Federal Ministry of Health

Central Medical Supplies Public Corporation



Joint Procurement Open Tender for Supply of Medicines, Vaccines and Medical Consumables

Tender No 02/2015
Closing Date 15/03/2015

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 $\sqrt{ تحت عمود نعم في }$ حالة وضع المستند في المظروف ووضع علامة X تحت عمود X في حالة عدم وضع المستند في المظروف:

X	نعم	البيان	الرقم
		شهادة مقدرة مالية	1
		شهادة مقدرة فنية	2
		شهادة خلو طرف من الضرائب أو إفادة بالإعفاء منها وأرفاق الرقم التعريفي الضريبي	3
		شهادة خلو طرف من الزكاة سارية المفعول أو إفادة بالإعفاء منها	4
		شهادة تسجيل القيمة المضافة أو إفادة بإعفاء من القيمة المضافة	5
		صورة من شهادة تأسيس الشركة أو اسم العمل سارية المفعول صادرة من المسجل التجاري	6
		إستيفاء الدمغة القانونية	7
		صورة من رخصة الشركة صادرة مجددة للعام 2015	8
		2% من قيمة العطاء *كتأمين مبدئي بخطاب ضمان مصرفي ساري لمدة 90 يوماً أو بشيك معتمد باسم مدير عام الهيئة العامة	9
		للإمدادات الطبية أو نقداً	

تنويه:

- 1. التأمين المبدئي وهو ما يعادل نسبة 2% من أعلى قيمة مقدمة لعروض الشركة ويجب معادلتها بالجنيه السوداني حسب سعر اليورو المحدد في كراسة الشروط وهو مايعادل 7.5 جنيه سوداني.
 - 2. ستتم مراجعة المستندات في حضور ممثلي الشركات.

بسم الله الرحمن الرحيم الهيئة العامة للإمدادات الطبية المركزية



وزارة الصحة الإتحادية الهيئة العامة للإمدادات الطبية المركزية لجنة الشراء الموحد

إعلان عطاء لتوريد أدوية ومستلزمات طبية لجميع المؤسسات والجهات الحكومية (الصندوق القومي للتأمين الصحي، القوات المسلحة، قوات الشرطة وجميع ولايات السودان) 2015/02

يدعو السيد المدير العام للهيئة العامة للإمدادات الطبية المركزية رئيس لجنة الشراء الموحد السادة شركات الأدوية والمستلزمات الطبية للتقديم لعطاء الهيئة المفتوح والذي سيتم التقديم له إلكترونيا هذا العام لتوريد أدوية وستلزمات طبية حسب الكميات والمواصفات والشروط المرفقة مع كراسة العطاء وذلك وفق الخطوات التالية:

على الراغبين في المشاركة في هذا العطاء الالتزام بالآتي:

- 1. يقدم طلب الحصول على شروط كراسة العطاء في ورق مروس باسم الشركة المقدمة للعطاء ومختوما بختمها العام.
 - 2. ملء الاستمارة الخاصة بذلك.
 - 3. تُستلم كراسة شروط العطاء من مكتب سكرتارية مدير الإدارة العامة للمشتريات يومياً خلال ساعات العمل الرسمية.
 - 4. مبلغ كراسة الشروط 3,000 جنيه سوداني لا ترد.
 - 5. تُعطى الشركة رمز الدخول وكلمة المرور ودليل إستخدام نظام الشراء الإلكتروني مباشرة بعد إبراز المستند المالي.
 - 6. شهادة مقدرة مالية.
- 7. شهادة مقدرة فنية، ما يفيد بتوظيف الوكيل بالسودان لكوادر مؤهلة من صيادلة ومهندسين طبيين (في حالة المستلزمات الطبية) ومخازن مهيئة.
 - 8. شهادة خلو طرف من الضرائب أو إفادة بالإعفاء منها وأرفاق الرقم التعريفي الضريبي.
 - 9. شهادة خلو طرف من الزكاة سارية المفعول أو إفادة بالإعفاء منها.
 - 10. شهادة تسجيل القيمة المضافة أو إفادة بإعفاء من القيمة المضافة.
 - 11. صورة من شهادة تأسيس الشركة أو اسم العمل سارية المفعول صادرة من المسجل التجاري.
 - 12. استيفاء الدمغة القانونية.
 - 13. صورة من الرخصة (أ) مجددة للعام 2015 من وزارة الصحة.

