Programme "Strengthening the Ghanaian Pharmaceutical Sector with a Focus on Vaccine Production" (PharmaVax Ghana)

Call for Applications: Enhancing Market Access and Technical Capacity of Ghana's Pharmaceutical Manufacturers

Applicant Information Pack

Deadline for Submission: 19.12.2025, 5pm GMT

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This call for applications is organized by the Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) GmbH and Luvent Consulting GmbH, A Chemonics Company (Luvent), in collaboration with the Ministry of Trade, Agribusiness and Industry (MOTAI) and the National Vaccine Institute (NVI) under the Ministry of Health. It is part of a programme implemented with the financial support of the European Union (EU) and the German Federal Ministry for Economic Cooperation and Development (BMZ) as part of the Team Europe Initiative MAV+. The contents of this document are the sole responsibility of GIZ and Luvent and do not necessarily reflect the views of the EU or the BMZ.

Implemented by

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1. Background

The "Strengthening the Ghanaian Pharmaceutical Sector with a Focus on Vaccine Production" (PharmaVax Ghana) programme is co-financed by the European Union (EU) and the German Federal Ministry for Economic Cooperation and Development (BMZ) as part of the Team Europe Initiative on Manufacturing and Access to Vaccines, Medicines and Health Technologies in Africa (MAV+). It is implemented by GIZ in partnership with the Government of Ghana, Luvent Consulting, a Chemonics Company, and other stakeholders. The programme aims to strengthen Ghana's pharmaceutical industry ecosystem including governance and regulation, skills development, research and development and private sector development.

As part of its private sector development component, the programme is inviting qualified Ghanaian private pharmaceutical manufacturing companies to submit responses to this **Call for Applications: Enhancing Market Access and Technical Capacity of Ghana's Pharmaceutical Manufacturers.** The call is organised by GIZ and Luvent Consulting, a Chemonics Company, and its consortium partners Quamed and Health Access Network, in collaboration with the Ministry of Trade, Agribusiness and Industry (MOTAI) and the National Vaccine Institute (NVI) under the Ministry of Health.

This call will identify interested companies to receive **tailored expert services-** a unique opportunity to strengthen competitiveness and expand the production of quality, safe, effective, and affordable vaccines and pharmaceutical products. Participation is limited, and selection will be based on merit and readiness to engage.

*Please note that this call for applications **targets medium and large-scale producers** (i.e. mainly members and associate members of the Pharmaceutical Manufacturers Association of Ghana) due to its focus on compliance with international regulatory standards and market access. A separate call for applications for small-scale producers will be launched in the coming months.*

*Please note: This initiative does **NOT** provide direct funding or co-financing. Support will be offered in the form of targeted technical and business assistance (e.g. specialized training and advisory support in areas outlined in section 3).*

2. Expected Outcomes for Participating Companies

By the end of the project, companies taking part in this initiative will be expected to achieve several key outcomes that align with the programme's overarching objectives. These outcomes are designed to ensure sustainable capacity development, competitiveness, and growth within Ghana's pharmaceutical manufacturing sector, including:

- **Navigating Regulatory Pathways**: Participating companies will build the necessary capacity, expertise, and relationships required to comply with the relevant national, regional, and international requirements for good manufacturing practices and innovations. This will strengthen their ability to comply with global standards, opening the door to broader market participation and recognition.
- **Accessing New Markets:** Companies will be empowered to develop and implement effective market entry strategies, underpinned by a robust understanding of demand forecasting, pipeline analysis, and procurement transparency. This will position them to successfully expand into new markets, both regionally and internationally.
- **Forging Strategic Partnerships:** The project will enable the establishment of business-to-business (B2B) partnerships with regional and global enterprises. Through these collaborations, participants will be better placed to facilitate technology transfers and the effectively manage intellectual property, further enhancing innovation and competitiveness.
- **Enhancing Operational Excellence:** Companies will be equipped to implement digital and environmentally sustainable (green) solutions within their operations and deploy effective and inclusive workforce management strategies. They will also optimise manufacturing and business processes, resulting in improved efficiency, higher productivity, and enhanced product quality.

