

وزارة الصحة الاتحادية
الصندوق القومي للإمدادات الطبية
الإدارة العامة للشراء والتعاقد



العطاء المفتوح لتوريد ادوية لجميع المؤسسات والجهات الحكومية
بجميع ولايات السودان للعام 2023

عطاء رقم 2023/1

تاريخ قفل الصندوق الاربعاء الموافق 2023/03/08

بيانات مقدم العطاء:

	اسم الشركة/اسم العمل
	عدد الأصناف المقدمة في الكراسة
	إجمالي مبلغ الأصناف المقدمة في الكراسة باليورو
	قيمة التأمين المبدئي للعطاء وتعادل 2% من القيمة الكلية للأصناف المقدمة
	اعتماد الشخص المسؤول بالشركة/اسم العمل
	ختم الشركة/اسم العمل

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 سارية المفعول أو إفادة بالإعفاء منها		
4	شهادة إبراء ذمة من الزكاة سارية المفعول أو إفادة بالإعفاء منها		
5	شهادة تسجيل القيمة المضافة سارية المفعول أو إفادة بالإعفاء منها		
6	صورة من الرقم التعريفي الضريبي الموحد		
7	صورة من رخصة الشركة/اسم العمل مجددة للعام 2022 أو إفادة من المجلس		
8	صورة من شهادة تسجيل الشركة/اسم العمل أو المصنع أو اسم العمل سارية المفعول		
9	شهادة مقدرة مالية		
10	المقدرة الفنية		

تنويه:

1. التأمين المبدئي وهو ما يعادل نسبة 2% من أعلى قيمة مقدمة لعروض الشركة/اسم العمل ويجب معادلتها بالجنيه السوداني بسعر 577.
2. ستتم مراجعة المستندات في حضور ممثلي الشركات مع التوقيع عليها.
3. اخر موعد للرد علي الاستفسارات عبر البريد الالكتروني سوف يكون قبل 5 ايام عمل من قفل العطاء.
4. بالموقع الالكتروني للصندوق القومي للإمدادات الطبية متوفر بالرابط www.nmsf.gov.sd/assets/content/TN_manual.pdf شرح كيفية التقديم الالكتروني للمشاركين في العطاء . الرجاء التكرم بالاطلاع عليه ولمزيد من المساعدة الرجاء التكرم بالتواصل مع موظفي تقنية المعلومات لتقديم المساعدة والدعم الفني في فترة أقصاها 5 أيام عمل قبل تاريخ قفل العطاء.
5. مرفق الصيغة المعتمدة من الصندوق القومي للإمدادات الطبية لخطاب ضمان حسن التنفيذ 10%.

وزارة الصحة الاتحادية

الصندوق القومي للإمدادات الطبية

اعلان العطاء المفتوح لتوريد أدوية لجميع المؤسسات والجهات الحكومية بجميع ولايات السودان

للعام 2023

عطاء رقم 2023/1

يدعو السيد المدير العام للصندوق القومي للإمدادات الطبية رئيس لجنة الشراء الموحد السادة الشركات العاملة في مجال الأدوية والمنتجات الطبية لتقديم لعطاء الصندوق المفتوح والذي سيتم التقديم له إلكترونياً اعتباراً من الأحد الموافق 2023/01/22 وذلك لتوريد منتجات طبية 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/ اسم العمل 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 (100,000 جنيه سوداني) نقداً أو بشيك مصرفي لا ترد.
5. تعطى الشركة/ اسم العمل المشاركة في العطاء رمز الدخول وكلمة المرور ودليل إستخدام نظام الشراء الإلكتروني مباشرةً بعد إبراز المستند المالي.
6. احضار شهادة مقدرة مالية.
7. احضار المقدرة الفنية (مايفيد بتوظيف الشركة/اسم العمل لكوادر مؤهلة ومخازن مهينة وعربات نقل مبردة).
8. احضار شهادة خلو طرف من الضرائب سارية المفعول أو إفادة بالإعفاء منها.
9. احضار شهادة إبراء ذمة من الزكاة سارية المفعول أو إفادة بالإعفاء منها.
10. احضار شهادة تسجيل القيمة المضافة سارية المفعول أو إفادة بالإعفاء منها.
11. احضار الرقم التعريفي الضريبي الموحد.
12. استيفاء الدمغة القانونية.
13. احضار صورة من شهادة تأسيس الشركة أو تسجيل اسم العمل صادرة من المسجل التجاري وزارة العدل.
14. صورة من رخصة الشركة/اسم العمل صادرة من المجلس القومي للأدوية والسموم مجددة للعام 2023 أو إفادة منه.

