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

Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) GmbH

CONFIDENTIAL

Project title:

Vaccines for Africa – Roll-out and Production in South Africa (SAVax)

Processing number:

21.2258.8-004.00 / G-011902-004

Country:

South Africa

Tender number:

81322845

Subject of the tender procedure:

MAV+: Technical assistance for selected companies in the pharmaceutical sector in South Africa for the SAVax project

0. List of abbreviations

BMF	*Bundesministerium der Finanzen*, Federal Ministry of Finance
BMZ	*Bundesministerium für wirtschaftliche Zusammenarbeit und Entwicklung*, Federal Ministry for Economic Cooperation and Development
CAPA	Corrective/preventative actions
cGMP	Current Good Manufacturing Practice
CSIR	Council for Scientific and Industrial Research
CV	Curriculum Vitae
EU	European Union
DoH	Department of Health
DSTI	Department of Science, Technology and Innovation
dtic	Department of Trade, Industry and Competition
GIZ	Deutsche Gesellschaft für Internationale Zusammenarbeit, German Development Cooperation
GMP	Good Manufacturing Practice
GTC	General Terms and Conditions of Contract for supplying services and work on behalf of the Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) GmbH
HR	Human Relations
ICH	International Council for Harmonization
IP	Intellectual Property
ISO	International Organization for Standardization
KOMP	Cost per output monitoring and forecast
KPI	Key Performance Indicator
LoI	Letter of intent
MoU	Memorandum of Understanding
mRNA	Messenger Ribonucleic Acid
NHI	National Health Insurance

PAVM	Partnerships for African Vaccine Manufacturing
QA	Quality Assurance
QC	Quality Control
QMS	Quality Management Systems
R&D	Research and Development
RMO	Risk Management Office
SADC	Southern African Development Community
SAHPRA	South African Health Products Regulatory Authority
SAVax	Vaccines for Africa: Roll out and Production in South Africa
SME	Small to Medium-Sized Enterprise
SOP	Standard Operating Procedure
TA	Technical Assistance
ToR	Terms of reference
TSP	Tailored Support Plan
TT	Technology Transfer
UNDESA	United Nations Department of Economic and Social Affairs
WHO	World Health Organization
WHO PQ	World Health Organization Prequalification

1. Context

The project “Vaccines for Africa: Roll out and Production in South Africa” (SAVax) is part of South Africa’s strategic objective to enhance the local production of vaccines, medicines, and health technologies. 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 initiative aligns with the goals of 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), to create a sustainable and competitive biopharmaceutical sector.

The SAVax programme has an overall 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.

Under this objective, the project aims at supporting selected South African biopharmaceutical companies with "ready-for-market" products by providing targeted technical assistance to improve their manufacturing capacity and facilitate market access at national, regional, and continental levels. These companies face challenges such as market intelligence gaps, demand forecasting difficulties, high production costs, and technology transfer obstacles, which impede their ability to meet growing health needs. Addressing these challenges requires long-term strategies, including off-take agreements, purchase guarantees, and investment in technology and skills development.

The project conducted a landscape assessment of South Africa’s biopharmaceutical industry, covering the pharmaceutical, biotechnological, and biomanufacturing sectors. A call for applications was also launched wherein companies were requested to identify their technical assistance needs. This call for applications will serve as the basis for selecting companies that will be offered technical assistance under this tender. Based on a set of pre-defined criteria, 7 companies are selected and will receive technical assistance under this tender. The call for proposals will be realized in Q3 of 2025, so that the list of selected companies will already be available once the technical assistance foreseen under this tender will start.

The objective of this assignment is to provide tailored non-financial technical assistance for the selected companies in the biopharmaceutical sector to address strategic challenges. This will include but is not limited to:

- Technology Platforms and Innovation Readiness
- Regulatory and Quality Systems Strengthening
- Intellectual Property and Commercial Strategy
- Organisational Resilience and Investment Readiness
- Human capacity development and collaboration

This technical assistance aims at enhancing the technical capacities of companies as well as skills necessary to advance their product market access.

The main partners on the governmental side for the implementation of the SAVax programme are the Department of Science, Technology and Innovation (DSTI), the Department of Health (DoH), and the South African Health Products Regulatory Authority (SAHPRA). For the cooperation with the private sector, the main stakeholder is the Department of Science, Technology and Innovation (DSTI) who will also play an important role in the technical

assistance, e.g. through jointly validating the operational planning and milestones with GIZ as well as participating in key events.

2. Tasks to be performed by the contractor

2.1 Term

The expected term of the contract for services must be specified in the 'Special terms and conditions of contract'. The definitive term and service delivery period are set out in the contract award notification.

2.2 Objectives, indicators, work packages, milestones

The contractor is solely responsible for achieving the objectives and indicators described in this document.

