

وزارة الصحة الاتحادية
الصندوق القومي للإمدادات الطبية
الإدارة العامة للشراء والتعاقد



عطاء لتوريد أدوية ومستهلكات خاصة بأمراض وجراحة الكلي لجميع المؤسسات
والجهات الحكومية بجميع ولايات السودان

عطاء رقم 2019/07

تاريخ قفل الصندوق يوم الأربعاء الموافق 2019/10/23م

بيانات مقدم العطاء:	
	اسم الشركة
	عدد الأصناف المقدمة في الكراسة
	إجمالي مبلغ الأصناف المقدمة في الكراسة بالجنيه السوداني
	قيمة التأمين المبدئي للعطاء وتعادل 2% من القيمة الكلية
	اعتماد الشخص المسؤول بالشركة
	ختم الشركة

قائمة تحقق مستندات الشروط العامة:

نرجو شاكرين التأكد من أن مستندات الشروط العامة قد وضعت في المظروف ووضع علامة √ تحت عمود نعم في حالة وضع المستند في المظروف ووضع علامة X تحت عمود لا في حالة عدم وضع المستند في المظروف:

الرقم	المستند	الاعتماد	
		نعم	لا
1	إستيفاء الدمغة القانونية		
2	إستيفاء التأمين المبدئي 2% من قيمة العطاء		
3	شهادة خلو طرف من الضرائب أو إفادة بالإعفاء منها		
4	شهادة إبراء ذمة من الزكاة سارية المفعول أو إفادة بالإعفاء منها		
5	شهادة تسجيل القيمة المضافة أو إفادة بالإعفاء منها		
6	صورة من الرقم التعريفي الضريبي الموحد		
7	صورة من رخصة الشركة مجددة للعام 2019		
8	احضار صورة من شهادة تأسيس الشركة أو تسجيل اسم العمل صادرة من المسجل التجاري وزارة العدل		
9	شهادة مقدرة مالية		
10	شهادة مقدرة فنية		

تنويه:

1. التأمين المبدئي وهو ما يعادل نسبة 2% من أعلى قيمة مقدمة لعروض الشركة ويجب معادلتها بالجنيه السوداني حسب سعر اليورو الرسمي المعلن من بنك السودان.
2. ستتم مراجعة المستندات في حضور ممثلي الشركات.

وزارة الصحة الاتحادية

الصندوق القومي للإمدادات الطبية

اعلان عطاء عام لتوريد أدوية ومستهلكات خاصة بامراض وجراحة الكلي لجميع

المؤسسات والجهات الحكومية بجميع ولايات السودان

عطاء رقم 2019/07

يدعو السيد المدير العام للصندوق القومي للإمدادات الطبية رئيس لجنة الشراء الموحد السادة شركات الأدوية والمستلزمات الطبية لتقديم لعطاء الصندوق المفتوح والذي سيتم التقديم له إلكترونياً اعتباراً من 2019/09/29 و ذلك لتوريد أدوية و مستهلكات غسيل خاصة بامراض و جراحة الكلي حسب الكميات والمواصفات والشروط المرفقة مع كراسة العطاء وذلك وفق الخطوات التالية:

على الراغبين في المشاركة في هذا العطاء الإلتزام بالآتي:

1. يُقدم طلب الحصول على كراسة الشروط في ورق مروس باسم الشركة المقدمة للعطاء ومختوماً بختمها العام.
2. ملء الاستمارة الخاصة بذلك.
3. تُستلم كراسة الشروط من مكتب سكرتارية مدير الإدارة العامة للشراء والتعاقد يومياً خلال ساعات العمل الرسمية طوال فترة إعلان العطاء.
4. مبلغ الكراسة (10,000) جنيه سوداني نقداً أو بشيك مصرفي لا ترد.
5. تُعطى الشركة المشاركة في العطاء رمز الدخول وكلمة المرور ودليل استخدام نظام الشراء الإلكتروني مباشرة بعد إبراز المستند المالي.
6. احضار شهادة مقدرة مالية.
7. احضار شهادة مقدرة فنية (ما يفيد بتوظيف الشركة لكوادر مؤهلة ومخازن مهيئة وعربات نقل مبردة).
8. احضار شهادة خلو طرف من الضرائب أو إفادة بالإعفاء منها.
9. احضار شهادة إبراء ذمة من الزكاة سارية المفعول أو إفادة بالإعفاء منها.
10. احضار شهادة تسجيل القيمة المضافة أو إفادة بالإعفاء منها.
11. احضار الرقم التعريفي الضريبي الموحد.
12. احضار صورة من شهادة تأسيس الشركة أو تسجيل اسم العمل صادرة من المسجل التجاري وزارة العدل.

