INTRODUCTION

This document has been prepared for the purchase of all types of Drugs and Vaccines.

The procedures of this document shall be subjected to the approved laws in Iraq and the (Dissolved) Coalition Provisional Authority Order No. No. 87 of 2004, or any superseding law, the instructions of implementing the effective government contracts and the controls attached thereto.

SECTORIAL STANDARD BIDDING DOCUMENT

For the Purchase of Drugs and Vaccines

Contracting Entity: [*Name of Contracting Entity*]

Project/ Tender name: [*Insert Project/ Tender name*]

Project/ Tender Reference: [*Project/Tender reference number as listed in the Budget*]

Date: Issued *on [insert date of Tender advertising]*

Letter of Invitation/ Advertising (Insert type of Tender)

To: M.S/

Subject/ [Insert name and number of Tender]

The [insert name of Contracting Entity] is pleased to invite sealed bids from eligible bidders for supply of [insert brief description of drugs and vaccines].

1. Interested eligible bidders may obtain further information from [insert name of Contracting Entity] and [insert office working days and hours] as stipulated in the ITB.

2. Bidders shall fulfil qualifications requirements including: [insert a list of legal, technical, financial and other requirements].

3. A complete set of Tender documents in may be purchased by interested bidders on the submission of a written application to the address stated in the Bid Data Sheet and upon payment of a fee [insert amount in Iraqi Dinar]

4. Bids shall be delivered to the following address [insert the full address of the Contracting Party] on the specified date [insert the submission date]. Late bids will be rejected and bids will be opened in the presence of bidders or their representatives who choose to attend at the following address [state the address] at [insert the time and date].

Note (the Contracting Entity can add other data suited to the nature of the Tender provided that they do not conflict with the legal legislation governing the procedures of the Iraqi Public Contracts)

[Signature]

[Insert the job title of the authorized representative of the contracting authority]

[insert the job title of the authorized representative of the Contracting Entity]

Contents

Part one- Contract Procedures

It contains the following sections

Section one: Instructions to Bidders (ITB)

This section of the Tender documents provides the information necessary for Bidders to prepare and submit responsive bids that meet the Contracting Entity's requirements. The ITB describe the critical steps of bid submission, opening and evaluation, and the award of contract. The ITB are to be used unchanged.

Section two: Bid Data Sheet

This section contains provisions concerning the supply process that supplement what is stated in Section one.

Section Three: Evaluation and Qualification Criteria

This section defines the criteria used to determine the least-cost bid, and the qualification requirements that the bidder possesses to complete the Contract

Section four: Bidding documents

This section includes the bidding documents, and the accompanying Price Schedule.

Section Five: Eligible Countries

This section includes information about the eligible countries.

Part two - Contracting Requirements

This Part contains the following:

Section Sixth: Schedule of Requirement

This Section contains the List of (drugs and vaccines) and Related Services, the Delivery and Completion Schedules, the Technical Specifications and the Drawings that describe the (drugs and vaccines) and Related Services to be Procured.

Part three: Conditions of Contract and Contract Forms

It contains the following sections

Section Seven. General Conditions of Contract (GCC)

This Section contains the general clauses to be applied in all contracts. The text of the clauses in this Section shall not be modified.

Section Eight. Special Conditions of Contract (SCC)

This Section contains clauses specific to each contract that amend or supplement Section Seven, General Conditions of Contract.

Section Ninth: Contract Forms

This Section contains the form for the **Agreement**, which, once completed, incorporates any corrections and amendments to the accepted Bid relating to amendments permitted by the Instructions to Bidders, the General Conditions of Contract, and the Special Conditions of Contract

Part one: Contracting Procedures

Section one - Instructions to Bidders

Articles/Clauses schedule

Instructions to Bidders

A. General

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 (drugs and vaccines) as specified in the **Bid Data Sheet** and Schedule of Requirements. The contract shall be financed from the amounts allocated in the budget specified in the **Bid Data Sheet**.
	1.2 The following terms will have the meanings specified in these tender documents: "writing" means any written or printed communication including the book / letter that is received by hand, or telex and fax; "today" means a solar day; the singular also means the plural.
2. Corruption and fraud	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) The contracting entity adopts the definition of "corruption and Fraud" according to the relevant Iraqi laws in force. For the purpose of this provision, the Contracting Entity will be guided further by the definition of the terms as set forth here below:
	(1) "corrupt practice" is the offering, giving, receiving or soliciting, directly or indirectly, of anything of value to influence improperly the actions of another party;
	(2) "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;
	(3) "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;
	(4) "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;

	(5) "obstructive practice" is
	(5.1) deliberate 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
	(5.2) practices 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) The contracting entity 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)The contracting entity will sanction any 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) The contracting entity 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 Tender documents	
3.Content of Tender documents	1-3 The tender documents are those contained below and they shall be read in conjunction with any issued appendixes according to ITB 5
	Section one. Instructions to Bidders (ITB) Section two. Bid Data Sheet (BDS) Section Three. Evaluation and Qualification Criteria Section four. Bidding documents

	Section Seven General Conditions of Contract (GCC) Section Eight. Special Conditions of Contract (SCC) Section Ninth Contract Forms
	3.2 The "Invitation for Bids" does not form part of the Tender documents.
4. Inquiries and Clarification of Tender documents	4.1 A prospective Bidder requiring any clarification of the Tender 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, for example, if the announcement period is (15) days, the inquiry shall be not less than (10) days.
	According to the period of dvertisement, copies of the Contracting Entity's response shall be sent to all prospective Bidders who have purchased the Tender 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 Tender documents	5.1 At any time prior to the deadline for submission of bids, the **Contracting Entity** may amend the Tender documents by issuing Addenda.
	5.2 Any addendum thus issued shall be part of the Tender documents pursuant to ITB Sub-Clause 3.1 and shall be communicated in writing to all purchasers of the Tender 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 In order to give potential bidders time to consider the appendix when preparing their bids, the contracting entity will, at its discretion, postpone the deadline for submitting bids. In this case, the contracting entity shall inform all bidders of the postponement of the deadline for submitting the bids via cable attached to a written notice to confirm this. It will also publish the announcement of the postponement of the deadline for submitting bids in the same manner in which the announcement of this tender was published.
C. Preparation of Bids	
6. Eligibility	6.1 This tender is (**********) for all companies legally qualified according to the laws in force in Iraq, including the instructions of the scientific offices for the year 1999. Companies can be prevented from participating in submitting the tender in the following cases:
	Companies with conflicts of interest. All bidders found to be in conflict of interest will be excluded. It may be considered that the bidder is in a conflict of interest with one or more

	parties during this bidding process, if:
	(1) they have a common controlling partner; 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 to provide specifications, and other documents to be used for the procurement of the (drugs and vaccines) described in these Tender 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 **Bid Data Sheet**.
7. Eligibility proving documents (Drugs and Vaccines) & services and their compliance with the tender documents	7.1 Pursuant to ITB Clause 12, the Bidder shall submit, as part of its bid, documents establishing, to the Contracting Entity's satisfaction, the eligibility of the (drugs and vaccines) to be supplied under the Contract.
	7.2 The documentary evidence of the eligibility of the **(drugs and vaccines)** shall consist of a statement in the Price Schedule of the country of origin of the **(drugs and vaccines)** offered that shall be confirmed by a certificate according to the requirements of the legislation in force and as proven in the data sheet.
	7.3 The proving documents of conformity of (Drugs and Vaccines) **as specified in Section Sixth Schedule of Requirements** may be in the form of literature, drawings, and data and shall consist of:
	(a) a detailed description of the essential characteristics of the drugs and vaccines;

