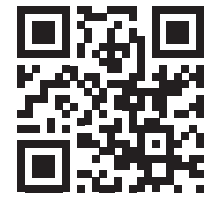


# Transformational Change for the Pharmaceutical Industry in Nigeria



FEDERAL MINISTRY OF  
**HEALTH**



## BACKGROUND

# Why WHO PQ?

A hand wearing a blue nitrile glove is shown holding a realistic image of the Earth. The hand is positioned on the left side of the frame, with the fingers gently cradling the globe. The background is a solid, vibrant blue. The text 'Why WHO PQ?' is overlaid on the image in large, white, bold, sans-serif font.

The World Health Organisation in 2001 established the WHO Prequalification of Medicines programme (WHO PQ) - a global standard to ensure medicines are safe and properly produced. WHO PQ plays a critical role in addressing the global scourge of substandard and falsified medicines, ensuring the quality of lifesaving medicines used today by millions of people across the globe. It guarantees that drugs, vaccines, diagnostics, vector-control products, and devices used for the prevention, treatment and diagnosis of priority diseases like HIV, tuberculosis, and malaria are safe, efficacious and meet stringent quality standards.

WHO Prequalification is the backbone of global health procurement. It aims to provide quality, safe and efficacious medicines for United Nations' (UN) procurement agencies and to countries for bulk purchasing and distribution of medicines in resource-limited countries. It also supports the response to public health emergencies.


Thus, medicines prequalification has made it possible to believe that everyone in the world will have access to quality, safe and efficacious medicines.



THE CASE FOR

# WHO PQ in Nigeria

The attainment of WHO PQ by the pharmaceutical manufacturers in Nigeria will establish their capability to produce medicines that consistently meet stringent standards of quality in line with WHO specifications and global standards. This will provide opportunities for increased sales and market access by conferring eligibility for international, donor-sponsored tenders for medicines; improved capacity to manufacture products for entry into stringently regulated markets; increased potential to compete successfully for contract manufacture for local markets; and faster registration. Thus, facilitating international procurement and distribution of locally produced medicines in Nigeria. Annually billions of dollars worth of products are donated to Africa without local participation in the tender because they are not WHO prequalified.



# About the organisers



**The National Institute for Pharmaceutical Research and Development NIPRD** is a Federal Government Parastatal under the Federal Ministry of Health. It is a critical part of the Nigerian health system with the primary aim of developing drugs, biological products and pharmaceutical raw materials.

As part of its research portfolio, the NIPRD carries out quality assurance tests for locally manufactured medicines and develops specifications for the production of such commodities.

For more information,  
visit [www.bloompublichealth.com](http://www.bloompublichealth.com)



**Bloom Public Health** was born out of the need to create Africa driven solutions to solve Africa's public health issues, especially in the pharmaceutical sector.

Bloom Public Health is a think tank that convenes the most innovative African minds in public health and forges global partnership to design interventions that are tailored to the continent. We are contributing our quota in the sector, mobilising the right skills to fulfil the many unmet critical needs in the public health space in Africa. We are strong believers in sustainability. As stakeholders, bloom public health is tackling Africa's challenges with more commitment.

We are building more African expertise and are flexible to the specific needs of the continent. Our vision and mission espoused our commitment to better healthcare in Africa.

For more information,  
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*I am pleased to see this initiative taking place in Nigeria's health sector. It shows that production, regulation and supply of quality-assured medicines is a shared endeavour of the public and private sectors. The concerted effort of both stakeholders is essential to assuring Universal Health Coverage for better population health and well-being, as well as addressing needs for protection of citizens from public health challenges*

**Dr. Osagie Ehanire**  
Honourable Minister of Health



*“By attaining WHO PQ, pharmaceutical manufacturers in Nigeria will establish their capability to produce medicines that consistently meet stringent standards of quality in line with global standards. Thus, facilitating international procurement and distribution of locally produced medicines in Nigeria*

**Hon. Ekumankama Joseph Nkama**  
Minister of State for Health



*This is a golden opportunity that Nigerian pharmaceutical manufacturers must leverage on to increase their capacity for local manufacturing, thereby strengthening Nigeria's health system for better epidemic preparedness and response*

**Alhaji. Mahmuda Mamman**

*Permanent Secretary Federal Ministry of Health*



*The National Malaria Elimination Programme is keen to ensure more local manufacturers of antimalarial commodities attain WHO Pre-qualification and Good Manufacturing Practice certification and will work with the Bloom Public Health and NIPRD to achieve this in line with Global best practices.*

**Dr. Perpetual Uhomobhi**

*National Coordinator, National Malaria Elimination Programme (NMEP)*



*After close to a decade in planning, our initiative to catalyze Nigeria's emergence as a world leader in Pharma manufacturing has finally begun. The capacity we will build in the Industry is key to achieving Medicines' Security. Ultimately, this will not only improve Health & Socioeconomic indices, it will also underpin Nigeria's emergence as the Pharma Hub within the AfCFTA.*

**Dr. Obi Adigwe**

*NIPRD Director General*



*I am really excited to be part of this huge landmark in Nigeria's journey towards being a global player in the pharmaceutical sector. This is certainly the biggest intervention so far. Its uniqueness is that it is internally driven. It shows a great leadership by the country.*

**Prof. Chimezie Anyakora**

*CEO Bloom*



## Challenges confronting WHO PQ in Nigeria

One of the major barriers to achieving WHO PQ in Nigeria is the high upfront cost. Pharmaceutical manufacturers would need to invest several millions of dollars to upgrade their factories and to hire or train qualified professional and technical personnel in order to meet WHO PQ requirements. Unfortunately, without the support from government or donor agencies, most Nigerian pharmaceutical companies lack the capacity for such enormous capital investment.

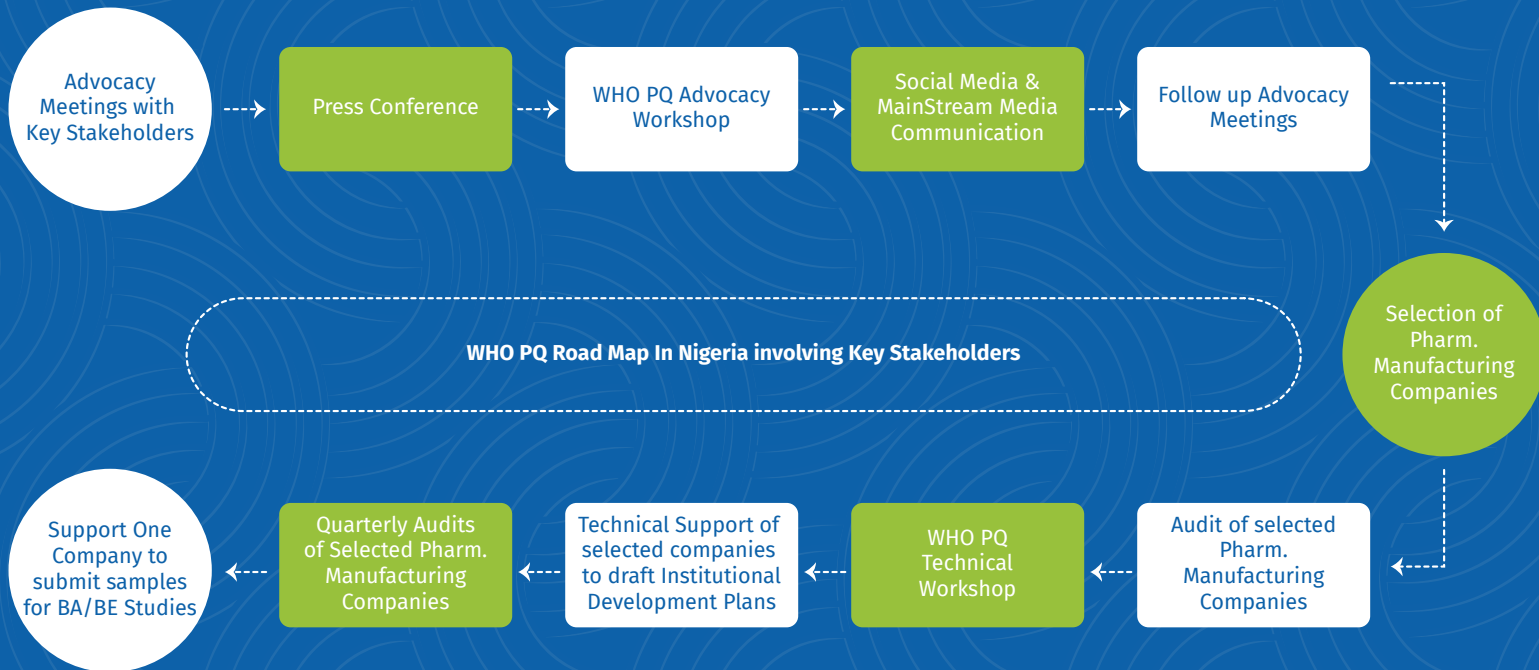
Another significant barrier is the poor technical support and limited expertise about achieving WHO PQ. Most Nigerian pharmaceutical companies have limited information on the specific requirements for WHO PQ and the application process. Attaining WHO PQ is a highly technical process, requiring comprehensive technical and professional support from experts in the field.

