

fThe Standard Documents of tender to specialist Sectors Buying the Medicine

Contracting Entity: Ministry of Health / Environment / The
State Company For Marketing Drugs
Medical Appliances (kimadia)

Project Reference/Tender: Contract For The Supply of
medicine will arranged on the recent balance

The Project Name/Tender: Med 2 /2019/

Title of the Task: buying the medicine

Date: issued in date (day)... .. 24... / 1 / 2019.



The Standard Documents of tender to specialist Sectors

General Tender Buying the Medicine

Tender: Med 2 /2019

Reference Tender: recent Iraqi Federal Budget

Date: / 24/1 /2019

Invitation for Bids (IFB)

Tender: General Tender to Buying the Medicine

Tender No.: Med 2/2019 on the recent Iraqi Federal Budget

IFB Number: 2.....

1. The Ministry of Health / Environment / The State Company For Marketing Drug AND Medical Appliances (kimadia) invites the a bidders qualified to present the tenders that sealed & signer for contracting on supplying of medicine
 2. will be adoption measures of public bidding in the process of tender where allowed to take part of all bidders from countries eligible legally as specified in the document of bidding.
 3. Interested eligible bidders may obtain further information's from Ministry of Health / Environment / The State Company For Marketing Drug and Medical Appliances (kimadia)/ **Drug Media Department& the Public Relations-** 5th floor , position of MOH (Ministry of Health), E-mail (dg@kimadia.iq) & Kimadia website is (WWW.kimadia.iq) and inspect the bidding documents at the address given below from (8:30 AM) to (2:30 PM) at Baghdad time.
 4. Bidders must meet the requirements of qualifications including: the legal, technical and financial requirements as mentioned in Bidding Document. A margin of preference for the pharmaceutical will be adopted from suppliers/ national factories goods . Additional details shall be specified in the Bidding Documents (see the clause(30) priority national from the Instructions To Bidders& clause (30) from Bid informations sheet.
 5. the interested bidders could purchase the complete set of Bidding Documents in English or Arabic Language upon submission of a written application to the address below and after payment of a non-refundable fee with lump sum as follows:
 - a- (1.000.000) one million Iraqi Dinar of the tender that less than (1.000.000) Dollars .
 - b- (2.000.000) two million Iraqi Dinar for the tender that more than (1.000.000) Dinar.Otherwise the offer will be neglected.
- The way of payment this duty will be cash & the Bidding Document will be sent as state in ITB (Instruction To Bidders) & the bidder who is previously participated in the re-announced bid to submit the previous purchasing receipt with the tender documents
6. Announcement date of this tender will be on 24 / 1 /2019 and The date of conference convening will be on 11 / 2 /2019 for responding the inquire of the participants against the tender.

Bids must be delivered at or before the end of formal work on { 17 / 2 / 2019}. The late bids will be rejected. Bids will be opened in the presence of the bidders' representatives who choose to attend in person at the address below .

The date of opening the tender will be the day after closing date in Kimadia and in publicly form.

. All bids must be accompanied by a Bid Security at ratio 1% from the estimated cost on condition issued from Iraqi dependable bank according to report issued from the Iraqi central bank for the bank financial performance & it depend on :

a- the primary insurance (Bid Bond) for the tender's applicant will not be accepted unless they are inform of guarantee letter or legalize check or svthj & the swift of a guarantee letter or direct bond are not accepted.

b- Bid Bond should submit by the bidder or any of the share holders of the company or companies participate under contract for the benefit of contracting party as mentioned in attached sample in Bidding Forms/part 4th.

c- Public companies exempt from submitting the bid bond & letter of guarantee good execution stipulated by instruction of implementation the contracts (no.2) year 2014.

d- the bond issued from company which contracted with it or with its legal authorized for issuing the bond under formal & certified authorization.

e- the submitting of bond should attached with letter of legalized issuing (private & secret) send to Ministry of Health / Environment / The State Company For Marketing Drug Medical Appliances (kimadia) by the bank who issued the bond.

f- the bond should not conditional & for the favor of The Ministry of Health / Environment / The State Company For Marketing Drug Medical Appliances (kimadia)

g- the bond must issued by two languages (Arabic & English).

h- the primary insurance will be confiscated for who to be the successful upon his abstain for signing the contract after the notification with awarding matter & all other legal procedures will be taken against him that indicated in these instructions & confiscate the bid bonds for those who referred to him the tender when withdraw its bid during the period of validity after the closing of tender or refused correction on his calculations mistakes in tender & its reflection or awarding decision & take legal actions set forth in the instructions of implementation the Government contracts against him.

i- the duration of validity of bid bonds be valid until after the end of validity tender specified in the documents of tender.

7. The address(es) referred to above is Baghdad/bab-Almadhm Ministry of Health / Environment / The State Company For Marketing Drug Medical Appliances (kimadia)/6th floor/Financial Dept. to submit the bid bond or Receipt & Opening the offers to submit the tenders

Tel.4157667, Mobil:707705419074, switchboard:8,7,5,4158401 (switchboard with 4 line)

Contracting Entity The Ministry of Health / Environment / The State Company For Marketing Drug Medical Appliances (kimadia) **Contracting Authority:** PH.MUDHAFAR ALI ABBAS
Title: Director General of The State Company For Marketing Drug Medical Appliances (kimadia)
Signature: { signed }



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MED/2/2019
لتوفير احتياج عام 20٢٠

- ☒ *All human products must be of human recombinant origin wherever these are available in the markets.*
- ☒ *For oral solution it is preferable: Syrup then Suspension and then Elixir*
- ☒ *Caution To be written if the products contain metabisulphite as following (Caution: this product contain metabisulphite may cause broncho spasm in atopic & Asthmatic subjects)*
- ☒ *It doesn't matter of all tablets that approved in the national list as scored tab to be plain tab (Not scored).*
- ☒ *The measuring unit of medical milk powder weight is 400gm up to 1000gm (as upper limit)*
- ☒ *لا تزيد نسبة الكحول الموجودة في الشرابات (بشكل عام) عن 10% N.M.T.*
- ☒ *فيما يخص شرابات الاطفال.. يفضل بدون كحول أو بنسبة ضئيلة 5% N.M.T.*
- ☒ *يجب استخدام soft gelatin Cap لمستحضرات (Oily prep)*
- ☒ *يجل الغاز الدافع CFC – free (HFA 134a) محل CFC.*
- وحدة قياس الحليب الطبي (بودرة) باعتماد الوزن هي ٤٠٠ غم لغاية ١٠٠٠ غم كحد أعلى*

note: Trade name is mentioned as an Example only and not limited to the trade name mentioned beside the item.

ملاحظة: ان الكلفة التخمينية هي للتعينة اما الاحتياج الكلي فهو للوحدة الواحدة
Note : The estimated cost is per packing size while the total need is for unit dose

NO	National code	Item	احتياج ٢٠٢٠	Packing	Mean brand Price	70% of mean price	45% of mean price	25% of mean price
1	06-E00-014	Fludrocortisone acetate 0.1mg Tablet	55500	100 tab	6.313	4.42	2.84	1.58
2	06-J00-010	mecasermin (recombinant human insulin - like growth factor - 1 rhI GF-1)Increlex inj mecasermin 10mg/ml (4 ml vial)	450	4ml vial	756.25	529.38	340.31	189.06

3	08-H00-016	Fibrinogen concentrate(Human):- Lyophilized powder for reconstitution 900 mg to 1300 mg for reconstitution with 50 ml of sterile water for injection-For Treatment of acute bleeding episodes in patients with congenital fibrinogen deficiency including afibrinogenemia & hypofibrinogenemia Not indicated for dysfibrinogenmia. ضرورة توفر الفحوصات المختبرية يحدد صرف هذه المادة في مراكز الامراض النزفية	530	1gm vial	425	297.50	191.25	106.25
4	09-AD0-023	calcitriol (1, 25 Dihydrocholecalciferol)(D3) 250 nanogram capsule	16500	100 cap	22.55	15.79	10.15	5.64
5	09-AD0-024	calcitriol (1, 25 Dihydrocholecalciferol)(D3) 1 mcg / ml injection (1 ml ampoule)	20	1ml ampoule	4.348	3.04	1.96	1.09



6	09-CD0-001	Anhydrous Sodium acid phosphate Anhydrous 1.936g+Sod.bicarbonate 350mg+Pot.bicarbonate 315mg equivalent to Phosphorous 500mg+Sod.468.8mg(20.4mmol Na+)+Pot.123mg(3.1mmol K+) Effervecent Tablet	10050	20 tab	4.1125	2.88	1.85	1.03
7	09-Ebh-001	milk formula for phenyketoneuria (PKU) patients for age (from birth-1year) Phenylalanine free.	5550	400 gm	49.652322	34.76	22.34	12.41
8	09-Ebh-002	milk formula for phenyketoneuria (PKU) patients for age(above1 - 3years) Phenylalanine free.	7800	500 gm	36.166	25.32	16.27	9.04



9	09-Ebh-003	milk formula for phenyketoneuria (PKU) patients for age (above3 - 8)year Phenylalanine free.	8700	500 gm	149.480165	104.64	67.27	37.37
10	09-Ebh-004	milk formula for phenyketoneuria (PKU) patients for age (8years and above) Phenylalanine free	1890	500 gm	126.201494	88.34	56.79	31.55
				30*27.8 gm sachet	406.7688	284.74	183.05	101.69



11	09-Ebi-001	milk formula for maple syrup urine disease (MSUD) patients for age (0_1) year Leucine,Isolucine and Valine free.	2000	400 gm	54.633766	38.24	24.59	13.66
12	09-Ebi-002	milk formula for maple syrup urine disease (MSUD) patients for age (above1 year) Leucine,Isolucine and Valine free	1100	500 gm	45	31.50	20.25	11.25
13	09-Ebj-001	milk formula for tyrosinemia for age (from birth-1year) phenylalanine,tyrosine free	500	400 gm	54.633766	38.24	24.59	13.66



14	09-Ebj-002	milk formula for tyrosinemia patients for age (above 1 year) phenylalanine,tyrosine free	100	500 gm	45	31.50	20.25	11.25
15	09-Ebk-002	milk formula for Homocystineuria patients for age (above 1year) Methionine free	150	500 gm	137.932942	96.55	62.07	34.48
				30*24gm sachet	292.40192	204.68	131.58	73.10

16	09-Ebl-001	milk formula for glutaric acid uria patients for age (from birth_ 1 year) lysine and tryptophan free	400	400 gm	54.633766	38.24	24.59	13.66
17	09-Ebl-002	milk formula for glutaric acid uria patients for age (above 1 year) lysine and tryptophan free	500	500 gm	137.932942	96.55	62.07	34.48
18	09-Ebn-001	• milk formula for Isovaleric acidemia patients suitable (from birth – 1year) Leucine free	600	400 gm	83.33	58.33	37.50	20.83

19	09-Ebn-002	<ul style="list-style-type: none"> • milk formula for Isovaleric acidemia patients suitable (above 1year) Leucine free 	300	500 gm	137.932942	96.55	62.07	34.48
20	09-Ebo-001	milk formula for methylmalonic academia / propionic acidemia patients suitable from birth. Methionine,Threonine, and Valine free	1260	400 gm	54.633766	38.24	24.59	13.66
21	09-H00-001	Mercaptamine (Cysteamine) as Bitartrate 50mg capsule (For nephrotic cystinosis)	176000	100 cap	153	107.10	68.85	38.25



22	09-H00-002	Mercaptamine (Cysteamine) as Bitartrate 150mg capsule (For nephrotic cystinosis)	139000	100 cap	405	283.50	182.25	101.25
23	09-H00-004	Laronidase 100 Untit / ml (5ml vial)	2200	5ml vial	792	554.40	356.40	198.00
24	09-H00-006	Zinc acetate 25 mg capsule	85000	250 cap	315	220.50	141.75	78.75



25	09-H00-008	Nitisinone (NTBC) 2 mg capsule or tab	2500	60 cap	705	493.50	317.25	176.25
26	09-H00-011	alglucosidase alfa 50 mg vial I.V. infusion	750	1 vial	630	441.00	283.50	157.50
27	09-H00-013	Mercaptamine (Cysteamine) 0.55 % eye drop	2600	5ml eye drops solution of 0.55%	1000	700	450	250



28	09-H00-017	L . carnitine : oral pediatric solution 300 mg /ml (30 %) (20 ml)	3390	20 ml	26.25	18.38	11.81	6.56
29	09-H00-018	L . carnitine 200 mg / ml (5ml ampoule)I.V , I.M	5020	5ml amp	14.875	10.41	6.69	3.72
30	09-H00-019	Miglustat 100 mg capsule	3400	84 cap	4917.7	3,442.39	2,212.97	1,229.43

31	09-H00-020	<p>imiglucerase. I.V infusion 400 unit/ vial ج/١٠٤٦ ج/١٠٤٥ لقرار الجلسة ١٠٢٩ وبعد استضافة اللجنة العلمية للأمراض "لاحقا مفصلة تقرر اقرار النادرة واستعراض الحقائق العلمية بصورة (imiglucerase & Velaglucerase) العقاريين بقائمة الامراض النادرة اللجنة العلمية للأمراض النادرة ونحول لعدد المرضى والحالات "تحديد كمية الاحتياج من كل مادة وفقا للحقائق العلمية مع الزام "الجديدة والقديمة وفقا المسجلة الشركات المجهزة بتوفير الفحوصات اللازمة لاثبات التشخيص والمتابعة لاستجابة المرضى وعدم التلؤ في ارسال النتائج وحسب ما كيماديا المرقم ١٢٩٦ في بموجب كتاب "جاء بمحضر اللجنة انفا ٢٠١٨/٩/٤ .</p>	11700	1 vial	1776	1,243.20	799.20	444.00
32	09-H00-023	<p>Betaine (anhydrous) powder 180 gm or300gm can</p>	70	180 gm	433.75	303.63	195.19	108.44

33	09-H00-024	galsulfate concentrate for I.V injection 1 mg\ml (5ml-vial)	5100	5ml vial	1227.5	859.25	552.38	306.88
34	09-H00-028	Sapropterin dihydrochloride 100 mg tab	23000	30 soluble tab	746.525	522.57	335.94	186.63
35	09-H00-029	Carglumatic acid 200 mg tab	2100	5 tab	603	422.10	271.35	150.75



38	15-B00-095	interferon gamma-1B100mcg/0.5mlvial for chronic granulomatase disease	540	6 vial	585	409.50	263.25	146.25
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**PART 1
BIDDING PROCEDURES**

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PART 1

BIDDING PROCEDURES Section I. Instructions to Bidders Instructions to Bidders A. INTRODUCTION

1. Scope of Bid

1.1 The Contracting Entity, as specified in the **Bid Data Sheet (BDS)** and in the **Special Conditions of Contract (SCC)**, invites bids for the supply of Goods (pharmaceuticals, vaccines, contraceptives, or medical equipment) as specified in the **Bid Data Sheet** and **Schedule of Requirements**.

1.2 Throughout these bidding documents, the terms “writing” means any typewritten or printed communication, including letters delivered by hand, telex, and facsimile transmission, and “day” means calendar day. Singular also means plural.

2. Fraud and Corruption

2.1 The Contracting Entity requires that bidders, suppliers, and contractors, their subcontractors and their staff shall observe the highest standard of ethics during the procurement and execution of contracts. In pursuance of this policy, the Contracting Entity:

(a) defines Fraud and Corruption as per the relevant applicable Iraqi laws. For the purpose of this provision, the Contracting Entity will be guided further by the definition of the terms as set forth here below:

(i) “corrupt practice” is the offering, giving, receiving or soliciting, directly or indirectly, of anything of value to influence improperly the actions of another party;

(ii) “fraudulent practice” is any act or omission, including a misrepresentation, that knowingly or recklessly misleads, or attempts to mislead, a party to obtain a financial or other benefit or to avoid an obligation;

(iii) “collusive practice” is an arrangement between two or more parties designed to achieve an improper purpose, including to influence improperly the actions of another party;

(iv) “coercive practice” is impairing or harming, or threatening to impair or harm, directly or indirectly, any party or the property of the party to influence improperly the actions of a party;

(v) “obstructive practice” is

(aa) deliberately destroying, falsifying, altering or concealing of evidence material to the investigation or making false statements to investigators in order to materially impede a Contracting Entity’s investigation into allegations of a

- corrupt, fraudulent, coercive or collusive practice in accordance with the applicable Iraqi laws; and/or threatening, harassing or intimidating any party to prevent it from disclosing its knowledge of matters relevant to the investigation or from pursuing the investigation; or
- (bb) acts intended to materially impede the exercise of inspection and audit rights provided for under Sub-Clause 2.1 (d) below in accordance with the applicable Iraqi laws.
 - (b) will reject the Bid if it determines in accordance with the applicable Iraqi laws that the bidder recommended for award has, directly or through an agent, engaged in corrupt, fraudulent, collusive, coercive or obstructive practices in competing for the contract in question;
 - (c) will sanction a firm or individual in accordance with the applicable Iraqi laws, including declaring ineligible, either indefinitely or for a stated period of time, to be awarded contract if it at any time it is determined by the competent Iraqi authorities that the firm has, directly or through an agent, engaged in corrupt, fraudulent, collusive, coercive or obstructive practices in competing for, or in executing, a Contracting Entity financed contract; and
 - (d) will have the right to inspect the accounts and records and other documents relating to the bid submission and contract performance of bidders, suppliers, and contractors and their sub-contractors and to have them audited by the competent authorities in accordance to the applicable Iraq Laws.

B. THE BIDDING DOCUMENTS

3. Content of Bidding Documents	<p>3.1 The Bidding Documents are those stated below and should be read in conjunction with any addendum issued in accordance with ITB Clause 5:</p> <ul style="list-style-type: none">Section I. Instructions to Bidders (ITB)Section II. Bid Data Sheet (BDS)Section III. Evaluation and Qualification CriteriaSection IV. Bidding FormsSection V. Eligible CountriesSection VI. Schedule of RequirementsSection VII. General Conditions of Contract (GCC)Section VIII. Special Conditions of Contract (SCC)Section IX. Contract Forms
4. Clarification of	<p>3.2 The "Invitation for Bids" does not form part of the Bidding Documents..</p> <p>4.1 A prospective Bidder requiring any clarification of the</p>

Bidding Documents

Bidding Documents shall contact the **Contracting Entity** in writing or by cable (the term “cable” is deemed to include electronic mail, telex, or facsimile) at the **Contracting Entity’s address indicated in the Bid Data Sheet**. The **Contracting Entity** will respond in writing to any request for clarification received no later than **fourteen (14) calendar days** prior to the deadline of submission of bids. Copies of the Contracting Entity’s response shall be sent to all prospective Bidders who have purchased the Bidding Documents, including a description of the inquiry but without identifying its source.

4.2 In order to maintain the confidentiality of the procedures during the Bid advertisement period, information about the names and addresses of Bidders and their agents shall not be disclosed to any unconcerned party.

5. Amendment of Bidding Documents

5.1 At any time prior to the deadline for submission of bids, the **Contracting Entity** may amend the Bidding Documents by issuing Addenda.

5.2 Any addendum thus issued shall be part of the Bidding Documents pursuant to ITB Sub-Clause 3.1 and shall be communicated in writing to all purchasers of the Bidding Documents and will be binding on them. Bidders are required to immediately acknowledge receipt of any such amendment, and it will be assumed that the information contained in the amendment will have been taken into account by the Bidder in its bid.

5.3 To give prospective Bidders reasonable time in which to take the amendment into account in preparing their bids, the **Contracting Entity shall extend**, at its discretion, the deadline for submission of bids, in which case, the Contracting Entity will notify all Bidders by cable confirmed in writing of the extended deadline. The Contracting Entity shall advertise any extension of the deadline for bid submission in same media as was done for the Short Procurement Notice of this tender.

C. PREPARATION OF BIDS**6. Eligibility**

6.1 This bidding process is **open to qualified firms from any Eligible country as specified in Section - V. The Firms may be excluded from bidding if:**

- (a) the firms have a conflict of interest. All Bidders found to have a conflict of interest shall be disqualified. A Bidder may be considered to have a conflict of interest with one or more parties in this bidding process, if :
- (1) they have a controlling partner in common; or
 - (2) they receive or have received any direct or indirect subsidy from any of them; or
 - (3) they have the same legal representative for purposes of this bid; or

- (4) they have a relationship with each other, directly or through common third parties, that puts them in a position to have access to information about or influence on the bid of another Bidder, or influence the decisions of the Contracting Entity regarding this bidding process; or
- (5) a Bidder submits more than one bid in this bidding process, either individually or as a partner in a joint venture. This will result in the disqualification of all such bids. However, this does not limit the participation of a Bidder as a subcontractor in another bid or of a firm as a subcontractor in more than one bid. or
- (6) a firm has been engaged by the Contracting Entity - or a Purchasing Agent that has been duly authorized to act on behalf of the Contracting Entity - to provide consulting services for the preparation of the design, specifications, and other documents to be used for the procurement of the Goods described in these Bidding Documents. or

6.2 Staff of the Government and Public Sector cannot participate directly or indirectly in Public Tenders

6.3 A firm declared Black listed or Suspended by the competent authorities shall be ineligible to bid during the period of time determined. A list in this regard is available on the website **specified in BDS**.

