National Agency for Food & Drug Administration & Control (NAFDAC)

Narcotics & Controlled Substances (NCS) Directorate

Guidelines for Warehouse Inspection

1. General

1.1 These Guidelines are for the interest of the general public and in particular, manufacturers' importers, distributors of controlled drugs and precursor chemicals in Nigeria.

1.2 This Guideline was developed following the Pharmaceutical Quality System ICH Q(10) requirement which applies to the systems supporting the development and manufacture of pharmaceutical drug substances, drug products, manufacturing and control of narcotics drugs.

1.3 The application of ICH (10) is appropriate and proportionate to lifecycle of pharmaceutical products not excluding proper storage of Narcotics drugs as required by international standard. CH (Q10) augments Good Manufacturing Practices applicable to this guideline.

1.4 All applications for permit to import should be submitted online through the Singe Window for Trade Portal (https://trade.gov.ng) to the Director, Narcotics and Controlled Substances, NAFDAC, Isolo, Lagos State by the Managing Director, Technical officer or Superintendent Pharmacist.

2. Documentation

2.1 The following documents are to be submitted on–line by every applicant for warehouse inspection of controlled drugs.

2.1.1. Application letter on company's letter head paper addressed to the Director-General, National Agency for Food and Drug Administration and Control (NAFDAC), ATTENTION: Director, Narcotics and Controlled Substances (NCS), Isolo Lagos and signed by either the Managing Director or the Superintendent Pharmacist.

2.1.2. Annual Licence to practice of Superintendent Pharmacist.

2.1.3. Previous import permit/authorization.

2.1.4. Copy of permit to clear/authorization letters.

2.1.5. Distribution record in current format.

2.1.6. Stock cards or utilization records.

2.1.7. Batch Manufacturing Records (for manufacturers).

2.1.8. Evidence of sales of controlled drugs (invoices/waybills/receipts).

2.1.9. Disposal of Poisons Book for controlled drugs (Form K).

2.1.10. Current Certificate of Registration/Retention of premises.

2.1.11. Copy of registration certificate of regulated products.

2.1.12. Evidence of payment for warehouse inspection.

2.1.13. GMP certificate issued by NAFDAC for manufacturers of controlled drugs.

2.2 The following documents are to be submitted online by applicants for warehouse inspection of importers/distributors of precursor chemicals.

2.2.1. Application letter on company's letter head paper addressed to the Director-General, National Agency for Food and Drug Administration and Control (NAFDAC), Attention: Director, Narcotics and Controlled Substances (NCS), Isolo, Lagos and signed by either the Managing Director or the Technical officer.

2.2.2. Letter of employment and acceptance of offer, credentials of technical officer with a minimum qualification of Ordinary National Diploma (OND) in any of the Sciences; and Passport photograph of the technical officer if a new technical officer wasemployed or if company is a new applicant.

2.2.3. Current Medical Certificate of Fitness of technical officer and other chemical handlers(carried out biannually).

2.2.4. Evidence of permit to import and clear for previous year.

2.2.5. Evidence of Listing Certificate (for marketers)

2.2.6. Utilization or disposal records (stock cards) for previous year's importation/localpurchase.

2.2.7. Invoices/waybills/delivery notes for chemicals sold or purchased locally.

2.2.8. Evidence of payment of rent/ownership of warehouse (Marketers only).

2.2.9. Evidence of waste disposal.

2.2.10. Evidence of Registration of regulated products (if applicable).

2.2.11. Batch Manufacturing Records (for manufacturers of precursor chemicals)

2.2.12. Names and addresses of customers (chemical marketers and manufacturers/distributors of precursor chemicals)

2.2.13. Evidence of payment of warehouse inspection fee

3. **Inspection**

3.1 Upon satisfactory review of the documents, the company is scheduled for the inspection oftheir storage facilities.

4. **Timeline**

4.1 The timeline for this process is 5 working days from the submission of a satisfactoryapplication.

4.2 Please note that the clock stops once compliances are issued.

5. **Tariff**

Please refer to Tariff section: https://nafdac.gov.ng/regulatory-resources/nafdac-tariff/

All correspondence should be addressed to:

Director-General (NAFDAC)
ATTENTION: The Director,
Narcotics and Controlled Substances Directorate
3rd Floor, NAFDAC Office Complex,
Apapa-Oshodi Expressway, Lagos state.

Website: www.nafdac.gov.ng.
E-mail address: ncs@nafdac.gov.ng

All submissions should be made at the Office of the Director, NCS, 3rd Floor, NAFDAC Office Complex, Isolo Industrial Estate, Oshodi-Apapa Express Way Isolo, Lagos or the nearest NAFDAC Office (outside Lagos).