

MINISTRY OF HEALTH

Supreme Committee for tender No. 1 - 2019

General conditions and guarantees for the supply of Medicines and medical supplies

Article (1) Supply of medicines and medical supplies for human use.

1. Medicine List (1) Central Items (1 / 1) .
2. Medicine List No (2) General Items (1/ 2) .
3. General & special medical devices (1/ 3) .
4. Laboratory and blood bank supplies (1/ 4) .
5. Radiology and Nuclear medicine (1/ 5) .
6. Dental Material (1/ 6) .
7. Orthopedic Material (1/ 7) .

Article (2) Quantities:

Quantities attached are indicative, and the buyer retains the right to request larger quantities or lesser quantities without any increase in prices, The supplier may submit an offer for the entire items or only some of them. The buyer has the right to purchase all the items or some of them the full quantity or only part of it .

Article (3) Participation:

Offers shall be accepted directly from manufacturers or their authorized agents, as well as from local companies whom have valid licenses to practice by law the activity of the supply of medicines, medical supplies and the International manufacturing companies which have invalid registration in Libya , and also the international manufacturing companies which were not registered in Libya and their pharmaceutical products are approved by EMEA or FDA or both, but they should proceed the registration process in MOH Libya in case of awarding in tender and before signing the contract .

Only one distributor must represent the manufacturing company, and he/she has to provide proof of that issued by manufacturer.

Article (4) Respect the terms of the tender:

The bidder has to respect and comply with all conditions mentioned in the texts of this document without any reservation to any term or condition contained in this document.

Article (5) Matching the deals:

The accepted offers must comply with all clauses and conditions listed at this documents including its advertisement and annexes which must be signed and stamped by the bidder as mentioned in article (3)

Soft copy of bids must be sending electronics to Supreme Committee for tender **No. 1/2019** official web site **reg.mhtc.ly** according to dates in table **No;2** in previous Announcement.

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Hard copy bids must be stamped by the company official stamp, and they should be signed either in blue or red color not in black, and delivered to the supreme committee address . A soft copy of the offered bids, exactly typical to the original hard copy.

Bids which do not comply with these requirements will be eliminated.

In case of variation between the hard and soft copy, the offered bids on the original hard copy will be considered. However, the Tender Committee shall have the right to eliminate the offered bid(s) if such variation is detected.

Article (6) Respect of the laws and regulations:

The General Conditions and detailed articles contained in the texts of this document are an integral part of the supply contract, which shall be subject to the contract provisions in all of its aspects and in accordance with the legislation, regulations and laws in force in the **Libyan State**.

Article (7) offer Submission:

The Offer shall include (3) files:

- A. Administrative file.
- B. Financial file.
- C. The technical file.

A. Administrative file shall contain the following :

1. license issued by the specific authorities to practices the activity for local companies and cooperatives .
2. Registration document from the commercial registration office at the economic and trade sector including the registration number for local companies and cooperatives .
3. The agent should have valid statement from the manufacturer empowering him/her to represent the company in all legal matters authenticated by the official authorities .
4. For the sole distributor must have written statement from the company or its agent authorizing him/her exclusivity to tender on their behalf .
5. A certificate approving that he/she is registered in the Chamber of Commerce .
6. Annex. (1) Has to be filled and signed (declaration of acceptance of the tender conditions).
7. Receipt to confirm tender fees payment .
8. Signed declaration to write the statement of Not for Sale (M.O.H) on each box or pack .
9. Registration Certificate issued by the Department of Pharmacy, Medical equipment and supplies at Ministry Of Health for drugs Manufactures and Local companies .
10. Offers will not be accepted unless otherwise accompanied by samples, with sufficient number of samples to carry out three complete tests by the National Center for food and drug control.
11. All requested documents must be submitted in separate file, carrying same numbers and sequence in order to facilitate the inspection and serial.revision

B. Financial file should include the following :

1. The financial annual report for the company enterprise in the country of origin, expressed in their last budget approved by the competent official authority.
2. Official certificate from the country of origin to prove Non-Bankruptcy, any legal or receiver action against the assets of the company.
3. **The financial offers:**
 - For local suppliers; the tender price must be offered in Libyan Dinars and should include the Item price, transports and all other expenses till delivered to the public sector stores W/W and to the Libyan port (C&F)
 - For manufacturing company, the tender price shall be in Euro to the Libya ports (C&F) and to the public store (w/w) .
 - The offer file should include the following (item number - item name - pack size - unit price - quantity as appeared in the tender document - total price) .

