

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

CONFIDENTIAL

Support to DTIC with regards to policy development on bilateral trade agreements with regards to pharmaceutical products	Project number/ cost centre: G-011902-004, 11902040000
	Tender number 10057398

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0. List of abbreviations

AfCFTA	African Continental Free Trade Area
ARV	Antiretroviral
BMZ	Federal Ministry for Economic Cooperation and Development (<i>Bundesministerium für wirtschaftliche Zusammenarbeit und Entwicklung</i>)
COMESA	Common Market for Eastern and Southern Africa
DSTI	Department of Science, Technology and Innovation
DoH	Department of Health
DTIC	Department of Science, Technology and Innovation
EAC	East African Community
ECOWAS	Economic Community of West African States
EU	European Union
FTA	Free Trade Agreement
REC	Regional Economic Community
SADC	Southern African Development Community
SAHPRA	South African Health Products Regulatory Authority

1. Context

The program “Vaccines for Africa: Roll out and Production in South Africa” (SAVax) supports South Africa’s strategic objective to enhance the local production of vaccines, medicines, medical technologies and health innovations. Co-financed by the German Federal Ministry for Economic Cooperation and Development (BMZ) and the European Union (EU), SAVax aims to strengthen local manufacturing capacity in the biopharmaceutical industry and improve access to essential health products. The program is implemented with key South African government partners, including the Department of Science, Technology and Innovation (DSTI), the Department of Health (DoH), and the South African Health Products Regulatory Authority (SAHPRA), and aligns with the Department of Trade, Industry and Competition (DTIC).

The SAVax program has duration from 01.01.2022 to 31.12.2027 with the following objective: Access to quality vaccines for all populations in South Africa has improved.

Supporting the Department of Trade, Industry and Competition (DTIC) in advancing bilateral pharmaceutical and MedTech export agreements aligns closely with the mandate of SAVax. By helping to unlock practical market access for South African manufacturers, SAVax can contribute to strengthening regional value chains, improving the availability of quality-assured medicines and MedTech across partner countries, and reducing dependency on extra-continental imports.

Advancing bilateral pharmaceutical and MedTech export agreements is critical for South Africa at a time when the African Continental Free Trade Area is still being operationalised, because it allows the country to move from ambition to tangible market access. While AfCFTA provides the long-term framework for continental integration, immediate barriers—particularly around regulatory approval, procurement access, and logistics—continue to limit trade in practice. Targeted bilateral agreements can help unlock these constraints more quickly, enabling South African manufacturers to expand into regional markets, achieve economies of scale, and strengthen supply chain resilience for essential medicines and health technologies. At the same time, such efforts can support broader industrial policy objectives, position South Africa as a regional hub for pharmaceutical production and MedTech, and contribute to improved access to quality-assured medicines and medical technologies across the continent, while remaining aligned with the longer-term vision of the AfCFTA.

To address this, SAVax seeks to engage a consultant through a competitive tender. The focus of this assignment is conducting a baseline assessment and supporting DTIC in strategic engagements with partner countries.

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2. Tasks to be performed by the contractor

WP1: Mapping of Existing Free Trade Agreements and Regional Economic Community Frameworks			
Objective: Objective: Provide a comprehensive mapping and analysis of existing bilateral Free Trade Agreements (FTAs), preferential trade arrangements, and Regional Economic Community (REC) frameworks relevant to South Africa's pharmaceutical and MedTech exports, in order to identify existing market access opportunities, constraints, and gaps for strategic engagement.	Key questions addressed: • What existing bilateral FTAs and preferential trade arrangements already govern South Africa's pharmaceutical and MedTech exports? • How do Regional Economic Communities (RECs) shape actual market access conditions beyond formal agreements? • Where are there overlaps, inconsistencies, or untapped opportunities that could be leveraged for improved market access? • How can these existing frameworks be aligned or used as stepping stones toward new bilateral agreements and the objectives of the African Continental Free Trade Area?	Tasks: • Identify and map relevant bilateral trade agreements between South Africa and priority partner countries affecting pharmaceuticals, health products, medical devices and diagnostics • Analyse Regional Economic Community frameworks, including but not limited to SADC, EAC, ECOWAS, and COMESA, focusing on trade provisions relevant to health products and medical technology • Assess actual implementation status of these agreements (beyond legal texts), including tariff application, rules of origin compliance, and non-tariff barriers • Identify preferential access regimes, exemptions, or health-sector-specific provisions relevant to pharmaceuticals and medical technologies	Outputs: • Mapping report of bilateral FTAs and REC trade frameworks relevant to pharmaceuticals and medical technologies • Visualised trade agreement landscape map (country × agreement × relevance to pharma) • Gap analysis of formal vs actual market access conditions • Summary of opportunities to optimise existing agreements before negotiating new ones • Strategic recommendations for DTIC engagement priorities and sequencing

		- Evaluate consistency and fragmentation across overlapping trade regimes (bilateral vs REC vs AfCFTA) - Identify practical market access pathways currently used by exporters (formal and informal) - Provide strategic options for how DTIC can leverage or renegotiate existing frameworks to support pharmaceutical exports	
WP2: Market Prioritisation & Opportunity Mapping			
Objective: Identify and justify priority partner countries and product segments.	Key questions addressed: - Where is demand highest and most accessible? - Which products are competitive for South Africa?	Tasks: - Analyse import dependency, disease burden, and procurement volumes in target countries - Map regulatory timelines and market entry barriers - Identify top product categories (e.g., ARVs, oncology generics, vaccines, diagnostics, medical devices and digital health solutions) - Benchmark South Africa's export competitiveness	Outputs: - Shortlist of 5–8 priority countries - Product–market match matrix covering pharmaceuticals and MedTech - Strategic rationale for engagement
WP3: Regulatory Landscape & Alignment Pathways			
Objective:	Key questions addressed: Which reliance pathways exist?	Tasks: Map regulatory requirements vs SAHPRA standards for	Outputs: Country-specific regulatory roadmaps for

Identify concrete regulatory pathways to enable fast market entry.	- How can approvals be accelerated? - What are the timelines for regulatory approvals?	pharmaceuticals and MedTech Identify existing reliance mechanisms	pharmaceuticals and MedTech - Recommendations for bilateral regulatory agreements (including regulatory reciprocity) - Risk assessment (approval timelines, duplication risks)
WP4: Trade, Tariffs & Logistics Assessment			
Objective: Ensure feasibility of exports.	Key questions addressed: What barriers exist in moving products across borders?	Tasks: - Assess tariffs, VAT, and exemptions on pharma and MedTech products - Map customs procedures and documentation requirements	Outputs: Trade barrier analysis per country
WP5: Pricing, Procurement & Market Access			
Objective: Determine commercial viability and access to public markets.	Key questions addressed: Can South African products realistically be sold?	Tasks: - Analyse procurement systems (tenders, central medical stores) for pharmaceuticals, medical devices and diagnostics - Map pricing regulations and reimbursement mechanisms - Identify entry points into public procurement	Outputs: - Market access strategy per country covering pharmaceuticals and MedTech - Pricing and reimbursement analysis - Procurement engagement roadmap
WP6: Bilateral Agreement Design			
Objective:	Key questions addressed: What should the agreement actually contain?	Tasks: Draft key provisions (regulatory cooperation,	Outputs: Draft bilateral agreement framework covering

Translate analysis into actionable agreements.		procurement access, tariffs) that ensure regulatory cooperation on pharmaceuticals but also medical devices as well as mutual recognition of conformity assessments and procurement access for diagnostics • Ensure alignment with African Continental Free Trade Area principles	pharmaceuticals and MedTech
WP7: Strategic Engagement & Negotiation Support for Bilateral Agreements			
Objective: Strengthen DTIC's capacity to strategically engage, negotiate, and position South Africa in bilateral pharmaceutical trade agreements, in alignment with national industrial policy and the African Continental Free Trade Area.	Key questions addressed: • How should South Africa position its interests in bilateral negotiations? • What are the priority asks and trade-offs in partner country engagements? • How can engagements be structured to support both short-term exports and long-term industrial goals?	Tasks: • Develop country-specific negotiation briefs (including interests, red lines, and concessions) • Provide strategic advisory support to DTIC during engagements (bilateral meetings, technical discussions) • Map and support engagement with key stakeholders (partner country ministries, (device) regulators, (hospital) procurement agencies, diagnostic suppliers, industry actors) • Develop core messaging and positioning aligned with	Outputs: • Negotiation briefs and engagement strategies per priority country • Stakeholder mapping and engagement plans • Strategic positioning paper for South Africa's pharmaceutical and MedTech exports • Advisory notes and debriefs following key engagements • Consolidated lessons learned and recommendations for scaling • Proposed bilateral and regional cooperation plans for the development and strengthening of regional value chains

		South Africa's industrial and health objectives • Ensure coherence and alignment with existing regional and continental frameworks (incl. AfCFTA) • Identify quick-win opportunities for early agreements or pilot initiatives • Capture lessons learned across engagements to inform future negotiations • Identify regional value chain opportunities for pharmaceuticals and medical technologies (e.g. device assembly, diagnostic manufacturing) • Identify possible areas of cooperation amongst Member States	
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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
Outputs of Work Packages 1-5	31.05.2027
Outputs of Work Packages 6-7	15.08.2027

Period of assignment: from 01.01.2027 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**.

The tenderer is required to describe its approach and procedure for coordination with the GIZ project (1.6.1), its personnel assignment plan (1.6.2) as well as its backstopping strategy (1.6.3) under **project management of the contractor**.

Further requirements (1.7)

Gender balance and diversity: Assessment of the proposed team's commitment to gender equality and diversity, including a balanced gender representation and diversity of professional expertise, backgrounds and perspectives. The bidder should demonstrate how

the proposed team composition contributes to inclusive and effective delivery of the assignment.

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 and Senior Trade & Policy Expert

Tasks of the team leader

- Overall responsibility for the advisory packages of the contractor (quality and deadlines) and ensure coherence across all work packages
- Coordinating and ensuring communication with GIZ, partners 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
- Map existing bilateral trade agreements, preferential trade arrangements and REC frameworks relevant to South African pharmaceutical exports
- Assess the implications of AfCFTA and existing regional trade frameworks for bilateral engagements
- Identify priority partner countries and define a sequencing strategy for engagement
- Develop strategic recommendations for DTIC on bilateral pharmaceutical and MedTech trade agreements
- Prepare country-specific negotiation briefs, including South African interests, priorities, potential trade-offs and key asks
- Provide strategic advisory support to DTIC during bilateral engagements and technical discussions
- Coordinate stakeholder consultations with DTIC, relevant government departments, industry and partner-country institutions
- Ensure alignment between trade policy, industrial policy and pharmaceutical/MedTech/health objectives
- Lead the development of the final bilateral pharmaceutical and MedTech trade engagement roadmap

Qualifications of the team leader

- Education/training (2.1.1): university degree (German 'Diplom'/Master) in Economics, International Trade, Law (trade law or economic law) or equivalent
- Language (2.1.2): C1-level language proficiency in English
- General professional experience (2.1.3): 10 years of professional experience in trade policy and international trade
- Specific professional experience (2.1.4): 7 years in drafting/analysis and implementation of Free Trade Agreements, Regional Economic Communities and/or AfCFTA

- Leadership/management experience (2.1.5): 3 years of management/leadership experience as project team lead or comparable leadership responsibility (including resource, time and quality management; coordination of short-term experts)
- Regional experience (2.1.6): 4 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): 3 years of experience in DC projects
- Other (2.1.8): 5 years of advisory experience for ministries or public institutions on trade policy topics (e.g. DTIC)

Key expert 1: Pharmaceutical/MedTech Industry & Market Access Expert

Tasks of key expert 1

- Assess South Africa's pharmaceutical and MedTech manufacturing and export capabilities and identify competitive product segments.
- Analyse pharmaceutical market opportunities in priority partner countries.
- Map demand, procurement systems, market structures and potential buyers.
- Identify key barriers to market entry, including pricing, reimbursement, procurement and localisation requirements.
- Assess opportunities for South African companies to participate in public and private procurement markets.
- Identify opportunities for regional pharmaceutical and MedTech value chains, joint ventures and local manufacturing partnerships.
- Assess opportunities for technology transfer and industrial cooperation.
- Identify financing and investment requirements for expanding pharmaceutical and MedTech exports.
- Develop country–product opportunity matrices and recommendations for priority export markets.
- Provide input into negotiation positions from an industry and commercial perspective.

Qualifications of key expert 1

- Education/training (2.2.1): Master's degree in Pharmacy, Pharmaceutical Sciences, Health Economics, Business/Management, Public Health, or equivalent
- Language (2.2.2): C1 -level language proficiency in English
- General professional experience (2.2.3): 10 years of professional experience in the pharmaceutical and MedTech industry and pharmaceutical market access, including roles in strategy, commercial development, or policy interface
- Specific professional experience (2.2.4): 7 years in market access and commercialization across African markets (pricing, reimbursement, procurement, tenders, localization)
- Leadership/management experience (2.2.5): n.a.
- Regional experience (2.2.6): 4 years of experience in Sub-Saharan Africa, including 2 years with direct South African ecosystem exposure (manufacturers, DTIC/DSI/DoH, SAHPRA, industry associations such as IPASA/PSSA/PHARMISA)
- Development Cooperation (DC) experience (2.2.7): n.a.
- Other (2.2.8): 5 years assessing pharma and MedTech manufacturing capabilities and export readiness (GMP, dossier readiness, regulatory pathways, quality systems)

Key expert 2: Regulatory & Pharmaceutical Trade Expert

Tasks of key expert 2

- Map pharmaceutical regulatory requirements in the priority partner countries.
- Compare partner-country requirements with South African/SAHPRA requirements.
- Identify opportunities for regulatory reliance, mutual recognition or accelerated registration pathways.
- Assess requirements related to GMP, product registration, quality assurance, pharmacovigilance and batch release.
- Identify regulatory and non-tariff barriers affecting South African pharmaceutical and MedTech exports.
- Analyse pharmaceutical and MedTech tariffs, import requirements, customs documentation and rules of origin.
- Identify opportunities to incorporate regulatory cooperation into bilateral agreements.
- Develop country-specific regulatory and market-entry roadmaps.
- Provide technical input to DTIC on pharmaceutical- and MedTech-specific provisions for trade negotiations.
- Support engagement with medicines regulatory authorities and other relevant technical institutions.

Qualifications of key expert 2

- Education/training (2.3.1): Master's degree in Pharmacy, Pharmaceutical Sciences, Regulatory Affairs, Health Economics/Policy, International Trade, or Law (trade/regulatory), or equivalent
- Language (2.3.2): C1 -level language proficiency in English
- General professional experience (2.3.3): 10 years of professional experience in pharmaceutical/MedTech regulation and pharmaceutical/MedTech trade policy, including interaction with national regulatory authorities and trade institutions
- Specific professional experience (2.3.4): 7 years in regulatory affairs across African or emerging markets, covering: product registration, GMP inspections, quality assurance, pharmacovigilance, batch release, and lifecycle maintenance
- Leadership/management experience (2.3.5): n.a.
- Regional experience (2.3.6): 4 years Sub-Saharan Africa experience, including 2 years with direct exposure to South African regulatory and industrial ecosystem (SAHPRA, NDoH, DTIC/DSI, NRCS, SABS; industry associations)
- Development Cooperation (DC) experience (2.3.7): n.a.
- Other (2.3.8): 5 years mapping and comparing regulatory frameworks across multiple jurisdictions, including reliance, mutual recognition, or accelerated/fast-track pathways

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
Team leader and Senior Trade & Policy Expert	1	28	28	
Key expert 1: Pharmaceutical/MedTech Industry & Market Access Expert	1	24	24	
Key expert 2: Regulatory & Pharmaceutical Trade Expert	1	20	20	

Transport	Quantity	Number per expert	Total	Comments
Fixed travel budget			EUR 20,010	A budget is earmarked for travel to the following countries: Sub-Saharan Africa (South Africa and possibly to one or more of the identified priority countries, see WP 2). A fixed budget of EUR 20,000 is earmarked for settling travel expenses against evidence. You can find further information on the travel expense budget in the 'Price schedule' document. Please use the 'Explanations' column in the price schedule to break down the individual items. Settlement is possible only until the budget is depleted.
CO₂ compensation for air travel				A fixed budget of EUR 900 is earmarked for settling carbon offsets against evidence.
Other costs	Number	Price	Total	Comments
Flexible remuneration			EUR 9,920	A budget of EUR 9,920 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.

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.

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.