	(b) an item-by-item commentary on the Contracting Entity's Technical Specifications demonstrating substantial responsiveness of the (drugs and vaccines) 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 (drugs and vaccines) to be supplied under the Contract shall be registered with the competent authority in Iraq. A Bidder who has already registered its (drugs and vaccines) by the time of bidding shall 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 (drugs and vaccines) 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) Exemption of registration is allowed according to the powers of the Minister of Health.
	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 (drugs and vaccines) 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) The Minister of Health may exclude the successful bidder from submitting the drug registration certificate upon signing the contract, in which case the contract shall be valid.
	7.5 For purposes of the commentary to be submited 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. Qualifications of the Bidder	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 Three Evaluation and Qualification Criteria.
	(b) in the case of a Bidder offering to supply (drugs and vaccines), 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 (drugs and vaccines) to supply the (drugs and vaccines) in Iraq as per format of Manufacturer's Authorization Form in Section four;
	(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 Three Evaluation and Qualification Criteria** (see additional clauses of Section Three for drugs and vaccines
9. One Bid per Bidder	9.1 A firm shall submit only one bid as an individual Bidder and in accordance with ITB 6.1.a.
10. Cost of Bidding	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 and all the correspondence and the documents exchanged between the Bidder and the Contracting Entity shall be prepared in the language referred to in the Bid Data Sheet. The Bidder may submit any of the literature related there to which constitute part of its bid in another language. The texts of the bid language shall be accompanied with an accurate translation. The translation will be adopted for the purpose of interpreting the bid.
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 four;
	(b) original form of bid guarantee in accordance with the provisions of ITB Clause 17 (Bid Guarantee);
	(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 the Drugs and Vaccines conform to the Tender 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 four
	(h) 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 Fourth indicating the drugs and vaccines to be supplied, a brief description of the (drugs and vaccines), 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 four all the specified components of prices shown therein. All the columns shown in the Price Schedule shall be filled up as required.
	14.2 The quoted prices for (drugs and vaccines) to be equipped domestically (drugs and vaccines) or (drugs and vaccines) of foreign origin located in Iraq shall be quoted in the Price Schedule given under **Section four (2).** The quoted prices for (drugs and vaccines) to be imported from abroad, shall be quoted in the Price Schedule given under **Section four (3).**
	14.3 While filling up the columns of the Price Schedule, the following aspects shall be noted for compliance:
	14.3.1For domestic (drugs and vaccines) or (drugs and vaccines) of foreign origin located in Iraq, the prices under column 5 in the corresponding Price Schedule in at Section four (2) shall be entered separately in the following manner:
	Column 5(a): The price of (drugs and vaccines), 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 (drugs and vaccines) quoted ex-factory etc. or on the previously imported (drugs and vaccines) 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 (drugs and vaccines) in Iraq if the Contract is awarded;
	Column 5(c): Inland Transportation, Insurance, Loading/ Unloading and other incidental

	costs till to delivery of the (drugs and vaccines) to their final destination as specified in the Schedule of Requirements.
	14.3.2 For (drugs and vaccines) offered from abroad, the prices under Column 5 in the corresponding Price Schedule as per format in Section four (3) shall be entered separately in the following manner:
	Column 5(a): The price of (drugs and vaccines) quoted CIP at port/airport of destination;
	Column 5(b): The price of (drugs and vaccines) quoted DDP (Delivery Duty Paid) at End-user site in Iraq as specified in the Schedule of Requirements.
	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, (as stipulated in the Bid Datat Sheet)
	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 and unchangeable 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 Sixth Schedule of Requirements**, these Tender documents allow Bidders to quote separate prices for one or more schedules (or lots). Bids shall be evaluated for each schedule (or lot) separately for one or more than one articles of those mentioned at the schedules. Bids shall be evaluated for articles and for each article seperatley with the proposal.

	14.8 Neglecting the offer based on a reduction of a percentage or a lump sum from any other bids submitted in the tender and not accepting any reservation and any reduction of the price submitted after the closing date of the bidding. The condition of not making changes after the notice of award shall be confirmed. Any letter requesting reduction after the closing date without the request of Kimadia will be neglected and not considered.
15. Bid Currencies	15.1 Prices shall be quoted in the following currencies:
	(a) The Bidder shall express its prices for such (drugs and vaccines) to be supplied from Iraq in the Iraqi Dinar.
	(b) The Bidder may express the bid price of the (drugs and vaccines) to be supplied from abroad as indicated in the **Bid Data Sheet**.
16. Bid Validity Term	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 to the conditions.
	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 there to shall be made in writing. A Bidder may refuse the request without forfeiting.Bid guarantee The Bidder agreeing to the request will not be required or permitted to amend its bid, but will be required to extend the validity of its Bid guarantee for the period of the extension.
17. Bid Guarantee	17.1 The Bidder shall submit as part of its bid a Bid guarantee the form of an unconditional guarantee and payable upon first demandand in any of the following modes or in the form of: (a) letter of credit (b) certified check (c) or any other form specified by the Contracting Entity in the Bid Data Sheet The amount of the Bid guarantee shall be as stipulated **in the Bid Data Sheet in section II** and in the **Schedule of Requirements in Section VI**..
	17.2 The Bid guarantee 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 guarantee shall, at the Bidder's option, be in the form of either a Letter of Credit or a Bank Guarantee from an accredited bank in Iraq and in accordance with the instructions of Central Bank of Iraq in the format provided in the Tender documents or any other form specified by the contracting party in the **Bid Data Sheet** or Guarantees issued by the Republic of Iraq. In the case of Bank Guarantee submited from the banks outside

	Iraq, it shall 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 guarantee shall be rejected by the Contracting Entity as nonresponsive to the conditions.
	17.5 Upon the approval of the contracting entity, the Contracting Entity has the right to release the Bid guarantee 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 guarantee of the first three (3) candidates Bidders shall be retained in view of ITB Sub-Clause 38.2
	17.6 The bid guarantee shall be repeated to the winning bidder after signing the contract agreement and submitting the required good performance guarantee.
	17.7 The Bid guarantee may be forfeited (a) if the Bidder withdraws its bid after closing the tender, except as provided in ITB Sub-Clauses 16.2 and 22.3; or
	(b) if the winning bidder has failed, during the specified term to: (1) sign the contract, or (2) submit the required good performance guarantee.
	(c) If an unsuccessful bidder submits a complaint or objection in accordance with Article 36 of the instructions to the bidders, and then it appears to the competent authorities that this complaint or this objection was for wrong or unjustified reasons; the value of the damages resulting from this delay in signing the contract will be compensated according to the laws Iraqi and effective procedures.

	17.8 If the Bid Guarantee 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 after closing the tender, except as provided in ITB Sub-Clause16.2, 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 submit a good performance guarantee in accordance with ITB Clause 38; the Contracting Entity may, if provided for in the Bid **Data Sheet**, can declare the bidder ineligible to award the contract on him, and proceed to implement the administrative procedures stipulated in the tender data sheet.
18. Format and Signing of Bid	18.1 The Bidder shall prepare an original of the bid and may include a compact disk of the technical offer. The financial offer shall be submitted in one original (paper) form.
	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. The additions and corrections shall be signed by the bidder, and the signature shall be in the first name or initials. 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 amendments to the Tender documents, except to correct errors made by the Bidder in preparing the Bid Forms and where accordingly such corrections shall be signed and initialled by the authorised person or persons signing the bid.
D. Delivery of Bids	
19. Sealing and Marking of Bids	19.1 (a) Bidders may always submit their bids by express mail, express courier or by hand as per the Bid Data Sheet.
	(b) The Bidder shall enclose the original and each copy of the bid in separate sealed

