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

Narcotics & Controlled Substances (NCS) Directorate

Guidelines for Obtaining Permit for Importation of Narcotic Drugs, Psychotropic Substances and Drug Precursors

Guidelines for Obtaining Permit for Importation of Narcotic Drugs, Psychotropic Substances, Drug Precursors and Nationally Controlled Drugs.

1. General

1.1. 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 (i.e API), drug products, including biotechnology and biological products, throughout the product lifecycle.

1.2. The Guidelines are for the interest of the general public and in particular, importers of Narcotic Drugs, Controlled/Psychotropic Substances, Drug Precursors and nationally controlled drugs into Nigeria.

1.3. It is necessary to emphasize that, no product containing Narcotic and Controlled Substances shall be manufactured, imported, exported, advertised, sold, distributed or used in Nigeria unless it has been registered in accordance with the provisions of NAFDAC Act CAP N1 (LFN) 2004, other related Legislations and the accompanying Guidelines.

1.4. It is also necessary to emphasize that Narcotics, Controlled/Psychotropic substances, Drug precursors and nationally controlled drugs should not be imported without obtaining Import Permit and Permit to Clear where applicable.

Step 1

2. Documentation

2.1. Companies intending to import Narcotic drugs, Psychotropic Substances, Drug precursors and other nationally controlled drugs should visit the Federal Government of Nigeria Single Window for Trade Portal (www.trade.gov.ng) to fill the electronic application form for Permit to import Narcotic drugs, Psychotropic Substances and Drug precursors. (Note: Only the Holder of the Certificate of Registration for Narcotic Drugs, Controlled/Psychotropic Substances, Drug Precursors and other nationally controlled drugs is permitted to apply for the permit to import and the permit to clear).

2.2. The following documents are required to be attached for a successful Submission of the electronic form: 2.2.1. An application on the company's letter head addressed to the Director-General, National Agency for Food and Drug Administration (NAFDAC), ATTENTION: Director, Narcotics and Controlled Substances (NCS) Directorate, NAFDAC Office Complex, Isolo Industrial Estate, Apapa-Oshodi Expressway, Isolo, Lagos state and duly signed by the Superintendent Pharmacist of the company.

The following should be indicated:

2.2.1 The name of substance(s) to be imported brand name(s) of registered controlled drug product(s) where applicable physical quantity of each item for finished products
  2.2.1.1. The quantity(ies) of substance(s) to be imported in kilogram
  2.2.1.2. Country of origin
  2.2.1.3. Name and address of the manufacturer
  2.2.1.4. Name and address of the (supplier) exporter
2.2.2 Valid Annual Licence to Practice of the Superintendent Pharmacist
2.2.3 Valid Certificate of registration/retention of premises
2.2.4 Letter of Recommendation from Registration and Regulatory Affairs Directorate (for new applicants only).
2.2.5 Proforma Invoice
2.2.6 Disposal records for previous importation(s) according to approved template.
2.2.7 Distribution records for finished product(s) according to approved template. (except for Energy drink importers and Non-governmental Organizations)
2.2.8 Evidence of product registration by NAFDAC

Step II

3. Processing of Permit
   3.1. Permit to Import will be processed for satisfactory applications.
   3.2. For unsatisfactory application/documentation, a Compliance Directive(s) will be issued to the company.

Step III

4. Collection of Permit

   4.1. (Collection of endorsed Permit to Import is at the office of the Director, NCS.) Endorsed electronic Permit to Import is printed from Company's profile on the Federal Government of Nigeria Single Window for Trade Portal (www.trade.gov.ng) where application was made.

   4.2. Requests for replicate copies of the electronic Permit to Import can be made at Narcotics and Controlled Substances (NCS) Directorate, NAFDAC Office Complex, Isolo Industrial Estate, Apapa-Oshodi Expressway, Isolo, Lagos state by submitting the following documents:
      4.2.1. Printed copy of electronic Permit to Import on Federal Government of Nigeria Single Window for Trade Portal
      4.2.2. Proforma invoice for the controlled substance/drug

4.2.3. Evidence of product registration by NAFDAC for finished products

4.3. Collection of endorsed replicate copies of Permit to Import is at the office of the Director, Narcotics and Controlled Substances Directorate.

5. Tariffs

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

6. Note:

6.1. Failure to submit adequate documents may lead to considerable delay in processing the application.

6.2. Failure to respond promptly to Compliance Directives will lead to suspension of further processing of the application.

6.3. Allocation of controlled substances is based on availability.

6.4. Submission of fake documents will be considered as a violation and may result in regulatory action and/or prosecution.

6.5. The Pharmacist's Annual License to Practice does not confer authorization to import and clear Narcotic drugs, Psychotropic Substances, Drug precursors and other nationally controlled drugs.

6.6. The consignment must not be shipped without obtaining a Permit to import from the Agency. Any applicant/importer that ships Narcotic drugs, Psychotropic Substances, Drug precursors and other nationally controlled drugs before Permit to import is issued will be sanctioned appropriately.

6.7. The consignment will only be cleared from the Ports upon obtaining a Permit to Import and Permit to Clear. Failure to present these documents will be considered an offence.

6.8. That permit expires on the 31st of December of the year of issuance and shipment should be done before or on 31st December. (and clearing of all shipments should be done before or on 31st December).

6.9. Only the Holder of the Certificate of Registration for Narcotic Drugs, Controlled/Psychotropic Substances, Drug Precursors and other nationally controlled drugs is permitted to apply for the permit to import and the permit to clear. No third-party importation is allowed for controlled substances

6.10. The Timeline for this process is 5 working days from the submission of a satisfactory application.

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)

The ICH Q9(R1) *Quality Risk Management Guideline* is intended to provide guidance on the principles and examples of tools for quality risk management that can be applied to different aspects of pharmaceutical quality and make limited and specific adjustments to specific chapters and annexes of the current ICH Q9 Guideline on Quality Risk Management (QRM).