

Hamburg, 17.03.2025

**Invitation to submit an offer:
Strengthening of the Pharmaceutical Sector in Senegal**

Dear Sir or Madam,

As part of our project with GIZ, we cordially invite you to submit an offer for the requested services. Offers can be submitted via email to: vorstand@african-german-health-association.de or by post to:

African German Health Association e.V.
Rödingsmarkt 20, 20459 Hamburg, Germany

Please note that offers will only be considered valid if all required documents, as outlined in the attached documents, are submitted on time and in compliance with the stated requirements.

Offers can be submitted by March 28, 2025, via email or post (date of receipt applies). The contract will be awarded no later than March 31, 2025. The expected service period is from April 2025 to February 2026.

By submitting an offer, you agree that in the event of non-conclusion or early termination of the contract between African German Health Association e.V. (AGHA) and GIZ, no further services will be provided, and no remuneration will be paid to you.

Best regards,



Lutz Schittko, Vorstand Finanzen
i.A. des Vorstands

Attachments

- I. Project Details
- II. Award Criteria
- III. Lot Descriptions and Requirements

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I. Project Details

Each activity will be carefully tailored to the needs of the participants, with durations and content adapted as necessary to ensure maximum impact and relevance. AGHA is committed to working closely with local partners, including GIZ Senegal, local SMEs, the Institut Pasteur and other relevant public and private entities, to ensure that all project activities are aligned with national priorities and contribute to the overarching goal of developing a robust and self-sufficient pharmaceutical sector in Senegal.

The following pages provide a detailed overview of each work package, including the rationale behind them, the specific objectives, and the expected outcomes.

Technical-methodological Concept

The following work packages will be addressed and implemented by AGHA as follows:

Work Package 1: Trainings and Mentoring on WHO-Pre-Qualification

Achieving WHO prequalification is a critical milestone for pharmaceutical manufacturers, as it enables them to meet international quality standards and gain access to global markets. Obtaining WHO prequalification is particularly important to expand their reach and sell pharmaceutical products to international organizations, such as the Generics and Biosimilars Initiative (GaBI) and global health agencies. This certification not only enhances their reputation for quality but also ensures compliance with stringent regulatory requirements, thus enabling participation in global procurement programs led by organizations like UNICEF, the Global Fund, President's Malaria Initiative

This work package includes comprehensive introductory training on WHO prequalification processes, tailored specifically for entities such as (potential) companies from the (pharmaceutical) sector interested in producing vaccines and medicines.

Additionally, it will provide mentoring support to help participants navigate the complexities of the prequalification process, identify potential gaps in their current practices, and develop actionable plans to achieve WHO standards. The goal of this work package to prepare for each joining SME a list of documents, that they need to prepare for the application to be WHO pre-qualified. Participants from other relevant public organizations and entities are also welcome to join the trainings.

The work package will cover the following aspects:

1. Introduction to WHO Prequalification: A detailed overview of the WHO prequalification process with focus on pharmaceuticals, including its requirements and procedures.
2. Tailored Mentoring for manufacturers that are targeting WHO-PQ:
 - Focus Areas: Specific emphasis on selected medicines, addressing their unique prequalification requirements.
 - Gap Analysis: Conducting a preliminary gap analysis to identify the consulting and training needs of selected entities, with an

evaluation of compliance with WHO guidelines, particularly in technology transfer.

- Milestone Identification: Establishing a clear understanding of the major milestones required for WHO prequalification, tailored to the needs of the participating entities.