7. Documents Establishing Eligibility of Goods and Services and Conformity to Bidding Documents

7.1 Pursuant to ITB Clause 12, the Bidder shall furnish, as part of its bid, documents establishing, to the Contracting Entity's satisfaction, the eligibility of the Health Sector Goods and Medical Equipment and services to be supplied under the Contract.

7.2 The documentary evidence of the eligibility of the Goods and Services shall consist of a statement in the Price Schedule of the country of origin of the Goods and Services offered that shall be confirmed by a certificate of origin to be issued at the time of shipment and approved by the competent Iraqi authorities in the country of origin; such an approval is waived for items of certified Arab origin.

7.3 The documentary evidence of conformity of the Goods and Services as **specified in Section VI Schedule of Requirements** may be in the form of literature, drawings, and data and shall consist of:

- (a) a detailed description of the essential technical and performance characteristics of the Goods;
- (b) an item-by-item commentary on the Contracting Entity's Technical Specifications demonstrating substantial responsiveness of the Goods and Services to those specifications, or a statement of deviations and exceptions to the provisions of the Technical

- Specifications;
- (c) any other procurement-specific documentation requirement as stated in the **Bid Data Sheet**.
- 7.4 Unless the **Bid Data Sheet** stipulates otherwise, the Goods to be supplied under the Contract shall be registered with the competent authority in Iraq. A Bidder who has already registered its Goods by the time of bidding should submit a copy of the Registration Certificate with its bid. Otherwise, the successful Bidder, by the time of Contract signing, shall submit to the Contracting Entity either:
- (a) a copy of the Registration Certificate of the Goods for use in the Iraq.
- OR, if such Registration Certificate has not yet been obtained,
- (b) evidence establishing to the Contracting Entity's satisfaction that the Bidder has complied with all the documentary requirements for registration as specified in the **Bid Data Sheet**.
- (c) it is permitted to take exception by the health minister.
- 7.4.1 The Contracting Entity shall at all times cooperate with the successful Bidder to facilitate the registration process within Iraq. The agency and contact person able to provide additional information about registration are identified in the **Bid Data Sheet**.
- 7.4.2 (a): If the Goods of the successful Bidder have not been registered in Iraq at the time of Contract signing, then the Contract shall become effective upon such date as the Certificate of Registration is obtained.
- (b) : minister of health has the right to take exception for the winner bidder from submitting registration certificate at the time of signing contract.
- 7.5 For purposes of the commentary to be furnished pursuant to ITB Sub-Clause 7.3 (b) above, the Bidder shall note that standards as well as references to brand names designated by the Contracting Entity in its Technical Specifications are intended to be descriptive only and not restrictive. The Bidder may substitute alternative standards, brand names, and/or catalog numbers in its bid, provided that it demonstrates to the Contracting Entity's satisfaction that the substitutions ensure substantial equivalence to those designated in the Technical Specifications.
- 8.1 The Bidder shall provide documentary evidence to establish to the Contracting Entity's satisfaction that
- (a) the Bidder has the financial, technical, and production capability necessary to perform the Contract, meets the Qualification Criteria specified in **Section III Evaluation and Qualification Criteria**.
- (b) in the case of a Bidder offering to supply Goods,

8. Qualifications of the Bidder

identified in the Bid Data Sheet, that the Bidder did not manufacture or otherwise produce, the Bidder has been duly authorized by the manufacturer or producer of such Goods to supply the Goods in Iraq as per format of Manufacturer's Authorization Form in Section IV;

- (c) in the case of a Bidder who is not doing business within Iraq (or for other reasons will not itself carry out service/maintenance obligations), the Bidder is or will be (if awarded the Contract) represented by a local service/maintenance provider in Iraq equipped and able to carry out the Bidder's warranty obligations prescribed in the Conditions of Contract and/or Technical Specifications; and
- (d) the Bidder meets the qualification criteria listed in the **specified in Section III Evaluation and Qualification Criteria**(see additional clauses of **Section III** for pharmaceuticals, vaccines and medical equipment).

- The companies should be submitted a letter of no objection issued by the general authority for taxes when participating in the tenders announced .

9. One Bid per Bidder
10. Cost of Bidding

- 9.1 A firm shall submit only one bid as an individual Bidder and in accordance with ITB 6.1.a.
- 10.1 The Bidder shall bear all costs associated with the preparation and submission of its bid, and the Contracting Entity will in no case be responsible or liable for those costs, regardless of the conduct or outcome of the bidding process.

11. Language of Bid

- 11.1 The bid, **as well as all correspondence** and documents **relating to** the bid exchanged by the Bidder and the **Contracting Entity**, shall be written in the language specified in the **Bid Data Sheet**. Supporting documents and printed literature furnished by the Bidder may be in another language provided they are accompanied by an accurate translation of the relevant passages **in the language specified**, in which case, for purposes of interpretation of the Bid, the translation shall **govern**.

12. Documents Constituting the Bid

- 12.1 The bid submitted by the Bidder shall comprise the following:
 - (a) duly filled-in Bid Form and Price Schedule, in accordance with the forms indicated in Section IV;
 - (b) original form of bid security in accordance with the provisions of ITB Clause 17 (Bid Security);
 - (c) written power of attorney authorizing the signatory of the bid to commit the Bidder;
 - (d) documentary evidence establishing to the Contracting Entity's satisfaction, and in accordance with Documents required as per ITB Clause 7 and that they conform to the Bidding Documents;

(e) documentary evidence establishing to the Contracting Entity's satisfaction, and in accordance with Qualification of the Bidder as per ITB Clause 8 that the Bidder is qualified to perform the Contract if its bid is accepted.

(f) Bidder's voucher of purchasing the Bidding Document.

(g) if applicable as per ITB Sub-clause 8.1(b), Manufacturer's Authorization Form as per format in Section IV

(h) **Bidder's voucher of purchasing the Tender Document.** Any other required document shall be **specified in the Bid Data Sheet**

13. Bid Form

13.1 The Bidder shall complete the Bid Form and the appropriate Price Schedule **provided under Section – IV** indicating the Goods to be supplied, a brief description of the Goods, their country of origin, quantity, and prices.

14. Bid Prices and Discounts

14.1 The Bidder shall quote their prices as per format of Price Schedule provided under **Section IV** all the specified components of prices shown therein. All the columns shown in the Price Schedule should be filled up as required. If any column does not apply to a Bidder, same should be clarified as "NA" (means Not Applicable) by the Bidder.

14.2 The quoted prices for goods offered for domestic goods or goods of foreign origin located in Iraq shall be quoted in the Price Schedule given under **Section IV** (2). The quoted prices for goods to be imported from abroad, shall be quoted in the Price Schedule given under **Section IV** (3).

14.3 While filling up the columns of the Price Schedule, the following aspects should be noted for compliance:

14.3.1 For domestic goods or goods of foreign origin located in Iraq, the prices under column 5 in the corresponding Price Schedule in at **Section IV** (2) shall be entered separately in the following manner:

Column 5(a): The price of goods, quoted ex-factory/ ex-showroom/ ex-warehouse/ off-the-shelf, as applicable, including all taxes and duties like Sales Tax, Custom Duty, Excise Duty etc. already paid or payable on the components and raw material used in the manufacture or assembly of the goods quoted ex-factory etc. or on the previously imported goods of foreign origin quoted ex-showroom etc. This will also include charges towards Packing & Forwarding,

Column 5(b): Any sales and other taxes and duties like Excise Duty, Sales Tax etc., which will be payable on the goods in Iraq if the Contract is awarded;

Column 5(c): Inland Transportation, Insurance, Loading/ Unloading and other incidental costs till to

delivery of the goods to their final destination as specified in the Schedule of Requirements.

Column 5(d): The Price of Incidental Services including installation, demonstration and onsite training at End-users' site, if applicable, as mentioned in Schedule of Requirements.

- 14.3.2 For goods offered from abroad, the prices under Column 5 in the corresponding Price Schedule as per format in **Section IV** (3) shall be entered separately in the following manner:

Column 5(a): The price of goods quoted CIP at port/airport of destination;

Column 5(b): The price of goods quoted DDP (Delivery Duty Paid) at End-user site in Iraq as specified in the Schedule of Requirements.

Column 5(c): The price of Incidental Services including installation, demonstration and onsite training at End-users' site, if applicable, as mentioned in Schedule of Requirements;

- 14.3.3 For Medical Equipment, Annual Maintenance Contract (AMC) at End-users' site for the stipulated years after warranty period in the Price Schedule as per format in **Section IV** (4), if applicable as specified in Schedule of Requirements. The cost of AMC may be quoted along with taxes applicable on the date of Bid Opening. The taxes to be paid extra, to be specifically stated. In the absence of any such stipulation the price will be taken inclusive of such taxes and no claim for the same will be entertained later. During AMC contract period the Supplier shall keep sufficient stock of spares required during and will to attend to the break down calls promptly. An UPTIME warranty of 'x'% per year during Annual Maintenance Contract, if applicable, **as specified in Section VI Schedule of Requirements** should be provided. In such cases if the Down Time exceeds (100-x) % per year during AMC period, it will extend the AMC period by double the down time period.

- 14.4 The terms EXW, FCA, FOB, CIF, CIP, DDP, etc., shall be governed by the international rules for interpreting trading terms as prescribed in the current edition of INCOTERMS® published by the International Chamber of Commerce, Paris.

- 14.5 The Bidder's separation of price components in accordance with ITB Sub clause 14.3 above will be solely for the purpose of facilitating the comparison of bids by the Contracting Entity and will not in any way limit the Contracting Entity's right to contract on any of the terms offered.

- 14.6 Price quoted by Bidder shall be fixed during the currency of the Contract and not subject to any variation on any account.
- 14.7 If more than one schedule (or lot) has been **specified in Section VI** Schedule of Requirements, these Bidding Documents allow Bidders to quote separate prices for one or more schedules (or lots). The Bidder may quote for one or more schedules (or lots) but are required to quote for all items and its full quantity of the goods of that schedule. The Schedules (or lots) must be listed and priced separately in the Price Schedules. Bids shall be evaluated for each schedule (or lot) separately.
- 15. Currencies of Bid**
- 15.1 Prices shall be quoted in the following currencies:
- (a) The Bidder shall express its prices for such goods to be supplied from Iraq in the Iraqi Dinar.
 - (b) The Bidder may express the bid price of the Goods to be supplied from abroad as indicated in the **Bid Data Sheet**.
- 16. Period of Validity of Bids**
- 16.1 Bids shall remain valid for the period stipulated in the **Bid Data Sheet** after the date of bid submission specified in ITB Clause 20. A bid valid for a shorter period shall be rejected by the Contracting Entity as nonresponsive.
- 16.2 In exceptional circumstances, prior to expiry of the original bid validity period, the Contracting Entity may request that the Bidders extend the period of validity for a specified additional period. The request and the responses thereto shall be made in writing. A Bidder may refuse the request without forfeiting its bid security. The Bidder agreeing to the request will not be required or permitted to modify its bid, but will be required to extend the validity of its bid security for the period of the extension.
- 17. Bid Security**
- 17.1 The Bidder shall furnish as part of its bid a bid security in the form of an unconditional guarantee and payable upon first demand and in any of the following modes:
- (a) a bank guarantee as per format in **Section IV** ; or
 - (b) a cashier's or certified check; or
 - (c) **or any mode depended by the contracting entity in data sheet.**
- The amount of the Bid Security shall be as stipulated in the **Bid Data Sheet** and in the **Schedule of Requirements in Section VI**.
- 17.2 The bid security shall be addressed to the Contracting Entity stating the number and title of the IFB and shall remain valid for a period of 28 days beyond the validity

period for the bid, and beyond any extension subsequently requested under Sub-Clause 16.2.

- 17.3 The bid security shall, at the Bidder's option, be in the form of either or a Bank Guarantee from an accredited bank in Iraq and in accordance with the instructions of Central Bank of Iraq or certified check in the format provided in the Bidding Documents **any mode depended by the contracting entity in data sheet.** In the case of Bank Guarantee furnished from the banks outside Iraq, it should be endorsed and countersigned by accredited bank in Iraq by way of back-to-back counter guarantee.
- 17.4 Any bid not accompanied by an acceptable bid security shall be rejected by the Contracting Entity as nonresponsive **excepting that of the producing drugs company or medical equipment manufacturing companies which are cover by the valid exeption of the minister of health**.
- 17.5 Upon the approval of the Contracting Authority, the Contracting Entity has the right to release the Bid Securities of the unsuccessful Bidders that are unlikely to be awarded the Contract before the end of the Bid Validity and after the referral recommendation has been made. In such a case, the Bid Securities of the first three (3) candidates Bidders shall be retained in view of ITB Sub-Clause 38.2
- 17.6 The bid security of the successful Bidder will be returned when the Bidder has signed the Contract and furnished the required performance security.
- 17.7 The bid security may be forfeited
- (a) if the Bidder withdraws its bid, except as provided in ITB Sub-Clauses 16.2 and 22.3; or
 - (b) in the case of a successful bidder, if the Bidder fails within the specified time limit to:
 - (i) sign the contract, or
 - (ii) furnish the required performance security.
 - (c) In the case of Complaint and Appeal as per Clause 36 by an unsuccessful Bidder and when this complaint or appeal is found by the competent authorities to be for false or unjustified reasons. The amount of damage resulting from delaying the contract signature will be recovered from the Bid Security of the here above unsuccessful Bidder. However, such amount **which forfeited from Bid Security which equale to the penalties value limited** in accordance with the applicable Iraqi laws and procedures.
- 17.8 If the bid security is not provided by some Bidders, due to exemption provided by the Iraqi applicable laws, as in the case of Public Companies or others as

- specified in **Bid Data Sheet** Sub-Clause 17.1, and
- a) if such a Bidder withdraws its bid during the period of bid validity specified by the Bidder on the Bid Submission Form, except as provided in ITB Sub-Clause 16.2, or
 - b) if such a Bidder is nominated as a successful Bidder and fails to: sign the Contract in accordance with ITB Clause 37; or furnish a performance security in accordance with ITB Clause 38;
- the Contracting Entity may, if provided for in the **Bid Data Sheet**, declare the Bidder disqualified to be awarded a contract by the Contracting Entity and proceed with the administrative actions as stated in the **Bid Data Sheet**.

18. Format and Signing of Bid

- 18.1 The Bidder shall prepare an original and it is permitted to be as (compact disk) with the technical bid , while the financial bid should be submitted in one written original copy .
- 18.2 The original and all copies of the bid, each consisting of the documents listed in ITB Sub-Clause 12.1, shall be typed or written in indelible ink and shall be signed by the Bidder or a person or persons duly authorized to bind the Bidder to the Contract. The authorization shall be indicated as specified in the **Bid Data Sheet** by those legally authorized to signed, which pursuant to ITB Sub-Clause 12.1 (c) shall accompany the bid. The Bidder has to ensure the signature of the Bid Submission Form and of every page of the Price Schedules and the attached documents to the Bid by the person signing the Bid. Noting that all pages of the bid where entries or corrections on entries have been made by the Bidder shall be signed or initialled by the person signing the bid. Prices shall be incorporated by the Bidder in words and figures as required in the Price Schedules. Any other requirement is specified in the **Bid Data Sheet**.
- 18.3 The Bid shall contain no interlineations, erasures, or modifications to the Bidding Documents, except to correct errors made by the Bidder in preparing the Bid Forms and where accordingly such corrections should be signed and initialled by the authorised person or persons signing the bid.

D. SUBMISSION OF BIDS

19. Sealing and Marking of Bids

- 19.1 Bidders may always submit their bids by express mail, express courier or by hand. The Bidder shall enclose the original and each copy of the bid in separate sealed envelopes, duly marking the envelopes as "ORIGINAL" or "COPY." The envelopes containing the

original and copies shall then be enclosed in **stamped outer envelope**.

- 19.2 The inner and outer envelopes shall:
- (a) bear the name and address of the Bidder and Bidder stamp on four corners;
 - (b) be addressed to the Contracting Entity at the address given in the **Bid Data Sheet**;
 - (c) bear the Tender, Tender number, and IFB number indicated in the **Bid Data Sheet**; and
 - (d) bear a statement "DO NOT OPEN BEFORE **[17 – 2 -2019]**" to be completed with the time and date specified in the Bid Data Sheet relating to ITB Sub-Clause 20.1.

19.3 If the outer envelope is not sealed, stamped and marked as required by ITB Sub-Clause 19.2 and in accordance with the applicable Iraqi laws, the Contracting Entity will assume no responsibility for the misplacement or premature opening of the bid.

20. Deadline for Submission of Bids

- 20.1 Bids must be received by the Contracting Entity at the address specified in ITB Sub-Clause 19.2 (b) no later than the time and date specified in the **Bid Data Sheet**. A receipt will be provided by the Contracting Entity against each Bid submitted. One copy of the receipt will be for the Bidder, and the second copy will be kept by the Contracting Entity for a further reference
- 20.2 The Contracting Entity may, at its discretion and before the deadline, extend the deadline for the submission of bids by amending the Bidding Documents in accordance with ITB Sub-Clause 5.3, in which case all rights and obligations of the Contracting Entity and Bidders previously subject to the deadline will thereafter be subject to the deadline as extended.

21. Late Bids

- 21.1 Any bid received by the Contracting Entity after the deadline for submission of bids prescribed in ITB Clause 20 will be rejected and returned unopened to the Bidder.

22. Modification and Withdrawal of Bids

- 22.1 The Bidder may modify or withdraw its bid after submission, provided that written notice of the modification, or withdrawal of the bids duly signed by an authorized representative with a valid proof of the authorization, is received by the Contracting Entity prior to the deadline prescribed for submission of bids.
- 22.2 The Bidder's modification or substitution shall be prepared, sealed, marked, and dispatched prior to the deadline for submission of bids and as follows:
- (a) The Bidder shall provide an original and the number of copies specified in ITB Sub-Clause **19.1** of any modifications to its bid, clearly identified as such, in two inner envelopes duly marked "BID MODIFICATION-ORIGINAL" or "BID SUBSTITUTION-ORIGINAL" and "BID MODIFICATION-COPIES" or "BID SUBSTITUTION-COPIES."

The inner envelopes shall be sealed in an outer envelope, which shall be duly marked "BID MODIFICATION" or "BID SUBSTITUTION."

- (b) Other provisions concerning the marking and dispatch of bid modifications shall be in accordance with ITB Sub-Clauses 19.2 and 19.3.
- 22.3 A Bidder wishing to withdraw its bid shall notify the Contracting Entity in writing prior to the deadline prescribed for bid submission. A withdrawal notice shall be received prior to the deadline for submission of bids and shall:
 - (a) be addressed to the Contracting Entity at the address named in ITB Sub-Clause 19.2 (b)
 - (b) bear the Invitation for Bids (IFB) title and number indicated in named in ITB Sub-Clause 19.2 (c) and the words "BID WITHDRAWAL NOTICE" and
 - (c) be accompanied by a valid written power of attorney authorizing the signatory of the withdrawal notice to withdraw the bid.
- 22.4 Bids requested to be withdrawn in accordance with ITB Sub-Clause 22.3, shall be returned unopened to the Bidders.
- 22.5 No bid may be withdrawn, substituted, or modified in the interval between the bid submission deadline and the expiration of the bid validity period specified in ITB Clause 16. Withdrawal of a bid during this interval may result in the forfeiture of the Bidder's bid security, pursuant to ITB Sub-Clause 17.7.

E. OPENING AND EVALUATION OF BIDS

23. Bid Opening

- 23.1 The Contracting Entity (Bid Opening Committee) will open all bids, including withdrawal notices and modifications, in public, in the presence of Bidders' representatives who choose to attend, at the time, on the date, and at the place specified in the **Bid Data Sheet**. Bidders' representatives shall sign a register as proof of their attendance.
- 23.2 Envelopes marked "WITHDRAWAL" shall be read out and the envelope with the corresponding bid shall not be opened but returned to the Bidder. No bid withdrawal notice shall be permitted unless the corresponding withdrawal notice with a valid authorization is read out at bid opening. Next, envelopes marked "SUBSTITUTION" shall be opened and read out and exchanged with the corresponding bid being substituted, and the substituted bid shall not be opened, but returned to the Bidder. No bid substitution shall be permitted unless the corresponding substitution notice contains a valid authorization to

request the substitution and is read out at bid opening. Envelopes marked "MODIFICATION" with a valid authorization shall be read out and opened with the corresponding bid.

- 23.3 All other Bids shall be opened one at a time, reading out: the name of the Bidder and the Bid Price of each item or schedule (or lot) including any discounts, and indicating whether there is: the presence or absence of a bid security, if required; the presence or absence of requisite powers of attorney; and any other such details as the Contracting Entity may consider appropriate. No bid shall be rejected at bid opening except for late bids pursuant to Sub-Clause 21.1.

All pages of the original of each Bid shall be stamped with the bid opening committee stamp and the bid opening committee members shall sign on all pages of the price schedules of the original of each Bid.

- 23.4 Bids (and modifications sent pursuant to ITB Sub-Clause 22.2) that are not opened and read out at bid opening shall not be considered further for evaluation, irrespective of the circumstances.

