

## 88INTRODUCTION

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:** [Ministry of Health

State Company For Marketing Drugs

Medical Appliances (kimadia]

Project/ Tender name: **MED/ 3 /2022**

**Project/ Tender Reference:** [Contract For The Supply of

medicine will arranged on the recent balance

]

**Date** : issued in date( day)... **8/ 2 /2022** .

## Letter of Invitation (Advertising)

**(Tender: General Tender to Buying the Medicine)**

To: M.S/

**Tender No.:** Med/ 3 /2022 on the recent Iraqi Federal Budget

1. The Ministry of Health / The State Company For Marketing Drug AND Medical Appliances (kimadia ) invites the a bidders qualified to present the tenders that sealed & signer for contracting on supplying of medicine

2. will be adoption measures of public bidding in the process of tender where allowed to take part of all bidders from countries eligible legally as specified in the document of bidding.

.Interested eligible bidders may obtain further information's from Ministry of Health / The State Company For Marketing Drug and Medical Appliances (kimadia )/ **Drug Information & the Public Relations Department**- 5<sup>th</sup> floor ,position of MOH(Ministry of Health),E-mail ([dg@kimadia.ig](mailto:dg@kimadia.ig)) & Kimadia website is([WWW.kimadia.ig](http://WWW.kimadia.ig)) and inspect the bidding documents at the address given below from ( 8:30 AM) to (2:30 PM) at Baghdad time

3. Bidders must meet the requirements of qualifications including: the legal, technical and financial requirements as mentioned in Bidding Document. A margin of preference for the pharmaceutical will be adopted from suppliers/ national factories goods . Additional details shall be specified in the Bidding Documents (see the clause(30) priority national from the Instructions To Bidders & clause (30) from Bid informations sheet.

4. the interested bidders could purchase the complete set of Bidding Documents in English or Arabic Language upon submission of a written application to the address below and after payment of a non-refundable fee with lump sum as follows:

- a- (1.000.000)one million Iraqi Dinar of the tender that less than (1.000.000) Dollars .
  - b- (2.000.000)two million Iraqi Dinar for the tender that more than (1.000.000) Dinar.
- Otherwise the offer will be neglected.

The way of payment this duty will be cash & the Bidding Document will be sent as state in ITB (Instruction To Bidders ) & the bidder who is previously participated in the re-announced bid to submit the previous purchasing receipt with the tender documents

5. Announcement date of this tender will be on 8/2 /2022 and The date of conference convening will be on 27 / 2 /2022 for responding the inquire of the participants against the tender.

Bids must be delivered at or before the end of formal work on 6 / 3/ 2022]. The late bids will be rejected. Bids will be opened in the presence of the bidders' representatives who choose to attend in person at the address below .

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

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

a- Bid Bond shall only be accepted if presented as a bank guarantee or legalize check or svtjh&of a receipt the swift of a guarantee letter or direct bond are not accepted.

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

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

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

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

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

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

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

i-Primary bid bond expiration date be valid until after the end of validity tender specified in the documents of tender.

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

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

**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]**

**Contracting Entity** The Ministry of Health / The State Company For Marketing Drug Medical Appliances

(kimadia) **Contracting Authority PH:** ALI HASAN AL-BALDAWI

**Title:** Director General of The State Company For Marketing Drug Medical Appliances (kimadia )

MED-3-2022
All human products must be of human recombinant origin wherever these are available in the markets.
For oral solution it is preferable: Syrup then Suspension and then Elixir
Caution To be written if the products contain metabisulphite as following (Caution: this product contain metabisulphite may cause broncho spasm in atopic & Asthmatic subjects)
It doesn't matter of all tablets that approved in the national list as scored tab to be plain tab (Not scored).
The measuring unit of medical milk powder weight is 400gm up to 1000gm (as upper limit)
لا تزيد نسبة الكحول الموجودة في الشرابات (بشكل عام) عن 10% .N.M.T.
فيما يخص شرابات الاطفال.. يفضل بدون كحول أو بنسبة ضئيلة 5% .N.M.T
يجب استخدام soft gelatin Cap لمستحضرات (Oily prep)
يحل الغاز الدافع CFC – free (HFA 134a) محل CFC.

ملاحظة: ان الكلفة التخمينية هي للتعبئة اما الاحتياج الكلي فهو للوحدة الواحدة

Note: The estimated cost is per packing size while the total need is for unit dose

	national code	Item	Total NEED 2023 (for unit dose)	PACK SIZE	MEAN BRAND Price (\$) / pack size	GENE RIC Europe an 70% mean price (\$) / pack size	GENERIC Asian including Arabic 45% mean price(\$) / pack size	GENERIC Far East 25% mean price (\$) / pack size
1	15-AA0-008	Cyclophosphamide 500mg Injection	102747	1 vial	4.9	3.43	2.2	1.22
2	15-AA0-010	Dacarbazine 200mg powder for reconstitution vial for inj (I.V. Infusion or I.V. infusion and Intra-arterial perfusion) Note: the drug after reconstitution and during infusion should be kept out of light	25401	1 vial	16	11.2	7.2	4
3	15-AA0-013	Ifosfamide 2g powder for reconstitution for I.V injection	28467	1 vial	55	39	24.75	13.75

4	15-AA0-018	Melphalan 2mg Tablet	2025	25 tab	59	41.3	26.55	14.75
5	15-AA0-025	Busulphan 60mg I.V Injection(10 ml vial) يحصر استخدامه في مراكز زرع نخاع العظم	355	vial(10 ml)	243.3	170.3	109.49	60.8
6	15-AA0-028	Temozolomide 100mg capsule	67279	5cap	130	91	58.5	32.5
7	15-AA0-030	Bendamustine hydrochloride 100mg vial powder for reconstitution يحصر استخدامه في مراكز امراض الدم وحسب الاستطابات المقررة في 1018 الجلسة Bendamustine vial to be use in :- a/ relapse chronic lymphocytic leukemia b/ relapse low grade non – hodykin lymph c/ in chronic lymphocytic leukemia in those not fit for RFC and failed to respond to R leukeran	10220	1 vial(50ml)	84.4	59	38	21.1

8	15-AB0-001	cytarabine (for S.C, I.V. , intrathecal ) 20mg/ml, 5 ml vial	29338	5 VIAL	26	18.2	11.7	6.5
9	15-AB0-008	Gemcitabine as Hcl powder for reconstitution or concentrate for solution for infusion (1g ) vial	68333	1 vial	20.8	14.4	9.3	5.1
10	15-AB0-009	6- mercaptopurine 50mg Tablet	372586	25 tab	30	18.6	11.96	6.64
11	15-AB0-010	Methotrexate 2.5mg Tablet (psoriasis) يصرف للاستخدام في علاج	769270	50 tab	7.14	5	3.21	1.78
12	15-AB0-011	Methotrexate inj as sodium salt 2.5 mg/ml, 2ml Ampoul OR vial ,subcutaneus,intrathecal للجذبية والكلية	38735	1 vial	4	3	2.3	1

13	15-AB0-019	Fludarabine phosphate 50mg vial, powder for reconstitution, for I.V. inj. or infusion.	2792	1 vial	97.7	68	43.9	24.4
14	15-AB0-020	Cladribine (2-CDA) 10mg / Vial, 5ml Or 10ml يحصّر استخدامه لعلاج اللوكيميا الشعيرية (Hairy cell Leukemia)	866	1 vial	187	130.6	84	46.75
15	15-AB0-022	cytarabine (for S.C, I.V. )100mg/ml, 10 ml vial. 20mg/ml في حالة الاعطاء Intrathecal يجب ان يكون التركيز هو 20mg/ml بطريقة الزرق	26388	1 vial	18	12.5	8.1	4.5
16	15-AB0-028	5-Fluorouracil 50mg/ml (10 ,20 ,50 ,100) ml vial for I.V inj. Or infusion oR intra-arterial infusion	91615	1 vial(20ml)	7.14	5	3.21	1.78
17	15-AB0-031	Decitabine I.V injection 50mg vial تستخدم فقط في مراكز امراض الدم والعيادات التخصصية لامراض الدم فقط MDS,, لعلاج اعتلال نخاع العظم	12306	1 vial(20ml)	761	533	342.6	190.3



18	15-AB0-033	Methotrexate vial 1g base i.v infusion 100mg/ml على ان لايتجاوز التركيز	11470	1 vial(10ml)	28.57	20	12.85	7.14
19	15-AB0-034	Pemetrexed (as disodium) 500mg vial powder for concentrate for solution for infusion or concentrate for solution for infusion ( IV use after dilution) تستورد بكميات قليلة (حصة مريض) ويصرف بموافقة لجنة استشارية حصراً (On need) فقط .. للتوضيحية مريض mesothelioma ولمرضى بمعنى كميات محدودة تودع لدى مخازن الشركة ولا تصرف الا عند الحاجة ومن قبل لجنة استشارية حصراً ولمرضى دواعي الاستخدام في Mesothelioma -سرطان الرئة هي الاتي :-Non Squamous, Non Small Cell Lung Cancer(NSCLC)which include the following subtypes: Adenocarcinoma Large cell NSCLC NOS(nonspecific subtype) It is indicated as neoadjuvant, adjuvant, and maintenance in locally advanced and metastatic non squamous NSCLC as a treatment option in first, second and third line treatment in patients with performance status 0-2	10828	1 vial	300	210	135	75
20	15-AC0-002	Bleomycin as sulphate 15000 units per vial dry powder for reconstitution	16619	1 vial	45.7	32	20.57	11.42

21	15-AC0-003	Dactinomycin 500mcg (Actinomycin D) I.V Injection	5875	1 vial	25	20	15	10
22	15-AC0-004	Daunorubicin 20mg I.V. Injection (as HCL) solution for injection or powder for reconstitution vial	10205	1 vial	59	41.3	26.5	14.7
23	15-AC0-008	Doxorubicin Hcl 50 mg I.V. inj , powder for reconstitution vial OR Doxorubicin Hcl 2mg/ml, 25 ml vial	72878	1 vial	14	9.8	6.3	3.5
24	15-AC0-014	Mitoxantrone as Hcl , concentrate for I.V. infusion, 2mg/ml, 10 ml vial	1074	1 vial(10 ml)	36.52	25.57	16.43	9.13
25	15-AC0-018	Doxorubicin Hcl (pegylated liposomal )conc.for i.v infusion 2mg/ml(10ml vial )i.e inj pegylated Doxorubicin Hcl 2mg /ml incapsulated in liposomes	9745	10 ml(vial)	388.39	271.87	174.78	97.1

26	15-AC0-019	Epirubicin Hcl 2mg/ml, 25 ml vial OR Epirubicin Hcl 50 mg (powder for reconstitution ) vial.	10200	1 vial	25	17.5	11.25	6.25
27	15-AD0-004	Etoposide concentrate for I.V. infusion 20mg/ml, 5 ml vial OR Ampoul	41294	1 vial(5 ml)	10.57	7.4	4.75	2.64
28	15-AD0-006	Vinblastine sulphate 1 mg/ml, 10 ml vial or ampoul.	9764	1 vial	22	15.4	9.9	5.5
29	15-AD0-007	Vincristine sulphate Injection 1mg/ml , 1 ml inj. for I.V. administration only not for intrathecal administration. يستعمل عن طريق الوريد فقط وليس بأي طريقة اخرى.	40623	5 vial	26	18.2	11.7	6.5
30	15-AD0-011	Vinorelbine as tartrate , concentrate for I.V. infusion 10 mg/ml, 5 ml vial.	8842	1 vial(5ml)	55	39	24.75	13.75

31	15-AD0-015	Vinorelbine as tartrate 30 mg capsule	67107	1 cap	85	59.5	38.25	21.2
32	15-AE0-003	Recombinant asparaginase (E-coli type ) 10.000 unit vial powder for concentrate for solution for infusion	7770	1 vial		235		
33	15-AF0-003	Cisplatin inj 50mg/vial I.V. infusion Cisplatin فيما يخص لا يوجد مستحضر خاص يعطى عن طريق التسريب الوريدي .. ونفس يستخدم لكلا الطريقتين أي بمعنى أن (sol. or powder)المستحضر المستحضر المثبت عليه طريقة الاعطاء بالزرع الوريدي يمكن استعماله عن طريق التسريب الوريدي	39225	1 vial	11.93	8.5	5.35	2.975
34	15-AF0-005	Oxaliplatin 100mg/vial powder for reconstitution I.V. Infusion OR concentrate for I.V. infusion 5mg/ml , 20 ml vial.	36168	1 vial	40	28	18	10
35	15-AF0-008	Carboplatin 10mg/ml (45ml) Vial i-e 450mg/45ml	38660	1vial	28	19.6	12.6	7

36	15-AF0-010	Hydroxyurea 500mg Capsule ايضا يستخدم كعلاج في sickle cell anemia) فقر الدم المنجلي (مرض الوراثة وخاصة مرض فقر الدم المنجلي)	930520	100 cap	28	20	12.8	7.1
37	15-AF0-011	Octreotide 0.05mg/ml Injection	35554	5 amp	20	14.45	9.29	5.1
38	15-AF0-018	Methyl prednisolon (as sod. Succinate) 250 mg IM,slow IV,IV infusion inj	57855	1 vial	10	7	4.5	2.5
39	15-AF0-030	Octreotide as acetate 20mg microspheres powder for suspension supplied with 2ml or 2.5ml diluent vial filled syringe. يخصص لداء العنقصة حصرا : ج 1069 (af0-069-قاعدة اقل الاسعار مع المادة بالرمز الوطني (15)	7442	1 vial	934.7	654.29	420.7	233.75
40	15-AF0-031	Tretinoin 10mg capsule (ALL-trans retnoic acid)	132740	100 cap	310	217	139.5	77.5

41	15-AF0-038	Capecitabine 500mg tablet	2816290	120 tab	51	36	23.1	12.85
42	15-AF0-044	<p>Bevacizumab 400 mg ;concentrate for intravenous infusion 25mg/ml, 16 ml viaOr its approved biosimilar</p> <p>لسرطان الثدي يقاف استعماله ان دواعي الاستخدام هي كالآتي في الحالات التالية</p> <ul style="list-style-type: none"> <li>• سرطان القولون المنتشر</li> </ul> <p>Metastatic colorectal carcinoma</p> <ul style="list-style-type: none"> <li>• سرطان الكلية المنتشر</li> </ul> <p>Bevacizumab in combination with IFN- alpha a treatment option for first line</p> <p>Treatment of patients with metastatic renal cell carcinoma, clear cell histology</p> <p>With good or moderate prognostic features</p> <p>Poor prognostic features include three or more of the following:</p> <p>LDH&gt;1.5 times upper limit of normal</p> <p>Corrected serum calcium level&gt; 10mg/ dl</p> <p>Interval of less than a year from original diagnosis to the start of systemic therapy</p> <p>Karnofsky performance score&lt;=70</p> <p>Two or more sites of organ metastasis</p> <p>sunitinib يعاد النظر بهذا الاستخدام بعد توفر علاج ال</p> <ul style="list-style-type: none"> <li>• سرطان المبيض المنتشر</li> </ul> <p>Second line treatment for recurrent or metastatic epithelial ovarian tumor</p> <p>And in combination with chemotherapy • فيما يخص اورام ( Glioblastoma multiforme ) الدماغ يعطى العقار فقط لنوع ج/ 1025/</p>	37666	1 vial	302	211.4	135.9	75.5

		ج\1071 لأمراض شبكية ( Bevacizumab 400 mg ) يرفع استخدام مادة العيون ج\1088						
43	15-AF0-051	Bortezomib( as mannitol boronic ester ).3.5 mg solution or powder for solution for i.v, s.c vial يستعمل للحالات المعقدة للعلاج التقليدي وغير المناسبة لغرس نخاع العظم ( multiple myeloma ) في ورم ليفي العظم المتعدد الخلايا يحدد صرف العقار للمرضى المصابين بأبيضاض الدم النقوي المتعدد	12883	1vial	185	129	83	47
44	15-AF0-059	(microsphere powder for aqueous suspension) Octreotide 30mg (as acetate) vial (in form of microspheres) supplied with 2.5ml or 2ml diluent filled syringe n form of microspheres) لداء العملاقة ( acromegaly ) , , ( احتياج منفصل ) , , استخدامه لاحتياج مرضى الاورام ( احتياج منفصل ) , , metastatic pancreatic Neuro- endocrine لداء العملاقة ( acromegaly ) , استخدامه لاحتياج مرضى ( acromegaly ) , ( ويصرف للمرضى المصابين الجلطة ( 967 ) , ( الاورام ) احتياج منفصل ج\1031 (af0-070-ج (1069) قاعدة اقل الاسعار مع المادة بالرمز الوطني(15)	4572	1vial	1264	884.9	568.8	316
45	15-AF0-061	Arsenic trioxide(Concentrate for intravenous infusion) 1mg/ml 10 ml amp to be use in :- يحصر استخدامة في . a/ مراكز امراض الدم وحسب الاستطابات المقررة في الجلطة 1018 relapsed acute promyelocytic leukemia b/ first line in acute promyelocytic leukemia in low risk group only (platelet less than 40,000 , WBC less than 10,000 )	10010	1 amp	355.5	249	160	88.8

46	15-AF0-069	anreotide acetate 90 mg sol. for Inj (PFS) Autogel قاعدة اف0-030) 15) اف0-030) مع المادة بالرمز الوطني (15	6906	1 pfs	925	648	417	231
47	15-AF0-070	lanreotide acetate 120 mg sol. for Inj (PFS) Autogel ج1069) 15) اف0-059) مع المادة بالرمز الوطني (15	4572	1 pfs	1180	826	531	295
48	15-AG0-008	Letrozole 2.5mg Tablet اف0-14) وعلى قاعدة اف0-14). 14).	2337800	30 tab	26.42	18.5	11.89	6.6
49	15-AG0-013	Tamoxifen as citrate 20mg Tablet	2651922	30 tab	5	3.5	2.25	1.25
50	15-AG0-014	Anastrozole tablet 1mg To be dispence by medical committee for these indications thromboembolic تختري في حالة وجود تاريخ مرضي - (Drug intolerability) /Tamoxifen في حالة عدم تحمل المريض لعلاج - Not to be used as an Alternative in case that	2337800	30 tab	6.14	4.3	2.76	1.53



		Tamoxifen tab are not available لايستعمل كبديل في حالة عدم توفر حبوب Tamoxifen (AG-08 -15) الاسعار مع وعلى قاعدة اقل						
51	15-AG0-015	Bicalutamide 50mg tablet Not use in cases of Localize prostatic disease لحالات سرطان البروستات المتقدم	170644	28 tab	60	42	27	15
52	15-B00-003	Anti-Thymocytic-Globulin 100mg/5ml (ATG) Vial (Rabbit type)(limited for kidney) م.تخصصي زرع الكلى	3611	1 vial	550	385	248	138
53	15-B00-004	Basiliximab 20mg /Vial ج/ 986 المستشفيات التي تجري فيها عمليات زرع الكلى	609	1 vial	1050	735	473	263
54	15-B00-008	Cyclosporine (Microemulsion)100mg/ml oral Solution ومنها الامراض ( Autoimmune disease ) لا مانع استخدامها لـ (الجلدية 989)	156554	1 vial	110	77	50	27

55	15-B00-012	Interferon alfa-2a (Recombinant) 9 million units prefilled syring (HSA free solution) Injection مشتركة بين الجهاز في الجلسة 973 تم تحويله من المستوى الثالث (حسب احتياجه 973) امراض الدم والاورام كلا , الهضمي	3787	pfs(90µg/0.5ml)	60	42	27	15
56	15-B00-029	Imatinib as mesylate (Protein – Tyrosine kinase inhibitor) 100mg Capsule OR TAB الشركة المجهزة ملزمة بتوفير الفحوصات التالية . لكل مريض "سنويا ( 3 مرات ) ( PCR BCR - ABL210 ) . "مرة واحدة للمرضى المشخصين حديثا ( FISH BCR - AB ) .	811460	120 tab	213.3	149.3	96	53.25
57	15-B00-050	Imatinib as mesylate (Protein - Tyrosine kinase inhibitor) 400mg Tablet or capsule يحصر في مدينة الطب+المركز الوطني لامراض الدم ) بابل+البصرة+نينوى+النجف+كركوك + كربلاء + + ج ( 1012 ) (الكرخ+واسط+الانبار+اربييل +سليمانية الشركة المجهزة ملزمة بتوفير الفحوصات	788670	30 tab	128	90	57.85	32
58	15-B00-053	Mycophenolic acid as sod.Salt i.e Mycophenolic acid as mycophenolate sod.360mg gastro-resistant Tablet يحصر صرفه لمرضى زرع الكلى ج / 949	8468981	120 tab	157	110	70	39
59	15-B00-058	Erlotinib as Hcl 150mg Tablet ج 987 ج/1045 (Gefitinib 250 mg tab) قاعدة اقل الاسعار مع 15-b00-099 ج\1089 وتلتزم الشركة المجهزة بتوفير الفحوصات الاتية مجانا اعتمادا على اعداد المرضى	78695	30 tab	2120.3	1484.2	954.13	530

		الفحوصات: EGFR exon19 deletions or exon21(L858R) substitutionErl						
60	15-B00-073	Anti-Thymocytic-Globulin (ATG,Rabbit type) for I.V. infusion powder for reconstitution; 25 mg vial OR ampoule يحدد احتياجه من قبل مراكز زرع الكلى ومراكز زرع نخاع يجب ان تعامل في الاستيراد معاملة الادوية الكيميائية مادة ATG	5610	25 mg vial powder	206.4	144.4	92.8	51.6
61	15-B00-088	Antithymocyte globulin equine 250 mg in 5 ml ampoule يستخدم لعلاج فشل نخاع العظم المكتسب على ان تراجع اللجنة الاستشارية ( Acquired aplastic anemia ) لامراض الدم الكمية المطلوبة من الدوائر بالتنسيق مع قسم تقدير الحاجة لتحديد اعداد المرضى الفعلي وفق قاعدة البيانات الرسمية المتوفرة لدى الدوائر اعلاه وحسب ما جاء بتوصيات اللجنة الاستشارية لامراض الدم السريية ج 987	4520	5 amp (5ml)	1706	1194.2	767.7	426.5
62	15-B00-099	Gefetinib 250 mg tab 1045/ج Erlotinib as Hcl 150mg (b-85-قاعدة اقل الاسعار مع ) 15 ج\1089 وتلتزم الشركة المجهزة بتوفير الفحوصات الاتية مجانا اعتمادا على اعداد المرضى الفحوصات: EGFR exon19 deletions or exon21(L858R) substitution	77595	30 tab	666.6	466.6	300	166.6

63	15-B00-111	<p>bosutinib 100 mg film coated tab  وتستخدم لعلاج مرضى ابيضاض الدم النقلياني بعد فشل عقار Imatinib وللمرضى الذين لايتحملون عقار اوحودوث مضاعفات جانبية مع الزام الشركة المجهزة بتوفير فحوصات PCR+FISH  bosutinib 400 mg film coated tab  يجهز بصورة مجانية  من احتياج مادة 5% وبنسبة  bosutinib 100 mg مادة اخرى من احتياج مادة 5% وبنسبة  bosutinib 500 mg  لمرضى CML ولنفس الاستطباباتال</p>	245000	28 tab	581.95	407.36	261.87	145.48
64	15-B00-112	<p>bosutinib 500 mg film coated tab  وتستخدم لعلاج مرضى ابيضاض الدم النقلياني بعد فشل عقار Imatinib اوحدوث مضاعفات مع الزام الشركة Nilotinib وللمرضى الذين لايتحملون عقار جانبية مع الزام الشركة Nilotinib PCR+FISH  المجهزة بتوفير فحوصات  bosutinib 400 mg film coated tab  يجهز بصورة مجانية  من احتياج مادة 5% وبنسبة  bosutinib 100 mg مادة اخرى من احتياج مادة 5% وبنسبة  bosutinib 500 mg  لمرضى CML ولنفس الاستطباباتال</p>	129775	28 tab	2948.78	2063.6	1326.6	737
65	15-B00-113	<p>palbociclib, 125mg tab  ج\1087  Abemaciclib 150mg قاعدة اقل الاسعار مع وتعطى للاستطبابات الاتية  Initial endocrine based therapy in postmenopausal patient with HR+ve , HER2-ve metastatic breast cancer  على ان تقوم الشركة المجهزة للعلاج بتوفير الفحوصات الاتية</p>	195247	21 cap	1500	1050	675	375
66	15-B00-114	<p>Abemaciclib 150mg, film coated tablet  ج\1087  palbociclib, 125mg tab قاعدة اقل الاسعار مع وتعطى للاستطبابات الاتية  Initial endocrine based therapy in postmenopausal patient with HR+ve , HER2-ve metastatic breast cancer  على ان تقوم الشركة المجهزة للعلاج ب</p>	519093	14 tab	808.15	565.7	363.66	202.03

67	15-C00-003	Filgrastim 300mcg(30MU) /1ml S.C/I.V infusion inj (solution) Vial or Filgrastim 300mcg(30MU) /0.5 ml pfs or it's approved biosimilar approved biosimilar 15) او (reference) (C00-003-بالنسبة للرمز الوطني (biosimilar) 15) وحسب التنافس سعري مع الرمز يختار النادتين اما (C00-009) وحسب قاعدة اقل الاسعار ج/1032	139902	5 pfs	70	49	31.5	17.5
68	15-C00-009	Lenograstim powder for reconstitution , 33.6 million IU ( 263 µg) vial (with 1 ml prefilled syringe water for injections) تخضع لقاعدة اقل الاسعار مع code 15-C00-003	134652	5 vial	400	280	180	100
69	15-D00-002	Docetaxel (Anhydrous or as Trihydrate )10mg/1ml ,8ml vial OR 20mg/1ml ,4ml vial OR 80mg/2ml Vial (all with diluent) يتم الخلط حسب النشرة الداخلية للمستحضر في المحاليل الوريدية وعدم خلطها بالاشكال الاخرى	43335	1 vial	23	16	10.35	5.75
70	15-D00-004	Paclitaxel 6mg/ml 50ml vial	36205	1 vial	44	31	19.8	11
71	15-D00-005	Docetaxel 10mg/1ml, 2ml vial or pfs OR Docetaxel 20mg/ml, 1 ml vial or pfs ( يتم الخلط حسب النشرة الداخلية ) للمستحضر في المحاليل الوريدية وعدم خلطها بالاشكال الاخرى) ج987 اضافة شكل صيدلاني	36730	1 vial(2ml)	15	10.5	6.75	3.75

72	15-E00-002	Irinotecan Hcl or Hcl Trihydrate 20mg/ml ( 5ml I.V. Infusion Vial )	24123	1 vial	22.8	16	10.2	5.7
73	15-B00-001	Azathioprine 50mg Tablet ومنها الامراض ( Autoimmune disease ) لا مانع استخدامها لـ (الجلدية 989)	1078092	100 tab	12	8.4	5.46	3
74	15-B00-071	Thalidomide 50 mg cap or tab تستعمل المادة وفق الضوابط المتعارف عليها وبصورة مشددة للرجل والمرأه في سن الانجاب منعا لحدوث تشوهات خلقية اذا حدث الحمل وتستعمل موانع الحمل بصورة فعالة (ج 1012) واكيدة للجنسين	23100	28 cap	410	290	184.5	102
75	15-B00-023	Mycophenolate mofetil 500mg Tablet ج 982 / ج 992 ج / 1033 / اعتماد البروتوكول العلاجي المرفق بالجلسة والمسند "لتوصيات اللجان الاستشارية المختصة انفا .	6476722	50 tab	22	15.5	9.9	5.5
76	15-B00-024	Tacrolimus 1mg Capsule يحدد صرفها ضمن مراكز زرع الكلى	3127600	100 cap	114.28	80	51.4	28.57

## Contents

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### Part 1- Contract Procedures

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It contains the following sections

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#### **Section I: 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.

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#### **Section II: Bid Data Sheet**

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

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#### **Section III: 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

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#### **Section IV: Bidding documents**

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

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#### **Section V: Eligible Countries**

This section includes information about the eligible countries.

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### Part 2 - Contracting Requirements

This Part contains the following:

**Section VI: Schedule of Requirements**

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 3: Conditions of Contract and Contract Forms**

**It contains the following sections:**

**Section VII. 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 VIII. Special Conditions of Contract (SCC)**



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

### **Section IX: 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 1: Contracting Procedures**

### **Section I - Instructions to Bidders**

## Articles/Clauses schedule

<b>A. General</b>	<b>7</b>
1 Scope of tender	7
2 Corruption and fraud	7
<b>B. Tender documents</b>	<b>9</b>
3 Content of Tender Documents	9
4 Clarification of Tender Documents	9
5 Amendment of Tender Documents	10
<b>C. Preparation of Bids</b>	<b>11</b>
6 Eligibility	11
7 Eligibility proving documents (Drugs. And Vaccines) & services and their compliance with the tender documents	12
8 Qualifications of the Bidder	14
9 One Bid per Bidder	15
10 Cost of Bid	15
11 Language of Bid	15
12 Documents Constituting the Bid	15
13 Bid Submission Form	16
14 Bid Prices and Discounts	16
15 Bid Currencies	18

16	Bid validity period	18
17	Bid Guarantee	19
18	Bid form and signature	21
	<b>D. Submission of Bids</b>	<b>22</b>
19	Sealing and marking of Bids	22
20	Deadline for Submission of Bids	22
21	Late Bids	23
22	Amendment and Withdrawal of Bids	23
	<b>E. Opening and Evaluation of Bids</b>	<b>25</b>
23	Opening of Bids	25
24	Clarification of Bids	27
25	Procedures Confidentiality	27
26	Initial auditing of bids and determining its response to the tender documents	28
27	Correction of Errors	29
28	Conversion to Single Currency	29
29	Evaluation and Comparison of Bids	29
30	Margin of Preference	30
31	Contracting Entity's Right to accept or reject all or any of the Bids	30
32	Eligibility and Qualification of bidder	30
	<b>F. Award of Contract</b>	<b>32</b>

33	Award Criteria	32
34	Contracting Entity's Right to amend Quantities at Time of Award	32
35	Notification of Award	32
36	Complaints and Appeals	33
37	Signing of Contract	33
38	Good Performance Guarantee	34

1. Scope of Bid

2. Corruption and fraud

(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  
(2.5) 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**

3-1 the tender documents are the documents mentioned below and shall be read with any schedules issued according to article 5 of the instructions delivered to the bidders

Section I. Instructions to Bidders (ITB)

Section II. **Bid Data Sheet** (BDS)

Section III. Evaluation and Qualification Criteria

Section IV. Bidding documents

Section V Eligible Countries

Section VI. Requirements list for Contract

Section VII General Conditions of Contract (GCC)

Section VIII. Special Conditions of Contract (SCC)

Section IX Contract Forms

3.2 The "Invitation for Bids"/Advertising 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 advertisement, 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 extension 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 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 of origin to be issued at the time of shipment of such items. The competent Iraqi authorities in the country of origin shall certify these certificates 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 VI Schedule of Requirements** may be in the form of literature, drawings, and data and shall consist of:

(a) a detailed description of the essential 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 submitted 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 III 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 IV;

(c) in the case of a Bidder who is not doing business within Iraq the Bidder is or will be (if awarded the Contract) represented by a local service/maintenance provider in Iraq equipped and able to carry out the Bidder's warranty obligations prescribed in the Conditions of Contract and/or Technical Specifications; and

(d) the Bidder meets the qualification criteria listed in the specified in **Section III Evaluation and Qualification Criteria**(see additional clauses of Section III for drugs and vaccines

The necessity for companies to submit a no-objection letter issued by the General Tax Authority when they participate in the announced overtures

**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 thereto 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 IV;
- (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 IV

(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 – IV 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 IV 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 or that of foreign origin located in Iraq shall be quoted in the Price Schedule given under Section IV (2). The quoted prices for (drugs and vaccines) to be imported from abroad, shall be quoted in the Price Schedule given under Section IV (3).

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

14.3.1 For 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 IV (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 IV (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.

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

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

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

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 VI 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 separately 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 thereto 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 demand in any of the following modes or in the form of:

(a) letter of credit

(b) certified check

(c) **All letters of guarantee are not accepted until after they are accepted by the Central Bank Of Iraq & entered on the Platform & the support of Central Bank Of Iraq for us to do .**

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 tender/LOI 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 entity in the **Bid Data Sheet** or Guarantees issued by the Republic of Iraq. In the case of Bank Guarantee submitted 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:

(i) sign the contract, or

(ii) 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-Clause 16.2, or

b) If this bidder becomes the winning bidder but fails to sign the contract in accordance with Article 37 of the Instructions to Bidders; Or in submitting a performance guarantee in accordance with Article 38 of the Instructions to the bidders; Then, the contracting entity - if the tender data sheet stipulates that - 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 the duly authorized person to bind the Bidder to the Contract. The authorization shall be indicated as specified in the **Bid Data Sheet** by those legally authorized to sign, 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. **given in the Bid Data Sheet**

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  
Submission of Bids**

for 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 19.1 of 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 not accepted 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, 23.4, 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 signatures 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 signed 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.

23.8 The 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 submitted, 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 value 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..

29.3 In order to compare and evaluate bids and determine the ranking of candidates, the following will be calculated:

- The prices of domestic (drugs and vaccines) or those of foreign origin located within Iraq, as brought out in ITB Sub-Clause 14.3. and stipulated in Price Schedule in format in **Section IV(2)**,

• The price of the annual maintenance contract (Annual Maintenance Contract-AMC) as stated in the price table attached in the second section of the bid data sheet,

and if the list of contract requirements and paragraph 3-14 of the instructions to bidders stipulate the necessity of providing maintenance for the years following a

period within the defects

- 
- 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 IV (3)**

29.4 If more than one schedule (or lot) has been specified in Section VI Schedule of Requirements, the Bidders are required to quote as stipulated in ITB Sub-Clause 14.7. Bids shall be evaluated for each schedules (or lots) separately.

29.5 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 ITB Clause 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 IX** 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 .

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 (**Within the period specified for signing the contract**) 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 Bidder whose offer is substantially responsive and is determined by the Contracting Entity to be qualified to perform the Contract satisfactorily. In that case the declined Bidder will be responsible for paying the difference in the bids prices in addition to forfeiture of the Bid Guarantee. These actions will be taken against the declined bidders provided they decline during their Bid validity.



## Section II

### Bid Data Sheet (BDS)

The following specific data 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.

#### A. General

ITB 1.1

Name of Contracting Entity: [Ministry of Health / Environment / The State Company for Marketing Drug and Medical Appliances].

Name of authorized Purchasing Agent: **authorized by contracting entity** : “none”

Type of goods: Medicine as mentioned in tender lists

Tender: Purchasing medicine

Tender Number: **Med/3 /2022** as listed in the Iraqi Federal Budget]

IFB Number

The number and identification of schedules (lots) comprising this IFB is detailed in Schedule of Requirements are: [Schedule (1)-(4) ] the year of the Federal Budget that certified by the competent authorities is from the funding of the contracts which will be 1/12 of the actual expense of KIMADIA contracts in **2022** to purchase the medicines for The Ministry of Health/ Environment / The State Company for Marketing Drug and Medical Appliances (Kimadia)

The source of funding for the contract(s) is: [Ministry of Finance ]

#### B. The Tender documents

ITB 4.1

**Contracting Entity’s Ministry of Health / The State Company For Marketing Drug and Medical Appliances (kimadia )/Drug Information & the Public Relations Department - 5<sup>th</sup> floor ,position of MOH(Ministry of Health),E-mail (dg@kimadia.iq ) phone no.(07705419074) Requests for Clarification are to be hand delivered or sent by mail or by express courier and accepted by E-mail**

**Adoption the bidder address which install in the tender & address for correspondence & communications, the bidder**

should notice the contracting party with any change to this address within seven days of receiving.

-additional to ITB :

- Specifying the date of conference specialized to answer all the participants in the bid inquiries will be on ( 27 / 2 /2022).

## C. Preparation of Bids

ITB 6.3

List of disqualified bidders is available on the following website address: [HTTP://WWW.mop.gov.iq](http://www.mop.gov.iq)

In addition to what is stated in the instructions to bidders, the following are added:

-Dilatory or violating the previous contractual obligations according to legal documents with the same contracting party or in other contracting parties.

- companies are blacklisted in the following cases:

A- when dealing with foreign blacklisted companies.

B-When it is proved that one of the government staff takes bribery.

C-When it is proved that there is a forgery in the offer or any tender documents.

D-When it is proved that they submit incorrect information or matters concerning the work assigned to them for the purpose of harming the public interest.

E-When there is a violation in the conditions of the tender or technical specifications contracted on, for the purpose of harming the public interest

F-When it is proved that there is a non-compliance with the profession principles by using unfair methods of competition.

G- When refrains signing after being informed about the decision of awarding

H-The withdrawal of work due to the delay in the execution of the tender or the breach of its contractual obligations.

ITB 7.2

The authentication of the certificate should be according to the instructions of implementing the

**governmental contracts No. (2) in 2014 concerning the items imported from the Arab country.**

ITB 7.3 (c)

Documentation requirements for eligibility of (drugs and vaccines).

For drugs

**Documentation requirements for eligibility of Goods. In addition to the documents stated in Sub-Clauses 7.2 and 7.3 (a) and (b), the following documents should be included with the Bid:**

**1- The certificate of origin ,of the imported materials in favor of the contracting party issued by the country of manufacture or product or country in which the final assembly takes place or country of shipment (country of export), should be submitted with reference to the origin of imported materials which must be accurate in terms of technical specifications for materials or equipment to be exported to Iraq on condition that there is a duly authenticated undertaking from the company of shipment which provide the imported materials bearing all the financial and legal responsibilities concerning the validity of the information mentioned in the original certificates of origin sent by the manufacturers or producers to the supplier in the last shipping country**

**2-To submit certificates of (U.S. FDA, GMP.,EMA,JAP.,MHLW , Canadian  
AUS - TAG , UK.MHRA , SWISS -MEDIC U.s )**

**3- To submit a certificate of company establishment for the manufacturer and supplier companies provided that the certificate should be original , authenticated and new .**

**4-Presenting the original and authenticated final balance sheet of the Manufacturer Company for the last five years which shows that there is a profit achieved during the last five years & stating the average rates provided . The final balance should be presented in English and Arabic languages only. In addition, the indicator of the final balance of the last five years should be positive.**

**5-The companies that participated in the tender shall submit their prices that are stated in their contracts with other countries and neighboring countries of Iraq provided that such prices should be attached to the tender supported by a confirmation ,stamp and signature of the bidder .**

**The following should be submitted for products manufactured from blood origin-:**

**1A- Certificates for plasma pool data and safety certificates during the manufacturing process.**

**B- Methods used to get rid of the viruses of HBV, HCV, HIV and others the manufacturing process.**

**C-Method of analysis and the safety certificate of the final product that the final product is free from viruses.**

**2-To submit documents stating that the gelatin which is used in manufacturing capsules is from botanic or animal (halal) origin to Islamic law**

**3- Companies supplying cancer drugs are obliged to re-issue the expired quantities of these medicines and not asking our companies consume them**

**4- The companies that supply the chemotherapeutic products should available all the diagnosis requirements and clinical follow up in accordance with the Iraqi guidance of CMI treatment.**

**-Special condition for medical milk:**

**1-Adopting the weight of 400grn as a unit of measurement. The maximum limit is 1000gm for Kimadia when contracting,**

**2- The milk should be mentioned in (BNF) OR (Martin)-last edition as the specifications can be varied according to the updates that may appear in the future.**

**3-The Milk should to be identical to recently updated British specifications.**

**4-The milk should be packed in the country of origin to avoid contamination during packaging.**

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

**Registration of goods is required in Iraq .**

**{Note: Bid security or performance security will not be confiscated if the bidder fails to register the goods .**

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 PerformanceGuarentee 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 requirementsor 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. }**

-In addition to what has been mentioned , the following shall be considered:

- 1- **1-The referral is for registered durgs exclusively**
- 2- **Kimadia is not obligated to accept the unregistered offers**
- 3- **In the event that offers that are not registered in the tender and there is no registered offer, all non registered offers are referred to the drug policy committee to take the appropriate decision.**

In the event, that the article of not registered &referred to it based on the decision of the medicines policy committee, the provider must:

1- The company should register its products before paying their shipped goods dues.

2- When the award is made for unregistered material ,the specifications, analysis method and standard material should be submitted upon the confirmation of the award at a maximum one- month period.

3- In case the item is not registered, no payment will be made for this contract unless the company proves submitting the documents of the material for the registration department or re- registered it.

ITB 7.4.1

**For the purpose of obtaining additional information about the requirements for registration, Bidders may contact { Ministry of Health/ Environment/Department of technical things /Registration section [Eighth floor].**

ITB 11.1

The language of the bid is: [Insert "Arabic" or "English"].

**Arabic and English, and there is a difference in the interpretation, the Arabic language shall be adopted as it is the official language of the State**

ITB 12.1

**In addition to the documents stated in Paragraphs 12.1 (a) through (f), the following documents must be included with the Bid.**

**1- The bidder who previously participated in the tender, should submit the prior purchase receipt together with the re-announced tender documents . In case there is an amendment in the prices of the tender documents, the bidder will bear the difference in the price when there is an increasing in the price and should attach the first and the second receipt with his tender.**

**2- When contracting ,the beneficiary from the documentary credit should be the same contracted party and the banking details should bear the name of that company . It should exclusively contain (name and address of the bank , name of owner of account (the company contracted with) (swift code and sort code and Iban.... . etc). The account should not bear a person name. Any change in the beneficiary name and address, , bank name and address, account no. and any other bank information after the agreement is considered a violence after informing the supplier about the information stated in the tender, a fine will be imposed on the supplier.**

**3-Submitting a the factory license renewal regarding the national factories.**

**4- Factories and their materials must be registered in the registration section of the Iraqi Ministry of Health , as the ministry will not market any unregistered product.**

**5-The displayed Items or materials should bear its commercial or brand name. In case items are displayed in scientific names, the pharmacopoeia should be stated**

**6- Companies are obligated to submit their final accounts for the last two years, if they exist (that is, the company does not have final accounts because it is a newly established)**

**7- The need for companies to submit a no-objection letter issued by the General Tax Authority when they participate in the announced overtures, and in the event that this is not possible, an amount that covers the tax will be withheld and will not be released until after receiving a clearance letter issued by the General Tax Authority**

**Sample clause:**

(h2) The bidder who is not a manufacturer (a manufacturer) / a major producer of the required drugs or vaccines, shall 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 shall submit a certificate from the competent regulatory authority (RA) proving that the manufacturer has the license to manufacture (drugsand Vaccines)

14.3 Equation of the maintenance contract as a separate contract, warranty and maintenance in the processing of goods.

A- Percentage of equipment and devices working properly and correctly at a rate of x% for the duration of the contract period

B. The percentage in case the fault period is exceeded, it will be x-100%. If a fault period is exceeded by x-100%, then the period of this contract must be extended twice the duration of the faults and pauses as compensation when the equipment stops for this period, provided that the extension period does not exceed the maintenance period fixed in the contract

14.4 INCOTERMS® current edition shall be adopted (state the issuance year of the INCOTERMS® current edition)

**14.6 -In addition to what mentioned in instructions devoted to the bidders, the following will be done:**

**-Neglecting the offer which is based on reduction a percentage or taking out a certain sum from any of the other presented offers in the tender. Any reservation and reduction of the price presented after the closing date of tender will be not accepted. We confirm the condition of not making any change after the notification of awarding. All letters regarding decreasing the offered items prices after the closing date of the tender without a request from KIMADIA will be neglected.**

ITB 15.1

**A)Foreign currencies: In US dollar or by ink or by printed Form in numbers and written forms and should be clear without erasing or scratching**

ITB 16.1

The bid validity period shall be (365) days after the deadline for bid submission, as specified below in reference to ITB Clause 20. Accordingly, each bid shall expire after 8/ 2 / 2023

Bid Guarantee shall be valid ( 28 ) days after the end of the bid validity period. Accordingly, a bid with a Bid Guarantee that expires before 8/ 3 / 2023 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 estimated cost of the tender] 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.

In addition to what mentioned in 17.1 be (c) or saftaja.

It is possible to submit the initial deposits in the form of a receipt paid directly to the treasury of the contracting party (Kimadia) deposit slip according to the amount of the insurance.

Taking into account the following:

1- Bidder should submit Preliminary Insurance (Bid Bond) or any of the share holders of the company or share according to share contract for the benefit of contracting party which should refer to the tender name and number.

2-The Guarantee Bond should be issued according to the order of the company with

Which we contracted with or with its legal authorized figure who gained the authority to issue the guarantee in accordance with formal authenticated authorization.

3-The guarantee Bond should be attached with a letter of authenticity of issuance.

(Private & confidential) send to kimadia by the bank who issued the guarantee.

-The guarantee should be issued in the Arabic and English languages.

4-In addition to what has been mentioned in 17.7 , the following should be taken into account

(or refuse to correct his statistical errors in the tender which have an effect on the decision of awarding , All the legal actions written in the instructions of the governmental contract implementation will be applied against him :

17.4

Concerning the approved companies & according to the approved companies conditions.

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.

In addition to what have been mentioned in the instructions to bidders, the following should be added:-

If the participants in the tender reject making the contract after notification by awarding, the following procedures will be taken against bidder

-Executing the contract on his expense without a need to warn him or take any other legal procedure

-In case of breach the two nominees( the first &second) the contracting party has the right to award the tender to a third bidder & each of the two breach will bear the difference of price according to the difference amounts for their nomination confiscating preliminary securities of the two.

-In case of the third nominee breaches the tender, his preliminary securities will be confiscated & re-announcing the bid while the three breach bidders will bear the difference of price according to the submitted price of each one of them confiscating the securities of the three breach bidders.

-The above procedures should be applied upon the three bidders when breached during the period of tender validity.

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).

The Offers should be submitted directly by the manufacturing company through the following

-Director General or his representative.

-Assistant of Director General or his representative

-Sales manager (marketing)

-Commercial manager.

-Authorized scientific bureau which has a legal authorization.

-We can accept the authorization of any representative of the company staff whose title is not stated above provided that his authorization should fulfill the legal form and the required authentications.

**-Special instructions concerning the authorization letters (A.L)**

**First**—The authorization letter should be authenticated officially by-

**A**-Chamber of commerce in the country of origin

**B**-Ministry of foreign affairs or notary public in the country of origin.

**C** -Iraqi embassy its representative in the country of origin.

**D**- Iraqi ministry of foreign affairs in Baghdad should fixed its stamp and signature to authenticate the stamp of the Iraqi embassy in the country of origin.

**E**-If the Iraqi embassy cannot stamp all the above mentioned documents either because there is no Iraqi embassy or there is no information about the identity of the persons who represented the company, the embassy of the country of origin in Iraq has to authenticate the official authorization letters in order to be legal and

Agreed upon.

**F**- If there is no (diplomatic representation)) between the country of origin the authentication should be made in a third country from the embassy of the country of origin and the Iraqi embassy in the third country then the ministry of foreign affairs has to authenticate the signature and the stamp of the Iraqi embassy

**Second**-The company should mention in the authorization letter whether it's a manufacturer or supplier (marketing company)

**A**- In case of being a supplier company, the followings should be clear -:

-names &specialties of the manufacturing companies

-It should have an authenticated authorization letter from the manufacturing companies as mentioned above item (first)

-your manufacturing company should mention that you are a sole and exclusive (supplier) for all its products in Iraq

**B**- In case of being a manufacturer company, your specialties (having special knowledge a particular system) should be mentioned and written down and you should mention that you are a sole &exclusive representative to deal with concerning all your products ,also the company should refer to the names of its factories and branches by submitting original authenticated certificates of establishment that proved the company factories & its branches.

**C** -the A.L should be authenticated as mentioned in item (First).

**D** —Catalogues with (CD) stating the company's products should be submitted by the manufacturing companies to **Drug Information & the Public Relations Department**. The manufacturing companies should write down their emails on the letters of authorization. Any authorization letter with no emails will be neglected.

**Third** —According to the instructions of scientific bureau no.4 of 1998.

(A) The company should specify the name of Iraqi scientific bureau & the name of pharmacist who is licensed from Iraqi syndicate of pharmacists for following up and completing the technical data upon request by the committee of study and analysis in case of submitting the tenders through the scientific bureau, or providing an authorization for signing the contract the list of the submitted tender and its documents as an agent. The scientific bureau should be the exclusive representative of all company products or dealing directly with the company through formal authorized figure as it is shown in item no. (6).

B- The scientific bureau will stay responsible till after the expiration of the authorization from foreign companies which authorized him unless the following Authorization has fixed the obligations of the previous foreign companies and its effects.

**Fourth**—The authorization letter must be entitled to kimadia, the state company for marketing drugs and medical appliances, General **Drug Information & the Public Relations Department** fifth floor —before the closing date.

**Fifth**- The name of scientific bureau should be added in the contract

**Sixth**-The authorization issued by the manufacturer to supplying company, (in case of necessity to make contract with supplying company), the capacities of the supplying company concerning the following should be clarified.

A-Signing the contract &executing all its obligations, provided that it should be signed by the manufacturer company exclusively

B-The negotiation about technical affairs and prices.

**C**- Specifying clearly and in details the beneficiary applicant from documents L/C& beneficiary from the bank account with the whole banking details noting that the one who signs the contract without company should be the beneficiary party itself.

**D**- Specifying the correspondences &the authorities concerning the tenders as for submitting, stamping, signing, opening &submitting the prices without being satisfied by issuing a general authorization which authorizes all these powers.

E-Confirming to go on executing all the contracting obligation. The marketing company will bear a legal responsibility for the period of execution the contract even when the period of authorization is expired.

Noting that all the procedures including registration the company ,its products . Full address and details of the manufacturing & supplying companies should be fulfilled. In addition, to accomplishing the stamps& legalizations as applicable now.

F-The contracted companies should submit the legal &required assurances according to the conditions of invitation within stipulated period in these

Instructions.

Seventh: Names of the authorized persons of signing & stamping the contracts & offers and their administrative description and samples of their signatures should be mentioned (written down)

7-Your offers should include a copy of all original authorization letters issued and legalized producing companies to the supplier ones in addition to the original authenticated copies as it is mentioned in item (4) from article (six) to be handed to (3RD bearing all above mentioned authentications).

## D. Submission of Bids

ITB 19.1 (a) Bidders are ["not entitled"] to submit their bids by e-mail.

(b) يجب ان تنضاف ملاحظة الانجليزي

ITB 19.2 (b) For bid submission purposes, the Contracting Entity's address is :

Attention: Baghdad – Bab Al-Moadham – Ministry of Health

Ministry of Health / Kimadia – sixth floor – receiving and opening tenders committee

City Baghdad

Country: IRAQ

ITB 19.2 (c) The Tender, Tender No. and IFB No are:

Tender 6/ 3 /2022

Tender No.: 3

Contracts of supplying medicine be arranged according to the current balance .

Reference letter invitation to tender :

In addition to what is mentioned in this article concerning the bids that are submitted through the fast mail, all authorization letters and documents (original and authenticated) should be included in a separated envelope in order to be checked and it should be reached to

Kimadia before the closing date, otherwise the offer will be neglected provided that the address of the company inside and outside Iraq and the additional attachments attached with the offer and the number of pages for each offer should be written on the envelope

{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: the date of closing the bid is the end of the official work on 7/3 /2022

If the closing day happens to be on an official holiday the new closing date shall be in the first working day following the holiday.

## E. Bid Opening and Evaluation

ITB 23.1

The bid opening shall take place at:

Street Address: Baghdad-Bab Al moadham -Ministry of Health

Floor/Room number: Ministry of Health /The state company for drug and medical appliances (Kimadia)-sixth floor -receiving and opening of tenders committee.

City: Baghdad

Country : Iraq

Date: [ 7- 3 -2022 ]

Time: [

{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..}

27

In addition to what are mentioned in the instruction to bidders:

- If an item or items are mentioned in the tender without their price , the cost of the item or items with all their specified quantities will be included within the total price of the tender

ITB 30.1

"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 10 %".]

-the second party undertakes to prioritize the raw materials manufactured inside Iraq for supplying the contract materials or for implementing the projects through the companies of the Ministry of Industry and Minerals according to the letter of Ministry of Planning no. 16135 dated 3/8/2017.

32 In addition to what is mentioned in this item of instructions for bidders, the following conditions should be taken into account .

Exclusion the bid which is less or greater than 20% or more of the estimated cost allocated for the awarding and in case there is an appropriate price of a bid that meets the required qualifications but there is a rate of diverse in the price analysis of some items (unbalanced) by more than 20% increase or decrease for each item separately and which constitute a total of not more than 10% of the total items , it is possible to accept the awarding and otherwise the bid will be excluded taking into account the exception provided by the office of Prime Minister no. 15773 on 10/11/2015 regarding the acceptance of bid which is less than 20% of the estimated cost .

ITB 34.1

34.1 In addition to the instructions mentioned in this paragraph to the bidders, the following conditions are taken into account.:

The contracting party may increase the quantity of non-consulting goods or materials or services or modify its technical specifications contracted to no more than the percentage of reserve amount stipulated in the annual budget implementation instructions provided that the financial allocation is available and that the prices of the paragraphs covered are increased in accordance with the quoted paragraphs (20%) of the quantity of the paragraph and the above is subject to the prevailing market prices taking into account the reflection of these variables on the contractual obligations as well as the financial guarantees with a contract attachment and under the same conditions contracted for projects listed in the balance sheet Exclusive

The contracting party may increase the quantity of non-consulting goods or materials or services, or amend their technical specifications contracted by not more than (20%) of the amount of the contract provided that the financial allocation is available and that the prices of the paragraphs included in the increase are approved in accordance with the paragraphs quoted by the contractor (20%) of the amount of the paragraph and the above is subject to prevailing market prices taking into account the reflection of these variables on contractual obligations as well as financial guarantees with a contract attachment for the projects included in the operating budget and special budgets issued by the approvals of the competent authorities For approval by the Ministry of Finance

The contracting party may deduct the non-advisory goods, materials or services, and not more than (15%) fifteen per cent of the contract amount

The contracting entity may partition the awarding of supplying the goods , materials or services required to be supplied .

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.

37.2B

In case that ,the judgment of the specialized court was on the contrary to the contracting party decision which has continued in the procedures of contracting, the bidder who appeal the judgment has to contact the specialized courts to ask for compensation if the appeal was based on true causes.

In case the procedures of contracting were stopped by specialized court order & judgment issued by the same court committing the contracting party to fulfill all the contracting procedures with the objecting bidder , contracting party could filled up a suitcase that claim to obligate the objecting bidder to compensate any damage that will appear in the future as a result of the contract execution.

The winning bidder, who is officially notified of the assignment, must sign the contract within a period not exceeding (30) days for foreign companies from the date of notification of the assignment.

ITB 38.1

A Good performance Guarantee shall be submitted within (Within the period specified for signing the contract ) from the date of issuance of the award letter and its official notification

It is possible to submit the final guarantees (a good performance guarantee) in the form of a receipt to be paid directly to the treasury of the contracting party (Kimadia) deposit slip according to the amount of the insurance.

Contracts amounting to 25 thousand dollars or less or its equivalent in Iraqi dinars based on the exchange rate of the Ministry of Finance are exempted, according to the year of allocation, from a letter of guarantee submitted by the company or scientific office approved by the Pharmacists Syndicate, the supplying or marketing company, or the commercial agent.

## Section III. Evaluation and Qualification Criteria

### 1. Evaluation Criteria

The Evaluation Criteria has been specified in Instructions to Bidders (ITB) in Section I and **Bid Data Sheet**(BDS) in Section II. The specific data **Bid Data Sheet**(BDS) for the (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

**(iii) The Bidder shall also submit the following additional information:**

- (a) a statement of installed manufacturing capacity;**
- (b) copies of its audited financial statements for the past three fiscal years;**
- (c) details of on-site quality control laboratory facilities and services and range of tests conducted;**
- (d) list of major supply contracts conducted within the last five years and relevant certifications endorsed by respective Clients. }**

{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 enveloping

ratification drug and its degree of meeting the technique specifications stated by the national committee of selecting medicines

### 2. Final accounts

(Submitting the general budget audited by the legal auditors presenting the financial position of the previous years (last 2 yrs ), 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.

- Liquid pecuniary (large contracts) in proportion of assessment cost to contract.
- Liquid pecuniary (medium contracts) range between (70%) to (100%) of assessment cost.
- Liquid pecuniary ( small contracts) range between (30%) to (50%) of assessment cost.

4. Annual revenue

annual income: of years from(1-10)yr

5- specialization experience (the Identical works

\* Number of required work in the document of tender range between (1-3)-(

\* Number of years required for similar works range between (5-10) years \*noting that requested similar works is "potential" in small works.

No	standard	For contracts whose estimate cost exceed 10billion dinars	For contracts that increase their estimate cost for 5 billion and up to 10 billion dinars	For contracts that do not increase their cost the is for 5 billion dinars
1	<p>Legal eligibility: it means The validity of the bidder to participate in the submission in terms of:</p> <p>1-his nationality</p> <p>2-conflict of interest</p> <p>3-List of lagging companies and blacklisted</p> <p>4-prevention according to decisions the united nation and international security council</p>	<p>1-Nationality: And it shall be implemented according to Article (1,4) of the instructions for bidders mentioned in the first section of the document</p> <p>2- Conflict of interests: they shall be implemented in accordance with Article (2, 4) of the instructions for bidders mentioned in the first section of the document.</p> <p>3 The list of lagging companies and the blacklist: they are dealt with according to Article (3, 4) of the instructions for bidders mentioned in the first section of the document</p> <p>4- Prevention according to United Nations and international security council</p> <p>It is dealt with in accordance with the fifth section of the eligible countries</p>	<p>1-Nationality: And it shall be implemented according to Article (1,4) of the instructions for bidders mentioned in the first section of the document</p> <p>2- Conflict of interests: they shall be implemented in accordance with Article (2, 4) of the instructions for bidders mentioned in the first section of the document.</p> <p>3 The list of lagging companies and the blacklist: they are dealt with according to Article (3, 4) of the instructions for bidders mentioned in the first section of the document.</p> <p>4- Prevention according to United Nations and international security council</p> <p>It is dealt with in accordance with the fifth section of the eligible countries</p>	<p>1-Nationality: And it shall be implemented according to Article (1,4) of the instructions for bidders mentioned in the first section of the document</p> <p>2- Conflict of interests: they shall be implemented in accordance with Article (2, 4) of the instructions for bidders mentioned in the first section of the document.</p> <p>3 The list of lagging companies and the blacklist: they are dealt with according to Article (3, 4) of the instructions for bidders mentioned in the first section of the document.</p> <p>4- Prevention according to United Nations and international security council</p> <p>It is dealt with in accordance with the fifth section of the eligible countries</p>

2	<p>Financial liquidity: liquid pecuniary is defined as a bank statement that shows the movement of the financial flow for the last fiscal efficiency year in the amount required through banking facilities and for the period preceding the closing date of the tender.</p>	<ul style="list-style-type: none"> <li>• liquid pecuniary = ESTIMATED COST</li> <li>• The required Financial liquidity must be proven in the document with a lump sum amount and not a percentage</li> </ul>	<ul style="list-style-type: none"> <li>• liquid pecuniary = ESTIMATED COST x 50%</li> <li>• The required Financial liquidity must be proven in the document with a lump sum amount and not a percentage</li> </ul>	<ul style="list-style-type: none"> <li>• liquid pecuniary = ESTIMATED COST x 20%</li> <li>• The required Financial liquidity must be proven in the document with a lump sum amount and not a percentage</li> </ul>
3	<p>The final balance defined as the general budget of the bidder, which reflect the financial position required for years in terms of the company's assets of fixed assets and moving with a statement of the amount of the company's expenses and revenues and the percentage of profit and loss in which</p>	<p>1-Presenting the general budget audited by certified accountants, showing the financial position for the last two years, and its rates should be profitable</p> <p>2-Final accounts may be submitted for the last two years preceding the financial crisis for a year</p>	<p>1-Presenting the general budget audited by certified accountants, showing the financial position for the last two years, and its rates should be profitable</p> <p>2-Final accounts may be submitted for the last two years preceding the financial crisis for a year</p>	<p>Not required</p>

4	<p>The annual income of revenue; the amount is received from the payments and advances on interim contracts completed Aoualemstmrh within the period required under close</p>	<p>1-The average annual revenue of the bidder should be in proportion to the estimated cost of the contract</p> <p>2-The annual revenue rate is calculated with a lump sum amount and not a percentage, and it must be proven in the document</p> <p>3-The bidder must present the annual rate of revenue for all contracts executed by him for a period of not less than two years and not more than ten years from the date of closing the tender, and the annual revenue rate is calculated according to the years submitted by him, taking into account that the years of work do not need to be sequential.</p>	<p>1-The average annual revenue of the bidder should be at a rate (70-100%) of the estimated cost</p> <p>2-The annual revenue rate is calculated with a lump sum amount and not a percentage, and it must be proven in the document</p> <p>3-The bidder must present the annual rate of revenue for all contracts executed by him for a period of not less than two years and not more than ten years from the date of closing the tender, and the annual</p>	<p>Not required</p>
5	<p>Specialized experience in supply contracts: It is previous experience in the field and specialization of this work as a main contractor or partner</p>	<p>Submission of one similar work completed within a period not exceeding (10) years before the deadline for submitting the bid at an amount of( 60-80%) of the project's estimated cost</p>	<p>Submission of one similar work completed within a period not exceeding (10) years before the deadline for submitting the bid at an amount of( 60% )of the project's estimated cost</p>	<p>Similar work is not required except in the event that it is of a special nature and has a specific technology, and in this case one similar work will be requested and completed within a period not exceeding 10 years before the deadline for submitting the bid with an amount equivalent to (30%) of the project's estimated cost.</p>

6. The kind of commercial sale and the method of supplying( transport, insurance & delivery and delivery place of the items.

