NATIONAL AGENCY FOR FOOD AND DRUGS ADMINISTRATION AND CONTROL (NAFDAC)

Drug Registration & Regulatory Affairs (D R & R) Directorate

GUIDELINES FOR REGISTRATION AND RELATED ACTIVITIES OF DRUGS, VACCINES AND IN-VITRO DIAGNOSTICS USING THE RELIANCE PROCEDURE

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INTRODUCTION

The World Health Organization (WHO) supports the principles of reliance by less resourced Health Authorities on other regulators' work to make the best use of available resources and expertise. This principle enables leveraging the output of others whenever possible while placing a greater focus at the national level on value added regulatory activities that cannot be undertaken by other authorities, such as in-country vigilance activities and oversight of local manufacturing and distribution. Reliance approaches facilitate timely access to safe, effective and quality-assured medical products and can help in regulatory preparedness and response, particularly during public heath emergencies. If implemented effectively, reliance can result in consistent regulatory processes, sound regulatory decision-making, efficiency of regulatory systems, and better public health outcomes.

These guidelines have been developed to provide guidance to applicants for an alternative pathway to the *Registration of Drug Products, vaccines and In-vitro Diagnostics*, for products whose quality, safety, and efficacy have been confirmed by a Stringent Regulatory Authority (SRA) as per WHO definition/classification and any other regulatory authority that the Agency has such Reliance agreement with such as WAHO, AMRH, Swiss Medic MAGHP procedure.

The instituted alternative pathways are deemed to facilitate conducting regulatory reviews and evaluations in a timely manner and simultaneously accelerate the evaluation process without compromising the quality, safety, and efficacy of medical products.

The aim is to speed up the evaluation of authorization applications towards timely approval. The process is achieved in a variety of ways, including information and/or work-sharing and reliance or recognition of dossier assessment reports, GMP/GCP Inspections, Clinical Trials (review of safety and

efficacy data) as it relates to marketing authorization approval, vigilance, and laboratory testing (QC) outcomes.

Mechanisms have been put in place to consider reliance on the product evaluation decisions made by other Regulatory Authorities and has established mechanisms and procedures for recognizing the marketing authorization decisions of SRAs as per WHO definition/classification (see definitions). NAFDAC may rely on the assessment report of such SRAs but retains its Sovereignty in decision-making.

NAFDAC may activate the reliance pathway to facilitate regulatory decisions either on a case-by-case basis or at the explicit request of the Applicant.

1. General Principles:

1.1. These guidelines are for the interest of the general public and in particular manufacturers / importers of Drugs, Vaccines and In-Vitro Diagnostics into the country which have been reviewed and approved by an SRA as defined by the WHO.

1.2. This guideline is based on the National Agency for Food and Drugs Administration and Control (NAFDAC)'s Regulatory Reliance Policy on adoption of regulatory reliance mechanisms to make regulatory decisions as is related to the granting of Marketing Authorisations, Clinical Trial Approval, and Conduct of Good Manufacturing Practice (GMP) Inspections, GCP Inspections, Clinical Trial data review for safety and efficacy, Vigilance and laboratory testing (QC) outcomes.

1.3. The Reliance Procedure is limited to Drugs, Vaccines, and In-Vitro Diagnostics that have been assessed and inspected by SRAs in line with the procedures and standards available.

1.4. Overseas manufacturers and non-resident applicants would be required to appoint a corporate entity with the requisite mandate to represent the manufacturer/applicant. The local representative would be required to submit relevant documentation including but not limited to a Power of Attorney (POA) or any other documentation confirming his/her appointment as a legal representative.

1.5. This guidance should be read in conjunction with the NAFDAC Guidelines for Registration of Pharmaceutical Products for Human Use

1.6. It is necessary to emphasize that, no drug shall be manufactured, imported, exported, advertised, sold distributed, or used in Nigeria unless it has been duly registered in accordance with the provisions of

NAFDAC Act CAP N1 (LFN) 2004, and other related Legislations and the accompanying guidelines.

