

**Request for Proposal  
for  
Technical services/ Pharmaceutical Products Registration in Chile**

<b>RFP Number:</b>	<b>TFCS-024-107</b>
<b>Issuance Date:</b>	<b>10/10/2024</b>
<b>Deadline for Offers</b>	<b>29/10/2024 - No later than 4:00 pm - Tuesday</b>
<b>For:</b>	<b>Beit Jala Pharmaceutical Company</b>
<b>Point of Contact:</b>	<b>Tharwat Al Shami, <a href="mailto:thalshami@tasdeer.ps">thalshami@tasdeer.ps</a></b>
<b>Location of Work</b>	<b>Beit Jala</b>
<b>Reporting Lines and Managerial Responsibilities:</b>	<b>Mr. Jad AlRifaie, Commercial Director</b>

## **Background**

Beit Jala Pharmaceutical Company in cooperation with Cowater International, acting for the Trade Facilitation and Customs Support Programme (Tasdeer), is soliciting quotations from eligible and responsible firms or individuals for the technical services of Pharmaceutical Products Registration in Chile and seeking a qualified pharmaceutical distributor/ agent. The Trade Facilitation and Customs Support Programme (Tasdeer) is an official program of the UK Foreign Commonwealth and Development Office (FCDO), Contract No. PO10054, and is being carried out in West Bank and Gaza. The objective of Tasdeer programme is to improve the Palestinian private sector competitiveness and the PA's capacity in the fields of trade, customs and import policy regulation and administration. TASDEER programme aims to increase sustainable private sector led economic growth and job creation in the Occupied Palestinian Territory, including the West Bank and Gaza Strip and the PA's fiscal sustainability while ensuring equitable access to increased trade, and improved institutional capacity. Gender Equality and Social Inclusion are main tools and objectives for Tasdeer to ensure the benefits of the programme are equally accessed by the diverse groups of men and women in the supply chain.

Suppliers are responsible for ensuring that their offers are received in accordance with the instructions stated herein. Failure to adhere with instructions described herein may lead to disqualification of a proposal from consideration.

## **Deadlines**

Questions regarding the technical or administrative requirements of this RFP may be submitted by email to [thalshami@tasdeer.ps](mailto:thalshami@tasdeer.ps). Questions must be submitted in writing; phone calls will not be accepted.

Offers must be received no later than 4:00 pm - Tuesday 29/10/2024. Offers received after this date or time will be considered late and will be considered only at the discretion of the Company address.

## Instructions for Submission of Offers

Each offeror must submit its proposal in two separate attachments: The Technical proposal shall be submitted in a separate attachment from the financial proposal.

All offers and related documents must be sent by mail to: [thalshami@tasdeer.ps](mailto:thalshami@tasdeer.ps). Please enter the following in the subject section:

**“Technical services/ Pharmaceutical Products Registration in Chile”**

All offers must be prepared in **English**.

# Terms of Reference

## Company Background

Beit Jala Pharmaceutical Company (BJP) is a multinational pharmaceutical company with a diverse range of high-quality pharmaceutical products with a commitment to the constant development of pure safe and effective pharmaceutical products. The company was first founded in 1969 in Beit Jala, Bethlehem Governorate, and was formerly known as Jordan Chemical Laboratory (JCL). Since 2013, BJP has been registered as public shareholding company with a net capital of 10 million JOD. BJP accumulated knowledge in the industry and built a professional team that ensured continued success and growth through successfully developing and expanding their products offerings. BJP company employs a total of 216 employees.

BJP produces more than 200 types of various pharmaceutical products. The products categories include the following 4 categories: Liquids (Oral Drops, Solutions, Spray, Suspensions, Syrups), Semi-Solids (Creams, Gels, Lotions, Medicated Shampoos, Ointments, Suppositories), Solids (Caplets, Capsules, Powders, Tablets), Sterile Products (Ampoules, Ear and Nose Drops, Ear and Nose Ointments, Eye Drops). BJP conducts its operations in accordance with the international standards and have the following certifications: ISO 9001:2015, ISO 14001:2015, Good Manufacturing Practices (GMP) according to WHO in 2007, JFDA (Jordan GMP) in 2008 and EU GMP in 2011.

BJP sells its products mostly in the local market (78.5% of total sales on average are in local market) and has started to export to Jordan in 2010. BJP now exports to around 11 international markets in MENA region, Europe, Central Africa and Southeast Asia. Exports represent 21.5% of total sales on average. Top export destinations are Jordan, Yemen, Algeria, Iraq, Tunisia, Oman, Macau - Hong Kong, Australia, Bolivia, Equatorial Guinea (country in central Africa).