The data must be submitted as annex (5) with the documents.

C. The technical file should include the following:

Each offer must be accompanied by technical files requested for each item and should be made into printed copies including the following:

1. Annex No. (5) Data to be filled.
2. **WHO** certificate of pharmaceutical products CPP authenticated by health authorities in the country of origin.
3. A) - (GMP) Certificate for the pharmaceutical manufacture.
B) - (GMP) or ISO 13485 certificates for Medical devices and diagnostics (CEmarketing or FDA approval) .
4. Declaration of the composition of the product active ingredients and additives.
5. Methods of analysis for the raw material and scientific references.
6. Certificate & methods of analysis for final product.
7. Stability study for the final product .
8. Certificate of bioequivalent for the solid and oily pharmaceutical product.
9. Accompanied sample's Certificate of analysis to include (the scientific name - the trade name , pharmaceutical dosage form and batch number, production date and expiry date in the form of (Day / month/ year) .
10. Sufficient number of samples of the final product to carry out three complete tests.

All samples must carry the code number as appeared in the tender document .

The above mentioned samples shall be transferred by the tender committee to the national center for food and drug control .

11. Certificate and methods of analysis for the batch of the samples .
12. Samples must be sent free of charge accompanied with all relevant documents including the packing list of the samples (see annex no.4) for clearance .
13. All samples received shall be the property of the buyer .
14. Samples should be submitted either directly or sent by express post to the address mentioned in the article (no. 9) to the tender committee of tender (1/ 2019).
15. Catalogue number, if any .
16. Method of sterilization

Notes...

The Samples and technical files are essential part for the choice during adjudication therefore; missing any of them will lead to the rejection of the whole offer .

Offers must be prepared as stated in annex (no 5).
However the offers must include details for every item and should not be connected to the content of any other offer, and it will be treated independently. There shall be no adherence to a minimum quantity or value .

Offers prepared in two copies accompanied by all relevant official documents stated in the tender brochure and it should include electronic copy according to the data prepared by the tender committee .

The offer content which consists of administrative file ,financial file ,technical file should every one of them be put separately in an envelop sealed and stamped with red wax .These envelops should be included in a large envelop sealed and stamped with red wax labeled with the tender number and all supplier details; Submitted against receipt to the address mentioned in article (9) .
All information and data on the soft copy should be identical to the hard copy data .

Article (8) Language of contract:

Arabic language is the official language of disclosure and contracting.

Article (9) Submission and delivery of the envelopes:

The envelopes should be delivered to the Supreme Committee of the tender (1 /2019) Of medicine and medical supplies labeled with any of the following numbers (1/ 1- 1/ 2 -1 /3 -1 /4 -1 / 5 -1 / 6 -1/ 7) on the address below

MENISTRY OF HEALTH

Supreme Committee of the tender (1/2019)

ALSHAT ROAD-near CENTRAL BLOOD BANCK /TRIPOLI

Email: info@mhtc.ly

Article (10) Offer validity :

The validity of the offer shall be a period of 18 months starting from the last day of the offers submission however this period could be extended by mutual agreement .

Bids rejected for any reasons have no right to claim refund of fees paid for tender participation neither any form of compensation and the buyer is not obliged to provide any reasons of justification for the rejection .

Offers validity shall be 18 months starts from the date of envelopes opening.

NO offer will be received according to the table 2 in announcing of the tender (1/2019). .

Receipt of tender copy purchase shall be attached to the pages of the offers submitted by the company.

Article (11) The validity of the supplied products :

Products submitted in the tender shall not have shelf life less than two-thirds of its validity of use upon receipt by the buyer.