2. Marketing Authorization Applications:

STEP 1: Submission of Expression of Interest

A written expression of interest requesting the processing of the New Product Registration via the reliance pathway should be made on the company's letterhead to the Director-General (NAFDAC), ATTENTION: The Director, Drug Registration & Regulatory Affairs (DR & R) Directorate, Ground Floor, NAFDAC Office Complex, Isolo Industrial Estate, Oshodi-Apapa Express Way, Isolo, Lagos State. Can be submitted via email to registration@nafdac.gov.ng

STEP 2: Submission of dossier / Screening

2.1 Following receipt of the expression of interest application, the applicant shall submit a full CTD dossier along with complete unredacted assessment reports where relevant via the dossier management system.

2.2 Non-public, complete, and unredacted assessment reports (see definitions) may also be obtained directly from the manufacturer when the company is able to access these reports from the SRA. Otherwise, manufacturers participating in the WHO SRA Collaboratory Reliance procedure should upload these reports on WHO SharePoint for SRA approved products that are not currently prequalified by WHO. WHO is responsible for sharing the assessment and inspection reports for the prequalified products.

The uploaded dossier will be screened and reviewed by DRT to determine completeness and sameness of the dossier with that approved by authority being relied on. A screening and review clearance letter will be issued for dossiers that meet the requirements

STEP 3: Documentation

The required documents (stated below) are to be uploaded on the NAPAMS portal after obtaining the necessary dossier clearance. The original copies of these documents should be submitted at the Liaison Office of the Director (LOD), R & R Directorate, Ground Floor, NAFDAC Office Complex, Oshodi-Apapa Express Way, Isolo, Lagos State or any NAFDAC Office (outside Lagos) for verification/authentication.

3.1 An online application form for Product Registration should be purchased at: http://registration.nafdac.gov.ng and completed.

3.2 A separate application form should be submitted for each product.

3.3 An application for registration of imported drugs should be made on the company's letterhead to the Director General (NAFDAC), ATTENTION: The Director, Drug Registration & Regulatory Affairs (DR & R) Directorate as part of the attachment of NAPAMS.

3.4 Notarized Declaration (Appendix I). To be completed (typed), signed by Declarant, and notarized by a Notary Public in Nigeria.

3.5 Power of Attorney (where the Applicant does not own the Brand name). The Power of Attorney shall be:

3.5.1 Issued by the manufacturer of the product.

3.5.2 Signed by the Managing Director, General Manager, Chairman,or President of the Company, stating the names of the products to be registered. The Power of

Attorney shall also state 'Authority to register product with NAFDAC'.

3.5.3 State ownership of Brand name(s)/Trademark.

3.5.4 Notarized by a Notary Public in the Country of manufacture.

3.5.5 Valid for at least five (5) years.

3.6 Contract Manufacturer Agreement (where the Applicant owns the Brand name). The Contract Manufacturing Agreement shall be:

3.6.1 Notarized by a Notary Public in the country of manufacture.

3.6.2 Signed by both parties stating names and designations of the signatories with the names of all the products to be registered and other relevant clauses clearly explained in an unambiguous language.

3.7 Evidence of Business Incorporation of the Applicant with Corporate Affairs Commission in Nigeria.

3.8 Manufacturing License/Certificate of Free Sale Evidence that they are licensed to manufacture drugs for sale in the country of origin (Manufacturer's Certificate). The license shall be issued by a relevant Health/Regulatory body in the country of manufacture.

3.9 Certificate of Pharmaceutical Product (COPP-WHO Format).There must be evidence by the competent Health Authority, that the sale of the product does not constitute a contravention of the drug laws of that country. The Certificate of Pharmaceutical Product (COPP) should;

3.9.1 Conform to WHO format.

3.9.2 Be issued by the Health/Regulatory body in the country of manufacture.

3.9.3 Be authenticated by the Nigerian Embassy or High Commission in the country of origin. In countries where no Nigerian Embassy exists, any Commonwealth or ECOWAS country can authenticate the COPP.

3.10 Current Good Manufacturing Practice (cGMP) of the manufacturing facility. This is to be:

3.10.1 Valid at the time of submission.

3.10.2 Be issued by the Health/Regulatory body in the country of manufacture or any SRA.

3.10.3 Be authenticated by the Nigerian Embassy or High Commission in the country of origin. In countries where no Nigerian Embassy exists, any Commonwealth or ECOWAS country can authenticate the document.