- 14. دفع تأمين مبدئي 2% من قيمة العطاء بخطاب ضمان مصرفي ساري لمدة 90 يوماً أو بشيك معتمد باسم مدير عام الهيئة العامة للإمدادات الطبية أو نقداً ترد لمن لا يرسو عليه العطاء و تكمل إلى 10% لمن يرسو عليه العطاء. على أن تكون ال 10% ضمان حسن التنفيذ سارية المفعول لمدة 6 أشهر قابلة للتجديد.
- 15. تُقدم مستندات العطاء (لا تشمل العروض) في مظروف محكم الإغلاق ومختوم بالشمع الأحمر ويوضع داخل صندوق العطاءات المعد لذلك في مكتب الاستقبال بالهيئة.
- 16. آخر موعد لاستلام مظروف العطاء (المستندات المطلوبة) يوم الأحد الموافق 2015/03/15 الساعة 12 ظهراً.
 - 17. تُسلم المستندات المطلوبة بالصندوق المعد لذلك باستقبال الهيئة.
- 18. لن ينظر في أي عطاء يصل بعد الزمن المحدد مهما كانت المبررات (نظام الشراء الإلكتروني يُغلق تلقائياً عند الساعة الثانية عشر ظهراً من يوم الأحد الموافق 2015/03/15).
- 19. ستفتح المظاريف والتي تشمل مستندات العطاء (لا تشمل العروض) في حضور ممثلي الشركات المقدمة للعطاء بعد قفل الصندوق مباشرة.
- 20. سيتم استعراض العروض إلكترونياً في حضور ممثلي الشركات يوم الأحد الموافق 2015/03/15 الساعة 12 ظهراً.
 - 21. فترة العطاء عامين من تاريخ توقيع العقد قابلة للتمديد.
 - 22. مدير عام الهيئة غير ملزم بقبول أدبى عطاء أو أي عطاء آخر.
 - 23. للإستفسار أثناء ساعات العمل الرسمية يُرجى الإتصال ب: 0120391175 أو البريد الألكتروني:tenderqueries@cms.gov.sd
 - 24. لمزيد من المعلومات يرجى الرجوع لموقع الهيئة: www.cms.gov.sd

تنويه: : على الراغبين في المشاركة في العطاء التسجيل في نظام الشراء الإلكتروني بالهيئة قبل إستلام الكراسة، يمكن التسجيل عبر موقع الهيئة الموضح أعلاه أو الحضور لمكتب خدمات العملاء بالإدارة العامة للمشتريات بمباني الهيئة.

د. نوال الطاهر بكري ع/مدير الهيئة العامة للإمدادات الطبية

بسم الله الرحمن الرحيم الموكزية العامة للإمدادات الطبية الموكزية



وزارة الصحة الإتحادية الهيئة العامة للإمدادات الطبية المركزية لجنة الشراء الموحد

تعلن الهيئة العامة للإمدادات الطبية المركزية عن برنامج تدريبي للسادة مستوردي الأدوية والمستلزمات الطبية الراغبين في المشاركة في العطاء المفتوح لسنة 2015 والذي سيكون التقديم له إلكترونيا، تسجيل أسمائهم لدى الإدارة العامة للمشتريات، علماً بأن التدريب سيكون مفتوح لمدة ثلاث أيام متتالية حسب أسبقية التسجيل. وسيبدأ التدريب إن شاء الله من يوم الثلاثاء الموافق 2015/01/27 عند الساعة الثانية عشر ظهراً.

