DOCUMENT TITLE: NAFDAC STRATEGIC PLAN FOR RISK BASED INSPECTION FOR FOREIGN PHARMACEUTICAL MANUFACTURING FACILITIES		
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Strategic Plan for Risk Based Inspection for Foreign Pharmaceutical Manufacturing Facilities

1. Introduction

The National Agency for Food and Drug Administration and Control (NAFDAC) is dedicated to ensuring the safety, effectiveness, and quality of all medicines available in Nigeria. Recognizing that a substantial portion of pharmaceuticals in the Nigerian market are imported, particularly from high-volume manufacturing regions like Asia, the Agency understands that it is crucial to adopt a strategic, risk-based approach to overseeing GMP compliance of the foreign manufacturing facilities.

This plan outlines NAFDAC's strategic vision and operational mechanisms for the regulation and control of foreign pharmaceutical manufacturers. It aligns with international regulatory standards, WHO GBT recommendations, and the principles of regulatory reliance and risk-based supervision. The primary goal is to establish a sustainable and cost-effective oversight framework that effectively maintains product quality and safeguards public health.

2. Strategic Goals

This strategic plan aims to achieve the following key objectives:

I. Leverage on the existing Memorandum of Understanding with National Regulatory Authorities (NRAs (listed below) and bodies for regulatory reliance and recognition for information sharing on GMP inspections

- Egyptian Drug Authority.
- South African Health Products Regulatory Authority
- Ministry of Food and Drug Safety (MFDS), S. Korea
- WHO Listed Authority regulatory Agencies, SRAs
- WHO ML3 NRAs in Africa
- WHO CRP Agreement

II. Continue the Clean Report of Inspection and Analysis (CRIA) scheme that was established in 2003 for India and China, but which was revised by strict guidance on the CRIA scheme in 2020.

- The revised scheme mandates the CRIA agents to, among others, conduct pre-shipment inspections, review documentation and verify products quality and GMP compliance status as well as regularly report overall deviations before shipment.
- Companies with CRIA satisfactory GMP Inspection reports are inspected every three years while those with unsatisfactory reports identified by product failures plus intrinsic product parameter and compliance (using a risk matrix) will be inspected at least every 18 months through NAFDAC Cluster Inspection Scheme until the reports become satisfactory (see the Risk Matrix, and Risk-based categorization and Inspection schedule link – Section 4 (III) .

III. Establish mandatory annual submission of GMP status from India and China manufacturers.

- Prioritize inspection and regulatory actions: Focus inspection efforts and regulatory interventions on facilities identified with safety issues or quality concerns. The Cluster Scheme will be used, and it involves assigning inspectors to inspect additional facilities (not more than two (2)) within the same zone or area in India or China for an extended period of three (3) to four (4) days over the regular five (5) days.

3. Current Progress Made

NAFDAC has made significant progress in implementing elements of a risk-based approach:

- **Risk Categorisation of Manufacturing Facilities:** Foreign manufacturing facilities have been categorized into low, medium, and high risk using a defined intrinsic and compliance risk matrix. This categorization guides the scheduling and planning of foreign GMP inspections, supported by an existing SOP (Doc. Ref. No: DER-301-06).
- **CRIA Scheme:** The Clean Report of Inspection and Analysis (CRIA) scheme is in place, where the agents conduct pre-shipment inspections and quality verifications to monitor compliance at the source. In line with section 12 of the Guidance document for carrying out CRIA services by the agents (Doc. Ref. No: NAFDAC-GCS-001-00), the Agents require manufacturers to submit a valid GMP certificate and other relevant documents before processing CRIA services and authorizing export to Nigeria.

- **The companies with failed products are categorized as Level 1, 2 and 3 based on severity of failures and impact on consumers.**

  Please refer to Annexure 8 of the SOP for Risk-Based Inspection Planning for Pharmaceutical Manufacturing Facilities (DER-301-06) for additional guidance

- **Reliance/Recognition:** NAFDAC has established a policy on regulatory reliance, allowing it to rely on GMP Assessment reports from recognized ML3 NRAs (such as EDA, SAHPRA, South Korea), WHO Listed Authorities (WLAs), SRAs and WHO Collaborative Registration Procedures (CRPs). The Policy includes reliance guidelines (Doc. Ref. No: NAFDAC-RRP-05-00) that details the requirements, criteria, and procedures for implementing reliance on GMP inspections performed by other national regulatory authorities.

- **Awareness and Stakeholders' Engagement:**

A critical component of this strategic plan involves robust awareness campaigns and proactive engagement with all foreign manufacturers and Market Authorization Holders through email notifications. These targeted communications will cover essential topics such as changes in regulatory requirements, reminders for annual GMP status submissions, notifications of guideline revisions, and other pertinent information necessary for maintaining compliance. This direct communication channel is vital for ensuring that stakeholders are well-informed and can proactively meet NAFDAC's expectations, thereby contributing to the overall effectiveness of the risk-based inspection framework. A virtual meeting was held on May 21, 2025 with CRIA Agents, India manufacturers and Nigerian importers for the sensitization campaign and information sharing. Over one hundred fifty (150) of the stakeholders attended the meeting.

4. Other Implementation Plans

In addition to the current efforts been made, NAFDAC will include the following activities to strengthen the foreign GMP inspection.:

I. **Continued Awareness and Stakeholders' Engagement:**

The stakeholders meeting will continue as a critical component of the strategic plan. NAFDAC will also leverage its official website as a primary channel to publish comprehensive and timely

information regarding revised regulatory requirements, updates to guidelines. This ensures transparency and provides a readily accessible resource for manufacturers, Marketing Authorization Holders (MAHs), and the public.

II. **Update Requirements and Revise Guidelines:**

NAFDAC will implement a formal process for the annual submission of manufacturer GMP status updates. This will require foreign manufacturers to provide current documentation from their respective National Regulatory Authorities confirming their GMP compliance status on an annual basis. Furthermore, NAFDAC is committed to revising existing guidelines to clearly specify these requirements regarding the GMP status of manufacturers. To reinforce the importance of this requirement and ensure compliance, NAFDAC will include a clear caveat under the "terms of use" stipulated on the product certificate. This caveat will explicitly mandate the MAH to ensure the timely submission of these annual GMP status reports from the reference NRA as a condition for maintaining product registration in Nigeria.

III. **Implementation of Risk-Based Inspections:**

A key implementation strategy involves conducting targeted on-site inspections of facilities categorized as high-risk at least every 18 months as referred to earlier. This frequency is determined by NAFDAC's robust risk categorization framework, which evaluates both intrinsic product risks and the manufacturer's compliance history, ensuring focused oversight on manufacturers posing the highest potential risk to public health and product quality. The roadmap provides a systematic approach for prioritization of onsite GMP inspections based on in-house data. The database of foreign manufacturing facilities, categorization and inspection schedule is seen on https://nafdac.gov.ng/regulatory-resources/foreign-gmp-plan/

To enhance efficiency and optimize the use of valuable inspection resources, a clustered GMP inspection approach will be utilized. This involves strategically grouping inspections of multiple facilities located within similar geographical regions into a single inspection trip, thereby reducing travel time and associated costs while maximizing the number of inspections conducted within a given period and ensuring a more efficient deployment of inspectors.

IV. **Enhanced Post-Marketing Surveillance:**

NAFDAC has significantly intensified its market surveillance activities, with a particular focus on medicines imported from facilities categorized as high-risk. This involves increased

sampling and testing of these products within the Nigerian market which has led to proactive identification of potential quality issues. NAFDAC has conducted annual survey of specific medicines since 2020 and has sanctioned different manufacturers and importers at different levels, from blacklisting, to suspension to publishing on the website to fines, depending on the severity of the regulatory violation. Products originating from manufacturers with a documented history of non-compliance with GMP standards or those linked to previous laboratory failures, such as failing dissolution tests, impurity limits, or below compendial limit of active pharmaceutical ingredient content, are specifically flagged. Examples of the regulatory actions including license revocation, suspension, publication on our website, delisting or fines depending on the severity of the violation for heightened regulatory scrutiny and information sharing with other NRAs or stakeholders. The publications on the NAFDAC website can be accessed via the following links https://nafdac.gov.ng/blacklisting-of-aveo-pharmaceuticals-and-banning-of-tapentadol-and-carisoprodol-combination-tafrodol-or-royal-225/ and https://nafdac.gov.ng/public-alert-no-14-2025-alert-on-the-declaration-of-over-100-medications-as-substandard-by-indian-authorities/.

V. **Continued Use of Clean Report of Inspection and Analysis (CRIA):**

CRIA agents will continue conducting pre-shipment inspections and quality verifications to monitor compliance at the source. The Agents will continue to require the submission of a valid GMP certificate by manufacturers before processing CRIA services and authorizing the export of products to Nigeria. Findings and data collected through the process will be integrated into NAFDAC's risk profiling system. This integration will inform inspection scheduling decisions and guide regulatory actions as referred to earlier in section 2 (II). This pre-shipment approach will be complemented by mandatory post-market laboratory testing conducted at the Central Drug Control Laboratory (CDCL) to further validate product quality and compliance.

5. Conclusion

This strategic plan underscores NAFDAC's commitment to implementing risk-based, efficient, and globally aligned regulatory practices. By strategically integrating regulatory reliance mechanisms, pre-shipment inspection through the CRIA scheme, enhanced post-marketing surveillance, and a data-driven approach to prioritization, NAFDAC can effectively and confidently assure the quality of medicines imported from foreign manufacturers.

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Approved by:

Director-General (NAFDAC)

Prof. (Mrs.) Mojisola Christianah Adeyeye

Signature:  Date: 20/5/2025