3.11 Evidence of Registration of Brand Name with Trademark Registry in the Ministry of Industry, Trade and Investment. This should be registered in the name of the owner of the Trademark/Brand name as the case may be (Trademark Class 5 for Drugs).

3.12 Copy of valid Annual License to practice for the Superintendent Pharmacist for Human Drugs or Veterinary Drugs, issued by the Pharmacists Council of Nigeria (PCN).

3.13 Evidence of valid Certificate of Retention of Premises for the facility.

3.14 Letter of Invitation for Good Manufacturing Practice (GMP) Inspection: A letter of invitation to inspect the factory abroad shall be written by the manufacturer and shall state the following:

3.14.1 MANUFACTURER INFORMATION: Name of Company, full location address of factory (not administrative office address), e-mail, and current phone no. Details (name, phone number, and email) of contact person overseas.

3.14.2 LOCAL REPRESENTATIVE INFORMATION: Name of company, full location address, functional phone no., e-mail address. Details (name, phone number, and email) of contact person. Names(s) of product(s) for registration.

STEP 4: Issuance of Import Permit and Label vetting

4.1 Upon successful screening of the dossier, and review of supporting documents, a Permit to Import Product Samples for Registration purpose shall be issued after which products are submitted for vetting.

4.2 The products submitted under this procedure shall comply with the NAFDAC Labelling requirements
https://www.nafdac.gov.ng/wp-content/uploads/Files/Resources/Guidelines/R_and_R_Guidelines/GENERAL/Quality-Guidelines-for- Registration-of-Pharmaceutical-Products26381.pdf#page=93
&
https://www.nafdac.gov.ng/wp-content/uploads/Files/Resources/Guidelines/R_and_R_Guidelines/More_On_R_and_R/Guidelines-for- Labelling-26375.pdf

STEP 5: Verification

5.1 NAFDAC shall conduct a verification to ascertain that the product intended to be registered, imported, and distributed in Nigeria has been duly registered or authorized by a stringent regulatory authority.

5.2 The product should have been registered for more than six (6) months, and the product characteristics (use, dosage, precautions) for local registration should conform to that agreed in the authorization by the SRA. In addition, there should be an assurance that the product is

either identical or similar to that approved by the SRA in terms of quality, safety, and efficacy.

5.3 NAFDAC receives applications for the same pharmaceutical product as the one registered by the SRA.

Within the context of this procedure, the same pharmaceutical product is characterized by the same or sufficiently similar product dossier as follows:

- The same manufacturing ~~chain,~~ processes, and control of materials
- The same active pharmaceutical ingredient (API) and finished pharmaceutical product (FPP) specifications
- The same essential elements of product information
- The same supporting safety, efficacy, and quality studies
- The same indications and conditions of use

Note: As part of the process, the manufacturer should confirm in the application that the product is the same or sufficiently similar and that the dossier contains the same information as much as possible, with consideration for any potential national requirements. Any differences should be justified by the manufacturer and NAFDAC shall determine the merit of using the SRA assessment reports or decisions.

STEP 6: Review and Assessment

6.1 NAFDAC has identified areas of regulatory decision reliance. The areas of reliance include registration and marketing authorization, GMP/GCP Inspections, Clinical Trials, Vigilance and Quality Control (QC) testing-related decisions to ensure full implementation and compliance to the reliance route.

6.2 As part of the process of reliance for registration and marketing authorization, the relevant Directorates shall be notified of the expression of interest of the applicant for product registration via the reliance pathway leading to an abridged assessment of the quality, safety, and efficacy/performance data considering information in the assessment and inspection reports of the reference regulatory authority.

6.3 NAFDAC shall verify the information submitted by the applicant together with the shared assessment reports, inspection reports **(which shall not exceed 3 years validity),** and any bridging report from the applicant to make an informed decision in accordance with NAFDAC's laid down processes to ensure appropriateness for the Nigerian population.

6.4 NAFDAC shall make a decision based on the review of all available information with input from Pharmacovigilance and Drug Evaluation and Research Directorate as regards the GMP/GCP/Cold-Chain Storage Facility (for applicable products) and Clinical Trials.