13. استيفاء الدمغة القانونية.
14. صورة من رخصة الشركة صادرة من المجلس القومي للأدوية والسموم ومجددة للعام 2019.
15. تُقدم النسخة الأصلية لمستندات العطاء (لا تشمل العروض المالية) في مظلوف محكم الإغلاق ومختوم بالشمع الأحمر ويوضع داخل صندوق العطاءات المعد لذلك في قاعة العطاءات بالصندوق المبني الشمالي - الطابق الأرضي المبني B.
16. أي شركة لم تقدم عرضها إلكترونياً تُستبعد من المنافسة.
17. دفع مبلغ 2% من قيمة العطاء كتأمين مبدئي يقدم بخطاب ضمان مصرفي معتمد من بنك محلي أو شريك معتمد باسم مدير عام الصندوق القومي للإمدادات الطبية أو خطاب ضمان من إحدى شركات التأمين أو نقداً تكمل لـ 10% لمن يرسو عليه العطاء، على أن تكون سارية المفعول لمدة 6 أشهر، قابلة للتجديد وترد لمن لا يرسو عليه العطاء.
18. تُقدم الأسعار باليورو وتشمل تسليم الأصناف ميناء الوصول (مطار الخرطوم أو ميناء بورتسودان).
19. الأسعار المقدمة يجب أن تكون نهائية و سارية طيلة فترة العطاء ولايجوز تعديلها او تجاوزها الا وفقاً للقانون.
20. آخر موعد لاستلام مظلوف العطاء (المستندات المطلوبة) يوم الأربعاء الموافق 2019/10/23 الساعة 12 ظهراً.
21. تُسلم مستندات الجودة (شهادات تسجيل المصنع والأصناف الصادرة من المجلس القومي للأدوية والسموم) مباشرة لإدارة تأكيد الجودة مع العينات.
22. الأصناف المسجلة يتم احضار Sample artworks لها بدلا عن العينات مع الالتزام بالعينات المسجلة بالمجلس القومي للأدوية و السموم عند التوريد، اما في حالة الأصناف الغير مسجلة يجب تسليم العينات لإدارة تأكيد الجودة بالصندوق في موعد اقصاه 2019/10/23 و في حالة العجز يتم احضار ال Sample artworks للأصناف التي لم يتم تسليم عينات لها علي ان تُسلم العينة الفعلية في موعد اقصاه 2019/10/30.
23. آخر موعد لاستلام العينات أو ال Sample artworks ومستندات الجودة يوم الأربعاء الموافق 2019/10/23 الساعة 12 ظهراً.
24. تُسلم المستندات المطلوبة بالصندوق المعد لذلك بقاعة العطاءات بالصندوق المبني الشمالي - الطابق الأرضي المبني B.
25. لن ينظر في أي عطاء يصل بعد الزمن المحدد مهما كانت المبررات (نظام الشراء الإلكتروني يُغلق تلقائياً عند الساعة الثانية عشر ظهراً يوم الأربعاء الموافق 2019/10/23).

26. ستفتح المظاريف والتي تشمل مستندات العطاء للشروط العامة (لا تشمل العرض المالي) في حضور ممثلي الشركات المقدمة للعطاء بعد قفل الصندوق مباشرة.
27. سيتم استعراض العروض إلكترونياً في حضور ممثلي الشركات يوم الأربعاء الموافق 2019/10/23 الساعة 12 ظهراً.
28. لمدير الصندوق الحق في إنقاص الكميات المطروحة بنسبة أقصاها 20% أو زيادتها بنسبة أقصاها 50%.
29. مدة العقد عامين قابلة للتجديد بموافقة الطرفين.
30. الكميات المعلنة لعامين.
31. الشركات التي تتم عليها الترسية النهائية عليها احضار رخصة مزاولة عمل وكيل تجاري و شهادة الوكالة (وكيل حصري او موزع معتمد) صادرة من مراقب الوكلاء التجاريين – المسجل التجاري بوزارة العدل، في مرحلة توقيع العقد.
32. في حالة عدم رغبة الطرف الثاني (الشركة المورد) في التمديد لفترة ثانية يجب عليه إخطار الطرف الأول (الصندوق القومي للإمدادات الطبية) قبل ثلاثة أشهر على الأقل من إنتهاء العقد المبرم بين الطرفين .
33. مدير عام الصندوق غير ملزم بقبول أدنى عطاء أو أي عطاء آخر.
34. للإستفسار أثناء ساعات العمل الرسمية يُرجى الإتصال ب: 0120391175 أو البريد الإلكتروني: tenderqueries@nmsf.gov.sd
35. لمزيد من المعلومات يرجى الرجوع لموقع الصندوق: www.nmsf.gov.sd
- تنويه: على الراغبين في المشاركة في العطاء التسجيل في نظام الشراء الإلكتروني بالصندوق قبل إستلام الكراسة، يمكن التسجيل عبر موقع الصندوق الموضح أعلاه أو الحضور لمكتب سكرتارية الإدارة العامة للشراء والتعاقد بمباني الصندوق خلال ساعات العمل الرسمية.

د. شهاب الدين علي صديق

ع/مدير عام الصندوق القومي للإمدادات الطبية

Republic of Sudan

National Medical Supplies Fund

P.O. Box: 297 Khartoum – Postal Code: 11111

Web site: www.nmsf.gov.sd

E-mail: tenderqueries@nmsf.gov.sd

Fax: +249-1-83-460935



Open Tender for Supply of Medicines and Consumables for Dialysis and Transplantation

2019 - 2021

NMSF Invitation To Bid - ITB No. (NMSF 07/2019)

For Supply of Medicines and Consumables for Kidney Dialysis and Transplantation

Opening Date 29/09/2019

Closing date Wednesday 23/10/2019

The National Medical Supplies Fund, hereafter referred to as NMSF, is pleased to announce the above mentioned Tender and hereby invites eligible bidders to bid for the supply of items in this Tender according to the following rules and conditions:

1. Bid Preparation and Submission:

1.1. All pharmaceutical products and their manufacturers should be registered in the National Medicines & Poisons Board (NMPB). In case of unregistered products the manufacturer must be registered in NMPB and/or the product documents have been submitted to NMPB (i.e. under process). All necessary documents should be submitted to prove the registration of medicines maximum three months after award.

