DOCUMENT TITLE: REGULATORY DIRECTIVE ON REGULATORY RELIANCE		
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NATIONAL AGENCY FOR FOOD & DRUG ADMINISTRATION AND CONTROL (NAFDAC)

REGULATORY DIRECTIVE ON REGULATORY RELIANCE

1.0. PURPOSE:

1.1 The purpose of this pathway is to accelerate the evaluation of such applications with the view of ensuring timely access to NAFDAC-regulated products.

1.2 This will be achieved by relying on and recognizing the work done in dossier assessment, GMP, GDP, and GCP inspection, safety assessment, post-market surveillance and market surveillance outcomes, as well as Lot release and the result of Laboratory testing.

2.0. SCOPE

2.1 The scope of this reliance policy will cover the assessment and/or analytical reports or expert opinions from:

2.1.1 World Health Organization (WHO) Listed Authorities (WLAs), VICH members, or ICH Observers.

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

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

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

2.1.5 Regional bodies:), West African Medicines Regulatory Harmonization (WA-MRH)

2.1.6 WHO Pre-Qualified or ISO/IEC 17025 Accredited National Quality Control Laboratories and other internationally recognised laboratories.

2.1.7 African Medicines Regulatory Harmonization (AMRH)

2.1.8 WHO Collaborative Registration Procedure for Medicines, IVDs, Vaccines, and vector control products.

2.1.9 Full members of the WHO National Control Laboratory Network for Biologicals.

2.1.10 **Swiss Medic MAGHP procedure - Swissmedic procedure** for scientific advice and Marketing Authorisation for Global Health Products.

2.1.11 European Medicine Agency- EU Medicines for All (EU-M4All)

2.2 The policy shall apply to marketing authorization, Pharmacovigilance, clinical trials/clinical investigations, post-market surveillance, market surveillance, Lot release of vaccines and other biologicals, laboratory testing, and regulatory inspections.

3.0. DIRECTIVE DETAILS:

3.1 General

3.1.1 This document seeks to define how the Agency will adopt regulatory reliance mechanisms in making its regulatory decisions as relates to the granting of Marketing Authorization, Clinical Trial/Clinical Investigation Approval, approval of Field Trial of Bio-pesticide, Bio-fertilizer and new pesticide molecules, the conduct of Good Manufacturing Practice (GMP) inspections, Pharmacovigilance, Post-Market Surveillance, Market Surveillance, Lot release of Vaccines and other Biologicals and Laboratory testing.

3.1.2 These mechanisms are designed to facilitate regulatory reviews and evaluations in a timely manner, without compromising the quality, safety, efficacy, and performance of medical products, as well as the design of clinical trials and clinical investigations for medical products.

3.1.3 These reliance pathways are applicable where the quality, safety and efficacy of medicinal, Bio/New molecule products, or the quality, safety and performance of medical devices including in vitro diagnostics (IVDs) have been confirmed or where any of the phases of a clinical trial has been initiated or approved in a jurisdiction with a well-resourced regulatory Agency or where the National Regulatory Authority (NRA) is a WHO Listed Authority or where experts within a competent body such as the WHO have evaluated the product.

3.1.4 This reliance pathway is not mutual but rather NAFDAC's strategy on making regulatory decisions by relying on the regulatory agencies and international organizations listed in section 3.1.

3.1.5 The Agency, however, maintains its right to make national decisions without compromising the quality, safety, and efficacy of medicinal and Biologic/New molecule products or the quality, safety, and performance of medical devices, including in vitro diagnostics (IVDs).

3.2 Procedure

3.2.1 The Applicant (an entity seeking approval for their submissions) should inform the applicable organization, as listed in 3.1 above, of their intended submission to ensure provision of access to relevant information by the Agency.

3.2.2 The Agency shall 'verify' that the product intended to be registered, imported, and distributed in Nigeria or the Clinical trial to be conducted in Nigeria has been duly registered or authorized by the relevant well-resourced organization.

3.3 Basis for Reliance

3.3.1 The product has been evaluated and listed as a WHO-prequalified product by the WHO Prequalification Program.

3.3.2 The Product has been evaluated and listed as a product of the WHO collaborative registration for WHO Listed Authority (WLA)-Authorized Products.

3.3.3 The product has been authorized by a WHO Maturity Level 3 National Regulatory Authority (NRA) and the NRA is willing to share the unredacted assessment and inspection reports with NAFDAC.

3.3.4 The product has been evaluated and listed as an output of the West African Medicines Regulatory Harmonization Initiative of the Economic Community of West African States (ECOWAS).

3.3.5 The product has been evaluated and listed as an output of Swissmedic procedure for scientific advice and Marketing Authorisation for Global Health Products.

3.3.6 The product has been evaluated and listed as an output of European Medicine Agency- EU Medicines for All (EU-M4All)

3.3.7 The Product has been registered and/or granted marketing authorization in either an ICH founding or standing regulatory member state or region or an IMDRF Management Committee/Official Observer member country or a VICH member country, as may be applicable and the unredacted assessment report is made available to NAFDAC.

3.3.8 The clinical trial/investigation or the investigational product has been authorized or granted marketing authorization in either an ICH founding or standing regulatory member state or region; or an IMDRF Management Committee/Official Observer member country or a VICH member country, as may be applicable.