7- domestic preference.

8- The availability of contracts and similar executed works within the specialization and the rate and level of execution and commitment of the company when implementing them.

9- certificate of trading in the country of origin.

- 10- manufacturing goods meets the requirement of good manufacturing Practices (GMP) other certifications (FDA) that are mentioned in bid documents and mechanisms of quality control.
- 11- Responding to the legal conditions ,technical specifications, standards of required rehabilitation, table prices meet samples of standard-documents as being the lowest price and balanced with the estimated cost.
- 12- duration of executing the contract.
- 13- company status from registration.
- 14- Status of the product from registration knowing that instructions that bidder shall begin to register in the specialized authorities and the contract will become effective from the date of receiving the registration certificate in case the product is not registered. If the product is registered or under the exception of the Minister of Health from submitting the registration certificate, the contract shall be effective from the date of its signature

**notes**

-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).

## Section IV. 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.

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

3. Price Schedules for (drugs and vaccines) to be imported from Abroad
4. Manufacturer's Authorization Form.

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

5. Sample Form for Performance Statement

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

## 1. Bid Submission Form

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

{The contracting entity shall insert: Tender Number: [insert number]}

IFB Number: [insert number]”}

To: Kimadia

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 VI or “as quoted in Price Schedule in Section-IV”] (the Bidder may select as appropriate clause).
3. We agree to all General Conditions of Contract in Section-VII read in conjunction with the Special Conditions of Contract in Section-VIII.
4. If our bid is accepted, we undertake to provide an advance payment security and 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 II and it shall remain binding upon us and may be accepted by you at any time before the expiration of that period.
6. Until the formal final Contract is prepared and executed between us, this bid, together with your written acceptance of the bid and your notification of award, shall constitute a binding Contract between us.
7. We understand that you are not bound to accept the lowest evaluated bid or any other bid that you may receive.



8. We agree to the following Eligibility Criteria:

- (a) We have nationality from Eligible countries as per ITB Sub-Clause-6.1 of Section-I.
  - (b) We do not have conflict of interest in accordance with ITB Sub-Clause-6.1 (a) of Section-I.
  - (c) We are not a Government-owned Entity in Republic of Iraq./ We are a Government-owned Entity in the Republic of Iraq and meet the requirement as per Sub-Clause 6.1(b) of Section - I.
  - (d) We including any of our subcontractors or manufacturers for any part of the contract, have not been declared ineligible by the Contracting Entity, under the Contracting Entity's country laws or official regulations or by an act of compliance with a decision of the United Nations Security Council.
  - (e) We have not been Black listed or Suspended by Ministry of Planning and declared ineligible to bid during the period of time determined as per ITB Clause 6.3 of Section-I.
9. We confirm that our website address is *[insert website address]* and our mail address is *[insert mailaddress]*, and that Mr. /Ms. *[insert name]* of Job Title *[insert jobtitle]* and e-mail address *[insert e-mailaddress]* 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]*

## 1. A. Price Schedule for Domestic Goods or Goods of Foreign Origin Located In Iraq

1

### Brief Description of Goods

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

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

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

### 1. B. Price Schedule for Domestic Goods or Goods of Foreign Origin Located In Iraq

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

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

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

Signature of Bidder \_\_\_\_\_

Name & Designation \_\_\_\_\_

Seal of the Bidder \_\_\_\_\_

Date: \_\_\_\_\_

Date \_\_\_\_\_

## 2.A. Price Schedule for Goods to be imported from Abroad

Serial no.		1						2	3 Description item of manufacturer company													4 Country origin.....			
		National code		National description			Unit		Qty.																
No. Of item	no. of tender receipt committee	Manufacturing comp. Code (K-code)	National item code	Generic name	Pharmaceutical from	Unit per blister	Unit per pack	Offer Quantity	Description item of manufacturer co.	Generic name of company item	Active ingredient	(sodium metabisulfate) existence in this comp and or not	Trade Name	volume	weight	Arrival way	Entry point to country	Shelf life of item	Supplying period	Item Registration Date & No.	Submission of Samples	origin of Raw material	Goods origin	Country origin	Registration No. Of Offer submitting company
			15-AA-0008	Cyclophosphamide 500mg Injection																					
			15-AA-0100	Dacarbazine 200mg powder for reconstitution vial for inj (I.V. Infusion or I.V. infusion and Intra-arterial																					



			15- AA 0- 03 0	<p>Bendamustine hydrochloride 100mg vial powder for reconstitution</p> <p>يحصّر استخدامة في مراكز امراض الدم وحسب الاستطبابات 1018 المقررة في الجلسة</p> <p>Bendamustine vial to be use in :-</p> <p>a/ relapse chronic lymphocytic leukemia</p> <p>b/ relapse low grade non – hodykin lymph</p> <p>c/ in chronic lymphocytic leukemia in those not fit for RFC and failed to respond to R leukeran</p>																	
			15- AB 0- 00 1	<p>cytarabine (for S.C, I.V. , intrathecal )</p> <p>20mg/ml, 5 ml vial</p>																	

		15-AB 0-00 8	Gemcitabine as Hcl powder for reconstitution or concentrate for solution for infusion (1g ) vial																		
		15-AB 0-00 9	6- mercaptopurine 50mg Tablet																		
		15-AB 0-01 0	Methotrexate 2.5mg Tablet (psoriasis) يصرف للاستخدام في علاج																		
		15-AB 0-01 1	Methotrexate inj as sodium salt 2.5 mg/ml, 2ml Ampoul OR vial ,subcutaneus,intrathecal للجلدية والكلية																		
		15-AB 0-01 9	Fludarabine phosphate 50mg vial, powder for reconstitution, for I.V. inj. or infusion.																		

			15- AB 0- 02 0	Cladribine (2-CDA) 10mg / Vial, 5ml Or 10ml يحصّر استخدامه لعلاج اللوكيميا الشعيرية (Hairy cell Leukemia)																		
			15- AB 0- 02 2	cytarabine (for S.C, I.V. )100mg/ml, 10 ml vial. 20mg/ml يجب ان يكون التركيز هو Intrathecal في حالة الاعطاء بطريقة الزرق																		
			15- AB 0- 02 8	5-Fluorouracil 50mg/ml (10 ,20 ,50 ,100) ml vial for I.V inj. Or infusion oR intra- arterial infusion																		
			15- AB 0- 03 1	Decitabine I.V injection 50mg vial تستخدم فقط في مراكز امراض الدم والعيادات التخصصية لامراض الدم ,,لعلاج اعتلال نخاع فقط MDS العظم																		



			15- AB 0- 03 3	Methotrexate vial 1g base i.v infusion 100mg/ml على ان لايتجاوز التركيز																			
			15- AB 0- 03 4	Pemetrexed (as disodium) 500mg vial powder for concentrate for solution for infusion or concentrate for solution for infusion ( IV use after dilution) تستورد بكميات قليلة (حصة مريض) ويصرف بموافقة لجنة استشارية حصراً ولمريض mesothelioma فقط .. للتوضيح حصة مريض بمعنى (On need) كميات محدودة تودع لدى مخازن الشركة ولا تصرف الا عند الحاجة ومن قبل لجنة استشارية حصراً ولمرضى دواعي الاستخدام في سرطان :-الرئة هي الاتي Mesothelioma :-Non Squamous,																			

				<p>Non Small Cell Lung Cancer(NSCLC)which include the following subtypes:          Adenocarcinoma          Large cell          NSCLC          NOS(nonspecific subtype)          It is indicated as neoadjuvant, adjuvant, and maintenance in locally advanced and metastatic non squamous NSCLC as a treatment option in first, second and third line treatment in patients with performance status 0-2</p>																		
			15-AC 0-00 2	<p>Bleomycin as sulphate 15000 units per vial dry powder for reconstitution</p>																		

			15-AC 0-00 3	Dactinomycin 500mcg (Actinomycin D) I.V Injection																					
			15-AC 0-00 4	Daunorubicin 20mg I.V. Injection (as HCL) solution for injection or powder for reconstitution vial																					
			15-AC 0-00 8	Doxorubicin Hcl 50 mg I.V. inj , powder for reconstitution vial OR Doxorubicin Hcl 2mg/ml, 25 ml vial																					
			15-AC 0-01 4	Mitoxantrone as Hcl , concentrate for I.V. infusion, 2mg/ml, 10 ml vial																					
			15-AC 0-01 8	Doxorubicin Hcl (pegylated liposomal )conc.for i.v infusion 2mg/ml(10ml vial )i.e inj pegylated Doxorubicin Hcl																					

				2mg /ml incapsulated in liposomes																	
			15- AC 0- 01 9	Epirubicin Hcl 2mg/ml, 25 ml vial OR Epirubicin Hcl 50 mg (powder for reconstitution ) vial.																	
			15- AD 0- 00 4	Etoposide concentrate for I.V. infusion 20mg/ml, 5 ml vial OR Ampoul																	
			15- AD 0- 00 6	Vinblastine sulphate 1 mg/ml, 10 ml vial or ampoul.																	
			15- AD 0- 00 7	Vincristine sulphate Injection 1mg/ml , 1 ml inj. for I.V. adminstration only not for intrathecal adminstration. يستعمل عن طريق الوريد فقط وليس بأي طريقة اخرى																	

			15-AD 0-01 1	Vinorelbine as tartrate , concentrate for I.V. infusion 10 mg/ml, 5 ml vial.																		
			15-AD 0-01 5	Vinorelbine as tartrate 30 mg capsule																		
			15-AE 0-00 3	Recombinant asparaginase (E-coli type ) 10.000 unit vial powder for concentrate for solution for infusion																		
			15-AF 0-00 3	Cisplatin inj 50mg/vial I.V. infusion Cisplatin فيما يخص لا يوجد مستحضر خاص يعطى عن طريق التسريب الوريدي .. ونفس (sol. or powder) المستحضر يستخدم لكلا الطريقتين أي بمعنى أن المستحضر المثبت عليه طريقة الاعطاء بالزرق الوريدي يمكن استعماله																		

				عن طريق التسريب البريتوني																			
			15- AF 0- 00 5	Oxaliplatin 100mg/vial powder for reconstitution I.V. Infusion OR concentrate for I.V. infusion 5mg/ml , 20 ml vial.																			
			15- AF 0- 00 8	Carboplatin 10mg/ml (45ml) Vial i-e 450mg/45ml																			
			15- AF 0- 01 0	Hydroxyurea 500mg Capsule ايضا يستخدم كعلاج في مراكز امراض الدم الوراثية وخاصة مرض فقر الدم sickle cell المنجلي anemia)																			
			15- AF 0- 01 1	Octreotide 0.05mg/ml Injection																			

			15- AF 0- 01 8	Methyl prednisolon (as sod. Succinate) 250 mg IM,slow IV,IV infusion inj																				
			15- AF 0- 03 0	Octreotide as acetate 20mg microspheres powder for suspension supplied with 2ml or 2.5ml diluent vial filled syringe. يخصص لداء العملاقة : حصرا قاعدة اقل الاسعار مع المادة بالرمز الوطني (15) ج 1069(af0-069)																				
			15- AF 0- 03 1	Tretinoin 10mg capsule (ALL-trans retinoic acid)																				
			15- AF 0- 03 8	Capecitabine 500mg tablet																				

				<p>Bevacizumab 400 mg ;concentrate for intravenous infusion 25mg/ml, 16 ml viaOr its approved biosimilar</p> <p>لسرطان يقاف استعماله الثدي :</p> <p>ان دواعي الاستخدام هي كالآتي في الحالات التالية</p> <ul style="list-style-type: none"> <li>• سرطان القولون المنتشر</li> </ul> <p>15- Metastatic colorectal carcinoma</p> <p>AF 0- سرطان الكلية المنتشر •</p> <p>04 Bevacizumab in combination with IFN- alpha a treatment option for first line</p> <p>4 Treatment of patients with metastatic renal cell carcinoma, clear cell histology With good or moderate prognostic features Poor prognostic features include</p>																	
--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--



			<p>three or more of the following:</p> <p>LDH&gt;1.5 times upper limit of normal</p> <p>Corrected serum calcium level&gt; 10mg/ dl</p> <p>Interval of less than a year from original diagnosis to the start of systemic therapy</p> <p>Karnofsky performance score&lt;=70</p> <p>Two or more sites of organ metastasis</p> <p>يعاد النظر بهذا الاستخدام بعد توفر علاج ال sunitinib</p> <ul style="list-style-type: none"> <li>• سرطان المبيض المنتشر</li> </ul> <p>Second line treatment for recurrent or metastatic epithelial ovarian tumor</p> <p>And in combination with chemotherapy</p> <ul style="list-style-type: none"> <li>• فيما يخص اورام الدماغ</li> </ul>																		
--	--	--	---	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--

			يعطى العقار فقط لنوع (Glioblastoma multiforme ) ج 1025/ ج\1071 ( يرفع استخدام مادة Bevacizumab 400 mg ) لأمراض شبكية العيون ج1088																	
			Bortezomib( as mannitol boronic ester ).3.5 mg solution or powder for solution for i.v, s.c vial 15- يستعمل للحالات AF المعندة للعلاج التقليدي 0- وغير المناسبة لغرس 05 نخاع العظم في ورم ليفي 1 العظم المتعدد الخلايا (multiple myeloma) , يحدد صرف العقار للمرضى المصابين بأبيضاض الدم النقائي المتعدد																	