1.2. The local agent must submit the following:

1.2.1. Certificate of company registration from the General Commercial Registrar of Companies, Ministry of Justice.

1.2.2. Free tax certificate or exemption from it.

1.2.3. Free Zakat certificate or exemption from it.

1.2.4. Appropriate stamp duty is fixed on the bid.

1.2.5. Value Added Tax Certificate (VAT) or exemption from it.

1.2.6. Please send artwork for all items with different concentrations in case of registered samples (the registered sample will be the reference one for delivery of goods). For unregistered items at least three non–returnable samples, including different concentrations for the single item shall be delivered through the company’s local agent during or before the closing date of the Tender. Each sample must be labeled with item code, serial number and the name of the local agent.

1.2.7. The bidder must mention the registration number for each item, and attach the relevant registration certificate.

1.2.8. A list indicating all details of submitted samples shall be attached (2 copies requested) **(Appendix 1)**.

1.2.9. The Dialysis kits must be supplied according to specification stated in (Appendix 2 & 3).

1.2.10. Acid concentrate formula approved by dialysis centers stated in (Appendix 4).

- 1.3.** The bidder shall bear all costs associated with the preparation and submission of his bid, and the NMSF will in no case be responsible or liable for those cost regardless of the conduct or outcome of the bidding process.
- 1.4.** Original bids documents must be submitted in a duly sealed envelope and labeled with the sticker.
- 1.5.** Bids must be submitted electronically, user name and password will be given to the local agent after declaration receipt issued voucher proving purchase of the Tender documents. **Non-conforming bids will not be considered and the electronically document will be the officially recognized document.**
- 1.6.** Receipt issued proving purchase of the Tender documents, should be attached with your bid.
- 1.7.** NMSF reserves the right to modify the submitted quantity of any item by increasing it up to 50% or decreasing it up to 20%, before the award notification, or to cancel any item without giving reasons. The bidder shall comply with this accordingly.
- 1.8.** The price of awarded item/s must remain valid for two years from date of signing the contract.
- 1.9.** If there is any difference in specifications or remarks regarding the general or technical terms of the Tender, the bidder must mention that on the remarks column in red ink. However, NMSF has the right to accept or reject such remarks without giving reasons.

- 1.10.** The quotation shall include all information regarding the item such as: manufacture name, country of origin, delivery details, dosage form, shelf life, pack size, strength or concentration, batch size, registration documents, and so on.
- 1.11.** Bids must be submitted electronically. The company should submit the related requirements in a sealed envelopes in the tender box at NMSF Reception, Khartoum South not later than 12 pm on Wednesday 23/10/2019
- 1.12.** No bid will be accepted after 12.00 pm of the closing date on Wednesday 23/10/2019
- 1.13.** The outer envelopes shall indicate the name and address of the bidder to enable the bid to be returned unopened in case it is declared “late”.
- 1.14.** If the outer envelope is not sealed and marked as required by paragraph (1.13) the NMSF will assume no responsibility for the bid misplacement or premature opening.
- 1.15.** Agents (are preferred with letter of authorization) shall be invited to witness the bid opening on Wednesday 23/10/2019at 12:00 pm.
- 1.16.** The applicable laws under which the contracts shall operate are the laws of the Republic of Sudan.
- 1.17.** A complete set of bidding documents may be purchased by the interested eligible local agent on submission of a written request to the General Procurement Directorate and upon payment of non-refundable fees of **SDG 10,000 (Ten thousand SDG only)**.
- 1.18.** The local agent has full responsibility with regard to all claims that may be raised.
- 1.19. Amendment of the bidding document:**
- 1.19.1.** At any time before the dead time for submission of bids, the NMSF may, for any reason, whether at its own initiative or in response to clarification requested by a prospective bidder, modify the bidding document by amendment.
- 1.19.2.** The amendment will be notified officially and submitted by hand, fax or e-mail to all prospective bidders, who have received the bidding documents.
- 1.19.3.** In order to afford prospective bidders reasonable time to take the amendment into account in the preparation of their bids, NMSF may at its discretion, extend the deadline for the submission of bids.
- 1.20.** NMSF reserves the right to accept or reject all bids and to annul the bidding process at any time prior to the award of contract without any liability to the affected bidders or any obligation to inform the affected bidders of the ground of the NMSF action.