Language:

French / English (if English speaking trainer, translator will be organised)

Activities:

- Coordination with Senegalese stakeholders, UNIDO and possibly Africa CDC and GIZ to schedule and execute training and workshop
- Preparation of training- and workshop materials according to WHO guidelines
- Execution of training "Comprehensive introductory training on WHO prequalification process" (one group = all interested companies)
- Execution of workshop "Preliminary Gap Analysis and Milestone Identification" (one group = one company; because this activity will be individually done for each company)
- Prepare individual company documentation based on the information from the workshop "Preliminary Gap Analysis and Milestone Identification"
- Execution of mentoring / consulting session
- Accompany each company in the Prequalification process and support to liaise with WHO PQ-Team

Rationale:

Achieving WHO prequalification is essential for pharmaceutical manufacturers that aim to access global markets and participate in international procurement programs. For the Institut Pasteur Dakar (IPD) and Senegalese pharmaceutical SMEs, WHO prequalification represents a significant opportunity to demonstrate their commitment to producing high-quality, safe, and effective vaccines and pharmaceutical products. This certification is a key requirement for selling to international organizations and agencies such as the Generics and Biosimilars Initiative (GaBI), UNICEF, the Global Fund, and Gavi, the Vaccine Alliance.

However, the WHO prequalification process is complex. Many local manufacturers may lack the necessary expertise and resources to navigate these requirements independently. Without proper training and mentoring, achieving prequalification can be a daunting task, potentially limiting the ability of these companies to expand their market reach and contribute to global health initiatives.

This work package addresses these challenges by providing targeted training and mentoring. The program aims to build local capacity by offering comprehensive guidance on the WHO prequalification process, enabling participants to identify gaps in their current practices and documentation. By fostering a deeper understanding of the standards and practices required for prequalification, this work package not only helps local manufacturers achieve compliance but also enhances their competitiveness in the global pharmaceutical market.

Ultimately, the rationale for this work package is to empower Senegalese manufacturers to produce high-quality, WHO-prequalified vaccines and pharmaceuticals, thereby improving public health outcomes both within Senegal and globally. By enhancing their ability to meet international standards, these manufacturers will be better positioned to participate in international tenders, attract investment, and contribute to the global fight against infectious diseases.

Outputs:

- At least one group will join the training "comprehensive introductory training on WHO prequalification process"; to be documented with a signed list of participants
- One group will join the workshop "Preliminary Gap Analysis and Milestone Identification"; to be documented with a signed list of participants

Impacts:

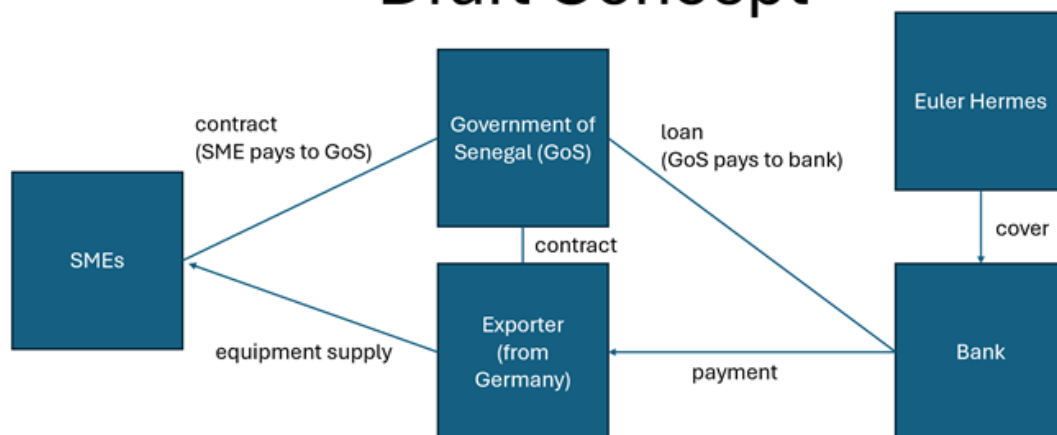
- Capacity building on topic of "comprehensive introductory training on WHO prequalification processes"
- Understanding / capacity building of the individual SMEs needs to comply with the WHO prequalification requirements

Work Package 2: Access to Funds

Small and Medium Enterprises (SMEs) are the backbone of any economic sector, driving innovation, creating jobs, and significantly contributing to a country's GDP. This is true not only in advanced economies but also in developing nations like Senegal. In Senegal, supporting SMEs, especially in the pharmaceutical industry, is crucial for public health, economic growth, and the overall well-being of the population. SMEs in this sector play a vital role in the production and distribution of essential medicines, ensuring that vital medications are accessible to all segments of society, including the most vulnerable.

However, one of the major challenges faced by both public and private stakeholders in Senegal, including SMEs in the pharmaceutical sector, is access to finance. Limited financial resources can hinder the ability of these enterprises to innovate, expand, and improve their services. To address this challenge, AGHA will use its network and expertise to facilitate possible cooperation of Commercial Bank(s) with FONSIS (Fonds Souverains d'Investissements Stratégiques) and / or SMEs to explore the possibility of developing a framework in which the government could provide a guaranteed line of credit to cover necessary acquisitions for SMEs. This initiative aims to create a more supportive financial environment for SMEs, enabling them to thrive and contribute more effectively to the pharmaceutical industry in Senegal. AGHA will facilitate further partnership building with international commercial banks. The goal is also, to discuss with the relevant stakeholders if the following funding structure may be appropriate to support SMEs getting access to funds for equipment and other investment assets, however also alternative funding options will be followed such as a framework loan secured by the Government of Senegal and direct lending structures to the SMEs:

SME Funding Structure Draft Concept



Activities:

- Desk Study on available financing possibilities in the local African pharmaceutical sector including international funders, Export banks, commercial banks, philanthropies etc. Create graphic overview with the different possibilities.
- Coordinate with Senegalese stakeholders and GIZ Senegal workshop / meeting with FONSIS and/or other stakeholders
- Assistance during meetings / meeting(s) with SMEs FONSIS and/or other relevant stakeholders identified through the desk study to discuss possible funding options for SMEs, backed by the government of Senegal or alternatively directly with SMEs
- Foster collaboration between Senegalese SMEs, European SMEs and facilitate cooperation with commercial banks (Exportbanks).

Rationale:

Access to adequate financing is crucial for any organization, especially for SMEs in the pharmaceutical sector, which require significant capital for research, development, production, and distribution activities. In Senegal, financial constraints are a major hurdle for both public and private stakeholders, including SMEs, limiting their ability to grow, innovate, and effectively contribute to the healthcare system. Addressing these financial barriers is essential to enable SMEs to invest in necessary infrastructure, technology, and operations to meet the country's public health needs.

By exploring a partnership with FONSIS to develop a framework for a government-backed line of credit would provide a significant boost to the financial capabilities of SMEs. Such a framework would reduce the financial risk for lenders, making it easier for SMEs to obtain the necessary funds for critical investments. This comprehensive approach to addressing financial barriers will empower SMEs in the pharmaceutical sector, fostering a more resilient and dynamic industry that can better serve the healthcare needs of Senegal's population.

Alternatively, the possibility to pathway for SMEs to get direct funding / finance particular to finance equipment purchases from international suppliers (e.g. through Euler Hermes support) will also be examined. Companies will be accompanied in liaising with banks for this purpose.

Outputs:

- Number of workshop and/or meeting was held with FONSIS and/or other relevant stakeholders; to be documented with a signed list of participants
- Number of collaborations initiated between Senegalese SMEs and European companies including banks (e.g. for procurement/packaging of equipment and tech-transfer); to be proven with an MoU between the companies, or other suitable documentation.

Impacts:

- Foster collaboration between FONSIS, other relevant stakeholders and the SMEs from the Senegalese pharma sector
- Assist SMEs from Senegal to get funding for their investment(s), if possible, also by collaborating with European banks and companies (e.g. for procurement, packaging, tech-transfer etc.)

Work Package 3: Planning and Networking Assistance for CPHI Frankfurt 2025

The work package aims to facilitate the participation of Senegalese pharmaceutical SMEs in the CPHI, one of the largest international trade fairs for the pharmaceutical industry, taking place 28-30 October 2025 in Frankfurt, Germany. Organized by SenPharm / local GIZ in Senegal, this delegation trip will provide a unique opportunity for SMEs to network with global industry leaders, explore potential partnerships, and gain insights into the latest industry trends and innovations.

To maximize the benefits of attending CPHI, we will offer tailored assistance to help SMEs engage with companies, organizations, and other participants that align with their specific interests and needs. A "one-pager" will be prepared for each company, that can be used to present their companies. Following this, AGHA will assist the SMEs to arrange appointments at CPHI. Additionally, during the event in Milan, an AGHA expert will be on-site to support the delegation, ensuring they make the most of their participation and networking opportunities. The AGHA expert from work package 2 (access to funds) may assist as well during the event.

SMEs, who do not join CPHI, will also be supported by AGHA in the preparation of a company fact sheet ("one pager"), that can be shared with possible collaboration partners, to seek finance or other issues.

Language:

French / English (if English speaking trainer, translator will be organised)

Activities:

- Preparation of company fact sheet ("one-pager") of all 7 existing Senegalese Companies
- Assistance to organise / schedule meetings at the CPHI Milan 2024 and Frankfurt 2025
- Assistance during CPHI Milan 2024 and Frankfurt 2025 by an AGHA expert

Rationale:

Participating in international trade fairs like CPHI is a valuable opportunity for Senegalese pharmaceutical SMEs to expand their networks, build strategic partnerships, and gain exposure to global markets. CPHI Milan is one of the largest gatherings of pharmaceutical professionals worldwide, providing a platform for industry stakeholders to exchange knowledge, showcase innovations, and explore business

opportunities. For SMEs in Senegal, attending such an event can significantly enhance their visibility, competitiveness, and access to new markets and technologies.

However, navigating a large international event can be challenging, especially for SMEs that may lack experience in global networking or the resources to independently arrange meaningful business meetings. Without adequate support, these companies risk missing out on key opportunities to connect with potential partners, clients, and investors.

This work package addresses these challenges by offering comprehensive planning and networking assistance tailored to the needs of Senegalese pharmaceutical SMEs. By identifying the specific interests and goals of each SME, we can ensure that their participation is strategically aligned with their business objectives and equipment and raw material needs. An AGHA expert will facilitate targeted meetings with relevant companies and organizations at CPHI Milan, allowing SMEs to make valuable connections and explore potential collaborations.

Additionally, English-German-French speaking on-site support from an AGHA expert during the event will provide SMEs with guidance and assistance in navigating the fair, enhancing their ability to engage effectively and maximize their participation. This proactive approach ensures that Senegalese SMEs are well-prepared and strategically positioned to capitalize on the opportunities presented at CPHI.

Outputs:

- Number of collaborations initiated between Senegalese SMEs and European companies; to be proven with a first meeting (e.g. screenshots of online meeting or e-mail copy of meeting confirmation) or an MoU between the companies, or other suitable proves - for this work package also a list of meetings of delegation participants at CPHI with European companies; to be documented with a list of the meetings
- For each company of the trip (and other SMEs from Senegalese pharma sector, who are supported by SenPharm) a "Company One-Pager" will be prepared, to be documented with a digital copy of the document
- AGHA expert assist delegation during CPHI; to be documented with a copy of the entrance ticket to CPHI Frankfurt 2025

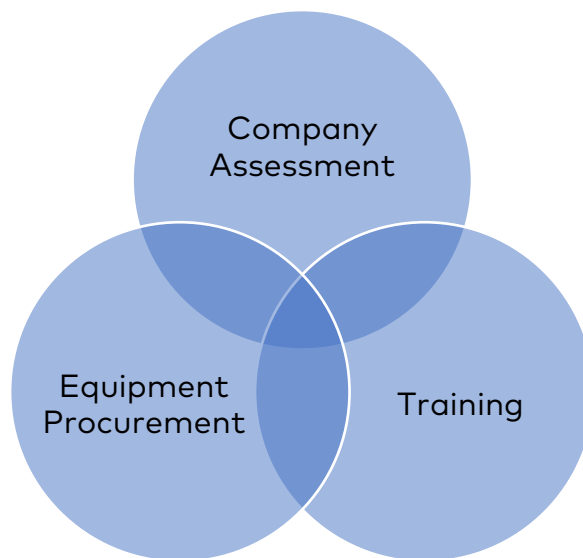
Impacts:

- Enhanced Networking and Partnership Opportunities: By participating in CPHI Frankfurt 2025 with structured planning and networking support, Senegalese pharmaceutical SMEs will have increased opportunities to connect with global industry leaders, potential clients, and strategic partners, fostering collaborations that can drive business growth and innovation.
- Improved Understanding of International Markets: SMEs will gain valuable insights into global market trends, regulatory requirements, and technological advancements through exposure to international stakeholders at

CPHI. This knowledge will help them adapt to and compete in the global pharmaceutical industry.

Work Package 4: Fire Hazard Assessment and Capacity Building

This work package is structured into three main areas with Senegalese SMEs from the Pharmaceutical Sectors as the target stakeholders. First, individual assessments will be performed in each company, followed by trainings on the different staff levels. In the third part relevant fire protection and training equipment, identified by the experts, will be procured for the companies from a dedicated budget.



Company Assessments:

A local fire protection expert will perform an assessment at each company in order to assess the current level of fire protection (strategy). This includes an assessment how many fire extinguishers and other equipment for facilities are already available, their functionality and how many (additional ones) are required. The assessment of escape and rescue routes, as well as the evaluation of the corresponding plans, also takes place. In addition, the equipment with fire and smoke detectors, the designated assembly points, and the evacuation concept are reviewed to ensure compliance with safety standards and regulations. Depending on the company size, the local expert will spend on average 1,5 days for each facility(s) including preparation, site visits and reporting.

The results of the assessment prepared by the local expert will then be verified by an international fire protection officer. This verification will take on average half day at each company`s location. The results for the assessment will then be made available to each company.

Capacity Building (Trainings):

The capacity building (trainings) will take place on three levels:

2 persons per company

Fire Safety
Management

2 persons per department

Fire and Evacuation
Assistance

All employees

Basic Introduction
to Fire Protection

All trainings will be performed by the international expert. For the local expert a total of 3,5 days (0,5 day / SME) is considered in the project to support the international expert during the trainings or as additional time for the other activities of the entire work package. The following table includes the name, duration, recommended target group and description of each training:

Name	Duration	Recommended target group	Description
Basic introduction to fire protection	4 hours	All employees	<p>To enable all personnel to contain the onset of a fire and the spread of fire and smoke in time, as well as to become familiar with fire extinguishers and their use in fighting incipient fires. The training includes a "hands-on" with fire extinguishers.</p> <p>Thanks to this extensive training program, every employee knows what to do in the event of a fire. This reduces the risk of dangerous and uncontrolled fires in healthcare facilities.</p> <p>The training "basic introduction to fire protection" will be executed at one location per SME, making a total of seven training executions.</p>

Fire and evacuation assistance	1 day	Across departments (2 persons per department)	<p>Ensure evacuation of employees in case of emergency. Support and documentation of preventive fire protection for the employer.</p> <p>The training "fire and evacuation assistance" will be centralised at a venue to be provided by GIZ Senegal. The training will be executed two times.</p>
Fire Safety Management	3 days	2 persons per company	<p>Prevent the occurrence of a fire in time by organizational and preventive measures, so that in the event of a fire it is possible to fight the fire effectively at an early stage. Responsible for fire safety management across entire company, e.g. availability of fire protection assets (signages, fire extinguishers...) and their conformity (e.g. validity dates). Also monitoring of evacuation plans and availability of sufficient trained staff (basic introduction to fire protection and fire and evacuation assistance) in the different departments.</p> <p>The training "Fire Safety Management" will be centralised at a venue to be provided by GIZ Senegal. The training will be executed one time.</p>

Procurement of Training Equipment:

A dedicated budget for the procurement of training equipment (specifications to be provided by the international expert) is considered in the project with the goal to procure:

- 1x Fire Trainer
- 6x Training Fire Extinguishers
- Propane Gas and other consumables

A compressed air compressor (at least 10 bar) will be borrowed locally. If costs may occur, those will be charged against the procurement budget.

Procurement of Fire Protection Equipment:

Based on the company assessments (see above) relevant equipment such as fire extinguishers and signages will be procured. A budget is considered in the project's budget plan.

Language:

French / English (if English speaking trainer / expert, translator will be organised)

Activities:

- Performing of company assessment on fire protection
- Preparation of company assessment report on fire protection
- Training- and fire protection equipment procurement (and installation)
- Preparation of training materials
- Training execution
- Preparation of Work Package Report

Rationale:

Ensuring fire safety is a critical component of risk management for pharmaceutical manufacturers, particularly for Senegalese SMEs striving to meet international quality and safety standards. Fire hazards in pharmaceutical production facilities pose significant risks to personnel, equipment, and critical supplies, potentially disrupting production and leading to severe financial and reputational losses. Compliance with fire safety regulations is not only a fundamental requirement for workplace safety but also an essential aspect of achieving and maintaining international certifications, such as WHO prequalification and Good Manufacturing Practice (GMP).

However, many local pharmaceutical SMEs in Senegal lack the necessary expertise, resources, and infrastructure to implement comprehensive fire prevention and response measures. Without a systematic approach to fire hazard assessment, companies may operate with unrecognized risks, inadequate fire protection systems, and insufficient emergency preparedness. The absence of well-defined fire safety protocols can jeopardize the entire supply chain, impacting both local and international stakeholders.

This work package addresses these challenges by conducting thorough fire hazard assessments of participating SMEs, identifying potential risks. The assessment will be followed by a procurement budget for essential fire protection equipment, ensuring that companies e.g. have access to fire extinguishers. Additionally, the work package will implement a structured capacity-building program.

Ultimately, the rationale for this work package is to strengthen fire safety standards within Senegal's pharmaceutical sector, protecting workers, infrastructure, and supply chains from fire-related disruptions. By investing in fire hazard assessment and capacity building, Senegalese SMEs will improve workplace safety, foster compliance with international safety regulations, and bolster their long-term sustainability in the global pharmaceutical market.

Outputs:

- Company assessment report for seven companies; to be documented with a copy of one assessment report per assessed company
- Training equipment procured and handed over to WEST AFRIC PHARMA or another company from the Senegalese Pharmaceutical Sectors; to be documented with handing over form(s)
- Fire protection equipment procured and handed over to the seven companies; to be documented with handing over form(s)
- Training materials; to be documented with a copy of the training materials
- Trainings completed; to be documented with list of participants

Impacts:

- Company will have an understanding of their current level of fire protection
- Capacity building on topic of fire protection and prevention
- Better availability of fire protection equipment in the companies
- Improved fire prevention and protection of the companies and their employees

II. Award Criteria

All work packages will be awarded according to the following selection process:

1. **Offer including all documents received in time** → If the offer, including all required attachments, is not received by the deadline stated in the cover letter, the offer is excluded from the selection process; otherwise, proceed to the next step.
2. **Evaluation of Minimum Qualifications of Expert(s)** → If the minimum qualifications are not met, the offer is excluded from the selection process; otherwise, proceed to the next step.
3. **Evaluation of Offer Requirements** → If the requirements are not met, the offer is excluded from the selection process; otherwise, proceed to the next step.
4. **Evaluation of Submitted Documents** → If one or more required documents are missing or invalid, the offer is excluded from the selection process; otherwise, proceed to the next step.
5. **Final Review of Offers by the Board** → If there are valid reasons for exclusion, the Board may unanimously decide to reject an offer. In this case, the offer is excluded from the selection process.
6. **Selection of the Best Offer** → If multiple offers remain, the one with the lowest daily rate will be selected.

III. Lot Descriptions and Requirements

Kindly check the lot description and requirements for each work package in the separate document. The award is based on the evaluation of qualifications and price, as summarised in the document Award Criteria. By submitting your offer, you commit to delivering the respective services upon acceptance. Travel expenses for experts will be covered separately in accordance with the association's guidelines and, if applicable, project-specific regulations.