			<p>Arsenic trioxide(Concentrate for intravenous infusion) 1mg/ml  10 ml amp to be use in :-  يحصّر . استخدامة في مراكز امراض الدم وحسب الاستطبابات المقررة في الـ1018a/الجلسة  relapsed acute promyelocytic leukemia  b/ first line in acute promyelocytic leukemia in low risk group only  (platelet less than 40,000 , WBC less than 10,000 )</p>																	
			<p>anreotide acetate 90 mg sol. for Inj (PFS) Autogel قاعدة اقل الاسعار مع المادة af0-15-بالرمز الوطني (15-030)</p>																	

		15- AF 0- 07 0	lanreotide acetate 120 mg sol. for Inj (PFS) Autogel ج\1069 قاعدة اقل الاسعار مع المادة بالرمز الوطني (15)- af0-059)																	
		15- AG 0- 00 8	Letrozole 2.5mg Tablet وعلى قاعدة اقل AG-14- الاسعار مع ( 15 ) ).																	
		15- AG 0- 01 3	Tamoxifen as citrate 20mg Tablet																	
		15- AG 0- 01 4	Anastrozole tablet 1mg To be dispence by medical committee for these indications thromboembolic في حالة وجود تاريخ تخثري مرضي - (Drug intolerability) /Tamoxifen في حالة عدم تحمل المريض																	

				<p>لعلاج  - Not to be used as  an Alternative in  case that  Tamoxifen tab are  not available  لايستعمل Tamoxifen  كبديل في حالة عدم توفر  حبوب  الاسعار وعلى قاعدة اقل  مع (AG-08 -15)</p>																		
			15- AG 0- 01 5	<p>Bicalutamide 50mg  tablet  Not use in cases of  Localize prostatic  disease لحالات  سرطان البروستات  المتقدم</p>																		
			15- B0 0- 00 3	<p>Anti-Thymocytic-  Globulin  100mg/5ml (ATG)  Vial (Rabbit  type)(limited for  kidney) م.تخصصي زرع  الكلى</p>																		

			15- B0 0- 00 00 4	Basiliximab 20mg /Vial ج / 986 المستشفيات التي تجري فيها عمليات زرع الكلى																
			15- B0 0- 00 00 8	Cyclosporine (Microemulsion)10 0mg/ml oral Solution لا مانع استخدامها ل (Autoimmune disease ) ومنها (الامراض الجلدية 989)																
			15- B0 0- 01 01 2	Interferon alfa-2a (Recombinant) 9 million units prefilled syring (HSA free solution) Injection تم تحويله من المستوى في الجلسة 973 الثالث مشتركة بين الجهاز امراض الدم , الهضمي حسب "والاورام كلا (احتياجه 973)																

			<p>15- B0 0- 02 9</p> <p>Imatinib as mesylate (Protein – Tyrosine kinase inhibitor) 100mg Capsule OR TAB الشركة المجهزة ملزمة بتوفير الفحوصات التالية ( PCR BCR - ABL210 ) ( 3 مرات ) . لكل مريض "سنويا ( FISH BCR - AB ) لمرة واحدة للمرضى . "المشخصين حديثا</p>																	
			<p>15- B0 0- 05 0</p> <p>Imatinib as mesylate (Protein - Tyrosine kinase inhibitor) 400mg Tablet or capsule ( يحصر في مدينة ) الطب+المركز الوطني لامراض الدم + بابل+البصرة+نينوى+النجف +ف+كركوك + كربلاء + الكرخ+واسط+الانبار+اربيل ج (ل +سليمانية 1012)) الشركة المجهزة ملزمة بتوفير الفحوصات</p>																	



			<p>Mycophenolic acid as sod.Salt i.e Mycophenolic acid as mycophenolate sod.360mg gastro-resistant Tablet</p> <p>يحصص صرفه لمرضى زرع الكلى ج / 949</p>																	
			<p>Erlotinib as Hcl 150mg Tablet ج 987 ج/1045 قاعدة اقل الاسعار مع (Gefitinib 250 mg tab) 15-b00-099 ج\1089 وتلتزم الشركة المجهزة بتوفير الفحوصات الاتية مجانا اعتمادا على اعداد المرضى الفحوصات: EGFR exon19 deletions or exon21(L858R) substitutionErl</p>																	

			<p>Anti-Thymocytic-Globulin (ATG,Rabbit type) for I.V. infusion</p> <p>15- powder for B0 reconstitution; 25 0- mg vial OR ampoule 07 3</p> <p>يحدد احتياجه من قبل مراكز زرع الكلى ومراكز زرع نخاع يجب ان ATG مادة تعامل في الاستيراد معاملة الادوية الكيماوية</p>																	
			<p>Antithymocyte globulin equine 250 mg in 5 ml ampoule يستخدم لعلاج فشل نخاع العظم المكتسب (Acquired aplastic anemia ) على ان 0- تراجع اللجنة الاستشارية 08 لامراض الدم الكمية 8 المطلوبة من الدوائر بالتنسيق مع قسم تقدير الحاجة لتحديد اعداد المرضى الفعلي وفق قاعدة البيانات الرسمية المتوفرة لدى الدوائر اعلاه وحسب ما جاء بتوصيات اللجنة</p>																	

			الاستشارية لامراض الدم السريرية ج987																			
		15- B0 0- 09 9	Gefetinib 250 mg tab ج/1045 قاعدة اقل الاسعار مع ) Erlotinib ( 15-b-85 ) as Hcl 150mg ج\1089 وتلتزم الشركة المجهزة بتوفير الفحوصات الاتية مجانا اعتمادا على اعداد المرضى الفحوصات: EGFR exon19 deletions or exon21(L858R) subsitution																			
		15- B0 0- 11 1	bosutinib 100 mg film coated tab وتستخدم لعلاج مرضى ابيضاض الدم النقلياني بعد فشل عقار Imatinib اوحودث مضاعفات جانبية وللمرضى الذين لايتحملون عقار مع الزام Nilotinib الشركة المجهزة بتوفير																			

				<p>PCR+FISH فحوصات bosutinib 400 mg film coated tab يجهز بصورة مجانية من احتياج 5% وبنسبة مادة bosutinib 100 mg وبنسبة 5% اخرى من bosutinib احتياج مادة 500 mg ولنفس لمرضى الاستطباباتال CML</p>																
			15- B0 0- 11 2	<p>bosutinib 500 mg film coated tab وتستخدم لعلاج مرضى ابيضاض الدم النقياني بعد فشل عقار Imatinib اوحدوث مضاعفات جانبية وللمرضى الذين لايتحملون عقار Nilotinib مع الزام الشركة المجهزة بتوفير PCR+FISH فحوصات bosutinib 400 mg film coated tab يجهز بصورة مجانية من احتياج 5% وبنسبة مادة bosutinib 100 mg وبنسبة 5% اخرى من</p>																

				<p>bosutinib احتياج مادة 500 mg ولنفس لمرضى الاستطابات CML</p>																	
			15- B0 0- 11 3	<p>palbociclib, 125mg tab ج\1087 قاعدة اقل الاسعار مع Abemaciclib 150mg وتعطى للاستطابات الاتية Initial endocrine based therapy in postmenopausal patient with HR+ve , HER2-ve metastatic breast cancer على ان تقوم الشركة المجهزة للعلاج بتوفير الفحوصات الاتية</p>																	
			15- B0 0- 11 4	<p>Abemaciclib 150mg, film coated tablet ج\1087 قاعدة اقل الاسعار مع palbociclib, 125mg tab وتعطى للاستطابات الاتية</p>																	

			Initial endocrine based therapy in postmenopausal patient with HR+ve , HER2-ve metastatic breast cancer على ان تقوم الشركة المجهزة للعلاج ب																				
		15- C0 0- 00 3	Filgrastim 300mcg(30MU) /1ml S.C/I.V infusion inj (solution) Vial or Filgrastim 300mcg(30MU) /0.5 ml pfs or it's approved biosimilar approved biosimilar بالنسبة للرمز الوطني 15)-C00-003) (reference) او (biosimilar) وحسب التنافس سعري مع الرمز -يختار النادئين اما(15) وحسب (C00-009) قاعدة اقل الاسعار ج/1032																				

			15- C0 0- 00 9	Lenograstim powder for reconstitution , 33.6 million IU ( 263 µg) vial (with 1 ml prefilled syringe water for injections) code 15-C00-003 تخضع لقاعدة اقل الاسعار مع																		
			15- D0 0- 00 2	Docetaxel (Anhydrous or as Trihydrate )10mg/1ml ,8ml vial OR 20mg/1ml ,4ml vial OR 80mg/2ml Vial (all with diluent) يتم الخلط حسب النشرة الداخلية للمستحضر في المحاليل الوريدية وعدم خلطها بالاشكال الاخرى																		
			15- D0 0- 00 4	Paclitaxel 6mg/ml 50ml vial																		

			15- D0 0- 00 5	Docetaxel 10mg/1ml, 2ml vial or pfs OR Docetaxel 20mg/ml, 1 ml vial or pfs ( يتم الخلط ) حسب النشرة الداخلية للمستحضر في المحاليل الوريديّة وعدم خلطها بالاشكال الأخرى) ج987 إضافة شكل صيدلاني																
			15- E0 0- 00 2	Irinotecan Hcl or Hcl Trihydrate 20mg/ml ( 5ml I.V. Infusion Vial )																
			15 - B0 0- 00 1	Azathioprine 50mg Tablet لا مانع استخدامها لـ (Autoimmune disease ) ومنها (الأمراض الجلدية) (989)																
			15 - B0 0- 07 1	Thalidomide 50 mg cap or tab تستعمل المادة وفق الضوابط المتعارف عليها وبصورة مشددة للرجل والمرأة في سن الانجاب منعا لحدوث تشوهات خلقية اذا حدث الحمل وتستعمل موانع الحمل																



				بصورة فعالة واكيدة (ج 1012) للجنسين																		
				Mycophenolate mofetil 500mg Tablet ج 982 / ج 992 ج / 1033 / اعتماد - البروتوكول العلاجي B0 المرفق بالجلسة والمسند 0- لتوصيات اللجان 02 "الاستشارية المختصة انفا 3 .																		
				15 - B0 0- Tacrolimus 1mg 02 Capsule يحدد صرفها 4 ضمن مراكز زرع الكلى																		

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

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

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

Agency Commission: \_\_\_\_\_ [Bidder may insert, if applicable]

Place: \_\_\_\_\_

Date: \_\_\_\_\_

Signature of Bidder \_\_\_\_\_

Name & Designation \_\_\_\_\_

Business address \_\_\_\_\_  
 Seal of the Bidder \_\_\_\_\_

## 2.B. Price Schedule for Goods to be imported from Abroad

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

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

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

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

Agency Commission: \_\_\_\_\_ [Bidder may insert, if applicable]

Place: \_\_\_\_\_  
Date: \_\_\_\_\_

Signature of Bidder \_\_\_\_\_  
Name & Designation \_\_\_\_\_  
Business address \_\_\_\_\_  
Seal of the Bidder \_\_\_\_\_

---

**4. BID SECURITY FORM (BANK GUARANTEE)**

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

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

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

**Date:**

**BID GUARANTEE No.:**

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

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

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

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

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

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

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

[signature(s)]

## 5. Manufacturer's Authorization

[The Bidder shall require the Manufacturer to fill in this Form in accordance with the instructions indicated. This letter 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]

**6. 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

7-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			

## Section V. Eligible Countries

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

1. The Purchaser 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 Purchaser state provided that the Purchaser 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 Purchaser'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 VI: SCHEDULE OF REQUIREMENTS

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

1		2					3	4	5	6
		<b>Brief description of goods</b> [Insert drugs or vaccines: product, dosage form, pharmacopoeial standards, package size. Only a brief description can be included]								
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]
(a)	(b)	Product (a)	Strength (b)	Dosages form (c)	Pharmacopoeia Standard (d)	Unit pack size (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 –IV

## 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

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

<u>Names of Drugs and Vaccines</u>	<u>Technical Specifications</u>
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.

**1.6 Upon award, the successful Bidder(Supplier) shall, on demand, provide a translated version in the language of the bid of the prescriber's information for any specific goods the Contracting Entity may request.**

#### 2. 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;
- (a) 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.]

## **Sample2:**

### **Technical Specification**

#### **Vaccines**

##### **1. Product Qualification Requirements** Option A

1. The (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.

**4. Packing Requirements**

3.3 All labeling shall withstand immersion in water and remain intact.

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) 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;
- (d) Place of manufacture (Made in \_\_\_\_\_).

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

- (a) Generic name and trade name of the vaccine;
- (b) Lot or batch number;
- (c) Expiration date (month and year in clear language, not code);
- (d) Manufacturer's name and registered address;
- (e) Manufacturer's national registration number;
- (f) Destination airport and routing;
- (g) Consignee's name and address in full;
- (h) Consignee contact name and telephone number;
- (i) Number of vials or ampoules contained in the carton;
- (j) Gross weight of each carton (in kg);
- (k) Carton #\_\_\_\_ of \_\_\_\_\_;
- (l) Instructions for storage and handling;
- (m) Contract number;

Place of manufacture (Made in\_\_\_\_\_)

**6. Quality Control for**

6.1 All vaccines shall:



## Supply

- (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 of basis for expiration dating and other stability data concerning the commercial final package upon request.

6.3 Pre-shipment inspection and testing: The Supplier will be required to provide the Purchaser or his representative with access to the product as packed for shipment at the sellers' factory and/or warehouse at a mutually agreeable time prior to shipment of the product.

- (a) The Purchaser may inspect and sample, or cause to be sampled, such product.

(b) The Purchaser may cause independent laboratory testing to be performed as deemed necessary to ensure that the (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 VII. General Conditions of Contract

### Notes on the General Conditions of Contract

The General Conditions of Contract (GCC) in Section VIII, read in conjunction with the Special Conditions of Contract (SCC) in Section VIII 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

1	Definitions	72
2	Application	74
3	Country of Origin	74
4	Standards	74
5	Use of Contract Documents and Information; Inspection and Audit	74
6	Certification of (drugs and vaccines) in Accordance with Laws of Republic of Iraq	75
7	Patent Rights	75

8	Good Performance guarantee	76
9	Inspections and Tests	76
10	Packing	77
11	Delivery and Documents	78
12	Insurance	81
13	Transportation	81
14	Payment	81
15	Prices	84
16	Amendment orders	84
17	Contract Amendments	85
18	Assignment	85
19	Delays in the Supplier's Performance	86
20	Arrears Fines (reduced by completion ratios)	86
21	Withdrawal of work by the Employer	87
22	Withdrawal of work for Insolvency	88
23	Force Majeure	89
24	Termination by the employer for Convenience	89
25	Settlement of Disputes	90
26	Limitation of Liability	91
27	Contract Language	91
28	Applicable Law	91
29	Notices	91

30	Taxes and Duties	92
31	Withholding and lien in respect of sums claimed	92

## General Conditions of Contract

### 1. Definitions

In this Contract, the following terms shall be interpreted as indicated:

- (a) "The Contract" means the agreement entered into between the Contracting Entity and the Supplier, as recorded in the Contract Form signed by the parties, including all attachments and appendices thereto and all documents incorporated by reference therein.
- (b) "The Contract Price" means the price payable to the Supplier under the Contract for the full and proper performance of its contractual obligations.
- (c) "Day" means calendar day.
- (d) "Effective Date" means the date on which this Contract becomes effective pursuant to GCC Sub-Clause 6.2.
  