- 1.21.** The notification of award will constitute the formation of the contract.
- 1.22.** Within 15 days of the receipt of the contract form, the successful bidder shall sign and date the contract and return it to the NMSF.
- 1.23.** Failure of the successful bidder to comply with the requirement of clause 1.22 shall constitute sufficient grounds for the annulment of the award and for forfeiture of the bid guarantee.
- 1.24.** No variation in or modification on the contract shall be made after signature by the concerned parties, only by the acceptance of the two parties.
- 1.25.** The payment can be carried out exceptionally to the local agent by account in Euro through Central Bank of Sudan (CBOS) or as agreed between NMSF and agent. The agent must notify NMSF about goods arrival date and submitting the original shipping documents at least five working days before estimated arrival date In case of air delivery and 20 working days in sea delivery.
- 1.26.** If the CBOS could not transfer the hard currency to the local agent account, NMSF will take responsibility of bank transactions. The supplier immediately on shipment dispatch of the contracted item/s, must advice NMSF by e-mail, fax, or hand the following details before five working days in air delivery and 20 working days in sea delivery of estimated arrival date:
- 1.26.1.** Packing list clearly written with full information and with details of quantities of each batch.
- In addition to:
- a.** Cartons should be numbered serially.
 - b.** If there is a completion quantity it should be mentioned clearly in the carton which contains that quantity and stated in the packing list with the serial number of carton.
 - c.** In case the working standard (not less than 3 gm with validity for at least one year) is shipped with the goods that should be mentioned clearly in the packing list the serial number of carton which contains the working standard.
- 1.26.2.** Commercial invoice signed and stamped in full details, items names must be written in generic names with full specifications (Trade names can be put between two brackets).
- 1.26.3** Certificate of origin certified as true and correct from the national Chamber of Commerce of the country of origin.
- 1.26.4** Certificate of analysis for each batch.
- 1.26.5** Air way bill or Way Bill of lading according to the mode of delivery in the award.
- 1.26.6.** Expected time of arrival.

- 1.27.** When NMSF take responsibility of bank transaction; clear instructions should be given for the shipper to clear the goods by a copy of the documents and:
- a.** Bank guarantee will be issued against this and the instruction of release should be submitted before at least 20 working days of goods arrival to Port Sudan; any delay to present the documents in time, the fees of the demurrage would be paid by the local agent.
 - b.** The supplier is responsible for providing the NMSF with all documents necessary for taking possession of supplies and clearing them. The supplier shall be held responsible for any expenses or losses incurred by incorrect, incomplete, or late provision of documents. The NMSF has the right to withhold payments and/ or cancel any outstanding transaction in the event of supplier default.
 - c.** Tracking No with details should be submitted immediately after submission of the document to the bank.
- 1.27.1.** An unexcused delay by the supplier in the performance of his obligations shall render the supplier liable to any or all the following sanctions:
- a.** Forfeiture of its performance guarantee.
 - b.** Imposition of liquidated damages.
- 1.28.** All Tender documents are part of the contract agreement.
- 1.29.** The General Director of NMSF is not bound to accept the lowest or any other bid.

2. Prices:

QUOTATION SHOULD BE SUBMITTED ON THE BASIS OF AWARDED PORT OF DESTINATION.

- 2.1.** Each company should quote CPT/ CFR Inco term 2010 price for each item.
- 2.2.** Unit price and total amount (i.e. unit price × quantity) are to be quoted against each item in (€) **only**.
- 2.3.** Unit price to be quoted for the specified smallest unit not more than four decimals (0.0000).
- 2.4.** If the total price does not coincide with the basic unit price multiplied by the quantity, the unit price will be only considered as the base of comparison with other offer for that item (i.e. any errors in calculating total amount will be ignored, and only the unit price is binding).

2.5. It is necessary to be clearly indicated that the prices offered do not include any custom duties, and the custom and any government charges will be balanced by NMSF with NMSF permissions.

3. Payment:

3.1. Payment will be by LC at sight issued by NMSF, or by deferred payment or as agreed between NMSF and local agent.

3.2. The payment can be carried out exceptionally to the local agent by account in Euro through Central Bank of Sudan (CBOS) or as agreed between NMSF and agent.

4. Bank Guarantee:

4.1. The covering letter should indicate the total amount of the bid as well as the value of the Bid Bond (Initial Bank Guarantee – IBG). This value must be according to the highest quoted price.

4.2. The bidder must submit a renewable Bid Bond (IBG) or certified cheque or Guarantee Letter from Insurance Company amounting to 2% of the total value of the highest bid; the Bid Bond must be issued by any Sudanese bank, valid at least for six months from the closing date (official CBOS rate value at the closing date)

4.3. The Bid Bonds (IBG) presented to this office after the closing date (Tender Deadline) will be neglected; and consequently, the company bid will be rejected.

4.4. Unsuccessful bidder's bids guarantee will be returned as promptly as possible.

4.5. Winner Company shall submit a Performance Bond (Final Bank Guarantee), certified cheque, or Guarantee Letter from Insurance Company amounting to 10% by SDG of the total value of each item awarded. The Performance Bond must be submitted individually within 30 days from the date of award, valid for 12 months, which shall be renewed automatically until final delivery and acceptance of goods and it will be returned to company after complete delivery.

4.6. A Performance Bond, which must be established in favor of NMSF, through a local bank in Sudan, shall be submitted, in order to release the Bid Bond (IBG).

4.7. The company is requested to clearly mention the highest total sum of quoted items in the covering letter.

5. Deposit on Acceptance of Tender:

The Supplier shall, within 15 days of the acceptance of his bid, furnish the NMSF with a guarantee from a local Bank for a sum equal to 10 % of the total money payable to the NMSF on due fulfillment of his agreement calculated on the tender or a declaration from a Bank showing that the supplier has deposited with such Bank or Treasury such a sum and that such a guarantee or sum is held by the Bank or Treasury at the disposal of the NMSF until such time as the supplier shall have completed his obligation to the satisfaction of the NMSF. Acceptance of a tender shall in all cases be conditional on receipt of the guarantee or declaration by the NMSF within the prescribed period. Such guarantee or declaration shall be in the form prescribed by the NMSF. The agreement hereby contemplated shall not be deemed to be operative unless and until such guarantee or declaration shall have been received by the NMSF and the NMSF shall have acknowledged receipt thereof in writing. Failure to deliver such guarantee or declaration within the prescribed time shall give the right to the NMSF to withdraw its acceptance of the tender.