ويمكن التسجيل بإرسال بريد الكتروني للعنوان: tenderqueries@cms.gov.sd أو تلفونياً للاتصال على الرقم: 0120391175

ننويه:

سيكون هنالك مندوب دائم من إدارة تقنية المعلومات بالهيئة للمساعدة متى ماطلب ذلك ويمكن التواصل معه عبر البريد الإلكتروني: tenderqueries@cms.gov.sd

أو على الرقم: 0120391175

التسجيل والتدريب مجاناً لكل الراغبين من السادة ممثلي الشركات ولا تتجاوز مدة التدريب ثلاثة ساعات.

وشكراً،،،

د.نوال الطاهر بكري ع/مدير الهيئة العامة للإمدادات الطبية



Republic of Sudan

Central Medical Supplies Public Corporation

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

Web site: www.cms.gov.sd

E-mail: tenderqueries@cms.gov.sd

Fax: +249-1-83-460935

Open Tender for Supply of Medicines, Vaccines and Medical Consumables

2015 - 2017

Invitation for bids for Tender No. (CMS 02/2015)

For supply of Medicines, Vaccines and Medical Consumables

Closing date Sunday 15/03/2015

The Central Medical Supplies Public Corporation, hereafter referred to as CMS, 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 and their manufacturers.

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 Zakaat 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.** At least Five 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.
- **1.2.7.** A list indicating all details of submitted samples shall be attached (2 copies requested) (Appendix 1).
- **1.2.8.** The bidder must mention the registration number for each item, and attach the relevant registration certificate.
- **1.3.** The bidder shall bear all costs associated with the preparation and submission of his bid, and the CMS 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.** CMS reserves the right to modify the submitted quantity of any item by increasing it up to 50% or decreasing it 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, CMS 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: country of origin, delivery details, dosage form, shelf life, pack size, strength, 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 CMS Reception, Khartoum South not later than 12 pm on Sunday 15/03/2015.
- **1.12.** No bid will be accepted after 12.00 pm of the closing date on Sunday 15/03/2015.
- **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 CMS 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 Sunday,15/03/2015 at 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 3,000 (three 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 CMS 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, CMS may at its discretion, extend the deadline for the submission of bids.
- **1.20.** CMS 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 CMS 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 CMS.

- **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 will be directly to the local agent by account in Euro through Central Bank of Sudan (CBOS) or as agreed between CMS and agent. The agent must notify CMS about goods arrival date by submitting a copy of the documents at least three working days before estimated arrival date.
- **1.26.** If the CBOS could not transfer the hard currency to the local agent account, CMS will take responsibility of bank transactions. The supplier immediately on shipment dispatch of the contracted item/s, must advice CMS by e-mail, fax, or hand the following details before three working days in air delivery and 20 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.
 - **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 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 Bill of lading.
 - **1.26.6.** Expected time of arrival.
- **1.27.** When CMS 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 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 CMS 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 CMS has the right to withhold payments and/ or cancel any outstanding transaction in the event of supplier default.
- **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 CMS is not bound to accept the lowest or any other bid.

2. Prices:

QUOTATION SHOULD BE SUMBITTED ON THE BASIS OF DELIVERY INSIDE THE MEDICAL STORES, KHARTOUM SOUTH.

- **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 \times quantity) are to be quoted against each item in $(\mbox{$\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 paid by CMS after submission of the official documents.

3. Payment:

- **3.1.** Value of the awarded items will be paid by CMS after complete delivery and after final acceptance of the item/s by the CMS at its main warehouses in Khartoum.
- **3.2.** The payment will be directly to the local agent in hard currency or as agreed between the CMS and the local agent. If the CBOS failed to transfer the hard currency to the local agent, the LC will be opened by CMS as deferred LC at least 120 days.
- **3.3.** Exact delivery date of the goods or part there to at the CMS stores shall be specified against every individual item tendered for.
- **3.4.** Payment for the goods or part there of shall be against due delivery of the same of the goods are to the satisfaction of the CMS.

