Contents

General information

a. Brief information on the project

The program “Cooperation for the Enhancement of Southern African Development Community (SADC) Regional Economic Integration” (CESARE) supports the Southern Africa Development Community (SADC) in economic development as well as good governance. Its main cooperation partner is the SADC secretariat in Gaborone, Botswana. The program is further implemented in cooperation with the national governments of SADC member states as well as with associations and companies of the private sector and civil society. One of the four measures of the program is the Joint Action “Support towards Industrialization and the Productive Sectors (SIPS) in the SADC region”. This Private Sector Development Action is financed by the EU and the German Government. GIZ is responsible for the implementation of two result areas of SIPS: to enhance the private sector participation in regional medical and pharmaceutical value chains, in this case specifically the anti-retroviral (ARV) value chain (VC), and to enhance the private sector participation in the regional leather value chain.

b. Context

The Joint Action SIPS is supported by the European Union (EU) under European Development Fund (EDF) 11 as approved by the European Commission in October 2018. The Action has been initiated to support the SADC Industrialisation strategy through developing and strengthening selected regional value chains.

The overall objective of the SIPS Program is to contribute to the SADC industrialisation and regional integration agenda. The project purpose (specific objective) is:

To improve the performance and growth of selected regional value chains and related services within the agro-processing, pharmaceutical and medical products sectors.

The SIPS Program addresses key concerns of the private sector that are currently impeding industrialisation in the SADC region, by addressing both market failures and coordination and linkages failures between the national and regional levels as well as between the public and private sectors. Accordingly, the program aims to achieve its objectives through two mutually reinforcing components:

- Component 1 (Result 1) is enhancing the policy, regulatory and business environment at national and regional levels for the development and sustainable operation of regional value chains (for selected products) in the agro-processing and pharmaceutical sectors.

- Component 2 (Results 2 and 3) is enhancing private sector participation in regional pharmaceutical and medical as well as leather value chains. More specifically, result 2 exclusively aims at enhancing private sector participation in regional anti-retroviral (ARV) and Covid-19-relevant medical and pharmaceutical products (CMPP) value chains (results 2.1 and 2.2, respectively).

The EU and the SADC Secretariat have identified the Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) GmbH as the lead implementing agency for the Results 2 and 3 of the SIPS Program (in the framework of a co-financed Contribution Agreement). GIZ is implementing the private sector component through a Multi-donor Action, the Joint Action SIPS, that is jointly co-financed by the European Union and the Federal Republic of Germany's Federal Ministry for Economic Cooperation and Development (BMZ). GIZ implements the Private Sector Component of SIPS as part of the BMZ-commissioned program "Cooperation for the Enhancement of SADC Regional Economic Integration" (CESARE II) which has an implementation period of up to 41 months, with effect from October 2019.

Economic and public health potential of the regional ARV value chain

The antiretroviral value chain is an important focal area given the impact of the HIV pandemic across the world, over 5 decades after it emerged as a major disease threat. The highest burden of HIV/AIDS resides within the African continent, particularly Sub-Saharan Africa, where approximately 67% of HIV positive cases are found. Furthermore, the SADC region has the highest prevalence on the continent. According to 2020 data, over 20 million individuals in East and Southern Africa are HIV positive, representing over 54% of the worldwide population, with the vast majority (17.3 million people) in the SADC region.

Currently, there are effective antiretroviral therapies (ART) that do not cure the infection but offer long term remission and reduction in viral load. Although antiretroviral therapies are widely available, and there has been a significant decline in the number of new HIV infections, the condition remains a major infectious disease risk. It is important to highlight that, of the estimated 17.3 million people living with HIV/AIDS in SADC, an estimated 13.1 million have access to antiretroviral therapy, meaning that 4.2 million people are not on treatment. Efforts are underway to increase access to ART in line with the UNAIDS 95-95-95 strategy aimed at ensuring that 95% of people living with HIV know their HIV status; 95% of people who know their status are on treatment; and 95% of people on treatment are virally suppressed. Given these targets, the uptake of ART in the region is likely to rise over time.

The majority of ARVs used in SADC are imported, and there is a clear economic opportunity for the region by increasing the local capture of this market through investment in pharmaceutical manufacturing in the ARV value chain. The region incurs an estimated annual expenditure of US$1.7 billion on ARVs. Most ARVs are currently imported by donor agencies from outside the continent, with the public sector in SADC Member states also procuring a sizeable amount directly. ARV production in the SADC region has the potential to shorten ARV procurement lead times for government or donors in the ARV supply chain and create new market opportunities for supporting industries. Therefore, the ARV value chain offers both public health and an economic opportunity for the SADC region.