STEP 7: Laboratory testing

7.1 The applicant shall provide samples for physical and laboratory evaluation with the following documents:

7.1.1 Letter of submission of laboratory samples

7.1.2 Evidence of payment of statutory fees to NAFDAC. https://www.nafdac.gov.ng/wp-content/uploads/Publications/Others/NAFDAC-2019-Tariff_hyperlinked_Final.pdf

7.1.3 A copy of the permit to import registration samples.

7.1.4 Certificate of analysis

The Certificate of Analysis must be presented on a letterhead of the quality control laboratory where the sample was tested/evaluated and should contain the under-listed information:

7.1.4.1 The brand name of the product/INN

7.1.4.2 The batch number of the product

7.1.4.3 The manufacturing and expiry dates

7.1.4.4 The name, designation, and signature of the analyst

7.2 Quality Control Laboratory leverages a provision that allows NAFDAC to rely on or recognize analytical reports from;

7.2.1 WHO Pre-Qualified Laboratories or ISO IEC 17025 accredited.

7.2.2 Quality Control Laboratory authorized by the Government in an SRA (Stringent Regulatory Authorities) country.

7.2.3 National Regulatory Authorities (NRAs) who are members or observers or associates of the ICHVICH. They include USA USFDA, Europe EMA, Japan, Swiss Medic, Health Canada, Australia, Norway, Iceland, Liechtenstein, Article 58.

7.2.4 WHO Listed Authorities.

7.2.5 National Regulatory Authorities NRAs operating at maturity level 3 (ML3) and maturity level 4 (ML4).

7.2.6 United States Environmental Protection Agency (USA-EPA).

7.2.7 International bodies World Health Organization (WHO), World Organization for Animal Health (OIE).

7.2.8 Regional bodies West Africa Health Organization WAHO, ECOWAS Medicines Regulatory Harmonization (MRH).

7.2.9 African Medicines Regulatory Harmonization (AMRH).

7.3 Notwithstanding Section 2.2, NAFDAC may choose to conduct laboratory testing of products submitted for registration under the reliance procedure.

STEP 8: Approval

8.1 Following submission of laboratory samples and forwarding of same to the laboratory the product is scheduled for the next Food and Drugs Registration Committee (FDRC) product approval meeting.

8.2 Upon satisfactory Dossier review/verification, Risk-Based GMP Categorization of the production facility, and satisfactory laboratory analysis (where applicable), products are presented to the FDRC for ratification.

8.3 NAFDAC will use the product-related information and documentation provided by the applicant, at its discretion, to come to its conclusion about national registration and make its decision on the registration within 60 working days (≈ 90 calendar days).

9 GMP Inspections

9.1 An application must be made to the Drug Evaluation and Research Directorate (as it relates to a New Drug Application) for facility status verification.

9.2 The Applicant must submit a completed Facility Status Verification Form to the Drug Evaluation and Research Directorate (DER) and follow the process to obtain facility verification status.
REVISION-01-SOP-for-FOREIGN-MANUFACTURING-FACILITY-GMP-CATEGORIZATION-Annexure-1-Facility-Status-Verification-Form-DER-607-01.pdf (nafdac.gov.ng)

9.3 The assessment of the application and documentation will be performed with the objective of determining whether the application contains enough evidence as proof of GMP compliance.

9.4 All sites are inspected upon payment of statutory fees, lines within a facility are also inspected when inspectors conduct an inspection. The GMP certificate received is used as a basis for the categorization to give

low priority to the inspection and allow for the completion of the registration process.

9.5 In specific, NAFDAC has a policy on Risk Categorization of Foreign Manufacturing facilities for facility status verification and a risk-based approach for conducting site inspections.
RISK_CATEGORIZATION_OF_FOREIGN_MANUFACTURING_FACILITIES.pdf (nafdac.gov.ng)

Note: Although there are provisions that allow for a risk-based approach on foreign NRAs inspections and enforcement actions, there are currently no mutual recognition agreements between NAFDAC and any other country/NRA for regulatory inspections. NAFDAC may leverage regulatory work performed by other competent and trusted authorities while retaining sovereignty of the final decision-making.

10 **Clinical Trials/Clinical Data**

Considerations of clinical trial applications to conduct a trial in Nigeria and Clinical data evaluation to support regulatory approval under the process of reliance shall be in relation to the existing Regulations and Guidelines for initiating and overall implementation of Clinical Trials including the evaluation/assessment of Clinical Trial Study report for registration purposes. An application must be made to the Clinical trial, Vaccines and Biologics Division of the Drug Evaluation and Research Directorate for safety and efficacy/effectiveness evaluation (as it relates to a New Drug Application or existing drug with a change in indication, new population, change in dosage regimen, route of Administration FDC, etc).

10.1 The application (protocol, Investigator brochure/study report, IMPD, ,and other relevant documents) should be identical to that submitted, evaluated, and approved by the SRA.

10.2 Under this procedure, NAFDAC shall subject such submissions for approval to an 'abridged' evaluation of the study report and/or a certain part of the application (e.g., relevant to use under local conditions) such as product quality data in relation to climatic conditions and distribution infrastructure and a benefit-risk assessment in relation to use in the local ethnic population (Genetic variation/Polymorphism), medical practice/culture and patterns of disease and nutrition, interchangeability/ dissolution profile (Generic brands). Examples:

10.2.1 If the product under investigation has already been evaluated and listed as a WHO Prequalified Product through the WHO PQ collaborative registration procedure between WHO and NRAs.

10.2.2 If the product under investigation has already been evaluated and listed as a product of either the WHO collaborative registration pilot for stringently authorized products, including through the EU's Article 58 Procedure or the Swissmedic's Marketing Authorization for Global Health products or the International Generic Drug Regulatory Programme (launched July 2014) and as determined by the Agency.

10.2.3 If either the trial or the investigational product has been authorized or granted marketing authorization for more than 6 months in either an ICH founding regulatory member state or region such as EC (EMA), United States (United States Food and Drugs Administration), Japan (MHLW/PMDA) or an ICH standing regulatory member state or region such as Canada (Health Canada), Switzerland (Swissmedic). Further, products registered by TGA of Australia, Iceland, Liechtenstein, and Norway may be considered through the reliance route on a case–by–case basis.

10.2.4 If either the trial or the investigational product has been evaluated and judged satisfactory at a joint review meeting facilitated by the WHO under the African Vaccine Regulatory Forum (AVAREF).

10.2.5 For Application to conduct a Clinical Trials in Nigeria, the Agency shall rely on outcome of the early human Phase study (Phase 1,2 conducted in Stringent NMRA as in 10.2.2 and 10.2.3 above and allow such applicant to proceed to a later phase of study (i.e. Phase 3) for which outcome can be used to support Product registration in Nigeria.

10.2.6 In cases where Genetic variation can affect the efficacy and/or safety concerns known to plausibly be associated with the drug product Pharmacology or outcome not clear to the Agency (Benefit-Risk Profile) data from stringent NMRA/Clime as in 10.2.2 and 10.2.3 above shall be relied upon, a full study may not be conducted and only a bridging study may suffice in Nigeria to substantiate unclear claims in our population. The data emanating from such a stringent environment shall form a sound scientific basis with the outcome of the bridging study to support product registration.

11 **Pharmacovigilance**

11.1 NAFDAC's mandate is safeguarding the health of the Nigerian people and continually ensuring the safety of marketed products through its established pharmacovigilance system. To ensure that safety issues are promptly identified, and the necessary interventions implemented, NAFDAC considers decisions from well-resourced NRAs on the safety of medical products that impact negatively on the health of patients. The regulatory decisions by NAFDAC – leveraging safety decisions from well–resourced or reference NRAs - are geared towards ensuring appropriate and safe use of registered medical products.

11.2 The medical product of concern should have been registered and/or granted marketing authorization in either an ICH founding regulatory member state or region (such as EC (EMA), United States (United States Food and Drugs Administration), Japan (MHLW/PMDA) or an ICH

standing regulatory member state or region (such as Canada (Health Canada), Switzerland (Swissmedic).

11.3 Furthermore, products registered by TGA of Australia, Iceland, Liechtenstein, and Norway, as well as those authorized through the EU's Article 58 Procedure or the Swissmedic's Marketing Authorization for Global Health products may be considered through the reliance route on a case-by –case basis.

11.4 The Agency may also require a marketing authorization holder to adhere to applicable guidelines where the Agency identifies safety concerns in the course of post-marketing surveillance. This does not discharge the marketing authorization holder of the responsibility of monitoring the safety of all its medicinal products through the established pharmacovigilance systems required by the Agency.