- 23.5 The Contracting Entity will prepare minutes of the bid opening at the end of the opening session, with the here above mentioned information of ITB Sub-Clauses 23.1, 23.2, 23.3, and 23.6 and including in minimum the following information about: --sealing and stamping of the envelopes;

- bid prices (unit price for each lot if it is available) in addition to any conditional pricing or discounts based on other Bids;
- marking (with the signature of the Chairman of Bids Opening Committee and the members) of any alteration, erasure, correction made by the Bidder on the prices schedules (while slashing un-priced items with horizontal lines);
- Bidder's signature of the Bid Submission Form and other attached Bid Forms and of every page of the price schedules;
- number of pages of each Bid;
- any other relevant remarks and reservations made by the Bidder on the Bid;
- any other remarks and general description and highlights to be made by the Committee on any attachments to the Bid. All Bid's content and attachments will be initialled by the Bids Opening Committee.

- 23.6 The Bidder's representatives who are present shall be requested to sign the minutes with the right to add any comment on the performance of the Committee. The omission of a Bidder's signature on the minutes shall

- not invalidate the content and effect of the minutes. The minutes should be distributed to all Bidders who wish to retain its copy.
- 23.7 All Bids' prices, technical specifications, and implementation periods will be officially placed on the Contracting Authority's bill board while stating that these are to be analysed and verified further.
- 23.8 The Bids will be referred by an official report to the Bids Evaluation Committee according to the agreement of The Contracting Entity chairman.
- 24. Clarification of Bids**
- 24.1 During evaluation of the bids, only the Contracting Entity (evaluation & analysis committee) may, at its discretion, ask the Bidder for a clarification of its bid. The request for clarification and the response shall be in writing, and no change in the prices or substance of the bid shall be sought, offered, or permitted, except to correct arithmetic errors identified by the Contracting Entity in the evaluation of the bids, in accordance with ITB Sub-Clause 27.1.
- If a Bidder does not provide clarifications of its bid by the date and time set in the Contracting Entity's request for clarification, its bid may be rejected.
- 25. Confidentiality**
- 25.1 Information relating to the examination, clarification, evaluation, and comparison of bids, and recommendations for the award of a Contract shall not be disclosed to bidders or any other persons not officially concerned with such process until the notification of Contract award is made to all Bidders.
- 25.2 Any effort by the bidder to influence the Contracting Entity (evaluation & analysis committee) in the Contracting Entity's bid evaluation, bid comparison, or contract award decisions may result in the rejection of the Bidder's bid.
- 25.3 From the time of bid opening to the time of Contract award, if any Bidder wishes to contact the Contracting Entity on any matter related to its bid, it should do so in writing.
- 26. Examination of Bids and Determination of Responsiveness**
- 26.1 The Contracting Entity (evaluation & analysis committee) will examine the bids to determine whether they are complete, whether any computational errors have been made, whether required Bid Securities have been furnished, whether the documents have been properly signed, and whether the bids are generally in order.
- 26.2 The Contracting Entity (evaluation & analysis committee) may waive any minor informality, nonconformity, or irregularity in a bid that does not constitute a material deviation, provided such waiver does not prejudice or affect the relative ranking of any Bidder.

- 26.3 Prior to the detailed evaluation, pursuant to ITB Clause 29, the Contracting Entity (evaluation & analysis committee) will determine whether each bid is of acceptable quality, is complete, and is substantially responsive to the Bidding Documents. For purposes of this determination, a substantially responsive bid is one that conforms to all the terms, conditions, and specifications of the Bidding Documents without material deviations, exceptions, objections, conditionality, or reservations. A material deviation, exception, objection, conditionality, or reservation is one: (i) that limits in any substantial way the scope, quality, or performance of the Goods and related Services; (ii) that limits, in any substantial way that is inconsistent with the Bidding Documents, the Contracting Entity's rights or the successful Bidder's obligations under the Contract; and (iii) that the acceptance of which would unfairly affect the competitive position of other Bidders who have submitted substantially responsive bids.
- 26.4 If a bid is not substantially responsive, it will be rejected by the Contracting Entity (evaluation & analysis committee) and may not subsequently be made responsive by the Bidder by correction of the nonconformity. The Contracting Entity's determination of a bid's responsiveness is to be based on the contents of the bid itself.
- 27. Correction of Errors**
- 27.1 Arithmetical errors will be rectified as follows. If there is a discrepancy between the unit price and the total price that is obtained by multiplying the unit price and quantity, the unit or subtotal price shall prevail. If there is a discrepancy between subtotals and the total price, the total price shall be corrected. If there is a discrepancy between words and figures, the amount in words will prevail. If a Bidder does not accept the correction of errors, its bid will be rejected. If the Bidder that submitted the lowest evaluated bid does not accept the correction of errors, its bid security shall be forfeited.
- 28. Conversion to Single Currency**
- 28.1 To facilitate evaluation and comparison, the Contracting Entity will convert all bid prices expressed in the various currencies in which they are payable to Iraqi Dinar at the selling exchange rate established for similar transactions by the Central Bank or a commercial bank in Iraq.
- 28.2 The currency selected for converting bid prices to a common base for the purpose of evaluation to common currency in Iraqi Dinar as on the date of Bid submission.

29. Evaluation and Comparison of Bids

- 29.1 The Contracting Entity (evaluation & analysis committee) will evaluate and compare the bids that have been determined to be substantially responsive, pursuant to ITB Clause 26.
- 29.2 For comparison for ranking purpose for evaluation, the comparison of the responsive Bids shall be carried out on Delivery Duty Paid (DDP) End-users' site basis / Free Delivery at End-users' Site basis. The quoted AMC (Annual Maintenance Contract), if applicable as per Schedule of Requirements as per ITB Sub-Clause 14.3.3 for subsequent stipulated years after warranty period will also be added for comparison/ranking purpose for evaluation.
- 29.3 For domestic goods or goods of foreign origin located within Iraq, the various prices as brought out in ITB Sub-Clause 14.3.1 and stipulated in Price Schedule in format in **Section IV(2)**, and for goods offered from abroad, the various prices brought out in ITB Sub-Clause 14.3.2 and stipulated in Price Schedule in format in **Section IV(3)** will be loaded for comparison/ranking purpose for evaluation. In addition, Annual Maintenance Contract (AMC) price, if applicable as per Schedule of Requirements as per ITB Sub-Clause 14.3.3 for stipulated years after Warranty period in Price Schedule in format in **Section IV(4)** will be loaded for comparison/ranking purpose for evaluation.
- 29.4 The rate of quoted Annual Maintenance Contract (AMC), if applicable, as per **Section VI Schedule of Requirements**, will be loaded for comparison/ranking purpose at Net Present Value (NPV) considering discount rate as brought out in **Bid Data Sheet**.
- 29.5 If more than one schedule (or lot) has been specified in Section VI Schedule of Requirements, the Bidders are required to quote as stipulated in ITB Sub-Clause 14.7. Bids shall be evaluated for each schedules (or lots) separately.
- 29.6 The Contracts may be awarded Schedule wise to the lowest responsive Bidder who meets the laid down Qualification Criteria as per ITB Clause 8 subject to Margin of Preference, as per Clause- 30.

30. Margin of Domestic Preference

- 30.1 As not contrary to what specified in **Bid Data Sheet**. Margin of domestic preference will be depended for the domestic bidders.

31. Contracting Entity's Right to Accept Any Bid and to Reject Any or All Bids

31.1 The Contracting Entity reserves the right to accept or reject any bid, or to annul the bidding process and reject all bids at any time prior to contract award, without thereby incurring any liability to the affected Bidder or Bidders.

In case of annulment, all bids submitted and specifically, bid securities, shall be promptly returned to the Bidders together with the fees of purchasing the Bidding Documents as paid by the Bidders.

32. Eligibility and Qualification of bidder

32.1 The Contracting Entity will determine to its satisfaction whether the Bidder that is selected as being eligible and having submitted the lowest evaluated responsive bid is qualified to perform the Contract satisfactorily, in accordance with the criteria listed in ITB Sub-clause 8.1.

32.2 The determination will evaluate the Bidder's financial, technical, and production capabilities. It will be based on an examination of the documentary evidence of the Bidder's qualifications submitted by the Bidder, pursuant to ITB Sub-Clause 8.1, as well as other information the Contracting Entity deems necessary and appropriate.

32.3 An affirmative Qualification of bidder determination will be a prerequisite for award of the contract to the eligible and lowest evaluated Bidder schedule wise. A negative determination will result in rejection of the Bidder's bid, in which event the Contracting Entity will proceed to the next-lowest evaluated Bidder to make a similar determination of that Bidder's capabilities to perform satisfactorily.

F. AWARD OF CONTRACT

33. Award Criteria

33.1 Pursuant to ITB Clauses 29, 30 and 32, the Contracting Entity will award the Contract to the eligible Bidder whose bid has been determined to be substantially responsive and has been determined to be the lowest evaluated bid, provided further that the Bidder is determined to be qualified to perform the Contract satisfactorily.

33.2 Before the award, the Contracting Entity has to verify from the competent authorities the validation of the substantial forms provided in the Bids including the Bid Security..

34. Contracting Entity's Right to Vary Quantities at Time of Award

34.1 The Contracting Entity reserves the right at the time of Contract award to increase or decrease, by the percentage of 20% the quantity of goods and services beyond that originally specified in the Schedule of Requirements without any change in unit price or other terms and conditions.

35. Notification of Award

35.1 Prior to the expiration of the period of bid validity, the Contracting Entity will notify the successful Bidder in writing or by cable, to be subsequently confirmed in writing by registered letter, that its bid has been

accepted. At the same time, the Contracting Entity shall also notify all other Bidders of the results of the bidding, and shall publish the results as per the applicable Iraqi Laws identifying the bid and lot numbers and the following information: (i) name of each Bidder who submitted a Bid; (ii) bid prices as read out at Bid Opening; (iii) name and evaluated prices of each Bid that was evaluated; (iv) name of bidders whose bids were rejected and the reasons for their rejection; and (v) name of the successful Bidder, and the Price and currency it offered, as well as the duration and summary scope of the contract awarded.

35.2 The notification of award will constitute the formation of the Contract subject to settlement of Appeal by unsuccessful bidder as per ITB Clause 36.

35.3 Upon the successful Bidder's furnishing of the signed Contract Form and performance security pursuant to ITB Clause 38, the Contracting Entity will promptly discharge the bid securities of the unsuccessful Bidders, pursuant to ITB Clause 17.

35.4 If, after notification of award, an unsuccessful Bidder wishes to ascertain the grounds on which its bid was not selected, which are not in pursuant to ITB Clause 36, it should address its request to the Contracting Entity. The Contracting Entity will promptly respond in writing to the unsuccessful Bidder.

36. Complaints and Appeals

Validation general government implementation contracts procedures represent the dependable criteria in viewing the complaints bidders.

37. Signing of Contract

37.1 Promptly after the Contracting Entity notifies the successful Bidder that its bid has been accepted and after lapse of the standstill period and settlement of Appeals as per ITB Clause 36 (as the case may be), the Contracting Entity will send the Bidder the Contract Form provided in **Section IX** of the Bidding Documents, incorporating all agreements between the parties and as indicated in **Bid Data Sheet**. The Contract has to be endorsed as indicated in **Bid Data Sheet**.

37.2 the successful Bidder shall sign, date, and return the Contract Agreement to the Contracting Entity within the permitted period. In case of an unsuccessful Bidder's appeal as per ITB 36.2, the Contracting Entity has still the right to proceed with the Contract with the Successful Bidder upon finding that the contract is fully compliant and it is in the public interest not to delay the commencement of the Contract and where the cancellation of the Contract will impose great damages on the public interest. Nevertheless, the Contracting Entity has to notify the relevant Administrative Court of

**38. Performance
Security**

such a decision with all above justifications. The Contracting Entity has the authority to implement the Contract after providing to the approval of the relevant Administrative Court a signed commitment for compensating the future damages resulting from implementing the Contract in case the ruling of the relevant Administrative Court was unfavourable to its decision.

- 38.1 Within fourteen (14) days of the receipt of notification of award from the Contracting Entity, or twenty nine (29) days in case of complaints as per ITB 36.1, the successful Bidder shall furnish the performance security in accordance with the Conditions of Contract, using the Performance Security Form provided under Contract Forms in **Section IX** of. If rules and regulation of Republic of Iraq grants exemption to Public Companies of the state and public sectors, they are accordingly exempted of submitting Performance Security.
- 38.2 Upon the failure of the successful Bidder to submit the above-mentioned Performance Security or sign the Contract within the period specified under ITB 37.2, the Contracting Entity will send an official notice for the successful Bidder to sign the Contract within fifteen (15) days from receiving this notice, after which the Contracting Entity has sufficient grounds to proceed with the annulment of the award and forfeiture of the bid security of the here above declined Bidder. In that event the Contracting Entity may award the Contract to the next lowest evaluated Bidder whose offer is substantially responsive and is determined by the Contracting Entity to be qualified to perform the Contract satisfactorily. In that case the declined Bidder will be responsible for paying the difference in the bids prices in addition to forfeiture of the bid security. These actions will be taken against the declined bidders provided they decline during their Bid validity.

SECTION II. BID DATA SHEET

Bid Data Sheet (BDS)

The following specific data for the Goods to be procured shall complement, supplement, or amend the provisions in the Instructions to Bidders (ITB). Whenever there is a conflict, the provisions in the Bid Data Sheet (BDS) shall prevail over those in the ITB.

A. GENERAL

ITB 1.1	<p>Name of Contracting Entity: [Ministry of Health / Environment / The State Company for Marketing Drug and Medical Appliances].</p> <p>Name of authorized Purchasing Agent: authorized by contracting entity : "none"</p> <p>Type of goods: Medicine as mentioned in tender lists</p> <p>Tender: Purchasing medicine</p> <p>Tender Number: Med/2/2019 as listed in the Iraqi Federal Budget]</p> <p>IFB Number: 2</p> <p>The number and identification of schedules (lots) comprising this IFB is detailed in Schedule of Requirements are: [Schedule (1)-(4)] the year of the Federal Budget that certified by the competent authorities is 2018 to purchase the medicines for The Ministry of Health/ Environment / The State Company for Marketing Drug and Medical Appliances (Kimadia)</p> <p>The source of funding for the contract(s) is: [Ministry of Finance]</p>
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\B. THE BIDDING DOCUMENTS

ITB 4.1	<p>Contracting Entity's Ministry of Health / Environment / The State Company For Marketing Drug and Medical Appliances (kimadia)/Drug Media Department & the Public Relations- 5th floor ,position of MOH(Ministry of Health),E-mail (dg@kimadia.iq) phone no.(07705419074) Requests for Clarification are to be hand delivered or sent by mail or by express courier and accepted by E-mail</p> <p>Adoption the bidder address which install in the tender & address for correspondence & communications, the bidder should notice the contracting party with any change to this address within seven days of receiving.</p> <p>-additional to ITB :</p> <p>- Specifying the date of conference specialized to answer all the participants in the bid inquiries will be on (11 / 2 /2019).</p>
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C. PREPARATION OF BIDS

ITB 6.3	<p>List of disqualified bidders is available on the following website address: HTTP://WWW.mop.gov.iq</p> <p>In addition to what mentioned in the instructions to the bidders the following will be added :</p> <ul style="list-style-type: none"> -or in breach of thier previous contractual obligations with the same contracting party or other contracting parties and under fundamentalism documents . -Companies will be black listed in the following cases:- A- When prove dealing with the provincial foreign companies. B-When prove a bribery action proved to one of official employees C- When prove there is forgery in the offer or any other tender documents. D-When prove a false detail is submitted and such false information lead to damage thecommon weal E-When prove there is a breach of tender document conditions or technical description conditions of supplying lead to damage the common weal F-When the seller insists on not adhering with the professional rules by following the illegal competitive ways. G-When the seller insists on not signing the contract after being notified him with the relegation quotation. H-drawing out the work because lagging of execute the tender or his breach of execute the tender or his breach with contractual Commitments.
ITB 7.2	<p>The legalization of certification will be per the instructions of implementation the contracts (No.2) year 2014 against the imported article from Arabic country.</p>
ITB 7.3 (c)	<p>Documentation requirements for eligibility of Goods. In addition to the documents stated in Sub-Clauses7.2 and 7.3 (a) and (b), the following documents should be included with the Bid:</p> <ol style="list-style-type: none"> 1-submit the certificate of origin for the imported materials in favor of the contracting party issued by the country of manufacture or product or country in which the final assembly or country of shipment (country of export) with reference to the origin of import mataterials which must be accurate in terms of technical specifications for materials or equipment to be exported to Iraq on condition that there is a duly authenticated undertaking from the truck company and equipped with the import materials,including carrying all the financial and legal responsibilities related to the validity of th information mentioned in the original certificates of origin sent by the manufacturers or producers to the supplier in the last shipping country

	<p>2- To submit original & legalized certificate for the company (U.S. FDA, GMP.,EMA,JAP.,MHLW , Canadian ,AUS – TAG , UK.MHRA , SWISS –MEDIC U.S)</p> <p>3- To submit a certificate of company establishment for the manufacturer and supplier companies with the offer (it should be original , legalized and new).</p> <p>4- Presenting the original and legalized final settlements which related to Manufacturer Company for the last five years (2012,2013, 2014, 2015 and 2016) final accounts which show a profit during the last five years & average rates and the final settlements should be presented in English & Arabic language only. & the indicator of final fundamentalism accounts for recent five years is appositive.</p> <p>5-The companies partisipating in the tender shall submit thier prices fixed in thier contracts with other countries and neighboring countries of Iraq provided that such prices are attached with the tender and with the support,stamp and signature of the bidder .</p> <p>- To -submit the following for products of human blood origin:-</p> <p>1-A- Certificates for plasma pool data and safety certificates during the producing process.</p> <p>B- The methods which used to extract the viruses of HBV, HCV, HIV and others during manufacturing process.</p> <p>C-The method of analysis and the final product safety certificate from the manufacture company which indicates that final product is free from viruses.</p> <p>2- To submit documents stating that the gelatin which used in manufacturing capsules is from botanic or animal (halal) origin according to Islamic law</p> <p>3- Companies equipped for cancer drugs are obliged to re-iss the failed and expaired quantities of these medicines and n resort to the request to be destroyed by our company.</p> <p>4- The supplying companies of chemotherapeutic products obliged to re-export the failed and expired quantities of such products and not requesting to destroy it by our company</p> <p>-Special condition for medical milk:</p> <p>1-Adoption weigh 400gm as unit of measurement &the maximum limit is 1000gm for Kimadia when contracting.</p> <p>2-to be mention either in (BNF) OR (Martindale) last edition</p> <p>3-Milk to be identical to recently updated British specifications.</p> <p>4-To be filled in the country of origin to avoid contamination during packaging.m</p>
ITB 7.4	<p>Registration of goods is required in Iraq .</p> <p>{Note: Bid security or performance security will not be confiscated if the bidder fails to register the goods .</p>
ITB 7.4 (b)	<p>By the time of Contract signing, the successful Bidder shall</p>

	<p>have complied with the following documentary requirements in order to register the Goods to be supplied under the Contract: conditions for registration approved by the Ministry of Health / Department of technical things / registration section / Eighth floor .</p> <p>{Note : Bidders should inquire about the conditions and procedures for registering the goods as soon as possible in order to avoid any delay that may result during the registration process by the various competent governmental bodies .}</p> <p>-In addition to what has been mentioned , the following shall be considered :</p> <ol style="list-style-type: none"> 1. company should register its products before payment their dues by the shipped goods. 2. If the unregistered item was awarded for the company, in such case the specifications, analysis method and standard reference substance should be forward upon the confirmation of the awarding at maximum one month before the irrevocable contract . 3. In case the item is not registered any settlement for this contract not be done unless presenting document prove that the sealer submit the legal document to registration department or re- registered it
ITB 7.4.1	For the purpose of obtaining additional information about the requirements for registration, Bidders may contact { Ministry of Health/ Environment/Department of technical things /Registration section /Eighth floor}.
ITB 11.1	<p>The language of the bid is: Arabic or English</p> <p>In case the tender documents and contract are received in both languages Arabic and English, when the interpretation is different, the Arabic language shall be adopted as the official language of the State.</p>
ITB 12.1	<p>In addition to the documents stated in Paragraphs 12.1 (a) through (f), the following documents must be included with the Bid.</p> <ol style="list-style-type: none"> 1- The bidder has the right which previously has been participating in the tender submit the prior purchase receipt together with tender documents which re announced, in case there is amendment in the prices of the tender documents the bidder will bear the difference in the price between two prices in case of increasing the price and attach with his offer the first receipt and the second . 2- In case of contracting the beneficiary from documentar credit should be the same side which contracted with it and the banking details with name of that company exclusively contains (bank name, no. of account, the name of owner c account (the company which contracted with it) (swift cod and sort code and Iban..... etc) and not accept the accour with person name. Any change of beneficiary name and