## Proposed solution - Transformational change for the pharmaceutical industry in Nigeria

This project is by far Nigeria's biggest pharmaceutical intervention and will achieve the first ever WHO PQ of pharmaceutical companies in Nigeria. It will have a tremendous impact on the Nigerian health system and build a national capacity for sustainable manufacturing, as well as position the pharmaceutical industry in Nigeria as a global competitor.

Work plan starting from - Selection

# OVERVIEW OF WHO PQ WORKPLAN



# WHO PQ WORKPLAN



## Step 1

Advocacy Meetings with Key Stakeholders & Press Conference

- This involves meeting with key stakeholders and liaising with key stakeholders which include government agencies, manufacturers and key players in the pharmaceutical sector.
- There will be a press conference to create awareness for the project and introduce the start of the project in the country.



## Step 2

WHO PQ Advocacy Workshop with Key Stakeholders

- A workshop will be held with top management of Government agencies, manufacturing companies and key players in the pharmaceutical sector to highlight the process involved, the importance and benefits of the project to the sector and also to get commitment to support the project.





### Step 3

Social Media and  
Mainstream Media  
Communications

- An Expression of Interest (EOI) will be put out on all social media and on selected mainstream media for Pharmaceutical Companies to apply and express and interest to be a part of the project.



### Step 4

Follow up Advocacy  
Meetings

- There is a need to get the buy in and full support of all key stakeholders in the pharmaceutical sector. The stakeholders will continually be engaged throughout the course of the project



### **Step 5**

#### Selection of Pharmaceutical Companies

- Selection criteria process and questionnaires (with a grading system) will be used in the selection of pharmaceutical companies who have expressed interest to be part of the project.



### **Step 6**

#### Audit of Selected Pharmaceutical Companies


- An intense and detailed audit will be carried out on selected companies with documentation to identify their capacity and highlight their strengths and needs to enable them achieve the WHO PQ.





**Step 7**  
WHO PQ Technical  
Workshop

- A workshop will be held with key staff of the selected companies and technical experts to discuss in the details the processes involved in attaining WHO PQ for their products and level of commitment, requirements and project expectations.



**Step 8**  
Technical Support of Selected  
Pharmaceutical Companies

- The selected companies will be supported to develop institutional development plans and tailored Technical Assistance and support will be provided to the individual selected companies according to their needs and their development plans.





**Step 9**  
Quarterly Audits of  
Selected Companies

- Audits of the selected companies will be conducted at least quarterly through out the time of the project and feedback will be provided to companies on their achievements.



**Step 10**  
Support of one company  
for BA/BE studies

- One company will be selected and technical assistance provided to submit their sample for BA/BE studies.





## **Benefit & Impact**

WHO PQ will create huge public health and economic impact in Nigeria by ensuring an increased availability of quality, efficacious and safe medicines and reduce over reliance on imports for public health interventions. Therefore, this ongoing initiative by NIPRD and Bloom Public Health is a golden opportunity that Nigerian pharmaceutical companies must leverage to increase their capacity for local manufacturing and strengthen Nigeria's pharmaceutical sector.



# WHO Pre-Qualification of Pharmaceutical Manufacturers in Nigeria

...Transformational change for the pharmaceutical industry in Nigeria!



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