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

Drug Registration & Regulatory Affairs (DR&R) Directorate

NAFDAC GUIDELINES FOR RISK CATEGORIZATION OF PRODUCT DOSSIERS FOR THE REGISTRATION OF DRUG PRODUCTS FOR HUMAN USE

1.0. GENERAL

1.1. 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 for human use in Nigeria.

1.2. 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.

1.3. 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 mechanisms.

1.4. The risk-based approach requires that product dossier be submitted for all drug products irrespective of the risk category.

1.5. This guideline shall be applicable to registration of all allopathic drugs for human use which are manufactured locally or imported.

2.0. RISK CATEGORIZATION OF APPLICATIONS FOR DRUG REGISTRATION

2.1. LOW RISK APPLICATION

2.1.1 An application of an already registered product contracted to a known manufacturer which has been in the Nigerian market for at least 5 years shall qualify as low risk.

The product shall have the ***same active ingredient, formulation, and container closure*** as the registered product, and must not have failed any survey conducted by NAFDAC or WHO. This shall not include injectables, sterile products and narcotic substances.

2.1.2 Manufacturer of imported products already registered by NAFDAC who as a result of the 5 + 5 policy is transferring the technology to Nigeria. This is subject to satisfactory survey outcome within the first two years post approval.

2.1.3 Products which have been approved by an SRA, WHO-ML3 agency for which the unredacted assessment report can be shared or accessed.

2.1.4 Products accepted by WAHO joint assessment, WHO Prequalified Products under WHO-PQ Collaborative procedure and WHO facilitated SRA-NRA Collaborative procedure and products approved through the Swiss Medic MAGHP procedures.

2.1.5 Topical preparations and products limited to the GIT with no systemic effect such as antacids.

2.2. DOSSIER REVIEW/ASSESMENT PATHWAY FOR LOW RISK

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

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

2.2.1.3 The assessment of the product dossier should focus on ensuring that the proposed specifications meet at minimum the requirement of one of the officially recognized pharmacopoeia and other relevant guidelines for non-compendial products and identify areas of improvement to be pursued with the manufacturer. Such deficiencies will not weigh in 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.

2.2.1.4 Where deficiencies are identified, a timeline (24 months) shall be set and supported with signed commitment letter provided by the applicant to implement the identified areas of improvement.

2.2.1.5 Dossier clearance and acceptance will be issued after the criteria stated above are met.

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 WHO-PQ Collaborative Registration Procedures (CRP)) for imported products would be adopted.

Eligibility criteria/document to be provided for products in 2.1.4, 2.1.5 and 2.1.6 ; shared and accessible assessment report from the primary agency, NAFDAC-SRA QIS and product dossier.

2.3 MEDIUM RISK APPLICATION

2.3.1 An application for an already registered generic product (injectables, sterile products, and narcotics substances) contracted to a known manufacturer which have been in the Nigerian market for at least 5 years shall qualify as medium risk. The product shall have the ***same active ingredient, formulation, and container closure*** as the registered product, and must not have failed in any survey by NAFDAC or WHO.

2.3.2 Products from SRA, for which unredacted assessment report(s) cannot be shared with NAFDAC.

2.3.3 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 five(5) years.

2.3.4 Manufacturer of imported products already registered by NAFDAC coming to manufacture in Nigeria without any contract manufacturing agreement and/or technology transfer agreement

2.4 DOSSIER REVIEW/ASSESMENT PATHWAY FOR MEDIUM RISK

2.4.1 Dossier screening

2.4.2 An abridged dossier review/ assessment

2.4.3 For identified areas of improvement which may take applicant a long time to implement, 24 months timeline shall be set and supported by a signed commitment to be provided by the applicant reflecting the set timeline over which the applicant/manufacturer is expected to implement the requested changes.

2.5 HIGH RISK APPLICATION

2.5.1 Products from new manufacturer from non-SRA and non-ML3 regions

2.5.2 A 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

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 using the comprehensive checklist.

2.6.2 Full dossier review

2.7 5+5 POLICY

For an application under **5+5 validity policy**, at least one of the following conditions shall apply:

a) Manufacturers executing transfer of technology for previously registered drug products in fulfilment of 5+5 policy, the requirements of low risk shall apply.

b) Applicants migrating to local manufacturing under contract manufacturing agreement in fulfilment of 5+5 policy, the requirements for low risk shall apply.

c) Manufacturers coming to Nigeria based on 5+5 policy with no technology transfer, the requirements of medium risk shall apply.

Note: Applicant/manufacturer that has been sanctioned and made to pay an administrative fine based on quality-related issues of the product shall be moved a step upward concerning the risk category it belongs (i.e a low category will be treated as medium risk application while a medium category will be treated as high risk application.)

****See attached Risk Categorization and Pathways Summary Table.***

RISK CATEGORIZATION AND PATHWAYS SUMMARY TABLE

S/N	PATHWAY	CATEGORY	ELIGIBILITY	REQUIREMENTS
https://www.msn.com/en-xl/news/other/summer-funcity-hall-launches-tender-for-alpine-coast	**RISK CATEGORIZATION**	**LOW**	1. Already registered generic products from the same manufacturer of the ***same active ingredient, formulationstrength (same or different strength but proportional formulation) and container closure*** for which the safety and quality has been established for at least 5years in the Nigeria market. 2. Local Contract Manufacture. 3. Products from SRA, WHO-ML3 countries 4. Products accepted under WAHO joint assessment, WHO-PQ & WHO-SRA NRA products 5. Products approved through the SwissMedic MAGHP ~~6.~~ Topical preparations and products limited to the GIT with no systemic effect such as antacids	**Eligibility 1 , 2 and 3** 1. Notarized letter of confirmation from the FPP manufacturer that the formulation, equipment and processes are the same as an already registered NAFDAC product 2. A copy of NAFDAC registration certificate for the product 3. Dossier submission in CTD format* **Eligibility** 1. Reliance pathways; Share and accessible unredacted assessment report from the primary agency, NAFDAC-SRA QIS and product dossier

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		MEDIUM	1. Existing manufacturer introducing a new formulation but of the same dosage form as those already registered.. The new product may be a product with: **(a) different active ingredient** (b) **same active ingredient but different formulation** 2. Products made in Nigeria from New manufacturer 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 five(5) years.	1. Dossier submission in CTD format.
		HIGH	1. Products from New Manufacturer from non-SRA region. 2. Known manufacturer introducing a new dosage form. 3. New Molecules 4. All other products that do not meet the criteria for low and medium products.	1. Pre-submission meeting 2. Dossier submission in CTD format.

2.		**5+5 POLICY**	1. Manufacturers executing transfer of technology for previously registered drug products in fulfillment of **5+5 policy.** 2. Manufacturers coming to Nigeria based on **5+5 policy** with products other than those previously registered, the requirements of medium or high risk shall apply. 3. Applicants migrating to local manufacturing under contract manufacturing agreement in fulfillment of **5+5 policy**, the requirements for low or medium risk shall apply on case by case basis.	1. Dossier submission in CTD format. 2. Post-approval variation certificate/document involving change of site.

⁎ Topical preparations will be treated as low risk.