6. General Conditions:

- 6.1.** While accepting any tender, the NMSF has the right to modify the submitted quantities by increasing up to 50% or decreasing it to 20%. In such a case the tenderer will have the right to refuse the acceptance of such increase or decrease.
- 6.2.** Particulars in the Tender Book must be filled clearly and with accuracy and any alteration or crossing must be initialed otherwise it will not be considered. Such particulars should be printed.
- 6.3.** The successful bidders must provide the NMSF, at the time of delivery, with a certificate confirming the compliance of the item with the quality and technical specifications.
- 6.4.** Any Certificate of Analysis so provided shall not bind the NMSF as to its contents. The item concerned will be subjected to analysis which will be carried out by the NMSF in the National Quality Control Laboratory and results of that analysis will be final and shall bind the NMSF and successful tenderer.
- 6.5.** The NMSF has the right to decide whether to accept substitutions of items in terms of money or in kind substitution when the item awarded fails to pass National Quality Control Laboratory test(s).

6.6. Tenderers must distinguish packages and labels of the item from those sold in the market by printing NMSF-Sudan, approved NMSF logo.

7. Quality, Specifications, Labeling and Samples:

The following specifications are required based upon requirements considered by the NMSF management, as supporting good pharmacy practice, clearance of goods, and in support of general medicines management and use.

7.1. Technical Conditions:

7.1.1. Goods to be supplied must be strictly in accordance with the original samples submitted with the bidder's offer that has been accepted by the NMSF.

7.1.2. If it is internationally or locally reported that a certain medicine has adverse reactions (i.e. unsafe to be used) or technical problems, the NMSF has the right to reject the remaining quantity of such medicines and to be refunded the amount if paid or to cancel it .

7.1.3. The shipping documents of each consignee must be accompanied with full specifications of the items, and an updated method of analysis, certificate of analysis for each batch, giving the full name and address of the manufacturing firm as well as the batch serial number of products and its conformity to all technical aspects.

7.1.4 Letters "NMSF-Sudan", approved NMSF logo and barcode must be printed on the outer and inner pack for each individual unit of the awarded items.

7.1.5. All labeling requirements that have been stated by NMPB policy for registration of pharmaceutical products 2010 should be followed strictly. Specifically the country of origin, the batch number and date of expiration, must be clearly printed on every individual container and on any package of the medicines. 5 copies of packing list must show batch numbers, expiry dates and dates of manufacture for the contents of each box or group of boxes as the case may be. The company should provide all necessary information, on the label of the inner pack, the outer pack of the items, export cartons and on the pro-forma invoices, full details of storage conditions, the manufacturer name and address, country of origin, batch number and manufacture & expiry dates of each product, trade and generic names, strength, carton full details of pack size and dosage forms.

7.1.6. Labeling of containers: The NMSF management is of the opinion that good pharmacy practice and the efficient use of medicines by clinic staff and the public will be promoted by using

Arabic as the language of instruction and directives on labels and documents. Please state in your QUOTATION whether you are in a position to provide documents and labeling of products and containers as indicated above. The containers (carton boxes) which are used to pack each medicines items for freight purposes must carry the following label, preferably in both English and Arabic: NMSF-Sudan and الإمدادات الطبية respectively.

7.1.7. The remaining shelf life should not be less than 75% for items with 2 years shelf life and not less than 2 years for items with shelf life more than 3years, when the item received in NMSF warehouses. Items with potency may be affected or which in any way could become unsuitable for their intended use if stored under local conditions, should be supplied from fresh stocks Companies should submit a certificate authenticated by the Health Authorities in the country of origin confirming that the blood used in the manufacturing of biological products are free from all contagious diseases that are transmitted through blood transfusions e.g. all types of hepatitis, HIV and Transmissible Spongiform Encephalopathy's agent (TSE). The donor has been away for six months from TSE infected countries.

7.1.8. The companies should mention in their offers in details, the product components if a Cow source is used, and the name of these components.

7.1.9. All medicines must be shipped in temperature controlled containers with USB data logger, according to the following:

- a. The container temperature should be not more than 30° C for the items that can be stored at room temperature.
- b. The storage conditions stated on the label should be adhered to during storage and transport for items that need special storage conditions.

7.1.10. The company should submit a bioequivalence study for one of its awarded items when needed from a research center recognized by NMPB.

7.1.11. Any documents required at any time for quality, safety and efficacy for any item/s must submitted upon request.

7.1.12. All official preparations must comply with the latest editions of the internationally known Pharmacopoeias that have been recognized by NMPB (i.e. BP, USP, EP, and Int. Pharm) in the registration policy of pharmaceutical products 2010.

7.1.13. Packs should contain a leaflet in Arabic or both Arabic and English languages giving all information of the supplied medicine. It should carry the same information as approved by NMPB.

7.1.14. The generic name should be more prominent than the trade name.

7.1.15. The company should import the lowest possible number of batches. Small number of batches (maximum number allowed is 5 batches per consignment) is preferable to minimize the quality control samples and cost of analysis.

7.1.16. Offers and supporting documents should be addressed to General Director of NMSF, in a sealed envelope to:

The Director General

National Medical Supplies Fund

Khartoum

Sudan

7.1.17. Biological and cold products must have certificate of analysis of finished product from manufacturer and must stick to their special requirements which stated by NMPB as mention in point 21, 22, and packed in insulated cartons with randomly packed USB data logger. The USB data logger must be digital with USB connector.

7.1.18. For biologicals and cold products the following requirement must be considered:

- a. Cold chain (USB Data Logger + temperature control material)
- b. Batch release certificate from National Medicine Regulatory Authorization (NMRA) of country of origin.
- c. Certificate of analysis of finished product from manufacturer.
- d. Complete Summary lot protocol according to WHO requirements
- e. When albumin is used as stabilizer, the following documents are required:
 1. Plasma quality certificate and its source.
 2. Batch release certificate of albumin from NRA of country of origin.
 3. Viral inactivation declaration
 4. Link between albumin batch and product batch.

7.1.19. For cold chain products stability budget from the manufacturer per item should be provided.

7.1.20. For blood product it must be offered from countries with Strong Medicine Regulatory Authority (SMRA) countries, and the following must be considered:

- a. Cold chain (USB Data Logger + temperature control material)
- b. Official Batch release certificate from NMRA of country of the origin.

- c. Certificate of analysis of finished product from manufacturer.
- d. Plasma quality certificate and its source.
- e. Batch release certificate of Plasma from NMRA of country of origin.
- f. Viral inactivation declaration.

7.1.21. Genetically modified biological and narrow therapeutic index products must be offered from originators or from Strong Regulatory Authority (SRA) countries and WHO listed authorities (**WLA**). The permission of NMPB is required for unregistered products.

7.1.22. Freeze watch indicator in addition to USB data logger should be packed with each carton of any products that can be affecting by freezing.

7.1.23. Climatic and other conditions, to which the goods are exposed during the course of transit and storage, call for the highest quality of packing and casing of supplies. Offers, therefore, must provide for such packing as specified in the Tender document. Alternative packing may be quoted for separately.

7.1.24. Each company shall specify the most safe and scientific way for item disposal (destruction). The recommended way of disposal must be universally accredited and innocuous to environment.

7.1.25. Working standard with minimum one year shelf-life and the quantity not less than 3g with certificate and method of analysis should be delivered with each item.

7.2. Quality Assurance:

7.2.1. According to the regulations of NMPB, all items should pass the **NATIONAL MEDICINES QUALITY CONTROL LABORATORY TESTS**. The Decision of the NMPB on the safety, efficacy, and quality of medicines and other pharmaceutical products and biological is final and is not subject to dispute or arguments.

7.2.2. Items, which fail to pass the Quality Control tests; supplier should either replace them by item/s accepted by NMSF or refund the NMSF. The supplier **MUST** inform the NMSF within not more than 15 working days about the option of substitution.

7.2.3. Names of original manufacturers and country of origin of the goods should be stated in the tender offer.

7.2.4. All labels must be in Arabic and/or English, permanently and firmly fixed and should bear the Tender name of the item or its international non-proprietary name if any.

7.2.5. Composition and dosage form must be shown on the label and enclosure in Arabic and/or English, and unless otherwise indicated by the NMSF in the Tender document, must be in metric measures.

7.2.6. A tenderer must also keep a sample of each item quoted for in the original container in case it is required for inspection. Such a sample should be delivered to the Director NMSF on request, free of charge within 72 hours of the receipt of such request. Failure to present any sample on request may lead to the rejection of that item.

7.2.7. Acceptance will be according to samples and artworks presented in the tender which should comply with the required specifications and description shown in the Tender offer against the item.

7.2.8. If the manufacturer has more rejected items and batches from the same manufacturing line all the items of this line will be rejected.

7.2.9. The suppliers of **preparations regarding immunity** shall ensure that these items are imported and delivered under ideal refrigeration conditions to avoid any loss of activity and potency. Storage conditions and date of expiry should be indicated on the label. These items should be imported by air freight from freshly manufactured stocks.

7.2.10. Fluids and Blood Plasma Substitutes should be stable on storage during shelf-life at the temperature stated in the label.

8. Delivery

8.1. Delivery of pharmaceutical products

Delivery of all ordered goods should be completed within 24 months from the date of signing the contract. Unless otherwise stated any remarks mentioned against each item and accepted by the NMSF, the order should be supplied in two equal shipments each of six month interval or as be scheduling by NMSF, except for those items which value of award is € 30,000 or less **considering shelf life**, or items to be asked to deliver to the central stores, can be supplied in one shipment to the central stores within four months from date of award (Deliveries should be made according to the delivery schedule attached with the award orders). If any custom duty or other governmental charges had been paid during clearance of goods an official receipt of that should be submitted to the NMSF. Delivery to be made at the NMSF' stores directly.

8.2. Delivery of Biological and other cold products

8.2.1. Clearance and Direct received should be made in the presence of NMSF staff.

8.2.2. All item requiring cool storage should be supplied by air with proper insulating packing ensuring products remains at temperature mentioned on the label.

8.2.3. Shipment should be scheduled to arrive on working days.

8.2.4. Shipment procedures for cold items, must be well arranged before shipping date. An e-mail, fax or hand message should be sent to the local agent as well as to NMSF General Directorate of Procurement indicating all shipping details (quantities, description of item/s, packing list, flight details, expected date of arrival at final destination and Airway Bill Number).

9. Transportation

9.1. Storage condition should be observed at all times, including during transportation. The requirements are applicable not only to medicines that need to be stored at low temperature (cold –chain products) but also to medicines that should be stored below 30C (temperature control - chain products).

9.2. Shipments of pharmaceuticals products should be suitable for their purpose and appropriately equipped to prevent exposure of products to conditions that could affect their stability and packaging integrity, and to prevent any contamination.

9.3. In temperature controlled containers with digital data logger with USB connect to record temperature and humidity.

9.4. In the cold –chain products cartons must be clearly labeled (keep cool) and the airway bill must also be clearly marked (keep cool during transport or transit).

9.5. Sea Shipment must be:

9.5.1. By Way Bill of Lading.

9.5.2. Present permission from the shipper permit to NMSF to carry the clearance process by shipping documents copies.

9.5.3. Clearance Permission Period from the shipper at least 30 days after the shipment arrive Port Sudan.

9.5.4. In case of shipping by Reefer containers you have to notify NMSF before 15 working days of expected arrival date.

10.Rejection, Termination and Recovery of Damages

10.1. If the Supplier shall at any time fail to perform or neglect to observe these conditions or shall become bankrupt or insolvent or make any arrangement with his creditors or for any reason become incapable of performing or observing the said conditions or if he shall deliver any

goods which do not conform to the conditions of the contract as to safety, efficacy, quality, quantity or time of delivery, the NMSF may forthwith terminate the agreement, without prejudice to any rights accruing or accrued to the NMSF, and may forfeit and retain all moneys deposited in pursuance of conditions 5 or such part thereof as the NMSF shall deem fit in respect of any neglect or default of the contractor either in full or part satisfaction of the claim of the NMSF for damages in respect of any such neglect or default.

10.2. Without prejudice to the provisions of paragraph 1 above and without prejudice to any right accruing or accrued to the NMSF under this contract, the NMSF may at any time whatsoever and at its own discretion:

10.2.1. Reject any goods whatsoever found delivered by the contractor which shall not strictly conform to the conditions of contract as to safety, efficacy, quality, quantity, time of delivery or any other specification and in particular the specification contained in condition 2 thereof and provisions pertaining to brand name of manufacturer and country of origin of the medicines and upon such rejection the supplier should immediately remove, at his own expense, all goods involved wherever they may be.

10.2.2. Accept any goods which are found acceptable on analysis but which are not up to the required quantity, in part performance of the supplier's obligation in respect of such delivery, and

10.2.3. Require the supplier to make good forthwith any shortage of goods occasioned by such rejection or by short delivery, or

10.2.4. Purchase at the risk and expense of the supplier sufficient amount of such goods to cover the shortage of goods from any other source and recover from the contractor any loss incurred by the NMSF in so doing.

10.2.5. Recover damages in respect of any neglect or default of the contractor, notwithstanding acceptance of goods, not in accordance with the agreement and notwithstanding the continuation of the agreement provided that where the goods are delivered after the due date such damages shall be 5 % of the value of such goods for each week or part of week of the due date, and the case of any other default or neglect, be such sum not exceeding 10 % of the sum deposited in pursuance of condition 5 as the NMSF may determine.

10.3. Without prejudice to any of its rights under the contract the NMSF shall always be entitled to the refund of any sum of money paid for any accepted item if the whole or part of that item deteriorates or becomes unsuitable for its intended use during storage in the NMSF stores or

any health facility in which such items are kept, before the end of its specified expiry date, or before the end of two years after delivery in the case of expiry date.

10.4. In every case in which money shall become payable to the NMSF by the supplier by virtue of these conditions, the same may be recovered in whole or in part by the NMSF from the money deposited with it by the contractor in accordance with conditions 5 and the contractor shall thereupon forthwith deposit on every such occasion a further sum equal to the amount so recovered.

10.5. All rejected pharmaceutical products **MUST** be removed by the **Local Agent** from NMSF's stores within 5 working days after the date of receiving a written notification by the Local Agent. Any delay will affect reputation of the Local Agent and NMSF will dispose the goods 2 days later after the deadlines and the local agent must pay all expenses of the disposal. This action will not affect the NMSF right in substitution of the disposed goods.

11. Specifications of Packaging:

11.1. Packages must be of strong materials and construction that can withstand rough handling and stacking (**cartons must be of five layers, three of double paper in between and two of corrugation**).

11.2. All boxes and cartons must comply with the following specifications:

11.2.1. Carton must bear up to three meters height, without any effect on the durability, they should be appropriate strength and packed in such a way as to protect the items from damage or deterioration from rough handling in transit to or in the warehouse and distribution from warehouse by air, or land to remote destination within the Sudan.

11.2.2. Carton must be in rectangular shape.

11.3. Each carton must be stenciled with item name as shown in the Tender documents, details of content, Tender Number, item Number, case/carton Number, carton weight in kg and NMSF-Sudan.

11.4. Each batch of each item must be packed in separate box(s) or carton(s) and must be clearly identified from other batches.

11.5. Each item should be shipped in pallets and wrapped with plastic not exceeding 1.5 ton per pallet, and height not exceeding 2 meters and each pallet should contain only one batch.

11.6. Security symbols (e.g. handle with care, protect from rain symbols etc....) should be marked clearly in the outer shipping pack.

12.Special Requirements for Specific Dosage Forms:

- 12.1.** All capsules and tablets should be supplied in blisters or strips of 10's unless another packaging is specified (Patient pack will be given preference).
- 12.2.** Each individual blister or strips must be clearly labeled with the INN or the generic name of the item, amount of the active ingredient(s) per capsule or tablet, expiry date, manufacturer name, country of origin and NMSF Logo.
- 12.3.** Labels on glass ampoules should be ceramic ally printed and easily readable by the naked eye. The label must show the amount of active ingredient(s) per ml / or /gm and the total volume of content of the ampoule, batch number, and expiration date and comply with NMPB requirement.
- 12.4.** For IV Fluids and other parenteral packed in plastic containers, the composition of the materials of these containers, including all additives must be given. PVC plastic containers are not acceptable. All containers should comply with national or international Standard that has been approved by NMPB.
- 12.5.** Packaging of photosensitive items must provide adequate protection from light. The label must bear the warning (**protect from light**).
- 12.6.** Cold storage items which need cold chain transportation and storage must be delivered in special cold transport boxes which will keep the temperature of the items within the required range of temperature till the items are delivered and received into NMSF cold stores with internal digital data logger with USB connector that can be easily checked by NMSF.

12.7. NOTICE:

THE ATTENTION OF ALL TENDERERS IS DRAWN TO THE COMPLIANCE WITH THE MEDICINES AND POISONS ACT 2009 AND ITS REGULATIONS: ALL TENDERERS FOR ITEMS OF MEDICINES AND PHARMACEUTICALS SHOULD BE IN POSSESSION OF A VALID WHOLESALER LICENCE (A) AS SPECIFIED BY THE LAW LICEINGING OF PHARMACUTICAL PREMISES. ALL MEDICINES SHOULD BE REGISTERED AND A VALID CERTIFICATE OF REGISTRATION SHOULD BE SUBMITTED FOR EACH ITEM.

13.Penalties:

- 13.1.** If the required pro-forma invoice and the Performance Bond are delayed in submission, in the correct and proper way, more than 15 days from the date of award notification, the NMSF has the right to confiscate the whole initial bank guarantee.

- 13.2.** Withdrawal of quotation after opening envelope or after award notification, shall consequently lead to confiscation of the Bid Bond.
- 13.3.** In case the bidder fails to fulfill his obligations, the NMSF shall have the right either to reject or accept the goods. After 4 week delay period, the NMSF reserves the right to confiscate the Performance Bond, and cancel the purchase order.
- 13.4.** If the delivered item (s) are not conforming to the specifications, tender's terms and conditions; or if they are not in accordance with the accepted bid or the country of origin, the bidder shall be responsible to replace the whole quantities within two months from the date of rejection .
- 13.5.** If physical change occurs in the specification of any item batch during storage period and within the shelf life, the supplier shall be responsible to ship back the defected quantity at his own expenses. Nevertheless, he or she must replace the same item or by other item(s) accepted by NMSF within two months from date of intimation.
- 13.6.** If the company fails to supply the replaced quantity within the specified period, NMSF reserves the right to confiscate the Performance Bond.
- 13.7.** If the company repeats the same discrepancy for the same item, then NMSF has the right to cancel the ordered quantity and to make claim for the paid amount and lead to confiscation of the Bid Bond.
- 13.8.** All bidders should send, within one month from the date of award, a renewal authorization letter, authenticated by the Sudan Embassy in the country of origin, to their local agents in Sudan in order to contact the General Directorate of Procurement at the NMSF, so as to avoid any delay in signing the contract, or any applicable delay penalties.
- 13.9.** In case of other violations that might have negative consequences, at its discretion NMSF have the right to apply the laws and all regulations applicable in Sudan.

14.Arbitration:

- 14.1.** Arbitration must be Alignment according to Sudanese arbitration act 2005.
- 14.2.** Any disputes arising between the NMSF and the supplier in connection with the Agreement between them or with respect to the interpretation or application thereof shall be referred for decision to an arbitral tribunal to be constituted in the following manner:
- 14.3.** Each party shall appoint an arbitrator within thirty days of the receipt by either party of a notice in writing from the other party of his intention to refer the dispute to arbitration.

14.3.1. The two arbitrators shall then agree upon a third arbitrator. The three shall constitute the arbitral tribunal. If either party fails to nominate its arbitrator or the two arbitrators, as the case may be, the arbitrator shall be appointed by the chief justice of Sudan upon application being made to him/her on behalf of or by either party, to make up the number of arbitrators to three.

14.3.2. The arbitrators will make their award by a majority vote. The award shall be final and binding on both parties.

14.3.3. All arbitral proceedings under this condition shall be conducted in Sudan.

14.3.4. Disputes on safety, efficacy and quality issues should be decided upon by the National Medicines and Poisons Board in Sudan and its decision should be final and binding to both parties (i.e. NMSF and Supplier)

14.4. Law Applicable and Jurisdiction: The Agreement shall be governed and construed in accordance with the laws of Sudan and the courts of Sudan shall have exclusive jurisdiction to hear and determine all actions and proceedings arising out of the agreements or connection therewith.

15. Clarification request

➤ A supplier that has been left out the tender has the right to know the reasons for exclusion, by a written request at any time after the date of announcement of the award & the feeding – back for this request has to be carried immediately

16. Appeal

➤ A supplier that has been left out the tender has the right to submit appeal, by a written request within two weeks (15 days) from the date of announcement of final award, and no any request will be seen after the specified period

Note:

Bidder, Tenderer, Supplier, Company and Manufacturer are used interchangeably.

Dr. Shihabeldin Ali Siddig
General Procurement and Contracting Director