	<p>address, corresponding, advising bank name's and address, account no. and any other bank information from the bidder side after awarding in contrast with offered tender will impose the bidder to penalty.</p> <p>3- Provide a renewal of the factory's license regarding the national factories .</p> <p>4- Factories and their materials must be registered in the registration section of the Iraqi Ministry of Health , as the ministry will not market any unregistered product .</p> <p>5- Items quoted, to be in their brand names. In case items are quoted in generic names, the pharmacopoeia should be stated</p> <p>6- <u>The companies should be submitted a letter of no objection issued by the general authority for taxes when participating in the tenders announced</u></p>
14	<p>14.6 -In addition to what mentioned in ITB will be : - Neglecting the offer based on reduction a percentage or fixed sum in any of the other presented offers in the tender and not accept any reservation and any reduction against the price presented after the closing date of tender we confirm on the condition for not made any change after the notification of awarding and any letter regarding decrease the prices of offered items after the closing date of the tender or direct invitation without request from KIMADIA will be neglect</p>
ITB 15.1	<p>b) Foreign currencies: In US dollar or by ink or by printing form (figures and letters) without rubbing or scratching .</p>
ITB 16.1	<p>The bid validity period shall be (365) days so , each bid must be valid until (17/2 /2020)</p> <p>Bid security must be valid twenty-eight (28) days after the end of the bid validity period. Accordingly, a bid with a bid security that expires before(16/3/2020) shall be rejected as nonresponsive.</p>
	<p>Public Companies of the state and public sector are exempted from submitting Bid Securities accordance with instructions of implementation the government contracts in force</p> <p>{If decided by the Contracting Authority ; {The Contracting Authority has decided not to ask for Bid Securities incase of obtaining exemptions from the competent authorities .}</p> <p>The amount of the bid security shall be 0 that is mean 1% from estimated cost of tender by Iraqi Dinar or its equivalent in a convertible currency from the list of currencies from which the Central Bank of Iraq quotes the rate of exchange to the Iraqi Dinar.</p> <p>In addition to what mentioned in 17.1 be (c) or saftaja .</p> <p>Taking into account the following :</p> <p>1- Bid bond should submit by the bidder or any of the share holders of the company or companies participate under contract for the benefit of contracting party and include a</p>

	<p>reference to the name and number of tender</p> <p>2- The bond should issued from company which contracted with it or with its legal authorized for issuing the bound under formal and certified authorization .</p> <p>3-The submitting of bond should attached with Litter of legalized issuing.</p> <p>(private & secret) send to kimadia by the bank who issued the bond.</p> <p>-the bond must issued by two languages (Arabic& English)</p> <p>4-In addition to what mentioned in 17.7 should taking into account the following statement :</p> <p>(or refuse to correct his calculation errors of the tender and its reflection on the decision of awarding and will be taking against him the legal actions stipulated in the instructions of implementation the government contracts).</p>
ITB 17.4	Related to depend companies & according to depend companies conditions.
ITB 17.8	<p>If the Bidder defaults under the actions prescribed in subparagraphs (i) or (ii) of this provision, the Contracting Entity will declare the Bidder in violation and will inform the Ministry of Planning and Economic Development to take the required actions against the violating Bidder (including Suspension or Black Listing) as per the applicable Iraqi laws.</p> <p>In addition to what mentioned in instructions to bidders should taking into account the following :</p> <p>If the participants in the tender reject executing the contract after notification with awarding, the following procedures will be taken against bidder:-</p> <p>-Executing the contract on his account without needing to warn him or take any other legal procedure</p> <p>--In case of breach the two candidate first &second the contracting side has the right to refer the tender on third bidder & each of two breach the difference of price according to the difference amounts for their nomination & confiscated the bid bond for two .</p> <p>-In case of breach the third candidate the bid bond will confiscate & re-announcing ear the three breach bidder the difference of price each on according to its price with confiscated the bid bond of three breach bidders.</p> <p>-- -Applied to three bidders the procedure which stipulated above when breached during the period of close date for tender.</p>
ITB 18.1	<p>Required number of copies of the bid in additino to the original bid is: [3 copies].</p> <p>What is mentioned in the paragraph 18,1 of ITB TO BE :</p> <p>-.Quotations have to be delivered in the same format as request for tender in disk, CD & hardcopy (derived from CD or Disk) originally signed and stamped all its paper and all the information should be compatible and When there</p>

	<p>are substantial discrepancies incurred between the paper offer and the disk our company (Kimadia) has the right to neglect the offer and to rely upon the paper offer in case of the availability of simple discrepancies taking into consideration that these differences will be specified whether they are simple or not by the analysis and studying committee .</p>
ITB 18.2	<p>The written confirmation of authorization to sign on behalf of the Bidder shall consist of: a Power of Attorney issued by the Bidder dated no more than 3 month or Company Registration Form (Certificate of establishment showing the authorized signatory).</p> <p>-- Offers should be submitted directly by the manufacturing company through either the following:</p> <ul style="list-style-type: none"> - Director General or his representative. - Assistant of Director General or his representative. - Sales manager (marketing) - Commercial manager. - Legalized scientific bureau <p>-We can accept the authorization of any representative of company not stated above provided that his authorization should fulfill the legal form and the required legalization.</p> <p>-Special instruction concerning the authorization letters (A.L)</p> <p>(I) –The authorization letter should be legalized officially by:-</p> <p>A-The chamber of commerce in the country of origin</p> <p>B-Ministry of foreign affairs in the country of origin or notary public.</p> <p>C -Iraqi embassy in the country of origin or its representative there .</p> <p>D- Iraqi ministry of foreign affairs in Baghdad should seal and legalize upon agreement & signature of the Iraqi embassy in the country of origin .</p> <p>E-In any way, if the Iraqi embassy can not seal all these documents above mention either there is no Iraqi embassy or knowing no exact information about a person's identity who is representative in the company so that embassy of the country of origin in Iraq should legalize and seal upon that official authorization letters in order to be legal and acceptable</p> <p>F- If there is no ((diplomatic representation)) between Iraq and country of origin , so the legalizations should be made in a third country from the embassy of the country of origin and the Iraqi embassy in the third country and these improved by ministry of foreign affairs on signing and sealing of Iraqi embassy .</p> <p>(II)-The company should mention in the authorization letter whether it's a manufacturer or supplier ((marketing company)</p> <p>(A) In case of being supplier, you should explain the following:-</p>

- names &specialties of the manufacturing companies.
- you should have a legalized authorization letter from the manufacturing companies as mentioned above icon no. **(I).**
- your manufacturing company should mention that you are a sole and exclusive (supplier) for all its products in Iraq.
- (B)** In case of being a manufacturer, you should explain the following:-
 - Mention &verify your specialties (having special knowledge a particular system)
 - should mention a sole &exclusive representative to deal with for all your products ,also should indicate names of your factories and branches by submitted an original establish certification & certified that proved the company factories & its branches.
- (C)** -the A.L should be legalized as mentioned in icon no (I).
- (D)** – submitting the manufacturing companies catalogue with (CD) laser including company's products to directorate general of medical information (DGMI) with certifying E-mail of manufacturing companies upon these authentic authorization and we will neglect any authorization which is not affix its E-mail.
- (III)** –(A)The company should specify the name of Iraqi scientific bureau & the name of pharmacist who is licensed from Iraqi syndicate of pharmacists follow up and validity of the completion of technical data upon request by the committee of study and analysis in case of submitting the tenders through scientific bureau, or to forward an authorization for signing the contract as an agent also on the list of the submitted tender and its documents, The scientific bureau should be the exclusive representative to all company products or dealing directly with the company through formal authorize as shown in article no.(6).
- (B)**- The continuance responsibility of scientific bureau till after the exp. of authorization from foreign companies which authorized him unless the attached Authorization has been fixed the obligations of previous foreign companies and its traces .
- (IV)** –The authorization letter must be entitled to kimadia, the state company for marketing drugs and medical appliances, directorate general of medical information ((DGMI) fifth floor – relation section and before the closing date.
- (V)**- The name of scientific bureau scientific bureau will added in contract.
- (VI)**-The authorization issued by the manufacturer to marketing company, (in case of the contract with marketing company) should clarify the competence of marketing company concerning the following .

	<p>A-The signing of contract & execution all its obligations, should be by the marketing company exclusively</p> <p>B-The negotiation about technical affairs and prices.</p> <p>C-To specify the beneficiary applicant & details from documents L/C & beneficiary from bank account with the whole banking details the beneficiary who sign the contract with our firm is the same beneficiary (side)</p> <p>D-To specify the correspondences & the authorities which concerning with tenders as far as submitting it, stamp it, sign it, open it & submitting the prices without satisfaction to issue free authorization which is authorize all these competence</p> <p>E-The confirmation to continuous of execution all contracting obligation & the marketing company will bear a legal responsibility for the period of execution the contract even the period of authorization is ended.</p> <p>With reference to complete the whole procedures included the register at the company & its products & full address & the details for manufacturing & marketing companies & to complete the stamps & legalizations as it done now.</p> <p>F-The contracted companies should submit the legal & required assurances according to the conditions of invitation within stipulated period in these instructions .</p> <p>(VII)-Mention the names of authorized persons who signing & stamping the contracts & offers and their administrative description examples of their signature</p> <p>7-Your offers should include copies of all original legalized authorization from the manufacturing companies to the marketing companies also to present original legalized copies as in point (4) from article (6) to be handed to DGMI include all legalization above.</p>
ITB18.3	<p>In addition to what mentioned in ITB the following will be added :</p> <p>The participant has no right to object any condition of the tender conditions .</p>

D. SUBMISSION OF BIDS

ITB 19.2 (b)	<p>For <u>bid submission purposes</u>, the Contracting Entity's address is :</p> <p>Attention: [Baghdad -Bab Al moaadham-Ministry of Health _____]</p> <p>Floor/Room number: <u>Ministry of Health /Environment (Kimadia) - sixth floor - receiving and opening of tenders committee</u> _____</p> <p>CityBaghdad _____</p> <p>Country: <u>IRAQ</u> _____</p>
ITB 19.2 (c)	<p>The Tender, Tender No. and IFB No are:</p> <p>Tender: Med/2/2019</p> <p><u>Tender No.:</u> contracts of supplying medicine should arranged on IFB.</p> <p><u>Reference letter invitation to tender :</u></p> <p>___ - Tenders that are sent by international express should be sent with all authorization letters and documented papers (original and legalized) in separated envelope in order to be checked and it should be reached to kimadia before the closing date, stating on the outer envelope <u>otherwise the offer will be neglected the address of the company inside and outside Iraq and</u></p> <p>the additional forward enclosures with the offer.</p> <p>umber of pages for each offer.</p>
ITB 20.1	<p>Deadline for bid submission is: the end of formal work on 17/2 / 2019</p> <p>If the closing day falls on an official holiday the new closing date shall be in the first working day following the holiday.</p>

E. BID OPENING AND EVALUATION

ITB 23.1	<p>The bid opening shall take place at: Street Address: <u>Baghdad-Bab Al moaadham -Ministry of Health</u> Floor/Room number: <u>Ministry of Health /Environment /The state company for drug and medical appliances (Kimadia)-sixth floor -receiving and opening of tenders committee.</u> City: <u>Baghdad</u> Country : <u>Iraq</u></p> <p>Date: <u>18 -2- 2019</u> Time: <u></u></p>
ITB 27	<p>In addition to what mentioned in ITB :</p> <p>- If paragraph or paragraphs did not record the price towards them in the tender .in this case the cost of the paragraph or paragraphs & with limits quantities assigned to the total price of tender.</p>
ITB 29.4	<p>Not applicable to the supplying of medicines</p>
ITB 30.1	<p>"In case of Pharmaceuticals goods and if the lowest responsive bid which meets the laid down Qualification Criteria offers foreign goods as per ITB 29, then a Domestic preference will be given to the responsive bid offered by National Private Sector Factories of the Republic of Iraq provided that the national product price does not exceed that of the foreign product by 10%".</p> <p>– the second party undertakes to prioritize the raw materials manufactured inside Iraq for supplying the contract materials or for implementing the projects and through the companies of the Ministry of Industry and Minerals according to the letter of Ministry of Planning no.16135 dated 3/8/2017.</p>
ITB 32	<p>32.2 In addition to what mentioned in this paragraph of ITB should taking into account the following condition :</p> <p>Exclusion the bid which is lees than or greater than 20% or more than the estimated cost allocated for the awardng and in case of a responsive and the most appropriate price analysis of some paragraphs (unbalanced) by more than 20% increase or decrease for each paragraph separately which is constitute atotal of not more than 10% of the totalparagraphs , it is possible to accept the awarding and otherwise the bid will be excluded . Taking into account theexception provided by the office of Prime Minister no. 15773 dated 10/11/2015 regardin the</p>

	acceptance of bid which is less than 20% of the estimated cost .
ITB 34	<p>34.1 amending this paragraph of ITB to be :</p> <p>Upon awarding ,the contracting entity reserves the right to increase or decrease the quantity of terms and services specified in the list of contracting requirement before contracting.</p> <p>The contracting entity may partition the awarding of supplying the goods , materials or services required to be supplied .</p>
ITB 37.1	<p>The Contract to be signed with the successful Bidder shall be written in the language in which the Bid was submitted, and which will be the language that shall govern the contractual relations between the Contracting Entity and the successful Bidder. A Bidder shall not sign a translated version of its Contract.</p> <p>In addition to that should be written an original contract copy in Arabic language</p> <p>The contract must be ratified in accordance with the procedures adopted in this regard in Iraq .</p>
ITB 37.2.b	<p>In case that ,the judgment of the specialized court was contrary to a contracting side's decision that has been continued the procedures contract, the bidder who appeal the judgment have to follow the specialized courts to compensate request if it was his appeal was for right reason. Or in case the procedures stopped by specialized court order & judgment issued from the same court the contracting procedures with the objecting bidder , contracting side could be effective the opposite suit that claim to obligate the objecting bidder to compensate any damage will result in future because of contract execution.</p>

Bid Data Sheet (BDS)
VACCINES
(Additional Clauses)

ITB 7.3 (c)	<p>[Sample clauses:</p> <ol style="list-style-type: none"><li data-bbox="544 493 1421 1186">1. The Goods to be supplied under the Contract must be licensed both in the country of manufacture and in Iraq by the time of Contract signing by a recognized NCA. An NCA is an organization that performs all six critical functions for control of biological products as defined by the World Health Organization, namely: licensing based on published set of requirements; surveillance of vaccine field performance; system of lot release for vaccines; use of laboratory when needed; regular inspections for good manufacturing practice and evaluation of clinical performance. The license from country of manufacture must state that the Bidder is licensed to manufacture the Goods by the NCA in the manufacturing country. Documentary evidence in the form of a certified copy of the license and a copy of the vaccine license/registration that the offered vaccine has been licensed by the NCAs of the manufacturer's country shall accompany the bid and a copy of the license issued by an NCA in Iraq must be submitted by Contract signing. If there is no NCA with specific biologics expertise in Iraq, the Bidder shall furnish evidence that the Goods meet the qualification criteria in the Technical Specifications.<li data-bbox="544 1186 1421 1333">2. If the Goods offered do not meet the specified pharmacopoeia standards as stated in the Technical Specification, the Bidder will provide testing protocols and alternative reference standards.
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SECTION III. EVALUATION AND QUALIFICATION CRITERIA

1. Evaluation Criteria

The Evaluation Criteria has been specified in Instructions to Bidders (ITB) in Section I and Bid Data Sheet (BDS) in Section II. The specific data Bid Data Sheet (BDS) for the Goods to be procured shall complement, supplement, or amend the provisions in the Instructions to Bidders (ITB). Whenever there is a conflict, the provisions in the Bid Data Sheet (BDS) shall prevail over those in the ITB.

2. Qualification Criteria

Qualification requirements for Bidders Goods are:

{Note: Contracting Entity may insert appropriate quantifiable qualification criteria for experience and / or financial viability etc depending upon type of good}

A) {For Health Sector Goods insert}

The following documents must be included with the bid:

Documentary evidence of the Bidder's qualifications to perform the Contract if its bid is accepted:

- (i) that, in the case of a Bidder offering to supply Goods under the Contract that the Bidder manufactures or otherwise produces (using ingredients supplied by primary manufacturers) that the Bidder:
 - (a) is incorporated in the country of manufacture of the Goods;
 - (b) has been licensed by the regulatory authority in the country of manufacture to supply the Goods;
 - (c) has manufactured and marketed the specific goods covered by this Bidding Document, for at least [insert two (2) years or as per market availability], and for similar Goods for at least five (5) years;
 - (d) has received a satisfactory GMP inspection certificate in line with the WHO certification scheme on pharmaceuticals moving in International Commerce from the regulatory authority (RA) in the country of manufacture of the goods or has been certified by the competent authority of a member country of the Pharmaceuticals Inspection Convention (PIC), and has demonstrated compliance with the quality standards during the past two years prior to bid submission;
- (ii) that, in the case of a Bidder offering to supply Goods under the Contract that the Bidder does not manufacture or otherwise produce,
 - (a) that the Bidder has been duly authorized by a manufacturer of the Goods that meets the criteria under (i) above to supply the Goods in Iraq; and
- (iii) The Bidder shall also submit the following additional information:
 - (a) a statement of installed manufacturing capacity;
 - (b) copies of its audited financial statements for the past three fiscal years;
 - (c) details of on-site quality control laboratory facilities and services and range of tests conducted;
 - (d) list of major supply contracts conducted within the last five years and relevant certifications endorsed by respective Clients. }

A1 {For Pharmaceuticals insert the following additional clauses}

Documentary evidence of the Bidder's qualifications to perform the Contract if its bid is accepted:

- (i) (e) has a Good Distribution Practice (GDP) Certificate where appropriate.
- (iii) The Bidder will submit the following additional information:
 - (e) list of pharmaceuticals being manufactured by the Bidder with product registration/license number and date.
 - (f) a Certificate of Pharmaceutical Product as recommended by the WHO for each item offered.]

A2 {For Vaccines insert the following additional clauses}

Documentary evidence of the Bidder's qualifications to perform the Contract if its bid is accepted:

- (i) (e) is certified by a competent authority in the country of manufacture according to resolution WHA 28 65 (2) of the World Health Organization's Certificate Scheme on the Quality of Pharmaceutical Products Moving in International Commerce.
- (iii) The Bidder will submit the following additional information:
 - (e) list of vaccines being manufactured by the Bidder with product registration/license number and date.]

B) further to mention above ,the Qualification criteria are:

- 1- the accurate technicality specification which contain specify the technical feature to the Goods & the related services that requested by contracting Entity.(it's technique feature & measure of quality Goods that requested by contracting Entity & degree of it's identity with specification which make the evaluation the tender process & have a clear indicator show the purpose of using Goods contain detailing of the work environment for Goods(warmth, wetness, storage condition, ...etc) & packing requirements ratification drug & it's degree identity with technique specification that state by the national committee to selection drug.
- 2- **finance capability & the ability**
 - a- the final counting for last (2)years & (5) years against the dependable company & certified by auditor & actualization the profit to his counting.
 - b-annual funds: to years from **(1) to (10)**.
 - 3-specialization experience (the same works)
 - Number of required work document of tender range between (1) to (3).
 - Number of works that must required to similar works range between (5) to (10) years .
 - **Noting that:** requested similar works is "potential" in small works.
- 4- the kind of commercial sale & the style of supplying(transport, insurance & delivery)& deliver place to items .
- 5- domestic preference.
- 6- Executed works in the similar filed & compliance & level of the implementation of the company.
- 7- certificate of trading in a country of origin.
- 8- manufacturing goods match with the requirement of the practices of good manufacturing & other certifications that mention in tender documents mechanisms of quality control.
- 9- respond to the terms & legal & specifications technical standers rehabilitation required & agree table prices & models documents standard being a lower piece & balanced with assessment cost.
- 10- duration of the contract.
- 11- company position of registration.
- 12- Position of product from registration knowing that it is in ITB the bidder shall begin to register with the competent authorities. The contract shall become effective from the date of receipt this registration certificate in case the product is not registered , if the product is registered or under the exception of the Minister of Health from submitting the registration certificate, the contract shall be effective from the date of its signature.

SECTION IV. BIDDING FORMS

NOTES ON THE BIDDING FORMS

The Bidding Forms provided in this SSBD provide standard formats for a number of the key documents that the Contracting Entity and Bidders will exchange in the process of bidding.

{The Contracting Entity shall fill in the Forms with the needed information relevant to each procurement before launching the Bidding Process. The required place for writing this information is under the paragraphs written in Italic style and shaded in grey. Any notes provided to the Contracting Entity which is underlined and shaded in yellow is for information only and shall be deleted before releasing the Bidding Documents.}

The Bidder will fill in his part of the form where it is designated between brackets or _____.

The Bidders must complete the Forms as indicated on the form, and submit them to the Contracting Entity.

Price Schedules: The price breakdown given in the sample Price Schedules generally follows the usual breakdown requested for procurement of Goods in order for the domestic preference procedure to be applied. It is essential that Bidders submit their prices in the manner prescribed by the Price Schedules. Failure to do so may result in loss of the preference, if applicable.

Manufacturer's Authorization Form: In accordance with ITB Sub-Clause 8.1 (b), Bidders must submit, as part of their bids, Manufacturer's Authorization Form(s) in the format provided in the SSBD for all items specified in the Bid Data Sheet.

Bid Security Form: Regarding ITB Clause 17, the Contracting Entity should include the Bid Security form provided in the SSBD in the Bidding Documents. The Contracting Entity must ensure that the submitted form substantially complies with the features of the form included here in respect to its degree of protection and clarity of conditions under which it can be made effective in accordance with the applicable Iraqi Laws.