3. Support Services Packages

Selected companies will receive non-financial, tailored expert consultant services, funded by the project, at no cost. These services are organised into four specific packages. Each package addresses a vital area of pharmaceutical and biological product / vaccine manufacturing, providing targeted support to help companies thrive.

Depending on their needs, companies can select up to four packages and define within each package their priorities for support (see the Application Form for detailed instructions). The specific activities within each package will later be customised in close consultation with each selected company to address unique needs. The examples provided here offer a general overview but are not exhaustive.

Package 1: Regulatory Compliance and International Certifications	
Topics to be supported	***Examples of activities***
A. Product Registration, Dossier Development in CTD format and Licencing / certification with national and international regulatory authorities: For local pharmaceutical manufacturers, compliance with international standards and obtaining	a. Assessing manufacturing gaps, quality control, and regulatory requirements. Help identify relevant international certifications. Provide support for registration dossiers (CTD format), mock assessments, technical documents, compliance audits, CAPA analysis,

certifications like WHO prequalification or ISO are vital for entering new markets and global tenders. Registration with regulatory authorities in international formats like CTD allows them to compete internationally by meeting strict requirements.	clinical trial applications, and mutual recognition mechanisms that enable cross-region product approvals. Offer hands-on training on Ghana FDA and other West and Central African countries as well as international regulatory standards for market authorization.
B. Quality Management Systems / Good Practices: A strongly designed quality system in accordance with international good practice (GxP) including manufacturing practices, documentation and quality control / laboratory practices precedes marketing and investment decisions. This service will address quality by design, documented best practices and fit-for-purpose quality assurance and lean sigma manufacturing, according to ICH/ISO principles.	b. Guidance on preparation and implementation of quality-relevant documentations (eg. SOPs) as well as quality certification (e.g., ISO 17025, 9001). Technical training in relevant cGMP aspects, analytical method development and validation, instrumentation techniques, new product research, and mentorship. Overview of GMP, GDP, GSP, GLP, and GDocP as outlined in WHO Technical Report Series. Where appropriate, this support will be provided in collaboration with Ghana FDA Industrial Support Services Directorate.
C. Facility and process design and workflow optimization: International GMP certification starts with optimized flow of raw material, in-process, finished products and personnel workflow seamlessly. With this service, participants will benefit from the application of machine learning and other tools to redesign process workflows, minimizing cross contamination, process deviation and product defects.	c. Evaluation of facility design and of upgrade of existing facilities, equipment specification and upgrades, and technology adaptation for advanced manufacturing processes. Work on flow design – raw material, in-process materials and finished products, movement across the production line as well as personnel safety, garment and manufacturing line movements.
D. Product development, and quality assessment. This guidance helps manufacturers prove both physical and biological similarity through comparative studies and analytical data, supporting more efficient regulatory submissions and faster generic or biosimilar approvals.	d. Technical advice and customized onsite support will be provided for product formulation and development. Assistance covers clinical trial application, evaluation, documentation, new product submission to regulatory authorities, registration, and post-market surveillance, focusing on product development, quality assessment, and bioequivalence.
E. Risk assessment, risk analysis, and data-driven post-market surveillance design. This topic explores risk-based prioritization of market surveillance critical quality control points, and post-market risk validation of medicines supply chain.	e. Risk assessment and prioritization of post market surveillance events, supply chain risk-based analysis, risk identification and mitigation plans, to address quality defects and to drive decisions on post-market adverse event reporting.

Package 2: Business Development, Access to Finance and Market Intelligence	
Topics to be supported	***Examples of activities***
A. **New business development, business expansion and break-even analysis:** Company/product specific market research to assess demand, pricing, competition, and policy environments across local and regional markets.	a. Conduct market feasibility studies, demand planning, volume-pricing analysis, and competitive landscape assessments. Provide support in evaluating business environments in West Africa and other regions.
B. **Assistance to access finance, including financial modelling and business case development:** Assistance in navigating and complying with local banks, international banking products, public procurement frameworks, including guidance on application processes and meeting eligibility requirements for donor-funded demand sources.	b. Advice on financing options for Ghanaian pharmaceutical manufacturers (Development Finance Institutions, and commercial sources) and help engage financiers, assistance on financial modelling and project feasibility analysis, support in preparing bankable business plans and investment proposals, assistance in preparing and organizing financial statements and accounts, and conduct training on cash flow and inventory management.
C. **Market intelligence data for new market entry:** Guidance on developing effective cost structures, business models, regulatory pathways and capital allocation strategies, encompassing budget planning, resource optimization, and financial forecasting to strengthen organizational sustainability.	c. Conduct market feasibility research, presenting recommendations to guide decisions about regions, costing structure, demand planning and forecasting of revenue for new market entry and expansion.
D. **Trade facilitation and assessment of barriers to regional and international market.** Guidance on bilateral, regional, continental and international free trade agreements, tariff and non-tariff barriers, trade incentives, and customs procedures.	d. Targeted participation in major regional trade events and exchange fora, such as those organised by the African Continental Free Trade Area (AfCFTA), to boost visibility and offer networking, partnerships, and distribution opportunities. Tailored awareness and training on customs related incentives, e.g. Advanced Economic Operators programme, tax exemption incentives.

Package 3: International Partnership and Intellectual Property Management	
Topics to be supported	***Examples of activities***
A. Designing or refining intellectual property (IP) strategies. Conducting freedom-to-operate analyses to ensure products in the pipeline can be commercialized without infringing on existing patents or to identify when patents expire and open opportunities for market entry.	a. Providing expertise on IP landscape to identify relevant patents strategies (potency, industrial designs, trade secrets and utility models), potential barriers, and negotiate licensing terms like royalties and technology transfer with manufacturers.

B. **Negotiating comprehensive technology transfer.** Support to negotiate fair terms for technology transfer of products or processes, including the associated IP, knowledge, expertise, documentation, and data necessary for production, registration, and commercialization within partnerships and technology transfer agreements	b. Discuss patentability criteria, examination, exceptions, compulsory licenses, and data protection versus exclusivity, especially as they relate to local manufacturing. Conduct workshops to inform manufacturers and policymakers about TRIPS Agreement flexibility and relevant WTO health safeguards for middle-income countries.
C. **Structuring and negotiating business partnership.** Support in structuring and managing public-private partnerships, B2B partnerships, consortia, and technology transfer agreements. Conducting due diligence, developing clear contractual frameworks, addressing IP considerations, and establishing effective governance models, such as decision-making structures and accountability mechanisms, to protect the interests of all parties involved.	c. Facilitate innovative partnerships between Ghanaian manufacturers and international companies in pharmaceuticals, vaccines / biological products, plant-based medicines, and related technologies. Advise and offer tailored support to manufacturers on partnerships, licensing, and commercialization agreements.
D. Business-to-business networking, information exchanges and joint ventures. Provide advice to individual companies on B2B partnerships, based on open and transparent negotiation.	d. Connect businesses through matchmaking, networking, and information exchange, hosting B2B events in Ghana and abroad to promote collaboration and investment. Organize annual forums, industry networking, and workshops linking local companies with international investors. Support B2B project development.

Package 4: Operational Efficiency, Digital Innovation, Sustainability and Productivity	
Topics to be supported	***Examples of activities***
A. **Operational efficiency review and sustainability.** Expert guidance on establishing robust operations to leverage digital transformation and strategic business models towards organizational sustainability.	a. Provide training and mentorship for audit readiness, grant and equity management, and scalable financial structuring. Review digital operations and offer customized support to manufacturers based on capacity and digital strategy maturity.
B. Green production capacity and continuous improvements. Sensitize public and private stakeholders on the importance of Green Production and Green Transformation for the pharmaceutical sector in Ghana.	b. Conduct Green Production and Transformation assessments at manufacturing sites, evaluating energy use and potentials for renewable energies, cold chain, environmental practices, water treatment, and waste management. Provide targeted workshops, mentorship, and ongoing improvement support.

C. Digitalization of processes, systems and adaptation. Create awareness of relevant digital processes and transformation in the pharmaceutical sector (e.g. smart-factory technologies, plant process management, asset management), also considering the approaches of other digitalization initiatives of German development cooperation and the EU, and establish a link to providers of digital solutions, e.g. through information events.	c. Conduct thorough digital assessments and optimize management systems by leveraging technologies such as the Internet of Things (IoT) for real-time inventory monitoring, machine learning for predictive maintenance and demand forecasting, and artificial intelligence to automate compliance checks and streamline workflows.
D. Human capital assessment, capture, diversity, equity and engagement. Provide advice, coaching and training for pharmaceutical manufacturers and associations to develop and implement gender policy and disability inclusion policies (e.g. industry wide standards or model policies and recommendations, company-specific policies and sensitization and training measures); advice on general HR management and development approaches	d. Provide advice on HR-related business development services, encompassing recruitment processes, induction frameworks, talent development initiatives, adherence to labour rights, strategies for diversity management, and the promotion of female-friendly work environments. This includes detailing the existence and implementation of company policies, as well as facilities such as breastfeeding rooms and childcare support.

4. Applicants' Commitments

To ensure success, selected companies must commit to a **24-month partnership**. This will be formalized in a Memorandum of Understanding (MoU) between GIZ, Luvent and the company. Applicants are expected to substantiate their own contributions and levels of engagement in the official application form. These commitments may include but are not limited to:

- **Dedicated Activity-Related Resources:** Provide required staff time, access to facilities, meeting rooms, and running costs for in-company trainings where possible, transport for staff, etc.
- **Investment:** Ensure the required investment in manufacturing facilities, equipment and staff needed to achieve the jointly identified priorities.
- **Implementation Drive:** Demonstrate a clear leadership-supported commitment to implementing expert recommendations and driving internal change.
- **Strategic Alignment:** Show a long-term commitment to growth, health impact, and strengthening Ghana's pharmaceutical sector.
- **Information:** Share the required information (including confidential information) for the support to be tailored and delivered effectively and agree to the dissemination of the results (without confidential details, of course).
- **Confidentiality & Ethics:** Adhere to all confidentiality, ethical, and code of conduct requirements outlined in the MoU.

5. Ethics Clauses and Code of Conduct

Absence of Conflict of Interest
Applicants must not be affected by any conflict of interest, nor have any equivalent relationship with other applicants or parties involved in the actions. Any attempt to obtain confidential information, enter into unlawful agreements with competitors, or influence the selection committee or authorities during the examination, clarification, evaluation, or comparison of applications will result in immediate rejection of the application.

Respect for Human Rights, Environmental Legislation, and Core Labour Standards
Applicants and their staff are required to comply with all human rights obligations. Specifically, in accordance with the applicable laws, applicants must adhere to environmental legislation, including multilateral environmental agreements, and uphold core labour standards as defined in relevant International Labour Organisation conventions. These standards include freedom of association and collective bargaining, the elimination of forced and compulsory labour, and the abolition of child labour.

Anti-Corruption and Anti-Bribery
Applicants must comply with all relevant laws, regulations, and codes related to anti-bribery and anti-corruption. If corrupt practices of any kind are discovered at any stage during the award process or project execution, support may be suspended or cancelled immediately.

Definition of Conflict of Interest
A conflict of interest arises when an applicant's personal, professional, or financial interests could improperly influence, or appear to influence, decisions or actions pertaining to this project. This includes situations where the applicant, their staff, or affiliates have direct or indirect relationships with other applicants, evaluators, or parties involved in the selection or implementation process, potentially compromising impartiality.

6. Eligibility and Evaluation Criteria

In the application form, companies are requested to provide general company information, describe business cases for select product areas, select support services they request, and describe their contributions and commitment.

Only applicants who meet the following minimum **eligibility criteria** will proceed to further evaluation:

1. Applicant is a company legally registered in Ghana.
2. Applicant holds a valid manufacturing license from the Ghana Food and Drugs Authority (FDA) or, for those companies not yet manufacturing, has presented a credible roadmap towards establishing manufacturing facilities to the FDA (manufacturing facility design approved by FDA)
3. Applicant submitted their application (**only one per company**) before the deadline using the official application form, fully completed.
4. Application form is fully endorsed by the designated point of contact with strategic decision-making authority such as the CEO

Eligible applications will be evaluated against the following **criteria**:

