









Competitive Call for Applications for the Provision of Technical Assistance to the Private Sector

Info Pack and Guidelines for Applicants

SAVax: Joint Action for enhancing manufacturing capacities and access to vaccines, medicines, and health technologies in South Africa

Team Europe Initiative (TEI) on Manufacturing and Access to Vaccines, Medicines and Health Technology in Africa (MAV+)

TEI MAV+

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Background

South Africa's biopharmaceutical sector is entering a critical phase of development. A recent landscape analysis identified key opportunities to strengthen the country's capabilities in vaccine production, biosimilars, and recombinant biologics. However, significant gaps remain in infrastructure, regulatory readiness, and manufacturing scale-up.

In support of this initiative the European Union (EU) launched the Team Europe Initiative (TEI) on Manufacturing and Access to Vaccines, Medicines, and Health Technologies (MAV+) in Africa. The EU and Bundesministerium für wirtschaftliche Zusammenarbeit und Entwicklung (BMZ) are jointly supporting manufacturing capacities in South Africa with the aim to enhance access to quality, safe, effective, and affordable vaccines, medicines, and health technologies. SAVax is a Joint Action, implemented by the Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ), integral to the implementation of MAV+ in South Africa and extends from ongoing efforts by the BMZ for vaccine distributions and the sustainable production of vaccines in South Africa for the African continent (GIZ SAVax). SAVax aims to support the development of a sustainable and competitive local biopharmaceutical sector. As part of this initiative, GIZ seeks to provide technical assistance to companies, based in South Africa, with established manufacturing capacity and high potential of market access for products currently under development. We now invite interested companies to submit an application pertaining to their technical assistance needs.

Please note: This initiative does **NOT** provide direct funding or co-financing. Support will be offered in the form of targeted technical assistance only (e.g. specialized training, advisory support, GMP guidance, short-term expert days for human capacity development, etc.).

Aims and Objectives of the Call for Applications

In service thereof, a Competitive Call for Applications (CfA) is being launched. Applications are sought that address the following aim:

- Support South African private sector in local pharmaceutical and health technologies production through research & development and developing skills (managerial capacities and higher education).
- Address human resource gaps and capacities, using a gender and disability-sensitive approach, for core and auxiliary functions linked to the production of human medicines and vaccines.

In doing so the following objectives should be prioritised:

- This technical assistance targets South African private sector companies across the biopharmaceutical value chain, prioritizing those with market potential.
- 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.
- Support South African manufacturers with established production of "ready-for-market" products in preparing for GMP/WHO Pre-Qualification assessments to improve their certification prospects.
- Support South African manufacturers with established production capabilities in meeting essential conditions for technology transfer readiness and support them through the transfer process.
- Provide technical assistance to South African private sector companies for strategic demand intelligence and forecasting of health-related technologies, including vaccines, medicines, and diagnostics, to evaluate demand viability, funding likelihood, and conduct price differential analyses across scenarios.
- Provide technical support to local manufacturers on sustainable business modelling enabling them to enhance their capacity to meet the requirements for innovative financing mechanisms.
- Support the development of innovative vaccines, pharmaceuticals, and diagnostics and healthcare technologies that address healthcare challenges in South Africa.
- Foster the translation of research findings into tangible products, market access, and solutions that benefit public health.

Project Flow & Milestones

Key Information	
Target Recipients	Private sector entities from the pharmaceutical, biotechnological, and biomanufacturing sectors registered in South Africa. Entities should have "ready for market" products that would benefit from technical assistance in order to accelerate market access.
Amount	This initiative does NOT provide direct funding or co-financing. Support will be offered in the form of targeted technical assistance only (e.g. specialized training, advisory support, GMP guidance, short-term expert days for human capacity development, etc.).
Duration	12-15 Months (ca. June 2026 – September 2027)
Launch of Call for Applications	25.08.2025
Virtual Information Session	08.10.2025
Application Deadline	31.10.2025
Shortlisting & Selection	03-07.11.2025
These timelines are indicative and for planning purposes and are subject to change.	