**1. Bid Submission Form**

Date: [insert: **date of bid**]
 {Contracting Entity to insert}: Tender Number: [MED/2/2019"]
 IFB Number: [2"]

To: {Contracting Entity to insert: [Name and address of Contracting Entity]}

Dear Sir or Madam:

Having examined the Bidding Documents, including Addenda Nos. [insert **numbers**], the receipt of which is hereby acknowledged, we, the undersigned, offer to supply and deliver the Goods under the above-named Contract in full conformity with the said Bidding Documents for the sum of:

[insert: amount of "Iraqi Dinar" in words]	[[insert: amount of "Iraqi Dinar" in figures]]
plus [insert: amount of "US Dollar" in words]	[[insert: amount of "US Dollar" in figures]]
plus [insert: amount of "Euro" in words]	[[insert: amount of "Euro" in figures]]

(hereinafter called "the Total Bid Price") or such other sums as may be determined in accordance with the terms and conditions of the Contract. The above amounts are in accordance with the Price Schedules attached herewith and are made part of this bid.

2. We undertake, if our bid is accepted, to deliver the Goods in accordance with the delivery schedule specified in the [insert "Schedule of Requirements in Section-VI" or "as quoted in Price Schedule in Section-IV"] (the Bidder may select as appropriate clause).
3. We agree to all General Conditions of Contract in Section-VII read in conjunction with the Special Conditions of Contract in Section-VIII.
4. If our bid is accepted, we undertake to provide an advance payment security and a performance security in the form, in the amounts, and within the times specified in the Bidding Documents.
5. We agree to abide by this bid, for the Bid Validity Period specified in Sub-Clause 16.1 of the Bid Data Sheet in Section II and it shall remain binding upon us and may be accepted by you at any time before the expiration of that period.
6. Until the formal final Contract is prepared and executed between us, this bid, together with your written acceptance of the bid and your notification of award, shall constitute a binding Contract between us.
7. We understand that you are not bound to accept the lowest evaluated bid or any other bid that you may receive.
8. We agree to the following Eligibility Criteria:
 - (a) We have nationality from Eligible countries as per ITB Sub-Clause-6.1 of Section-I.
 - (b) We do not have conflict of interest in accordance with ITB Sub-Clause-6.1 (a) of Section-I.
 - (c) We are not a Government-owned Entity in Republic of Iraq./ We are a Government-owned Entity in the Republic of Iraq and meet the requirement as per Sub-Clause 6.1(b) of Section - I.



- (d) We including any of our subcontractors or manufacturers for any part of the contract, have not been declared ineligible by the Contracting Entity, under the Contracting Entity's country laws or official regulations or by an act of compliance with a decision of the United Nations Security Council.
- (e) We have not been Black listed or Suspended by Republic of Iraq and declared ineligible to bid during the period of time determined as per ITB Clause 6.3 of Section-I.

9. We confirm that our website address is **insert web side** _____, and our mail address is: _____, and that Mr. /Ms. _____ of Job Title: _____ and e-mail address: _____ will be following up all matters relevant to any Clarifications.

Dated this **insert: number** day of **insert: month**, **insert: year**.

Signed: _____

Date: _

In the capacity of **insert: title or position**

Duly authorized to sign this bid for and on behalf of **insert: name of Bidder**



**2. A. Price Schedule for Domestic Goods or Goods of Foreign Origin Located In Iraq**

1																				
Brief Description of Goods																				
No. of bid to receipt committee	Code of manufactur company	Offers submission	National code	Generic name	Generic name related to company that submit the bid	Trade name	Active item	Pharmaceutical from	volume	weight	Registration item no.	Registration item date	Quality certificate	Sample submission	sodium meta bisulfate) existence in this compand or not)	Raw material	Registration product no.	Registration product date	Per unite of package	Per unite of sheet

Grand Total of Bid price in Iraqi Dinar: _____ (In figures) _____ (In words)

Delivery Period: _____ [Bidder may insert quoted delivery period] as per INCOTERMS® current edition _____ [Insert Incoterms].

Signature of Bidder _____
Name _____ &
Designation _____
Seal _____ of _____ the _____ Bidder

Date: _____

**2. B. Price Schedule for Domestic Goods or Goods of Foreign Origin Located In Iraq**

2		3		4			5					6
Quantity offered		Country of origin		Price per physical unit Iraq currency (NO. , Write)			Price & the transport way					Total Price
Quantity of bid submitted	Free goods	The name of producing company	The origin of producing company	Package price	Per unit price	Currency type	Ex-factory/ex-warehouse/ex-show room/off-the shelf including packing and forwarding charges (a)	Sales and other taxes and duties payable if contract is awarded (b)	Inland transportation insurance loading/unloading and incidental costs till end-users site (c)	Incidental services as definal in schedule of requirement (d)	Price on DDP/free delivery at end-users e=(a+b+c+d)	Total Price on DDP/Free Delivery at End-users' site. (Iraqi Dinar) quantityX 5 (e)

Grand Total of Bid price in Iraqi Dinar: _____ (In figures) _____ (In words)

Delivery Period: _____ [Bidder may insert quoted delivery period] as per INCOTERMS® current edition _____ [Insert Incoterms].

Signature of Bidder _____
Name & Designation _____
Seal of the Bidder _____
Date: _____

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Grand Total of Bid price: [Bidders may insert permissible Currency] _____ (In figures) _____ (In words)

Delivery Period: _____ [Bidder may insert quoted delivery period] as per INCOTERMS® current edition _____ [Insert Incoterms].

Agent Name & Address: _____ [Bidder may insert, if applicable]

Agency Commission: _____ [Bidder may insert, if applicable]

Place: _____

Date: _____

Signature of Bidder _____

Name & Designation _____

Business address _____

Seal of the Bidder _____

3.B. Price Schedule for Goods to be imported from Abroad

4																	5							6
.....Country origin																	Unit price (CIP)							Total Price (CIP)
Date of registration of offer submitting company	Name of offer submitting company	Origin of offer submitting company	Manufacturer company name	Certificates obtained	Registration no of manufacturer company	Registration date of manufacturer company	Company address	Company phone no	Company email	Company website	Name of scientific bureau in Iraq that represent the company	Beneficiary name	Bank name	Bank address	Bank phone no	Account no	Price per pack	Price per unit (CIP)(A)	Currency type	Secondary services as defined in table(B)	Free goods	Payment method	Price CIP {C=(A+B)}	Total price CIP of the offered Qty. (C x Qty.)

Grand Total of Bid price: [Bidders may insert permissible Currency] _____ (In figures) _____ (In words)

Delivery Period: _____ [Bidder may insert quoted delivery period] as per INCOTERMS® current edition _____ [Insert Incoterms].

Agent Name & Address: _____ [Bidder may insert, if applicable]

Agency Commission: _____ [Bidder may insert, if applicable]

Place: _____
Date: _____

Signature of Bidder _____
Name & Designation _____
Business address _____
Seal of the Bidder _____



Republic of Iraq



5. Bid Security Form (Bank Guarantee)

[The Bank shall fill in this Bank Guarantee Form in accordance with the instructions indicated.]

[insert **Bank's Name**, and **Address** of Issuing Branch or Office]

Beneficiary: [insert **Name and Address of Contracting Entity**]

Date: _____

BID GUARANTEE No.: _____

We have been informed that [insert **name of the Bidder**] (hereinafter called "the Bidder") has submitted to you its bid dated (hereinafter called "the Bid") for the execution of [insert **name of tender/project**] under Invitation for Bids No. [insert **IFB number**] ("the IFB").

Furthermore, we understand that, according to your conditions, bids must be supported by a bid guarantee.

At the request of the Bidder, we [insert **name of Bank**] hereby irrevocably undertake to pay you any sum or sums not exceeding in total an amount of [insert **amount in figures**] ([insert **amount in words**]) upon receipt by us of your first demand in writing accompanied by a written statement stating that the Bidder is in breach of its obligation(s) under the bid conditions, because the Bidder:

- (a) has withdrawn its Bid during the period of bid validity specified by the Bidder in the Form of Bid; or
- (b) having been notified of the acceptance of its Bid by the Contracting Entity during the period of bid validity, (i) fails or refuses to execute the Contract Form, if required, or (ii) fails or refuses to furnish the performance security, in accordance with the Instructions to Bidders.
- (c) has complained or appealed as per ITB clause 36 and it is decided by the competent authorities for this Bidder to compensate all damages resulting from delaying the contract signature for false or unjustified reasons.

This guarantee will expire: (a) if the Bidder is the successful bidder, upon our receipt of copies of the contract signed by the Bidder and the performance security issued to you upon the instruction of the Bidder; or (b) if the Bidder is not the successful bidder, upon the earlier of (i) our receipt of a copy of your notification to the Bidder of the name of the successful bidder and the bidder has not complaint or appeals to the Contracting Entity; or (ii) twenty-eight days after the expiration of the Bidder's Bid and the bidder has not complaint or appeals to the Contracting Entity.

Consequently, any demand for payment under this guarantee must be received by us at the office on or before that date.

This guarantee is subject to the Uniform Rules for Demand Guarantees, ICC Publication No.758.

[signature(s)]



6. Manufacturer's Authorization

[The Bidder shall require the Manufacturer to fill in this Form in accordance with the instructions indicated. This letter of authorization should be on the letterhead of the Manufacturer and should be signed by a person with the proper authority to sign documents that are binding on the Manufacturer. The Bidder shall include it in its bid, if so indicated in the BDS.]

Date: [insert: **date** (as day, month and year) **of Bid Submission**]

IFB No.: [insert: **number of bidding process**]

To: [insert: complete name of Contracting Entity]

WHEREAS

We [insert: **complete name of Manufacturer**], who are official manufacturers of [insert: **type of goods manufactured**], having factories at [insert: **full address of Manufacturer's factories**], do hereby authorize [insert: **complete name of Bidder**] to submit a bid the purpose of which is to provide the following Goods, manufactured by us [insert: **name and or brief description of the Goods**], and to subsequently negotiate and sign the Contract.

We hereby extend our full guarantee and warranty in accordance with Clause 15 of the General Conditions of Contract, with respect to the Goods offered by the above firm.

Signed: [insert: **signature(s) of authorized representative(s) of the Manufacturer**]

Name: [insert: **complete name(s) of authorized representative(s) of the Manufacturer**]

Title: [insert: **title**]

Duly authorized to sign this Authorization on behalf of: [insert: **complete name of Bidder**]

Dated on _____ day of _____, _____ [insert: **date of signing**]



7. Sample Form for Performance Statement

Contract placed by	Order No and date	Order placed on	Description of Goods	Quantity	Date if completion of Contract		Reasons of delay, if any	Are the goods supplied satisfactory?
					As per Contract	Actual		
1	2	3	4	5	6	7	8	9





PART 2
PROCUREMENT REQUIREMEN



SECTION VI SCHEDULE OF REQUIREMENTS

NOTES ON THE SCHEDULE OF REQUIREMENTS

The Schedule of Requirements provides a concise description of each product and the quantity required, along with any technical specifications unique to that item.





SCHEDULE OF REQUIREMENTS

Schedule: I List of Goods, Delivery Schedule and Terms of Delivery:

1		2					3	4	5	6
Schedule No.	Item No.	Brief Description of Goods [Insert for Pharmaceuticals, Product, Strength, Dosage form, Pharmacopoeia Standard and Unit pack size. For Medical Equipment only Brief Description of goods may be mentioned]					Quantity and physical unit	Bid security amount in Iraqi Dinar [Note Insert Bid Security amount Schedule wise as one percent of Estimated Value]	Final Destination [Note Insert End-users' address]	Required Delivery period as per [insert Incoterms® current edition]
		Product	Strength	Dosages form	Pharmacopoeia Standard	Unit pack size				
(a)	(b)	(a)	(b)	(c)	(d)	(e)				
[Insert]	[Insert]	[Insert]	[Insert]	[Insert]	[Insert]	[Insert]	[Insert]	[Insert]	[Insert]	[Insert]
	[Insert]	[Insert]	[Insert]	[Insert]	[Insert]	[Insert]	[Insert]	[Insert]	[Insert]	[Insert]
[Insert]	[Insert]	[Insert]	[Insert]	[Insert]	[Insert]	[Insert]	[Insert]	[Insert]	[Insert]	[Insert]

Terms of Delivery: The Bidders are required to quote prices as per the terms of delivery stipulated in Price Schedule in Section -IV



ScheduleII: Scope of Incidental Services:

[Insert:“**Nil**” for Health Sector Goods

OR “Required Installation, Demonstration and onsite Training” for Medical Equipment]

ScheduleIV. Technical Specifications

The purpose of the Technical Specifications (TS) is to define the technical characteristics of the Goods and Related Services required by the Contracting Entity

Technical Specifications

- 1-the items offer should be stated by it's commercial name if it offer in it's scientific name should be stated in pharmacopoeia standards. **PHARMACEUTICALS**
- 2-stat the shelf life.
- 3-stat the origin of a material.

**Technical Specifications
PHARMACEUTICALS**

- 1. Product and Package Specifications**
- 1.1 The Goods to be purchased by the Contracting Entity under this Invitation for Bids are included in Iraq's current national essential drugs list or national formulary. The required packing standards and labeling must meet the latest requirements of the World Health Organization (WHO) good manufacturing practices (GMP) standards in all respects. (These standards are contained in "Good Practices in the Manufacture and Quality Control of Drugs.")
- 1.2 Product specifications indicate dosage form (e.g., tablet, capsules, dry syrup, liquid, ointment, injectable, emulsion, suspension, etc.) and the drug content (exact number of mg or international units [IU] or % v/v, w/w or v/w acceptable range). The Goods should conform to standards specified in the following compendia: [The Contracting Entity should specify an acceptable pharmacopoeia standard from one of the following: the British Pharmacopoeia, the United States Pharmacopoeia, the French Pharmacopoeia, the International Pharmacopoeia, or the European Pharmacopoeia, the latter particularly for raw materials.] The standards will be the latest edition unless otherwise stated by the Contracting Entity or other if applicable. In case the pharmaceutical product is not included in the specified compendium, but included in the Iraq's national essential drug list, the Contracting Entity should clearly indicate acceptable limits and the Bidder (Supplier), upon award of the Contract, must provide the reference standards and testing protocols to allow for quality control testing.
- 1.3 Not only the pharmaceutical item, but also the packaging and labeling components (e.g., bottles, closures, and labeling) should also meet specifications suitable for distribution, storage, and use in a climate similar to that prevailing in Iraq. All packaging must be properly sealed and tamper-proof and packaging components must meet the latest compendium standards and be approved for pharmaceutical packaging by the manufacturer's national regulatory authority (RA). The Contracting Entity should specify any additional special requirements.

2. Labeling Instructions

- 1.4 All labeling and packaging inserts shall be in the language requested by the Contracting Entity or English if not otherwise stated.
- 1.5 Goods requiring refrigeration or freezing or those that should not fall below a certain minimum temperature for stability must specifically indicate storage requirements on labels and containers and be shipped in special containers to ensure stability in transit from point of shipment to port of entry.
- 1.6 Upon award, the successful Bidder(Supplier) shall, on demand, provide a translated version in the language of the bid of the prescriber's information for any specific goods the Contracting Entity may request.
- 2.1 The label of the primary container for each pharmaceutical and vaccine products shall meet the W210 GMP standard and include:
 - (a) The international nonproprietary name (INN) or generic name prominently displayed and above the brand name, where a brand name has been given. Brand names should not be bolder or larger than the generic name;
 - (b) dosage form, e.g., tablet, ampoule, syrup, etc.;
 - (c) the active ingredient "per unit, dose, tablet or capsule, etc.;
 - (d) the applicable pharmacopoeia standard;
 - (e) the Purchaser's logo and code number and any specific color coding if required;
 - (f) content per pack;
 - (g) instructions for use;
 - (h) special storage requirements;
 - (i) batch number;
 - (j) date of manufacture and date of expiry (in clear language, not code);
 - (k) name and address of manufacture;
 - (l) any additional cautionary statement.

3. Case Identification

- 2.2 The outer case or carton should also display the above information.
- 3.1 All cases should prominently indicate the following:
 - (a) Purchaser's line and code numbers;
 - (b) the generic name of the product;
 - (c) the dosage form (tablet, ampoule, syrup);
 - (d) date of manufacture and expiry (in clear language not code);
 - (e) batch number;
 - (f) quantity per case;
 - (g) special instructions for storage;
 - (h) name and address of manufacture;
 - (i) any additional cautionary statements.
- 3.2 No case should contain pharmaceutical products from more than one batch.

4. Unique Identifiers

- 4.1 The Contracting Entity(Purchaser) shall have the right to request the Supplier to imprint a logo, if the quantity so justifies it, on the labels of the containers used for packaging and in certain dosage forms, such as tablets,

**5. Standards of Quality Control for Supply**

and ampoules and this will be in the Technical Specifications. The design and detail will be clearly indicated at the time of bidding, and confirmation of the design of such logos shall be provided to the Bidder (Supplier) at the time of contract award.

- 5.1 The successful Bidder (Supplier) will be required to furnish to the Contracting Entity:
- (a) With each consignment, and for each item a WHO certificate of quality control test results concerning quantitative assay, chemical analysis, sterility, pyrogen content uniformity, microbial limit, and other tests, as applicable to the Goods being supplied and the manufacturer's certificate of analysis.
 - (b) Assay methodology of any or all tests if requested.
 - (c) Evidence of bio-availability and/or bio-equivalence for certain critical Goods upon request. This information would be supplied on a strictly confidential basis only.
 - (d) Evidence of basis for expiration dating and other stability data concerning the commercial final package upon request.
- 5.2 The Supplier (Bidder) will also be required to provide the Contracting Entity (Purchaser) with access to its manufacturing facilities to inspect the compliance with the GMP requirements and quality control mechanisms.]

**[Sample:
Technical Specification
VACCINES**

**1. Product
Qualification
Requirements**

Option A

- 1.1 The Goods to be purchased by the Contracting Entity under this Invitation for Bids must be produced under the control of a recognized, well-functioning National Control Authority (NCA) for biologicals, which performs all six critical functions as defined by the World Health Organization (WHO):
- (a) licensing based on published set of requirements
 - (b) surveillance of vaccine field performance
 - (c) system of lot release for vaccines
 - (d) use of laboratory when needed
 - (e) regular inspections for Good Manufacturing Practices (GMP)
 - (f) evaluation of clinical performance

Or state the following:

Option B

- 1.1 The Goods under this Invitation for Bids should be purchased from WHO-approved sources only.
- 1.2 The Goods to be purchased by the Contracting Entity under this Invitation for Bids must be produced in accordance with the GMP recommendations of WHO for biological products.
- 1.3 The Goods to be purchased by the Contracting Entity under this Invitation for Bids must be registered by the National Control Authority (NCA) of Iraq.

**2. Product
Specification
s**

- 2.1 Dosage form (e.g.: oral or injectable; liquid or freeze dried with sterile diluents packed separately, etc.).
- 2.2 Type (e.g.: "live attenuated," "manufactured from purified inactivated (...) obtained from human plasma or manufactured using recombinant DNA technology," etc.).
- 2.3 Administration (e.g.: "intended for intramuscular injection," etc.).
- 2.4 Description of intended use (e.g.: "immunization of newborn infants," etc.).
- 2.5 Dosage size (if not restrictive), or expected immunogenic reaction (e.g.: each dose shall contain that amount of Hbsag protein with micrograms/ml specified by the manufacturer for newborn dosage, that when given as part of a primary immunization series [3 doses] is capable of producing specific humoral antibody [anti HBs] at a level of at least 10 milli international units in >-90 percent of recipients," etc.).
- 2.6 Dose package (e.g.: "5 infant dose sterile glass vials," etc.).
- 2.7 Filling volume (e.g.: "final product should contain 15% overfill," etc.).
- 2.8 Closures (e.g.: "vaccine vials shall be fitted with closures that conform to ISO standard 8362-2").
- 2.9 Storage temperature (e.g.: "2-8 degrees C. Do not freeze," or as appropriate, etc.).



3. Labeling Requirements

- 2.10 The product should remain stable up to the indicated test expiry date if kept according to the required storage temperature.
- 2.11 Standards (e.g.: "The vaccine should conform to standards established by Iraq or, where no standard has been adopted, meet current requirements published by the WHO Expert Committee on Biological Standardization, or requirements of an established body of equivalent stature such as the U.S. Pharmacopoeia, the British Pharmacopoeia, the French Pharmacopoeia, or the International Pharmacopoeia").
- 3.1 Each vial or ampoule shall carry the manufacturer's standard label in Iraqi language, if available at no extra charge; otherwise, the label shall be in English.
- 3.2 Each vial or ampoule label shall state the following:
 - (a) name of the vaccine;
 - (b) name of the manufacturer;
 - (c) place of manufacture;
 - (d) lot number;
 - (e) composition;
 - (f) concentration;
 - (g) dose mode for administration;
 - (h) expiration date;
 - (i) storage temperature;
 - (j) any other information that is appropriate.
- 3.3 All labeling shall withstand immersion in water and remain intact.