Recommended ARV Chain interventions

Based on stakeholder engagement and analysis of the ARV wider value chain conducted during the inception phase of Result area 2.1 of the Joint Action SIPS, a comprehensive inception report was compiled, and it forms part of the information pack for this assignment. The report profiles the regional ARV market, procurement dynamics, the current state of the industry and the opportunities and challenges that exist, along with proposed interventions.
Given the very different parameters that govern and drive the identified market segments, the interventions are structured to take account of these individual market segments, which are:

1. **The public market**.
   This represents government procurement (tenders). It is the highest priority and main focal area for the Joint Action SIPS project due to its relative size and accessibility by local manufacturers, it is the main sales opportunity for local manufacturers and essential in ensuring the viability of local manufacturers. SIPS component 1 and component 2 will work in tandem to increase the accessibility of this market by manufacturers in the region.

2. **The donor market.**
   This represents ARV procurement by donor agencies such as PEPFAR or Global Fund on behalf of governments and is the largest market by size in all countries, excluding South Africa which is dominated by the private sector; however, it is largely 'locked' to most local manufacturers since they need to attain World Health Organization Prequalification (WHO-PQ) or Stringent Regulatory Authority quality standard to access it and as competitive prices for larger donor procurements depend on economies of scale of manufacturers outside SADC.

3. **The private market.**
   This represents private insurance or out-of-pocket purchases of ARVs. The only substantial private market in the region is South Africa. From a value perspective, it is attractive; however, the presence of non-tariff barriers, multinational competition, and the presence of a sizable South African pharmaceutical manufacturing base, makes it challenging to compete for companies of other SADC member states.

Based on the above analysis and findings from the inception report, the following interventions are relevant for the three markets and these include (1) to evaluate and promote production of inputs such as active pharmaceutical ingredients (API) and packaging materials, (2) to improve the manufacturing production and business operational efficiency, (3) to attain and maintain acceptable good manufacturing practice (GMP) standards, (4) to link private sector pharmaceutical manufacturers and academic institutions to develop academic programmes that address the existing skills gap in the sector and (5) to facilitate access to affordable, flexible and innovative financing arrangements for spearheading ARV manufacturing projects.

These Terms of Reference will focus specifically on bridging the gaps identified in academic and TVET integration in pharmaceutical manufacturing within SADC.

Intervention for the Development of a Regional Academic Programme

The Joint Action SIPS aims to improve the transfer of knowledge and know-how to enhance the performance and growth of regional value chains and related services. Highly certified production facilities are required to meet international standards to improve the production standards of locally produced antiretrovirals (ARV). Similarly, highly qualified pharmaceutical personnel, namely pharmacists, pharmaceutical assistants, and pharmaceutical personnel, are also essential for developing the pharmaceutical value chain.

Some SADC Member States have established universities and other relevant TVET institutions that offer a variety of relevant programmes to the pharmaceutical manufacturing process. For instance, there is substantial training capacity at the bachelor's level for all pharmaceutical training in some countries with a varying intake of 30 to 90 students per program per year. However, pharmaceutical programmes predominantly focus on hospital pharmacy and community health to counteract the existing shortage of qualified pharmaceutical personnel in the healthcare sector in relation to the population. Therefore, there is a predominant gap in skilled pharmaceutical personnel to specifically meet the labour demand from existing and newly developed pharmaceutical companies in the SADC region.

Specialised training at the master's level is indispensable for building training capacity for certain sub-steps of pharmaceutical production. Within the SADC region, there are Member States that have these programmes, which could serve as a starting point. In Tanzania, for example, there is an existing industrial pharmacy Pharm program at the Muhimbili University of Health and Allied Sciences (MUHAS). In addition, the University of Zambia recently launched a master's in industrial pharmacy and the University of Namibia is planning on developing an MPharm in Industrial Pharmacy. These programmes offer an opportunity to tailor the training program to the needs of the pharmaceutical industry.

The Joint Action SIPS Description of Action (DoA) Sub-result 2.1.1 aims to enhance business, entrepreneurial and subject matter knowledge skills. The indicative activities within this sub-result include facilitating the development of effective industry-knowledge clusters involving companies active in the ARV value-chain and knowledge institutions (e.g. by developing a curriculum for industrial pharmacists based on private sector needs). Accordingly, the main objective of this intervention is to facilitate dialogue, build and support linkages between the private sector pharmaceutical manufacturers and academic institutions to develop or improve academic programmes that address the existing skills gap in the sector.

This will be achieved by supporting the development of a regional SADC Industrial Pharmacy Fellowship Program in which universities and training institutions in at least 3 SADC Member States partner to jointly educate and train students in courses related to industrial pharmacy. The fellowship program will be jointly developed with the universities and training institutions as well as the private sector to ensure that the skill needs in the regional pharmaceutical manufacturing sector are met.

c. GIZ shall hire the individual consultant (contractor) for the anticipated contract term, from October 2022 to January 2023.

d. The contractor shall provide the following work/service:

The overall objective of the contractor is to develop a project proposal for the implementation of a regional SADC Industrial Pharmacy Fellowship Program (IPFP) in coordination with the Joint Action SIPS and the respective stakeholders. Stakeholders in the project include universities and training institutions in South Africa, Zambia and Tanzania as well as regional pharmaceutical manufacturing companies, regional associations and the SADC Secretariat. The Joint Action SIPS Team will create a working group with representatives from each stakeholder institution before the contract begins. The contractor will facilitate the collaboration between the members in the working group to develop a project proposal for the SADC IPFP and draft relevant Memoranda of Understanding between stakeholders participating in the program.

The contractor will undertake the following activities:

1. Desk review:

    1.1. Conduct a desk review of existing/similar regional/national fellowship programmes
    1.2. Review and enhance the current SADC IPFP draft concept note of the fellowship program.
    1.3. Identify any other relevant stakeholders

2. Needs Assessment:

The aim of the needs assessment is to understand the gap between the expectations from the private sector in industrial pharmacy and the current capabilities of the academic and TVET institutions who intend to participate in the SADC fellowship. The needs assessment should also consider the perspectives of the national regulatory agencies, students, and other relevant stakeholders.

2.1. Design a needs assessment questionnaire for identified pharmaceutical manufacturing companies, identified academic and TVET institutions and other relevant stakeholders to identify missing gaps between the various curricula of the current courses provided and the skills needed in the private sector. The needs assessment should build on the existing report skills audit report which will be provided by the Joint Action SIPS team. After design, the questionnaire and data collection plan need to be validated by the GIZ SIPS team and the M&E (Monitoring & Evaluation) Specialist.
2.2. Carry out field research by interviewing with all identified stakeholders and conferring with the working group. Joint Action SIPS will support the organisation of the meetings with the stakeholders.
2.3. Analyse data and present the data to the working group for discussion and validation. The data will be presented in a 3-hour online workshop using the Joint Action SIPS Microsoft Teams platform.
2.4. Prepare a needs assessment report with incorporated comments from the working group.

3. Project Proposal:

The project proposal and joint action plan should outline the need for the fellowship, the organisational arrangements, how the fellowship will fulfil the identified needs and the impact statement. The proposal will also include the fellowship planning details which include the length and structure of the fellowship, admission requirements, educational objectives and outcomes, collaborating partners and their roles, resource requirements and accreditation requirements. The project proposal shall include a tentative budget and

a comprehensive time schedule for all involved stakeholders, taking into consideration the end of SIPS in September 2023.

3.1. Prepare the draft project proposal, project budget and the Gantt chart jointly with the identified working group using provided templates. Two rounds of revisions will be conducted by the Joint Action SIPS before the document is finalised.
3.2. Finalise all relevant documentation for the SADC IPFP project proposal.
3.3. Ensure that the final proposal aligns with the SADC Protocol on Education and Training
3.4. Prepare draft Memorandum of Understanding documents outlining implementation arrangements of the fellowship and the roles played by different stakeholders to guide the implementation process.

4. Organise and facilitate a physical SADC IPFP planning workshop with all relevant stakeholders to develop the fellowship program in a joint approach to ensure ownership. The workshop with an estimated 25 participants will be conducted physically for 1.5 days in Johannesburg, South Africa. The planned physical workshop should adhere to COVID-19 regulations. The contractor will:

4.1. Present the draft fellowship proposal to the stakeholders.
4.2. Facilitate the discussion for stakeholder inputs.
4.3. Develop a joint action plan with the working group to implement the SADC IPFP.