	envelopes, duly marking the envelopes as "ORIGINAL" and "COPY." The envelopes containing the original and copies shall then be enclosed in another 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 [date and time]" 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, marked 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 shall 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 Tender 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.
22. Amendment and Withdrawal of Bids	22.1 The Bidder may amend or withdraw its bid after submission, provided that written notice of the amendment, 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 amendment 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 **Bid Data Sheet** article 19.1of any amendments to its bid, clearly identified as such, in two inner envelopes duly marked "BID AMENDMENT-ORIGINAL" or "BID SUBSTITUTION-ORIGINAL" and "BID AMENDMENT-COPIES" or "BID SUBSTITUTION-COPIES." The inner envelopes shall be sealed in an outer envelope, which shall be duly marked "BID AMENDMENT" or "BID SUBSTITUTION."
	(b) Other provisions concerning the marking and dispatch of bid amendments 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 Guarantee pursuant to ITB Sub-Clause 17.7.
E. Opening and Evaluation of Bids	
23. Bid Opening	23.1 The Bid Opening Committee at the contracting entity will open all bids, including notices of withdrawals and modifications, in a public session in the presence of the bidders or representatives of the bidders (authorized), at the time, date and location as specified in the bidding **data sheet**. Bidders or representatives of bidders shall sign the attendance record 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 "AMENDMENT" 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 Guarantee 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 Clause 21.1 of the instructions to bidders.
	All pages of the original of each Bid shall be marked 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 amendments 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; - the price of the bid (per lot) if any, including any discounts, any conditional prices or any other bid discounts; - marking clearly any alteration, erasure, correction made by the Bidder on the prices schedules, signed by the head and the members of the Bid Opening Committee - slashing un-priced items with horizontal lines; along with the signature of the chairman and members of the Bid Opening Committee - the Bidder's signitures on 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 marked by the Bids Opening Committee. All the pages of the quoted Price Schedule of the Bidders shall be singed by the chairman and members of the 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 shall 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 entity's bill board while stating that these are to be analysed and

	verified further.
	23.8The Bids will be referred to the Bid Evaluation and Analysis Committee after having approval of the Head of the Contracting Entity.
24. Clarification of Bids	24.1 During evaluation of the bids, only the Contracting Entity (Bid Evaluation and 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 (Bid Evaluation and 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 shall do so in writing.
26. Initial auditing of bids and determining its response to the tender documents	26.1 The Contracting Entity (Bid Evaluation and Analysis Committee) will examine the bids to determine whether they are complete, whether any computational errors have been made, whether required Bid Guarantee have been submited, whether the documents have been properly signed, and whether the bids are generally in order.
	26.2 The contracting entity (Bid Evaluation and Analysis Committee) can accept any minor formalities, inconsistencies or minor deviations in the bid, if this does not constitute a fundamental deviation, provided that this acceptance does not prejudice or affect the arrangement of any bidder in the evaluation.
	26.3 Prior to the detailed evaluation, pursuant to ITB Clause 29, the Contracting Entity (Bid Evaluation and Analysis Committee) will determine whether each bid is of acceptable quality, is complete, and is substantially responsive to the Tender documents. For purposes of this determination, a substantially responsive bid is one that conforms to all the terms, conditions, and specifications of the Tender documents without material deviations, exceptions, objections, conditionality, or reservations. A material deviation, exception, objection, conditionality, or reservation is one:

	(1) that limits in any substantial way the scope, or quality of the (drugs and vaccines) and related Services;
	(2) that limits, in any substantial way that is inconsistent with the Tender documents, the Contracting Entity's rights or the successful Bidder's obligations under the Contract; and
	(3) 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 (Bid Evaluation and 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 Guarantee shall be forfeited.
28. Conversion to Single Currency	28.1 In order to facilitate the procedures of analysis and comparison, the contracting entity (Bid Evaluation and Analysis Committee) shall transfer all bid prices submitted in different currencies to the Iraqi dinar, using the exchange rate approved for similar sales issued 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 opening.
29. Evaluation and Comparison of Bids	29.1 The Contracting Entity (Bid Evaluation and Analysis Committee) will evaluate and compare the bids that have been determined to be substantially responsive, pursuant to ITB Clause 26.
	29.2 In order to compare and evaluate bids and determine the ranking of candidates, 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 price, if applicable as per Schedule of Requirements as per ITB Sub-Clause 14.3.3 for subsequent stipulated years after defects warranty period.
	29.3 In order to compare and evaluate bids and determine the ranking of candidates, the following will be calculated:

	• The prices of domestic (druges and vaccines) or those of foreign origin located within Iraq, as brought out in ITB Sub-Clause 14.3.1 and stipulated in Price Schedule in format in **Section four**(2),
	• The prices of (drugs and vaccines) offered from abroad, as per ITB Sub-Clause 14.3.2 and as stipulated in Price Schedule in format in **Section four** (3)
	29.4 If more than one schedule (or lot) has been specified in Section Sixth 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.
	29.5 Contracts for each schedule (or group) can be awarded separately, according to the bidder who submitted the responsive and lowest-costed bid (Lowest Evaluated Bid) as per ITB Clause 8 subject to Margin of Preference, as per Clause- 30.
30. Margin of Preference	30.1 Unless otherwise stated in Bid Data Sheet, a margin of priority shall be adopted for bids from local bidders.
31. Contracting Entity's Right to accept or reject all or any of the 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 Guarantee shall be promptly returned to the Bidders together with the fees of purchasing the Tender 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 Guarantee
34. Contracting Entity's Right to Amend Quantities at Time of Award	34.1 The Contracting Entity reserves the right at the time of Contract award to increase by a percentage no more than 20% or decrease no more than 15% of the value of contract (as stipulated in **Bid Data Sheet**) 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 awarding the bid, and shall publish the results as per the applicable Iraqi Laws identifying the bid and lot numbers and the following information: (1) name of each Bidder who submitted a Bid; (2) bid prices as read out at Bid Opening; (3) name and evaluated prices of each Bid that was evaluated; (4) name of bidders whose bids were rejected and the reasons for their rejection; and (5) 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 (initial contract) subject to settlement of Appeal by unsuccessful bidder as per ITBClause 36.
	35.3 After submitting the contract signed by the winning bidder attached to a performance bond in accordance with Article 38 of the instructions to the bidders, the contracting entity will immediately return the bid guarantees to the unsuccessful bidders according 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, it shall address its request to the Contracting Entity. The Contracting Entity will promptly respond in writing to the unsuccessful Bidder.
36. Complaints and Appeals	The mechanism used in considering the complaints of the Bidders is adopted in accordance with the instructions for the implementation of the general government contracts in force.

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 Ninth** of the Tender 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 winning bidder has to sign the contract agreement and return it to the Contracting Entity within the specified period. In case of an unsuccessful Bidder's appeal as per ITB 36 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. (a) Notifying the competent court of its decision with all details and justifications. (b) Securing the consent of the competent court by submitting a signed commitment to compensate for any damages that may arise in the future due to the execution of the contract, if the judgment of the competent court is contrary to the decision of the Contracting Entity.
38 Good Performance Guarantee	38.1 Within fourteen (14) days of the receipt of notification of award from the Contracting Entity, or twenty nine (29 days) as of the date of receiving the notification of the award decision issued by the Contracting Entity, the successful Bidder shall submit the Good performance Guarantee in accordance with the Conditions of Contract. 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 Good performance Guarantee
	38.2 Upon the failure of the successful Bidder to submit the above-mentioned Good performance Guarantee or signing 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 this period the Contracting Entity has sufficient grounds to proceed with the annulment of the award and forfeiture of the Bid Guarantee 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 declinedBidder will be responsible for paying the difference in the bids prices in addition to forfeiture of the Bid Guarantee These actions will be taken against the declinedbidders provided they decline during their Bid validity.

Section two

Bid Data Sheet BDS (Drugs Or Vaccines)

The following specific data for the (Drugs or Vaccines) 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	Name of Contracting Entity: [insert: **name of Contracting Entity**] Type of (drugns or vaccines): [insert **Drugs and Vaccines**]. Project or Tender: [Name of Project or Tender] Tender Number: [**Project/Tender reference number as listed in the Iraqi Budget**] **IFB Number:** [insert **IFB reference number**] The number and identification of schedules (lots) comprising this IFB is detailed in Schedule of Requirements are :[insert **number of schedules(lots)**] [Specify **the year of the Budget as endorsed by competent authorities with the reference number**] for [***name of Contracting Entity***] The source of funding for the contract(s) is: :[**Sorce of Funding**]

B. The Tender documents

ITB 4.1	Contracting Entity's / duly authorized Purchasing Agent's address: [*insert: **Contracting Entity's address, e-mail address, telephone, telex, and facsimile numbers; also specify a responsible contact person or officer to whom Bidder communications shall be addressed***]. Requests for Clarification are to be hand delivered or sent by express courier and [insert **"are" or "are not"**] accepted by cable.