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 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 (Euro rate for calculation of IBG value is 7.5 SDG).
- **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) or certified cheque, 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 CMS, 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 30 days of the acceptance of his bid, furnish the CMS with a guarantee from a local Bank for a sum equal to 10 % of the total money payable to the CMS 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 CMS until such time as the supplier shall have completed his obligation to the satisfaction of the CMS. Acceptance of a tender shall in all cases be conditional on receipt of the guarantee or declaration by the CMS within the prescribed period. Such guarantee or declaration shall be in the form prescribed by the CMS. The agreement hereby contemplated shall not be deemed to be operative unless and until such guarantee or declaration shall have been received by the CMS and the CMS shall have acknowledged receipt thereof in writing. Failure to deliver such guarantee or declaration within the prescribed time shall give the right to the CMS to withdraw its acceptance of the tender.

6. General Conditions:

- **6.1.** While accepting any tender, the CMS 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 CMS, 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 CMS as to its contents. The item concerned will be subjected to analysis which will be carried out by the CMS in the National Quality Control Laboratory and results of that analysis will be final and shall bind the CMS and successful tenderer.
- **6.5.** The CMS 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 distinguished packages and labels of the item from those sold in the market by printing CMS-Sudan, approved CMS logo and barcode.

7. Quality, Specifications, Labeling and Samples:

The following specifications are required based upon requirements considered by the CMS 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 CMS.
- **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 CMS 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 "CMS-Sudan", approved CMS 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 in the by-law 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 manufacture batch number and expiry dates of each product, trade and generic names, strength, and dosage forms.
- **7.1.6.** Labeling of containers: The CMS 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: CMS-Sudan and الإمدادات الطبية respectively.

- **7.1.7.** The remaining shelf life should not be less than 75% when the item received in CMS 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 and should be consigned within two months of the date of manufacturing.
- **7.1.8.** The manufacturing date must be mentioned in the certificate of analysis.
- **7.1.9.** The shelf life of all vaccines and sera must not be less than eighteen months.
- **7.1.10.** 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.
- **7.1.11.** The companies should mention in their offers in details, the product components if a Cow source is used, and the name of these components.
- **7.1.12.** All medicines must be shipped in temperature controlled containers with 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.
- **7.1.13.** 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 20 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).
- **7.1.14.** All liquid oral products must not contain alcohol. However percentage of alcohol, if any should be mentioned in the formula for all liquid preparations.
- **7.1.15.** The company should submit a bioequivalence study for one of its awarded items when needed from a research center recognized by NMPB.

- **7.1.16.** Any documents required at any time for quality, safety and efficacy for any item/s must submitted upon request.
- **7.1.17.** 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 its by-law registration of pharmaceutical products 2010.
- **7.1.18.** 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.
- **7.1.19.** The generic name should be more prominent than the trade name.
- **7.1.20.** 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.
- **7.1.21.** Offers and supporting documents should be addressed to General Director of CMS, in a sealed envelope to:

The Director General

Central Medical Supplies Public Corporation

Khartoum

Sudan

- **7.1.22.** All vaccines, 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 data logger. The data logger must be digital with USB connector.
- **7.1.23.** 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.
- **7.1.24.** 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.
- **7.1.24** Genetically modified biological and Narrow therapeutic index products must be offered from originators or from Strong Regulatory Authority (SMRA) countries. The permission of NMPB is required for unregistered products.
- **7.1.25.** Anti snake venom and Anti scorpion venom must comply with Sudanese Species (see Appendix 2).
- **7.1.26.** Freeze watch indicator in addition to USB data logger should be packed with each carton of the following items:
 - a. Hepatitis B vaccine.
 - b. Tetanus vaccine.
 - c. Meningococcal vaccine.
 - d. Any other products that can be affecting by freezing.
- **7.1.27.** All kinds of eye drops and ointments shall be supplied in individually packed containers with the leaflet.
- **7.1.28.** 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.

- **7.1.29.** 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.
- **7.1.30.** 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 CMS or refund the CMS. The supplier **MUST** inform the CMS 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 CMS 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 CMS 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 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.