4. Packing Requirements

- 4.1 Inner boxes: Inner Boxes shall contain not more than (number) individual vials/ampoules and shall be constructed of sturdy white cardboard outfitted with individual segments for protecting and separating each vial/ampoules.
- 4.2 Printed materials: Each inner box shall contain at least (number) manufacturer's standard package inserts in the Iraqi language if available at no extra charge; otherwise, package insert shall be in English.
- 4.3 Over packing: Inner boxes shall be over packed so that the vaccine remains refrigerated as designated in Sub-Clause 2.9. The over packing must be suitable for export handling and be in accordance with WHO Expanded Program of Immunization (EPI) Guidelines on International Packaging and Shipping of Vaccines including all measures needed to maintain required temperatures for seventy-two (72) hours. It must have adequate insulation and sufficient refrigerant to ensure that the warmest storage temperature of the vaccine does not rise above that designated in Sub-Clause 2.9 when exposed to continuous outside temperature of +43 degrees C, nor fall below that specified of -20 degrees C during transit and for a period of at least twenty-four (24) hours after arrival at the airport destination. Additional cushioning shall be provided sufficient to protect the vials/ampoules from breakage during transit and handling.

- 4.4 Exterior shipping cartons: Product and printed materials, packaged as described above, shall be packed in weather-resistant, triple-wall corrugated fiberboard cartons with a bursting test strength of not less than 1,900 kPa. The overall dimensions of the exterior shipping cartons should be such that the product does not become damaged during transportation and storage.

No shipping carton should contain vaccine from more than one lot.

- 4.5 Cold chain monitor cards: Each insulated shipping container must include appropriate temperature-monitoring devices designated by the Contracting Entity.

- (a) At least two suitable cold chain monitor cards, as approved by the Contracting Entity, shall be packed in each transport case of vaccine.
- (b) Freeze watch indicators shall be included in each transport case at the direction of Contracting Entity.

5. Marking Requirements

- 5.1 All containers and invoices must bear the following information:

- (a) the name of the vaccine;
- (b) expiration date of the vaccine;
- (c) appropriate storage temperature.

- 5.2 Inner boxes: The inner boxes containing vaccine vials or ampoules shall be marked with the following information in a clearly legible manner that is acceptable to the Contracting Entity:

- (a) Generic name and trade name of the vaccine;
- (b) Manufacturer's name and trade registered address;
- (c) Manufacturer's national registration number;
- (d) Lot or batch number;
- (e) Composition and concentration;
- (f) Number of vials contained in box;
- (g) Expiration date (month and year in clear language, not code);
- (h) Instructions for storage and handling;
- (i) Place of manufacture (Made in _____).

- 5.3 Exterior Shipping Cartons: The following information shall be stenciled or labeled on the exterior shipping cartons on two opposing sides in bold letters at least 30mm high with waterproof ink in a clearly legible manner that is acceptable to the Contracting Entity.

- (a) Generic name and trade name of the vaccine;
- (b) Lot or batch number;
- (c) Expiration date (month and year in clear language, not code);
- (d) Manufacturer's name and registered address;
- (e) Manufacturer's national registration number;
- (f) Destination airport and routing;
- (g) Consignee's name and address in full;
- (h) Consignee contact name and telephone number;



- (i) Number of vials or ampoules contained in the carton;
- (j) Gross weight of each carton (in kg);
- (k) Carton #_____ of _____;
- (l) Instructions for storage and handling;
- (m) Contract number;
- (n) Place of manufacture (Made in_____).

6. Quality Control for Supply

- 6.1 All goods must:
 - (a) meet the requirements of manufacturing legislation and regulation of vaccines in the country of origin;
 - (b) meet internationally recognized standards for safety, efficacy, and quality;
 - (c) conform to all the specifications and related documents contain herein;
 - (d) be fit for the purposes expressly made known to the Bidder by the Contracting Entity;
 - (e) be free from defects in workmanship and materials; and
 - (f) be certified by a competent authority in the manufacturer's country according to resolution WHA 28-65(2), of the WHO release certificate.
- 6.2 The Supplier will be required to furnish to the Contracting Entity with each consignment;
 - (a) A certificate of quality control and test results in conformity with the WHO release certificate.
 - (b) Assay methodology of any or all tests if required.
 - (c) Evidence of basis for expiration dating and other stability data concerning the commercial final package upon request.
- 6.3 Pre-shipment inspection and testing: The Supplier will be required to provide the Purchaser or his representative with access to the product as packed for shipment at the sellers' factory and/or warehouse at a mutually agreeable time prior to shipment of the product.
 - (a) The Purchaser may inspect and sample, or cause to be sampled, such product.
 - (b) The Purchaser may cause independent laboratory testing to be performed as deemed necessary to ensure that the Goods conform to prescribed requirements. The testing laboratory shall be of the Purchaser's choice and suitably equipped and qualified to conduct quality control test on biological products.



PART 3
CONDITIONS OF CONTRACT AND CONTRACT FORMS

SECTION VII. GENERAL CONDITIONS OF CONTRACT

NOTES ON THE GENERAL CONDITIONS OF CONTRACT

The General Conditions of Contract (GCC) in Section VII, read in conjunction with the Special Conditions of Contract (SCC) in Section VIII and other documents listed in the Contract Agreement, should be a complete document expressing all the rights and obligations of the parties.

GCC must remain unaltered. Contract-specific information, deletions, extensions, and modifications to the GCC shall be introduced only by the Contracting Entity through the SCC.



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**General Conditions of Contract****1. Definitions**

- 1.1 In this Contract, the following terms shall be interpreted as indicated:
- (a) "The Contract" means the agreement entered into between the Contracting Entity and the Supplier, as recorded in the Contract Form signed by the parties, including all attachments and appendices thereto and all documents incorporated by reference therein.
 - (b) "The Contract Price" means the price payable to the Supplier under the Contract for the full and proper performance of its contractual obligations.
 - (c) "Day" means calendar day.
 - (d) "Effective Date" means the date on which this Contract becomes effective pursuant to GCC Sub-Clause 6.2.
 - (e) "End User" means the organization(s) where the goods will be used, as named in the Schedule of Requirements.
 - (f) "GCC" means the General Conditions of Contract contained in this section.
 - (g) "The Goods" means all of the pharmaceuticals including nutritional supplement and oral and injectable forms of contraception, vaccines, condoms and medical equipment that the Supplier is required to supply to the Contracting Entity under the Contract.
 - (h) "The Purchaser" means the organization or the Contracting Entity purchasing the Goods, as **named in the SCC.**
 - (i) "Registration Certificate" means the certificate of registration or other documents in lieu thereof establishing that the Goods supplied under the Contract are registered for use in the Iraq in accordance with the Applicable Law.
 - (j) "SCC" means the Special Conditions of Contract.
 - (k) "The Services" means those services ancillary to the supply of the Goods, such as transportation and insurance, and any other incidental services, such as installation, demonstration and onsite training at End-users' site, and other such obligations of the Supplier covered under the Contract.
 - (l) "The Site," where applicable, means the place or places of End-users' site as per Schedule of Requirements
 - (m) "The Supplier" means the individual or firm supplying the Goods and Services under this Contract, as **named in the SCC.**
 - (n) **Fraud and Corruption :**
The Purchaser defines Fraud and Corruption as per the relevant applicable Iraqi laws. For the purposes of this Sub-Clause, the Purchaser will be guided further by the definition of the terms as set forth here below:
 - (i) "corrupt practice" is the offering, giving, receiving or soliciting, directly or indirectly, of anything of value to influence improperly the actions of another party;
 - (ii) "fraudulent practice" is any act or omission, including a misrepresentation, that knowingly or recklessly misleads, or attempts to mislead, a party to obtain a financial or



- other benefit or to avoid an obligation;
- (iii) “collusive practice” is an arrangement between two or more parties designed to achieve an improper purpose, including to influence improperly the actions of another party;
 - (iv) “coercive practice” is impairing or harming, or threatening to impair or harm, directly or indirectly, any party or the property of the party to influence improperly the actions of a party;
 - (v) “obstructive practice” is
 - (aa) deliberately destroying, falsifying, altering or concealing of evidence material to the investigation or making false statements to investigators in order to materially impede a Purchaser’s investigation into allegations of a corrupt, fraudulent, coercive or collusive practice in accordance with the applicable Iraqi laws; and/or threatening, harassing or intimidating any party to prevent it from disclosing its knowledge of matters relevant to the investigation or from pursuing the investigation, or
 - (bb) acts intended to materially impede the exercise of the Purchaser’s inspection and audit rights as per the applicable Iraqi laws and as per Sub-Clause 5.4.

2. Application

- 2.1 These General Conditions shall apply to the extent that they are not superseded by provisions of other parts of the Contract.

3. Country of Origin

- 3.1 For purposes of this Clause, “origin” means the place where the Goods were mined, grown, or produced, or from which the Services are supplied. Goods are produced when, through manufacturing, processing, or substantial and major assembly of components, a commercially recognized new product results that is substantially different in basic characteristics or in purpose or utility from its components.
- 3.2 The origin of Goods and Services is distinct from the nationality of the Supplier.

4. Standards

- 4.1 The Goods supplied under this Contract shall conform to the standards mentioned in the Technical Specifications and, when no applicable standard is mentioned, to the authoritative standards appropriate to the Goods’ country of origin. Such standards shall be the latest issued by the concerned institution.

5. Use of Contract Documents and Information; Inspection and Audit

- 5.1 The Supplier shall not, without the Purchaser’s prior written consent, disclose the Contract, or any provision thereof, or any specification, plan, drawing, pattern, sample, or information furnished by or on behalf of the Purchaser in connection therewith, to any person other than a person employed by the Supplier in the performance of the Contract. Disclosure to any such employed person shall be made in confidence and shall extend only as far as may be necessary for purposes of such performance.
- 5.2 The Supplier shall not, without the Purchaser’s prior written consent, make use of any document or information enumerated in GCC Sub-Clause 5.1 except for purposes of performing the Contract.

5.3 Any document, other than the Contract itself, enumerated in GCC Sub-Clause 5.1 shall remain the property of the Purchaser and shall be returned (all copies) to the Purchaser on completion of the Supplier's performance under the Contract if so required by the Purchaser.

5.4 In accordance with the applicable Iraqi laws, the Supplier shall permit the Purchaser through the competent authorities to inspect the Supplier's offices and/or the accounts and records of the Supplier and its sub-contractors relating to the performance of the Contract, and to have such accounts and records audited by auditors. The Supplier's attention is drawn to Clause 23, which provides, inter alia, that acts intended to materially impede the exercise of the Purchaser's inspection and audit rights provided for under this Sub-Clause constitute a prohibited practice subject to contract termination as well as to a determination of ineligibility pursuant to the Iraqi's prevailing sanctions procedures in Iraq.

6. Certification of Goods in Accordance with Laws of Republic of Iraq

6.1 If required under the Applicable Law, Goods supplied under the Contract shall be registered for use in the Iraq. The Purchaser undertakes to cooperate with the Supplier to facilitate registration of the Goods for use in the Iraq.

6.2 Unless otherwise **specified in the SCC**, the Contract shall become effective on the date ("the Effective Date") that the Supplier receives written notification from the competent authority in Iraq that the Goods have been registered for use in Iraq.

7. Industrial ownership or Patent Right

7.1 The Supplier shall indemnify the Purchaser against all third-party claims of infringement of patent, trademark, or industrial design rights arising from use of the Goods or any part thereof in Iraq.

8. Performance Security

8.1 Within 14 days, or twenty-nine (29) days in case of Complaints and Appeals raised by unsuccessful Bidders, of receipt of the notification of Contract award, the successful Bidder shall furnish to the Purchaser the performance security of 5% of Contract Price. If rules and regulations of Republic of Iraq grant exemption to Public Companies of State and Public Sector, they are accordingly exempted of submitting Performance Security.

8.2 The proceeds of the performance security shall be payable to the Purchaser as compensation for any loss resulting from the Supplier's failure to complete its obligations under the Contract.

8.3 The performance security shall be denominated in the currency or currencies of the Contractor in a freely convertible currency acceptable to the Purchaser and chosen from the list of currencies from which the Central Bank of Iraq quotes the rate of exchange to the Iraqi **Dinar**. The Security shall be an unconditional guarantee payable upon first demand and in one of the following forms:

(a) A bank guarantee issued by accredited bank in Iraq in



accordance with the instructions of Central Bank of Iraq in the format provided in the Bidding Documents. In the case of a Bank Guarantee furnished from the banks located outside Iraq, it shall be endorsed and countersigned by an accredited bank in Iraq by way of back-to-back counter guarantee. Or

- (b) an irrevocable letter of credit or
- (c) Republic of Iraq bonds

8.4 The performance security will be discharged by the Purchaser and returned to the Supplier not later than thirty (30) days following the date of completion of the Supplier's performance obligations under the Contract, including any warranty obligations. The performance security shall be released after the final certificate regarding satisfactory completion of Supplier's performance obligations has been issued and final payment settlements have been done.

9. Inspections and Tests

9.1 The Purchaser or its representative shall have the right to inspect and/or to test the Goods to confirm their conformity to the Contract specifications. **The SCC** and the Technical Specifications shall specify what inspections and tests the Purchaser requires and where they are to be conducted. The Purchaser shall notify the Supplier in writing, in a timely manner, of the identity of any representatives retained for these purposes.

9.2 As **specified in the SCC**.

9.3 Nothing in GCC Clause 8 shall in any way release the Supplier from any warranty or other obligations under this Contract.

10. Packing

10.1 The Supplier shall provide such packing of the Goods as is required to prevent their damage or deterioration during transit to their final destination, as indicated in the Contract. The packing shall be sufficient to withstand, without limitation, rough handling during transit and exposure to extreme temperatures, salt, and precipitation during transit and open storage. Packing case size and weights shall take into consideration, where appropriate, the remoteness of the Goods' final destination and the absence of heavy handling facilities at all points in transit.

10.2 The packing, marking, and documentation within and outside the packages shall comply strictly with such special requirements as shall be expressly provided for in the Contract, including additional requirements, if any, **specified in the SCC** or Technical Specifications, and in any subsequent instructions ordered by the Purchaser.

11. Delivery and Documents

11.1 Delivery of the Goods shall be made by the Supplier in accordance with the terms specified in the Schedule of Requirements. The details of shipping and/or other documents to be furnished by the Supplier are **specified in the SCC**.

11.2 For purposes of the Contract, "EXW," "CIF," "CIP," "DDP" and other trade terms used to describe the obligations of the parties shall be governed by the



international rules for interpreting trading terms as prescribed in the current edition of INCOTERMS® published by the International Chamber of Commerce, Paris.

11.3 Documents to be submitted by the Supplier are **specified in the SCC.**

12. Insurance

12.1 The Goods supplied under the Contract shall be fully insured in a freely convertible currency chosen from the list of currencies from which the Central Bank of Iraq quotes the rate of exchange to the Iraqi Dinar, against loss or damage incidental to manufacture or acquisition, transportation, storage, and delivery. Where delivery of Goods is required by Purchaser on a CIF or CIP basis, the supplier shall assure the insurance of an amount equal to 110 percent of the CIF or CIP value of the Goods from “warehouse” to “warehouse” on “All Risks” basis, including war risks and strikes.

12.2 Where delivery of the Goods is required by the Purchaser on a CIF or CIP basis, the Supplier shall arrange and pay for cargo insurance, naming the Purchaser as beneficiary. Where delivery is on an FOB or FCA basis, insurance shall be the responsibility of the Purchaser.

13. Transportation

13.1 Where the Supplier is required under Contract to deliver the Goods FOB, transport of the Goods, up to and including the point of putting the Goods on board the vessel at the specified port of loading, shall be arranged and paid for by the Supplier, and the cost thereof shall be included in the Contract Price. Where the Supplier is required under the Contract to deliver the Goods FCA, transport of the Goods and delivery into the custody of the carrier at the place named by the Purchaser or other agreed point shall be arranged and paid for by the Supplier, and the cost thereof shall be included in the Contract Price.

13.2 Where the Supplier is required under Contract to deliver the Goods CIF or CIP, transport of the Goods to the port of destination or such other named place of destination in the Purchaser's country, as shall be specified in the Contract, shall be arranged and paid for by the Supplier, and the cost thereof shall be included in the Contract Price.

13.3 Where the Supplier is required under the Contract to transport the Goods to a specified place of destination within Iraq, defined as the Site, transport to such place of destination in Iraq, including insurance and storage, as shall be specified in the Contract, shall be arranged by the Supplier, and related costs shall be included in the Contract Price.

13.4 Where the Supplier is required under Contract to deliver the Goods CIF or CIP, no restriction shall be placed on the choice of carrier.

14. Incidental Services & AMC

14.1 The Supplier shall provide such incidental services, if any, as are **specified in the Schedule of Requirements.**

**15. Warranty****16. Payment**

14.2 The Supplier shall provide Annual Maintenance Contract (AMC), if any, after warranty period for number of years as specified in the Schedule of Requirements.

15.1 Warranty shall be as **specified in the SCC**.

16.1 The method and conditions of payment to be made to the Supplier under this Contract shall be **specified in the SCC**.

16.2 The Supplier's request(s) for payment shall be made to the Purchaser in writing, accompanied by an invoice describing, as appropriate, the Goods delivered and Services performed, and by documents submitted pursuant to GCC Clause 11, and upon fulfillment of other obligations stipulated in the Contract.

16.3 Payments shall be made promptly by the Purchaser, but in no case later than sixty (60) days after submission of an invoice or claim by the Supplier. In case of delay beyond 60 (sixty) days, the resolution of this delay shall be settled as **specified in the SCC**.

When applicable, the advance security shall be payable upon an on demand and unconditional guarantee issued by an accredited bank in Iraq as per the official publication of the Iraqi Central Bank. If the security is issued by a Bank located outside Iraq, the issuer shall have a correspondent accredited financial institution located in Iraq to make it enforceable. In the case of a bank guarantee, the security shall be submitted using the Bid Security Form included in Section IX (Contract Forms) or in another substantially similar format with the prior approval of the Purchaser as per the applicable Iraqi laws.

16.4 Payment will be made in the currency or currencies in which the payment has been requested in the Supplier's bid.

16.5 Irrevocable non – transferable and unconfirmed Letter of Credit (LC) shall be opened by the Purchaser in accordance with the applicable Iraqi regulations. However, if the Supplier requests specifically to open confirmed LC, the extra charges would be borne by the supplier. If LC is required to be extended and/or amended for reasons not attributed to the Purchaser, the charges thereof shall be borne by the Supplier. However, if the LC is amended to make LC as per Contract requirements then charges thereof shall be borne by the Purchaser.

17. Prices

17.1 Prices charged by the Supplier for Goods delivered and Services performed under the Contract shall not vary from the prices quoted by the Supplier in its bid, prices shall be fixed and firm for the duration of Contract.

18. Change Orders

18.1 No changes shall be introduced to the contract unless for the circumstances (a-e) listed herebelow. In such case, the Change should be limited to minimum and would be applicable for the following reasons:

- a) If the change is not introduced, a major damage will result economically and technically;
- b) If the change is not introduced, the Goods cannot be useful upon completion;

- c) If the change will realize savings in the cost of the Project;
- d) If the change does not result in a major modification to the pre-determined scope of supply;
- e) If the change will result in earlier time for completion but not to result in inferior technical specification or scope of supply

The Purchaser may as per the applicable Iraqi laws, by a written order given to the Supplier pursuant to GCC Clause 31, make changes within the general scope of the Contract in any one or more of the following:

- (a) specifications, where Goods to be furnished under the Contract are to be specifically manufactured for the Purchaser;
- (b) the method of shipment or packing;
- (c) the place of delivery; and/or
- (d) the Services to be provided by the Supplier.

18.2 If any such change causes an increase or decrease in the cost of, or the time required for, the Supplier's performance of any provisions under the Contract, an equitable adjustment shall be made in the Contract Price or delivery schedule, or both, and the Contract shall accordingly be amended. Any claims by the Supplier for adjustment under this clause must be asserted within fifteen (15) days from the date of the Supplier's receipt of the Purchaser's change order.

19. Contract Amendments

19.1 Subject to GCC Clause 18, no variation in or modification of the terms of the Contract shall be made except by written amendment signed by the parties.

20. Assignment

20.1 The Supplier shall not assign, in whole or in part, its obligations to perform under this Contract, unless specified otherwise **in the SCC**.

21. Delays in the Supplier's Performance

21.1 Delivery of the Goods and performance of Services shall be made by the Supplier in accordance with the time schedule prescribed by the Purchaser in the Schedule of Requirements.

21.2 If at any time during performance of the Contract, the Supplier or its subcontractor(s) should encounter conditions impeding timely delivery of the Goods and performance of Services, the Supplier shall promptly notify the Purchaser in writing of the fact of the delay, its likely duration, and its cause(s). As soon as practicable after receipt of the Supplier's notice, the Purchaser shall evaluate the situation and may at its discretion extend the Supplier's time for performance, with or without liquidated damages, in which case the extension shall be ratified by the parties by amendment of Contract.

21.3 Except as provided under GCC Clause 24, a delay by the Supplier in the performance of its delivery obligations shall render the Supplier liable to the imposition of liquidated damages pursuant to GCC Clause 22, unless an extension of time is agreed upon pursuant to GCC Sub-Clause 21.2 without the application of liquidated damages.