15. تُقدم النسخة الأصلية لمستندات العطاء (لا تشمل العروض المالية) في م ظروف محكم الإغلاق ومختوم بالشمع الأحمر ويوضع داخل صندوق العطاءات المعد لذلك في قاعة العطاءات بالصندوق المبنى الشمالي
- الطابق الأرضي المبنى B.

16. أي شركة لم تقدم عرضها إلكترونياً تستبعد من المنافسة.

17. دفع مبلغ 2% من قيمة العطاء كتأمين مبدئي من الوكيل المحلي بالجنيه السوداني يقدم بشيك مصرفي معتمد باسم مدير عام الصندوق القومي للإمدادات الطبية أو خطاب ضمان معتمد من بنك محلي أو خطاب ضمان من إحدى شركات التأمين وترد لمن لا يرسو عليه العطاء.

18. تكمل 2% إلى 10% (ضمان حسن التنفيذ) لمن يرسو عليه العطاء، على أن تكون ال 10%:
1.18 سارية المفعول طيلة فترة تنفيذ العقد.

2.18 بخطاب ضمان مصرفي ساري لمدة 6 أشهر علي الأقل أو بشيك معتمد باسم مدير عام الصندوق القومي للإمدادات الطبية أو بخطاب ضمان صادر من إحدى شركات التأمين (بالصيغة المعتمدة من الصندوق القومي للإمدادات الطبية).

19. تُقدم الأسعار باليورو شاملة تسليم الأصناف مخازن الصندوق القومي للإمدادات الطبية.

20. الأسعار المقدمة يجب أن تكون نهائية وسارية طيلة فترة العطاء ولايجوز تعديلها أو تجاوزها الا وفقاً للقانون.

21. آخر موعد لإستلام م ظروف العطاء (المستندات المطلوبة) يوم الاربعاء الموافق **2023/03/08** الساعة 12 ظهراً.

22. تسلم مستندات الجودة(شهادات تسجيل المصنع والأصناف الصادرة من المجلس القومي للأدوية والسموم سارية المفعول او افادة منه) مباشرة لإدارة تأكيد الجودة.

23. الأصناف المقدمة في العطاء وفق مطلوبات المجلس القومي للأدوية والسموم وقانون الصندوق القومي للإمدادات الطبية لسنة 2015.

24. تسلم المستندات المطلوبة بصندوق العطاءات المعد لذلك بقاعة العطاءات بالصندوق المبنى الشمالي - الطابق الأرضي المبنى B.

25. لن يُنظر في أي عرض يصل بعد الزمن المحدد مهما كانت المبررات (نظام الشراء الإلكتروني يغلق تلقائياً عند الساعة الثانية عشر ظهراً" يوم الاربعاء الموافق **2023/03/08**.

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 إستعراض العروض إلكترونياً في حضور ممثلي الشركات يوم الاربعاء الموافق **2023/03/08** الساعة 12 ظهراً.

28. لمدير الصندوق الحق في إنقاص الكميات المطروحة بنسبة أقصاها 20% أو زيادتها بنسبة أقصاها 50%.

29. مدة العقد عامان قابلة للتجديد بموافقة الطرفين.

30. الكميات المعلنة بالعبء لمدة عامين.

31. مدير عام الصندوق غير ملزم بقبول أءنى عبء أو أي عبء آءر.

32. للإستفسار يُرجى التواصل عبر البريد الإلكتروني INT-TENDER@nmsf.gov.sd

33. لمزيد من المعلومات يرجى الرجوع لموقع الصندوق: www.nmsf.gov.sd

تنويه: على الراغبين في المشاركة في العبء التسجيل في نظام الشراء الإلكتروني بالصندوق قبل استلام الكراسة، يمكن التسجيل عبر موقع الصندوق الموضح أعلاه أو الحضور لمكتب سكرتارية الإدارة العامة للشراء والتعاقد بمباني الصندوق خلال ساعات العمل الرسمية.

د. جميلة بدر عبد الرحمن

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

2023 - 2024

Invitation to Bid

NMSF Tender No.1/2023

Opening Date Sunday 22/01/2023

Closing date Wednesday 08/03/2023

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 terms and conditions:

1. Bid Preparation and Submission:

1.1. Source of Medicines:

- 1.1.1 All medicines and their manufacturers should be registered in the National Medicines & Poisons Board (NMPB).
- 1.1.2 Unregistered medicines must be from; countries with Stringent Regulatory Authorities (SRAs) determined by NMPB or WHO prequalified product.
- 1.1.3 Medicines with narrow therapeutic index ,high toxicity , biological products, serums, vaccines and medicines used to treat the most prevalent endemic and epidemic diseases must be from their originators or from sources that have WHO pre-qualification or from countries with Stringent Regulatory Authorities (SRAs) determined by NMPB .

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 valid certificate or exemption from it.
- 1.2.3. Free Zakat valid certificate or exemption from it.
- 1.2.4. Appropriate stamp duty is fixed on the bid.
- 1.2.5. Value Added Tax valid Certificate (VAT) or exemption from it.
- 1.2.6. The bidder must attach the relevant registration certificate.

1.2.7. At least Three non–returnable samples, in their final shape in which they are registered and marketed in Sudan, for each item (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 and the name of the local agent. Only two samples of biological products should be submitted. Fill the QC information in the attached form (Appendix (1))

1.3. Original bid documents must be submitted in a duly sealed envelope and labeled with local agent name.

1.4. 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.

Only electronically authorized bids will be considered.

1.5. Receipt issued voucher of purchasing the tender book, should be attached with the bid envelope.

1.6. NMSF reserves the right to amend the tender quantity of any item by increasing it up to 50% or decreasing it by 20%, before the award notification, or to cancel any item without giving reasons.

1.7. The price of the awarded item/s must remain fixed within the validity of the contract according to the law.

1.8. 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. However, NMSF has the right to accept or reject such remarks without giving reasons.

1.9. The quotation should include all information regarding the item: manufacture name, country of origin, delivery details, dosage form, shelf life, pack size (number of units “tab, amp, pcs,” per carton), strength/concentration or measurement, manufacturer’s batch size per unit, manufacturer and item registration status, storage conditions, ...etc.).

1.10. Offers must be submitted electronically. The company should submit the tender documents in a sealed envelope/s in the tender box at NMSF tenders’ hall building (B) ground floor, before or at 12:00 pm on **Wednesday 08/03/2023**.

1.11. No bid will be accepted after 12:00 pm of the closing date on **Wednesday 08/03/2023**.

1.12. The outer envelope/s **should** indicate the name and address of the bidder to enable the bid to be returned unopened in case it is declared “late”.

1.13. NMSF will assume no responsibility for the bid misplacement or premature opening of the unsealed or marked outer envelope/s as required by paragraph (1.12).

1.14. Agents are invited to witness the bid opening on **Wednesday 08/03/2023**. At 12:00 pm.

- 1.15.** The laws of the Republic of Sudan are the applicable laws under which the contracts shall operate.
- 1.16.** A written request to the General Directorate Procurement and contracting to purchase the tender book by the interested eligible local agent upon payment of non-refundable fees of **SDG 100,000 (One hundred thousand SDG only)**.
- 1.17.** The local agent has full responsibility with regard to all claims that may be raised.
- 1.18. Amendment of Tender documents:**
- 1.18.1.** NMSF for any reason, whether at its own initiative or in response to clarification requested by a prospective bidder can amend the tender documents before the dead time for submission of bids.
- 1.18.2.** The amendment will be notified officially and submitted by hand, e-mail to all prospective bidders, who have received the tender books.
- 1.18.3.** 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.
- 1.19.** The GM of NMSF reserves the right to accept or reject all bids and to annul the bid at any time prior to the award of contract without any liability or any obligation to inform the affected bidders of the NMSF action.
- 1.20.** The notification of award will constitute the formation of the contract.
- 1.21.** The contract should be signed within 5 days of the receipt of the contract form.
- 1.22.** Failure of the awarded bidder to comply with the requirement of clause 1.21 should constitute sufficient grounds for the annulment of the award and confiscation of the bid guarantee.
- 1.23.** No variation in or modification on the contract should be made after signature by the concerned parties, only upon acceptance of the two parties.
- 1.24.** Immediately on shipment dispatch of the contracted item/s, the supplier must notify NMSF by e-mail, fax or by hand the following details:-
- 1.24.1.** 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.** Incomplete cartons are not accepted, the quantity should be delivered with multiple of the pack size.
 - c.** The pack size should be fixed through the tender.
 - d.** Number of batches delivered must match the batch size stated in the offer.

e. Number of enclosed data loggers should be mentioned clearly with their serial numbers and locations and should be linked with carton and pallet serial numbers.

1.24.2. Commercial invoice signed and stamped in full details, items names must be written in generic names with full specifications, expiry date, manufacturer name, country of origin, storage condition & tender prices in Euro.

1.24.3. Certificate of Origin (COO) certified as true and correct from the national Chamber of Commerce of the country of origin.

1.24.4. Certificate of analysis for each individual batch.

1.24.5. Batch release certificate for individual item.

1.24.6. The supplier should shipped on the basis of awarded port of destination.

1.24.7. Notification delivery form should be submitted 5 working before arrival of shipment.

1.25. An unexcused delay by the supplier in the performance of his obligations will render him liable to any or all the following penalties:

a. Confiscation of its performance guarantee.

b. Imposition of liquidated damages.

1.26. All Tender documents are part of the contract agreement.

1.27. 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 AS STATED IN THE TENDER BOOK.

2.1. Each company should quote CPT/CFR Incoterm 2020 for each item plus the cost of transportation from airport or sea port to NMSF Stores. Price for each item, (Manufacturer warehouses to NMSF warehouses).

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. It is necessary to be clearly indicated that the prices offered do not include custom duties and any official governmental fees, these will be paid by NMSF after declaration of the documents.

3. Payment:

3.1 Value of the awarded items will be paid by NMSF after complete delivery and after final acceptance of the item/s by the NMSF at its main warehouses in Khartoum.

- 3.2 The payment will be directly to the local agent in Sudanese Pounds (SDG). Rate of exchange of € to SDG will be the managed flexible price of the Central Bank of Sudan on the date of payment.
- 3.3 Exact delivery date of the goods to the NMSF stores shall be specified against every individual item tendered for.
- 3.4 The receipt of official governmental fees and custom duties which had been paid during clearance of goods should be submitted to the NMSF for payment.
- 3.5 The value will be paid includes all official governmental fees except for the **demurrage**.

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 (local agent) 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 in SDG, valid at least for six months from the closing date.
- 4.3. The Bid Bond (IBG) presented after the closing date (Tender Deadline) will be neglected; and consequently, the company bid will be rejected.
- 4.4. IBG of Unsuccessful bidders will be returned as promptly as possible.
- 4.5. Winner Company “local agent” 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 quantity requested. The Performance Bond must be submitted valid for 6 months, which shall be renewed automatically during contract period 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 should mention the highest total sum of quoted items in the covering letter.

5. Deposit on Acceptance of Tender:

The Supplier shall, within 5 days of the acceptance of his bid, furnish NMSF with a guarantee from a local Bank for a sum equal to 10 % of the total money payable to 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 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 NMSF within the prescribed period. Such guarantee or declaration shall be in the form prescribed by NMSF. The agreement hereby contemplated shall not be deemed to be operative unless and until such guarantee or declaration shall have been received by NMSF and NMSF shall have acknowledged receipt thereof in writing. Failure to deliver such guarantee or declaration within the prescribed time shall give the right to NMSF to withdraw its acceptance of the tender.

6. General Conditions:

- 6.1. While accepting any tender, NMSF GM has the right to modify the submitted quantities by increasing up to 50% or decreasing it by 20%.
- 6.2. The successful bidders must submit certificate of analysis to NMSF for each consignment for each individual batch.
- 6.3. Any Certificate of Analysis provided shall not bind NMSF as to its contents. The item concerned will be subjected to analysis which will be carried out by NMSF in the National Medicines Quality Control Laboratory (NMQCL) and the results of that analysis will be final and shall bind the NMSF and successful tenderer.
- 6.4. NMSF has the right to decide whether to accept compensation of items in terms of money or in kind compensation when the item awarded fails to pass (NMQCL) test/s.
- 6.5. Bidders must distinguish packages and labels of the item from those sold in the market by printing NMSF-Sudan, approved NMSF logo and Barcode.

7. Quality: Specifications, Labeling, Samples and Certificates:

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

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, NMSF has the right to reject the

remaining quantity of that medicine and refunded the amount if paid or to cancel it if not delivered.

7.1.3. The shipping documents of each consignee must be accompanied with full specifications of the items in generic name, an updated method of analysis, certificate of analysis for each batch, method of sterilization used and its reference, giving the full name and address of the manufacturer as well as the batch serial number of the products.

7.1.4. Valid certificate of registration from National Medicines & Poisons Board (NMPB) for the manufacturer and for each item should be submitted.

7.1.5. Certificate of analysis from (NMQCL) for each item should be submitted.

7.1.6. Manufacturers should submit all supported certificates for all items.

7.1.7. For consumables ,manufacturers should submit the registration certificate in NMBP for manufacturer and the items or a statement from NMBP , in addition to all supported certificates: e.g. (FSC, ISO 13485:2016, EC certificate applicable to device classification, USFDA Approval, Registration certificate in one of the following countries (European Union, Japan, Australia, Republic of Korea, Canada, KSA and Brazil).

7.1.8. 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.

7.1.9. All labeling requirements that have been stated by NMPB policy for registration of pharmaceutical products should be followed strictly. The company should provide all necessary information on the label of the inner pack, outer pack, export cartons of the items, full details of trade and generic names, strength, volume, specification (European Pharmacopeia, International Pharmacopeia, BP and USP), the manufacturer name and address, country of origin, batch number and manufacture& expiry dates for each batch of the product, storage conditions, carton full details of pack size and dosage forms.

7.1.10. Carton weight and volume (dimensions) should be printed on each carton.

7.1.11. Packing list must show number of cartons, pallets, batch numbers, manufacture and expiry dates for the contents of each box or group of boxes.

7.1.12. Labeling of containers: The NMSF manager 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.

7.1.13. The remaining shelf life should not be less than 75% for items when received in NMSF warehouses.

7.1.14. The manufacturing date must be mentioned in the certificate of analysis.

7.1.15. The shelf life of all sera must not be less than eighteen months.

7.1.16. 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.

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

7.1.18. All medicines must be shipped in temperature controlled containers, according to the following:

a. The container temperature should not be 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.

7.1.19. Readable USB Data loggers should be placed by the manufacturers with goods and mentioned in the packing list, and link the external and internal data logger's number with the carton serial number and pallet number in the packing list.

7.1.20. Stability study and stability budget for each item must be submitted

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

7.1.22. All official preparations must comply with the latest editions of the internationally known

Pharmacopoeias that have been recognized by NMPB i.e. (European Pharmacopeia, International Pharmacopeia, BP and USP) in the registration policy of pharmaceutical products 2009 (Appendix1).

7.1.23. All kinds of eye drops and ointments shall be supplied in individually packed containers with the leaflet.

7.1.24. All kinds of syrups, elixirs, powder for suspension and suspensions should be exported in well packed, screw capped bottles with a measuring device to be supplied with each bottle in the same pack. Number of units per export carton should not exceed 50 bottles (It can be packed as small cartons of 10 – 12 bottles and each 6 - 8 small cartons can be packed in a large one).

7.1.25. All liquid oral products must not contain alcohol. However percentage of alcohol, if any should be mentioned in the formula for all liquid preparations.

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

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

7.1.28. Maximum number allowed is 5 batches per consignment to minimize the quality control samples and cost of analysis.

7.1.29. 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.

7.1.30. 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.

7.1.31. Reference standard with minimum one year shelf-life not less than 100 mg with certificate and method of analysis should be submitted upon NMSF request & NMQCL analysis requirements

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

The Director General

National Medical Supplies Fund

Khartoum

Sudan

7.2. Quality Assurance:

7.2.1. According to the regulations of NMPB, all items should pass the NATIONAL MEDICINES QUALITY CONTROL LABORATORY (NMQCL) tests.

The Decision of the NMPB on the safety, efficacy, and quality of medicines 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 NMSF within not more than 15 working days about the option of compensation.

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

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

7.2.8. All sera ,vaccines, biological and cold products must have certificate of analysis of finished product from manufacturer and must be stick to their special requirements which stated by NMPB and packed in insulated cartons with randomly packed data logger. The data logger must be digital with readable USB connector.

7.2.9. Vaccines must be WHO prequalified and the following requirement must be considered:

- a. Cold chain (Data Logger + ice bags + vaccine vial monitor (VVM).
- 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.

7.2.10. 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 (Data Logger + ice bags).

- 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.

7.2.11. Genetically modified biological and narrow therapeutic index products must be offered from originators or from countries with Stringent Regulatory Authorities (SRAs). For narrow therapeutic index products, the applicant should submit bio-equivalence study.

7.2.12. Freeze watch indicator in addition to readable USB data logger should be packed with each carton for all products that can be affected by freezing.

7.3 REHYDRATION FLUIDS AND BLOOD PLASMA SUBSTITUTES:

7.3.1. These fluids shall be packed according to specifications outlined against each item in the Tender Book.

7.3.2. These fluids should remain sterile, pyrogen free and clear, and free from any visible particles or particles when closely examined under a strong light against a black or white background during shelf life validity at ordinary room temperature (below 30° C).

7.3.3 It must be non-toxic and pyrogen-free and must not induce sensitization or antigenic reactions.

7.3.4 The viscosity and osmotic pressure of infusion must be similar to those of plasma

7.3.5 It must not act as a diuretic

7.3.6 It should not disturb blood grouping reactions or unduly increase the erythrocyte sedimentation rate.

7.3.7 It should be stable on storage during shelf-life at the temperature stated in the label.

7.3.8 These items should be imported by air freight from freshly manufactured stock

7.3.9 Administration sets should be sterile and individually packed inside sterile packs. Each set should have two recipient needles for adults and children.

Specification of infusion set:

Infusion set for Solution Administration P.V.C., Disposable Sterile and Pyrogen Free Macro drip 20 drops/1ml, Hydrophobic Adequate Air Vent, Filter, Precision roller clamp flow regulator, Tubing not less than 1.5 meter and Diameter (I.D 3mm & O.D 4 mm), Fitted with Needle G21 to Luer Lock Device for Injection of drugs at distal end.

8. Delivery

8.1 Delivery of all ordered goods should be completed within 24 months from the date of signing the contract and the schedule as agreed by NMSF and the awarded supplier officially.

8.2 The receipt of official governmental fees and custom duties which had been paid during clearance of goods should be submitted to the NMSF, Delivery to be made at the NMSF' stores directly.

8.3. Delivery of all sera, vaccines, Biological and other cold items should be shipped on a direct flight with a cold chain system.

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

9. Transportation

9.1 Shipments of 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.

9.2 State in the bill of lading or Air way bill that the consignments are for the interest of the NMSF in order to apply the exemptions granted to the NMSF (C/O NMSF or Notify for NMSF).

9.3 Readable USB Data loggers should be placed by the manufacturers with goods and mentioned in the packing list, and link the external and internal data logger's number with the carton serial number and pallet number in the packing list.

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, NMSF may forthwith terminate the agreement, without prejudice to any rights accruing or accrued to NMSF, and may forfeit and retain all moneys deposited in pursuance of conditions 5 or such part thereof as NMSF shall deem fit in respect of any neglect or default of the contractor either in full or part satisfaction of the claim of 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 NMSF under this contract, 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 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 in the case of any other default or neglect, be such sum not exceeding 10 % of the sum deposited in pursuance of condition 5 as NMSF may determine.
- 10.2.6 Without prejudice to any of its rights under the contract 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 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.
- 10.2.7 In every case in which money shall become payable to 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.

10.2.8 All rejected 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 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 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 net and gross weight in kg, Carton dimension and NMSF-Sudan.

11.4 Each batch of each item must be packed in separate 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 one ton per pallet, and height not exceeding two and half meters and each pallet should contain only one batch.

11.6 Items should be shipped in wooden Euro pallet size 120cm*80cm.

11.7 Handling and Storage symbols (e.g. handle with care, protect from rain symbols ...etc) should be marked clearly in the outer shipping pack.

11.8 Items with different strengths and measurements should be differentiated by colors or symbols e.g. gloves, catheters, etc.

12 NOTICE:

THE ATTENTION OF ALL BIDDERS IS DRAWN TO THE COMPLIANCE WITH THE MEDICINES AND POISONS ACT 2009 AND ITS REGULATIONS: ALL BIDDERS FOR ITEMS OF MEDICINES

AND PHARMACEUTICALS SHOULD BE IN POSSESSION OF A VALID WHOLESALER LICENCE (A) AS SPECIFIED BY THE LAW LICENSING 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 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 and

contracting 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 (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 one week from the date of announcement of initial award, and no any request will be seen after the specified period.

Note:

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

Dr. Gamila badr Abd Elrhman
Director of General Directorate of Procurement and Contracting