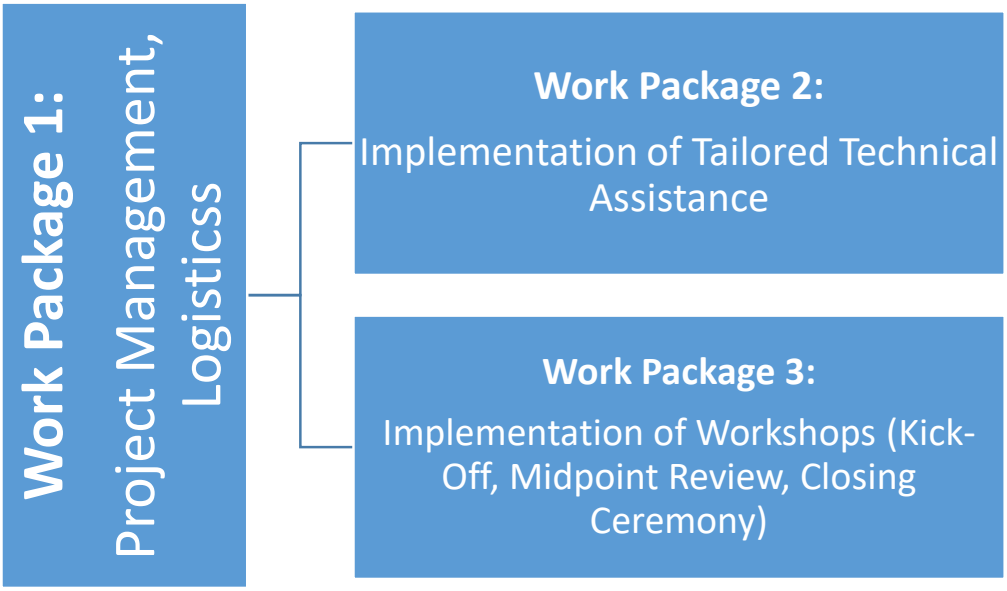
The project requests (for BMZ Output 4/EU output indicator 3.3.) international expertise to:

a) to provide tailored technical assistance for the selected companies in the biopharmaceutical sector in order to enhance their capacities for market access of their products. The ultimate goal is to equip these companies with needed knowledge and skills necessary to advance their products to market access.

EU Specific Objective 3 (Outcome): The market dynamics for locally produced goods including forecasting, procurement and distribution of quality medical products is assessed and increased.

BMZ Output 4/EU Output 3 (relating to Outcome 3): Improve the technical capacity of South African actors to conduct market analyses and design market shaping measures for vaccines, medicines and health technologies produced in South Africa.

EU Output Indicator 3.3: Up to 7 private sector companies operating within South Africa's biopharmaceutical industry have received technical assistance, including guidance on Good Manufacturing Practices (GMP), Intellectual Property (IP) management, and market demand and forecasting by 2027.The contractor is responsible for providing the following work packages and for achieving the corresponding milestones:



Work package 1: Project Management and Logistic Support

This work package is concerned with the support function of work packages 2 and 3 in terms of project management and logistics that comprise the present Terms of Reference and the elaboration, review and adaption of operational plans for all work packages and their activities as well as their logistical support.

The contractor will be expected to deliver the following: a detailed operational plan for work packages 2 and 3 and their activities as well as a proposal of how to engage short-term experts across all work streams. The operational plan is to be updated quarterly according to progress in the different work packages.

The implementation of the tailored technical assistance and its associated workshops requires comprehensive logistical and operational support to ensure smooth and timely delivery and communication, as well as effective stakeholder engagement. The selected contractor will be responsible for managing the full scope of logistical coordination, in close collaboration with GIZ, participating companies, and the short-term expert team.

Logistics support for technical tailored assistance: The contractor will be expected to provide logistical support for the planning, scheduling, and implementation of company-specific technical assistance package, including the deployment of short-term experts.

Key Tasks:

- Coordinate the deployment of short-term experts for individual assignments, including travel planning, accommodation, and on-site logistical support.
- Manage the expert calendar to ensure availability aligns with companies' timelines and readiness for service.
- Liaise with companies to agree on visit schedules and ensure adequate preparation on both sides.
- Track and manage expenditures related to expert assignments (e.g. per diems, transport, venue access).
- Maintain a database of expert deployments, topics covered, and logistical needs met per company.
- Support onboarding of experts with briefing packages (sector context, company profile, safety info, etc.).

Logistics support for workshops and events: The contractor will also coordinate all operational aspects of the three key events: the kick-off, midpoint review, and closing ceremony, as well as any common training workshops agreed upon during implementation.

Key tasks:

1. Workshop/Event Planning and Delivery

- Define and confirm event dates in alignment with GIZ and company schedules.
- Identify potential venues in relevant provinces of the country (e.g. Gauteng, KZN and Western Cape) according to practicality and agree on final selection with the GIZ team based on suitability, availability, and cost.
- Book venues and coordinate venue-specific requirements (conference rooms, layout, AV equipment, Wi-Fi access, breakout rooms, signage).
- Manage workshop logistics, including catering, registration, delegate packs, attendance sheets, and evaluation forms.

2. Participant Coordination

- Work with GIZ and supported companies to select appropriate participants for each workshop or training session, based on their technical roles and organisational responsibilities in the selected companies.
- Communicate professional and operational profiles to ensure the right match between workshop content and participant skills.
- Confirm delegate attendance with each company and track RSVPs for all events and training sessions.

3. Internal and External Coordination

- Coordinate with the GIZ team regarding internal participation, visibility, and communications activities for all events.
- Ensure alignment of messaging and visibility requirements with GIZ's communications team (e.g. logos, banners, press releases, documentation).

Support external communications where needed, including event announcements and post-event updates.

Milestones for work package 1	Delivery period
Initial Operation Plan for Work Packages (2 and 3)	Month 0-1
Updated Operation Plans for Work Packages (2 and 3)	Monthly

Work package 2: EU Output Indicator 3.3: Implementation of Tailored Technical Assistance to 7 selected companies

This work package concerns the core of work to be delivered by the contractor. Under this work package, selected companies will receive targeted, non-financial support addressing the technical, organisational, and regulatory challenges they face in advancing biopharmaceutical products to market.

The 7 companies were selected through a Call for Applications. Additionally, targeted support may be extended to existing partner companies of SAVax.

Support areas may include, but are not limited to, the following:

1. **Technology Platforms and Innovation Readiness**
   - mRNA Technology Transfer Support: Assistance in understanding, adapting, or implementing mRNA-based platforms, including guidance on formulation, delivery systems, process design, cold-chain logistics, and regulatory considerations for mRNA therapeutics or vaccines.
   - Digitalisation of cGMP Systems: Support in planning and implementing digital systems for Good Manufacturing Practice (GMP) compliance. This includes electronic batch records, quality management systems (QMS), equipment calibration tracking, and data integrity solutions aligned with international norms.

2. **Regulatory and Quality Systems Strengthening**
   - Regulatory Submission Process: Tailored support for measures relating to that assesses and ensures the quality, safety, and efficacy of medical products (e.g. WHO Prequalification), and market access by SAHPRA and other relevant authorities including dossier preparation, planning and conducting clinical trial, mutual reliance mechanisms, and fast-track processes. Also includes strategic regulatory planning for biosimilars and advanced therapies.
   - Quality Management Systems Strengthening: Support in designing, upgrading, or implementing fit-for-purpose Quality Management Systems (QMS) based on ICH Q10 principles. This includes standard operating procedures (SOPs), change control, deviation management, and risk-based approaches to quality oversight.
   - ISO Certification Readiness: Technical support to prepare for ISO 9001, 13485 or other relevant certifications, including gap assessments, internal audits, documentation guidance, and quality culture development.
   - GMP Training and Compliance Advisory: Provision of technical training in GMP principles, inspection readiness, and facility hygiene requirements, adapted to different staff levels (operators, QA/QC, management etc.). May include site-specific support for corrective/preventive actions (CAPA).

3. **Intellectual Property and Commercial Strategy**
    - Intellectual Property (IP) Strategies: Support in designing or refining IP strategies including freedom-to-operate analyses, IP landscaping, filing strategies (local and international), and licensing terms. Emphasis on protection in the context of partnerships and technology transfer.
    - Optimising Commercialisation Pathways: Advisory services to develop and refine commercial strategies, including go-to-market models, pricing approaches, and health economic value propositions. May include support in understanding procurement systems (e.g. NHI, pooled African mechanisms).
    - Market Assessment and Market Access Support: Tailored market research to evaluate demand, pricing, competition, and policy environments in local and regional markets. Support may include alignment with public procurement frameworks and donor-funded demand sources.

4. **Organisational Resilience and Investment Readiness**
    - Financial Restructuring and Strategy Advisory: Guidance on cost structures, business modelling, and capital allocation to improve organisational sustainability. Support may include preparing for audits, understanding grant or equity implications, or structuring financials for growth.
    - Managing Investor Relations: Capacity-building on investor engagement, including pitch deck refinement, term sheet review, investor reporting frameworks, and relationship management practices that align with sector expectations.
    - Mentorship Programmes: Pairing of companies with seasoned executives, technical experts, or entrepreneurs who can provide continuous coaching in technical, strategic, and commercial areas. Structured mentorship plans with KPIs will be encouraged.

5. **Human Capital and Collaboration**
    - Strategies for Talent Development and Retention: Development of internal workforce strategies including upskilling plans, career progression models, and organisational culture interventions to reduce talent attrition in critical areas like QC, regulatory affairs, and bioprocessing.
    - Managing Strategic Partnerships: Support in structuring and managing public-private partnerships, consortia, and technology transfer agreements. This includes due diligence, contractual frameworks, IP considerations, and governance models to ensure mutual value.
    - Facilitation of International Training Exchanges: Design of outbound and inbound staff exchange opportunities with regional or international centres of excellence, including identification of partner institutions, logistics coordination, and documentation of learning outcomes.

The contractor is to provide training material, if relevant, to the companies. Training material can include, but is not limited to: presentation, case studies, practical exercises and reading material.

Milestones for work package 2	**Delivery period**

Individual Technical Needs Confirmation & Scoping Meetings (if necessary, through site visits)	Months 1-2 after assignment start
Development of 8 Tailored Support Plans (TSPs) (one per company)	Months 2-3
Technical Assistance Delivery – Phase I	Months 4-8
Midpoint Progress Check & Adjustment of TSPs	Month 8
Technical Assistance Delivery – Phase II	Months 9-12
Results Documentation & Company Case Notes	Month 13

Work package 3: Implementation of Workshops/Events (Kick-Off, Midpoint Review, Closing Ceremony)

Work package 3 accompanies the technical assistance provided in Work Package 2. Work package 3 concerns the delivery of 3 workshops/events to build networking, accountability and learning into the technical assistance process.

The **Kick-Off Event** aims at formally launching the technical assistance programme, align expectations between all stakeholders (companies, technical assistance providers, GIZ, political partners) to create a shared understanding of the approach, available support and responsibilities.

Key goals include: introducing the overall SAVax technical assistance framework, presenting findings of the landscape assessment and the call for applications, clarifying how tailored support will be co-developed with companies, introducing the expert pool and technical focus areas, as well as creating networking opportunities among selected companies and key stakeholders.

The Kick-Off Event should be a half- or full-day event in person (Johannesburg or Cape Town), possibly with a hybrid option, for 40-50 people.

The **Midterm Review and Peer Learning Workshop** aims at taking stock of the progress after the first phase of technical assistance delivery, surfacing lessons learned, allowing companies to share experiences and make adjustments to tailored support plans if needed.

Key goals include: Reviewing progress against each company's Tailored Support Plan, identifying emerging success stories or bottlenecks, encouraging cross-company learning (e.g. shared regulatory strategies, training needs), enabling adaptive management of the remaining TA period, and providing targeted peer discussion groups by thematic cluster (e.g. regulatory market access, workforce development).

This midpoint review should include an evaluation system where companies provide feedback and the possibility to adjust and reconduct the technical assistance provided to them, if necessary. Feedback should be shared and jointly assessed with GIZ to ensure companies' needs are met. Both of these aspects are to feed into the GIZ monitoring system.

The Midpoint Review and Peer Learning Workshop should take place as an interactive one-day workshop with breakout sessions, guided by a structured progress template. The

participants should include representatives of the supported companies, the TA provider, the GIZ team as well as invited observers from partner organizations (e.g. DSTI, dtic, SAHPRA).

The **Closing Ceremony and Knowledge Sharing Forum** aims at reflecting on the outcomes of the technical assistance process, documenting and sharing lessons learned and fostering connections for post-programme sustainability and collaboration.

Key goals include: Highlighting achievements and transformation journeys of supported companies, sharing final outputs (case studies, capability improvements, regulatory milestones, etc.), facilitating panel discussions with companies, experts and institutional actors, capturing feedback on the TA model and recommendations for replication or scale-up, and recognising participation and promoting the community of South African biopharma actors.

The format should be a high-visibility event with a networking component with participants from all companies, the TA provider, GIZ, donor representatives as well as governmental and regional stakeholders. The results of the lessons learnt should be included in the reporting.

Milestones for work package 3	**Delivery period**
3 Workshops held	Months 1-15
- Kick-Off Workshop	Month 4
- Midpoint Review Workshop	Month 8
- Final Reflection Workshop / Peer Learning Event	Month 12

2.3 Project and knowledge management requirements

Requirements on the assignment of experts:

- The contractor is responsible for selecting, preparing, training and steering the experts assigned to carry out the advisory services.

Requirements on materials and equipment and operating costs:

- The contractor makes the required materials, equipment and consumables available and covers their operating and administrative costs.

Requirements on expenditure management and cost control:

- The contractor manages costs and expenditures, accounting processes and invoicing in line with GIZ requirements.

***Information** on cost-output monitoring (KOMP): 100% of the tasks are apportioned to BMZ Output 4/EU Output 3.*

Monitoring and reporting requirements:

- The contractor plays an active role in the results-based monitoring of the project. Regular monitoring activities must cover at least the following areas:
  - Degree to which activities are implemented
  - Degree to which the objectives, indicators and milestones listed in section 2.2 of these ToR have been achieved using monitoring tools provided by the GIZ programme
  - Results that have occurred in the contractor's sphere of responsibility
  - Results that have occurred outside the contractor's direct sphere of responsibility
  - Evaluation of level of satisfaction with TA received

The contractor reports to GIZ as follows:

Instead of the reporting language stipulated in GIZ's General Terms and Conditions of Contract (German), the contractor provides the following reports in the following language: English:

- Inception report: by month 3, the inception report should include information about the Kick-Off Event, Tailored Support Plans, and other activities already implemented
- Ad hoc and on demand brief information on the progress on activities, e.g. if GIZ is requested to provide updates to the donors of the programme
- Final report: at least 1 month before the end of the contract. This should include evaluations with the companies receiving technical assistance.

The final report should provide information about the progress made towards objectives in each of the monitoring areas specified above.

Additionally, the contractor is required to produce:

- Contributions to the report to GIZ's commissioning party upon request (annual reports to EU and BMZ)
- Brief quarterly reports on the implementation status of the project (5-10 pages), which should be accompanied by a virtual meeting between the contractor and GIZ

Requirements for company-wide learning, knowledge and innovation:

- The contractor's experts contribute to SAVax' online presentations in GIZ's sector networks on demand (e.g. the technical exchange group on Cooperation with the Private Sector).
- The contractor provides support in implementing a project evaluation with special emphasis on ensuring the effectiveness of the knowledge management process.

Backstopping requirements:

The contractor ensures appropriate backstopping. The following services form part of the standard backstopping package. In accordance with GIZ's General Terms and Conditions for supplying services and work on behalf of the Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) GmbH, these services – as well as the ancillary personnel costs – must be priced into the fee schedules of the staff listed in the tender:

- The contractor's responsibility for its own staff;
- Ensuring the flow of information between GIZ and the contractor's field staff;
- Process-oriented technical and conceptual steering of the consulting services;

- Steering adaptations to changing framework conditions;
- Performance monitoring;
- Ensuring the administrative management of the project;
- Ensuring compliance with reporting requirements;
- Technical support by the contractor's staff for its personnel on the ground;
- Making local use of and sharing the lessons learned by the contractor with the GIZ team.

2.4 Data protection and information security

The provisions on data protection and information security of the current version of GIZ's General Terms and Conditions of Contract (section 1.10 Data protection) apply.

2.5 Other requirements

Safeguards and gender measures with specific reference to services:

In order to promote gender equality and avoid or mitigate possible unintended negative impacts in its area of responsibility, the contractor should implement the following measures:

- Gender equality:
  The activities should aim at representative participation in capacity building of women in order to promote equal opportunities in the pharmaceutical field to expand the promotion of women in traditionally male-dominated fields.
- Environmental protection and climate action (climate change mitigation/adaptation):
  The project takes into account the European Commission Communication *Strategic Approach to Pharmaceuticals in the Environment* which covers all phases of the lifecycle of pharmaceuticals, from design and production through use to disposal. This has to be taken into consideration wherever applicable during training.
- Conflict and context sensitivity:
  Not applicable
- Human rights:
  The project applies a human rights-based approach by respecting the following principles: respect of all human rights, participation, non-discrimination, accountability, and transparency in all phases. This should be taken into consideration when planning the implementation of the work packages of these terms of reference.

The contractor's staffing profile should be balanced in terms of gender and age.

3. Technical-methodological concept

In this section, the tenderer is required to reflect on the objectives and terms of reference of the tender at hand, describe the partner system and its processes in the area of responsibility and present the technical-methodological concept for completing the tasks listed in section 2

and achieving the set objectives. In addition, the tenderer must describe the design of the project management process.

3.1 Interpretation of objectives (section 1.1 of the assessment grid)

The tenderer is required to interpret the objectives for which it is responsible. Simple repetition of the objectives formulated in section 2 of the ToR is not desired. Rather, the contractor is to describe and interpret the changes in the partner system that are to be directly achieved by the object of the tender procedure. The resulting positive impact on the partner system (**section 1.1.1 of the assessment grid**) should also be presented.

The contractor must undertake a critical examination of the ToR (**section 1.1.2 of the assessment grid**), by:

- undertaking an assessment of the appropriateness of the personnel concept for implementing the scheduled tasks;
- providing an assessment of the results hypotheses for achieving the objectives and possible risks in implementation;
- making an assessment of the technical concept e.g. in consideration of further sectors or actors, process adjustments, etc.

3.2 Processes and actors in the partner system (section 1.2 of the assessment grid)

Processes describe actions or sets of tasks that are necessary in order to render specific services in a sector or in the cooperation/partner system. Specific actors are given responsibility for determining and implementing these actions and sets of tasks in line with the regulations. Actors are usually institutions such as ministries, local governments, associations and chambers, non-governmental organisations, companies in a sector or individual businesses, universities or banks, but may also be individuals (e.g. a person with higher decision-making authority).

The tenderer is required to describe, using existing documents where possible (see annexes), the processes in the sector or partner system that are relevant to the services put out to tender (**section 1.2.1 of the assessment grid**).

The tenderer is required to present the actors (partners and others) who are relevant for the tender in the form of a map of actors. As far as possible, it should list the actors by name. Their mandates as well as strengths, weaknesses and interests with respect to the services put out to tender are also to be briefly presented (**section 1.2.2 of the assessment grid**).

In addition, the tenderer is required to describe the interaction between the actors mentioned above. This can consist of a description of the specific collaboration between individual actors in the processes listed above, of the dependencies or conflicts between the actors and their consequences or of existing dialogue and communication formats (**section 1.2.3 of the assessment grid**).

3.3 Strategy (section 1.3 of the assessment grid)

The strategy for delivering the services in the tender is the core element of the technical-methodological concept. It is composed of the following elements:

- Procedure for achieving the objectives stated in section 2.2 of these ToR
- Development of partnerships with the relevant actors
- Approaches for leverage effects and measures for scaling-up
- Consideration of environmental and social compatibility requirements (including gender equality)
- Appropriate consideration of further requirements

3.3.1 Strategic approach to achieving the objectives mentioned in the ToR (section 1.3.1 of the assessment grid)

The tenderer is required to describe and justify the approach it plans to adopt in order to achieve the milestones, objectives and results (see section 2) for which it is responsible. Following this, the tenderer presents and justifies the explicit strategy with which it intends to provide the services for which it is responsible

3.3.2 Building partnerships with the relevant actors (section 1.3.2 of the assessment grid)

The tenderer is required to develop and describe a strategy for developing the cooperation with the actors in the partner system who are relevant for the implementation of the services in the tender. The project partnerships already mentioned in section 1 must also be taken into account.

3.3.3 Approaches for leverage effects and measures for scaling-up (section 1.3.3 of the assessment grid)

The tenderer is required to state whether there are promising approaches for leverage effects beyond the measures mentioned in section 2 (for example through targeted measures in the field of ‘knowledge management’) and to describe them. In doing so, the tenderer is required to present and explain measures that promote both horizontal and vertical scaling-up. In particular, the tenderer must submit proposals on how innovations that have been developed in the context of implementation can be disseminated beyond the sphere of influence of the project.

3.3.4 Consideration of environmental and social compatibility requirements (section 1.3.4 of the assessment grid)

Gender equality

The tenderer is required to outline in the tender how it can prevent negative impacts on gender equality in its area of responsibility and how it can contribute to improving gender equality through corresponding measures (see also relevant requirements in section 2.5).

Human rights

The tenderer is required to outline in the tender how it can prevent negative impacts on the human rights situation in its area of responsibility and how it can contribute to improving the human rights situation through corresponding measures (see also relevant requirements in section 2.5).

Requirement: 'Gender equality':	7 points out of 10 (maximum)
Requirement: 'Human rights':	3 points out of 10 (maximum)

3.4 Project management (section 1.4 of the assessment grid)

In this section, the tenderer presents the operational plan for implementing the services in the tender, describes the procedure for coordination with GIZ or the project and the project partners, and explains its monitoring procedure.

3.4.1 Operational plan (section 1.4.1 of the assessment grid)

The tenderer is required to draw up and explain an operational plan for implementing the strategy described in section 3.3, including a plan for the assignment of all the experts included in the tender. The operational plan must include the assignment times (periods and expert days) and assignment locations of the individual experts, the milestones as presented in section 2 and, in particular, describe all the necessary work stages in detail and in chronological order. The tenderer can define further milestones beyond those prescribed in section 2 and map them out in the plan of operations.

3.4.2 Coordination with GIZ or the commissioning project (section 1.4.2 of the assessment grid)

In the tender, the tenderer is required to describe the procedure for coordinating with GIZ or with the commissioning project.

3.4.3 Steering or coordination of measures with the relevant implementing partner (section 1.4.3 of the assessment grid)

In the tender, the tenderer is required to name the implementing partners relevant for implementing the services and to describe and explain the procedure for steering or coordinating the measures with them.

3.4.4 Monitoring (section 1.4.4 of the assessment grid)

In the tender, the tenderer is required to describe how it will regularly capture and document the status of completion of the tasks, the achievement of objectives, the results achieved and the risks in the area for which it is responsible in accordance with the specifications set out in section 2.

3.5 Further requirements (section 1.5 of the assessment grid)

- Not applicable -

4. Personnel

The tenderer is required to provide 'experts' for the positions referred to and described (scope of tasks and qualifications) in this section on the basis of corresponding CVs. **The requirements on the format and content of the CVs are described in section 6.**

When selecting personnel, the contractor must ensure that the team is well-balanced with respect to gender, age etc.

The qualifications mentioned below correspond to the requirements for achieving the highest number of points in the technical assessment.

'One year of professional experience' is therefore defined as a cumulative 12 expert months with at least 18 expert days per month, provided no diverging definition is specified for individual qualifications.

Expert 1: Team leader (section 2.1 of the assessment grid)

This position is a **key expert**.

Tasks of expert 1:

General Tasks:

- Overall responsibility for the advisory packages of the contractor
- Ensuring the coherence and complementarity of the contractor's services with other services delivered by the project at local and national level (such as grants and trainings already provided by the project)
- Responsibility for taking cross-cutting themes into consideration (for example, gender equality)
- Staff management, in particular identifying the need for short-term assignments within the available budget, planning and managing the assignments and supporting experts
- Ensuring that monitoring procedures and quality control measures are carried out
- Regular reporting to GIZ in accordance with deadlines

Specific Tasks:

- Serve as a focal point for GIZ for planning, coordinating, and reporting on all Work Packages
- Planning and coordinating all technical assistance activities
- Oversee the development and implementation of Tailored Support Plans (TSPs)
- Coordinate needs validation meetings with selected companies
- Supervise expert deployment and ensure alignment with SAVax goals
- Ensure delivery quality and consistency across technical areas: monitor and evaluate the quality of the TSPs and the level of satisfaction of the recipients with the TA received. Adjust TA as needed to meet needs and expectations

- Lead stakeholder engagement in close coordination with SAVax (e.g. DSTI, dtic, SAHPRA, industry)
- Facilitate learning events/workshops
- Flag risks, challenges, and opportunities to GIZ

Qualifications of expert 1:

Education/training (section 2.1.1 of the assessment grid):	University degree (e.g. master's level or equivalent) in Life Sciences (e.g. Biotechnology, Biochemistry, Microbiology, Pharmacology), Public Health, Pharmaceutical Sciences, Industrial Engineering with biotech/manufacturing focus, Business Administration or Economics (with proven biopharma/health industry focus)
Language (section 2.1.2 of the assessment grid):	Knowledge of English, C1-level in the Common European Framework of Reference for Languages
General professional experience (section 2.1.3 of the assessment grid):	10 years of professional experience in • The sector of Biopharmaceuticals, pharmaceuticals, health innovation, biotech or life sciences (4/10 points) • The sector development, industrial policy, or innovation ecosystems in health-related manufacturing (3/10 points) • Project management or programme coordination roles in public-private contexts (3/10 points)
Specific professional experience (section 2.1.4 of the assessment grid*):*	5 years of professional experience in • Designing or managing technical assistance or capacity development programmes for firms or institutions in the biopharma/life sciences field (4/10 points) • Working with or advising manufacturers (biologics, vaccines, biosimilars) on issues such as regulatory strategy, GMP compliance, innovation strategy, or tech transfer (3/10 points) • Coordinating multi-stakeholder partnerships across government, industry, and academia (3/10 points)
Leadership/management experience (section 2.1.5 of the assessment grid):	5 years of management experience in projects, companies or other organisations with disciplinary leadership responsibility for 10 people
International professional experience outside the country/region of assignment (section 2.1.6 of the assessment grid):	3 years of professional experience in Sub-Saharan Africa in: Working with SADC or African Union-related initiatives (e.g. African Medicines Agency, PAVM)
Professional experience in the country/ region of assignment (2.1.7 of the assessment grid):	3 years of professional experience in South Africa in: Biopharma, public health innovation, or industrial development Working with South African institutions such as SAHPRA, DSTI, dtic, CSIR, universities, or industry platforms
Experience in the field of development cooperation (section 2.1.8 of the assessment grid):	5 years of experience in development cooperation projects, focusing on delivering technical assistance

Other (section 2.1.9 of the assessment grid):	Not applicable

<u>Expert 2: Pool 1 Short term expert pool' with 10 experts</u> (section 2.2 of the assessment grid)

In derogation from the number of experts mentioned above, **10** CVs must be added to the tender. The ability of the tenderer to offer the pool of experts required here is assessed solely on the basis of these exemplary CVs.

The actual number of experts assigned from the pool may differ from the number of experts required in section 4 of the Terms of Reference. For experts not named in the tender, GIZ must confirm before the assignment that their qualifications are equivalent to those of the short-term experts proposed in the tender.

<u>Tasks of the expert pool</u>:

- Provide on-demand, specialised technical support to companies based on confirmed needs: Experts will be mobilised on a demand-driven basis depending on the type, depth, and timing of support required by individual companies. Individual assignments may range from 5-25 days, depending on the topic and delivery format.

<u>Expert Profiles Include:</u>

- GMP and Quality Assurance Experts: for training, audits, QMS design
- Regulatory Affairs Specialists: SAHPRA dossier preparation, WHO PQ, biosimilar pathways
- Bioprocess Engineers: for digitisation, scale-up, and facility planning
- mRNA Technology Experts: for platform optimisation and process design
- IP and Licencing Advisors: freedom-to-operate, patent strategy, tech transfer
- Commercialisation and Market Access Experts: public procurement, pricing, demand forecasting
- HR and Talent Development Specialists: workforce planning, training needs analysis
- Business Strategy and Finance Advisors: investment readiness, restructuring, investor relations
- Mentorship Programme Coordinators: for onboarding and managing mentors
- Internal Training Liaison: to facilitate study visits or technical exchanges abroad

<u>Qualifications of the expert pool</u>:

Education/training (section 2.2.1 of the assessment grid):	10 experts with a university degree (e.g. master's or equivalent) in Biotechnology, Biochemistry, Pharmaceutical Sciences, Chemical or Bioprocess Engineering, Public Health or Health Sciences, Regulatory Affairs or Quality Assurance, Business Administration with relevant sector focus, or Intellectual Property Law, Economics, or Innovation Management

Language (section 2.2.2 of the assessment grid):	10 experts with knowledge of English, C1-level in the Common European Framework of Reference for Languages
General professional experience (section 2.2.3 of the assessment grid):	10 experts with 7 years of professional experience in the following sectors: • Biopharmaceuticals or pharmaceuticals • Biotechnology (applied research or industrial scale) • Regulatory affairs or quality systems in health product manufacturing (sector experience must include interaction with regulatory authorities, e.g. SAHPRA, WHO PQ) • Healthcare innovation; R&D or public-private partnership in life sciences • Intellectual property management or tech transfer in health technologies • Workforce development, skills training or organisational capacity-building
Specific professional experience (section 2.2.4 of the assessment grid):	10 experts with 5 years of professional experience Each expert must demonstrate at least: 5 years of specific experience in one or more of the following technical domains relevant to the assignments: • GMP and Quality Assurance: GMP audits, SOP design, QMS implementation, GMP training delivery • Regulatory Affairs: Dossier compilation, SAHPRA interaction, clinical trial applications • mRNA/Bioprocessing: Scale-up, formulation, purification, analytical method validation • Technology Transfer: Managing or supporting TT agreements, localising licenced processes • IP and Licencing: Freedom-to-operate analysis, patent drafting, licencing negotiations • Commercialization: Market entry strategies, pricing models, value chain analysis • Financial Strategy: Business modelling, investor engagement, restructuring for growth • Workforce and Talent: Designing or delivering biotech training, HR planning for SMEs • Mentorship/Coaching: Providing structured support to entrepreneurs or leadership teams • International Training Design: Coordinating study visits, exchange (Each CV can get 1 point if the professional experience requirement is fulfilled, it has to be clearly marked on the CV which field of specific experience is to be considered)
Leadership/management experience (section 2.2.5 of the assessment grid):	Not applicable
International professional experience outside the country/region of assignment (section 2.2.6 of the assessment grid):	Not applicable

Professional experience in the country/ region of assignment (2.2.7 of the assessment grid):	Each of the 10 experts must have 3 years of professional experience in Southern Africa (in accordance with UN DESA Statistics Division)
Experience in the field of development cooperation (section 2.2.8 of the assessment grid):	Not applicable
Other (section 2.2.9 of the assessment grid):	Not applicable

UN DESA regions are defined as East Africa, Central Africa, North Africa, Southern Africa, West Africa, South America, the Caribbean, Central America, North America, Central Asia, East Asia, South Asia, Southeast Asia, West Asia/Middle East, Eastern Europe, Northern Europe, Southern Europe, Western Europe, Australia, Melanesia, Micronesia and Polynesia; refer to USND methodology for country assignment.

The tenderer must assign all the proposed experts to the required qualifications and clearly present them in a separate table preceding the CVs. The summary presentation must mention only qualifications that are actually indicated in the CVs. Professional experience must be evidenced by meaningful references in the CVs. It is advisable to make explicit reference to each example of professional experience.

Soft skills of team members

In addition to their specialist qualifications, all team members are also expected to have the following qualifications:

- Team skills
- Initiative
- Communication skills
- Sociocultural and intercultural skills
- Efficient partner- and client-oriented working methods
- Interdisciplinary thinking

Soft skills are not evaluated.

5. Costing requirements

5.1 Assignment of experts

In your tender, please do not deviate from the specification of quantities required in these ToR (the number of experts and expert days, the budget specified in the price schedule). This is part of the competitive tender and is used to ensure that the tenders can be compared objectively. Please note: only services that were commissioned by GIZ and rendered by the contractor will be remunerated. We would also like to point out that it may not be necessary to make use of the total number of proposed expert days.

The number of expert days corresponds to full working days.

Expert	Expert days in the country of residence /remote	Availability of expert in the country of assignment* in expert days	Expert days in total	Consecutive stay > 3 months (see General Terms and Conditions, section 3.3.2)	Number of international flights	Number of national flights
Expert 1: Team Leader	40	40	**80**	No	3 Return flights	3 Return flights
Pool: Short-term experts	0	200	**200**	No	10 Return flights	20 Return flights
Backstopping	n/a	n/a	**n/a**	n/a	0	0

5.2 National administrative staff

– Not applicable –

5.3 Travel expenses

5.3.1 Travel – sustainability considerations

GIZ would like to reduce greenhouse gas emissions (CO_2 emissions) caused by travel. When preparing your tender, please incorporate options for reducing emissions, for example by selecting the lowest-emission booking class (economy) or using means of transport, airlines and flight routes that are more CO_2-efficient. For short distances, travel by train (second class) or e-mobility are the preferred options.

CO_2 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 has published a list of standards (only in German available). GIZ recommends using the standards specified there.

5.3.2 Travel expense requirements

The following costs have been calculated by the contracting authority:

Travel expenses item	**Quantity/budget**
Total number of international flights	13 Return Flights/EUR 31.200
Total number of regional/national flights	23 Return Flights/EUR 13.800
CO_2 offsets for flights	EUR 4.580 An unalterable budget for CO_2 offsets for settlement against evidence is specified.
Transport costs (rail travel, car travel, public transport)	EUR 5.040 (equivalent to a monthly lump sum of EUR 360)
Per-diem allowances	EUR 5.040, equivalent to up to 140 days (Johannesburg rates – 36 EUR per 24h), or 152 days (Cape Town rates – 33 EUR per 24 hours), or 173 days (SA rates per 24 hours)
Accommodation allowances	EUR 18.200, equivalent to up to 140 nights (the highest rate of EUR 130 for Cape Town is considered, but the accommodation allowance for Johannesburg amounting to EUR 129 and the rest of South Africa amounting to EUR 109 would need to be respected for accommodation in these areas)
Other travel expenses (visa, project-related travel expenses outside the place of business etc.)	EUR 5.000

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 (download at https://www.bundesfinanzministerium.de).

Accommodation allowances are reimbursed **against evidence** 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 (download at https://www.bundesfinanzministerium.de).

5.4 Materials and equipment

– Not applicable –

5.5 Operating costs in the country of assignment

– Not applicable –

5.6 Workshops, education and training

The contractor runs the following workshops:

- Kick-Off Event
- Midpoint Review and Peer Learning Workshop
- Closing Ceremony and Knowledge Sharing Forum

Workshop budget: **EUR 15.000**

The fixed, unalterable budget above is earmarked for workshops and entered in the price schedule. The budget includes the following costs relating to the planning and running of workshops:

- Room hire
- Technical systems
- Moderation services
- Translation/interpreting services
- Catering
- Workshop materials
- Travel expenses for partner experts (subsistence, accommodation, travel costs), this concerns participants from government organizations, but not participants from companies receiving technical assistance
- Other costs relating to the workshops

The budget does not include the fees and travel expenses for the contractor's experts incurred in connection with the planning and running of the workshops. These are covered by the corresponding number of expert days and travel expenses (see sections 5.1 and 5.3 above).

5.7 Local contributions

– Not applicable –

5.8 Other costs

– Not applicable –

5.9 Flexible remuneration item

Budget for flexible remuneration: **EUR 40.000**

The fixed, unalterable budget above is earmarked in the price schedule for flexible remuneration. Flexible remuneration is intended to facilitate the flexible management of the contract by the commission manager at GIZ. The contractor can make use of the funds in accordance with section 3.3.5.7 of the General Terms and Conditions.

6. Requirements on the format of the tender

The structure of the tender must correspond with the structure of the ToR. It must be legible (for example Arial, font size 11 or larger) and clearly formulated. The technical tender must be written in English.

The technical-methodological concept of the tender (section 3 of the ToR) must not exceed 40 pages (not including the cover page, list of abbreviations, table of contents, brief introduction and CV for the backstopper). Additional annexes not requested will not be assessed. External content (e.g. links to websites) will also be disregarded.

The CVs of the staff proposed in accordance with section of the ToR must be in the **EuropeAid format** and not more than four pages in length. The CVs can also be submitted in English.

The CVs must clearly and unequivocally show what position the proposed person held, which tasks they performed and how long they worked during which period in the specified references. **The references contained in the CVs must therefore include the following information:**

- Name of the company/organisation/reference project in which the expert worked
- Position held and task(s) performed by the expert in the company/organisation/reference project
- Work outcomes or products produced by the expert, or expert's contribution to the completion of these outcomes and projects (if relevant)
- Duration of the expert's assignment in the company/organisation/reference project per calendar year in full-time expert days, weeks or months (for example: 2019: 2 months, 2020: 10 months, 2021: 1 month)
- Leadership experience/management: clear information on the reference projects or fixed positions within the company/organisation in which the requirements specified in section 4 were fulfilled (for example, period, number of persons for whom the expert had disciplinary responsibility, project budget) (if relevant)
- International professional experience/professional experience in the country of assignment: clear information on the reference projects or fixed positions in the company/organisation in which the requirements specified in section 4 were fulfilled (for example, actual duration of assignment on the ground in full-time expert days, weeks or months) (if relevant)

In order to facilitate the assessment, we request that you number the references sequentially and provide only references that are clearly related to the object of this tender.

7. Options or follow-on contract

7.1 Option to expand the service content/extend the contract term pursuant to section 132 (2) no. 1 German Act against Restraints of Competition (GWB)

GIZ can exercise the following option if it wishes to expand the tendered services. This is described in detail below.

Nature and scope:

While retaining the overall character of the contract, there is a possibility of GIZ continuing to obtain the services specified in section 2 of these Terms of Reference and/or of expanding the contract to include further services of the same kind. The overall contract term must not exceed three times the original contract term, and the overall contract value must not exceed twice the original contract value.

Precondition:

GIZ's commissioning party extends and/or provides additional funding for the current project or commissions a follow-on project.

7.2 Option to procure materials and equipment pursuant to section 132 (2) no. 1 German Act against Restraints of Competition (GWB)

- Not applicable -

7.3 Follow-on contract pursuant to Section 14 (4) no. 9 German Ordinance on the Award of Public Contracts (VgV)

Pursuant to Section 14 (4) no. 9 VgV, GIZ reserves the right to award a follow-on contract to the contractor in order to procure similar services.

Scope of possible services:

The term of the follow-on contract must not exceed twice that of the original contract, and the value of the follow-on contract must not exceed twice that of the original contract.

Condition: The above option is subject to GIZ receiving a commission from the commissioning party or the conclusion of an agreement for cofinancing of the measure. Any follow-on contract must be awarded within three years of the award date of the original contract.

A follow-on contract under 7.3 can be considered only as an alternative to the option in 7.1.

8. Annexes

a) Project Factsheet

b) Landscape Assessment Landscape Assessment of the Biopharmaceutical Industry in South Africa