BJP is working with Tasdeer program to expand and enter new export markets, improving its production capacity, and implementing an export growth plan which entails enhancing the company's creativity and capacity to provide high-quality products to be able to compete in the international markets. BJP is planning to expand its exports to Latin America (LATAM) countries, starting from Chile. One of the key activities required to achieve the desired growth of exports and to enter Chile market is contracting with a qualified local distributor/agent in Chile, & product registrations in Chile. BJP is seeking an external consultant/ consulting firm with deep expertise in pharmaceutical and health products distribution structure & players, & the registration of pharmaceutical and health products in the Chile market to achieve the registration of selected BJP products in Chilean market.

## Objectives of this assignment:

BJP Company with the support of the Tasdeer program will contract an external consultant/ consulting firm (referred to as the consultant) with deep experience in the field of pharmaceutical and health products distribution and registration in Chile market to achieve the following objectives:

- 1- To provide expert guidance and support to BJP company in preparing the required documentation for the specific registration process based on the selected product types.
- 2- To register the selected Beit Jala Pharma items at the relevant authorities in Chile. At least 3 products will be registered.
- 3- To find a local agent/distributor to store & distribute registered items at Point-of-Sales - POSs (pharmacies).

## Scope of the assignment:

To achieve the above objective, the consultant will be responsible to follow and apply all regulatory requirements through undertaking the following tasks in coordination with BJP team:

1. Coordination and following up with the Regulatory Authority. The main regulatory body for health and pharmaceutical products in Chile is the Institute of Public Health (ISP).
2. Identify the types of products to be registered to specify the specific steps and requirements for registration. The ISP oversees the registration of pharmaceuticals, medical devices, disinfectants, and sanitizers.
3. Based on the products types the Registration Process is summarized as follows, the consultant is responsible to specify the requirements of the relevant process and implement it:
  - a. **Pharmaceuticals:** All pharmaceutical products must be registered with the ISP. The process includes submitting detailed documentation about the product, including the product composition, manufacturing process, clinical data, and quality control measures. The consultant is responsible for preparing the required documentation in cooperation with BJP regulatory affairs team. Products under this category/ type might also need to be registered in the Sanitary Registry of Pharmaceutical Products maintained by the ISP. The consultant is responsible for the whole registration process.
  - b. **Medical Devices:** Currently, only certain medical devices like contraceptives, gloves, needles, and syringes require mandatory registration. BJP is willing to register products that are classified as health/ non-pharmaceutical products. The consultant is required to investigate the required documentation and the specific registration process and work on registering these products.
  - c. **Special Procedures:** There are expedited registration procedures for products already approved by major international regulatory bodies like the FDA or EMA, which can significantly shorten the registration time. The consultant needs to check with BJP where their products are already registered and any other factors that might shorten the registration process and time.
4. **Online Registration:** The initial registration process can be conducted online through the ISP's platform.
5. Any other tasks necessary to fulfil the regulatory requirements and achieve the products registration.

## Duration:

This consultancy spans a period of 4 months, starting October 2024 (estimated level of effort is 40 working days).

## Type of the Contract:

Consultancy assignment

## Deliverables:

The Consultant will be expected to achieve the following Deliverables:

#	Deliverable	Due date
1	Products Registration certificates and marketing authorization for 3 products.	By January 2025
2	Singing a distribution contract between Beit Jala Pharma and a local agent/ distributor in Chile.	By December 2024

### Technical proposal requirements

The Technical Volume should describe the offeror's proposed plan for providing the services described in detail. It should demonstrate a clear understanding of the work to be undertaken, and the responsibilities of all parties involved. The plan should include details on equipment, personnel, and if any subcontractors that the offeror will make available to carry out the required activities. The plan should also provide the anticipated delivery schedule details, including an estimated completion date. CVs of the key team members shall also be attached, showing how their skills are fulfilling the needed technical skills for this assignment.

### Qualifications, skills, and professional experience

1. The consultant should demonstrate experience in the Chilean market in specific and LATAM in general, and its regulatory framework.
2. The consultant should demonstrate experience and success stories in similar previous assignments (registration of pharmaceutical and/ or health products in Chile).
3. The consultant is required to have strong knowledge and experience in pharmaceutical products registration procedures and its regulatory authorities in Chile.
4. Preferred to have Arabic speakers among the team to facilitate effective and efficient communication with Beit Jala team.
5. The consultant/ team is expected to have educational degrees relevant to the assignment, such as a minimum of BA degrees in Pharmacy/ Business/ Legal field... etc.
6. Strong analytical and problem-solving skills.
7. Excellent communication, coaching and training abilities.

All electronic copies of documents in the Technical Volume must be in PDF.

**The information contained in the Technical Volume should not contain any cost- or price-related information.**

### Basis for Award

The award will be made to a responsible offeror whose offer follows the RFP instructions, meets the eligibility requirements, and is determined via a trade-off analysis to be the best value based on the application of the following evaluation criteria. The relative importance of each individual criterion is indicated by the number of points below:

#### **Work Methodology and Experience – 70 points** This will include:

- **Technical approach – 30 points:** Responsiveness to the technical specifications and requirements. This will evaluate the offeror's proposed methodology, understanding of the assignment and work plan.
  1. The methodology should demonstrate a comprehensive understanding of the scope of work and firm grasp of the purpose of the required deliverables. (15 points)

2. The Work plan (meeting deadlines and milestones) should include the organization of the tasks illustrating maximization of time and clarity in the assignment of personnel. (15 points)

- **Consultant Team Composition - 20 points:**

This will include an evaluation of the qualifications of the proposed consultants; mix of experience and technical capabilities and assignment of tasks to maximize resources and meet deadlines. Evaluation of the CV's and reference if needed.

- **Consultant Experience – 20 points:** This will include an evaluation of the capacity of the consultant/ consulting firm to perform the scope of work, review of success stories of previous experience in similar jobs and the ability to illustrate past successes in performing similar assignment.

No.	Criterion	Max
<b>1</b>	<b>Technical approach</b>	<b>30</b>
	Detailed Methodology and understanding of the work scope	<b>15</b>
	Work Plan / Meeting deadlines and milestones	<b>15</b>
<b>2</b>	<b>Consultants Composition</b>	<b>20</b>
	Qualified Consultant/ Consultant team CVs for the Specific Tasks	<b>20</b>
<b>3</b>	<b>Consultant Experience</b>	<b>20</b>
	Consultant's/ Consulting Firm's Relevant Experience for the Assignment	<b>20</b>
<b>Total</b>		<b>70</b>

- **Cost Proposal – 30 points:** The overall cost presented in the offer.

- For technical proposals that get a score less than 55/70, the financial offer might not be considered.
- Proposals short-listed based on the highest scores in the technical evaluation may be required to make a presentation, after which the technical scoring will be adjusted for those short-listed proposals.

Best-offer quotations are requested. It is anticipated that the award will be made solely based on these original quotations. However, BJF Company reserves the right to conduct any of the following:

- May conduct negotiations with and/or request clarifications from any offeror prior to award.
- May cancel this RFP at any time.

### Cost Proposal

The Cost Volume must include a unit cost breakdown for every line item described in Annex I, as well as a description of any other costs involved; see the Price Schedule in Annex I for the required format. The offer must preserve and clearly indicate the line-item numbers. All items, services, transportation costs, etc. must be clearly labelled and included in the total price. Prices must be quoted on a lump-sum, all-inclusive basis. No other costs, taxes, and/or fees may be added later.

**Quotations must be fixed price, expressed in USD including VAT/ Income Tax.**

## Payment Method

The payment of the contract is planned on a deliverable basis. The number of payments is in accordance with the required deliverables.

- First payment upon submission of the first deliverables as in ANNEX I.
- Second payment upon submission of the second deliverables as in ANNEX I.

## Annex I: Cost Proposal

Item No.	Item Name	# / Unit	Unit Price (\$)	Total Price (\$)
1.	Products Registration certificates and marketing authorization for 3 products.	3/ products		
2.	Singing a distribution contract between Beit Jala Pharma and a local agent/ distributor in Chile.	Lump sum		
<b>GRAND TOTAL IN USD excluding VAT/ income tax</b>				<b>\$</b>
<b>VAT</b>				<b>\$</b>
<b>Income Tax (5%)</b>				<b>\$</b>
<b>GRAND TOTAL IN USD including VAT/ income Tax</b>				<b>\$</b>

## Validity Period

Offers must remain valid for at least 90 calendar days after the offer deadline.

## Consultant's info:

<b>Total Price in words including TAX/ income tax or VAT:</b>	
<b>Offeror Name:</b>	
<b>Phone Number:</b>	
<b>Address:</b>	
<b>Signature:</b>	