	{Note: Do not use similar mailbox or addresses }

C. Preparation of Bids

ITB 6.3	List of disqualified bidders is available on the website address of the Ministry of Planning.
ITB 7.2	Insert the mechanism of certification required by the Contracting Entity.
ITB 7.3 (c)	Documentation requirements for eligibility of (drugs and vaccines).
	For drugs
	For drugs [Sample clause:]:
	The drugs provided shall conform to the prescribed pharmacopeia standards as described in the technical specifications. If the (drugs) provided are not included in these measures (for example, in the case of a new drug), the Bidder shall provide alternative testing and reference protocols for these (drugs)].
	For vaccines [Sample clause]:
	1. Vaccines to be provided under this Contract shall be licensed in the country of origin and in Iraq upon signature of the contract by a recognized (NCA-National Control Authority). The National Control Authority is an institution that performs all six vital functions to monitor biological products as determined by the World Health Institution, especially, 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 perform ance. The license from the country of origin shall specify that the Bidder has the license from the National Control Authority to manufacture these (drugs and vaccines). A certified copy of this license, together with a copy of the registration of the vaccine by the National Control Authority in the country of origin, shall be attached to the tender. A certified copy of the license given by the National Monitoring Authority in Iraq shall be provided upon signing the contract. In the absence of a national control body with biological expertise in Iraq, the Bidder shall provide evidence that the vaccines provided are identical.

ITB 7.4	Iraq *[insert: "**does**" or "**does not**"]* require registration of (drugs and vaccines). {Note: If Iraq does not require registration (drugs and vaccines), delete paragraphs 7.4 (b
	and 7.4.1 listed below and enter the following sentence: "**ITB Sub-Clause 7.4 is inapplicable. The Applicable Law does not require registration of the (drugs and vaccines) to be supplied under the Contract**".} **Note:** There shall be no forfeiture of a bid or a Good Perforemence Guarantee based on the failure to obtain registration.
ITB 7.4 (b)	By the time of Contract signing, the successful Bidder shall have complied with the following documentary requirements in order to register the (drugs and vaccines) to be supplied under the Contract: [insert: **specific documentary requirements or any other special conditions in accordance with relevant and applicable Iraqi laws**
	{Note: Bidders shall inquire about the conditions and procedures for registering (drugs and vaccines) as soon as possible, in order to avoid any delay that may result during the registration process by the various competent government authorities).
ITB 7.4.1	For the purpose of obtaining additional information about the requirements for registration, Bidders may contact [insert: **Department of Registration of Pharmaceuticals in the Ministry of Health, contact person, phone/fax/email address**].
ITB 11.1	The language of the bid is: [Insert "**Arabic**" or "**Kurdish**" or "**English**"]. {If more than one language is adopted, insert : **"In case of more than two permitted languages to Bid, the Bidders are permitted, at their choice, to submit their bids in one of the languages above indicated. Bidders shall not submit bids in more than one language"**]}.
ITB 12.1	In addition to the documents stated in Paragraphs 12.1 (a) through (f), the following documents shall be included with the Bid ***[insert list of documents***: An example of this: The bidder who is not a manufacturer (a manufacturer) / a major producer of the required drugs or vaccines, must provide the documents proving that (the drugs and vaccines) that he will provide conform to the quality standards approved by the main manufacturer of these (drugs and vaccines), and that he has The ability to provide the required quantities. A "major manufacturer" is defined as a company that undertakes all stages of manufacturing and producing drugs or vaccines, including processing, blending, formulating, filling, packing, labeling and quality testing (quality testing). The bidder must submit a certificate from the competent regulatory authority (RA) proving that the

	manufacturer has the license to manufacture (drugs and Vaccines)
14.4	INCOTERMS® current edition shall be adopted (state the issuance year of the INCOTERMS® current edition).
ITB 15.1	b) Foreign currencies: [insert: **"Up to any three currencies of any country, provided that the currency/currencies selected by the Bidder shall be from the list of currencies from which the Central Bank of Iraq quotes the rate of exchange to the Iraqi Dinar"** or **"Not applicable"** .]
ITB 16.1	The bid validity period shall be [insert: **number (X)**] days after the deadline for bid submission, as specified below in reference to ITB Clause 20. Accordingly, each bid shall expire after [insert: the actual **date of the expiration of the bid validity period**, i.e. day and date]
	Bid Guarantee shall be valid ( ) days after the end of the bid validity period. Accordingly, a bid with a Bid Guarantee that expires before [insert: **the actual date of the expiration of the Bid Guarantee, i.e., day and date**] shall be rejected as nonresponsive.
	{**Note:** Many bids are rejected due to minor errors in calculating the validity period of the bid guarantee. Therefore, the contracting entity shall specify clearly the expiry date of the tender guarantee period.}
ITB 17.1	{Note: Upon necessity, insert: **"As per the order of the provisional coalition authority (dissolved) No. 87 for the year 2004 or any superseding law and the instructions of implementing governmental contracts (exempt, not exempt), Public Companies of the state and public sector are exempted from submitting Bid Guarantee" }**
	{In case the contracting entity decides this, **[insert: "The contracting entity has decided not to ask for Bid Guarantee from the Decent Firms in accordance with the Iraqi applicable laws and regulations"**}
	The amount of the Bid Guarantee shall be [insert a percentage between 1% - 3% of the tender estimated value] 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**.
ITB 17.8	If the Bidder defaults under the actions prescribed in subparagraphs (1) or (2) 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.
ITB 18.1	Required number of copies of the bid: [insert: **number) of copies]**.
ITB 18.2	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).
D. Submission of Bids	
ITB 19.1	(a) Bidders are **["entitled" or "not entitled"]** to submit their bids by e-mail.
	(b) The number of copies of the tender required in addition to the original tender is: [specify **:(number of copies**)].
ITB 19.2 (b)	For **bid submission purposes**, the Contracting Entity's address is : Attention: [insert_____] Street Address: [insert _____] Floor/Room number: [insert _____] City [insert _____] ZIP Code: [insert _____] Country: [insert _____]
ITB 19.2 (c)	Insert (name and number of the Tender/IFB number)
	{Note: The contracting entity shall establish for its contracts a clear and identifiable numbering system. Failure to adopt a clear numbering system usually leads to misunderstandings between the parties involved in daily / routine communication, to delays in reviews, and to improperly monitoring project implementation}.}
ITB 20.1	Deadline for bid submission is: [insert: **day and date and time in hours and minutes and specifying if local time Baghdad-Iraq or else**].
E. Bid Opening and Evaluation	
ITB 23.1	The bid opening shall take place at: Street Address: [insert _____] Floor/Room number: [insert _____] City : [insert _____] Country:[insert _____] Date: [insert _____] Time: [insert _____]

	{Note: The bid opening date shall be the same as the deadline for receipt of bids or immediately after it, in order to reduce potential complaints related to unsafe storage of bids. In exceptional cases and when it is not possible to perform the bid opening at the same deadline for submitting bids, and after the approval of the contracting entity, the date for opening the bids may be determined on the morning of the next working day, in accordance with the Iraqi laws in effect. .}
ITB 30.1	[Insert: "**applicable Not applicable"**]
	"**In case of Pharmaceuticals and if the lowest responsive bid which meets the laid down Qualification Criteria offers foreign (drugs and vaccines) as per ITB 29, then a Margin of 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 %**".]
ITB 34.1	Insert any exceptions or restrictions ( )
ITB 37.1	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.
	The Contract shall be certified according to the procedures adopted in Iraq.
ITB 38.1	A Good performance Guarantee shall be submitted within (insert the number of days) from the date of issuance of the award letter and its official notification.

