supporting research and development, skills development, regulatory strengthening, and market access for locally manufactured products.

Within this framework, a strong and effective national regulatory authority is essential to ensure the quality, safety, and efficacy of medicines and vaccines, while also enabling innovation and supporting the development of the local pharmaceutical manufacturing sector.

A key partner in this effort is the South African Health Products Regulatory Authority (SAHPRA), which is responsible for regulating medicines, vaccines, and other health products in South Africa. SAVax provides technical assistance to strengthen regulatory systems and supports SAHPRA in fulfilling its mandate more effectively.

SAHPRA was established in 2018 as a Schedule 3A public entity under the National Department of Health (South Africa), replacing the former Medicines Control Council (MCC). The transition from the MCC to SAHPRA created a more independent regulatory authority with an expanded mandate. However, this transition was not accompanied by a comprehensive organizational development and change management process. As a result, SAHPRA continues to face structural and operational challenges in fully aligning its organizational configuration, processes, and culture with its mandate and long-term strategic ambitions.

SAHPRA’s strategic vision is to become an agile, trusted and data-driven regulator and to position itself as a leading regulatory authority on the African continent. A key objective is the achievement of World Health Organization (WHO) Maturity Level 4 (ML 4) and ultimately recognition as a WHO Listed Authority (WLA). Achieving these milestones requires strengthened organizational capacity, efficient regulatory systems, and a highly skilled workforce.

At the same time, South Africa’s growing pharmaceutical manufacturing sector requires a regulatory authority capable of supporting innovation, enabling market entry of locally manufactured products, and contributing to regional regulatory harmonization initiatives such as those led by the African Medicines Agency and the African Union Development Agency (AUDA NEPAD).

To meet these ambitions, SAHPRA aims to strengthen its organisational structure, operational processes, leadership capacity, digital systems, and stakeholder engagement mechanisms.

Within the SAVax programme, the assignment contributes to strengthening the pharmaceutical regulatory environment and supporting SAHPRA’s organizational transformation. The objective is to support SAHPRA in repositioning itself organizationally so that it can effectively deliver on its mandate, achieve WHO ML4/WLA status, and provide a regulatory environment that enables innovation and private sector growth.

The organisational development support will contribute to:

- Positioning SAHPRA as a leading regulatory authority in Africa.
- Enable local manufacturing ambitions, cultivate a regulatory environment that can respond to a growing private sector. A growing private sector is a strategic lever to contribute to health security and economic development and, support reliance pathways.
- Supporting regional harmonization initiatives e.g., AUDA-NEPAD, African Medicines Agency (AMA), Southern African Development Community (SADC), East Africa Community (EAC).
- Leverage digitalization and AI for operational efficiencies.
- Strengthen continental regulatory capacity through its RCORE designation.

**Despite these ambitions, SAHPRA faces several organizational challenges:**

Like many National Regulatory Authorities (NRAs), SAHPRA operates under persistent resource constraints while facing increasing regulatory workloads. At the same time, local pharmaceutical manufacturers are calling for faster and more predictable regulatory review timelines.

Addressing these pressures requires strengthening management capabilities in specialised regulatory areas, closing critical skills gaps, and reviewing current development pathways for regulatory staff to ensure both retention of expertise and effective knowledge transfer. These challenges are compounded by siloed regulatory functions, aspects of organisational design that limit coordination, and sub-optimal spans of control that hinder collective progress. In addition, SAHPRA aims to foster a more performance-driven organisational culture capable of responding to the needs of the evolving pharmaceutical sector.

Strengthening stakeholder engagement will also be important. A more sophisticated approach to communication and messaging can support strategic partnerships and improve transparency and trust. In parallel, the implementation of regulatory reliance mechanisms will be key to streamlining international regulatory collaboration and improving operational efficiency.

To ensure coherence with ongoing institutional efforts, the service provider is expected to consider and align with several initiatives currently underway within SAHPRA.

The organisational transformation should build on and complement existing processes, including:

- Regional Centre of Regulatory Excellence (RCORE) design recommendations - ensuring seamless integration
- WHO Global Benchmarking Tool (GBT) benchmarking assessment findings as well as and WHO ML4 and WLA pathway requirements
- SAHPRA skills audit results and identified competency gaps
- SAHPRA competency framework for all regulatory functions
- Future Human Resource (HR) plans and goals from SAHPRA's latest annual report
- Ongoing digitalization initiatives and AI implementation projects

- Fee structure alignment with organizational structure for financial sustainability

## Scope of Work

The assignment will support SAHPRA through a structured organisational development process that includes organisational diagnostics, future-state organisational design, development of implementation roadmaps, and support to early implementation and change management.

The work will focus on several interconnected areas, including:

- Organisational structure and governance
- Human resources, leadership and management capacity
- Regulatory processes and operational systems
- Stakeholder communication and partnerships
- Technological infrastructure and digitalisation
- Financial sustainability and funding models
- Regulatory workforce development, including the concept of multi-functional regulators
- Alignment with legislative and policy frameworks

The contractor will work closely with SAHPRA leadership and technical teams to ensure that proposed organisational reforms are aligned with SAHPRA's strategic vision and international regulatory standards.

## 2. Tasks to be performed by the contractor

The contractor is responsible for providing the following work packages:

### Work Package 1: Program Inception and Initial Organizational Assessment

The first work package will establish the foundation for the assignment and provide an initial high-level assessment of SAHPRA's current organizational status across key areas.

This includes reviewing the current organizational structure, human resources capacity, management and leadership arrangements, regulatory processes, stakeholder engagement mechanisms, digital infrastructure, and alignment with SAHPRA's strategic objectives.

The assessment will draw on existing documentation and initiatives, including WHO GBT assessments, skills audits, organizational reports, and other relevant analyses. Consultations with SAHPRA leadership and key stakeholders will be conducted to identify major strengths, gaps, and priority areas for organizational development.

Outputs will include a high-level organizational diagnostic summarizing the current state, identifying priority areas for reform and informing the subsequent work packages.

The **first key objective** of work package 1 will be to establish robust program governance,

planning infrastructure, and team mobilization to ensure successful transformation execution.

Key tasks for Program Governance Establishment will include defining a program governance structure; decision-making authority, and escalation pathways; establishing roles and responsibilities for SAHPRA leadership, working team, and contractor; creating a program steering committee with clear terms of reference; defining approval processes for deliverables and major decisions and establishing quality assurance mechanisms.

Key deliverables for Program Governance Establishment will include:

- Program Governance Framework document
- Responsible Accountable Consulted Informed (RACI) matrix for all key stakeholders
- Steering committee terms of reference
- Decision-making authority matrix
- Quality assurance plan

The **second key objective** for work package 1 will be to ensure program planning & infrastructure setup. Program planning & infrastructure setup will include conducting a leadership kick-off workshop to align vision and expectations; conducting a working team kick-off meeting to establish collaboration protocols; developing a comprehensive program plan with timeline, milestones, and dependencies; create monitoring and evaluation (M&E) framework with KPIs; developing a risk management plan with mitigation strategies; setting up collaboration tools (shared drives, project management software) and establishing meetings cadence and communication protocols.

Key deliverables for program planning & infrastructure setup will include:

- Detailed Program Implementation Plan (Gantt chart with dependencies)
- M&E Framework with baseline metrics and targets
- Risk Register with mitigation strategies
- Communication Plan and meeting schedule
- Leadership and working team kick-off workshop reports

The **third key objective** for work package 1 will be the preparation of data and documentation requests. The preparation of data collection and documentation requests will include the preparation of comprehensive data request list covering all transformation components; the issuing of formal documentation requests to relevant SAHPRA departments; the establishment of data collection protocols and timelines; the assignment of focal points for data provision and the set up a secure data repository.

Key deliverables for data collection and documentation requests will include:

- Comprehensive Data Request Template (covering 50+ data points)
- Documentation Request Letter to SAHPRA departments
- Data Collection Tracker with responsibility assignments

## **Work Package 2: Strategic Vision Alignment and Benchmarking**

This work package will support SAHPRA in further articulating its future organizational vision and positioning it as a leading regulatory authority in Africa.

The contractor will conduct benchmarking of selected national regulatory authorities and analyse the best international practices in regulatory organizational models, regulatory workforce development, and digitalization.

Particular attention will be given to organizational approaches that support WHO ML4/WLA achievement, regulatory reliance models, and regulatory environments that support pharmaceutical innovation and local manufacturing.

The outputs will inform SAHPRA's future organizational model and strategic positioning.

**Key objective** of work package 2 is to design a future-state model on how SAHPRA will operate. It is envisioned that a future stated model will include the design of a multi-functional regulatory framework including skills matrix, competency requirements, training pathways, rotation mechanisms, and assessment criteria. This package will include the preparation of an NRA benchmarking report and a best practices compendium.

Key deliverables for work package two's future-state vision definition, external benchmarking & best practices include:

- Design of a future-state SAHPRA operating model integrating the defined strategic vision.
- Design a Multi-Functional Regulator Framework including skills matrix, competency requirements, training pathways, rotation mechanisms, and assessment criteria
- Preparation of an NRA benchmarking report covering 4-6 leading NRAs documenting organizational structures, multi-functional approaches, staffing models, and operational efficiencies.
- Preparation of a best practices compendium for regulatory organizational design synthesizing international standards and approaches.
- Conducting a WHO ML4 and WLA pathway analysis and gap assessment mapping current state against WHO Global Benchmarking Tool Maturity Level 4 requirements with specific gap closure recommendations.

### **Work Package 2 3: Organizational Design and Institutional Strengthening**

Based on the findings of the diagnostic and benchmarking work, this work package will support the development of a future-state organizational model for SAHPRA.

The work will include reviewing and refining SAHPRA's organizational structure, clarifying reporting lines and operational responsibilities, and identifying required adjustments to staffing structures and workforce development approaches.

Particular attention will be given to strengthening leadership and management structures, improving coordination across regulatory functions, and developing mechanisms for regulatory staff to work across product disciplines and regulatory processes.

This work package will also address organizational systems such as performance management, regulatory workflows, stakeholder communication structures, and digital infrastructure required to support efficient regulatory operations.

Outputs will include a proposed organizational structure and key institutional strengthening recommendations.

**Key deliverables for work package 3 include:**

- Creating alternate organizational design models weighing out the pros/cons.
- Organizing a leadership workshop on future state organizational models. Selection of target operational model. Facilitating decision-making for preferred model.
- Developing a detailed future state organizational structure, developing organogram, reporting lines and staffing levels.
- Clarifying the future state organizational structure. Re-defining the operational responsibilities and scope of authority.
- Creating optimized process maps for key regulatory workflows showing streamlined processes and efficiency improvements.
- Developing a Sustainable Funding Model. Proposing a revised fee structure. Developing a financial sustainability roadmap and policy position paper on budget allocation.
- Developing a comprehensive talent management & HR strategy.
- Proposing training programs, competency-based job profiles, career pathways, and talent retention strategies.
- Re-designing the framework for Performance Management.
- Designing a cascaded KPI framework showing linkage from organizational strategy to unit KPIs to individual objectives with clear line of sight.
- Design a performance monitoring and reporting dashboard.

**Work Package 3 4: Implementation Roadmap and Early Implementation Support**

~~This work package~~ The key objective of work package 4 will translate the proposed organizational design into a practical roadmap for implementation.

The roadmap will outline priority reforms, sequencing organizational changes, and key actions required to implement the new organizational model. It will also identify resource implications, organizational change considerations, and alignment with SAHPRA's strategic and operational planning processes.



Where appropriate, the contractor will also begin supporting early implementation steps, including piloting selected organizational improvements, supporting leadership alignment, and facilitating internal planning processes.

The key objective of work package 4 will be to design the future state organizational model that addresses identified challenges, leverages opportunities, and positions SAHPRA for WHO ML4 achievement and continental leadership.

Key deliverables for work package 4 include:

- The development of a Strategic Transformation Roadmap
- The development of a Detailed Operational Roadmap
- The development of a Risk Management & Mitigation Plan
- The creation of a Leadership alignment charter
- Creating alternate organizational design models weighing out the pros/cons.
- Organizing a leadership workshop on future state organizational models. Selection of target operational model. Facilitating decision-making for preferred model.
- Designing a detailed future state organizational structure, developing organogram, reporting lines and staffing levels.
- Clarifying the future state organizational structure. Re-defining the operational responsibilities and scope of authority.
- Creating optimized process maps for key regulatory workflows showing streamlined processes and efficiency improvements.
- Developing a Sustainable Funding Model. Proposing a revised fee structure. Developing a financial sustainability roadmap and policy position paper on budget allocation.
- Developing a comprehensive talent management & HR strategy.
- Proposing training programs, competency-based job profiles, career pathways, and talent retention strategies.
- Re-designing the framework for Performance Management.
- Designing a cascaded KPI framework showing linkage from organizational strategy to unit KPIs to individual objectives with clear line of sight.
- Design a performance monitoring and reporting dashboard.

#### **Work Package 4 5: Implementation Support and Organizational Strengthening**

This work package will provide ongoing support to SAHPRA during the initial implementation phase of the organizational reforms.

Support may include strengthening program management structures, assisting with implementation of revised organizational arrangements, supporting the introduction of

improved regulatory workflows and systems, and contributing to workforce development initiatives.

The contractor will work closely with SAHPRA leadership and relevant departments to ensure that organizational reforms are implemented in a coordinated and sustainable manner.

**Key deliverables for work package 5 will include:**

- The development of a Strategic Transformation Roadmap
- The development of a Detailed Operational Roadmap
- The development of a Risk Management & Mitigation Plan
- The creation of a Leadership alignment charter

Key to implementation support will include the Develop Project Management Office (PMO) operational model, provide on-site implementation support including on multi-functional regulator implementation, process implementation and SOP roll-out. Key outputs will include support of the Program Management Office (PMO) Operations, on-site implementation support, multi-functional regulator implementation and process implementation & SOP rollout

### **Work Package 5 6: Change-Management and Capacity Strengthening**

Throughout the assignment, organisational transformation requires not only technical adjustments but also effective change management. The success and sustainability of organisational reforms depend on how staff experience and engage with the process.

Transparent communication, meaningful staff involvement, and opportunities to raise concerns are essential to prevent uncertainty from turning into resistance. Organisational change can be perceived as a threat to roles, expertise, or job security; proactively addressing these concerns and fostering psychological safety can strengthen trust, ownership, and commitment to the reform process.

This work package will support SAHPRA in implementing a structured change management approach, including internal communication, stakeholder engagement, leadership support, and targeted capacity development to ensure sustainable organisational transformation

Key deliverables for work package 6 will include:

- Comprehensive Stakeholder Analysis and Mapping
- Stakeholder Engagement Plan
- Change Readiness Assessment Report
- Change Management Strategy Document
- Communication Materials
- Training Needs Assessment Report and Training Program Portfolio

Milestones	Key deliverables	Deadlines
Work Package 1: Program Inception and Initial Organizational Assessment	<ul style="list-style-type: none"> <li>▪ Inception Report, Initial Organizational Assessment and Program Governance Framework</li> </ul>	1 month after project start
Work Package 2: Strategic Vision Alignment and Benchmarking	<ul style="list-style-type: none"> <li>▪ Vision establishment</li> <li>▪ External Benchmarking report</li> <li>▪ Best practices compendium</li> <li>▪ WHO ML 4 &amp; WLA pathway analysis and gap assessment</li> </ul>	1 – 3 months after project start
Work Package 3: Organizational Design and Institutional Strengthening	<ul style="list-style-type: none"> <li>▪ Organizational Architecture Review</li> <li>▪ Human Capital &amp; Skills Analysis</li> <li>▪ Process &amp; Workflow Mapping</li> <li>▪ Workload &amp; Capacity Analysis</li> <li>▪ Technology &amp; Digital Readiness</li> <li>▪ Funding &amp; Financial Sustainability</li> <li>▪ Legislative &amp; Strategic Alignment</li> <li>▪ Communication and stakeholder relations</li> <li>▪ Consolidated Assessment for a multi-functional approach</li> <li>▪ Creating alternate organizational design models weighing out the pros/cons.</li> <li>▪ Organizing a leadership workshop on future state organizational models. Selection of target operational model. Facilitating decision-making for preferred model.</li> <li>▪ Developing a detailed future state organizational structure, developing organogram, reporting lines and staffing levels.</li> <li>▪ Clarifying the future state organizational structure. Re-defining the operational responsibilities and scope of authority.</li> <li>▪ Creating optimized process maps for key regulatory workflows showing streamlined processes and efficiency improvements.</li> <li>▪ Developing a Sustainable Funding Model. Proposing a revised fee structure. Developing a financial sustainability roadmap and policy position paper on budget allocation.</li> <li>▪ Developing a comprehensive talent management &amp; HR strategy.</li> <li>▪ Proposing training programs, competency-based job profiles, career pathways, and talent retention strategies.</li> <li>▪ Re-designing the framework for Performance Management.</li> <li>▪ Designing a cascaded KPI framework showing linkage from organizational strategy to unit KPIs to individual objectives with clear line of sight.</li> </ul>	2 – 5 7 months after project start

	Design a performance monitoring and reporting dashboard.	
Work Package 4: Implementation Roadmap and Early Implementation Support	<ul style="list-style-type: none"> <li>Design detailed future state organizational structure</li> <li>Create optimized process maps for key regulatory workflows</li> <li>Develop a Sustainable Funding Model</li> <li>Develop a comprehensive talent management, retention and HR strategy</li> <li>Re-design the framework for Performance Management.</li> <li>Strategic Transformation Roadmap development</li> <li>Detailed Operational Roadmap development</li> <li>Risk Management &amp; Mitigation Plan</li> <li>Leadership Alignment charter</li> </ul>	<p>4 – 7 months after project start</p> <p>6 – 8 months after project start</p>
Work Package 5: Implementation Support and Organizational Strengthening	<ul style="list-style-type: none"> <li>Strategic Transformation Roadmap development</li> <li>Detailed Operational Roadmap development</li> <li>Risk Management &amp; Mitigation Plan</li> <li>Leadership Alignment charter</li> </ul>	6 – 8 months after project start
	<ul style="list-style-type: none"> <li>Support PMO operations model</li> <li>On-Site implementation support</li> <li>Multi-functional Regulator implementation</li> <li>Process implementation &amp; SOP Rollout</li> </ul>	7 – 12 months after project start
Work Package 6: Change Management and Capacity Strengthening	<ul style="list-style-type: none"> <li>Comprehensive Stakeholder Analysis and Mapping</li> <li>Stakeholder Engagement Plan</li> <li>Change readiness assessment report</li> <li>Change Management strategy document</li> <li>Communication narrative and materials</li> <li>Training needs assessment report and training program portfolio</li> </ul>	1 – 12 months. entire project duration

This comprehensive scope of work provides a clear roadmap for SAHPRA's organizational transformation. The phased work package approach, detailed activities, and specific deliverables to ensure:

- Clarity on what will be delivered at each phase
- Accountability through specific, measurable deliverables
- Comprehensive coverage of all transformation dimensions
- Integration with existing SAHPRA initiatives (e.g., RCORE, digitalization, AI projects)
- Multi-functional regulator model with clear implementation pathway
- Sustainable funding model aligned with organizational structure
- Robust change management throughout the transformation
- Quality assurance and risk management embedded in delivery approach

Period of assignment: from Beginning of July 2026 until 30.09.2027.

### 3. Concept

In the tender, the tenderer is required to show *how* the objectives defined in Chapter 2 (Tasks to be performed) are to be achieved, if applicable under consideration of further method-related requirements (technical-methodological concept). In addition, the tenderer must describe the project management system for service provision.

Note: The numbers in parentheses correspond to the lines of the technical assessment grid.

#### Technical-methodological concept

**Strategy (1.1):** The tenderer is required to consider the tasks to be performed with reference to the objectives of the services put out to tender (see Chapter 1 Context) (1.1.1). Following this, the tenderer presents and justifies the explicit strategy with which it intends to provide the services for which it is responsible (see Chapter 2 Tasks to be performed) (1.1.2).

The tenderer is required to present the actors relevant for the services for which it is responsible and describe the **cooperation (1.2)** with them. The tenderer must describe the relevant actors (partners and others) for the service put out to tender and their interactions (section 1.2.1 of the assessment grid). The tenderer is required to develop a concept that shows how the cooperation with these actors is to be established and put into practice (section 1.2.2 of the assessment grid).

The tenderer is required to present and explain its approach to **steering** the measures with the project partners (1.3.1).

The tenderer is required to describe the key **processes** for the services for which it is responsible and create an **operational plan** or schedule (1.4.1) that describes how the services according to Chapter 2 (Tasks to be performed by the contractor) are to be provided. In particular, the tenderer is required to describe the necessary work steps and, if applicable, take account of the milestones and **contributions** of other actors (partner contributions) in accordance with Chapter 2 (Tasks to be performed) (1.4.2).

#### Project management of the contractor (1.6)

The tenderer is required to explain its approach for coordination with the GIZ project (1.6.1). In particular, the project management requirements specified in Chapter 2 (Tasks to be performed by the contractor) must be explained in detail.

The tenderer is required to draw up a **personnel assignment plan** (1.6.2) with explanatory notes that lists all the experts proposed in the tender; the plan includes information on assignment dates (duration and expert days) and locations of the individual members of the team complete with the allocation of work steps as set out in the schedule.

The tenderer is required to describe its **backstopping concept** (1.6.3). The following services are part of the standard backstopping package, which (like ancillary personnel costs) must be factored into the fee schedules of the staff listed in the tender in accordance with Section 3.1 of the GIZ AVB:

- Service-delivery control

- Managing adaptations to changing conditions
- Ensuring the flow of information between the tenderer and GIZ
- Assuming personnel responsibility for the contractor's experts
- Process-oriented steering for implementation of the commission
- Securing the administrative conclusion of the project

#### **Further requirements (1.7)**

The consultants are expected to integrate gender and diversity perspectives throughout their work. This includes ensuring that analyses, recommendations, and outputs are gender-sensitive and inclusive, taking into account the needs, perspectives, and participation of all relevant groups.

The consultants should actively contribute to the promotion of equality and avoid reinforcing biases or exclusion. Gender and diversity considerations should also be reflected in the composition of the consultant team, ensuring a balanced and inclusive mix of skills, backgrounds, and perspectives.

#### **4. Personnel concept**

The tenderer is required to provide personnel who are suited to filling the positions described, on the basis of their CVs (see Chapter 7), the range of tasks involved and the required qualifications.

The below specified qualifications represent the requirements to reach the maximum number of points in the technical assessment.

##### **Team leader**

###### Key tasks of the team leader

- Overall engagement oversight, strategic design leadership, quality assurance, stakeholder management, deadlines
- Coordinating and ensuring communication with GIZ, SAHPRA and others involved in the project
- Personnel management, in particular identifying the need for short-term assignments within the available budget, as well as planning and steering assignments and supporting local and international short-term experts
- Regular reporting in accordance with deadlines

###### Qualifications of the team leader

- Education/training (2.1.1): Master's degree in public health, regulatory affairs, health policy, health economics, business administration, development management or related disciplines.
- Language (2.1.2): C2-level language proficiency in English language
- General professional experience (2.1.3): 7 years of professional experience in the managing complex projects, preferably in the health or regulatory sectors.

