

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

CONFIDENTIAL

**Consultancy Service for Local Manufacturing Governance and
Regulatio**

**Project number/
cost centre:
G-011902**

Tender number

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0. List of abbreviations

AG	Commissioning party
AN	Contractor
AVB	General Terms and Conditions of Contract for supplying services and work
FK	Expert
FKT	Expert days
KZFK	Short-term expert
ToRs	Terms of reference

1. Context

The programme “Vaccines for Africa: Roll-out and Production in South Africa” (SAVax) is co-financed by German 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 is implemented in cooperation with the Department of Science, Technology and Innovation (DSTI), the Department of Health (DoH), and the South African Health Products Regulatory Authority (SAHPRA). The project's overall objective is to support the implementation of South Africa to increase local manufacturing of vaccines and improve access for the population. The specific objectives are to: support the enabling environment for local production through research, development, and skills development; strengthen the regulatory environment; and support the demand and supply of locally manufactured products.

The GIZ SAVax programme focuses on strengthening South Africa's vaccine manufacturing capabilities by supporting local production and the entire vaccine value chain as part of its core mandate. The programme aims to improve access to high-quality vaccines for all population groups in South Africa by enhancing the local development and manufacturing ecosystem, reinforcing regulatory frameworks, and ensuring sustainable production and distribution of vaccines. Governance and facilitating an enabling environment are key elements.

To achieve these objectives, the programme requires a consultancy tandem with specialised expertise in both local manufacturing governance and regulatory processes, comprising a senior advisor focused on trade and local manufacturing governance and a second expert dedicated to regulatory affairs connected to the private sector. The highly specialised, advisory support is required to address complex governance, trade, financing, and regulatory issues involving multiple public institutions and private-sector stakeholders.

The consultancy tandem will provide targeted strategic analysis and senior-level advisory input to strengthen policy dialogue, programme positioning, and long-term impact.

2. Tasks to be performed by the contractor

The contractor is responsible for providing the following services:

Strategic and executive advice on local manufacturing governance

- **Government & Private-Sector Engagement & Strategic Briefing:** Advise managers on the programme's engagement with government institutions and private-sector umbrella bodies; prepare decision-oriented briefing notes and discussion papers for steering with SAVax political partners (e.g. through steering committee meetings). Formulate concrete messages to government and facilitate the dialogue between government and (multinational and national) private sector companies.
- **Governance & Trade Strategy:** Provide continuous strategic advice to the SAVax management team on South Africa's industrial, trade, and localisation policies affecting the vaccine, pharmaceutical and other health product manufacturing. Assess implications

for programme interventions and support engagement strategies with respective partner structure of SAVax.

- **Public Procurement & Market-Shaping Advice:** Advise the programme on how public procurement frameworks and localisation requirements can be leveraged to stimulate local manufacturing; analyse systemic barriers for SMEs and larger manufacturers; and advise on engagement strategies with procuring entities.
- **Financing Landscape & Programme Positioning:** Analyse government-supported financing tools for start-ups, SMEs and larger companies, assess which sectors benefit most and why, and compare these experiences to the biopharmaceutical sector to inform programme design and advocacy.
- **Biopharmaceutical-Specific Financing & Bottlenecks:** Provide targeted strategic advice on financing instruments available to South African biopharmaceutical firms; diagnose recurring challenges (access criteria, collateral requirements, approval timelines, repayment terms); and recommend areas for policy dialogue or programme intervention.
- **BEE & Localisation Strategy:** Advise the programme on B-BBEE frameworks; support positioning of the programme within national transformation agendas; and inform engagement with industry and government on inclusive industrialisation.

Regulatory strategic advice

- Advise SAVax management team on the needs of private sector in regulatory processes and SAHPRA's regulatory approach
- Advise SAVax management team on key conditions to allow SAHPRA to function as an enabler for local manufacturing, while maintaining high safety and quality standards (potentially focusing on clearer guidance for applicants, early scientific advice, priority pathways for strategic products), without compromising their independence
- Advise SAVax management team on the current legislative framework applicable to the regulator and the associated gaps and opportunities. Propose implementable reform proposals or concepts that could be taken forward by government and SAHPRA, including private sector support mechanisms.
- Support SAVax management in structured engagement between SAHPRA, government and the private sector through concise briefing notes to SAVax programme team with the goal to advance regulatory modernisation as part of South Africa's industrial development agenda.

Specific Outputs:

- Briefing papers on the following topics as mentioned under "Strategic and executive advice on local manufacturing governance" and "Regulatory strategic advice"
- Conceptualisation, facilitation and documentation of workshops and strategic meetings

Certain milestones, as laid out in the table below, are to be achieved during the contract term:

Milestones/process steps/partial services	Deadline/place/person responsible
Up to 10 briefing papers	from 15.06.2026 until 30.09.2027
Up to 5 workshops	from 15.06.2026 until 30.09.2027

Period of assignment: from **15.06.2026** 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 is required to present and explain its approach to **steering** the measures with the project partners (1.3.1) and its contribution to the **results-based monitoring system** (1.3.2).

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).

The tenderer is required to describe its contribution to knowledge management for the partner (1.5.1) and GIZ and to promote scaling-up effects (1.5.2) under **learning and innovation**.

Further requirements (1.7)

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

Tasks of the team leader

- Overall responsibility for the advisory packages of the contractor (quality and deadlines)
- Coordinating and ensuring communication with GIZ
- 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): university degree (German 'Diplom'/Master) in Economics, Law, Public Policy, International Trade, Industrial Policy, Development Economics, Health Economics, or Business Administration or similar field
- Additional specialised training in trade, public finance, or regulatory/market-shaping policy is an asset.
- Language (2.1.2): C2-level language proficiency in English
- General professional experience (2.1.3): 20 years of professional experience in advising governments and private sector, development programmes, or multilateral organisations on industrial development, trade, or economic transformation.
- Specific professional experience (2.1.4): 15 years in demonstrated engagement with high-level decision makers (senior government and private sector), strong experience preparing policy briefs, strategic analyses, and decision-oriented recommendations, experience facilitating public-private dialogue in complex stakeholder environments.
- Leadership/management experience (2.1.5): 15 years of management experience as project team leader or manager in a company or organisation, including executive roles and in leadership positions
- Regional experience (2.1.6): 15 years of experience in projects in Sub-Saharan Africa (region), of which 2 years in projects in South Africa (country)
- Development cooperation (DC) experience (2.1.7): 15 years of experience in DC projects
- Other (2.1.8) The consultant must demonstrate substantial experience in most of the following areas: (1) Industrial policy & localisation and financing instruments: Trade policy, sector development strategies, and localisation frameworks, (2) (Bio)-pharmaceuticals, Medical Technology (MedTech), Diagnostics, (3) Transformation & sustainable value chain: Experience working with government and private sector on policies or programmes that help include local and smaller businesses in the local manufacturing sustainable value chain, (4) Government & private-sector engagement: Structuring dialogue processes and preparing high-level briefing material.

Regulation Expert (key expert 1)

Tasks of Regulation Expert (key expert 1)

- Advise management on strengthening regulatory processes in line with private sector needs.
- Identify enabling conditions for effective, high-quality and independent regulation.
- Assess the legislative framework and propose practical reform options.

Qualifications of key expert 1

- Education/training (2.2.1): Master's degree (or higher) in pharmacy, regulatory science, law, public policy, health economics, pharmaceutical sciences, or related field
- Additional training/certification in medicines regulation, quality assurance (GxP), or regulatory affairs is an asset
- Language (2.2.2): C2 -level language proficiency in English
- General professional experience (2.2.3): 10 years of professional experience in the health, pharmaceutical, biotechnology, or medical products sector
- Specific professional experience (2.2.4): 10 years of experience working with or alongside regulatory authorities, government institutions, or industry associations
- Leadership/management experience (2.2.5): 5 years of experience advising senior management or public institutions on policy or strategic matters
- Regional experience (2.2.6): 5 years of experience in projects in Sub-Sahara Africa (region), of which 2 years in projects in South Africa (country)
- Development Cooperation (DC) experience (2.2.7): 2 years of experience in DC projects
- Other (2.2.8): 5 years of (1) Direct experience with medicines or health-product regulatory systems (registration, approval pathways, compliance, or regulatory reform) (2) Experience analysing legislation and proposing implementable policy or regulatory reform measures

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

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 (CO₂ 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 CO₂ efficiency. For short distances, travel by train (second class) or e-mobility should be the preferred option.

CO₂ 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 Team Leader	1	45	45	
Designation of Key Expert 1	1	35	35	
Travel expenses	Quantity	Number per expert	Total	Comments
Per-diem allowance in country of assignment	12	2	24	
Overnight allowance in country of assignment	12	2	24	<p>Overnight stays abroad:</p> <p>Note: Under the BMF travel expense regulations, overnight allowances not exceeding 100% of the lump sum amounts can be submitted for reimbursement against evidence. Up to 75% of the maximum rates specified in the travel expense regulations can be submitted for reimbursement on a lump-sum basis.</p> <p>Please indicate in the price schedule whether your offer is on a lump-sum basis or against evidence.</p>

				<p>Overnight stays in Germany (deviation from the travel expense regulations):</p> <p>Note: Overnight allowances of up to EUR 130 can be submitted for reimbursement against evidence. Up to EUR 80 can be submitted for reimbursement on a lump-sum basis.</p> <p>Please indicate in the price schedule whether your offer is on a lump-sum basis or against evidence.</p>
Transport	Quantity	Number per expert	Total	Comments
International flights	n.a.			Travel to the place of service delivery
Domestic flights	12	2	24	Flights within the country of assignment during service delivery. A total of 6 return flights per expert.
CO₂ compensation for air travel	12	2	26,400 ZAR	A fixed budget of ZAR 26,400 is earmarked for settling carbon offsets against evidence.
Travel expenses (train, car)				Travel within the country of assignment, transfer to/from airport etc.
Other travel expenses				e.g. visa costs
Other costs	Number	Price	Total	Comments
Flexible remuneration.	1	58,000 ZAR	58,000 ZAR	<p>A budget of ZAR 58,000 is foreseen for flexible remuneration. Please incorporate this budget into the price schedule.</p> <p>Use of the flexible remuneration item requires prior written approval from GIZ.</p>
Workshops	n.a.			The budget contains the following costs

Subcontracts	n.a.			The budget contains the following costs .
Procurement of materials and equipment	n.a.			The budget contains the following costs .
Local contributions	n.a.			The contractor administers the following local <i>contributions</i> in accordance with Section 2.7 AVB: .
Other costs	n.a.			The budget contains the following costs .

6. Inputs of GIZ or other actors

GIZ and/or other actors are expected to make the following available:

- Logistics for workshops: Provided by GIZ

7. 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 10 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 can 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.