**22. Delay penalties
(reduced
according the
achievement
percentage**

22.1 Subject to GCC Clause 24, if the Supplier fails to deliver any or all of the Goods or to perform the Services within the period(s) specified in the Contract, the Purchaser shall, without prejudice to its other remedies under the Contract, deduct from the Contract Price, as liquidated damages as per following formula:

Total Contract Price X 10% - 25% = delay penalty per day

Total validity contract (days)

OR could be deducted as followoing formula :

**Unperformed Contract Price X 10% = Liquidated damages
per day**

Delivery period (days)

In the above formula the unperformed Contract Price applicable will be a sum equivalent to delivered price of the delayed Goods or unperformed Services until actual delivery or performance, up to a maximum deduction of the 10% percentage of Contract Price. Once the maximum is reached, the Purchaser may consider termination of the Contract pursuant to GCC Clause 23.

**23. Termination for
Default**

23.1 The Purchaser, without prejudice to any other remedy for breach of Contract, by written notice of default sent to the Supplier, may terminate this Contract in whole or in part in accordance with the Iraqi applicable laws:

- (a) if the Supplier fails to deliver any or all of the Goods within the period(s) specified in the Contract, or within any extension thereof granted by the Purchaser pursuant to GCC Clause 21; or
- (b) if the Goods do not meet the Technical Specifications stated in the Contract **within 30 days from date of receiving the wrtten notification issued by the purchaser;**
or
- (c) if the Supplier fails to provide any registration or other certificates in respect of the Goods within the time specified in the Special Conditions.
- (d) if the Purchaser determines as per the applicable Iraqi laws that the Supplier has engaged in corrupt, fraudulent, collusive, coercive or obstructive practices in accordance with GCC Sub-Clause 1.1.n, in competing for or in executing the Contract, then the Purchaser may, after giving **15** days notice to the Supplier, terminate the Supplier's employment under the Contract and cancel the contract, and the provisions of Clause 23 shall apply as if such expulsion had been made under Sub-Clause 23.1.
- (e) should any employee of the Supplier be determined to have engaged in corrupt, fraudulent, collusive, coercive, or obstructive practice in accordance with GCC Sub-Clause 1.1.n during the purchase of the Goods, then that employee shall be removed.
- (f) if the Supplier fails to perform any other obligation(s) under the Contract.
- (g) if the supplier withdraw completely or partially rom the contract to another supplier or sign un-official contract with another supplier



23.2 In the event the Purchaser terminates the Contract in whole or in part, pursuant to GCC Sub-Clause 23.1, the Purchaser may procure, upon such terms and in such manner as it deems appropriate, Goods or Services similar to those undelivered, and the Supplier shall be liable to the Purchaser for any excess costs for such similar Goods or Services. However, the Supplier shall continue performance of the Contract to the extent not terminated.

24. Termination for Insolvency

-The Purchaser may at any time terminate the Contract by giving written notice within 15 days to the Supplier if the Supplier becomes bankrupt or otherwise insolvent. Without retuning to the court as following cases :

- (a) if the supplier has been insolvency , poverty, or subjected to dissolution his assets or submit a request to become under Insolvency or poverty.
- (b) if the relevant court issued a judgment to put the supplier assets under the hand of Insolvency secretary .
- © if the supplier has agreed to carryout his contractual obligations under the observation of inspection committee consist of his creditors.
- (d) if the supplier assets have been holding (blocked) by the relevant court which lead to inability to commit with his contractual obligations.

In this case , the contract will be under determination without any compensation to the supplier & without exceed to the purchaser rights or compensations according to the contract or what are resulted beyond.

25. Force Majeure

25.1 Notwithstanding the provisions of GCC Clauses 21, 22, and 23, the Supplier shall not be liable for forfeiture of its performance security, liquidated damages, or termination for default if and to the extent that it's delay in performance or other failure to perform its obligations under the Contract is the result of an event of Force Majeure.

25.2 For purposes of this clause, "Force Majeure" means an event beyond the control of the Supplier and not involving the Supplier's fault or negligence and not foreseeable. Such events may include, but are not restricted to, acts of the Purchaser in its sovereign capacity, wars or revolutions, fires, floods, epidemics, quarantine restrictions, and freight embargoes.

25.3 If a Force Majeure situation arises, the Supplier shall promptly notify the Purchaser in writing of such condition and the cause thereof. Unless otherwise directed by the Purchaser in writing, the Supplier shall continue to perform its obligations under the Contract as far as is reasonably practical and shall seek all reasonable alternative means for performance not prevented by the Force Majeure event.

26. Termination for Convenience

26.1 The Purchaser, by written notice sent to the Supplier, may terminate the Contract, in whole or in part, at any time for the following cases :

- (a) for general benefit .



(b) in case there is no way to achieve the contract for any reason agreed which are outside the will of the two parties, which lead to impossible supplying.

For its convenience. The notice of termination shall specify that termination is for the Purchaser's convenience, the extent to which performance of the Supplier under the Contract is terminated, and the date upon which such termination becomes effective.

26.2 For the remaining goods, the Purchaser may elect:

- (a) to have any portion completed and delivered at the Contract terms and prices; and/or
- (b) to cancel the remainder and pay to the Supplier an agreed amount for partially completed Goods and Services and for materials and parts previously procured by the Supplier.

26.3 If the Contract is terminated for convenience of the Purchaser, the rights, duties and obligations of the parties, including all dues to the Supplier, shall be in accordance with the procedure set forth in Clause 27.

27. Settlement of Disputes

27.1 If any dispute or difference of any kind whatsoever shall arise between the Purchaser and the Supplier in connection with or arising out of the Contract, the parties shall make every effort to resolve amicably such dispute or difference by mutual consultation.

27.2 If, after thirty (30) days, the parties have failed to resolve their dispute or difference by such mutual consultation, then either the Purchaser or the Supplier may give notice to the other party of its intention to commence arbitration, as hereinafter provided, as to the matter in dispute, and no arbitration in respect of this matter may be commenced unless such notice is given.

27.2.1 Any dispute or difference in respect of which a notice of intention to commence arbitration has been given in accordance with this Clause shall be finally settled by arbitration. Arbitration may be commenced prior to or after delivery of the Goods under the Contract.

27.2.2 Arbitration proceedings shall be conducted in accordance with the rules of procedure **specified in the SCC**.

27.3 Notwithstanding any reference to arbitration herein,

- (a) the parties shall continue to perform their respective obligations under the Contract unless they otherwise agree; and
- (b) the Purchaser shall pay the Supplier any monies due the Supplier.

28. Limitation of Liability

28.1 Except in cases of criminal negligence or willful misconduct, and in the case of infringement pursuant to Clause 7,

- (a) the Supplier shall not be liable to the Purchaser, whether in contract, tort, or otherwise, for any indirect or consequential loss or damage, loss of use, loss of production, or loss of profits or interest costs, provided that this exclusion shall not apply to any obligation of the Supplier to pay liquidated damages to the Purchaser

29. Governing

29.1 The language of the Contract shall govern its



- Language** interpretation. All correspondence and other documents pertaining to the Contract that are exchanged by the parties shall be written in the same language.
- 30. Applicable Law** 30.1 The Contract shall be interpreted in accordance with the Iraqi Law and guardianship of Iraqi judicial system.
- 31. Notices** 31.1 Any notice given by one party to the other pursuant to this Contract shall be sent to the other party in writing or by cable (the term "cable" is deemed to include electronic mail, telex, or facsimile) and confirmed in writing to the other party's address **specified in the SCC.**
- 31.2 A notice shall be effective when delivered or on the notice's effective date, whichever is later.
- 32. Taxes and Duties** 32.1 A Supplier supplying Goods from abroad shall be entirely responsible for all taxes, stamp, duties, license fees, and other such levies imposed outside Iraq.
- 32.2 A Supplier supplying Goods offered from within Iraq shall be entirely responsible for all taxes, duties, license fees, etc., incurred until delivery of the contracted Goods to the Purchaser.
- 32.3 **The awarded company bears (the 2nd part that contracted with our company) all customs fees.**
- 33. Withholding and lien in respect of sums claimed** 33.1 Whenever any claim or claims for payment of a sum of money arises out of or under the Contract of Republic of Iraq against the Supplier, the Purchaser shall be entitled to withhold and also have a lien to retain such sum or sums in whole or in part from the security, if any, deposited by the Supplier and for the purpose aforesaid, the Purchase shall be entitled to withhold the said cash security deposit or the security, if any, furnished as the case may be and also have a lien over the same pending finalization of any such claim. In the event of the security being insufficient to cover the claimed amount or amounts or if no security has been taken from the Supplier, the Purchaser shall be entitled to withhold and have lien to retain to the extent of the such claimed amount or amounts referred to supra, from any sum or sums found payable or which at anytime thereafter may become payable to the Supplier under the same Contract or any other Contract with the Purchaser or the Republic of Iraq, pending finalization of any such claim and that The Supplier shall have no claim for interest or damages whatsoever on this account or on any other ground in respect of any sum of money withheld or retained under this clause and duly notified as such to the Supplier.

**SECTION VIII. SPECIAL CONDITIONS OF CONTRACT****NOTES ON THE SPECIAL CONDITIONS OF CONTRACT**

{Similar to the Bid Data Sheet in Section II, the clauses in this Section are intended to assist the Purchaser in providing Contract-specific information in relation to corresponding clauses in the General Conditions of Contract (GCC).

The provisions of Section VIII complement the GCC included in Section VII, specifying contractual requirements linked to the special circumstances of the Purchaser Iraq, the sector, and the Goods purchased.

In preparing this section, the following aspects should be checked:

- (a) The correct version of the Special Conditions of Contract must be used as a base, dependent upon the type of Goods being procured.
- (b) Information that complements provisions of Section VII, GCC, must be incorporated
- (c) Amendments and/or supplements to provisions of Section VII, GCC, as necessitated by the circumstances of the specific purchase, must also be incorporated.}

**Special Conditions of Contract**

The following Special Conditions of Contract shall supplement the General Conditions of Contract. Whenever there is a conflict, the provisions herein shall prevail over those in the General Conditions of Contract. The corresponding clause number of the GCC is indicated in parentheses.

GCC 1.1 (h)	The Purchaser is: [Ministry of Health / Environment / The State Company for Marketing Drugs and Medical Appliances (Kimadia)].
GCC 1.1 (m)	The Supplier is: [insert: name of Supplier].
GCC 5	5.3 In addition to what mentioned in ITB the following will be added : 1-- To furnish second party with official letters which relative to contract execution and first party will never be responsible about the results of these correspondences. 2- adoption the original copy and signed by two parties and saved at the first party as it is practice in case of difference
GCC 6.2	The Effective Date of the Contract is : from date of Contract signing if either: (i) the Goods have already been registered . (ii) excluded from registration . Effective from the date receipt of the registration certificate if the goods to be submitted by the successful bidder upon signing the contract are not registered .
GCC 8	- Performance bond: a- To be L/C form and stay valid along the period of the contract until complete his contractual obligations provided that submit after issuing the letter of awarding. And before signing the contract and before the opening the L/C and, equal to 5% from the contract amount and valid for the duration of the contract and should not be cancelled until you receive a notification from kimadia, on condition submitting commitment with the offer in this respect. b--The Bank guarantee Should be issued by Iraqi governmental or private Iraqi Bank, and that reliable government banks hasn't the right to issue bank guarantee to foreign company unless submitting requital guarantee issued by foreign Bank (Back to Back) Which has classification issued by one of International classification organizations (Moody's standard and poor) and others or by each insurance not less than guarantee amount and without intermediate from T.B.I and the guarantee should be in Arabic and English language and the Arabic language is one which depend on. c- performance bond should issued from company which contracted with it or with its legal authorized for issuing the bond under formal and certified authorization should be submitted to the bank and include on the term of bond or attached letter issues from the bank which issuing it . d- The submitting of performance bond should attached with letter of legalized issuing (private and secret) send to kimadia by the bank who issued the bond which not conditional and for the favor of (kimadia). And Kimadia has the right to extend or confiscate the performance bond if required to do so,

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	<p>without objection of correspondents or suppliers and with the first written claim</p> <p>e -The companies & scientific bureaus should take in consideration the following when issued the performance bond:-</p> <ol style="list-style-type: none"> 1-The letters of guarantee should issues by name of company which signed the contract exclusively. 2-You should confirm the availability of contract no.at letter of guarantee. 3-You should mention the following article in letter of guarantee (this bond subject and explain in all matters according to the Iraqi laws. 4-The letter of guarantee should financially covered by the bank. 5-Any letter of guarantee will not be received unless attaché with formal letter issuing from the bank who issued the bond and with the signature of director manager in bank or who represents him 6-The letter of guarantee should be by (Arabic & English) and the Arabic language is the one to rely upon when having any dispute. 7-Should be valid for one year from date of issuing. 8-Should be not direct or conditional. 9- In case of the suppliers un acceptance to make the amendmets or extensions on the performance bond or will be a breach of supplier ,the amount of bond will be confiscated and deposit it at the account of our company. 10-The letters of guarantee issued by the approved banks shall be received in accordance with a(bulletin –brochure) issued by central bank of Iraq. 11-The letter of guarantee must be in the contract currency .
GCC 3.8	The guarantee formula in paragraph A of the general conditions of the Contract is adopted , paragraph (8.3) .
GCC 9.1	<p>Receiving items will never be considered as confirmation for compliance to the specification and technical conditions but it will relay on the results of laboratory tests issued by labs. .of Iraqi public health (National Center for control and medical research, Central Health Laboratory). After issuing the acceptance and testing decision by the central committee which formed for that, and not only the result of analysis lab.</p> <p>Sample will be sent to national center for control and medical research, for test and evaluation and their results are reliable.</p> <p>19. Standard reference substances (i.e. B.P.C Rst U.S.P Rst E.U.C Rst) not working standard together with method and legalized certificate of analysis are to be sent with the order to our national center for medicine control & research</p> <p>– Any materials or quantity that fails in analysis as confirmed by our national center for control and medical research should be compensated by the supplier</p>
GCC 9.2	<p>“9.2.1. (a) Said inspection and testing is for the Purchaser’s account. In the event that inspection and testing is required prior to dispatch, the Goods shall not be shipped unless a satisfactory inspection and quality control report has been issued in respect of those Goods.</p> <p>(b) The Supplier may have an independent quality test conducted on a batch ready for shipment. The cost of such tests will be borne by the Supplier.</p> <p>(c) Upon receipt of the Goods at place of final destination, the Purchaser’s</p>

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	representative shall inspect the Goods or part of the Goods to ensure that they conform to the condition of the Contract and advise the Purchaser that the Goods were received in apparent good order. The Purchaser will issue an Acceptance Certificate to the Supplier in respect of such Goods (or part of Goods). The Acceptance Certificate shall be issued at the earliest within fifteen (15) days of receipt of the Goods or part of Goods at place of final destination.
	9.2.2. Where the Supplier contests the validity of the rejection by the Purchaser or his representative, of any inspection as required by 9.1 above conducted before shipment or at ultimate destination, whether based on product or packing grounds, a sample drawn jointly by the Supplier and Purchaser or his or her representative and authenticated by both, will be forwarded for umpire analysis within four weeks of the time the Supplier contests to an independent agency mutually agreed by the Purchaser and Supplier. The umpire's finding, which will be promptly obtained, will be final and binding on both parties. The cost of umpire analysis will be borne by the losing party."}
GCC 10.2	<p>– Medical items should be shipped in a form of palette covered by nylon and placed on a wooden basis.</p> <p>--Print on outside pack (pallet or big carton) the national code, order no., and Q well as print on inside pack and small pharmaceutical unit (ampoule or bottle sheet) on well form the mark of (MOH-Iraq) and beneficiary name and shelf (MF& Exp. Date) and to print (Batch no.) on all inside and outside packs as well small pharmaceutical unit.</p> <p>-Pallets should be with the following dimension in order to facilitate the process of receiving and storage of the arrived shipments.</p> <ul style="list-style-type: none"> * Length 1200 M.M * Width 1000 M.M * Height 1000 M.M (Including the height of pallet based) * And weight of each pallet should be not more than 800 kilo <p>-All materials must be shipped in a cooled condition and for all transporting ways till it reach MOH/Kimadia stores and the seller will be responsible for the compensation of any material which fails in the analysis because of the unsuitable temperature degree during the transport</p>
GCC 11.1 & 11.3	<p>{ Sample provision (CIF/CIP/DDP terms)</p> <p>For Goods supplied from abroad:</p> <p>Upon shipment, the Supplier shall notify the Purchaser and the insurance company in writing the full details of the shipment including Contract number, description of the Goods, quantity, date and place of shipment, mode of transportation, and estimated date of arrival at place of destination. In the event of Goods sent by airfreight, the Supplier shall notify the Purchaser a minimum of forty-eight (48) hours ahead of dispatch, the name of the carrier, the flight number, the expected time of arrival, and the waybill number. The Supplier shall fax and then send by express courier the following documents to the Purchaser, with a copy to the insurance company:</p> <p>(i) three originals and two copies of the Supplier's invoice, showing Purchaser</p>

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- as [enter correct description of Purchaser for customs purposes]; the Contract number, Goods description, quantity, unit price, and total amount. Invoices must be signed in original, stamped, or sealed with the company stamp/seal;
- (ii) one original and two copies of the negotiable, clean, on-board through bill of lading marked "freight prepaid" and showing Purchaser as [enter correct name of Purchaser for customs purposes] and Notify Party as stated in the Contract, with delivery through to final destination as per the Schedule of Requirements and two copies of non-negotiable bill of lading, or three copies of railway consignment note, road consignment note, truck or air waybill, or multimodal transport document, marked "freight prepaid" and showing delivery through to final destination as per the Schedule of Requirements;
 - (iii) four copies of the packing list identifying contents of each package;
 - (iv) copy of the Insurance Certificate, showing the Purchaser as the beneficiary; in case CIP , CIF .
 - (v) one original of the manufacturer's or Supplier's Warranty Certificate covering all items supplied;
 - (vi) one original and six copies of the Supplier's Certificate of country of Origin covering all items supplied and associated trading lists endorsed by the relevant Iraqi Commercial Agencies outside Iraq. For items originating from countries member of the Arab Common Market, the certificates of origin and associated trading lists endorsed by the competent country of origin authority shall be sufficient;
 - (vii) original copy of the Certificate of Inspection furnished to Supplier by the nominated inspection agency and six copies (where inspection is required);
 - (viii) any other procurement-specific documents required for delivery/payment purposes.

For Goods from within Iraq:

Upon or before delivery of the Goods, the Supplier shall notify the Purchaser in writing and deliver the following documents to the Purchaser:

- (i) two originals and two copies of the Supplier's invoice, showing Purchaser, the Contract number; Goods' description, quantity, unit price, and total amount. Invoices must be signed in original and stamped or sealed with the company stamp/seal;
- (ii) two copies of delivery note, railway consignment note, road consignment note, truck or air waybill, or multimodal transport document showing Purchaser as [enter correct name of Purchaser] and delivery through to final destination as stated in the Contract;
- (iii) copy of the Insurance Certificate, showing the Purchaser as the beneficiary;
- (iv) four copies of the packing list identifying contents of each package;
- (v) one original of the manufacturer's or Supplier's Warranty certificate covering all items supplied;
- (vi) one original of the Supplier's Certificate of country of Origin covering all items supplied and associated trading lists endorsed by the relevant Iraqi Commercial Agencies outside Iraq. For items originating from countries

	<p>member of the Arab Common Market, the certificates of origin and associated trading lists endorsed by the competent country of origin authority shall be sufficient;</p> <p>(vii) original copy of the Certificate of Inspection furnished to Supplier by the nominated inspection agency and six copies (where inspection is required)</p> <p>(viii) other procurement-specific documents required for delivery/payment purposes.</p> <p>Note: In the event that the documents presented by the Supplier are not in accordance with the Contract, then payment will be made against issue of the Acceptance Certificate, to be issued in accordance with SCC 9 (GCC 9) above.</p> <p>In addition to what mentioned the following will be added :</p> <p>All shipment should be attached with commercial shipping lists , original packing lists and certificate of origin .</p> <ul style="list-style-type: none"> - The supplier should submit the shipping documents before the arrival of the consignment with a period not less than 15 days and be responsible for any shortage or any delay caused by the lack of shipping documents . - Delivery shall be as soon as possible within the period of credit validity and the shipping schedule shall be as the required of Kimadia . - - Receiving the supplied items upon their arrival to MOH/ Kimadia stores and the insurance of it (CIP) and not free from this obligation till organizing the report of the fundamentalist dump in the place of delivery agreed upon. -The contract should be supplied in a limited number of lots and the quantity of each lot should mentioned in the shipping list with the manufacture and expiry date.
GCC 15	<u>15.1</u>
	<p>"15.1 All goods must be of fresh manufacture and must bear the dates of manufacture and expiry. The Supplier further warrants that all Goods supplied under the Contract will have remaining a minimum of five-sixths (5/6) of the specified shelf life upon delivery at port/airport of entry for goods with a shelf life of more than two years and three-fourths (5/6) for goods with a shelf life of two years or less, unless otherwise specified herein; have "overages" within the ranges set forth in the Technical Specifications, where applicable; are not subject to recall by the applicable regulatory authority due to unacceptable quality or an adverse drug reaction; and in every other respect will fully comply in all respects with the Technical Specifications and with the conditions laid down in the Contract.</p>
	<p>15.2 The Purchaser shall have the right to make claims under the above warranty for three months after the Goods have been delivered to the final destination indicated in the Contract. Upon receipt of a written notice from the Purchaser, the Supplier shall, with all reasonable speed, replace the defective Goods without cost to the Purchaser. The Supplier will be entitled to remove, at his own risk and cost, the defective Goods once the replacement Goods have been delivered.</p>
	<p>15.3 In the event of a dispute by the Supplier, a counter analysis will be carried</p>