Article (12) Packaging :

All products must be packed and wrapped in such a way that, the inner and the outer pack ensures the safety of handling , transport and storage conditions, commensurate with the nature of the product taking into consideration the following points :

- A. Products that are affected by heat and humidity shall be kept in temperature and humidity appropriate to the nature of the product and all packs must be attached to them monitors and special cards in Arabic or English, clearly showing change in temperature that may has occurred in any packets during transport and storage.
- B. Light-sensitive materials must be packed in opaque containers.
- C. Supplied materials must arrive to the recipient in good condition, the products sent in containers and must be closed in a manner to ensure detection of any attempt to tamper with or damage them that may be exposed to during transport.

Article (13) providing the goods :

The goods must be supplied according to the specifications set out in Annexes No. (5) and which are entered in the disk supplied to you, such goods must be received in parcels on wooden pallets in containers .

Article (14) labeling :

Each box and parcel must carry the necessary data, which should be clearly written with indelible ink or non erasable in both Arabic and English language as follows: -

- Name and address of the supplier , manufacturer and country of origin .
- Name and address of the buyer in boldface .
- Application number and code of each item as appeared in the tender documents .
- Number of boxes or parcels conform to the packing list (shipping data) .
- The logo of the producing company .
- The number of the items and their names contained in each box .
- Batch number.
- Red crescent logo .
- Each box or pack must show clearly manufacturing and Expiry date of the products and the instructions necessary for handling and storing .
- Each pack or box must carry the sign. (MOH - NOT FOR SALE) .
- Generic name must be written on the box outside and on the inside pack .
- The words (MOH - NOT FOR SALE) should be printed on each glass bottle ,plate - tube Etc.
- In case of products that require immediate preparation (such as powders for the preparation of suspensions, eye drops ... etc.) the information on the bottle must be clarified as follows :
 - 1-The line shows the level of filling after reconstitution, period of use, any other instructions, such as (Shake the bottle before use),The instruction must specify the dose clearly in Weight units or unit measurement

2-The concentration of the drug must be written in abbreviation using international units such as (G) for gram, (MG) for Milligram, (MCG) for the microgram Etc., and these abbreviations Must be made clearly readable specially in case of multiple doses .

3-Name of the company or participatory supplier and his/her commercial registration Numbers .

4-Batch number - Date of manufacture - Expiration date, all of which should be written Clearly on each (strip - bottle - Etc)

Pamphlet : Must be written clearly in Arabic and English language including :

- The generic and commercial names and pharmaceutical form stating the active ingredients and the added substances .
- Type of pack (bottle, tape, etc ...).
- The amount of active ingredient per unit dose, unit pack.
- Storage conditions required.
- Indications and the doses.
- Contraindications.
- Side effects.
- Treatment of poisoning in the case of overdose.
- Methods of administration , use, and precautions for use, all the important instructions for the proper use of the product (such as chewing, injection method Etc.), these data must be written in full and should not be in abbreviation form.

Article (15) Clarity of writing :

The writing of the instructions and signs should be clear, and complete on every unit pack, in particular the name of the item and its concentration, code number and Any warnings for the use of the product safely. Arabic & English languages are necessary

Article (16) Flammable or hazardous products :

With respect to the, flammable or hazardous materials the buyer has to provide the necessary shipping licenses upon receipt of the following documents:

1. The final invoice .
2. The expected shipping date of goods .
3. Name and address of the shipper .
4. Temperature during the transportation or shipping.
5. The supplier provides the buyer with all the necessary information needed it for transport, storage and distribution and any other precautions .
6. The original way bill and other documents must be sent before at least one week from the delivery time of shipment and should avoid the official holidays.

Article (17) Tables and classification :

Classification of the goods must be in accordance with the schedules of each item according to Annex No. (5)(1/1 / 1/2- / 1/3-1/4- 1/5- 1/6-1/7).

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Article (18) Transport conditions :

The supplier must transport pharmaceuticals and medical supplies according to good transporting practices for medical supplies on refrigeration vehicles suitable for the nature of the products .

Article (19) Price ;

Prices stated in the offer:

1-for local suppliers in Libyan Dinar C&F to any Libyan port, and(W/W) to the stores of relevant public sector .

2-for the manufacturer companies in Euro C&F to any Libyan port and if possible (W\W) to the store of relevant public sectors .

Accepted prices should be stable and final and any change is not permitted during contract validity.

