Local production of pharmaceuticals in sub-Saharan Africa: Is this an option for increasing access to HIV prevention and MPT products?

8:00 a.m. – 9:00 a.m. (EST), February 13

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MATRIX
Advancing R&D of Innovative HIV Prevention Products for Women

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Microbicide R&D to Advance HIV Prevention Technologies through Responsive Innovation and eXcellence **(MATRIX)**

- MATRIX is a USAID that is being implemented by Magee-Womens Research Institute (MWRI) in close collaboration with 19 partner organizations from North America and Africa.
- The mission of MATRIX is to develop a range of acceptable, affordable, scalable and deliverable products to meet the unmet needs of women at risk of HIV and other infectious diseases.

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Business, Market Dynamics and Commercialization Hub **(BACH)**

As an activity hub of MATRIX, BACH aims to accelerate commercialization and market uptake of HIV prevention and MPT products by helping product developers refine their commercialization strategies, develop their business case frameworks and access plans, and foster public health-oriented collaborations among public- and private-sector resources.

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Today’s speakers

- **Margaret Ilomuanya**, Associate Professor of Pharmaceutics in the Department of Pharmaceutics and Pharmaceutical Technology, Faculty of Pharmacy University of Lagos.
- **Perrer Tosso**, Director of Pharmaceutical Programs at the U.S. Pharmacopeia
- **Richard Gordon**, Director of International Business Development at the South African Medical Research Council (SAMRC)

MATRIX
Advancing R&D of Innovative
HIV Prevention Products for Women

Strengthening Pharmaceutical manufacturing in Africa

Margaret Okonawan **ILOMUANYA** PhD.
Department of Pharmaceutics and Pharmaceutical Technology
University of Lagos
13th February 2023

Outline

- Pharmaceutical manufacturing in sub-Saharan Africa
- Potential pathway to strengthen the pharmaceutical industry
- Leveraging regional production for their pharmaceutical products
- Collaborative R&D: A pathway way for growing Pharma manufacturing in SSA

Pharmaceutical manufacturing in sub-Saharan Africa

Pharmaceutical manufacturing in sub-Saharan Africa

- US$ 20 billion annually is a figure that represents Pharmaceutical manufacturing in SSA.

- Manufacturing of life-saving medicines is concentrated in very few countries: South Africa, Nigeria, Ghana, Kenya and Uganda

Pharmaceutical manufacturing in sub-Saharan Africa

- The overall African Pharmaceutical sector is currently worth about US$ 65 billion. However, the pharmaceutical manufacturing sector in Africa contributes less than 30% of the continent’s needs.

Pharmaceutical manufacturing in sub-Saharan Africa

- The pharmaceutical sector is seen as a strategic sector, and high dependency on imports of essential medicines have raised security concern about the continuity of supply.

Pharmaceutical manufacturing in sub-Saharan Africa

Eastern Africa

Pharmaceutical manufacturing in sub-Saharan Africa

- The combined Pharmaceutical market size of the East African Community in 2020 was about US$ 3 billion

- Antibiotics, Antimalarials, Anthelmintics, Disinfectants, Analgesics and Anti-Retroviral medicines

Pharmaceutical manufacturing in sub-Saharan Africa

A Regional Pharmaceutical Manufacturing Plan of Action to guide partner states of the EAC towards collective and synergistic evolution of

- an efficient and effective pharmaceutical production sector,
- capable of making significant contributions to meeting national, regional and international demand for medicinal products until 2027 and beyond was developed in 2012.

Pharmaceutical manufacturing in sub-Saharan Africa

- The action plan is closely aligned to the short, medium and long-term goals and policies of the EAC and individual member states and serves to complement past and present regional economic community and pan-African strategies.

Pharmaceutical manufacturing in sub-Saharan Africa

South Africa

Pharmaceutical manufacturing in sub-Saharan Africa

- Stats SA released the 2022 mid-year population estimates report on the country's population, estimated to be 60.6 million. About **8 million people** in the country are HIV positive.

- South Africa remains the largest pharmaceutical market in Sub-Saharan Africa for manufactured ARVs and MPTs.

Pharmaceutical manufacturing in sub-Saharan Africa

- Total pharmaceutical expenditure was estimated to be $4.1 billion in 2019 and $3.6 billion in 2020 (2019, Fitch Solutions).