Focus Areas & Scope

This call seeks to solicit applications from South African private sector entities that intend to undertake product development and market introduction. This call is for the provision of Technical Assistance, NOT Financial Assistance.

Eligible applicants must:

- Be registered and operating in South Africa.
- Be engaged in the development or manufacturing of biopharmaceuticals, including vaccines, biosimilars, monoclonal antibodies, recombinant proteins, etc.
- Have at least one product or platform at a viable technical stage (e.g. pilot, clinical, or commercial readiness).
- Demonstrate a commitment to long-term growth, health impact, and local production.
- Applications must focus on the development of vaccines, therapeutics, or diagnostics/health technologies or the upstream/downstream contribution to the development thereof.

Selected companies may apply for tailored technical assistance, including topics such as:

- Technology Platforms and Innovation Readiness.
- Regulatory and Quality Systems Strengthening.
- Intellectual Property and Commercial Strategy.
- Organisational Resilience and Investment Readiness.
- Human Capital and Collaboration.

We encourage:

- Product development (vaccines, pharmaceuticals, diagnostics, and health technologies), commercial manufacturing, and market access initiatives.
- Innovations in product formulation and development for underserved patient groups.
- Application of new technologies in pharmaceutical manufacturing in general.
- Formulation innovations (including dosage forms and rapid diagnostics).
- Applications that include cost-effectiveness and/or market analyses.
- Robust innovative technologies that advance product development tailored for humanitarian/emergency settings.
- Emphasis is placed on 'last mile' support to companies and institutions that are advanced in their innovation and technological journey and are close to market readiness.
- Applications should highlight the technical assistance requirement and the specific pipeline this will contribute to in terms of product development and market readiness, to scaling manufacturing.
- Specifically, therefore SMME's are a key target group, especially those that require support to accelerate towards market readiness.
- Applications should highlight the contribution to the strengthening of capacity in manufacturing, leveraging innovation in the biotechnology, pharmaceutical, and biomanufacturing sectors, while making a concerted contribution to the public health impact in Africa.

We exclude:

- Requests for financial assistance.
- Formative research (those that need to conduct preliminary studies before a larger research study can be designed or product be developed).
- Clinical validation of drugs, vaccines and diagnostics as well as Phase 1, or clinical validation/bioequivalence studies/trials.

Core areas within the biotechnology, pharmaceutical, and biomanufacturing sectors that are of particular interest are presented in Figure 1, including but not limited to;

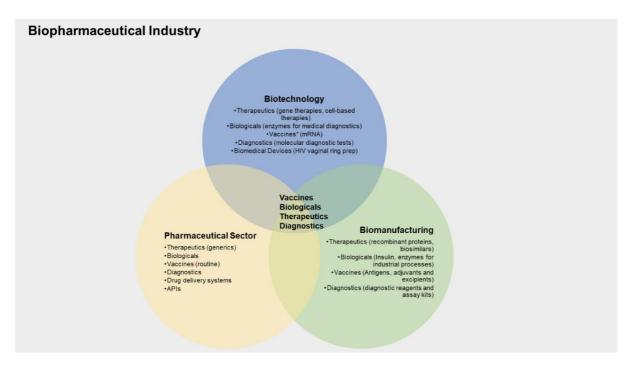


Figure 1: Key Intersections - Biopharmaceutical Sector

Therapeutics:

- Generics, Gene therapies, Cell based therapies, Recombinant proteins, Biosimilars.

Biologicals:

 Enzymes for medical diagnostics, Enzymes for industrial processes, Insulin, Monoclonal antibodies.

Vaccines:

- Routine vaccines, mRNA, Antigens, Adjuvants, Excipients.

Diagnostics/Health Technologies:

- Diagnostic reagents, Diagnostic assay kits, Molecular diagnostic tests.

Technical Assessment Criteria and Selection

Details of the evaluation and technical assessment matrix for the scoring of applications are also listed below. This follows a 5-step process elaborated below. Please see also diagrammatic summary in Appendix 1: Application Selection Flow Diagram.

Step 1: Formal Eligibility Screening

Step 2: Technical Eligibility Screening

Step 3: Technical Scoring and Shortlisting

Step 4: Interviews (Optional – if clarification required)

Step 5: Project Selection

The following criteria (or any combination thereof including those not mentioned here) are proposed for the weighted assessment of proposals. These are intended to provide a detailed and clear indications of the strengths and weaknesses of the eligible proposals over a range of key strategic areas. The categories (definitions and weighting as described below) will be presented as part of the launch/information sessions to ensure potential applicants are aware of the evaluation criteria and can tailor their proposal accordingly.

Table 1: Technical Scoring Matrix			
Category/Criteria	Description	Weight	
Product Pipeline Maturity	Strength and readiness of products under development; proximity to clinical trials, regulatory filing, or market entry.	20%	
Technical Capacity	Presence of relevant infrastructure, labs or manufacturing space; ability to absorb and apply technical guidance. 20%		
Regulatory Engagement	Existing interaction with SAHPRA or other regulators; preparedness for filing, audit readiness.		
Market Access Potential	Alignment with local or regional demand; potential to supply under NHI or regional pooled procurement.		
Scalability & Impact	Ability to grow operations, create jobs, reduce import reliance, and enhance local production.		
Strategic alignment with national, DSTI, and SAVax goals surrounding healt security, localisation, sustainability; and a clear commitment to technical collaboration.		10%	
Diversity & Transformation Marker	Female- or black-owned; inclusive employment initiatives and growth opportunities; meaningful transformation leadership; diversity and representation in management, and staff.	5%	

Rules for this Call for Applications

Number of applications and configuration

Applications can be comprised of one or more private sector entities collaborating on a single product. ALL entities are required to be registered in South Africa and cannot be subsidiary of a company based in Germany or the European Union.

- The Lead Applicant may not submit **more than one application** under this call for applications.
- The Lead Applicant <u>may not be a Co-Applicant</u> in another application at the same time, under this call for applications.
- A Co-Applicant may not be the Lead- or Co-Applicant in **more than one** application under this call for applications.

Applicants are therefore encouraged to select the consortia and product with due consideration.

Ethics Clauses and Code of Conduct

a) Absence of conflict of interest

The applicant must not be affected by any conflict of interest and must have no equivalent relation in that respect with other applicants or parties involved in the actions. Any attempt by an applicant to obtain confidential information, enter into unlawful agreements with competitors or influence the selection committee or the contracting authority during the process of examining, clarifying, evaluating and comparing applications will lead to the rejection of its application.

b) Respect for human rights as well as environmental legislation and core labour standards

The applicant and its staff must comply with human rights. In particular and in accordance with the applicable act, applicants who have been awarded contracts must comply with the environmental legislation including multilateral environmental agreements, and with the core labour standards as applicable and as defined in the relevant International Labour Organisation conventions (such as the conventions on freedom of association and collective bargaining; elimination of forced and compulsory labour; abolition of child labour).

c) Anti-corruption and anti-bribery

The applicant shall comply with all applicable laws and regulations and codes relating to anti-bribery and anti-corruption. GIZ reserves the right to suspend or cancel project financing and/or support, if corrupt practices of any kind are discovered at any stage of the award process or during the execution of a contract. For the purposes of this provision, 'corrupt practices' are the offer of a bribe, gift, gratuity or commission to any person as an inducement or reward for performing or refraining from any act relating to the award of a contract or execution of a contract already concluded with the contracting authority.

Templates

Below are details related to the project template associated with the Competitive Call for Applications. It is important to use the hyperlinks provided in this document as these will navigate the reader to most current versions of the appropriate documents.