In the case of awarding any item to any company and found that the same company marketed the same item at a less price for any other country of the region, the Ministry of Health has the right to bind the company the same less price. and in the case of refusal Ministry of Health may cancel their share of the awarded quantity and purchase the required quantity on their account and loaded with differences in prices (if any) However, Ministry of Health shall consider such violation as negative point on this company profile and take into account negatively against the company at the time of subsequent competitions.

Note: Manufacturers or their authorized agents wishing to register their products of medicines and sterile medical supplies at the Libyan Ministry of Health should take advantage of this opportunity and provide the most suitable prices for the completion of the registration of their products for a period of five years according to the adopted bylaw of registration of products and sources in Libya.

Article (20) Payment Terms :

Payment shall be done by opening letter of credit (L/C) as follows:

- A. 95% payment on presenting the following documents:
 1. invoice certified by the tax authority for local suppliers.
 2. Receiving permission from the recipient.
 3. Certificate of final release.
- B. The remaining 5% shall be released by a letter from a medical supply organization addressed to the bank, The supplier has no rights to call for change terms of payment which has been agreed upon between the two parties for any reason. On other hand any request for extension or amendment during ,the valid period of the L/C all costs shall be borne by the supplier .

Article (21) international Inspection :

Suppliers are subjected to an inspection and they must provide accredited certificate from a professional inspection companies recognized by the first party (medical supply organization)

Article (22) preferences :

If two offers are equal financially and technically, then preference shall be given to the offer which provides free of charge technical assistance in any of the areas of training such as training in warehouse management, sales or maintenance of medical equipment, offering

courses and medical conferences or any other benefits offered by the second party and accepted by the first party.

Article (23): Method of execution of the contract :

The supplier will be notified of the items adjudicated to him/her with quantities that are awarded which in turn subject to the conditions and procedures for implementing the provisions of the contract. The implementation of this procedure shall be in the period specified by the buyer from the last day of the receipt of offers.

The commitment to supply the goods must be in accordance with the contract, which shall be concluded in this regard.

Article (24). Primary insurance :

Each offer must be accompanied by the value of primary insurance no attention will be paid to any offer which is not accompanied by a full primary insurance value of (0.5% half per cent) of the stipulated value of the offer intended to be supplied by the bidder and insurance should be submitted by a certified bank check or letter of guarantee . This value will be refunded in the case of non-awarded items, however this value will be raised to the full insurance value of the ordered items . for the awarded items the period of letter of guarantee will not be less than 60 days after the deadline for the tender period.

The company that have been accepted and awarded, should submit a bank guarantee equivalent to (2%) of the total amount of the contract.

Article (25) The method of delivery of goods :

The supplier shall ensure that the arrival of the goods conform to the invoice .

WE should receive the original bill of loading and the other documents before the arrival of the shipment in a period of time not less than seven working days(7days).

Packs shall be subject to external examination to make sure that the visual absence of any damage or deficiency in the contents .. Etc.

The buyer retains the right to conduct any test or tests to ensure quality of the products received. In case the test results does not conform to the specifications, the supplier shall bears all the responsibilities to cover expenses incurred. The buyer shall claim compensation from the supplier for the full quantities of the batches rejected .

In the event of any differences the buyer shall, apply the terms of the provisions of Article No. (27) and be binding for both parties .

Article (26) Quality Assurance :

The supplier shall be committed to ensure the quality of all materials and products supplied according to the terms and conditions with all technical specifications adopted in this tender.

The products supplied must match the samples provided with the same data specified as in the analysis file annexed to the shipping documents. The supplier must commit him/herself to supply quality goods ensuring the quality of components involved in the manufacture of the final products as well as the quality of final preparation itself. This responsibility shall remain until the end of the expiry date of each product.

Article (27) Penalties :

If the supplier delayed the shipment of goods within the period specified, in the agreement whole or in part, the supplier shall pay a penalty of delay of 2% (two percent) for each week of delay of the value of the quantities of the goods delayed, which reaches to a maximum of up to 10% (ten percent) of the same value, and inability for the implementation of the orders, buyers are entitled to the following penalties:

- A. Call for another company, to supply the goods at the same price as the original supplier prices, the supplier shall bear at his own expense the price difference and any other expenses arising there from .
- B. Confiscation of insurance warranty and cancelling the name of the company from the register of suppliers, if does not comply with the condition of paragraph (a) of this article .

Article (28): Cancellation of the contract :

In case of breach of terms of the contract by the supplier or fails to perform his/her contractual duty, the buyer will inform the supplier with that and shall demand from him/her to abide by and fulfill its obligations within thirty (30) days from the claim date . the buyer shall consider the following :

1. In case of the failure of the supplier to fulfill his/her obligations within thirty days. The buyer retains the right to cancel the contract in accordance with the legislation in force in the LYBIAN STATE.
2. The supplier have no right to object to the buyer to cancel the contract or claiming for any damage as a result of negligence or failure to perform his/her duty as stated in the contract including the confiscation of the insurance warranty and the signing of the final delay fines.

Article (29): Disputes

It Is not permitted to challenge or appeal against the results of the tender adjudication award whatever the reasons and in the event of any disputes for reasons other than the award between the parties . The dispute will be settled amicably , and if conflicts in this way can not be settled and reaches to a dead end, the dispute will be referred to the Libyan courts. The only party that has the right to settle such disputes.

Annex (1)
Tender (2019 /1)
Adoption of the acceptance of tender conditions

I here by declare that I accept the tender conditions :

1. Company Name :
2. Address :
.....
3. The legal form of : (company - participatory - Agent).....
4. Registration number..... Date of registration.... /... /...place of registration :
.....
5. The origin of products:
6. The names and attributes of employees authorized to sign on behalf of :
 - A.
 - B.
 - C.
7. The function and name of the signatory :.....
.....
8. I hereby acknowledge that in case of cancellation of the contract or in the case of errors of implementation that the company will adhere to the requirements of the laws in force in LYBIAN STATE including the confiscation of the final deposit and the signing of demurrage.
9. Assure that the products offered are not of Israeli origin .
10. For the implementation of this contract I pledge to maintain the laws and regulations in force in LYBIAN STATE
11. I pledge to respect all the conditions contained in the brochure, the detailed conditions and guarantees which are the basis of the tender.

Name and title of the signatory:.....

Signature:

Date:

Stamp:

Annex (2)
Tender (2019 /1)
Supplier and product data

1. The supplier name:
2. Manufacturer:
3. Nationality of the factory:
4. The legal status of the bidder: (company - participatory -agent)
5. Full address:.....
6. Item number:
7. Specifications:
8. The brand name
9. Number of samples:
- 10.Expiry date.....
- 11.Place of manufacture:
- 12.Pack size.....
- 13.a) Unit price until the public stores
-
- b) Unit price o the ports of STATE OF LYBIA
-
- 14.Any other information:

Name and title of the signatory:

Signature:

Date:

Stamp

Annex (3)
Tender (2019 /1)
the authorization of signatory

I, the undersigned:

Family name:.....

First Name:

Position:

Headquarters Address of the company's.....

Authorize:

full Name:	full Name:
Signature:	Signature:
Position:	Position:

To sign all contracts and documents with the buyer

Name and title of the signatory:

Signature:

Date:

Stamp:

ملحق رقم (4)

Annex (4)

عطاء 2019/1

جدول المعلومات الخاص بالعينات

Data of samples

المستندات المرفقة Document no (1 او 2)	رقم العينة Sample no	الاسم الجنييس Generic/name	الاسم التجاري Trade name	الشكل الصيدلاني والتركيز Dosage form/strength	رقم البند بمراسة العطاء Code no

Note : please specify how the documents to be delivered :

1. These documents attached with the offer file.
2. These documents sent with Sample on fast mail.

Signature:

Date :

Stamp :

ملحق رقم (5)
Annex (5)

عطاء (2019 /1)
Tender (2019 /1)

الرقم الاشاري Item Code	مواصفات البند Item Specifications	الكميات المطلوب Quantity Required	وحدة العبوة Unit Pack	سعر القطعة Piece/price	السعر الإجمالي Total Price	الفصنع Manufacturer	مكان التصنيع Site of Production	مدة الصلاحية Shelf Life	عدد الوحدات بالعبوة Unit/Pack	التسليم Delive Tim

Name : الاسم
Signature : التوقيع
Position : الوظيفة
Date : / / 2019 التاريخ : م 2019 / /
Stamp : الختم

..... الختم: