Access to New Medicines and Biologics in Africa – Workforce and Regulatory Challenges

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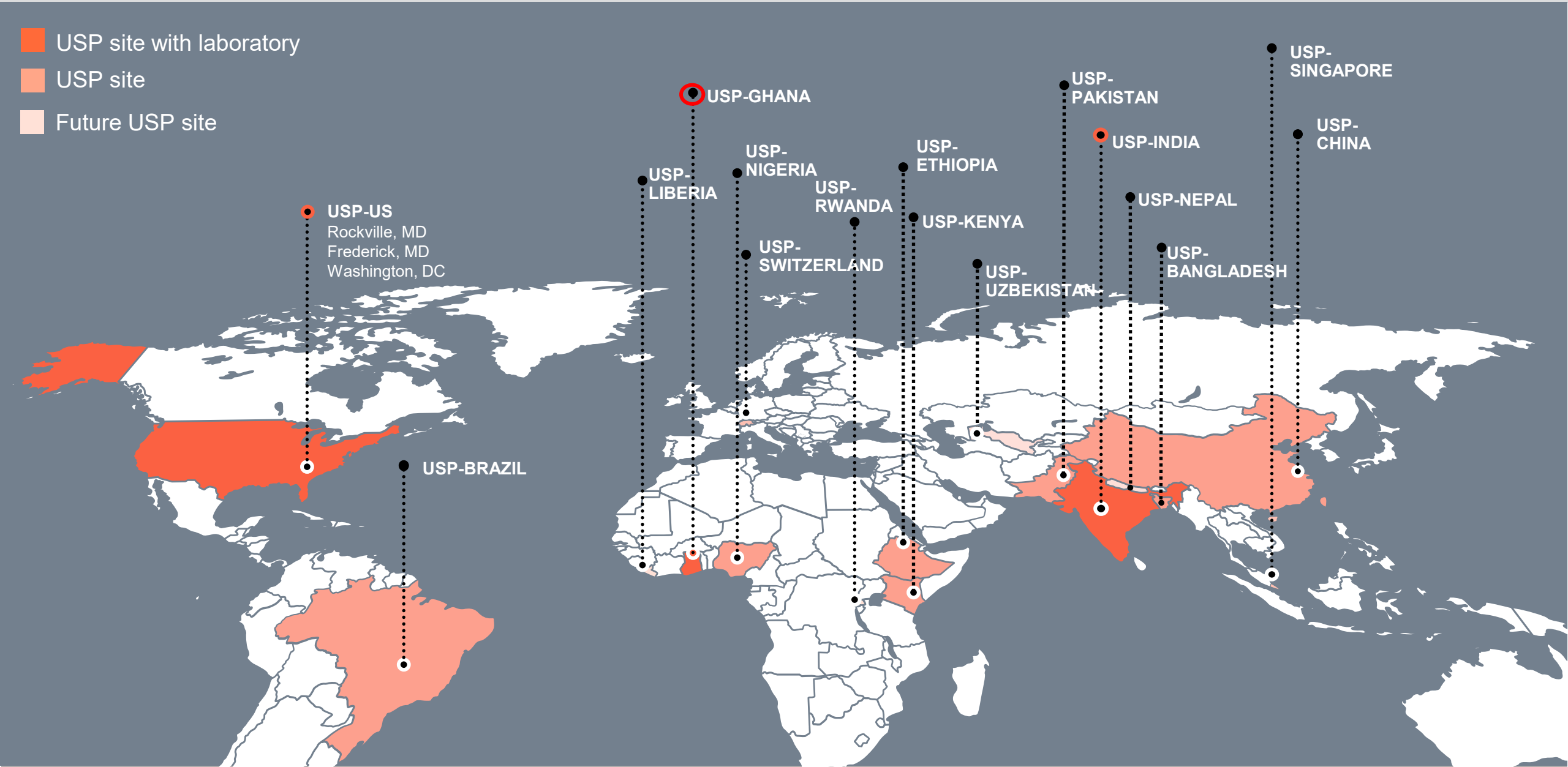
Contents

- USP's mission to improve global health through public standards and related programs.
- Africa's current pharmaceutical sector challenges – diseases burden, manufacturing, workforce, and regulatory capacity.
- Ongoing initiatives to strengthen workforce, manufacturing, and regulation of medical products in Africa.
- Contributions of the Promoting the Quality of Medicines Plus (PQM+) Program to Nigeria and to the African Medicines Agency.

USP’s enduring mission

To improve global health through public standards and related programs that help ensure the quality, safety, and benefit of medicines and foods.

USP: GLOBAL FOOTPRINT AND COUNTRY OFFICES



Key USP Stakeholders & Collaborators

- Industry

- International Regulatory Bodies

- Patient & Consumer Groups

- Academia

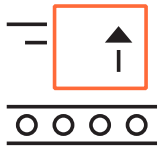
- Health Practitioner, Professional and Scientific Associations

More than 9,000 USP standards support quality across the supply chain

Manufacturing

- Standards
  - Drug and API monographs
  - Compounding monographs
  - General chapters
  - Characterized reference materials
- Manufacturer capability building
  - Advanced Manufacturing, incl. Pharmaceutical Continuous Manufacturing
  - USAID-funded PQM+ program
  - API and excipient verification

Distribution



- Standards
  - Good Distribution Practices
  - Packaging and distribution

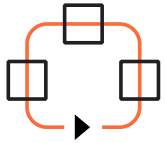
Administration

- Standards
  - Labeling
  - Nomenclature
- COVID-19 Vaccine Handling Toolkit

Collaborations

- USAID-funded PQM+ program for regulatory capability building in low- and middle- income countries
- APEC Center of Excellence on product and supply chain quality
- Co-hosted summits with WHO to advocate for medicines quality around the world
- Collaboration towards pharmacopeial convergence within the Pharmacopeial Discussion Group (PDG)

Supply chain diagnosis and monitoring



- Medicine Supply Map – identifying, characterizing and quantifying risk in the upstream supply chain

