Subject: CMS Requirements

Referring to the above mentioned subject, we would like to inform you that the following requirements must be considered carefully in dealing with CMS.

A) Quality Requirements

1. Only Pharmacopeias items are acceptable (BP, USP, EUP and Int Pharm.c).
2. Working standard for **un-registered** items not less than 3 gm with validity for at least one year should be dispatch with the goods, for every item (Consumables and vaccines are excluded), and carton containing the working standard should be marked clearly. Otherwise you have to send it by courier prior receiving the item/s.
3. Certificate of analysis for working standard.
4. Certificate of analysis for the item batches.
5. Pro-forma invoice and commercial invoice must be written in generic name in full specification (Trade name can be put between two brackets).
6. The validity of every item must not be less than 75% of its shelf life on delivery at CMS warehouses.
7. The inserted leaflet should be in both Arabic and English languages, giving and explaining all information about the supplied medicine; such information should be identical to the leaflets that used in the country of origin.

8. All companies must supply the minimum possible number of batches (in all case must not exceed 10 batches), other wise the consignment will be rejected.
9. The company should provide all necessary information's on the label of inner and outer pack of each item, on export cartons (at least five (5) layer cartons must be supplied) giving full details of storage conditions, the batch number, manufacturer, country of origin, manufacturing date and expiry dates of each item, trade and generic names and strength.
10. All drugs must be shipped in heat insulated containers, according to the following:
    a. The containers temperature shall be between 20-25C for the items that can be stored at room temperature.
    b. The storage conditions must be stated on the label of internal and external packs and on the internal leaflet must be adhered to during storage and transport for items that need special handling and storage conditions.
11. **All cold items** must be packed in insulated cartons with ice packs, Data Logger and suitable temperature monitor cards must be packed with each carton.(Product should not be in direct contact with the ice bags).
12. Freeze watch (indicator) in addition of indicator card should be packed with each carton of the following items:-
    a) Hepatitis B vaccine.
    b) Tetanus vaccine.
    c) Meningococcal vaccine.
    d) Any other vaccine that can be affected by freezing.
13. Packages must be made of strong materials and constructions that can withstand rough handling and stacking.
14. All boxes and cartons (5 layers) must comply with the following specifications:
    a. Physical alignment: the shape should be symmetric and identical in appearance, size and dimensions for each item.

b. Corrugation construction: several corrugated layers (rectangular shape).
c. Cartons of the I.V. fluids must be of strong construction that can withstand several rough loading and unloading and stacking one over the other to a height of 4 meters, otherwise the label on cartons must show the maximum number of carton-rows which should not be exceeded in storing these cartons.
d. Overlapping and Gaps: None.
e. Net weight of each carton of large volume I.V fluids (500ml or more) should not exceed 12Kgs. Solutions and liquids should not exceed 20 bottles per carton.
f. Each batch of each item must be packed in separate box(s) or carton(s) and must be clearly identified from other batches.

15. Each item/s should be shipped in pallets and wrapped and not exceed 1.5 ton.
16. In each pallet there should be one item and one batch only.
17. The test result from the National Quality Control Laboratory is crucial and final and is not subject to the dispute or arguments.
18. Items, which fail to pass the Quality Control tests; supplier should either replace them only by item/s agreed and approved by CMS or refund the CMS. The supplier must inform the CMS within not more than 15 working days about the option of substitution.

B) Shipping Documents

The following requirements must be sent through bank for original documents and shipping copies of documents must be sent before 72 hours (3 working days) for by air shipment and before 15 days for by sea shipment (forwarder BL is not acceptable):

1. Certificate of origin (1original + 3 copies) certified that true and correct from the national chamber of commerce of the country of origin.
2. Packing list (I Original +3 copies).
3. In the packing list the following requirements are must:

a. Packing list should be clearly written in full information with details of quantities for each batch.
b. Cartons should be serially numbered.
c. Batch NO and par cod should be written in inner of the item/s pack as well as in the external pack and outside carton.
d. If there is a completion quantity, it will be mentioned clearly on the cartons which contain that quantity.

- **In case if the working standard shipped with the goods, please mention the carton no clearly in the packing list.**

4. Clear instructions should be given for the shipper to clear the goods by copies of the documents; any delay to present the documents in time, the fees of the demurrage would be paid by the local agent.

C. Delivery

1. All vaccines, sera and other cold items should be shipped on a direct flight whenever possible. (Air Emirates is strongly recommended).
2. Shipping should be scheduled to arrive on working days (Sunday to Thursday).
3. Vaccine, sera and other cold items, shipment procedures, 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 Procurement Department indicating all shipping details (quantities, description of item/s, flight No, expected date of arrival at final terminal and Airway Bill No).
4. Containers and cartons must be clearly labeled (keep cool). The airway bill must also be clearly marked (keep cool during transport or transit).
5. Vaccines should be supplied using vaccine vial monitor (VVM).

D. For EX-Stock purchased locally

The following requirements are requested:

1. Certificate of analysis for the item/s for the same batch mention release from the Sudan national lab.

2. Import and distribution permission from National Medicines & Poisons Board.
3. Commercial invoice must be written in generic name in full specifications (Trade name can be put between two brackets).
4. Cold storage items which need cold chain transportation and storage must be delivered in special cold transport boxes with internal temperature recorder that can easily be checked by CMS (e.g. Data Logger) with sufficient quantity of ice packs which will keep the temperature of the items within the required range of temperature till the items are delivered and received into CMS stores.
5. Each item/s should be shipped in pallets and wrapped and not exceed 1.5 ton.
6. In each pallet there should be one item and one batch only.

Note

- Failure to fulfill any of the above mentioned requirements would be considered serious and final in the evaluation of supplier performance.
- Failure to fulfill any of the above mentioned requirements for cold items will reject the item/s.
- E-mails of procurement personnel attached with this documents for more communications.
- For shipping documents please send a copy mail to all above e-mail address.
- Not complete set of shipping documents will not consider at all.

Thank You for Your Cooperation,,,

Nawal Eltahir Barky

General Procurement Director