Section Three. Evaluation and Qualification Criteria

1-Evaluation Criteria

The Evaluation Criteria has been specified in Instructions to Bidders (ITB) in Section one and **Bid Data Sheet** (BDS) in Section two. The specific data **Bid Data Sheet** (BDS) for the (drugs and vaccines) 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 are:

{Note: The contracting entity can specify appropriate qualification criteria that are quantifiable, according to the requirements of experience and / or financial ability, etc., depending on the type (drugs and vaccines) that are the subject of the bid.)

A) The following documents shall be included with the bid:

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

(1) that, in the case of a Bidder offering to supply (drugs and vaccines) 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 (drugs and vaccines);

(b) has been licensed by the regulatory authority in the country of manufacture to supply the (drugs and vaccines);

(c) has manufactured and marketed the specific (drugs and vaccines) covered by this Bidding Document, for at least [insert two (2) years or as per market availability], and for similar (drugs and vaccines) 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 (drugs and vaccines) 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;

(e) Details of the field quality control facilities, services and set of tests conducted

(2) that, in the case of a Bidder offering to supply (drugs and vaccines) 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 (drugs and vaccines) that meets the criteria under (1) above to supply the (drugs and vaccines) in Iraq; and

{For **drugs and pharmaceutical products** insert the following additional clauses}

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

(e) The bidder has a certificate of Good Distribution Practice, as the case may be.

The Bidder shall submit the following additional information:

(f) list of drugs and pharmaceutical products being manufactured by the Bidder with product registration/license number and date.

(g) Certificate of the pharmaceutical product for each of the bid items in accordance with the recommendations of the World Health Organization.

{**For vaccines**, insert the following additional clauses}

1- The documents proving the bidder's qualifications to implement the contract if his bid was accepted:

(E) The bidder shall obtain a permit from the competent authority in the manufacturer's country in accordance with Resolution No. WHA 28 65 (2) related to the WHO certification scheme on vaccine quality.

2- The bidder shall provide the following additional information:

(F) A list of the vaccines under manufacturing currently by the bidder with the number and date of the license / registration of the products.

1. Accurate technical specifications...

These are the technical characteristics and scale of (drugs and vaccines) required by the Contracting Entity and related services and their conformity with specifications, which facilitate the evaluation process of the bid and contain clear indicators and include details of the working environment conditions for these (drugs and vaccines) such as (temperature, humidity, storage conditions .. .., etc) and the requirements of packaging, packing and envloping

2. Final accounts

(Submitting the general budget audited by the legal auditors presenting the financial position of the previous years ( ), showing the financial efficiency and future profit forecast of the Bidder and endorsed by the auditor)

3. Cash flow

The Bidder shall provide the financial resources with the value of its submitted bid ( ) according to the required bid currency.

4. Annual revenue

Minimum Annual Revenue Rate, the revenue of the Bidder is ( ) for the works executed for the contracts completed or continuing during the years( )

6. (insert any other criteria …….)

-Final accounts are required for the last two years prior to the date of Tender announcement. (In the absence of

work carried out by companies in the last two years due to the financial crisis, final accounts will be submitted for the two years prior to 2014.

-**Cash flow** is defined as the clarification of financial capacity and the provision of cash flow, and its financial value varies according to size of the contracts (large, medium, small) of the estimated cost of the contract to be executed

-Annual revenue is required according to the size of the contract (large, medium, small) and for the previous years ranging between (5-10) years .

Section four. Bidding documents

Notes on the Bidding documents

The Bidding documents 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 include the required information in these model documents in proportion to the requirements of each tender, prior to launching the tender process. The space required to include these notes is in spaces in italics with a gray background in parentheses. Any notes addressed to the contracting entity that are in {} brackets and written in a yellow background and background are for information only and shall be removed prior to issuing the tender documents.}

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

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

1. Bid Submission Form.
2. Price Schedules for domestic (drugs and vaccines) or goods of foreign origin available in Iraq.
3. Price Schedules for (drugs and vaccines) to be imported from Abroad
4. Manufacturer's Authorization Form.
5. Sample Form for Performance Statement

1. Bid Submission Form

Date: [insert: **date of bid**]

{The contracting entity shall insert: Tender Number: [insert number]"}
IFB Number: [insert number]"}
To: { The Contracting Entity shall insert: [**Name and address of Contracting Entity**]}
Dear Sir or Madam:

Having examined the Tender documents, including Addenda Nos. [insert **numbers**], the receipt of which is hereby acknowledged, we, the undersigned, offer to supply and deliver the (drugs and vaccines) under the above-named Contract in full conformity with the said Tender 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 (drugs and vaccines) in accordance with the delivery schedule specified in the [insert "Schedule of Requirements in Section Sixth **or** "as quoted in Price Schedule in Section Fourth"] (the Bidder may select as appropriate clause).

3. We agree to all General Conditions of Contract in Section Seven read in conjunction with the Special Conditions of Contract in Section Eight.

4. If our bid is accepted, we undertake to provide an advance payment security and Good performance Guarantee in the form, in the amounts, and within the times specified in the Tender 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 two 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 one.

(a) We do not have conflict of interest in accordance with ITB Sub-Clause-6.1 (a) of Section one.

(b) 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 one.

(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 Ministry of Planning and declared ineligible to bid during the period of time determined as per ITB Clause 6.3 of Section one.

9. We confirm that our website address is [*insert* ***website address***] and our mail address is [*insert* ***maild address***], and that Mr. /Ms. [insert name] of Job Title [*insert* ***job title***] and e-mail address [*insert* ***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****]*

3. Price schedule for drugs and vaccines to be imported from abroad

3. Price Schedules for domestic (drugs and vaccines) or goods of foreign origin available in Iraq

1

Brief Description of drugs and vaccines

No. of bid tpreciept committee	Code of manufacture company	Offers submission	National code	The scientific name	The scientific 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) existance 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: IQD_____ (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		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 producting company	The origin of producting 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 defincal 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: IQD_____ (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 _____

Country of Origin Declaration Form

Item	Description	Code	Country

A confirmed certificate of origin shall be issued for all imported drugs and vaccines at the time of shipment

4. Manufacturer's Authorization

[The Bidder shall require the Manufacturer to fill in this Form in accordance with the instructions indicated. Thisletter of authorization shall be on the letterhead of the Manufacturer and shall 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 drugs and vaccines 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 drugs and vaccines, manufactured by us [insert: **name and or brief description of the drugs and vaccines**

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**]

5. Sample Form for Good Performance Statement

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

Section Five. Eligible Countries

Regarding the eligibility of the Bidders for the provision of (drugs and vaccines), Works and Services in Public Contracts financed by the Purchuser:

1. The Purchuser permits firms and individuals from all countries to offer (drugs and vaccines), works and services for projects financed by the Government of Iraq. As an exception, firms of a Country or (drugs and vaccines) manufactured in a Country may be excluded if:
    a- If the legislation or official instructions in force prohibit the Bidder's country from establishing commercial relations with the Purchuser state provided that the Purchuser is convinced that such prohibition will not prevent the fruitful competition for supplying goods or executing works.
    b- by an Act of Compliance with a Decision of the United Nations Security Council taken under Chapter VII of the Charter of the United Nations, the Purchuser's country is forbidden to import any goods or pay any amounts to the Bidder's country.
2. For the information of bidders, at the present time firms, (drugs and vaccines) and services from the following countries are excluded from this bidding:
    (a) With reference to paragraph: 1-a _____ *[Insert]* _____

    (b) With reference to paragraph: 1-b
    _____ *[Insert]* _____

PART 2

Contracting

REQUIREMENT

Section Sixth : LIST OF CONTRACTING REQUIREMENTS

Schedule: I List of (drugs and vaccines), Delivery Schedule and Terms of Delivery:

1		2					3	4	5	6
Schedule No.	**Item No.**	**Brief Description of (drugs and vaccines) [Insert for Pharmaceuticals, Product, Strength, Dosage form, Pharmacopoeia Standard and Unit pack size. For Medical Equipment only Brief Description of (drugs and vaccines) may be mentioned]**					**Quantity and physical uni**	**Bid Guarantee amount in Iraqi Dinar [Note Insert Bid Guarantee 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**	**Pharmacopeia 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]**	**[Insert]**

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

Technical Specifications

{The Contracting Entity shall include information and specifications in the schedules of drugs (including pharmaceuticals and vaccines, as necessary)}.