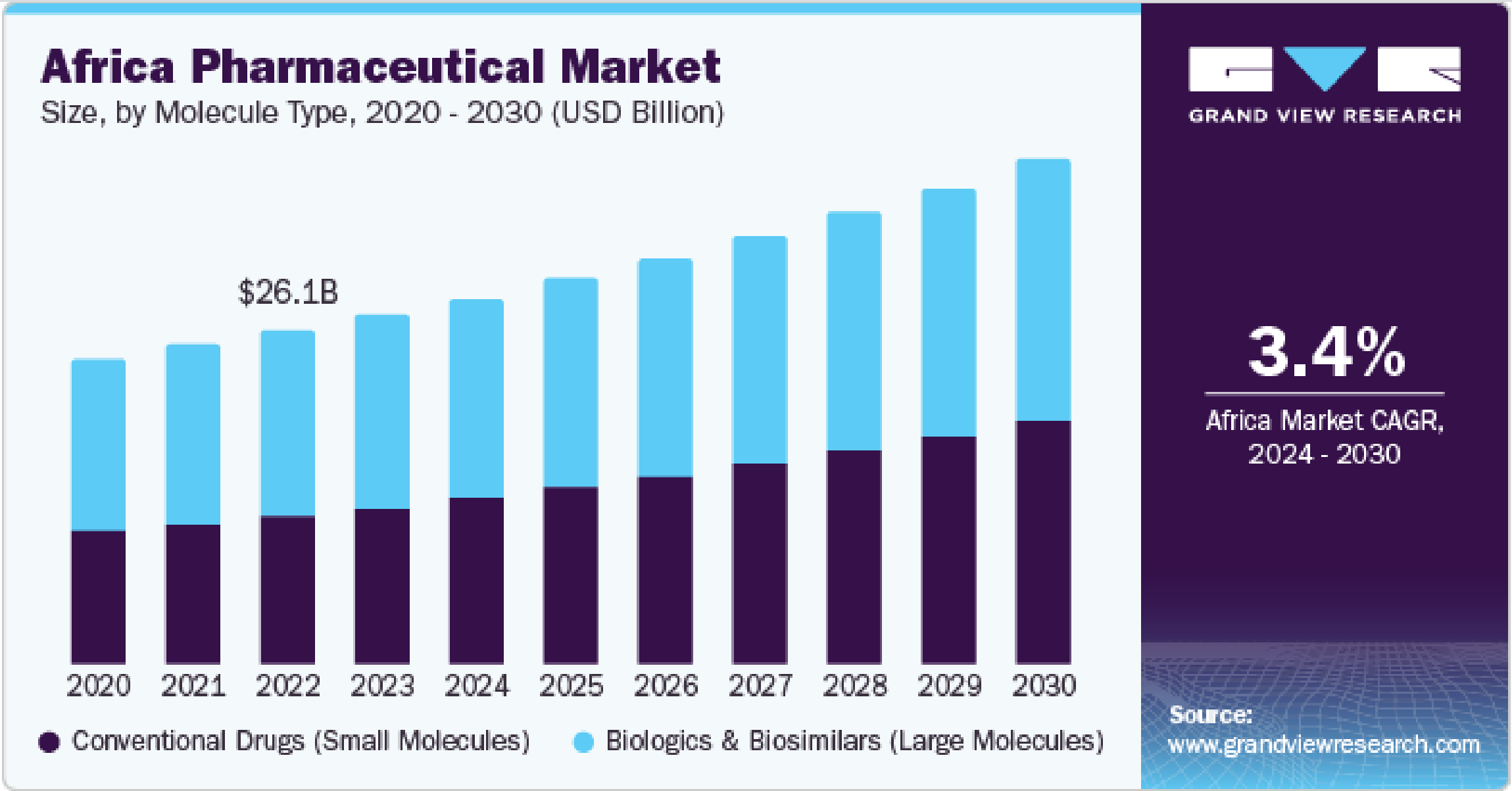
Africa’s disease burden

- Disease burden – 12% of global population, 25% of global disease burden
- 66% of PLWHA
- 94% of malaria cases
- Disease outbreaks and emergencies – cholera, measles, meningitis, EVD, COVID-19, mpox, etc.

Manufacturing capacity

- Africa pharmaceutical market - estimated to be worth $26.85b
- Manufacturers - 600 local pharmaceutical manufacturers; 80% of concentrated in eight countries - South Africa, Egypt, and Nigeria as top 3
- Imports 99% of vaccines and 80-90% of medicines.
- Capacity – FPP formulation manufacturing and packaging.
- APIs – very limited, largely imported.

Africa's Pharmaceutical market size



The AU set a goal to ensure 60% of the vaccines administered in Africa by 2040 are produced on the continent, and mandated PAVM to oversee this task

Context

The African Union calls for a **New Public Health Order** aimed at safeguarding the health and economic security of the continent


THE LANCET
Global Health

COMMENT | VOLUME 5, ISSUE 11, E1064-E1065, NOVEMBER 01, 2017

A new public health order for Africa's health security

John Nkengasong • Benjamin Djoudalbaye • Olawale Maiyegun

Open Access • Published: November, 2017 • DOI: https://doi.org/10.1016/S2214-109X(17)30363-7