5. Present the project proposal and action plan to the Joint Action SIPS team and all relevant stakeholders.

6. The contractor will be expected to participate in online meetings with relevant stakeholders occasionally.

Deadlines and Deliverables:

Tasks	Deliverables	Deadline	Comments
Kick-off meeting	n/a	When contract starts	The meeting will be organised by the SIPS team.
Desk Review	Short report of existing/similar regional/national fellowship programmes (2 pages)	1 week after the contract has started	n/a
Needs Assessment	Needs Assessment questionnaire	1.5 weeks after the contract has started	
	Short needs assessment report (2-5 pages)	3 weeks after the contract has started	Based on the input from selected companies from the private sector as well as other stakeholders.
	Online presentation of the data from the need's assessment to the working group	3 weeks after the contract has started	Online workshop will be organised by the Joint Action SIPS team
Project Proposal	Draft project proposal, budget and Gantt chart	6 weeks after the contract has started	Based on the first proposal draft
Memorandum of Understanding	Draft Memorandum of Understanding between stakeholders	6 weeks after the contract has started	Based on input from needs assessment

			and consultation with stakeholders
Organisation and facilitation of physical fellowship planning workshop	• Presentation of a draft proposal • Workshop notes for a way forward	7 weeks after the contract has started	n/a
Finalisation of project proposal and action plan	• Finalized project proposal • Finalized action plan	9 weeks after the contract has started	
Presentation of final project proposal and action plan to stakeholders and SIPS team	Presentation of the finalised proposal and action plan	By end of the contract	

Period of assignment: from October 2022 until January 2023. The activity focal persons Technical Advisor Support towards Industralisation and the Productive Sectors in the SADC region (SIPS) and Technical Advisor - Support towards Industrialisation and the Productive Sectors in the SADC region (SIPS) Covid-19 relevant Medical and Pharmaceutical Products (CMPP) Value Chain, Antiretroviral Value Chain

Tender requirements

1. Qualifications of proposed individual consultant

1.1 Expert 1:

1.1.1 General qualifications

University qualification (first degree/master's) in education, pharmacy/ biomedical sciences, human resource development or a related field

Professional experience:

- Min 10 years' experience in curriculum development, development and implementation of university programmes and fellowship programmes. Private sector and value chain experience is an advantage.
- Excellent methodological skills (including data analysis, sector and value chain analysis).
- Experience in designing and conducting needs assessments.
- Knowledge / relevant experience with institutions providing in-service labour market skills for the pharmaceutical industry, preferably in Africa/ SADC;
- Networking experience with the academic institutions, private sector actors and support programmes of other development partners.
- Proven track record in capacity development in a public or private sector context; experience in facilitating multi-stakeholder processes.
- Ability to interact in different cultural and professional environments and to create good working relationships at local and international levels.
- Extensive experience drafting project reports in the development sector.

1.1.2 Experience in the region/knowledge

- Work experience in Africa/ SADC.
- Work experience with regional/ international (industry) development organizations (e.g. UNIDO, GIZ, Sida, AFD, USAID) or working with regional inter-governmental communities such as SADC, ECOWAS, EAC) or regional university associations such as SARUA.

1.1.3 Language skills:

- Excellent business language skills in English required
- French language skills are an advantage
- Portuguese language skills are an advantage

2. Specification of inputs

The number of work-man days is up to 30 days

Fee days	**Number of experts**	**Number of days per expert**	**Comments**
• Preparation/debriefing	1	3	
• Implementation	1	27	
Travel expenses	**Number of experts**	**Number of days/nights per experts**	**Comments**
• Per-diem allowance in country of assignment	1	3	This relates to the physical workshop in Johannesburg, South Africa
• Overnight allowance in country of assignment	1	3	This relates to the physical workshop in Johannesburg, South Africa
• Travel costs (train, private vehicle)	n/a	n/a	Only where applicable
Flights	**Number of experts**	**Number of flights per experts**	**Comments**
• International flights	1	1	This relates to the physical workshop in Johannesburg, South Africa
• Domestic flights	n/a	n/a	Only where applicable
Other costs	**Number of experts**	**Amount per experts**	**Comments**
• Flexible remuneration	n/a	n/a	

Calculate your financial bid exactly *in line with the quantitative requirements of the specification of inputs above. There is no contractual right to use up the full days/travel or workshops or budgets. The number of days/travel/workshops and the budgets will be contractually agreed as* ***maximum amounts****. The regulations on pricing are contained in the price sheet.*

Note:

If restrictions are introduced to combat coronavirus/COVID-19 (restrictions on air travel and travel in general, entry restrictions, quarantine measures, etc.), GIZ and the contractor are obliged to make adjustments to their contractual services to reflect the changed circumstances on the basis of good faith; this may involve changes to the service delivery period, the services to be delivered and, if necessary, to the remuneration.