- Its prescription drug market is valued at approximately $3.0 billion

Pharmaceutical manufacturing in sub-Saharan Africa

- South Africa has the presence of multinational companies manufacturing

- **Cipla –** established in 1935
- **Pfizer** South Africa
- **Portfolio** Pharmaceuticals Pty Ltd-currently has 3 formulation plants – two in South Africa and one in Botswana.
- **Pharma Q** (Pty) Ltd

Pharmaceutical manufacturing in sub-Saharan Africa

- One of the outcomes of the COVID-19 pandemic and the resulting shortfall in vaccines for Africa is the recognition that South Africa needs to develop its own production hub to manufacture vaccines to mitigate the supply challenges posed by future pandemics.

- In mid-2021, the WHO announced that it is setting up an mRNA site in South Africa, which will produce COVID vaccines for the region.

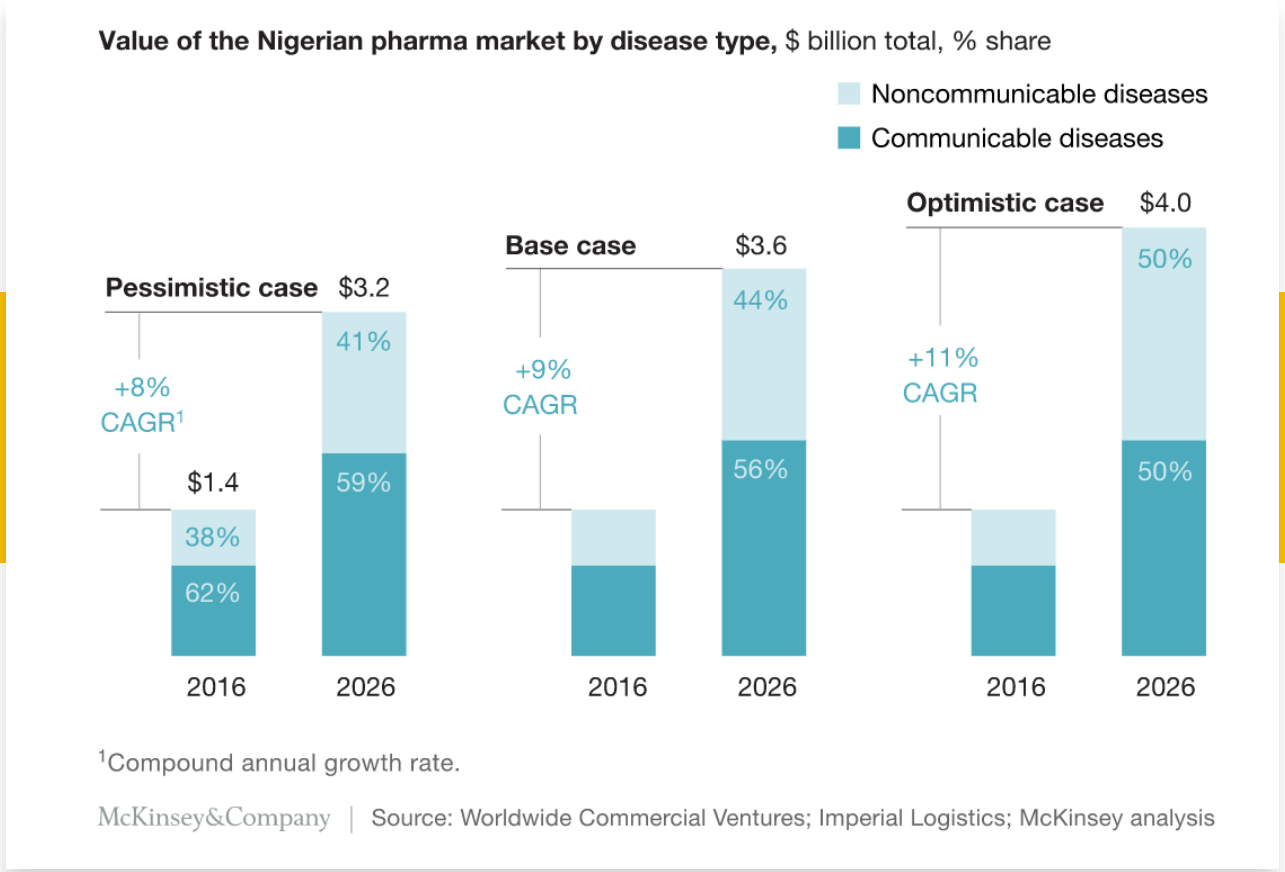
Pharmaceutical manufacturing in sub-Saharan Africa

Nigeria

Pharmaceutical manufacturing in sub-Saharan Africa

- Nigeria has a population of over 195 million people, In 2021, 1.9 million people in Nigeria were living with HIV, with Women being the most affected group.

- As of 2020, Nigeria had over 160 active local pharma manufacturers registered and NAFDAC has been ensuring they adhere to WHO global bench-marking.



Nigeria's Pharma market

Nigeria remains the largest pharmaceutical market in Sub-Saharan Africa

Pharmaceutical manufacturing in sub-Saharan Africa

- WHO officially announced Nigeria's National Regulatory Agencies as a Stable, well-functioning and integrated regulatory system maturity level 3 rating scale of the Global Benchmarking Tool.

- Tanzania, Ghana, Nigeria, and Egypt have been ranked ML3 as effective regulatory systems on the African continent. Fewer than 30% of the world's regulatory authorities are considered fully functioning and operational.

Pathways to strengthen pharmaceutical manufacturing in SSA

Pathways to strengthen pharmaceutical manufacturing in SSA

- Promotion of competitive and efficient pharmaceutical production regionally; Through usage of incentives such as preferences of up to 15 per cent on tenders for locally manufactured products

- Facilitation of increased investment in pharmaceutical production regionally; this is through restricting certain imported products that can be locally (regionally) manufactured

Pathways to strengthen pharmaceutical manufacturing in SSA

- Strengthening of pharmaceutical regulatory capacity in the region

- Development of appropriate skills and knowledge on pharmaceutical production in the region

Pathways to strengthen pharmaceutical manufacturing in SSA

- Utilisation of TRIPS flexibilities towards improved local production of pharmaceuticals, and

- Mainstreaming innovation, research and development within regional pharmaceutical industry

Leveraging regional production for their pharmaceutical products

- Developing local manufacturing in conjunction with already established Pharmaceutical Industries who are enjoying significant regional market share.

Leveraging regional production for their pharmaceutical products

- **Business mentoring** to increase production efficiencies and cost savings, and to improve business planning
- **Promotion of investment and technology transfer** through 1) working with local companies and partners, and 2) matchmaking platforms and activities between both North-South and South-South, brokering win-win arrangements, including through Public-Private Partnerships

Leveraging regional production for their pharmaceutical products

- **Strengthening regional and continental pharmaceutical manufacturers associations** who represent and promote the industry, provide services to its members and engage with decision makers to address remaining challenges.

Leveraging regional production for their pharmaceutical products

- Political will to ensure that Africa produces its own medicines can be leveraged upon to establish lasting collaborations between industries.

Leveraging regional production for their pharmaceutical products

- **Policy advice** to formulate and implement pharmaceutical sector strategies, policies and programmes

- **Technical guidance to companies** to achieve international production standards such as Good Manufacturing Practices (GMP)

Leveraging regional production for their pharmaceutical products

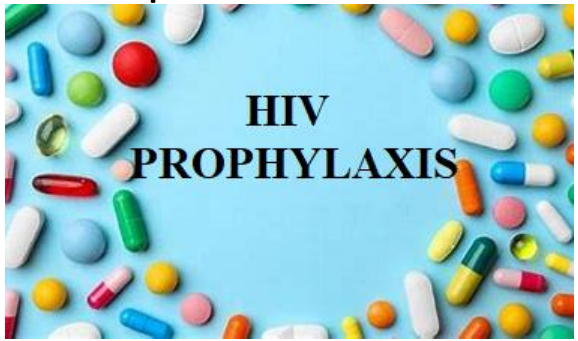
- Utilizing the skilled African workforce present within the continent via a concerted efforts to allow talent work in SSA irrespective of country of origin.

Leveraging regional production for their pharmaceutical products

- **Human resources development** to ensure further expansion and long-term sustainability of local production
- **Analysis and research** for developing sector policies and strategies, including on the economics of production and on market data, as a basis for rational decision making by companies, investors and policymakers

Collaborative R&D::A pathway way for growing Pharma manufacturing in SSA

There’s a positive cycle where you go from detection and diagnosis to research and development to treatment, and this creates an ecosystem of experts who tackle different dimensions of medical challenges.



NOVEL PRODUCT

PRODUCT

1. Kaduna State University, Kaduna State;
2. Gombe State University, Gombe State;
3. Delta State University, Delta State;
4. University of Ilorin, Kwara State;

THANK YOU FOR LISTENING

References

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- HIV and AIDS | UNICEF Eastern and Southern Africauction in developing countries | UNIDO
- WHO Certifies NAFDAC as ML3 Regulatory Authority – NAFDAC
- APIFA | API for Africa
- Pharma Manufacturing and Distribution in Sub-Saharan Africa: Logistics Solutions (worldcourier.com)
- The state of African pharmaceuticals | Monitor
- Winning in Nigeria: Pharma's next frontier | McKinsey
- The Strategic Imperative of Boosting Local Pharmaceutical Production in Africa | WHO | