**Pharmacy Quality Control Mission, Jordan**

**- Terms of Reference -**

1. **CONTEXT**
   1. **General context of the program**

La Chaîne de l’Espoir (LCDE) has been working in Jordan since late 2012 to improve access to high quality medico surgical care for vulnerable children. In Jordan, in partnership with a network of national and international health providers, LCDE has developed a medico surgical program aiming at identifying, operating on and ensuring a post-operative follow-up for vulnerable children and young adults in the field of orthopedic and cardiac surgery. To date, several hundreds of children living with congenital heart diseases, orthopedics pathologies, malformations and injuries were operated on.

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JFDA vision stAtement

To excel regionally and globally as a pioneer in the

eld of food, drugs and related materials, so as to

enhance public health and consumer condence.

JFDA mission stAtement

Ensuring food safety and quality, as well as

ecacy, quality and safety of the drugs and related

materials, through the application of control

systems based on the scientic and international

standards, strengthen the cooperation with

partners and increase citizen awareness of proper

handling and use of food and drug.

Legal and Regulatory Update

The Jordan FDA: A culture of quality

and continuous improvement

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ABSTRACT

The Jordan Food and Drug Administration was formally established in 2003 in order to address scientic and

global developments in food & drug control in the Hashemite Kingdom of Jordan. In its rst decade, the JFDA

has embraced its role as a national competent authority for food and drug control, and has become the national

Jordanian umbrella agency empowered to develop and implement unied standards, and lead cooperation and

development programs through bilateral agreements with many national, regional and international bodies.

The JFDA is entitled to exercise all legal actions that are deemed necessary to achieve its goals through setting &

implementing legislations, monitoring & surveillance, and raising the public awareness.

The agency has adopted the user-fee model for both food and drug programs. Fees are paid to both directorates.

All JFDA directorates and units are self-funded).

Importantly, the creation of the JFDA has been essential to the country’s eort towards more eciency and

transparency in medicines regulation and supply, as pharmaceuticals are among the most-regulated products in

the country

* 1. **Context of the pharmacy quality control mission**

LCDE has been working in Al Gardens hospital since 2015 for pediatric cardiac surgery, 2019 for pediatric orthopedic surgery. LCDE selected this hospital based on i) a prequalification assessment on site; ii) a financial and technical assessment. The technical assessment was made through a detailed questionnaire (see Annex 1) completed by all tendering hospitals.

The technical questionnaire completed by Al Gardens hospital (Annex 2) is an integral part of the contract. Al Gardens hospital is responsible for implementing quality insurance measures for its own services and supplies provided by external parties, including in terms of management of pharmaceutical and medical supplies. The contract signed between Al Gardens and LCDE also allows LCDE to carry out or commission audits to verify compliance with its contractual, legislative and regulatory obligations.

The current medico-surgical care has been funded by DG ECHO (European Commission, Civil Protection and Humanitarian Aid) since 2016. As part of the framework partnership agreement signed with DG ECHO, LCDE is accountable for applying specific rules whenever purchasing pharmaceutical and medical supplies, even indirectly i.e. through a partner hospital like Al Gardens, and ensuring their quality (see Annex 3 and Annex 4).

For instance, criteria for the selection of suppliers include:

* respect of WHO principles for the production and handling of medical supplies such as Good manufacturing practice (GMP) and where relevant: Good storage practices (GSP), Good laboratory practice (GLP), Good Clinical Practice (GCP), WHO model quality assurance standards (MQAs), WHO's or the EU's Good Distribution Practices (GDP)
* Ongoing monitoring of the production and quality control activities
* Monitoring of customers’ complaints and remedial follow-up
* Any other recognition ensuring compliance with at least one of the following standards or equivalent standards: United States QS 21 CFR part 820) on quality system regulation, ISO9001/2008 on quality management system ISO9002/1994 on quality assurance in production, installation and servicing

Award criteria refer to the quality of the supplies:

* respect of minimum quality standards (WHO65 principles, GMP, GSP, GDP, GLP)
* Respect of the national drug regulation in the country of destination
* Respect of any intellectual property and patent regulation applicable in the country of operation.

Of note, the Hashemite Kingdom of Jordan established in 2003 the Jordan Food and Drug Administration (JFDA) which is the competent authority for food and drug control and an umbrella agency empowered to develop and implement unified standards as well as exercise legal actions including setting and implementing legislations, monitoring and surveillance and raising the public awareness.

Taking into account this framework, LCDE intends to conduct an assessment of the pharmacy management procedures and their implementation at Al Gardens hospital in order to ensure that pharmaceutical and medical supplies provided in the scope of the current project reach high quality standards meeting its obligations towards all stakeholders (patients and donors in particular).

1. **SCOPE of THE MISSION**
   1. **Objectives of the mission**

General objective: Contribute to enhance the quality of LCDE medico-surgical care for vulnerable children living with cardiac and orthopedic impairments in Jordan and Lebanon.

Specific objective: Assess the pharmacy management and quality control procedures and their implementation at LCDE partner hospital with reference to internationally recognized standards (WHO, EU and other Stringent Regulatory Authorities or equivalent).

Expected results:

* Provide an in-depth analysis of the pharmacy management and quality control procedures at LCDE partner hospital with reference to internationally recognized standards.
* Check and evaluate the actual implementation of procedures set by LCDE partner hospital and described in the technical questionnaire as well as potential gaps.
* Assess the risk related to existing pharmacy management procedures and their implementation for LCDE interventions in pediatric orthopedic and cardiac surgery.
* Provide recommendations to LCDE and its partner hospital (mitigating and improvement measures).

1. **DESCRIPTION OF THE MISSION**
   1. **Consultant(s)’ profile**

* Specialized degree in hospital pharmacy
* Experience in conducting similar assessments is appreciated.
  1. **Service duration and location**

The service duration is estimated to 5 working days in Amman, Jordan, to be organized between in April, May or June 2020.

* 1. **Deliverable**

A detailed reported is expected at the end of the mission including:

* A description of the methodology used for the assessment
* Detailed findings
* Recommendations
  1. **Methodology**
* Review of key procedures and guidelines about pharmacy management and quality control available at Al Gardens.
* Interviews with key informants at LCDE’s partner hospital.
* Observations on site.
* Other methods of assessment and verifications can be suggested by the volunteer

**Annex 1**. Technical questionnaire (template)

**Annex 2**. Technical questionnaire completed by Al Gardens (as part of the framework contract)

**Annex 3**. DG ECHO, Framework Partnership Agreement (FPA) Guidelines, 2015 - SPECIAL PROVISIONS FOR THE PROCUREMENT OF MEDICAL SUPPLIES AND FOOD

**Annex 4.** DG ECHO, Review of Quality Assurance (QA) Mechanisms for Medicines and Medical Supplies in Humanitarian Aid, June 2006.