7.3. 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 at the stated temperature.
- **7.3.3.** Administration sets should be sterile and individually packed inside sterile packs. Each set should have two recipient needles for adults and children.
- **7.3.4** For the Mannitol 20% the administrative set should be filter type.
- **7.3.5.** Blood plasma substitutes shall comply with the following:
 - **a.** It must be non-toxic and pyrogen free, sensitation or antigenic reactions. It should be pyrogen-free.
 - **b.** The viscosity and somatic pressure of infusion must be similar to those of plasma.
 - c. It must not act as a diuretic.
 - **d.** It should not disturb blood grouping reactions or unduly increase the erythrocyte sedimentation rate.
 - **e.** It should be stable on storage during shelf-life at the temperature stated in the label.
 - f. The suppliers of anti sera, antitoxins and other preparations regarding immunity etc. 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.

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 CMS, the order should be supplied in two equal shipments each of six month interval or as be scheduling by CMS, except for those items which value of award is \in 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 CMS. Delivery to be made at the CMS' stores directly.

8.2. Delivery of Vaccines, Sera, Biological and other cold products:

- **8.2.1.** Clearance and Direct received should be made in the presence of CMS staff.
- **8.2.2.** All vaccines, 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.
- **8.2.3.** Shipment should be scheduled to arrive on working days.
- **8.2.4.** Shipment procedures for vaccine, sera and other 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 CMS 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 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.** Sea Shipment must be in temperature controlled containers with digital data logger with USP 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.** Vaccines should be supplied using vaccine vial monitor.

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 CMS may forthwith terminate the agreement, without prejudice to any rights accruing or accrued to the CMS, and may forfeit and retain all moneys deposited in pursuance of conditions 5 or such part thereof as the CMS shall deem fit in respect of any neglect or default of the contractor either in full or part satisfaction of the claim of the CMS for damages in respect of any such neglect or default.

- **10.2.** Without prejudice to the provisions of paragraph1 above and without prejudice to any right accruing or accrued to the CMS under this contract, the CMS 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 CMS 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 CMS may determine.
 - **10.3.** Without prejudice to any of its rights under the contract the CMS 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 CMS 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 CMS by the supplier by virtue of these conditions, the same may be recovered in whole or in part by the CMS 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 CMS'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 CMS 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 CMS 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 ware house by air, or land to remote destination within the Sudan.
 - **11.2.2.** Carton must be in rectangular shape.
- **11.3.** Net weight of each carton of large volume I.V fluids (500ml or more) with giving sets inside the same carton should not exceed 15 Kgs. Solutions and liquids should not exceed 20 bottles per carton unless offered by the supplier and accepted by CMS.
- **11.4.** Each carton must be stenciled with item name as shown in the Tender documents, <u>details of content</u>, <u>Tender Number</u>, item Number, case/carton Number, carton weight in kg and CMS-Sudan.
- **11.5.** Each batch of each item must be packed in separate box(s) or carton(s) and must be clearly identified from other batches.

- **11.6.** Each item should be shipped in pallets and wrapped with plastic not exceeding 1.5 ton per pallet, and height not exceeding 2 meters.
- **11.7.** Security symbols (e.g. handle with care, protect from rain symbols etc....) should be marked Cleary 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 CMS Logo.
- **12.3.** For IV Fluids and other parenterals 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.
- **12.4.** 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 and the total volume of content of the ampoule, batch number, and expiration date and comply with NMPB requirement.
- **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 CMS cold stores with internal digital data logger with USB connector that can be easily checked by CMS.

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 30 days from the date of award notification, the CMS 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 CMS shall have the right either to reject or accept the goods. After 4 week delay period, the CMS 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 CMS within two months from date of intimation.
- **13.6.** If the company fails to supply the replaced quantity within the specified period, CMS reserves the right to confiscate the Performance Bond.
- **13.7.** If the company repeats the same discrepancy for the same item, then CMS 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 CMS, 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 CMS 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 CMS 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. CMS 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. Appeal:

- **15.1** It can be done within 15 days as the award confirmed after 15 days.
- **15.2** A supplier that has been left out the tender has a right to know the reasons for exclusion, by a written request within two weeks from the date of announcement of award (not seen any request after the specified period).

Note:

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

Dr. Nawal Eltahir Bakri General Procurement Director