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

Narcotics & Controlled Substances (NCS)Directorate

Guidelines on Risk Categorization of Importers, Manufacturers, Distributors of Narcotic Drugs, Psychotropic Substances and Precursors

Definitions and Abbreviations

1.1 Risk: The effect of uncertainty on objectives i.e., combination of the consequences of an event including changes in circumstances and the associated likelihood of occurrence. (ISO 31000).

1.2 Risk assessment: The overall process of risk identification, risk analysis and risk evaluation.

1.3 Risk Management: Coordinated activities to direct and control an organization with regard to risk.

1.4 Risk Treatment Strategy/Plan: A scheme within the Risk Management framework specifying the approach, the management components and resources to be applied to the management of risk.

1.5 Risk Identification: Process of finding, recognizing and describing risk.

1.6 Risk Analysis: Process to comprehend the nature of risk and to determine the level of risk.

1.7 Risk Evaluation: Process of comparing the result of Risk analysis with risk scores to determine if the risk and/or its magnitude is acceptable or tolerable.

1.8 Risk Scores: terms of reference against which the significance of a risk is evaluated.

1.9 Residual Risk: Risk remaining after risk treatment.

1.10 Establishing the context: Determining the external and internal issues that are relevant to its purpose and strategic direction and that affects its ability to achieve the intended result(s) of its quality management system.

1.11 SWOT: Strength, Weakness, Opportunity and Threats

1.12 PESTEL: Political, Economic, Social, Technological, Environmental and Legal.

Introduction

Risk categorization is the process of grouping risks into categories based on their characteristics such as:

Risk type: Strategic, operational, financial, compliance, environmental, health and safety, cybersecurity, reputation, etc.

Risk level: High, medium, low, based on the likelihood and impact of the risk.

Risk source: Internal, external, or a combination of both.

Risk impact: Financial, reputational, operational, strategic, etc.

Risk likelihood: High, medium, low, based on the probability of the risk occurring.

Risk categorization is one of the tools used to ensure control of Narcotics, psychotropic,

precursors and controlled substances and access for legitimate use while preventing diversion.

The National Agency for Food and Drug Administration and Control (NAFDAC) ACT Cap N1, LFN 2004 empowers the Agency to control and regulate the manufacture, importation, exportation, distribution, advertisement, sale and use its regulated products. This mandate requires that the Agency ensures the quality, safety and efficacy of all regulated products. The Narcotics and controlled substances directorate, therefore, has developed Risk categorization guide which considers intrinsic and compliance risk to ensure control and accessibility of Narcotics, psychotropic, precursors and controlled substances while preventing diversion for illicit use.

Regulations and guidelines which stipulate the minimum standards that manufacturers are required to adhere to ensure the quality of Narcotics, psychotropic, precursors and controlled substances are referenced in this guideline.

This guideline was developed following the ICH Q9(R1) Quality Risk Management requirement and one of the tools amongst others, used in this guideline is Cause and Effect Diagrams (also called an Ishikawa diagram or fish bone diagram).

The ICH Q9(R1) *Quality Risk Management Guideline* provides guidance on the principles and examples of tools for quality risk management that can be applied to different aspects of pharmaceutical quality.

Scope: This guideline applies to importers, manufacturers and distributors of Narcotics, psychotropic, precursors and controlled substances based on their risk rating for the issuance of permit to import.

Key indicators to consider subject to inspection of pharmaceutical companies and verification of usage of Narcotics, psychotropic, precursors and controlled substances for the purpose of risk categorization.

1. **Utilization of active pharmaceutical ingredients of** Narcotics, psychotropic, precursors and controlled substances
   - Batch manufacturing records
   - Disposal of Controlled Substances Book.
2. **Inventory keeping tools**
   - Current premises registration with Pharmacy Council of Nigeria.
   - Distribution record/ Stock cards

- Status of Superintendent Pharmacist's registration
- Status of product registration

Violation

Violations shall include but not limited to the following categories of companies/persons/cases:

1. Importation Narcotics and Controlled substances above NAFDAC's approved strength.
2. Importation of Narcotics and Controlled substances/products is within NAFDAC approved strength but import quantity more than that for which permit was granted.
3. Importation of Narcotics and Controlled substances/products is within NAFDAC approved strength but whose products are unregistered.
4. Cases where legitimate import of narcotics, psychotropics and precursors are investigated and proved to be diverted.
5. Distribution formulations of controlled substances without adherence to distribution guidelines.
6. Importation of controlled substances without NAFDAC's Permit.
7. Importation of controlled substances /products without NAFDAC's registration/Permit.
8. Importation of controlled substances /products outside NAFDAC's permit validity Period.
9. Importation of formulations of controlled substances / products that do not comply with labelling regulations.
10. Companies whose distribution chain integrity are unsatisfactory.

Penalty

1. Suspension or cancel of certificate of permit to import.
2. Reduction in allocation of Narcotics, psychotropics, precursors and controlled substances.
3. Administrative charges.

References

1. Controlled Medicines Regulations 2021
2. Counterfeit and Fake Drugs and Unwholesome Processed Foods (Miscellaneous Provisions) Act Cap C.34 LFN 2004.
3. Drug and Related Product Labelling Regulations 2019.
4. Guidelines for obtaining Permit for Importation of Narcotics, psychotropics, precursors and controlled substances.
5. Guidelines for obtaining Permit for Importation of Schedule 1 Narcotic Drugs.
6. Guidelines for Labelling of Investigational Medicinal Products 2021.
7. Guidelines for obtaining Permit to Clear Narcotics, psychotropics, precursors and controlled substances.
8. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use ICH Harmonised Guideline. Quality Risk Management Q9(R1) Final version Adopted on 18 January 2023.
9. NAFDAC Good Manufacturing Practice for Pharmaceutical Products Guidelines 2021.
10. Reviewed NAFDAC Good Distribution Practices Guidelines for Pharmaceutical Products 2023.