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	<p>out on the manufacturer's retained samples by an independent neutral laboratory agreed by both the Purchaser and the Supplier. If the counter analysis confirms the defect, the cost of such analysis will be borne by the Supplier as well as the replacement and disposal of the defective goods. In the event of the independent analysis confirming the quality of the product, the Purchaser will meet all costs for such analysis.</p>
15.4	<p>If, after being notified that the defect has been confirmed pursuant to GCC Sub-Clause 15.2 above, the Supplier fails to replace the defective Goods within the period for the replacement of defective goods of [insert period for replacement of defective goods], the Purchaser may proceed to take such remedial action as may be necessary, including removal and disposal, at the Supplier's risk and expense and without prejudice to any other rights that the Purchaser may have against the Supplier under the Contract. The Purchaser will also be entitled to claim for storage in respect of the defective Goods for the period following notification and deduct the sum from payments due to the Supplier under this Contract.</p>
15.5	<p>Recalls. In the event any of the Goods are recalled, the Supplier shall notify the Purchaser within fourteen (14) days, providing full details of the reason for the recall and promptly replace, at its own cost, the items covered by the recall with Goods that fully meet the requirements of the Technical Specification and arrange for collection or destruction of any defective Goods. If the Supplier fails to fulfill its recall obligation promptly, the Purchaser will, at the Supplier's expense, carry out the recall."}</p>
	<p>-- In case the item failed in the analysis as verified by our national center for medicine control & research or any concerned party so administrative charges will be added equal to 15% from the total value of failed item & a delay Penalty in case the company not shipped the compensation item within the agreed period in the contract and with the agreed percentage.</p> <p>the supplier has to compensate the exp .qty which not spent in stores of MOH/Kimadia at ratio100% of the total QTY of exp. items.</p> <ul style="list-style-type: none">- The seller should compensate the defaults items (failed items) in analysis and the exp.. For technical reasons belong to supplier at ratio 100% with 15% management charges from the total QTY of exp. items and impose delay penalty in case not shipping the compensation Qty with same period and ratio and to impose delay penalty if non shipping the compensation Qty in the same period and ratio which agree upon in contract.- The second party has to ensure the hidden defects or any frailer in the product in duration parallel to shelf life of the product, regarding products without specified shelf life the 2nd party to ensure above defects for five years, calculating of the above periods to begin from the date of receiving tests results) As well as the same ratio of Penalty will be as per in article (A) in case the company not from the date of notifying him and the calculation of the shipping period per 2nd shipment will be started after the arrival of the compensated shipment if the contract was partial shipments otherwise a delay penalty will be imposed according to the ratio that mention on agreed penalties articles and in case the company has not compensate within a/m period kimadia has the right to buy the item from another source on

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	<p>contractor account and bearing him the difference price and to confiscate all insurance and has the right to turn concerned court in order to obtain its rights</p> <p>-The seller is responsible to compensate the buyer for the defected items or shortage that appear after the distribution, usage of goods in the hospital after the necessary checking & analysis and if it is due to a manufacturing defect.</p> <p>-(the seller should compensate the damaged , failed in analysis, missing, shortages items, and the items which not comply with specification required within delivery period stated in contract provided that started calculate from the date of notification company by the fail or shortage or missing taken into yr. consideration that the period must be within the period of execution the contract and the other shipments must be shipped within the same shipping schedule from the date of shipping the compensation Qty otherwise the delay penalty will be imposed at the same percentage stated in penalties terms which agreed upon in case the company not compensate within a/m period, kimadia has the right to buy the item from other source and on contractor account as well as he will bear the difference in price and management charges and confiscates all insurance and added the administrative charges and has the right to resource to special courts to obtain its rights</p> <p>-The seller must stamp the phrase (failed & not fit to consumption MOH-KIMADIA) on the failure qty. or not compliance to specification in MOH/Kimadia stores on supplier account</p> <p>Any item or quantity that fails in analysis as verified by our national center for medicine control & research is to be compensated by the manufacturer.</p> <p>24. In case the item failed in the analysis or have been expired & the company not respond for compensation within 15 days after sending a warning letter including the compensation & draw the failed or expired item, kimadia has the right to destroy the failed or expired items & dropping the right of the company for getting back the item or its value.</p>
GCC 16.1	<p>{Sample provision:</p> <p>The method and conditions of payment to be made to the Supplier under this Contract shall be as follows:</p> <p>{In case the Supplier is a Public Entity (Public Sector Company), then the Contracting Entity may increase the Advance Payment to x% from the value of contract.and according to instructions }</p> <p>A. Payment for Goods supplied from abroad:</p> <p>Payment of foreign currency portion shall be made in [USD and ID]in special exception cases in the following manner:</p> <p>(i) Advance Payment:(not applied) section VIII</p> <p>(ii) On Shipment:the purchaser should pay to the supplier according to percent of the Contract Price of the Goods shipped shall be paid through irrevocable confirmed letter of credit opened in favor of the Supplier in a bank in its country, upon submission of documents specified in GCC Clause 11 . Opening charges and charges for amendment of the letter of credit at the request of or due to a fault or default of the Purchaser are for the account of</p>

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	<p>the Purchaser. Confirmation charges and charges for amendment to letters of credit at the request of or due to a fault or default on behalf of the Supplier are for the account of the Supplier.</p> <p>- Payment terms:</p> <ul style="list-style-type: none"> - .50% upon submitting shipping documents. - 50% after the arrival of materials to the warehouses of kimadia and acceptance. <p>and release award</p> <p>shall be paid within [thirty (30)] days of receipt of the Goods upon submission of an invoice (showing Purchaser's name; the Contract number, description of payment and total amount, signed in original, stamped or sealed with the company stamp/seal) supported by the Acceptance Certificate issued by the Purchaser.</p> <p>B. Payment for Goods and Services supplied from within the Iraq:</p> <p>Payment for Goods and Services supplied from within Iraq shall be made in Iraqi Dinar, as follows upon receipt the financial allocation :</p> <ul style="list-style-type: none"> (i) Advance Payment: 10% operational advance and upon receipt the financial allocation of the contract based on the instructions of implementation the federal budget . (ii) the remaining 90% after success of item in the laboratory tests and (iii) the condition which mention above will be agreed by two parties as per kind of item & contract amount.
GCC 16.3	The payment or payments will be settled as soon as possible after receipt the result of laboratory tests according to the conditions announcement .
GCC 18	18.2 the contracting entity may increase the quantity of goods or materials or non-consulting services or amendment its technical specifications which contracted by not more than 20% of the contract amount .
GCC 19	19.1 - any change not allowed in contract unless there are agreement between the two parties otherwise the 2nd party considered a breach by his contractual commitments and kimadia has the right to take legal procedures or impose penalty at ratio not less than 1% and not more than 5% for shipping Qty for the arrival item and not comply with our contractual conditions.
GCC 20.1	can not be waived of contract or apart of it
GCC 21	<p>21.2 in addition to what mentioned in general conditions of contract consider the following reasons upon extension the contract :</p> <p>First:</p> <p>A.</p> <p>f any increase or change occurred in the required supplying qty (qualitative, quantitative) which may effect on executing program has been agreed upon</p>

	<p>and according to original contract.</p> <p>B.</p> <p>f the delay for executing the contract related to reasons or procedure for contracting side (our company) or any side which has been authorized legally</p> <p>C.If an exceptionable condition have occurred after contracting which is out of contractors hand which can't be avoided or expected upon contracting which caused a delay in completing the works or supplying the required items according to the contract.</p> <p>Second :</p> <p>The application of the rules per A/M clauses (A, B, C) stipulated that the supplier should submit a written request for contracting side within 15 days started from the date of the reason arising which accordingly the extend has been requested indicating the accurate and complete details for any request to extend the period and any request for extension will not be accepted if presented after issuing the primary receiving certificate mentioned in the contract conditions</p>
GCC 22	<p>22.1 a- Amount of contract (original amount of contract \pm any amendment in amount) / the total duration of contract (original duration of contract \pm any change in duration) \times 10% = fine per day that dose not exceed 10%from amount of contract and after reaching the delay penalty maximum so they can be take legal action under the text of articles (10,30 from instructions of implementing the government contracts no.(2) year 2014.</p> <p>b- Penalties are reduced according to completion rates of the contractual obligation specified in the plat form of implementation the contracts which issued a certificate of first delivery for preformed work or supplier item or service required matching and ready for use according to the conditions of contract and the application of equation as follows</p> <p>The value of commitment not implemented /total duration of contract \times 10% =fine per day</p> <p>c- The first party has the right to take legal action against the second party after warning him officially within the approved and installed email in the contract within (15) days from date of warning and before reaching the delay penalties its max.</p> <p>-When the contracted company hide any essential information which will be discovered later on , legal procedures will be taken or imposing a panalty at rate not less than 1% and not more than 5% of the quantity shipped for the arrived material and violated of our contractual conditions.</p>
GCC 23	<p>2 3.1 In addition to what is stated in this paragraph of the general condition : In case the supplier does not respond during the warning period and through the approved email approved by the contract the legal procedures shall be taken in accordance with the provisions of articale 10 of the instruction for implementing government contract no.2 of 2014 with respect to the confiscation or retention of legal insurance provided that the contract is excuted on his account according to the text of article 3 of the above instruction and according to the methods of implementation .</p>
GCC 24	<p>Paragraph 24 should be deleted from general conditions</p>



GCC 27.2.2	This clause from general conditions contract it should be as:
	<p>for contracts with Supplier national of Iraq:</p> <p>"In the case of a dispute between the Purchaser and a Supplier who is a national of Iraq, the dispute shall be referred to conciliation or arbitration in accordance with the laws of the Iraqi Laws and guardianship of the Iraqi judicial system and according to adopted procedures."</p> <p>-Any amount in the second party account which resulted from breaching any contractual commitment the first party has the right to claim the amount in the specialized court as well as the confiscation in case the requirements have been achieved</p> <p>- In case of the bidder has not complied with executing the conformed order and according to the agreed conditions a legal procedure will be taken against him.</p>
GCC 28	Deleted
GCC 31.1	[insert:the Purchaser's address for notice purposes and if by cable is acceptable] [insert:the Supplier's address for notice purposes and if by cable is acceptable]
GCC 32	<p>The collection of Government debts will be applicable as per the Iraqi Law for collecting government debts No.56 of year 1977.</p> <p>- The Contract is subject to Iraqi laws including the laws of tax No. 113 for the year 1982 & instruction of accounting tax against contracts between Iraqi contracting entry with foreign side NO2 for the year 2008 & the stamp fee NO71 for the year 2012 & Notary fees & re-announcement charges.</p> <p>1- Interpolation amount (100) hundred thousand Iraqi Diner upon request for exchange the border outlet .</p> <p>2- Interpolation amount (25) twenty five thousand Iraqi Diner for each unloaded & loading receipt for each shipment that arrived to the target store</p> <p>3- Interpolation amount (10) ten thousand Iraqi Dinar for parking & overnight the trucks that specified for transport the drug & appliances to our warehouse.</p> <p>4- Interpolation amount (250) two hundred fifty thousand Iraqi Dinar for each objection request presented by the Scientific Bureau or company for any Import relegation</p> <p>- All bank charges (opening, issuing for L/C and amendments fees ...etc) inside and outside Iraq are on the seller account</p>

Special Conditions of Contract
PHARMACEUTICALS
(Additional Clauses)

{ **Note: The below data should be included in the Special Conditions of Contract used in Bidding Documents for the procurement of pharmaceuticals, otherwise, delete**}

GCC 11.1 & 11.3	<p>For Goods supplied from abroad:</p> <p>(ix) One original of the Certificate of Pharmaceutical Product as recommended by the WHO for each of the items supplied.</p> <p>(x) Certificate of quality control test results in conformity with</p>
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	<p>the World Health Organization “Certification Scheme on the Quality of Pharmaceutical Products Moving in International Trade” stating quantitative assays, chemical analysis, sterility, pyrogen content, uniformity, microbial limit, and other tests as appropriate to the Goods.</p> <p>(xi) Original copy of the certificate of weight issued by the port authority/licensed authority and six copies.</p>
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Special Conditions of Contract
VACCINES
 (Additional Clauses)

GCC 11.1 & 11.3	<p>For Goods supplied from abroad:</p> <ul style="list-style-type: none"> (ix) one copy of the Lot Release Certificate issued by the NCA of the country of manufacture for each lot shipped. (x) Certificate of quality control test results in conformity with the World Health Organization "Certification Scheme on the Quality of Pharmaceutical Products Moving in International Trade" stating quantitative assays, chemical analysis, sterility, pyrogen content, uniformity, microbial limit, and other tests as appropriate to the Goods. (xi) Original copy of the certificate of weight issued by the port authority/licensed authority and six copies. <p>For Goods from within the Purchaser's country:</p> <ul style="list-style-type: none"> (x) one copy of the Lot Release Certificate issued by the NCA of the country of manufacture for each lot shipped.
GCC 15.1	<p>[Sample clauses:</p> <p>The Purchaser reserves the right to request evidence of bio-availability and/or bio-equivalence data and/or evidence of the basis for expiration dating and other stability data concerning the Goods to verify shelf life claimed for the Goods.</p> <p>If an adverse event following immunization (AEFI) occurs in the Purchaser's country and the cause of such event cannot be immediately established, the Purchaser will, with all urgency and in accordance with the procedures laid down by the NCA of the Purchaser's country, take steps to advise the Supplier in order that an investigation may be launched immediately. If the vaccine has been supplied through an agency of the United Nations, the most current procedures laid down by the WHO for such situations will be used.]</p>



SECTION IX. CONTRACT FORMS

NOTES PREPARING THE CONTRACT FORMS

The Sample Contract Forms provided in this SSBD provide standard formats for a number of the key documents that the Purchaser and Supplier will exchange in the process awarding and implementing the Contract.

Form of Contract Agreement: Except as indicated by blanks and/or instructions to fill in information, the text of the Contract Agreement should be left unaltered in the Bidding Documents from how it appears in this SSBD. It would be at the time of Contract award when the Contracting Entity has an opportunity to add the final details needed in the Contract Agreement form, by making any necessary insertions or changes to paragraph 2.

Performance Security Form: Pursuant to GCC Sub-Clause 8.1, the successful Bidder is required to provide the performance security within fourteen (14) days of notification of Contract award, or twenty-nine (29) days in case of Complaints and Appeal as per ITB 36.1.

Advance Payment Bank Guarantee: Pursuant to GCC Sub-Clause 16.1, the successful Bidder is required to provide a bank guarantee securing the advance payment, if SCC related to GCC Sub-Clause 16.1 requests for one.



CONTRACT FORMS

1. Form of Contract Agreement
2. Performance Security Bank Guarantee
3. Bank Guarantee Form for Advance Payment

1. Form of Contract Agreement

THIS CONTRACT AGREEMENT is made
the [insert: **number**] day of [insert: **month**], [insert: **year**].

BETWEEN

- (1) [insert: **Name of Purchaser**], a [insert: **description of type of legal entity**, for example, an agency of the Ministry of of the Government of Iraq, or corporation incorporated under the laws of Iraq and having its principal place of business at [insert: **address of Purchaser**] (hereinafter called "the Purchaser"), and
- (2) [insert: **name of Supplier**], a corporation incorporated under the laws of [insert: **country of Supplier**] and having its principal place of business at [insert: **address of Supplier**] (hereinafter called "the Supplier").

WHEREAS the Purchaser invited bids for certain goods and ancillary services, viz., [insert: **brief description of goods and services**] and has accepted a bid by the Supplier for the supply of those goods and services in the sum of [insert: **contract price in words and figures**] (hereinafter called "the Contract Price").

NOW THIS AGREEMENT WITNESSETH AS FOLLOWS this agreement confirm that the two parties are agreement as follow :

1. In this Agreement words and expressions shall have the same meanings as are respectively assigned to them in the Conditions of Contract referred to.
2. The following documents shall constitute the Contract between the Purchaser and the Supplier, and each shall be read and construed as an integral part of the Contract:
 - (a) This Contract Agreement
 - (b) Special Conditions of Contract
 - (c) General Conditions of Contract
 - (d) Technical Requirements (including Technical Specifications)
 - (e) The Supplier's bid and original Price Schedules
 - (f) Schedule of Requirements
 - (g) The Purchaser's Notification of Award
 - (h) [Add here: **any other documents**]
3. In consideration of the payments to be made by the Purchaser to the Supplier as hereinafter mentioned, the Supplier hereby covenants with the Purchaser to provide the Goods and Services and to remedy defects therein in conformity in all respects with the provisions of the Contract.
4. The Purchaser hereby covenants to pay the Supplier in consideration of the provision of the Goods and Services and the remedying of defects therein, the Contract Price or such other sum as may become payable under the provisions of the Contract at the times and in the manner prescribed by the Contract.

For and on behalf of the Purchaser

Signed: _____

in the capacity of [insert: **title or other appropriate designation**]

in the presence of _____

For and on behalf of the Supplier

Signed: _____

in the capacity of [insert: **title or other appropriate designation**]

in the presence of _____

Tender/Number: MED1/2019

Contracting Entity: Ministry of Health / Environment / The State Company For Marketing

Drugs Medical Appliances (kimadia)



CONTRACT AGREEMENT

Dated the [insert: **number**] day of [insert: **month**], [insert: **year**]
BETWEEN
[Insert: **name of Purchaser**], “the Purchaser”
and
[insert: **name of Supplier**], “the Supplier”



2. Performance Security Bank Guarantee

[The Bank shall fill in this Bank Guarantee Form in accordance with the relevant conditions of Contract.] & it prefer us the central Iraqi Bank form .

_____ [insert: **Bank's Name and Address of Issuing Branch or Office**]

Beneficiary: _____ [insert: **Name and Address of Purchaser**]

Date: _____

PERFORMANCE GUARANTEE No.: _____

We have been informed that [insert: **name of Supplier**] (hereinafter called "the Supplier") has entered into Contract No. [insert: **reference number of the contract**] dated _____ with you, for the supply of [insert: **description of goods**] (hereinafter called "the Contract").

Furthermore, we understand that, according to the conditions of the Contract, a performance guarantee is required.

At the request of the Supplier, we [insert: **name of Bank**] hereby irrevocably undertake to pay you any sum or sums not exceeding in total an amount of [insert: **amount in figures**] (____) [insert: **amount in words**] upon receipt by us of your first demand in writing accompanied by a written statement stating that the Supplier is in breach of its obligation(s) under the Contract, without your needing to prove or to show grounds for your demand or the sum specified therein.

This guarantee shall expire no later than the ____ day of **month** _____, 2_____, and any demand for payment under it must be received by us at this office on or before that date.

This guarantee is subject to the Uniform Rules for Demand Guarantees, ICC Publication No. 458, except that subparagraph (ii) of Sub-article 20(a) is hereby excluded.

[signature(s)]

3. Bank Guarantee Form for Advance Payment

[The Bank shall fill in this Bank Guarantee Form in accordance with the relevant conditions of Contract.] & it prefer us the central Iraqi Bank form .

_____ [insert: **Bank's Name and Address of Issuing Branch or Office**]
Beneficiary: _____ [insert: **Name and Address of Purchaser**]

Date: _____

ADVANCE PAYMENT GUARANTEE No.: _____

We have been informed that [insert: **name of Supplier**] (hereinafter called "the Supplier") has entered into Contract No. [insert: **reference number of the contract**] dated _____ with you, for the supply of [insert: **description of goods**] (hereinafter called "the Contract").

Furthermore, we understand that, according to the conditions of the Contract, an advance payment in the sum [insert: **amount in figures**] (____) [insert: **amount in words**] is to be made against an advance payment guarantee.

At the request of the Supplier, we [insert: **name of Bank**] hereby irrevocably undertake to pay you any sum or sums not exceeding in total an amount of [insert: **amount in figures**] (____) [insert: **amount in words**] upon receipt by us of your first demand in writing accompanied by a written statement stating that the Supplier is in breach of its obligation under the Contract because the Supplier used the advance payment for purposes other than toward delivery of the goods.

It is a condition for any claim and payment under this guarantee to be made that the advance payment referred to above must have been received by the Supplier on its account number _____ at _____ [insert: **name and address of Bank**].

This guarantee shall expire, at the latest, upon our receipt of copy (ies) of _____¹, or on the ____ day of _____, 2____,² whichever is earlier. Consequently, any demand for payment under this guarantee must be received by us at this office on or before that date.

This guarantee is subject to the Uniform Rules for Demand Guarantees, **in Iraq**

[Signature]

¹ Insert documents establishing "delivery" of the goods in accordance with the particular INCOTERMS® selected. (See SCC 11.)

² Insert the delivery date stipulated in the original delivery schedule. The Purchaser should note that in the event of an extension of the time to perform the Contract, the Purchaser would need to request an extension of this guarantee from the Guarantor. Such request must be in writing and must be made prior to the expiration date established in the guarantee. In preparing this guarantee, the Purchaser might consider adding the following text to the form, at the end of the penultimate paragraph: "The Guarantor agrees to a one-time extension of this guarantee for a period not to exceed [six months/one year], in response to the Purchaser's written request for such extension, such request to be presented to the Guarantor before the expiry of the guarantee."