Criteria and Weight	Description and Indicators
1. **Technical, Operational and Scalable Capacity (25%)**	Evidence of a solid foundation and readiness to absorb support at scale. • **Facilities & Equipment:** Current state of manufacturing facilities (e.g., evidence of cGMP compliance, age/condition of key equipment, available space for expansion) and/or robust plans for facilities (for new companies) or expansion • **Regulatory Track Record:** History with Ghana FDA (e.g., successful product registrations, no major compliance issues). • **Quality Systems:** Existence of a documented Quality Management System (QMS), even if basic. • **Technical Team:** Qualifications and experience of key technical staff (production, quality control, regulatory affairs).
2. **Market Access Potential (25%)**	Potential to leverage support to achieve tangible commercial outcomes. • **Product-Market Fit**: Portfolio/pipeline aligns with clear market needs (e.g., Essential Medicines List, high-burden diseases, regional demand). Provide specific product examples. • **Market Entry Strategy:** Clarity of thought on target markets (regional/international) and identified barriers. • **Financial Health:** Basic evidence of operational sustainability (e.g., audited statements, revenue streams) to support co-investment. • **Business Plan**: A credible, high-level business case for expansion or new product introduction.
3. **Strategic Alignment (15%)**	Alignment with program goals and demonstrable commitment to implementation. • **Public Health Impact**: How the company's growth will improve health security, access to medicines, or affordability in Ghana and West Africa. Applications concerning priority areas such as vaccine-preventable diseases, other epidemic and endemic infectious diseases such as malaria, HIV and TB are particularly encouraged but the call is open to any pharmaceutical product addressing conditions of significant public health concern in the region.
4. **Environmental, Social, Governance (ESG**) & **Digital Innovation (10%)**	Commitment to sustainable, ethical, and forward-looking business practices. • **Environmental:** Existing or planned green practices (e.g., waste management, energy/water efficiency, pollution control). • **Social (Diversity & Inclusion):** Evidence of policies/practices and commitment on gender equality, inclusion of persons with disabilities, fair labour standards. • **Digital & Technological Adoption:** Interest or existing steps in digitalization (e.g., inventory management, data systems) and innovative processes

5. **Company Commitments and Collaboration (25%)**	Tangible commitment of resources, demonstrating skin in the game. • **In-Kind Contributions:** Detailed commitment of staff time (FTEs), access to facilities, logistical support. • **Financial Co-Investment**: Clear outline of planned investment in facilities, equipment, or technology upgrades aligned with the support. • **Information Sharing**: Willingness to share necessary data and agree to non-confidential reporting of results. • **Commitment to Change:** Willingness to implement recommendations (e.g., past history of adopting new processes, clear statement of intent). • **Leadership Engagement**: The application is endorsed by a CEO-level authority who will champion the project internally.

The evaluation will be done by a jury of independent experts determined by GIZ and Luvent Consulting. The identities and affiliations of the evaluation committee members remain confidential and shall not be disclosed to applicants. **The evaluation committee members will be bound by non-disclosure agreements.** The evaluation will be done on the basis of the application form and supporting documentation (certificates, business plans etc.) submitted, and where necessary subject to interviews and site visits to validate submission.

7. Application process

The tentative calendar for the call is the following (subject to change):

- 19.11.2025 Call opens
- 02-04.12.2025 Information sessions in Accra and Kumasi (separate invites will follow)
- **19.12.2025 Deadline for submission (5pm GMT)**
- **20.01.2026** Selection and notification (of successful and unsuccessful applicants)
- **01.02.2026** Anticipated signing of MoU and start of implementation

8. How to Apply

1. Complete the official **Application Form** (separate file).
2. Gather all required **supporting documentation**.
3. Submit your full application via email by the deadline of **19.12.2025 by 5:00 pm GMT** to: pharmavax-ghana@luvent-consulting.com **Subject Line: Submission for Call for Applications.** Late submissions will not be considered
4. Applicants must submit a **completed application form, in Microsoft Word or Adobe PDF are accepted.** Only applications using this form plus **requested relevant supporting documentation will be accepted**.

For inquiries, please contact: Dr. Farouk A Umaru, Country Team Lead, fumaru@luvent-consulting.com