National Agency for Food & Drug Administration & Control (NAFDAC)
Drug Evaluation & Research (DER) Directorate

GUIDELINES FOR GOOD STORAGE PRACTICE (GSP) / GOOD DISTRIBUTION PRACTICE (GDP) INSPECTION OF COLD CHAIN FACILITIES FOR STORAGE OF VACCINES & BIOLOGICS.

1. GENERAL

1.1 These guidelines are for the interest of individuals intending to engage in importation and distribution of vaccine, biologics and related products in Nigeria.

1.2 This prescribes the minimum GSP and GDP requirements for the facilities for storage and distribution of vaccines, biologics and related products to ensure quality and safety.

1.3 It is necessary to emphasize that, no regulated product should be manufactured, imported, exported, advertised, sold or distributed in Nigeria unless it has been registered in accordance with the provisions of the Food, Drugs and Related Products Act Cap F33 LFN 2004 (formerly decree 19 of 1993) and the accompanying guidelines.

1.4 Vaccines and biologics should not be imported into Nigeria unless the facility has been inspected and found to comply with Good Storage Practice and Good Distribution Practice.

1.5 These guidelines prescribe the minimum requirements necessary for the inspection of a facility for compliance with GSP and GDP for the registration of vaccines, biologics and related products.

2. APPLICATION FOR INSPECTION

2.1 An application for Inspection should be made on the company's letter-headed paper and addressed to:
The Director-General, National Agency for Food and Drug Administration and Control (NAFDAC),
ATTENTION: Director, Drug Evaluation & Research Directorate, NAFDAC Office Complex, Apapa-Oshodi Expressway. Isolo, Lagos. The exact location address (NOT P.O. Box) of the proposed cold store, functional e-mail address, telephone number(s) and products intended for registration should be stated.

2.2 The application letter should be submitted to The Director, Drug Evaluation & Research Directorate; 1st Floor, NAFDAC Office Complex, Isolo, Lagos or the nearest NAFDAC office (for applicants outside Lagos) with the evidence of business registration or company incorporation with CAC.

2.3 A request for Cold Storage Facility Inspection for the applicant is received from the Drug Registration & Regulatory Affairs Directorate and the Director Drug Evaluation and Research (DER) issues a directive for the applicant to pay for the inspection.

2.4 The applicant should follow the below-listed steps to make payment for the inspection:

- 2.4.1 Collect a payment advice for the inspection from the Drug Evaluation & Research (DER) Directorate; 1st Floor, NAFDAC Office Complex, Isolo Industrial Estate, Apapa-Oshodi Express Way Isolo, Lagos or the nearest NAFDAC office (for applicants outside Lagos).
- 2.4.2 Visit **www.remita.net** to generate a Remita invoice and print out a copy of the invoice.
- 2.4.3 Visit the nearest commercial bank to make the payment.

2.5 The applicant should collect an official receipt of payment from the Finance & Accounts Section; 3rd Floor, NAFDAC Office Complex, Isolo, Lagos or the nearest NAFDAC office (for applicants outside Lagos).

3. SCHEDULING OF FACILITY FOR INSPECTION

3.1 Upon submission of evidence of payment to DER Directorate, the facility is scheduled for inspection at the earliest convenient date.

4. GOOD STORAGE PRACTICE AND GOOD DISTRIBUTION PRACTICE REQUIREMENTS

4.1 Personnel

4.1.1 There should be sufficient number of personnel to suit operations of the facility.
4.1.2 Persons in charge of cold chain facility should have a minimum of Ordinary National Diploma (OND) in a relevant science discipline.
4.1.3 Current annual license to practice of the Superintendent Pharmacist.
4.1.4 Personnel should wear protective apparel.
4.1.5 Personnel should practice good sanitation and hygiene practices.
4.1.6 Personnel should undergo medical fitness test at least once a year.

4.2 Building/Facilities

4.2.1 The building should be segregated into storage areas and cloak rooms.
4.2.2 The storage facility should have adequate space to ensure proper placement of storage units to allow for good air circulation.
4.2.3 The rooms should be adequate for the orderly placement of storage equipment showing different categories of materials.
4.2.4 Windows and entrance doors should be screened with insect-proof netting and the doors to storage areas should be secure. Access into the storage facility should be controlled.
4.2.5 Adequate ventilation and illumination should be provided.
4.2.6 The facility should be kept clean at all times.
4.2.7 There should be adequate storage areas for ancillary packaging components

4.3 Equipment

4.3.1 The cold room should be qualified and the temperature monitoring devices in the refrigerators/cold room should be calibrated.
4.3.2 The equipment must be cleanable and be routinely cleaned.
4.3.3 The refrigerator or cold room should have its exterior door that seals tightly and properly.
4.3.4 Each Equipment should be dedicated for strictly the storage of vaccines and biologicals and have sufficient capacity to store the volume they require.
4.3.5 The equipment should have thermostat controls and must be able to maintain the required temperature range.
4.3.6 A preventive maintenance schedule should cover all equipment.

