1. REQUIREMENTS

1.1 General requirements

1.1.1 The product description (strength, composition, dosage form, etc.) shall correspond with the schedule of quantities and any samples supplied.

1.1.2 Products shall comply with official compendia such as:

- BP (British Pharmacopoeia),
- USP (United States Pharmacopoeia),
- EurP (European Pharmacopoeia),
- IP (International Pharmacopoeia)
- In-house specifications or standards accompanied by scientific justification and proof of validation.

1.1.3 The product remaining shelf-life at the time of receipt at Central Medical Stores shall be at least 80% or greater of the total product shelf-life.

1.2 Special requirements

1.2.1 Oral drug dosage form products containing Chloroform, Tartrazine, Phenylpropanolamine or any banned substances shall not be allowed.

1.2.2 For Oral Liquid preparations, the alcohol content shall not exceed 10%

1.2.3 For all coated tablets, the type of coating shall be clearly indicated.

1.3 Cold chain requirements

1.3.1 All cold chain products shall be delivered packed in insulated packaging materials appropriate for shipping of pharmaceutical products.

1.3.2 All cold chain products consignments shall be:

- Accompanied by a temperature monitoring devices (data loggers) during delivery.
- Transportation processes shall be supported by documentary proof of validation stating the validated temperatures and duration.

1.3.3 All vaccines shall have a Vaccine Vial Monitor (VVM) on the label as per World Health Organization (WHO) requirements.

1.1.4 **Product registration requirements**

1.4.1 Central Medical Stores shall give preference to drugs registered with Botswana Medicines Regulatory Authority (BoMRA) over similar unregistered products.

1.4.2 For registered products no much documentation is required to be submitted. However Central Medical Stores may request if necessary.

1.4.3 All unregistered drugs require an exemption approval from the Botswana Medicines Regulatory Authority (BoMRA) before procurement and delivery in the country.

1.4.4 Unregistered products with documentary proof of registration by other Regulatory authorities or registration in the countries of origin may be given preference over products with no alternative registration

1.4.5 If an unregistered product is awarded due to the absence of a registered product, the Supplier shall apply for an Exemption to BoMRA as per the Exemption Guidelines provided in the BoMRA website (https://www.bomra.co.bw/index.php/bomra-downloads/guidelines-manuals/category/41-human-medicines) and required import permits as required by paying the stipulated fees.

1.4.6 The following documentation is required for all unregistered products:

- Registration certificate from country of origin.
- Valid GMP certificate from the country of origin.
- A copy of the most recent Certificate of analysis.
- For an **injectable** product, a valid cGMP certificate for the Finished Pharmaceutical Product manufacturing site, issued by either ICH member countries prior to 23 October 2013, regulatory authorities that participate in the PIC/S, WHO or National Medicines Regulatory Authorities in Namibia, Zambia, Zimbabwe, South Africa, Tanzania and Uganda.
- For a **Biosimilar** product, a valid Registration Certificate for the product must be provided from ICH member countries as defined prior to 23 October 2013.

1.4.7 In exceptional circumstances Central Medical Stores - Quality Assurance unit may request additional information from the bidder. If requested the bidder shall provide the required information to Central Medical Stores within ten (10) working days.

1.2 Packaging requirements

1.2.1 Packaging material shall be suitable for the purpose and have no detrimental effects on the pharmaceutical product.

1.2.2 Packaging shall be user friendly.

1.2.3 Primary packaging shall give adequate protection against external influence and potential contamination.

1.2.4 The primary container - closure system / material shall be tamper proof with a suitable seal.

1.2.5 Secondary packaging material shall be strong enough to withstand transportation, stacking (on pallets), storage and normal handling conditions.

1.2.6 All light sensitive pharmaceuticals shall be packed in amber or opaque containers.

1.2.7 Liquid products formulations shall be packed as follows:

100ml bottles:	Not more than 100 bottles per carton / box
200ml bottles:	Not more than 50 bottles per carton / box
500ml bottles:	Not more than 24 bottles per carton / box
1.0 litre bottles:	Not more than 12 bottles per carton / box
2.5 litre bottles:	Not more than 6 bottles per carton / box
5.0 litre bottles:	Not more than 4 bottles per carton / box

Bottles shall be sufficiently partitioned or cushioned to prevent any breakages.

1.2.8 The primary containers or immediate containers of such liquid formulations shall preferable have screw type closures or lids that can adequately close the bottle throughout duration of use.