Summary of technical specifications of drugs (including pharmaceuticals) or vaccines

Names of Drugs and Vaccines	**Technical Specifications**
1.	
2.	
3.	

[Sample 1: Technical Specifications Pharmaceuticals

Drugs

1. Product and Package Specifications

1.1 The drugs 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 shall meet the latest requirements of the World Health Institution (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 (drugs and vaccines) shall conform to standards specified in the following compendia: [The Contracting Entity shall 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 shall clearly indicate acceptable limits and* the Bidder (Supplier), upon award of the Contract, shall 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*) shall also meet specifications suitable for distribution, storage, and use in a climate similar to that prevailing in Iraq. All packaging shall be properly sealed and tamper-proof *and packaging components shall meet the latest compendium standards and be approved for pharmaceutical packaging by the manufacturer's national regulatory authority (RA). The Contracting Entity shall specify any additional special requirements*.

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 (drugs and vaccines) requiring refrigeration or freezing *or those that shall not fall below a certain minimum temperature* for stability shall 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.

2. Labeling Instructions

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 shall 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) date of manufacture and date of expiry (in clear language, not code);

(j) date of manufacture and date of expiry (in clear language, not code);

(k) name and address of manufacture;

(l) any additional cautionary statement.

2.2 The outer case or carton shall also display the above information.

3. Case Identification

3.1 All cases shall 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;

(t) any additional cautionary statements.

3.2 No case shall 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, *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 logo shall be provided to the Bidder (Supplier) at the time of contract award.*

5. Standards of Quality Control for Supply

5.1 The successful Bidder (Supplier) will be required to submit 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 (drugs and vaccines) 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 (drugs and vaccines) 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 No. (2)

Technical Specification

Vaccines

Option A

1. Product Qualification Requirements

1. The (drugs and vaccines) to be purchased by the Contracting Entity under this Invitation for Bids shall 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 Institution (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 vaccines under this Invitation for Bids shall be purchased from WHO-approved sources only.

1.2 The vaccines to be purchased by the Contracting Entity under this Invitation for Bids shall be produced in accordance with the GMP recommendations of WHO for biological products.

1.3 The vaccines to be purchased by the Contracting Entity under this Invitation for Bids shall be registered by the National Control Authority (NCA) of Iraq.

2. Product Specifications

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 in activated (...) obtained from human plasma or manufactured using recombinant will benefit 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 Dose size (if not specified) - or Dosage size (if not restrictive), or expected immunogenic reaction (eg: 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 shall contain 15% overfill,” etc.).

2.8 Closures (e.g. “vaccines 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.).

2.10 The product shall remain stable up to the indicated test expiry date if kept according to the required storage temperature.

2.11 Standards (e.g.: “The vaccine shall 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. Labeling Requirements

3.1 Each vial or ampoule shall carry the manufacturer’s standard label in Arabic 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 Arabic 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 shall 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 shall 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 shall be such that the product does not become damaged during transportation and storage.

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

4.5 Cold chain monitor cards: Each insulated shipping container shall 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) (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 shall 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;
(d)Manufacturer's national registration number;
(e)Destination airport and routing;
(f)Consignee's name and address in full;
(g)Consignee contact name and telephone number;
(h)Number of vials or ampoules contained in the carton;
(i)Gross weight of each carton (in kg);
(g)Carton #____ of _____;
(k)Instructions for storage and handling;
(l)Contract number;
(m) Place of manufacture (Made in_____)

6. Quality Control for Supply

6.1 All vaccines shall:

(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 purpose 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 submit 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 documents on the basis of calculating the expiration date and other data related to the stability of vaccines in their final commercial 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 (drugs and vaccines) 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.

Section Seven. General Conditions of Contract

Notes on the General Conditions of Contract

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

GCC shall remain unaltered. Contract-specific information, deletions, extensions, and

amendments to the GCC shall be introduced only by the Contracting Entity through the SCC.

Table of Contents

General Conditions of Contract

	In this Contract, the following terms shall be interpreted as indicated:
1. **Definitions**	(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) "Final user" means the institution(s) where the (drugs and vaccines) will be used, as named in the Schedule of Requirements.
	(f) "GCC" means the General Conditions of Contract contained in this section.
	(h) "The Purchaser" means the institution or the Contracting Entity purchasing the drugs (including pharmaceutical products), as **named in the SCC.**
	(i) "Registration Certificate" means the certificate of registration or other documents in lieu thereof establishing that the drugs (including pharmaceutical products) 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 drugs (including pharmaceutical products), such as transportation and insurance, and any other incidental services.
	(l) "The Site," means the place or places belonging to the contracting entity (the beneficiary) according to the list of contracting requirements.
	(m) "The Supplier" means the individual or firm supplying the drugs (including

	pharmaceutical products) and Services under this Contract, as **named in the SCC.**
	(a) 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**:**
	(1) "corrupt practice" is the offering, giving, receiving or soliciting, directly or indirectly, of anything of value to influence improperly the actions of another party;
	(2) "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;
	(3) "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;
	(4) "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;
	(5) "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 other provisions.
3. Country of Origin	3.1 For purposes of this Clause, "origin" means the place where the drugs (including pharmaceutical products) or vaccines are manufactured, grown, or produced, or from which the Services are supplied. the drugs (including pharmaceutical products) or vaccines 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 the drugs (including pharmaceutical products) or vaccines and Services is distinct from the nationality of the Supplier.
4. Standards	4.1 The drugs (including pharmaceutical products) or vaccines 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 of 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 submited 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 The supplier shall allow the buyer, through the competent authorities, to monitor and inspect his offices, files, and / or accounts and records, and he shall submit these accounts and records for audit by authorized auditors, in accordance with the Iraqi laws in force. The attention of the supplier is drawn to Article 23 of the general conditions of the contract, which specifies, inter alia, that the practices aimed at impeding or obstructing the buyer or the clearly competent authorities in exercising their right to inspect and audit under this article, are prohibited practices that expose the supplier to terminate The contract and to suspend his participation in other tenders or blacklist his name according to the relevant Iraqi laws in force.
6. Certification of (drugs and vaccines) in Accordance with Laws of Republic of Iraq	6.1 If required under the Applicable Law, (drugs) 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 (drugs) 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 drugs have been registered for use in Iraq.
7. Patent Rights	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. Good Performance Guarantee	8.1 Within 14 days, or twenty-nine (29) days including warning period in case of Complaints and Appeals raised by unsuccessful Bidders, of receipt of the notification of Contract award, the successful Bidder shall submit to the Purchaser the Good Performance Guarantee 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. Good Performance Guarantee
	8.2 The proceeds of the Good Performance Guarantee 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 Good Performance Guarantee 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 demand and it shall 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 Tender documents. In the case of a Bank Guarantee submited 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
	8.4 The Good Performance Guarantee will be discharged by the Purchaser and returned to the Supplier following the date of completion of the Supplier's performance obligations under the Contract, and expiry of the warranty period, the issuance of the satisfactory completion certificate and the final payment settlements.
9. Inspections and Tests	9.1 The Purchaser or its representative shall have the right to inspect and/or to test the (drugs and vaccines) 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 (drugs and vaccines) 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 (drugs and vaccines)' 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 submited by the Supplier are **specified in the SCC.**
	For Goods supplied from abroad: 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:
	(1) three originals and two copies of the Supplier's invoice, showing Purchaser as [insert correct name of Purchaser for customs purposes]; the Contract number, Goods description, quantity, unit price, and total amount. Invoices shall be signed in original, marked, or sealed with the company stamp/seal; one original and two copies of the negotiable, clean, on-board through bill of lading marked "freight prepaid" and showing Purchaser as [insert 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;
	(2) four copies of the packing list identifying contents of each package;
	(3) copy of the Insurance Certificate, showing the Purchaser as the beneficiary;
	(4) one original of the manufacturer's or Supplier's Warranty Certificate covering all items supplied;
	(5) one original and *[number]* 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;
	(6) one original and (6) copies of the Certificate of Inspection submited to Supplier by the nominated inspection agency (where inspection is required);
	(7) 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:
	(1) two originals and two copies of the Supplier's invoice, showing Purchaser, the Contract number; Goods' description, quantity, unit price, and total amount. Invoices shall be signed in original and marked or sealed with the company stamp/seal;
	(2) two copies of delivery note, railway consignment note, road consignment note, truck or air waybill, or multimodal transport document showing Purchaser as [insert correct name of Purchaser] and delivery through to final destination as stated in the Contract;
	(3) copy of the Insurance Certificate, showing the Purchaser as the beneficiary;
	(4) four copies of the packing list identifying contents of each package;
	(5) one original of the manufacturer's or Supplier's Warranty certificate covering all items supplied;
	(6) 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. Foritems 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;
	(7) original copy of the Certificate of Inspection submited to Supplier by the nominated inspection agency and six copies (where inspection is required)
	(8) other procurement-specific documents required for delivery/payment purposes.
	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.
	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 Unless otherwise specified in **the SCC**, the drugs and vaccines supplied under the Contract shall be fully insured in a freely convertible currency of an eligible country, against loss or damage incidental to manufacture or acquisition, transportation, storage, and delivery.
13. Transportation	Unless otherwise specified in **the SCC**, the responsibility for regulating the transport of Drugs and Vaccines shall be as prescribed in the current edition of INCOTERMS®
14. Payments	14.1 The method and conditions of payment to be made to the Supplier under this Contract shall be as follows: If the supplier is a public entity (state company and public sector), the buyer can raise the advance payment according to the instructions in force} .
	a. Payment for Goods supplied from abroad: Payment of foreign currency portion shall be made in the following currency: ***[insert contract currency]*** in accordance with the following:
	(1) Upon shipment: the buyer shall pay to the supplier [eighty (80)]% of the price of the goods to be shipped, by means of a confirmed and irrevocable letter of credit, which shall be opened for the supplier in a bank in his home country. Payment shall be made in accordance with the letter of credit after presenting the documents specified in GCC Clause 11;