NOTE: Dormitory style (freezer and fridge unit with one external door) refrigerator is not permitted.

4.4 Environmental Sanitation

4.4.1 Waste should be disposed in an appropriate and sanitary manner.

4.4.2 Fumigation of the facility should be carried out quarterly.
4.4.3 Water system toilets and hand washing facilities should be appropriately located away from the storage area and kept clean.
4.4.4 Eating, drinking and smoking should not be permitted in the storage area.

4.5 Documentation

The following documents should be made available during the inspection:

4.5.1 Company's Organogram.
4.5.2 Current annual license of superintendent pharmacist.
4.5.3 Current certificate of registration of premises.
4.5.4 Credentials of cold chain personnel.
4.5.5 Standard Operating Procedure (SOP) for cleaning equipment.
4.5.6 SOP for handling vaccines and biologics.
4.5.7 SOP for handling and disposal of expired vaccines and Biologics
4.5.8 SOP for Distribution.
4.5.9 SOP for Cleaning of Facility Premises.
4.5.10 SOP for recall.
4.5.11 SOP for Preventive maintenance.
4.5.12 SOP for gowning (where applicable).
4.5.13 Medical certificate of fitness for personnel.
4.5.14 Certificate of fumigation of the facility.
4.5.15 Personnel File Records (Letter of Appointment and Acceptance of offer, certificates, job description, training records).
4.5.16 Evidence of acceptance of Trade Mark.
4.5.17 Evidence of cold chain maintenance along the distribution channel.
4.5.18 Product labels should be in English language and should contain the following:
4.5.18.1 Name of product (Brand/ Generic Name)
4.5.18.2 Net weight/volume
4.5.18.3 Batch Number/ Lot NO
4.5.18.4 Manufacturing Date
4.5.18.5 Expiry Date
4.5.18.6 Provision for NAFDAC REG. NO
4.5.18.7 List of ingredients (For BCG to include No. of culturable particles)
4.5.18.8 Full name & Exact factory location address (Not P.O. Box)
4.5.18.9 Directions for use
4.5.18.10 Storage conditions
4.5.18.11 Cautions (where necessary)
4.5.19 NOTE:
4.5.19.1.1 Any Vaccines/ Biological product whose name, package, or Label bears close resemblance to an already registered product or is likely to be mistaken for another shall not be considered for registration.
4.5.19.1.2 Vaccines labeled in foreign language would not be considered for registration unless an English translation is included on the label & package insert.

4.5.19.1.3 Information or indications on Package & Leaflet insert of imported vaccines products shall not differ from that in other countries & in particular the Country of origin of the product.

4.6 Distribution System

4.6.1 Records of product distribution network must be properly kept for easy recall of defective products.

4.6.2 Distributors names, addresses, telephone numbers, email addresses, quantity of products issued, batch numbers, dates of manufacture and expiry should be maintained.

4.6.3 Record of maintenance of cold chain along distribution channel should be maintained.

4.7 Transportation and Handling

4.7.1 Products should be handled and transported under conditions specified by the manufacturer to maintain the cold chain to prevent deterioration, spoilage and breakage to ensure that the product quality is maintained up to the time of delivery to the consumer.

5. TARIFF

5.1 Please to refer to the appropriate section in the NAFDAC Approved Tariffs available at www.nafdac.gov.ng

5.2 All fees attract 5% VAT.

6. CORRESPONDENCE

All correspondence should be addressed to:
The Director-General (NAFDAC)
Attn: The Director,
Drug Evaluation & Research Directorate
1st Floor, NAFDAC Office Complex, Isolo Industrial Estate, Oshodi-Apapa Expressway Isolo, Lagos State.
NAFDAC website: www.nafdac.gov.ng
E-mail address: der.headquarters@nafdac.gov.ng
Telephone Number:

Note:

- **All submissions should be made at the Office of the Director, DER; 1st Floor, NAFDAC Office Complex, Isolo Industrial Estate, Apapa-Oshodi Expressway Isolo, Lagos or the nearest NAFDAC Office (for applicants outside Lagos).**
- **Unsatisfactory outcome of inspection leads to issuance of compliance directives and a stop in the process clock until the applicant responds satisfactorily to the directives.**