

NAFDAC PHARMA STAKEHOLDER ENGAGEMENT

PHARM (MRS) EDOSA OGBEIDE

Director, Drug Registration and Regulatory Affairs

FEBRUARY 6, 2023



NAFDAC

NATIONAL AGENCY FOR FOOD AND DRUGS ADMINISTRATION AND CONTROL

...safeguarding the health of the nation

CONTENTS

- Mandate
- Introduction
- Interventions
- Advisory
- Challenges
- Conclusion



NAFDAC

NATIONAL AGENCY FOR FOOD AND DRUGS ADMINISTRATION AND CONTROL

...safeguarding the health of the nation

MANDATE

NAFDAC was established by Decree 15 of 1993 as amended by Decree 19 of 1999 and now the National Agency for Food and Drug Administration and Control Act Cap N1 Laws of the Federation of Nigeria, 2004.

This Act mandates NAFDAC to regulate and control the manufacture, importation, exportation, distribution, advertisement, sale and use of food, drugs, cosmetics, chemicals, detergents, medical devices and packaged water (known as regulated products).



NAFDAC

NATIONAL AGENCY FOR FOOD AND DRUGS ADMINISTRATION AND CONTROL

...safeguarding the health of the nation

INTRODUCTION

On March 30, 2022 WHO announced that Nigeria's medical products regulatory agency - NAFDAC had reached maturity level 3 (Alongside Egypt's). This means that NAFDAC has been found to function well and that she could be eligible for inclusion into the transitional WHO Listed Authorities, a list that will comprise the world's regulators of reference – *that is, regulatory authorities that should be globally recognized as meeting WHO and other international standards.*



NAFDAC

NATIONAL AGENCY FOR FOOD AND DRUGS ADMINISTRATION AND CONTROL

...safeguarding the health of the nation

INTRO CONT'D

Nigeria has *reached maturity level 3 for medicines and imported vaccines* whilst Egypt and South Africa have reached maturity level 3 for vaccines regulation (locally produced and imported). The three countries join Ghana and Tanzania as effective regulatory systems on the African continent. Several other African regulators are currently under assessment.

A status that is sacrosanct that we maintain and improve upon.



NAFDAC

NATIONAL AGENCY FOR FOOD AND DRUGS ADMINISTRATION AND CONTROL

...safeguarding the health of the nation

DUTY BOUND

WHO's assessment of regulatory authorities is based on the '[Global Benchmarking Tool](#)' – an evaluation tool that checks regulatory functions against a set of more than 260 indicators – covering core regulatory functions such as *product authorization, testing of products, market surveillance* and *the ability to detect adverse events* – to establish their level of maturity and functionality. Regulatory authorities that reach maturity levels 3 and 4 will be eligible for inclusion among WHO-listed authorities, after additional evaluation of their performance.



NAFDAC

NATIONAL AGENCY FOR FOOD AND DRUGS ADMINISTRATION AND CONTROL

...safeguarding the health of the nation

INTERVENTION

The DG through the Drug R&R has put in place measures to help the industry cope with this new normal

1. Progressing applications submitted pre-dossier submission
2. Grant of Rolling Clearance
3. Reliance
4. Stakeholder Trainings – Better/Quality submissions
5. Increased officers in assessment unit
6. Continuous training of assessors
7. Continuous participation of assessor's in the WHO PQ assessment to further strengthen capacity
8. Open window for responses to compliance



NAFDAC

NATIONAL AGENCY FOR FOOD AND DRUGS ADMINISTRATION AND CONTROL

...safeguarding the health of the nation

NEW INTERVENTIONS

1. Reorganization of DRR directorate
2. Dossier Review Team Management changes – rotational Scheme of reviewers/screeners
3. Capacitation of assessors – provision of working tools
4. Setting of task force to clear pending dossiers
5. Provision of dedicated dossier assessment room for effectiveness & efficiency
6. Motivation of assessors through – incentives
7. Procurement of a Dossier Management Software
8. Increasing the number of assessors – 21 to 50
9. Training and re-training of assessors



NAFDAC

NATIONAL AGENCY FOR FOOD AND DRUGS ADMINISTRATION AND CONTROL

...safeguarding the health of the nation

ADVISORY

1. **Regulatory officers** should be capacitated – poor written dossiers affect response time negatively
2. **Importers** can import products from PQ manufacturers or a manufacturer with good dossiers (we will activate reliance)
3. **Local Manufacturers** can purchase APIs from a validated source
4. Continuous engagement with the Agency



NAFDAC

NATIONAL AGENCY FOR FOOD AND DRUGS ADMINISTRATION AND CONTROL

...safeguarding the health of the nation

CHALLENGES

- Poor Dossiers
- Inability to communicate screening outcome –clearance/CD
 - No name
 - No email
 - Incorrect email
- Disregarding the instructions in the dossier upload guide
- Some application have not been submitted on NAPAMS



NAFDAC

NATIONAL AGENCY FOR FOOD AND DRUGS ADMINISTRATION AND CONTROL

...safeguarding the health of the nation



*Thank
you*



NAFDAC

NATIONAL AGENCY FOR FOOD AND DRUGS ADMINISTRATION AND CONTROL

...safeguarding the health of the nation