

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

**Drug Registration & Regulatory Affairs (DR&R) Directorate**

**NAFDAC RISK CATEGORIZATION AND PATHWAYS FOR REGISTRATION OF DRUG PRODUCTS FOR HUMAN USE**

* 1. **GENERAL**
  2. The risk categorization and pathways aimed to establish risk-based approach for the assessment/ evaluation of dossiers submitted for the purpose of registration of drug products in Nigeria.
  3. The objective of this approach is to ensure seamless registration processes using different pathways to register both made in Nigeria and imported drug products. The pathways will optimize the registration processes and ensure efficient and effective use of both human and material resources whilst providing support for continual and realistic improvement for manufacturers of pharmaceutical products.
  4. The focus of the Agency is to ensure the quality, safety and efficacy of NAFDAC regulated products through regulatory activities i.e market authorization, laboratory testing, facility inspection, pharmacovigilance and post marketing surveillance of approved products and through reliance on WHO or ICH region and other reference countries and other NRAs.
  5. The risk-based approach requires that product dossier be submitted for all drug products irrespective of the risk category except for **topical preparations**.
  6. This guideline shall be applicable to registration of all allopathic drugs for human use, biological products which are manufactured locally or imported except those for topical use.

**2.0. RISK CATEGORIZATION OF APPLICATIONS FOR DRUG REGISTRATION**

**2.1. LOW RISK APPLICATION**

2.1.1 Already registered generic products from the same manufacturer (i.e., application for a drug product from a manufacturer with a similar drug product(s) (same molecule and form) already on the Nigerian market) for which the safety and quality has been established for a least 10years.

2.1.2 Local applications for contract manufacture of a product, where same drug product has already been registered for which the safety and quality are fully established and the product is marketed in Nigeria for at least 5 years.

2.1.3 .Products from Toll Manufacturing facility (Local applicant) approved by NAFDAC on the same line as an already registered product by the Agency that has been on the market for two(2) years.

2.1.4 Products which have been approved by an SRA, WHO-ML3 agency for at least six months for which the assessment report can be shared or accessed.

2.1.5 Products accepted by WAHO joint assessment, WHO Prequalified Products under WHO PQ-NRA Collaborative procedures and WHO facilitated SRA-NRA Collaborative procedures.

2.1.6 Products approved through the SwissMedic MAGHP procedure.

**2.2. DOSSIER REVIEW/ASSESMENT PATHWAY FOR LOW RISK**

**2.2.1 *Products in 2.1.1 & 2.1.2***

2.2.1.1 Notarized letter of confirmation from the FPP manufacturer that the formulation, equipment and processes are the same as that already registered by NAFDAC.

2.2.1.2 A copy of NAFDAC registration Certificate for the already registered products.

2.2.1.3 A CTD dossier should be submitted which will be used to identify areas of improvement to be pursued with the manufacturer.

2.2.1.4 Dossier clearance would be issued after the criteria stated above have been met

2.2.1.5 The assessment of the product dossier should focus on ensuring that the proposed specifications at least meet pharmacopeia standard, specifications of the mother or established product and identify areas of improvement to be pursued with the manufacturer and such deficiencies will not weigh on the registration of the product. If the container closure for the product is different from the product already on the market, then stability data will need to be evaluated for the new product before a shelf-life can be assigned.

2.2.1.6 Timeline (24 months) shall be set and supported with signed commitment letter provided by the applicant to implement the identified areas of improvement.

**2.2.2 *Products in 2.1.3, 2.1.4 & 2.1.5***

*2.2.2.1* The already established Procedure for external reliance ( WHO facilitated SRA-NRA and Collaborative Registration Procedures (CRP) for imported products would be adopted.

**2.3 MEDIUM RISK APPLICATION**

2.3.1 Known/ existing manufacturer introducing a new product but of the same dosage form as those already registered from the same manufacturer:

* different active ingredient
* same active ingredient but different formulation or
* same active ingredient/formulation but a different strength.

2.3.2 Products made in Nigeria from new manufacturer (will be afforded *Pre-submission meeting (Only for new manufacturer from Nigeria)*

2.3.3 3. Products from Toll Manufacturing facility (imported products) approved by an NRA on the same line as an already registered product that has been in the Nigeria market for Ten (10) years.

**2.4 DOSSIER REVIEW/ASSESMENT PATHWAY FOR MEDIUM RISK**

2.4.1 Dossier screening will be carried out.

2.4.2 Abridged dossier review/ assessment should be performed.

2.4.3 The proposed specification should at least meet compendia standard.

2.4.4 For identified areas of improvement which may take applicant a long time to implement, timeline shall be set and supported by a signed commitment to be provided by the applicant reflecting the set timeline over which the manufacturer is expected to implement the requested change.

2.4.5 Pre-submission meeting to establish the level of commitment to quality standards of the toll manufacturer

**2.5 HIGH RISK APPLICATION**

2.5.1 Products from new manufacturer from non-SRA region

2.5.2 Known manufacturer introducing a new dosage form.

2.5.3 New Molecules

2.5.4. All other products that do not meet the criteria for low and medium risk and products whose effects are limited to the GIT.

***Note: Applicant/manufacturer will be afforded opportunity for Pre-submission meeting.***

***2.6* DOSSIER REVIEW/ASSESMENT PATHWAY FOR HIGH RISK**

2.6.1 Dossier screening

2.6.2 Full dossier review

**2.7 5+5 POLICY**

Applicants implementing **5+5 policy** shall be covered under the following provisions.

1. For manufacturers executing transfer of technology for previously registered drug products in fulfilment of **5+5 policy**, post-variation requirements involving change of site shall apply. However, due to the national call for local manufacturing, a rolling submission will be allowed for the site / tech transfer to Nigeria.

1. For manufacturers coming to Nigeria based on **5+5 policy** with products other than those previously registered, the requirements of low or medium risk shall apply.
2. For applicants migrating to local manufacturing under contract manufacturing agreement in fulfilment of **5+5 policy**, the requirements for low or medium risk shall apply on case by case basis.