1.2.9 All the oral liquid formulations shall be supplied in child resistant container and closure system.

1.2.10 All products supplied shall adhere to the manufacture's original packing configurations. Any variations shall be communicated in writing prior to delivery and Central Medical Stores reserves the right to accept or reject any alternative packing configurations.

1.3 **Labelling requirements**

1.3.1 All labels and package inserts instructions shall be in English.

1.3.2 All labels shall be legible and clear.

1.3.3 For injections and oral liquid preparations, the strength of the active ingredients shall be given in the quantity of the active ingredient per dosage unit.

1.3.4 The name and amount of preservatives, colouring agents and antioxidants shall be stated.

1.3.5 Primary packaging material (products immediate containers) shall amongst others be clearly labelled with the:

- Brand / Generic name ·

Batch number

- Expiry date
- Manufacturing date
- Name and physical address of the manufacturer

1.3.6 Secondary packaging material (cartons / boxes) shall be clearly labelled with:

- Brand / Generic name
- Batch number
- Expiry date
- Manufacturing date
- Number of units per carton / box
- Name and physical address of the manufacturer

1.3.7 Labels shall be printed directly on the primary / secondary / tertiary package

1.3.8 Labels shall comply with international labelling requirements or as stipulated by the "Medicines and Related Substances Act" No 8 of 2013.

1.4 Delivery requirements

1.4.1 Each batch shall be accompanied by a certificate of analysis.

1.4.2 Different batches shall **not** be mixed in cartons or pallets. Mixing of batches in cartons shall automatically be rejected. If mixing in one pallet is inevitable, such pallets shall be clearly and appropriately marked.

1.4.3 The invoice or delivery note shall bear the following information:

- A full product description including the strength and dosage form as indicated on the Government Purchase Order (GPO)
- Government Purchase Order (GPO) number
- Contact details of the person to communicate with in case of non-conformities.

1.4.4 All products shall be transported in closed and clean delivery vehicles.

1.4.5 If there are any non-conformities to the tender requirements, the consignment shall not be offloaded. The supplier shall be required to make arrangements to take the goods back immediately. Central Medical Stores shall not take any responsibility for the warehousing of rejected consignments.

2. INFORMATION

2.1. Samples

2.1.1. Samples are required for all products, except where already submitted as per 2.1.2 below. However, samples are not required for drugs registered with Botswana Medicines Regulatory Authority (BoMRA) (unless in special circumstances, they are specifically requested by Central Medical Stores).

2.1.2. If the bidder is quoting a product for which they have previously submitted a sample they may liaise with Central Medical Stores-Quality Assurance unit and agree not to submit another sample (this shall be at the discretion of Central Medical Stores-Quality Assurance unit). Central Medical Stores takes no responsibility for any samples not available at the time of product evaluation.

2.1.3. It is the responsibility of the bidder to ensure that the sample on record matches the product quoted. Central Medical Stores reserves the right to reject any consignment that does not match the sample on record.

2.1.4. For Habit forming drugs, Vaccines and cold chain products submit package artwork and package insert are sufficient for evaluation.

2.2. Product track record

2.2.1 Any product with an outstanding quality compliant with Central Medical Stores or an alert from Botswana Medicines Regulatory Authority (BoMRA) or any other regulatory authority at the time of tender evaluation will be reviewed by Central Medical Stores and Botswana Medicines Regulatory Authority (BoMRA) and decision taken to accept or reject.

2.3. Health and safety

2.3.1 Material safety data sheets (MSDS) shall be submitted for the following category of products:

- Caustic and inflammable substances
- Cytotoxic substances
- Anti-infectives
- Vaccines and Biological products
- Inhalational anaesthetics
- Any drug that has known or potential to cause hypersensitivity or allergy.

2.4. Product information sheet

2.4.1 For all unregistered products, bidders shall be required to submit completed product information data sheets.

2.4.2 Registered products do not require product information data sheet unless specifically requested by Central Medical Stores.

2.5 Supplier performance

2.5.1 Central Medical Stores shall monitor the supplier's performance in terms of quality, delivery and price. The measurements shall be an input into the evaluation process.

2.6 Technical evaluation

2.6.1 The technical evaluation shall be based on the following factors:

- Completeness and adequacy of the submitted documentation.
- Completeness and accuracy of manufacturer and supplier documentation
- Visual inspection of samples
- Compliance to packaging specifications
- Compliance to labelling specifications
- Any outstanding compliant or past recalls
- Package artworks and package inserts