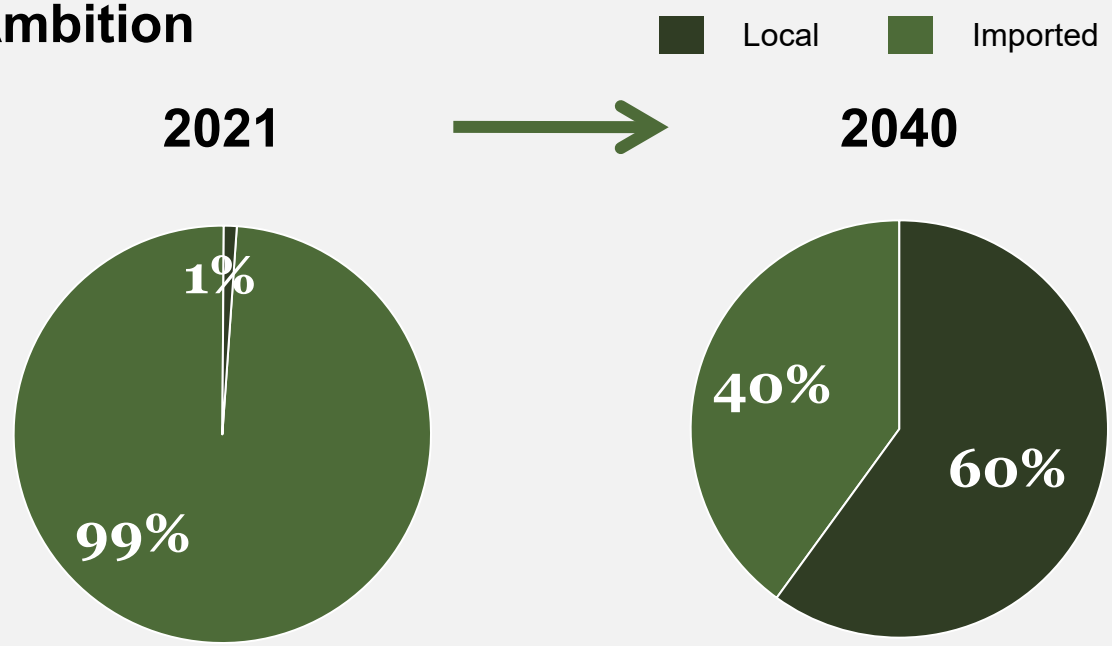
References

Article Info

On July 3, 2017, African heads of state and government issued a declaration and committed to accelerating implementation of the 2005 International Health Regulations (IHR)[1] and tasked the Africa Centres for Disease Control and Prevention (Africa CDC), the African Union Commission (AUC), and WHO with supporting the venture.[1]

The first pillar of the New Public Health Order is **expanded manufacturing of vaccines**, diagnostics and therapeutics[1]

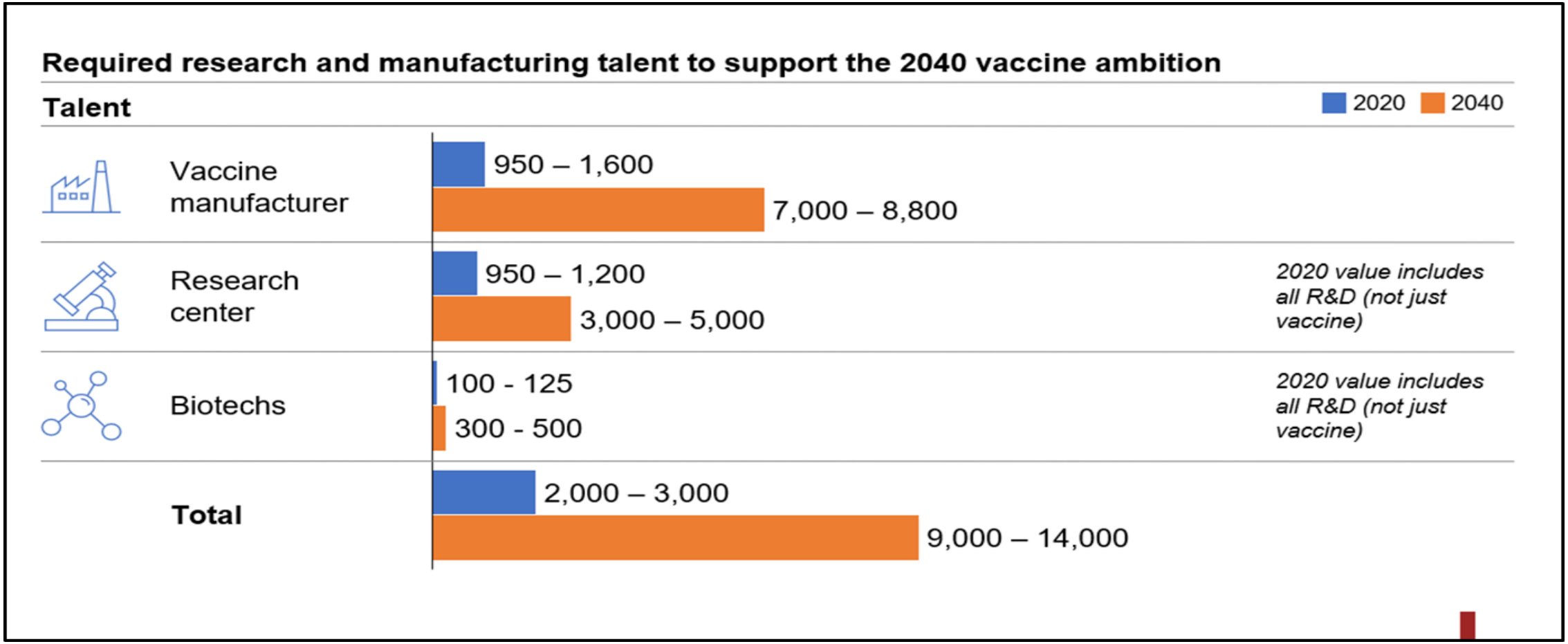
Ambition



The African Union has set a goal to **increase vaccine manufacturing on the African continent to meet 60% of the demand by 2040** and mandated the Partnerships for African Vaccine Manufacturing (PAVM) to **develop a framework for action to execute this**

1. Other pillars include: Strengthened public health institutions, Strengthened public health workforce, Respectful, action-oriented partnerships

Research and manufacturing FTE requirements, 2020 (existing) vs 2040 (forecast)



Source - Request for Proposals: Establishment of Regional Capability and Capacity Networks for Biomanufacturing Workforce Development – Africa CDC

Workforce capacity

Disaggregated table of Africa's pharmaceutical workforce for the years 2020, 2030, and 2040, divided into those working with medicines and biologics:

Year	Medicines Workforce	Biologics Workforce
2020	300,000	75,000
2030	480,000	120,000
2040	800,000	200,000

These projections reflect the growing emphasis on both traditional pharmaceuticals and biologics, driven by advancements in biotechnology and increased local production capabilities[12].

Source – Microsoft CoPilot search.