Application

Project applications are to be submitted through the **Kobo Toolbox** platform.

There are a total of 2 (two) sections to the application.

Section 1: Organisational Details

- Lead Applicant Details
- Lead Applicant: Commercial Suitability
- Co-Applicant Details
- Co-Applicant: Commercial Suitability

Section 2: Product Details

- Title
- Product Summary
- Product Pipeline Maturity
- Technical Capacity
- Regulatory Engagement
- Market Access Potential
- Scalability and Impact
- Strategic Alignment
- Diversity and Transformation

Technical Assistance Initiatives

Ongoing technical assistance to the various recipients is anticipated and is expected to take on a range of configurations. These will comprise bespoke offerings intended to speak to the unique requirements of the specific organisational and product development needs. In addition, support from the GIZ and key stakeholders including DSTI is anticipated. Selected companies will receive targeted, non-financial support addressing the technical, regulatory, organisational, and strategic challenges they face in advancing biopharmaceutical products to market.

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.
- Digitisation 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

- Navigating Regulatory Pathways: Tailored guidance for interacting with SAHPRA and other relevant authorities (e.g. WHO Prequalification), including dossier preparation, clinical trial applications, reliance mechanisms, and fast-track pathways. Also includes strategic regulatory planning for biosimilars and advanced therapies. Quality Management Process 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). 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 and support 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.

Appendices

Appendix 1: Application Selection Flow Diagram

Formal Eligibility

- Applications that are not complete or do not have the requisite documents will be excluded.
- Applications that are not eligible based on the Eligibility Criteria will also be excluded.
- Numbers and reasons for exclusion will be recorded.

Technical Eligibility

- Filtering for whether applications fit within the Focus Areas/Scope of the Joint Action.
- ±15 Applications (Prospective Recipients) will be agreed and sent to Selection Committee for Technical Scoring.
- Numbers and reasons for exclusion will be recorded.

Technical Scoring

- Applications from (Prospective Recipeints) ± 15 sent sent for independent scoring by selection committee.
- Workshop to discuss proposals and tally scores and rank proposals accordingly.
- Top 10 applications will be shortlisted for interviews if further clarification is required.
- Scoring and ranking will be recorded.

Interview & Site Visit

- GIZ and partners reserve the right to conduct interviews and site visits.
- Interview guides and scoring will be recorded.

Project Selection

- Workshop to discuss interviews, tally scores and rank applications accordingly.
- Top 8 applicantions will be invited to elaborate on their needs assessment to receive technical assistance.

Appendix 2: Call for Applications









TECHNICAL ASSISTANCE FOR ENHANCING MANUFACTURING CAPACITIES AND ACCESS TO VACCINES, MEDICINES, AND HEALTH TECHNOLOGIES IN SOUTH AFRICA

CALL FOR APPLICATIONS

The GIZ (Deutsche Gesellschaft für Zusammenarbeit) SAVax project on behalf of the BMZ and the European Union, together with the South African National Department of Science, Technology and Innovation (DSTI), launches this Competitive Call for Applications to support the enabling environment for local pharmaceutical and health technologies production through the provision of tailored technical assistance to private sector entities operational in South Africa.

For this call, applications are welcomed, but not limited to the following:

- Product development (vaccines, pharmaceuticals, diagnostics, and health technologies), commercial manufacturing, and market access initiatives.
- Innovations in product formulation and development for underserved patient groups.
- Application of new technologies in pharmaceutical manufacturing in general.
- Formulation innovations (including dosage forms and rapid diagnostics).
- Robust innovative technologies that advance product development tailored for humanitarian/emergency settings.
- Emphasis is placed on 'last mile' support to companies that are advanced in their innovation and technological journey and are close to market readiness.

Technical assistance offerings through this call include support with topics such as:

- Technology Platforms and Innovation Readiness.
- Regulatory and Quality Systems Strengthening.
- Intellectual Property and Commercial Strategy.
- Organisational Resilience and Investment Readiness.
- Human Capital and Collaboration.