- (e) "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 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.

(n) Corruption and Fraud:

The Purchaser defines Corruption and Fraud 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 the purposes of this article, "origin" means the place from which drugs (including pharmaceuticals) are manufactured, vaccines were grown or produced, or the place or place in which services are provided. We mean drugs (including pharmaceutical preparations) or manufactured vaccines, which are drugs (including pharmaceuticals) or that which becomes a distinctive, commercially recognized product that differs fundamentally (in basic characteristics, purpose or use) from its components, through manufacturing, processing, or balanced or substantial assembly processes (or component combinations).
- 3.2 The origin of the drugs (including pharmaceutical products) or vaccines and 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 submitted 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)** 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

**and vaccines) in  
Accordance with Laws of  
Republic of Iraq**

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 the period specified for signing the contract**, 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 be 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 submitted 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 submitted 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 submitted 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. 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;

- (7) original copy of the Certificate of Inspection submitted 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. **Where delivery of Goods is required by Purchaser on a CIF or CIP basis, the supplier shall assure the insurance of an amount equal to 110 percent of the CIF or CIP value of the Goods from "warehouse" to "warehouse" on "All Risks" basis, including war risks and strikes.**

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

## 13. Transportation

13.1 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®

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

## 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 VIII.

(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 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 possible 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.

15.2 The supplier must guarantee and undertake that the goods provided under the contract are new, unused and of the latest style and include the most recent developments (or current developments) in design and materials, unless the contract specifies otherwise.

The supplier must also warrant and pledge that the goods provided under the contract will not include defects (that may appear during the normal use of the goods in the conditions prevailing in Iraq) resulting from design or defects resulting from used materials or workmanship (except in cases where the buyer determines Designs or materials are required in the technical specifications) or defects due to any act performed by the supplier or any negligence thereof.

15.3 This guarantee shall be effective for a period of two: (1) [Enter No.] month from the date of receipt of the goods or any part thereof according to the case, at the final location specified in the contract and its acceptance by the buyer, or (2) [Enter No. (6 + \*) ] month from the date of commencing the shipment from the place of loading from the country of origin.

Note: The value "x" shall be determined in months based on a market study. Generally, it is 12 months.

15.4 The purchaser shall send written notice of any claim that may arise as a result of this guarantee, as soon as possible.

15.5 Upon receipt of the supplier's notice to the buyer, he must within [enter the number of days, preferably 15 days] and with reasonable speed, to fix the defects or replace the defective goods or parts thereof, without any additional cost to the buyer, except, according to the case, the following costs The cost of the delivery inside Iraq and to the final destination, for goods or parts that have been repaired or replaced, from (EX-factory), (EX-Showroom) or (EX-Works).

15.6 If the supplier, after notifying him in writing, fails to remedy the defects within the time limit specified for that in the special conditions of the contract, then the buyer has the right to take the necessary measures to address the matter as needed, at the responsibility and expense of the supplier and without prejudice to any other rights or compensation that the buyer has under the contract.

15.7 Enter "Not applicable" or for essential and sensitive medical equipment / devices, enter the following: "]" \*\*% annually [enter for example 95% or 98%] during the UPTIME warranty period and in case the downtime period is exceeded during the annual maintenance contract, a percentage of (100- \*), then the period of this contract must be extended to twice the value of the downtime periods. "]

#### 16. Amendment orders

16.1 No changes shall be introduced to the contract unless for the circumstances (a-e) listed herebelow. 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 submitted 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, its likely duration, and its cause(s). As soon as practicable after receipt of the Supplier's notice, the Purchaser shall evaluate the situation and may at its discretion extend the Supplier's time for performance, with or without, Delay Compensation (DelayPenalty) 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 Delay Compensation (DelayPenalty) pursuant to GCC Clause 22, unless an extension of time is agreed upon pursuant to GCC Sub-Clause 21.2 without the application of Delay Compensation (DelayPenalty)

**20.**

**Arrears Fines**

20.1 Subject to GCC Clause 22 if the Supplier fails to deliver any or all of the (drugs and 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 Delay Compensation (DelayPenalty)

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 ..

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

$\text{Total Contract Price} \times 10\% - 25\% = \text{delay penalty per day}$

Total validity contract (days)

OR could be deducted as following formula :

$\text{Unperformed Contract Price} \times 10\% = \text{Liquidated damages per day}$

Delivery period (days)

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

**21. work withdraw  
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 Which stipulates that supplier in such case shall incur the difference in cost 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).

## **22. Work withdrawl 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.

## **23.**

### **Force Majeure**



24.

Contract Termination by  
employer for convenience

25. Settlement of Disputes

26. Limitation of  
Liability

27.

**Contract Language**

28. **Applicable Law**

29. **Notices**

30. **Fees and taxes**

31. **Withholding and lien in  
respect of sums claimed**

#### **Section VIII: 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/Directorate)].

GCC 1.1 (m) The Supplier is: [insert: name of Supplier].

GCC5 5.3 In addition to what has mentioned in ITB (instructions to bidders) the following will be added.

1- Provide the second party with the official letters related to contract execution and first party will never be responsible about the results of these correspondences.

2- adoption the original copy of the contract which is signed by the two parties and which is saved at the first party as it is the copy that will refer to in case of any misunderstanding.

Submit the original commercial lists to the import department before shipment are sent for each shipment otherwise, the 1<sup>st</sup> party will impose an import penalty according to the text of article GCC 22

**E-Confirming to go on executing all the contracting obligation. The marketing company will bear a legal responsibility for the period of execution the contract even when the period of authorization is expired.**

GCC6 - the supplier must provide the first party with a certificate of analysis issued by the laboratory of the manufacturing company, sealed with their seal with every shipment.

GCC6.1

- the second party must register the preparations produced by him at the registration department of the Ministry of Health for unregistered materials and re-registration for previously registered materials that require re-registration and submission of documents proving this to the registration department

- In the event that the article of not registered and referred to it based on the decision of the medicines policy

committee, the provider must:

- The seller must register his company and materials with the Iraqi Ministry of health
- The seller must register his company within one month from The date of the referral with the Iraq Ministry of Health ,provided that it does not exceed a period of six months to complete the registration otherwise the buyer stops dealing with the seller
- in the event that the material is not registered ,then the companys dues for this contract will not be paid unless the evidence is submission the material registration or re- registration documents to the registration section

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.**”]

The effect in date the contract starts from date of signing the contract of both sides

GCC8 **- Presentation of Performance bond:**

- a- The final insurance shall be presented in the form of performance bond for the contract at the rate of 5% of the contract amount after notification in the letter of warding and before signing the contract, the guarantee shall not be canceled unless there is a notification by Kimadia,**
- b- Foreign companies may submit the final insurance within 21 days of signing the contract, after the approval of**

**the Central Committee for Review and Approval of the letter of forwarding at the contracting authority.**

**c- Final guarantees are not released until after the issuance of the final acceptance certificate and settling of - accounts. A portion of the amount of performance bond may be released after the final delivery of these parts and the issuance of the acceptance certificate to them in a manner that supports their qualification for use Taking into account the controls related to final insurance.**

d-The Bank guarantee Should be issued by Iraqi governmental or private Iraqi Bank. These reliable government banks do not have the right to

issue bank guarantee to foreign company unless submitting a guarantee

issued by foreign Bank (Back to Back) which has classification Issued by

one of International classification organizations (Moody's standard and poor) and others or against monetary insurance not less than guarantee amount without the help of T.B.I . The guarantee should be in Arabic and English and the Arabic languages and the Arabic version should be the effective one.

e- performance guarantee should be issued by the order of the company which contracted with or with its legal authorized person for issuing the guarantee in accordance with an official authenticated authorization submitted to the bank and included in the term of guarantee or attached letter issued by the issuing bank .

f- The submission of the guarantee should be attached with an authentication letter of issuance (personal and confidential) send to kimadia by the bank who issued the guarantee. This guarantee should be unconditional and for the favor of (kimadia). Kimadia has the right to extend or confiscate the guarantee if required to do so, without any objection of correspondents or suppliers started from the first written claim

g- The companies and scientific bureaus should take in consideration the following when issued the good performance guarantee:-

1-The letters of guarantee should be issued by the name of the company which signed the contract .

2-Be sure that the contract no. is mentioned in the letter of guarantee .

3-the following statement should be written in the letter of guarantee (this guarantee is subject and explain in all matters according to the Iraqi laws).

4-The letter of guarantee should financially covered by the bank.

5-Any letter of guarantee will not be received unless attaché with a formal letter issued by the bank who issued the letter of guarantee signed by the director

of the bank or the one who represents him.

6-The letter of guarantee should be written in (Arabic &English) and the Arabic language is the one to rely upon when having any dispute.

7-It should be valid for one year from date of issuing.

8-It should not be direct or conditional.

9- In case the supplier doesn't accept to make the modifications or extensions to the letters of performance guarantee or the supplier breaches, the amount of guarantee will be confiscated and deposit it in the account of our company.

10-The letters of guarantee issued by the approved banks shall be received in accordance with a(bulletin —brochure) issued by central bank of Iraq. **All letters of guarantee are not accepted until after they are accepted by the Central Bank Of Iraq &entered on the Platform &the support of Central Bank Of Iraq for us to do .**

11-The letter of guarantee must be the same as the contract currency .

**12- It is possible to submit the final guarantees (a good performance guarantee) in the form of a receipt to be paid directly to the treasury of the contracting party (Kimadia) deposit slip according to the amount of the insurance.**

**13-Contracts amounting to 25 thousand dollars or less or its equivalent in Iraqi dinars based on the exchange rate of the Ministry of Finance are exempted, according to the year of allocation, from a letter of guarantee submitted by the company or scientific office approved by the Pharmacists Syndicate, the supplying or marketing company, or the commercial agent.**

**GCC8.3** The guarantee formula in item A of the general conditions of the contract is adopted , item (8.3) .

GCC 9.1

In addition to what have been mentioned in the general conditions of the contract, the following are added:

Receiving items will never be considered as confirmation for compliance to the specifications and technical conditions but it will rely on the results of laboratory tests issued by labs of Iraqi public health (National Center for control and medical research, Central Health Laboratory). After issuing the acceptance and testing decision by the central release committee formed for that purpose and not only the result of lab analysis.

-Samples will be sent to national center for control and medical research, for test and evaluation and their results are reliable.

-Standard analysis substances (i.e. B.P.C Rst U.S.P Rst E.U.C Rst) not working standard together with method and authenticated certificate of analysis are to be sent with the request to our national center for medicine control & research

Any material or quantity that fails in the analysis as confirmed by our national center for control and medical research should be compensated by the supplier

GCC 9.2

“9.2.1. (a) Said inspection and testing is for the Purchaser’s account. In the event that inspection and testing is required prior to dispatch, the Goods shall not be shipped unless a satisfactory inspection and quality control report has been issued in respect of those Goods.

(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 Goods at place of final destination, the Purchaser’s representative shall inspect the Goods or part of the Goods to ensure that they conform to the condition of the Contract and advise the Purchaser that the Goods were received in apparent good order. The Purchaser will issue an Acceptance Certificate to the Supplier in respect of such Goods (or part of Goods). The Acceptance Certificate shall be issued at the earliest within fifteen (15) days from the date of supplying material entrance to the place of supplying specified by the first party

9.2.2. In case the supplier objection with the results of test carried out by the labrotatories referred to in pharagraph GCC9.1 the test shall be repeated at thecenterallabrotatories of the public health and the results will be conclusive.

GCC 10.2

Medical items should be shipped in a form of palette covered by nylon and placed on a wooden basis.

- on the outside cover of the pack (pallet or big carton) the national code, order no., and the quantity should be printed and on inside pack and small

Pharmaceutical unit (ampoule or bottle or sheet) on good the mark of (MOH-Iraq) , beneficiary name and shelf life(MF&Exp. Date) and to print (Batch no.) on all inside and outside packs as well as the smallest pharmaceutical unit.

-Pallets should be with the following dimension in order to facilitate the process of receiving and storage of the arrived shipments.

\*Length 1200 M.M

\*Width 1000 M.M

\*Height 1000 M.M (Including the height of pallet based(

\*The weight of each pallet should be not more than 800 kilos

-All materials must be shipped in a cool condition and for all transporting ways till it reaches MOH/Kimadia stores.

The seller will be responsible for the compensation of any material which fails in the analysis because of the unsuitable temperature degree during the transportation

GCC 11.1 &  
11.3

{ **Sampleprovision (CIF/CIP/DDP terms)**

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

In addition to what mentioned, the following are added:

-All shipments should be attached with commercial shipping lists packing lists and a true authenticated copy of certificate of origin.

-The supplier should submit the shipping documents before the arrival of the consignment within a period not less than 15 days and be responsible for any shortage or any delay caused by the lack of shipping documents.

-Delivery shall be as soon as possible within the period of credit validity and the shipping schedule shall be as required of Kimadia

-Receiving the supplied items upon their arrival to MOH/ Kimadia stores and the insurance of it (CIP) and not to be free from this obligation till organizing a formal minute of finishing in the place of delivery agreed upon.

-The contract should be supplied with a limited number of lots and the quantity of each lot should mentioned in the shipping list along with

the manufacturing and expiry date.

GCC 15 “15.1 All goods must be of fresh manufacture and must bear the manufacture and expiry dates. The Supplier further warrants that all Goods supplied under this Contract unless otherwise specified by the contract , will have remaining a minimum of five-sixths (5/6) of the specified shelf life upon arrival to KIMADIA stores for goods with a shelf life of more than two years and the items with a shelf life of two years not more than 3 months (maximum) passed upon their manufacturing; otherwise a financial penalty will be imposed according to the ratios mentioned in paragraph GCC22.

15.2 The Purchaser shall have the right to make claims under the above warranty for three months after the Goods have been delivered to the final destination indicated in the Contract. Upon receipt of a written notice from the Purchaser, the Supplier shall, with all reasonable speed, replace the defective Goods without cost to the Purchaser. The Supplier will be entitled to remove, at his own risk and cost, the defective Goods once the replacement Goods have been delivered.

15.3 Not applicable (In the event of a dispute by the Supplier, a counter analysis will be carried out on the manufacturer’s retained samples by an independent neutral laboratory agreed by both the Purchaser and the Supplier. If the counter analysis confirms the defect, the cost of such analysis will be borne by the Supplier as well as the replacement and disposal of the defective goods. In the event of the independent analysis confirming the quality of the product, the Purchaser will meet all costs for such analysis.)

15.4 If, after being notified that the defect has been confirmed pursuant to GCC Sub-Clause 15.2 above, the Supplier fails to replace the defective Goods within the period for the replacement of defective goods of [insert **period for replacement of defective goods**], the Purchaser may proceed to take such remedial action as may be necessary, including removal and disposal, at the Supplier’s risk and expense and without prejudice to any other rights that the Purchaser may have against the Supplier under the Contract. The Purchaser will also be entitled to claim for storage in respect of the defective Goods for the period following notification and deduct the sum from payments due to the

Supplier under this Contract.