3.3.9 The clinical trial/investigation or the investigational product has been evaluated and judged satisfactory at any other bilateral or multilateral joint review meeting endorsed by NAFDAC for the purpose of such review and pronouncement.

3.3.10 The clinical trial/investigation or the investigational product has been authorised or adjudged satisfactory at a joint meeting facilitated by the World Health Organisation under the African Vaccine Regulatory Forum (AVAREF) platform.

3.3.11 The relevant documents and products presented to NAFDAC should be identical to those submitted, evaluated, and approved by the well-resourced or reference NRA or relevant international organization.

3.3.12 The analytical reports should be from National Quality Control laboratories that are WHO Pre-qualified or ISO/IEC 17025:2017 accredited and other internationally recognized laboratories.

3.3.13 The Lot release certificate should be from National Control laboratory (NCL) that is a full member of the WHO National Control Laboratory Network for Biologicals.

3.3.14 Safety information or report should be from WLAs, the WHO, Maturity Level 3 NRAs, an IMDRF Management Committee/Official Observer member country or ICH/VICH founding or standing regulatory member state or region.

APPROVED BY:

DIRECTOR-GENERAL (NAFDAC)

PROF. (MRS.) MOJISOLA CHRISTIANAH ADEYEYE

SIGNATURE: **DATE:** 26.08.25

CHANGE HISTORY & RATIONALE			
Effective date of superseded Policy	Document Ref. No.:	Reviewer	Reason for Review
19-10-2020	NAFDAC-RRP-05-00	AD(QAU), VBM-LSD	'Lot release of Vaccines and Other Biologicals' and 'Biopharmaceuticals' inserted in 1.1. 2. 'Lot release' inserted in 2.2 3. 'Full members of WHO National Control Laboratory Network for Biologicals' inserted in 3.1.6 4. 'Lot release of vaccines and other biologicals, Laboratory testing and regulatory' inserted in 3.2 'The Lot release certificate should be from national Control laboratory (NCL) that is a full member of the WHO National Control Laboratory Network for Biologicals' inserted in 5.10.
14/02/2023	NAFDAC-RRP-05-01	AD(QAU), VBM-LSD	1. 'This reliance path way is not mutual but rather NAFDAC's strategy on making regulatory decisions by relying on the regulatory agencies and international organizations listed in section 3.1.' inserted in 1.1 Review of section 3.1

	NAFDAC-RRP-05-02	VBM-R&R Quality Team/NAFDAC-SCMs	1. Reviewed to include: a) medical devices and the criteria for selecting organizations for reliance in the policy. b) reliance on clinical investigation reports or assessments from recognized NRAs for all medical devices, including IVDs. c) reliance on post-market surveillance and market surveillance outcomes from recognized organizations in the Policy. 2. Replaced "NAFDAC-RRP" with "NAFDAC-RDRR" being the current requirement. 3. Formatted/renumbered 1.0 (Introduction) 4. Added GDP and post-market surveillance and market surveillance outcomes under the heading "Purpose"in 2.2 line 2 5. added Post-Market Surveillance, Market Surveillance in 1.1 line 5. 6. Added "and performance" after efficacy and clinical

			investigations for medical products in 1.1 paragraph 2 (now 1.2). **7.** Added or the quality, safety and performance of medical devices including in vitro diagnostics (IVDs) in 1.1 paragraph 3 line 2 (now 1.3) 8. Replaced the roman numerals with numbers in 3.1 **(Scope).** 9. Removed Stringent Regulatory Authorities (SRAs) in 3.1 line i now 3.1.1 having being replaced with WLA being the current nomenclature. 10. Added WHO Collaborative Registration Procedure to 3.1 (scope of reliance policy). 11. Added clinical investigations, post-market surveillance and market surveillance to 3.2. 12. Included or an IMDRF Management Committee/Official Observer member country or a VICH member country, as applicable to 5.4 (now 5.5) and 5.5 (now 5.6).
30-07-2025	NAFDAC-RDRR-05-03	NAFDAC-SCM/CDCL Quality Teams /DR&RA Quality Team	Review; 1. Section 2.1.6 - to read "WHO Pre-qualified or ISO 17025 accredited **National Quality Control** Laboratories **and other internationally recognized laboratories"** 2. **Section** 3.3.10 – to read "analytical reports should be from **National Quality control** laboratories that are WHO Pre-

			qualified or ISO/IEC 17025:**2017** accredited **and other internationally recognized" laboratories.** 3. to include Regulatory bodies WA-MRH in 2.1.5 , Swiss Medics MAGHP procedure in 2.1.10 and European Medicine Agency -EU Medicines for All (EU M4ALL) in 2.1.11 4. Include willingness of NRA to share unredacted assessment and inspection report with NAFDAC in 3.3.3 5. Include that the product has been evaluated and listed as an output of Swissmedic procedure for scientific advice and Marketing Authorisation for Global Health Products in 3.3.5 6. Include that the product has been evaluated and listed as an output of European Medicine Agency- EU Medicines for All (EU-M4All) in 3.3.6 7. Inclusion of the unredacted assessment report be made available to NAFDAC in 3.7 .