	The Purchaser shall bear the costs of opening the letter of credit and the costs of amending it for reasons related to the Purchaser or caused by its fault or default. The supplier shall bear the costs of fixing the letter of credit and the costs of amending it.
	(2) **On Delivery & Acceptance:** the Purchaser shall pay to the supplier *[twenty (20)]*% of the total contract value within [thirty (30) days] of the date of receipt of the goods, after submitting a payment request (indicating the Purchaser's name, contract number, description of payment and total amount, signed in original, marked or sealed with the company stamp/seal) supported by the Acceptance Certificate issued by the Purchaser.
	The Purchaser shall pay to the supplier the payments in the currency agreed upon in the terms of the Contract within [*thirty (30) days]* from the date of submitting the payment request (indicating the Purchaser's name, contract number, description of payment and total amount, signed in original, marked or sealed with the company stamp/seal) supported by the Acceptance Certificate issued by the Purchaser.
	B. Payments for goods supplied from within Iraq:
	Payments for goods and services supplied within Iraq shall be made in Iraqi Dinars according to the following:
	(1) **Advance Payment**:The Purchaser shall pay to the supplier *[insert percentage as per instructions) to local factories]* after the submission of a payment request (indicating the Purchaser's name, contract number, description of payment and total amount, signed in original, marked or sealed with the company stamp/seal) in addition to the advance payment Guarantee in accordance with the document attached to Section Eight.
	(2) Upon receipt (acceptance): The Purchaser shall pay to the supplier [[insert percentage as instructed]% of the total contract value after submitting a payment request (indicating the Purchaser's name, contract number, description of payment and total amount, signed in original, marked or sealed with the company stamp/seal) supported by the Acceptance Certificate issued by the Purchaser
	Please note that the percentages specified above can be adjusted to meet specific contracting requirements or approved business standards.}
	14.2 The Supplier's request(s) for payment shall be made to the Purchaser in writing, accompanied by an invoice describing, as appropriate, the (drugs and vaccines) delivered and Services performed, and by documents submitted pursuant to GCC Clause 11, and upon fulfillment of other obligations stipulated in the Contract.
	14.3 Payments shall be made as soon as psible by the Purchaser in accordance with the work context of the Ministry of Health and in accordance with the terms of the tender advertising. The SCC shall specify the procedures to be followed if the

	Purchaser fails to pay the sums due. When applicable, the advance Guarantee 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 Guarantee 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 according to the formula adopted by banks.
	14.4 Payment will be made in the currency or currencies specified in the SCC.
	14.5 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.
15. Prices	15.1 Prices charged by the Supplier for (drugs and vaccines) delivered and Services performed under the Contract shall not amend from the prices quoted by the Supplier in its bid, prices shall be fixed and firm for the duration of Contract.
16. Amendment orders	16.1 No changes shall be introduced to the contract unless for the circumstances (a-e) listed here below**.** In such case, the Change shall 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 (drugs and vaccines) 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 amendment 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 (drugs and vaccines) to be submited 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.
	16.2 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 shall be asserted within fifteen (15) days from the date of the Supplier's receipt of the Purchaser's change order.
17. Contract Amendments	17.1 Subject to GCC Clause 17, no variation in or amendment of the terms of the Contract shall be made except by written amendment signed by the parties.
18. Assignment	18.1 The Supplier shall not assign, in whole or in part, its obligations to perform under this Contract, to any other party in accordance with the legislation in force.
19. Delays in the Supplier's Performance	19.1 Delivery of the (drugs and vaccines) 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.
	19.2 If at any time during performance of the Contract, the Supplier or its subcontractor(s) shall encounter conditions impeding timely delivery of the (drugs and vaccines) and performance of Services, the Supplier shall promptly notify the Purchaser in writing of the fact of the delay, it's 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, Arrears fines (Delay Penalty) in which case the extension shall be ratified by the parties by amendment of Contract.
	19.3 Except as provided under GCC Clause 23, a delay by the Supplier in the performance of its delivery obligations shall render the Supplier liable to the imposition of Arrears fines (Delay Penalty) pursuant to GCC Clause 22, unless an extension of time is agreed upon pursuant to GCC Sub-Clause 21.2 without the application of Arrears fines (Delay Penalty).
20.	20.1 Subject to GCC Clause 22 if the Supplier fails to deliver any or all of the (drugs and

Arrears Fines	vaccines) 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 Arrears fines (Delay Penalty) as a sum equivalent to delivered price of the delayed (drugs and vaccines) Specified in the special conditions of the contract for each delay week or part of it until the actual delivery or execution. the Purchaser may consider termination of the Contract pursuant to SCC and according to the instructions and controls issued by the Ministry of Planning and any legislation in force ..
21. work withdrawal by the employer	21.1 The buyer can, without prejudice to any other rights or compensation incurred by him upon breach of contract, withdraw the work through a written warning for a period of (15) fifteen days of breach addressed to the supplier, according to the Iraqi laws in force that include charging the two teams and in the following cases:
	(a) if the Supplier fails to deliver any or all of the (drugs and vaccines) and related services 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 (drugs and vaccines) do not meet the Technical Specifications stated in the Contract; or fail to replace it within thirty days of receiving a written notice by the purchaser.
	(c) if the Supplier fails to provide any registration or other certificates in respect of the (drugs and vaccines) 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 administrative corruption, 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, withdraw the work from the Supplier on this basis, and the provisions of Clause 22 shall apply as if withdrawal of work had been made under Sub-Clause 22.1.
	(e) shall 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 fired.
	(f) if the Supplier fails to perform any other obligation(s) under the Contract.
	(y) If the supplier waived in part or wholly to another supplier or subcontractor with other supplier.
	(n) If parts of the supplied materials were awarded to another supplier without prior approval of the purchaser.
	21.2 In the event the Purchaser withdraw the work in whole or in part, pursuant to GCC