- Specific professional experience (2.1.4): 7 years in organizational transformation and pharmaceutical regulatory sector
- Leadership/management experience (2.1.5): 7 years of management/leadership experience as project team leader or manager leading multi-disciplinary teams, engaging with high-level stakeholders, and coordinating multi-stakeholder processes
- Regional experience (2.1.6): 4 years of experience of projects in South Africa

## **Key expert 1 – Senior Organizational Development Expert**

### Key tasks of key expert 1

- To support design management and coordination of the entire duration of the project.
- Design a detailed future state organizational structure, developing organogram, reporting lines and staffing levels
- Clarify future state organizational structure. Re-define the operational responsibilities and scope of authority
- Develop a roadmap for implementation.
- Lead implementation

### Qualifications of key expert 1

- Education/training (2.2.1): Master's Degree in Organizational Development, Organizational Design, Change Management, Industrial Psychology, Business Administration, Behavioral Sciences or closely related disciplines
- Language (2.2.2): C2 -level language proficiency in English language
- General professional experience (2.2.3): 6 years in National Regulatory Authority or Regulatory Body Experience
- Specific professional experience (2.2.4): 6 years in Organizational Development experience
- Leadership/management experience (2.2.5): 6 years of management/leadership experience leading multi-disciplinary teams, engaging with high-level stakeholders, and coordinating multi-stakeholder processes
- Regional experience (2.2.6): 3 years of experience of projects in South Africa

## **Key expert 2 – Regulatory Expert**

### Key tasks of key expert 2

- Conduct an external benchmarking study covering 4-6 leading NRAs documenting organizational structures, multi-functional approaches, staffing models, and operational efficiencies. Provide a comparative analysis matrix comparing SAHPRA's current state against benchmarked NRAs across SAHPRA's organizational dimensions
- Provide a best practices compendium for regulatory organizational design synthesizing international standards and approaches
- Conduct a WHO ML4 pathway analysis and gap assessment mapping current state against WHO Global Benchmarking Tool Maturity Level 4 requirements with specific gap closure recommendations
- Conduct a diagnostic on the current regulatory functional structure. Provide a Multi-Functional Regulator Framework including skills matrix, competency requirements, training pathways and cross training plan, rotation mechanisms, and assessment criteria. Provide a Multi-Functional Regulator training program that includes



curriculum design, learning pathways by level, assessment approach, and implementation plan

#### Qualifications of key expert 2

- Education/training (2.3.1): Master's degree in pharmacy, medicine, life sciences, or regulatory affairs, biochemistry, clinical epidemiology or closely related disciplines.
- Language (2.3.2): C2 -level language proficiency in English language
- General professional experience (2.3.3): 6 years in National Regulatory Authority or Regulatory Body Experience
- Specific professional experience (2.3.4): 6 years of experience in regulatory oversight, quality assurance, and compliance, with familiarity in applying international standards (e.g., WHO guidelines, ICH guidelines, PICs).
- Leadership/management experience (2.3.5): 6 years of management/leadership experience leading multi-disciplinary teams, engaging with high-level stakeholders, and coordinating multi-stakeholder processes
- Regional experience (2.3.6): 3 years of experience of projects in South Africa

### **Key expert 3 – Change Management and Organizational development Expert**

#### Key tasks of key expert 3

- To support design management, and coordination of the entire duration of the project
- Develop a change management strategy document
- Conduct a change readiness assessment report
- Conduct a comprehensive stakeholder analysis and mapping
- Develop comprehensive stakeholder engagement narrative and communication materials
- Co-ordination of necessary training program

#### Qualifications of key expert 3

- Education/training (2.4.1): Master's degree in business administration, psychology, human resources or closely related disciplines.
- Language (2.4.2): C2 -level language proficiency in English language
- General professional experience (2.4.3): 6 years in national ministry or health sector experience
- Specific professional experience (2.4.4): 6 years of experience in change management, large-scale transformation
- Leadership/management experience (2.4.5): 6 years of management/leadership experience leading multi-disciplinary teams, engaging with high-level stakeholders, and coordinating multi-stakeholder processes
- Regional experience (2.4.6): 3 years of experience of projects in South Africa

### **Key expert 4 – Human Resource & Capacity Development Expert**

#### Key tasks of key expert 4

- Evaluate changes proposed to the job descriptions, systems and processes, reporting lines, and support HR deliverables and processes throughout the project.
- Develop a comprehensive talent management & HR strategy



- Training program design to support the project operationalization and informed decision making of the project

#### Qualifications of key expert 4

- Education/training (2.5.1): Master's degree in Instructional Design/Information Technology, Education, Organizational Development, Social Sciences, Human Resources or closely related discipline.
- Language (2.5.2): C2 -level language proficiency in English language
- General professional experience (2.5.3): 6 years of experience in national government ministry or the health sector
- Specific professional experience (2.5.4): 6 years of human resource or capacity development experience
- Leadership/management experience (2.5.5): 5 years of management/leadership experience leading multi-disciplinary teams and coordinating multi-stakeholder processes
- Regional experience (2.5.6): 3 years of experience of projects in South Africa

#### Soft skills of team members

In addition to their specialist qualifications, the following qualifications are required of team members:

Team skills

Initiative

Communication skills

Socio-cultural skills

Efficient, partner- and client-focused working methods

Interdisciplinary thinking

#### **Short-term expert pool with minimum 4, maximum 5 members**

For the technical assessment, an average of the qualifications of all specified members of the expert pool is calculated. Please send a CV for each pool member (see below Chapter 7 Requirements on the format of the bid) for the assessment.

#### Tasks of the short-term expert pool

- Provide specialized expertise as needed in IT/digitalization - Support to include assessment of technology infrastructure, assessment of the digitalization strategy and support with proposed digitalization opportunities
- Finance – Support to include assessment of financial implications of the proposed organizational transformation
- Analyst - Support to include data collection, analysis, process mapping, documentation. Analyst to bridge complex data to inform the strategic decision making of the project and to provide workshop support
- Legislation – Support to provide an analysis of workforce implications in accordance with labour law, and to provide instruction on what is mandated in accordance with the law on mandatory staff engagement requirements

#### Qualifications of the short-term expert pool

- Education/training (2.6.1):

- 1 expert with university qualification (Masters) in Computer Science/Information Technology, Finance, Analytics, Law or closely related disciplines
- 1 expert with university qualification in (Masters) in Finance, Accounting, Economics or closely related discipline
- 1 expert with university qualification (Master) in Data science, analytics, statistics, mathematics, business administration or closely related disciplines.
- 1 expert with university qualification (Master) in Law, human resource management or closely related discipline.
- Language (2.6.2): 4 experts with C2-level language proficiency in English language
- General professional experience (2.6.3): 4 experts with 3 years of professional experience in the health, regulatory or public administration sector
- Specific professional experience (2.6.4):
  - 1 expert with 6 years of professional experience in trouble-shooting, advanced system engineering, data bases, software development, writing code or closely related discipline
  - 1 expert with 6 years of professional experience in financial analysis, modeling, risk management or closely related discipline;
  - 1 expert with 6 years of professional experience in analytics and documentation
  - 1 expert with 6 years of public experience in human resource /legal department
- Regional experience (2.6.5): 3 experts with 3 years of experience in South Africa

The tenderer must provide a clear overview of all proposed short-term experts and their individual qualifications.

## 5. Costing requirements

### Assignment of personnel and travel expenses

Per diem allowances are reimbursed as a lump sum up to the maximum amounts permissible under tax law for each country as set out in the country table in the circular from the German Federal Ministry of Finance on travel expense remuneration (downloadable from the [German Federal Ministry of Finance – tax treatment of travel expenses and allowances for international business travel as of 1 January 2026 \(GERMAN ONLY\)](#)).

Accommodation allowances are reimbursed as detailed in the specification of inputs below.

With special justification, additional Accommodation costs up to a reasonable amount can be reimbursed against evidence.

All business travel must be agreed in advance by the officer responsible for the project

### Sustainability aspects for travel

GIZ has undertaken an obligation to reduce greenhouse gas emissions (CO<sub>2</sub> emissions) caused by travel. When preparing your tender, please incorporate options for reducing emissions, such as selecting the lowest-emission booking class (economy) and using means of transport, airlines and flight routes with a higher CO<sub>2</sub> efficiency. For short distances, travel by train (second class) or e-mobility should be the preferred option.

CO<sub>2</sub> emissions caused by air travel must be offset. GIZ specifies a budget for this, through which the carbon offsets can be settled against evidence.

There are many different providers in the market for emissions certificates, and they have different climate impact ambitions. The [Development and Climate Alliance \(German only\)](#) has published a [list of standards \(German only\)](#). GIZ recommends using the standards specified there.

#### Specification of inputs

Fee days	Number of experts	Number of days per expert	Total	Comments
Designation of TL	1	37	37	This included desk-based assignment and on-site (South Africa) assignment
Designation of Key expert 1	1	37	37	This included desk-based assignment and on-site (South Africa) assignment
Designation of Key expert 2	1	30	30	This included desk-based assignment and on-site (South Africa) assignment This included desk-based assignment and on-site (South Africa) assignment
Designation of Key expert 3	1	37	37	This included desk-based assignment and on-site (South Africa) assignment
Designation of Key expert 4	1	20	20	This included desk-based assignment and on-site (South Africa) assignment This included desk-based assignment and on-site (South Africa) assignment
Designation of short-term pool (expert pool)	4	15	60	This included desk-based assignment and on-site (South Africa) assignment
Travel expenses	Quantity	Number per expert	Total	Comments
Per-diem allowance in country of assignment	4	4	16	in accordance with the Federal Travel Expenses Directive for South Africa. A budget of 576 EUR is foreseen for per-diem allowance in country of assignment.

Overnight allowance in country of assignment	4	4	16	in accordance with the Federal Travel Expenses Directive for South Africa. A budget of 2,064 EUR is foreseen for overnight allowance in country of assignment.
<b>Transport</b>	<b>Quantity</b>	<b>Number per expert</b>	<b>Total</b>	<b>Comments</b>
International flights	4	1	4	Travel to the place of service delivery South Africa
Domestic flights	4	1	4	Flights within the country of assignment during service delivery
CO <sub>2</sub> compensation for air travel	1	1.040,00	1.040,00	A fixed budget of EUR <b>1.040,00</b> is earmarked for settling carbon offsets against evidence.
Travel expenses (train, car) • e-hailing services; rented vehicle, train	8	5	40	Travel within the country of assignment, transfer to/from airport etc.
<b>Other costs</b>	<b>Number</b>	<b>Price</b>	<b>Total</b>	<b>Comments</b>
Flexible remuneration	1	8.000,00	8.000,00	A budget of EUR <b>8.000,00</b> is foreseen for flexible remuneration. Please incorporate this budget into the price schedule.  Use of the flexible remuneration item requires prior written approval from GIZ.
Workshops	1	3.000,00	3.000,00	The budget contains the following costs <b>3.000,00</b> EUR for workshops.

## Workshops, events and trainings

The contractor implements the following workshops/study trips/training courses:

- Room hire
- Technical systems
- Translation/interpreting

- Catering
- Workshop materials
- Travel expenses for workshop participants (subsistence, accommodation, travel costs)
- Other costs relating to the workshops

## **6. Requirements on the format of the tender**

The structure of the tender must correspond to the structure of the ToR. In particular, the detailed structure of the concept (Chapter 3) should be organised in accordance with the positively weighted criteria in the assessment grid (not with zero). The tender must be legible (font size 11 or larger) and clearly formulated. It must be drawn up in English language.

The complete tender must not exceed 15 pages (excluding CVs). If one of the maximum page lengths is exceeded, the content appearing after the cut-off point will not be included in the assessment. External content (e.g. links to websites) will also not be considered.

The CVs of the personnel proposed in accordance with Chapter 4 of the ToRs must be submitted using the format specified in the terms and conditions for application. The CVs shall not exceed 4 pages each. They must clearly show the position and job the proposed person held in the reference project and for how long. The CVs must also be submitted in English language.

Please calculate your financial tender based exactly on the parameters specified in Chapter 5 Quantitative requirements. The contractor is not contractually entitled to use up the days, trips, workshops or budgets in full. The number of days, trips and workshops and the budgets will be contractually agreed as maximum limits. The specifications for pricing are defined in the price schedule.

## **7. Data Protection and Information Security**

The performance of the contract may be associated with the processing of personal data by the contractor, such as (but not limited to) names and contact information. In such cases, the contractor shall act as an independent DATA CONTROLLER and must alone comply with ALL applicable data protection obligations, including those stemming from regional and local laws, specifically the Protection of Personal Information Act (POPI Act). The contractor shall process personal data only when a given goal cannot be reasonably attained without such data. The data protection principles such as lawfulness, data minimization, accuracy, purpose limitation, storage limitation, transparency, integrity and confidentiality, and accountability, as well as the numerous rights of the data subject must be paid due attention. GIZ is NOT in any way responsible for such processing.

Whenever the contractor executes the instructions of a partner to the GIZ with regard to such processing, the partner shall be the data controller, and the data processing shall be carried out in accordance with the partner's instructions as well as laws and standards to which it is subject.

Unless explicitly required by GIZ, assessments, reports, surveys, or any other data and information shared with GIZ must be provided strictly anonymously, meaning that any information relating to an identified or identifiable natural person ('data subject') must be excluded. Specifically, personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, trade union membership, as well as genetic data, biometric

data, or data concerning health or data concerning a natural person's sex life or sexual orientation must only be collected in a strictly anonymous and aggregated manner.

The present assignment might deal with sensitive and confidential information. Under no circumstances are the consultants of the contractor (as a company and as individuals) allowed to provide, share, release or disclose any information or materials of the partner.