Workforce need exists across the entire product life-cycle

- Drug discovery
  - Prehuman/Preclinical
  - IND
- Phase I
- Phase II
- Phase III
- Regulatory Approval
- Phase IV

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ARTICLE

Empowering Africa's healthcare future: The crucial role of human capital development in bio- and pharmaceutical manufacturing

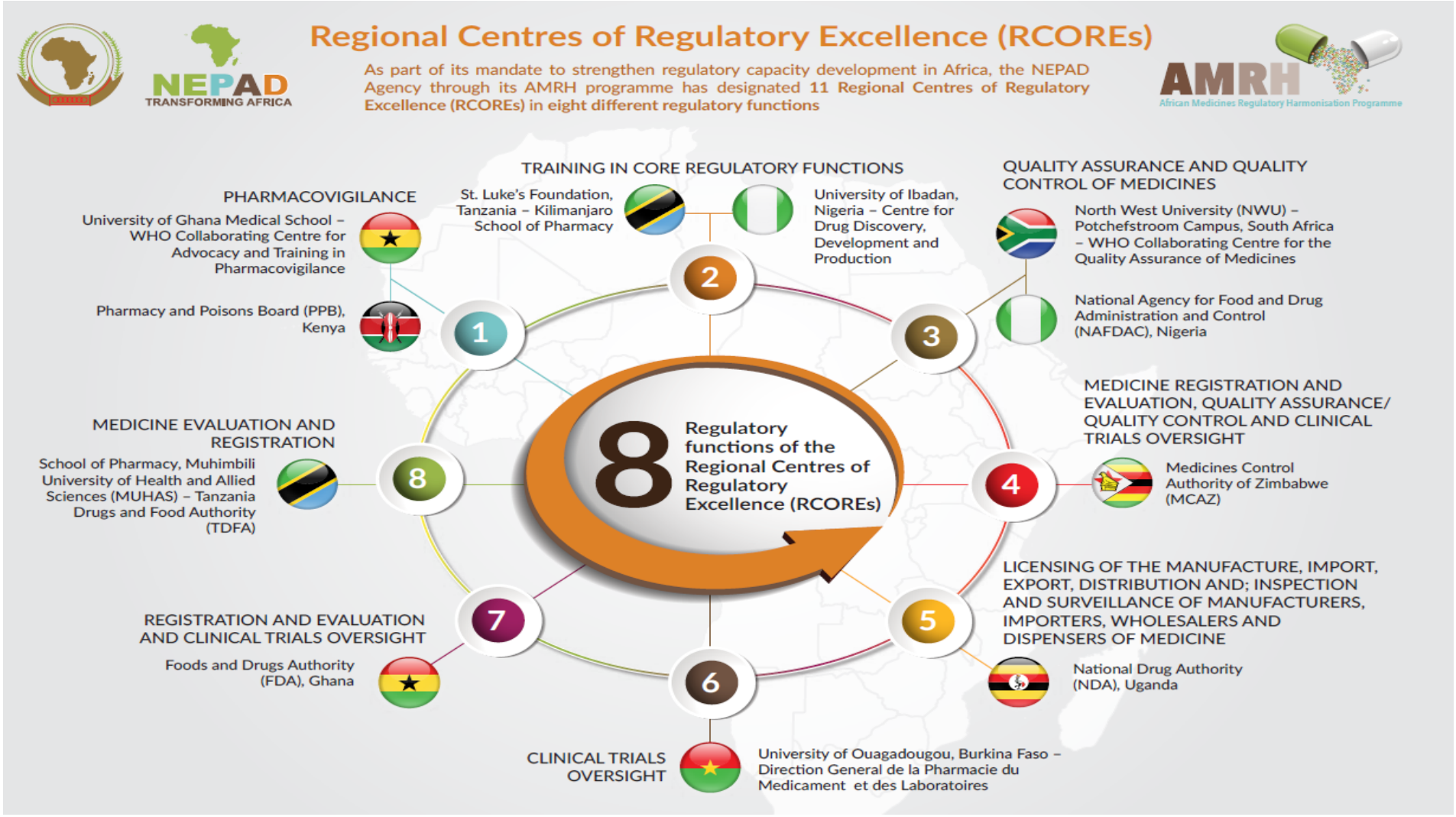
MICHAEL MYNHARDT[1], CHILUBA MWILA[2], MAHLET K. HABTEMARIAM[2], AKHONA TSHANGELA[2], MAR MARTINEZ[3], NGASHI NGONGO[2], JEAN KASEYA[2] and NICAISE NDEMBI[2]

[1]Co-Founder & Chief Executive Officer at MMH and Partners Africa, Dakar, Senegal; [2]Africa Centres for Disease Control and Prevention (Africa CDC); [3]Health Policy, Global Development, European Commission, Brussels, Belgium

DOI: 10.4081/jphia.2024.2866

Regulatory capacity and systems strengthening

- AMRH
- RECS
- RCORES
- NRAs

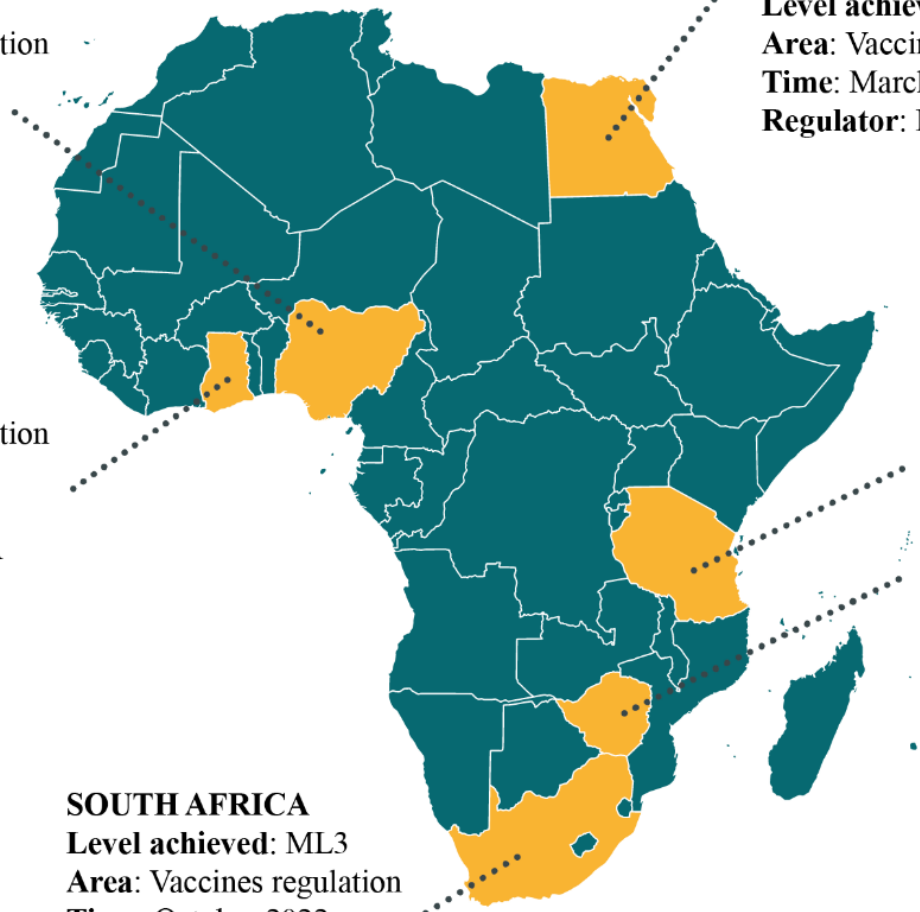


WHO Maturity Level 3 countries in Africa

Six Mature National Regulatory Authorities (NRA) in Africa

NIGERIA
Level achieved: ML3
Area: Medicines regulation and imported vaccines
Time: March 2022
Regulator: NAFDAC

GHANA
Level achieved: ML3
Area: Medicines regulation and imported vaccines
Time: April 2020
Regulator: Ghana FDA



EGYPT
Level achieved: ML3
Area: Vaccines regulation
Time: March 2022
Regulator: EDA

TANZANIA
Level achieved: ML3
Area: Medicines regulation and imported vaccines
Time: May 2018
Regulator: TMDA

ZIMBABWE
Level achieved: ML3
Area: Medicines regulation and imported vaccines
Time: May 2024
Regulator: MCAZ

SOUTH AFRICA
Level achieved: ML3
Area: Vaccines regulation
Time: October 2022
Regulator: SAHPRA

Adapted from Medicines for Africa

African Medicines Agency

AMA scope of Products –

Biotechnology products, including Biosimilars, for all treatment areas; NCEs for AIDS/HIV, TB, Malaria, Cancer, Diabetes & cardiovascular diseases, neglected tropical diseases, and antibiotics; Vaccines for all treatment areas.

AMA coordinates joint assessment for all products areas in the following situations: emergency situations (e.g., public health crisis, Ebola epidemics); API inspections for all products.

Initiatives for strengthening manufacturing and regulation in Africa

- USAID-funded PQM+ Program implemented by USP
- Partnerships for African Vaccine Manufacturing, PAVM
- Platform for Harmonized African Health Products Manufacturing, PHAHM (Afreximbank $2b facility, also for APPM)
- Africa Pooled Procurement Mechanism, APPM
- African Pharmaceutical Technology Foundation, APTF (established by the African Development Bank)
- African Vaccine Manufacturing Accelerator, AVMA (financial instrument of up to $1b over ten years to support the sustainable growth of Africa's manufacturing base)

How AVMA works

01 Vaccine manufacturer

The process begins with a vaccine manufacturer with the ambition to supply a Gavi-supported vaccine from a facility located on the African continent. An initial application processis foreseen to ensure that potential beneficiaries are aware of the conditions required to receive incentives through AVMA.

02 Obtaining regulatory approval

The manufacturer applies for approval, or 'prequalification', from the World Health Organization (WHO) for their product. This requires meeting global standards of quality, safety and efficacy. WHO prequalification is required before Gavi can support the procurement of any vaccine; and all receiving countries require this (or an equivalent certification) before allowing importation and use of biological and medical products. Additional due diligence criteria will be communicated prior to AVMA's launch.

When these eligibility steps are completed for vaccines that are a priority for manufacture on the continent, an AVMA 'milestone payment' can help bridge the long period without revenue until production at commercial scale begins.

03 Entering the marketplace

The manufacturer responds to UNICEF tenders on a competitive basis to supply Gavi-supported vaccines through UNICEF procurement processes.

04 Vaccine purchase

Should the manufacturer win the tender, they will be eligible for an 'accelerator payment' as the vaccines are delivered.

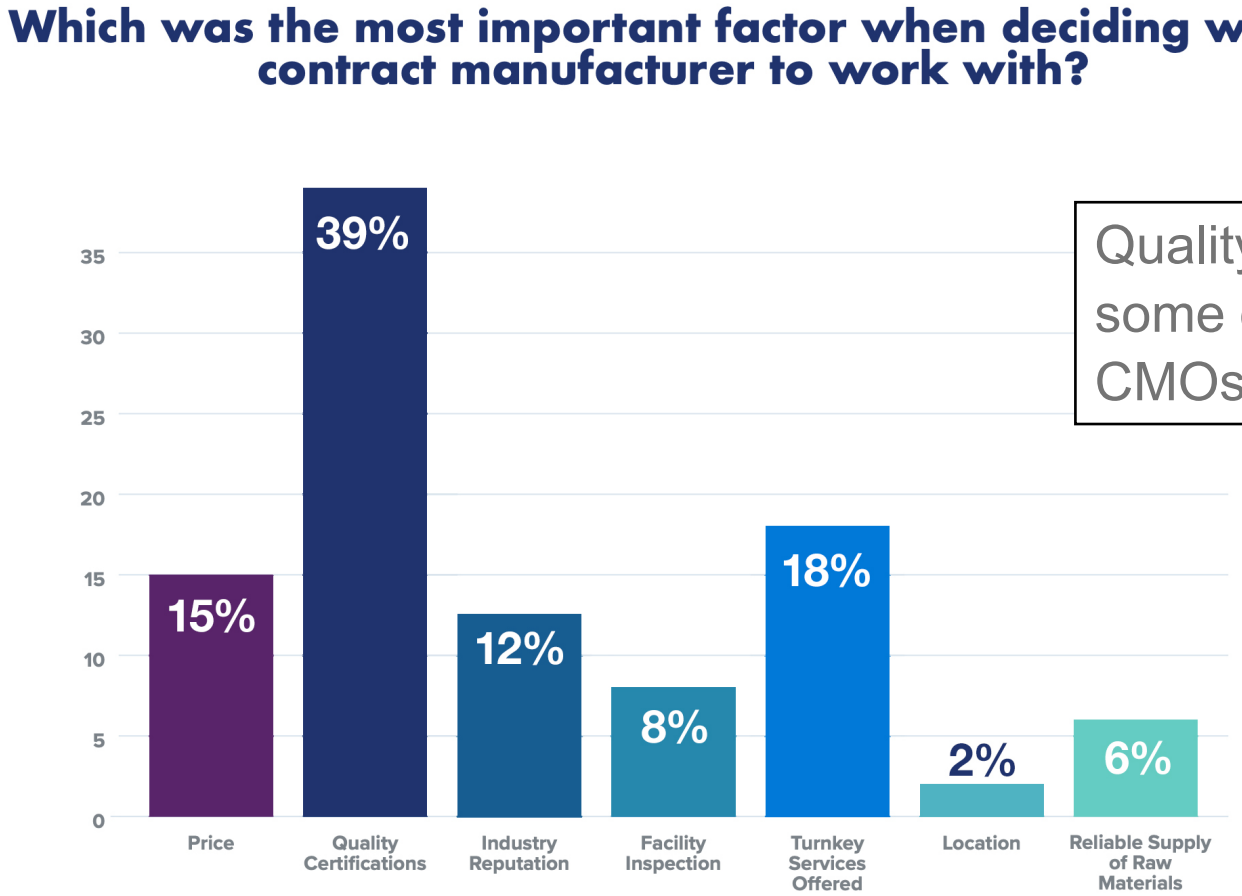
An 'accelerator payment' is paid in addition to the tendered price for vaccines manufactured on the continent and procured through a UNICEF tender. This allows manufacturers to operate on competitive terms from day one, by receiving additional time-limited support to bridge higher initial costs of operation during early-years production on the African continent. Payments will be made subject to satisfaction of specified conditions notified during the initial phase. As with milestone payments, accelerator payments will be contingent upon capitalisation of the manufacturing facility and certain caps on payments.

Manufacturing sector development – key considerations

- Quality focus
- Growth in service industry – labs, CRO/CDMOs - as magnet for technology transfer
- Competitive sourcing of raw materials, API
- Procurement - GMP as a condition for market entry

In 2021 top factors CMO selection were quality certifications and turnkey services

From Contract Pharma & Nutraceuticals World's Jan./Feb. 2021 Annual Contract Manufacturing Survey:1



Quality, reputation, and consistency are some of the top features sought in CMOs/CDMOs; location is unimportant.

Sources: [1] Moloughney (2021: 74 [5]);

USAID FROM THE AMERICAN PEOPLE

Promoting the QUALITY OF MEDICINES Plus

Case Study – PQM+

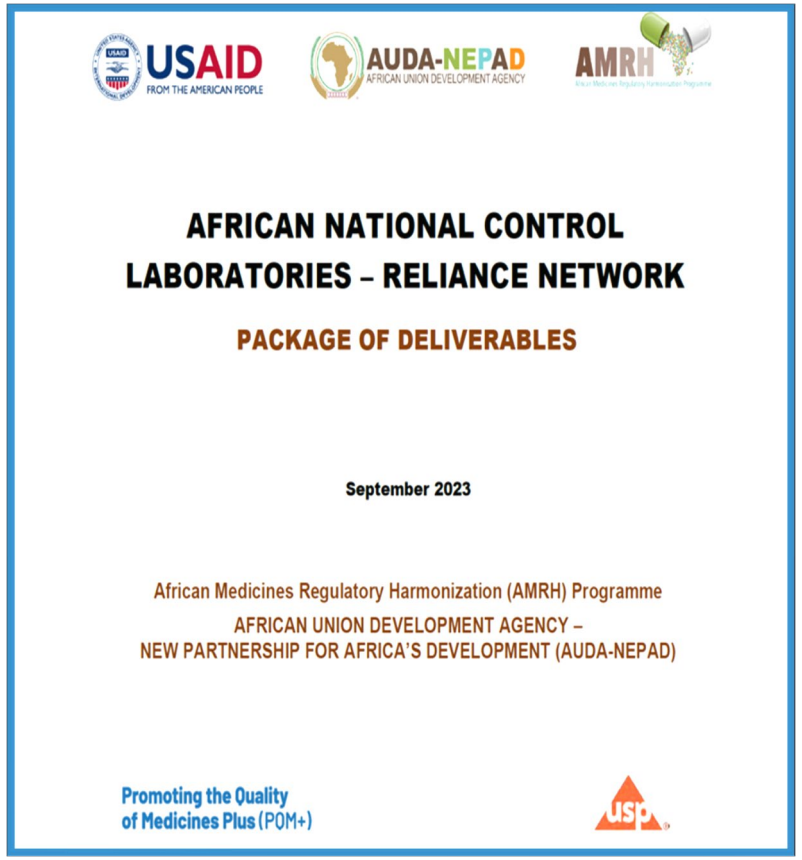
PQM+ technical assistance advances pharmaceutical sector development

PQM+ is a cooperative agreement between USAID and USP to sustainably strengthen medical product quality assurance systems in low-and middle-income countries.

USAID FROM THE AMERICAN PEOPLE + USP

Support for the operationalization of the African Medicines Agency

- CRO/BE capacity –
  - TWG on harmonization of requirements for BE studies to support the approval of generic medicines
  - CRO business plan to aid policy makers and business leaders on the BE market
- API regulation – developed APIMF guidelines and API database
- Continental network of reliance laboratories - developed Network of African Reliance Laboratories, NARL.



PSM & CMC support

PQM+ is building GMP capacity for decentralized manufacturing in Africa and Asia

AFRICA
16 manufacturers
12 different products
5 countries

ASIA
18 manufacturers
10 different products
6 countries

Essential Medicines Approvals in 2023

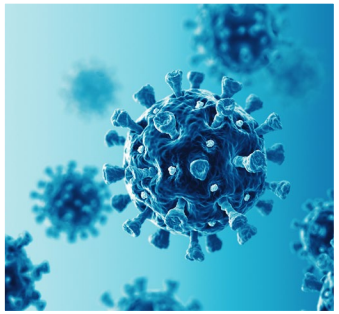
PQM+ supported the WHO PQ of the following essential medicines.

- Zinc sulphate in Pakistan (1st WHO PQ syrup in-country)
- Zinc sulphate in Nigeria (1st WHO PQ in West Africa)
- Albendazole in India (in-progress, facility approved by WHO)

Antivirals for the treatment of COVID-19

In Pakistan:

- PQM+ supported the technology transfer of Remdesivir to a manufacturer
- PQM+ is supporting a Pfizer-MPP sublicensee towards local manufacture of Paxlovid.



Advanced Manufacturing Technology

- PQM+ supported development and technology transfer of continuous manufacturing rifapentine API synthesis process using novel readily available nitrosamine-free starting materials to minimize nitrosamine formation.

PQM+ Global VAX

USAID provides $7.1 million to USP to build trust in the supply of vaccines through the Promoting the Quality of Medicines Plus (PQM+) Program

New funding will help expand access to COVID-19 vaccines by strengthening manufacturing capacity and regulatory oversight

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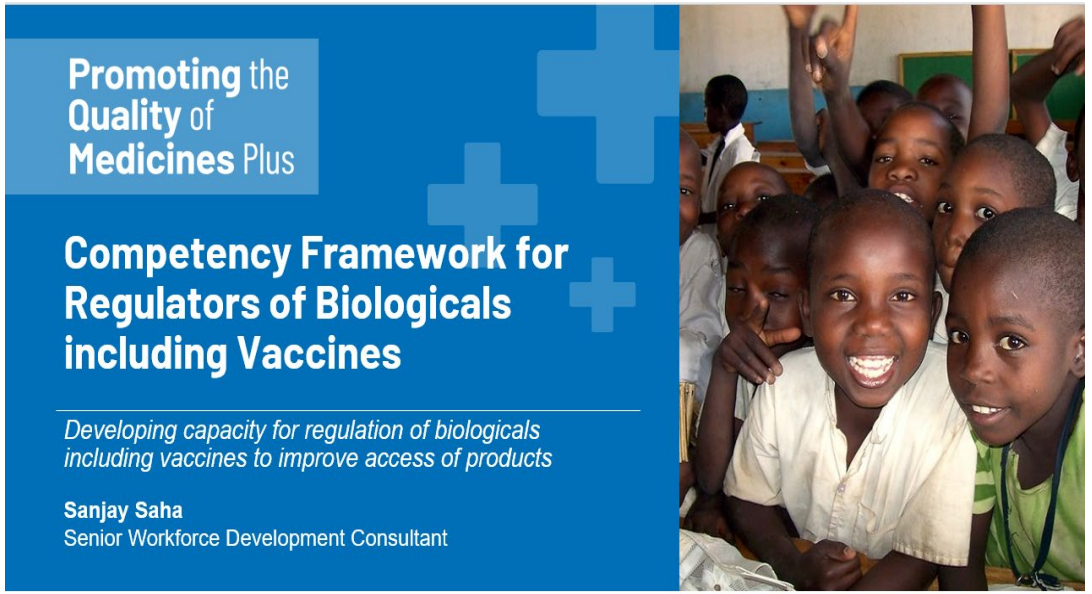
Mobile: +1-240-701-3242

Rockville, Md., August 2, 2022 – As part of the U.S. Government's Initiative for Global Vaccine Access, also known as Global VAX, the U.S. Agency for International Development (USAID) has obligated $7.1 million in additional funding to the U.S. Pharmacopeia (USP) through the Promoting the Quality of Medicines Plus (PQM+) program.



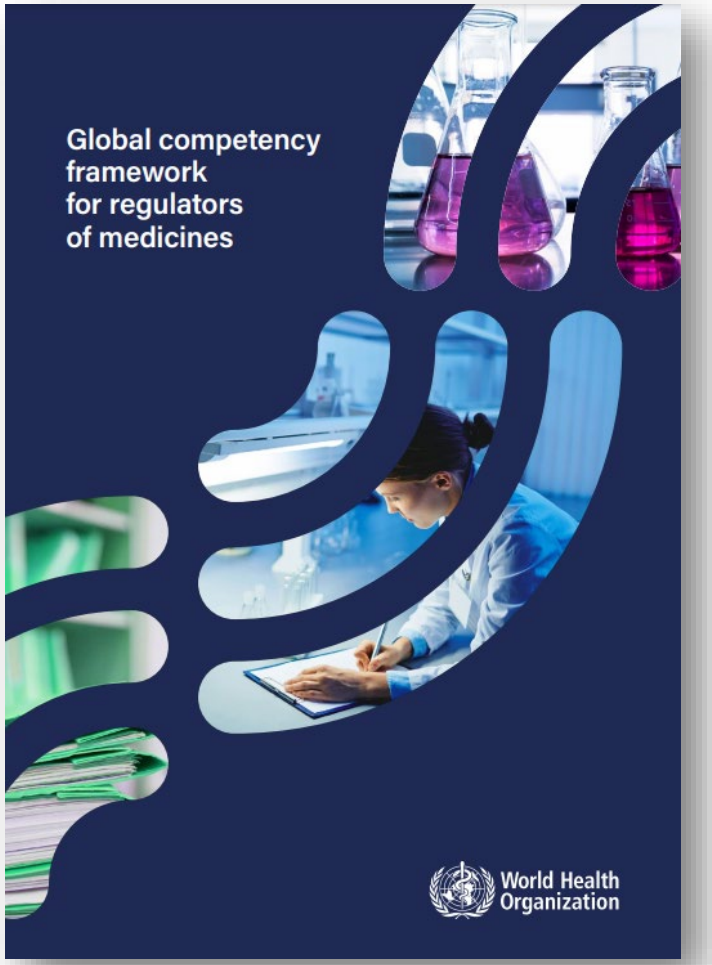
"For decades, USP has worked in Africa to break down barriers to the advancement of pharmaceutical quality and – more recently – to lay the groundwork for vaccine manufacturing in Africa," said Jude Nwokike, Director of the PQM+ program. "We are thrilled to continue our longstanding partnership with USAID and to provide crucial support to countries to strengthen their regulatory systems and help ensure the quality of medical products, including vaccines."

Competency Framework for Regulators of Biologicals Including Vaccines

- Presents the competencies expected of personnel who provide regulatory oversight in dossier review, inspection, laboratory testing and pharmacovigilance.
- Complementary to the WHO Global Competency Framework for Regulators (Nov. 2023), focusing specifically on the competencies required to regulate vaccines and other biologicals.
- Aims to define competencies for NRAs to help them establish a consistent approach for professional and organizational development while supporting them organize training needs analyses (using the OCAT) of staff and developing a competency-based recruitment and performance management system

Use of Existing Tools and Resources for Regulatory Systems Strengthening:

WHO's Global competency framework for regulators of medicines



Framework for best practices and general considerations aimed at harmonizing workforce development efforts for the regulation of medicines by establishing an internationally accepted set of organizational and role-specific competencies.

Recommendations for the competency requirements for regulators across the identified regulatory functions and maturity levels, as defined by the Global Benchmarking Tool (GBT).

The framework was used by PQM+ as the basis for a competency needs assessment of South African Health Products Regulatory Authority (SAHPRA)

Competency Needs Assessment of SAHPRA for Vaccines and Biomanufacturing to Address Regulatory Needs

Objective

Evaluate SAHPRA's internal staff capacity, skills and knowledge, training needs, access to technical resources, and efficiency to fulfil its regulatory responsibility.

Methodology

WHO's global competency framework was adapted into a Microsoft Excel® tool and used for the assessment in combination with a desk review and interviews with staff in each regulatory function.

Output

Comprehensive evaluation report describing:

- Organizational structure of the agency including the roles and responsibilities of each unit/subunit.
- Outline of the strengths, weaknesses, opportunities, and threats for each unit/subunit.
- Proposed Recommendations for each unit/subunit to strengthen their competencies.

Impact

The report shaped where continued PQM+ support focused and provided an advocacy tool for SAHPRA to seek out additional assistance from any interested partners to implement proposed recommendations.

PVAC's activities in the next 3 years aim to increase local manufacturing of pharmaceutical products to 70% and create at least 30k new jobs by 2030

PRELIMINARY

Key Objectives

A **Increase the spectrum of health products and technologies manufactured in the country**

B **Expand local capabilities in R&D and early-stage production**

C **Expand and improve the level of healthcare services provision**

D **Strengthen the competitive position and growth of Nigeria's life science sector leaders**

E **Increase investment attraction across Nigeria's health value chains**

F **Strengthen locally developed entrepreneurial solutions**

2030 Goals

1. Increase local manufacturing of pharmaceutical products in Nigeria to at least 70% of total consumption
2. Increase the total direct FTEs working in the life sciences manufacturing sector by at least 30,000, from approximately 20,000 today
3. Establish at least 2 commercial vaccine plants across the health sector
4. Establish at least 5 new medical supplies and diagnostics plants
5. Produce locally at least 10 - 20% of API consumption
6. Establish 1 vaccine mRNA R&D plant focused on pandemic preparedness
7. Reduce the value of medical tourism by at least 50%
8. Double Nigeria's pharmaceutical market share in Africa to at least 15%
9. At least quadruple the total FDI into the sector between 2025-2030 vs. 2018-2023
10. Increase the number of active Nigerian healthcare startups in Series B+ rounds to at least 3

Source- Presidential Initiative: Unlocking Healthcare Value Chains, PVAC Nigeria

30

Examples of key accomplishments in Nigeria

2 Assisted two pharmaceutical regulators to achieve ISO 9001: 2015 accreditation and WHO GBT Maturity Level 3 (ML3)

5 ISO accredited quality control laboratories

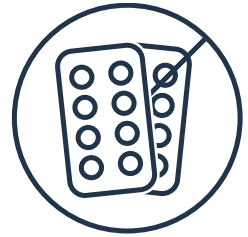
50-60% reduction in laboratory reaccreditation costs

3000+/5000+

Supported PCN to **register/train** more than 3000/5000 patent medicine stores/medicines shop owners across 6 states of operation

3 Contributed to national level policy developments including the National Medicines Quality Assurance Policy (NQAP), Pharmaceutical Quality System curriculum

4 Supported the conduct of four post-marketing surveillance exercises, introducing a more efficient risk-based approach



National Agency for Food and Drug Administration and Control API and Excipients workshop July 29-31, 2024

Supported NAFDAC's 2nd Regional Workshop on Active Pharmaceutical Ingredients (APIs) and Excipients in Nigeria, under the President's Unlocking the Healthcare Value Chain initiative.

USP provided 8 subject matter experts (SMEs) from USP/PQM+ EDQM, USFDA and WHO.

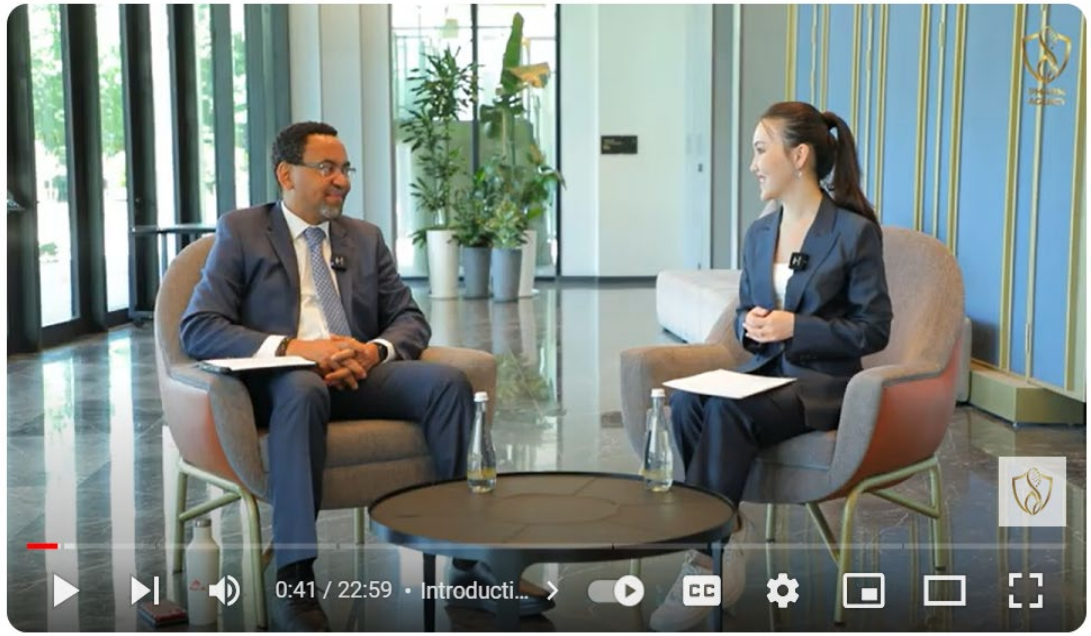
Event was designed to build the capacity of regulators and local manufacturers on API governance and improve access to safe, effective, and affordable medicines in the region.

Over 100 attendees across academia, national regulatory authorities, and industry participated in the workshop.

Health security – common theme across countries

Nigeria - USP MOU with PVAC

Uzbekistan – Agency for the Development of Pharmaceutical Industry



"Empowering Healthcare: A Conversation with Dr. Jude Nwokike on Global Health Initiatives"

Thank You!

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Serving on Expert Committees, Panels and Sub-Committees, they collaborate to develop quality standards and other solutions that help build a more resilient supply of quality medicines.

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