	Sub-Clause 22.1, the Purchaser may supply, upon such terms and in such manner as it deems appropriate, (drugs and vaccines) or Services similar to those undelivered, and the Supplier shall be liable to the Purchaser for any excess costs for such similar (drugs and vaccines) or Services.
22. Work withdrawal for bankruptcy	The purchaser may at any time and after sending a written notice to the supplier for fifteen (15) days, may withdraw the work without resorting to the court in the following cases:
	a- If the supplier becomes bankrupt or insolvent or his assets were liquidated or submitted application of bankruptcy of insolvency.
	b- If a decision was issued by the competent court to put the supplier's funds at the hand of the liquidator.
	c- If the supplier made a reconciliation that protects him from bankruptcy or waived his right to the benefit of his creditor.
	d- If the supplier approved executing his contractual obligations under the supervision of control commission consisted of his creditors.
	e- If seizure was conducted on the funds of the supplier by a competent court, this seizure may lead to the inability of the supplier to fulfill his contractual obligations.
	In this case, the withdrawal of work is done without compensating the supplier, and without prejudice to any right or compensations that are on the liability of the purchaser according to the contract or which results later.
23. Force Majeure	23.1 Notwithstanding the provisions of GCC Clauses 12, 21, and 22, 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 as much as the performance is affected by this condition.
	23.2 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, wars or revolutions, fires, floods, epidemics, quarantine restrictions, and freight embargoes.
	23.3 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.
24.	24.1 The Purchaser, by written notice sent to the Supplier, may terminate the Contract, in

Contract Termination by employer for convenience	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.
	This is to be done after sending a written notice to the supplier to terminate the contract.
	24.2 For the remaining (drugs and vaccines), the Purchaser may elect:
	(a) to have any portion completed and delivered at the Contract terms and prices;
	(b) to cancel the remainder and pay to the Supplier an agreed amount for partially completed (drugs and vaccines) and Services and for materials and parts previously procured by the Supplier.
	24.3 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 26.
25. Settlement of Disputes	25.1 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.
	25.2 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.
	25.2.1 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 (drugs and vaccines) under the Contract. If arbitration is not agreed upon, Iraqi law shall be applied to settle disputes
	25.2.2 Arbitration proceedings shall be conducted in accordance with the rules of procedure **specified in the SCC**.
	25.3 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.
26. Limitation of Liability	26.1 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 Arrears fines (DelayPenalty) to the Purchaser and
	(b) the aggregate liability of the Supplier to the Purchaser, whether under the Contract, in tort or otherwise, shall not exceed the total Contract Price.
27. Contract Language	27.1 The language of the Contract shall govern its interpretation. All correspondence and other documents pertaining to the Contract that are exchanged by the parties shall be written in the same language.
28. Applicable Law	28.1 The Contract shall be interpreted in accordance with the Iraqi Law and guardianship of Iraqi judicial system.
29.Notices	29.1 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.**
	29.2 A notice shall be effective when delivered or on the notice's effective date, whichever is later.
30. Fees and taxes	30.1 A Supplier supplying (drugs and vaccines) from abroad shall be entirely responsible for all taxes, stamp, duties, license fees, and other such levies imposed outside Iraq in accordance with the legislations in force.
	30.2 A Supplier supplying (drugs and vaccines) offered from within Iraq shall be entirely responsible for all taxes, duties, license fees, etc., incurred until delivery of the contracted (drugs and vaccines) to the Purchaser.
31. Withholding and lien in	31.1 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,

respect of sums claimed	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, submitted as the case may be and also have a lien over the same pending finalization of any such claim. In the event that the bank guarantee is not sufficient to cover the amount or amounts claimed, or in the absence of a letter of guarantee submitted by the supplier, then the buyer may deduct and retain (as he enjoys the privilege to withhold the amount or amounts mentioned above), and to the extent of the value of these claimed amounts, Any amount or amounts due or will be due to the supplier at any later time under this contract or in accordance with any other contract (if any, and in the absence of it, to take legal measures regarding it) between the supplier and the buyer or between the provider and the Republic of Iraq, until such a claim is settled And without any right for the supplier to claim any benefits or damages as a result of the foregoing and whatever their nature and on this basis or any other basis related to any sum deducted or held under this Article, provided that the provider is notified accordingly as appropriate.

Section Eight: 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.	
{Notes were provided to the contracting entity on how to complete the special conditions of the contract as needed, in italics and gray background. These in-kind provisions were submitted for the purpose of clarifying the provisions that the buyer shall prepare in particular for each tender.}	
GCC 1.1 (h)	The Purchaser is: [insert: **name of Purchaser]**. *(Ministry / Department)*
GCC 1.1 (m)	The Supplier is: [insert: **name of Supplier]**.

GCC 6.2	The Effective Date of the Contract is [insert: **date of Contract signing** if either: (1) the (drugs and vaccines) have already been registered at the time of Contracting signing or (2) registration of the (drugs and vaccines) is not a requirement under the Applicable Law. Otherwise, delete and insert **"NOT USED."**]
GCC 9.1	[Insert: any additional requirement related to the **inspections and tests**]
GCC 9.2	9.2.1. Said inspection and testing is for the Purchaser's account. In the event that inspection and testing is required prior to dispatch, the (Drugs and Vaccines) shall not be shipped unless a satisfactory inspection and quality control report has been issued in respect of those (Drugs and Vaccines).
	(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.
	(c) Upon receipt of the (Drugs and Vaccines) at place of final destination, the Purchaser's representative shall inspect the (drugs and vaccines) or part of the (drugs and vaccines) to ensure that they conform to the condition of the Contract and advise the Purchaser that the (drugs and vaccines) were received in apparent good order. The Purchaser will issue an Acceptance Certificate to the Supplier in respect of such (drugs and vaccines) (or part of (drugs and vaccines)). The Acceptance Certificate shall be issued at the earliest within [insert "ten (10) days" or "thirty (30) days"] of receipt of the (drugs and vaccines) or part of (drugs and vaccines) 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	[Insert: Any necessary additional requirements with respect to packing and marking or state that "**Additional requirements are indicated in the Technical Specifications**".**]**
GCC 11.1 & 11.3	Insert any other documents ( )
GCC 14.3	[Insert: **"The payment or payments will be settled during …. Days after receipt the result of laboratory tests according to the conditions announcement].**

GCC 25.2.2	The dispute resolution mechanism to be applied shall be as follows: (a) for contracts with foreign Supplier: "Any dispute, controversy, or claim arising out of or relating to this Contract, or breach, termination or invalidity thereof, shall be settled by arbitration in accordance with the UNCITRAL ArbitrationRules as at present in force." or any rules specified by the valid legislations.
	(b) for contracts with Supplier national of Iraq: "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 under the jurisdiction of the Iraqi judicial."]
GCC 29.1	[insert: the **Purchaser's address** for notice purposes and if by cable is acceptable, provided that it is followed with a written notice] [insert: the **Supplier's address** for notice purposes and if by cable is acceptable, provided that it is followed with a written notice]

Section Ninth: Contract Forms

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

NOW THIS AGREEMENT WITNESSETH AS FOLLOWS:

1. In this Agreement words and expressions shall have the same meanings as are respectively assigned to them in the General 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 (drugs and vaccines) 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 (drugs and vaccines) 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

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) Letter of Acceptance Form

{letterhead paper of the Employer}

[insert number]

[insert date]

To: (Supplier name and address)

Subject / Acceptance of supply [insert name of the contract and identification number]

This is to notify you that your Bid dated [insert date] for execution of the [name of the contract and identification

number, as given in the SCC] for the Contract Price [amount in words and figures], [insert Currency] as corrected and modified in accordance with the Instructions to Bidders is hereby accepted by our Company.

You are hereby requested to submit Good Performance Guarantee within 14 days of the receipt of this letter of acceptance, as stated in the SCC and GCC. A copy of the contract agreement with its general and special conditions is attached.

Yours faithfully,

Attachments

Contract Agreement Form

General Conditions of Contract

Special Conditions of Contract

Authorized Signature: ……

Name and Title of Signatory:… …

Name of Employer:……