Further detailed information and downloads are available on the <u>GIZ South Africa Website</u> Interested applicants must submit their applications through the application platform.

The submission of applications deadline is <u>17:00 close of business (COB) SAST on Friday 31</u>
<u>October 2025</u>. Queries can be directed to: <u>savaxjointaction@giz.de</u>.

Appendix 3: Virtual Information Sessions Agenda

Topic: SAVax Joint Action - Technical Assistance: Call for Applications: Information Session

Date: 08 October 2025 **Time:** 12:00 – 13:30 (SAST)

Meeting Details: MS Teams Link

Meeting ID: 359 886 679 813 1

Passcode: V46s3WK6

Agenda

- General information on the SAVax Programme
- Background to Call Applications
- Priority areas for the Call (Focus Areas and Scope)
- Target Beneficiaries and Eligibility Criteria
- Technical Assistance Offering
- Number of applications and applicants
- How to apply and procedures to follow
- Selection process and timelines
- Technical scoring
- Questions from Participants

Appendix 4: Frequently Asked Questions

Frequently Asked Questions (FAQ)		
Question	Answer	
How many consortia/companies will be awarded in this call?	The GIZ seeks to select up to 8 applications from eligible applications for tailored technical assistance.	
	This initiative does NOT provide direct funding or co-financing. Support will be offered in the form of targeted technical assistance only.	
Are companies operational in other countries eligible for this Call for Applications?	To be eligible for the receipt of Technical Assistance under this call, companies need to be registered and operational in South Africa. While it is permitted to simultaneously be registered and operational in other jurisdictions, this cannot be in Germany or the European Union.	
Can profit making legal entities participate as applicant?	Yes. The target group for this call for applications are private sector entities. Importantly companies need to be registered and operational in South Africa and cannot have tax liability in Germany or the European Union. Companies can also not constitute a subsidiary of a company that has tax liability in Germa y or the European Union.	
Where should applications be submitted?	All applications and supporting documentation should be submitted via the KOBO Toolbox .	
Where can queries be directed?	Any queries can be directed to the dedicated email address savaxjointaction@giz.de.	

This document will be updated periodically based on the queries received via the email above and the information session. Please consult this document for any updates while the call for applications is open for queries and submissions.

Appendix 5: Kobo Toolbox Instructions

- 1. **Signal Bars:** The signal bars indicate whether the form can be launched offline or not. Web forms are built to be able to collect data while you are offline, however, it is essential to visit the form URL with an internet connection before going offline. Once your form has been loaded and cached, you'll see the offline availability icon (empty "signal bars" and a check mark) in the top-left corner indicating that you can now access the form offline.
- 2. **Printer Icon:** The printer icon provides you access to print your form or save it as a PDF version. For this, press the printer icon and then select Destination (an appropriate printer connected to your device to print out your survey form or Save as PDF to save your survey form as a PDF).
- 3. **Save as Draft:** Use this feature to edit or update your records before submitting it to the KoboToolbox server. Once you have checked Save as Draft you will have an option to Save Draft. The draft record gets queued but does not sync with KoboToolbox server. To sync it with the server you will have to open the record from the queued list and uncheck Save as Draft and press Submit.
- 4. **Submit:** Press the Submit button if you have completed collecting information and wish to send the filled-up form to the KoboToolbox server. After pressing the Submit button, you will not have an option to edit the records on your device.
- 5. **Queued Records Counter:** The Queued Records Counter shows you the total number of records submitted and waiting to be uploaded to a server. The queued records are uploaded automatically in the background every 5 minutes when the web page is open, and an internet connection is available.
- 6. **Queue Records Pane:** Clicking the side button shows you the records that are available as drafts (which can still be edited) and finalized submitted records queued to be either uploaded to your server with an internet connection or exported as zip file as outlined in the <u>support article here</u>.