15.5 Recalls. In the event any of the Goods are recalled, the Supplier shall notify the Purchaser within fourteen (14) days, providing full details of the reason for the recall and promptly replace, at its own cost, the items covered by the recall with Goods that fully meet the requirements of the Technical Specification and arrange for collection or destruction of any defective Goods. If the Supplier fails to fulfill its recall obligation promptly, the Purchaser will, at the Supplier's expense, carry out the recall.”}

-In case the item failed in the analysis of the national center for medicine control & research or any specialized party, the administrative charges will be added as equal to 15% from the total value of failed item with a delay fine in case the company will not ship the compensation item within the agreed period in the contract and with the agreed percentage.

- The supplier has to compensate the exp. QTY which are not used in stores of MOH and Kimadia stores at ratio 100% of the total QTY of exp. items.

-The seller should compensate the items failed in the analysis and the exp.. For technical reasons to the supplier at ratio 100% with 15% administrative charges from the total QTY of exp. items and impose a delay penalty in case not shipping the compensation QTY with same period and ratio which agreed upon in contract.

-The second party has to ensure the hidden defects or any failure in the product in duration parallel to shelf life of the product concerning the products subject for shelf life the and the products that do not subject for shelf life, the 2nd party has to ensure above defects for five years starting

from the date of receiving tests results.

-in case the company does not ship the compensation products within the same agreed period in the contract starting from the date of notifying him . The calculation of the shipping period per 2nd shipment will be started after the arrival of the compensated shipment if the contract was multiple shipments otherwise a delay penalty will be imposed according to the ratio that mentioned on the agreed penalties articles and in case the company has not compensate within the mentioned period, kimadia has the right to buy the products from another

source on contractor expense and making him bear the difference in price and confiscate all insurance. In addition, it has the right to go to the concerned court in order to obtain its rights

-The seller is responsible to compensate the buyer for the defected items or shortage that appear after the distribution, usage of goods in the hospital and after the necessary checking and analysis and if it is due to a manufacturing defect.

-the seller should compensate the damaged , failed in analysis, missing, shortage items, and the items which not comply with specification required within delivery period stated in contract provided that the period starts from the date of notifying the company about the fail or shortage or missing taken into consideration that the period must be within the period of execution the contract and the other shipments must be shipped within the same shipping schedule from the date of shipping the compensation QTY otherwise the delay penalty will be imposed at the same percentage stated in penalties terms which agreed upon in case the company does not compensate within mentioned period, kimadia has the right to buy the products from another source on contractor expense and making him bear the difference in price and confiscate all insurance.

In addition, it has the right to go to the concerned court in order to obtain its rights.

-The seller must stamp the phrase (failed and not fit to consumption MOH-KIMADIA) on the failure qty. or not compliance to specification in MOH/ Kimadia stores on. The supplier shall bear all the expenses.

Any item or quantity that fails in analysis of the national center for medicine control & research is to be compensated by the manufacturer.

In case the item failed in the analysis or have been expired and the company does not respond for compensation within 30 days after sending a warning letter including the compensation & draw the failed or expired item, kimadia has the right to destroy the failed or expired items & dropping the right of the company for getting back the item or its value.

GCC16 {Sample provision:

.1 The method and conditions of payment to be made to the Supplier under this Contract shall be as follows:

{In case the Supplier is a Public Entity (Public Sector Company), do not apply then the Contracting Entity may increase the Advance

Payment to x% from the value of contract.and according to instructions }

**A. Payment for Goods supplied from abroad:**

Payment of foreign currency portion shall be made in [ USD and ID]in special exception cases in the following manner:

- (1) **Advance Payment:**( not applied) section VIII
- (2) **On Shipment:**the purchaser should pay to the supplier according to percent of the Contract Price of the Goods shipped shall be paid through irrevocable confirmed letter of credit opened in favor of the Supplier in a bank in its country, upon submission of documents specified in GCC Clause 11 . Opening charges and charges for amendment of the letter of credit at the request of or due to a fault or default of the Purchaser are for the account of the Purchaser. Confirmation charges and charges for amendment to letters of credit at the request of or due to a fault or default on behalf of the Supplier are for the account of the Supplier.

- Payment terms:

- .50% upon submitting shipping documents.

- 50% after the arrival of materials to the warehouses of kimadia and acceptance.

and release award

shall be paid within [thirty (30)] days of receipt of the Goods upon submission of an invoice (showing Purchaser's name; the Contract number, description of payment and total amount, signed in original, stamped or sealed with the company stamp/seal) supported by the Acceptance Certificate issued by the Purchaser.

**The supplier must submit health certificates for all goods and crews working on board of ship or airplane certified that they are free from corona virus issued from the country of shipment before requesting the opening of letter of credit**

B. Payment for Goods and Services supplied from within the Iraq: Payment for Goods and Services supplied from within Iraq shall be made in Iraqi Dinar, as follows upon receiving the financial allocation:

1 -It is 100% after examination and acceptance and after financial allocation has been recieved

2-the conditions which are mentioned above will be agreed on by the two parties as per kind of item & contract amount.

**GCC16.** The payment or payments will be settled as soon as possible after receiving the result of the laboratory tests according

3 to the conditions of the announcement

GCC18 18.2 the contracting entity may increase the quantity of goods or materials or non-consulting services or amend its technical specifications which contracted upon by not more than 20% of the contract amount .

GCC19 19.1 - In addition to what have been mentioned in the general conditions of the contract, the following are added:  
any change is not allowed in contract by the supplier unless there is an agreement between the two parties otherwise the 2nd party considered a breach of his contractual commitments and kimadia has the right to take the legal procedures or impose penalty A contractual fine (1-5%) of the contract value if the contract consists of one shipment, and a contract fine (1-10%) of the contract value if the contract includes more than one shipment.

GCC **-can not be waived of contract or apart of it**

20.1

**The -second party has no right to relinquish the contract or transfer it to another person, whatever the reasons.**

GCC21

21.2in addition to what mentioned in the general conditions of contract ,

the following reasons should be taken into consideration upon extension the contract:

First:

A. If any increase or change occurred in The required supplying quantity(qualitative, quantitative) which may effect the executing program which has been agreed upon as it can not be fulfilled within the agreed period in the original contract.

B. If the delay of executing the contract related to reasons or procedures of the contracting party or any authorized legal party or to any reason of other contactors which the company owner used.

C.If an exceptionable condition have occurred after contracting which is out of contractors control and which can't be avoided or expected upon contracting and which caused a delay in completing the works or supplying the required items according to the contract.

Second:

The application of the provisions of this article stipulated that the supplier should submit a written request for contracting party within 20 days a job started from the date of the cause arising which accordingly the extend has been requested indicating in it the accurate and

complete details for any request to extend the period, Any request for extension will not be accepted if presented after issuing the primary receiving certificate mentioned in the contract conditions

GCC22

22.1 First: contract penalties:

1- KIMADIA has the right to impose penltylegal procedures or impose penalty A contractual fine (1-5%) of the contract value if the contract consists of one shipment, and a contract fine (1-10%) of the contract value if the contract includes more than one shipment.cases of :

a-Any change in the contract by the supplier without the consent of the first party as mentioned in paragraph GCC 19.1

b-In case of any shourtage in any document required from the supplier

c-In case of contrary to paragraph 15.1 regarding to life of material

d-In case of contrary to paragraph GCC10 regarding to packaging .

e- In case of contravention by the supplier (second party) need to impose penalty from the first party

second: Delay penalties

a- delivery of the materials according to the scheduling of shipping and delivery mentioned in the paragraph of delivery and shipping and

Otherwise, the deduction of the delay fine shall be fixed at 25% as a maximum in contracts

otherwise impose a delay day without prior notice and according to the following equation:



1- If the contract is for one shipment, the equation is as follows:

One-day fine = Contract amount +/- Any change in contract amount / Contract duration +/- Any change in duration X25%.

2- If the contract has more than one shipment, the equation is as follows

: One-day fine = shipment amount / shipment period x 25%

After the delay penalty reaches its maximum , legal actions can be used according to articles 10,3 from the instructions of implementing the governmental contracts no.(2) year 2014

b-The delay penalty shall be deducted upon expiry of the original contract period with any additional period or upon desert in case of partialshipment

c- Penalties are reduced according to the completion rates of the contractual obligation specified in the text of implementing the contracts which has a certificate of first delivery according to the following equation :-

The value of not implemented commitment /total duration of contract X

25% =fine per day

-When the contracted company hide any essential information which will be discovered later on , legal procedures will be taken or imposing a penalty at rate not less than 1% and not more than 5% of the quantity shipped for the arrived material and violated of our contractual conditions.

**GCC23** 23.1 In addition to what is stated in this item of the general condition: In case the supplier does not respond during the warning period and through the approved email which is written down in the contract the legal procedures shall be taken in accordance with the provisions of article 10 of the instruction of implementing the governmental contractno.2 in 2014 with respect to the confiscation or retention of legal insurance provided that the contract is executed on his expense according to the conditions of article 3 of the above instruction and according to the methods of implementation

**GCC24** In the event of the company's bankruptcy, the paragraphs mentioned shall be based on the conditions mentioned in paragraph 24 of the general conditions of the contract

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 Arbitration Rules 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.”]

**GCC27. for contracts with Supplier national of Iraq:**

**2.2** “In the case of a dispute between the Purchaser and a Supplier who is a national of Iraq, the dispute shall be referred to conciliation or arbitration in accordance with the laws of the Iraqi Laws and guardianship of the Iraqi judicial system and according to adopted procedures.”]

-Any amount in the second party account which resulted from breaching any contractual commitment the first party has the right to claim the amount in the specialized court as well as the confiscation in case the requirements have been achieved

- In case of the bidder has not complied with executing the conformed order and according to the agreed conditions a legal procedure will be taken against him.

**GCC28 Deleted**

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 ]

GCC31. Kimadia email is: dg@kimadia.iq

1

Insert :the supplier's address for the purpose of notifying and if by cable is acceptable provided that it should be followed by a written letter

-The scientific bureau which represents the company and authorized representative of the company ( Trade manager, manager...etc) is the one to which the Judicial notifications will be sent.

-email is considered one of the approved methods of directing warning

**-Instructions for the implementation of government contracts No.2 of 2014 and the controls attached to it is an integral part of the contract.**

GCC32

Any right arising from the first party shall be obtained under the Government Debt Collection Law No. 56 of 1977

-The Contract is subject to Iraqi laws including laws of tax No. 113 for the year 1982 ,instruction of accounting tax of contracts between Iraqi contracting entry with foreign parties N02 for the year 2008 , the stamp fee N071 for the year 2012 , Notary fees and re-announcement charges. 1- Earning an amount of (100) one hundred thousand Iraqi Dinars upon request for exchanging the border outlet.

2- Earning an amount of ( 25) twenty five thousand Iraqi Dinars for each unloaded and loading receipt for each shipment that arrived to the target store

Earning an amount of (10) ten thousand Iraqi Dinars for parking and parking overnight for the trucks that specified for transporting the drug and appliances to the stores of kimadia/Ministry of Health.

Earning an amount of (250) two hundred&fifty thousand Iraqi Dinars for each objection request presented by the Scientific Bureau or company for any Importing status.

- All bank charges (opening, issuing for L/C and amendments fees ...etc) inside and outside Iraq are on the seller

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expenses till reaching the company stores

The awarded company bears (the 2nd part that contracted with our company ) all customs fees.

-The amount of selling the form & disk (cd) of National Board For Selection Of The Drugs/NBSD is paid for (50) fifty thousand dinars for National Master List Of Drugs .

- The amount of selling the form & disk (cd) of National Board For Selection Of The Drugs/NBSD is paid for (50) fifty thousand dinars for List Essential Drugs Products .

-Interpolation amount for the first announcement charges & re-announcement

-The inclusion of the Internet system in the contracts of supplying Thalassima drugs in order to organize the work.

Submitting a stamp fee of 0.003 of the contract value

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

GCC 11.1 & 11.3

**For Goods supplied from abroad:**

- (1) One original of the Certificate of Pharmaceutical Product as recommended by the WHO for each of the items supplied.
- (2) Certificate of quality control test results in conformity with the World Health Organization “Certification Scheme on the Quality of Pharmaceutical Products Moving in International Trade” stating quantitative assays, chemical analysis, sterility, pyrogen content, uniformity, microbial limit, and other tests as appropriate to the Goods.
- (3) Original copy of the certificate of weight issued by the port authority/licensed authority and six copies.

**Special Conditions of Contract**

**VACCINES**

(Additional Clauses)

GCC 11.1 & 11.3

**For Goods supplied from abroad:**

- (9) one copy of the Lot Release Certificate issued by the NCA of the country of manufacture for each lot shipped.
- (10) Certificate of quality control test results in conformity with the World Health Organization “Certification Scheme on the Quality of Pharmaceutical Products Moving in International Trade” stating quantitative assays, chemical analysis, sterility, pyrogen content, uniformity, microbial limit, and other tests as appropriate to the Goods.
- (11) Original copy of the certificate of weight issued by the port authority/licensed authority and six copies.

**For Goods from within the Purchaser’s country:**

- (x) one copy of the Lot Release Certificate issued by the NCA of the country of manufacture for each lot shipped.

GCC 15.1

**[Sample clauses:**

The Purchaser reserves the right to request evidence of bio-availability and/or bio-equivalence data and/or evidence of the basis for expiration dating and other stability data concerning the Goods to verify shelf life claimed for the Goods.

If an adverse event following immunization (AEFI) occurs in the Purchaser’s country and the cause of such event cannot be immediately established, the Purchaser will, with all urgency and in accordance with the procedures laid down by the NCA of the Purchaser’s country, take steps to adv

ise the Supplier in order that an investigation may be launched immediately. If the vaccine has been supplied through an agency of the United Nations, the most current procedures laid down by the WHO for such situations will be used.]

**The awarded company bears (the 2<sup>nd</sup> part that contracted with our company ) all customs fees.**

1. Form of Contract Agreement

THIS CONTRACT AGREEMENT is made

the [insert: **number**] day of [insert: **month**], [insert: **year**].

BETWEEN

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

(2) [insert: **name of Supplier**], a corporation incorporated under the laws of [insert: **country of Supplier**] and having its principal place of business at [insert: **address of Supplier**] (hereinafter called "the Supplier").

WHEREAS the Purchaser invited bids for certain (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. PERFORMANCE SECURITY BANK GUARANTEE

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

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

**Beneficiary:** \_\_\_\_\_ [insert: **Name and Address of Purchaser**]

**Date:** \_\_\_\_\_

**PERFORMANCE GUARANTEE No.:** \_\_\_\_\_

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

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

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

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

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

\_\_\_\_\_  
[signature(s)]



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

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

**Beneficiary:** \_\_\_\_\_ [insert: **Name and Address of Purchaser**]

**Date:** \_\_\_\_\_

**ADVANCE PAYMENT GUARANTEE No.:** \_\_\_\_\_

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

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

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

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

This guarantee shall expire, at the latest, upon our receipt of copy (ies) of \_\_\_\_\_<sup>1</sup>, or on the \_\_\_ day of \_\_\_\_\_, 2\_\_\_\_,<sup>2</sup> whichever is earlier. Consequently, any demand for payment under this guarantee must be received by us at this office on or before that date.

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

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

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

[Signature]

**(2) Letter of Acceptance Form**

{leterhead paper of the Emplier}

[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:.....