12 **Post Approval Changes:**

12.1 Any changes to the quality sections of the product dossier for an API or an FPP and any administrative changes must be in accordance with the NAFDAC Guidelines on Variations to a registered Pharmaceutical product and Guidelines on Variations to a registered Vaccine for Human Use as applicable.
https://www.nafdac.gov.ng/wp-content/uploads/Files/Resources/Guidelines/DR_And_R_Guidelines/NAFDAC-Guidelines-on-Variations-to-a-Registered-Pharmaceutical-Product.pdf
https://www.nafdac.gov.ng/wp-content/uploads/Files/Resources/Guidelines/DR_And_R_Guidelines/Guidelines-on-Variations-to-a-Registered-Vaccine-for-Humans.pdf

12.2 In addition to the requirements listed in the above guideline, where the variation applied for has already been approved by an SRA, evidence of

variation approval by the SRA should be included to facilitate regulatory reliance-based decisions on the variation.

12.3 The submission of SRA approval for the variation may facilitate an abridged review of the variation submitted to NAFDAC which may expedite the variation timeline.

12.4 Pending variations with the SRA should not be included in the application submitted to NAFDAC in order for the application to qualify for reliance.

13 **Lot Release**

13.1 Each batch of human vaccines and other biological products is subject to a Lot release program before being marketed in Nigeria, following a risk-based approach. Applicants must apply to the Vaccines, Biologicals, and Medical Devices Laboratory Services Directorate (VBM-LSD) and submit documents for batches that are subject to independent lot release, as outlined in the NAFDAC Guideline For Lot Release Of Human Vaccines And Other Biologicals 2023

13.2 Routine independent lot release testing requirements will be determined based on a risk assessment and the potential for reliance. This risk assessment takes into account the post-marketing experience concerning the safety and quality of the product. Depending on the availability of a Lot Release Certificate issued by a National Control Laboratory (NCL) that is a full member of the WHO National Control Laboratory Network for Biologicals (WHO-NNB), reliance on some or all tests, or a reduction in independent testing, may be considered, as detailed in the NAFDAC Regulatory Directive on reliance.

14 **Definition of terms**

Abridged regulatory pathways are regulatory procedures facilitated by the use of reliance, whereby the regulatory decision is solely or widely

based on the application of reliance. Normally this would also involve some degree of work by the relying NRA. The expectation is that the use of reliance in these pathways would save resources and shorten the timelines compared to the standard pathways while ensuring that the standards for regulatory oversight are maintained.

Assessment: The term "assessment" covers the outcome of any evaluation conducted by NAFDAC (e.g., evaluation for a clinical trial application, evaluation of an initial authorization for a regulated product, evaluation of safety data, evaluation as part of an inspection, etc.

Full unredacted assessment report: Non-public complete and unredacted regulatory reports that comply with data privacy laws as applicable.

Reliance: The act whereby NAFDAC considers and gives significant weight to assessments performed by another Regulatory Authority or trusted institution, or to any other authoritative information in reaching its own decision. The relying authority remains independent, responsible, and accountable regarding the decisions taken, even when it relies on the decisions and information of others.

Sovereignty: The decision to practice reliance, and how best to implement reliance, rests with the country. Reliance does not imply dependence. In applying reliance in their daily practice, NAFDAC shall maintain independence, sovereignty, and accountability in regulatory decision-making.

Stringent Regulatory Authority (SRA): is defined as a well-resourced authority as defined by the WHO that is:

a. a member of ICH prior to 23 October 2015, namely: the US Food and Drug Administration, the European Commission, and the Ministry of Health, Labour and Welfare of Japan also represented by the Pharmaceuticals and Medical Devices Agency; or
b. an ICH observer prior to 23 October 2015, namely: the European Free Trade Association, as represented by Swissmedic and Health Canada; or
c. a regulatory authority associated with an ICH member through a legally binding, mutual recognition agreement prior to 23 October 2015, namely: Australia, Iceland, Liechtenstein and Norway.

NAPAMS – NAFDAC Automated Product Administration and Management System.

DMS- Dossier Management System

Swiss Medic MAGHP procedure – Swiss medic procedure for scientific advice and Marketing Authorisation for Global Health Products.

WAHO – West African Health Organization

AMRH – African Medicine Regulatory Harmonization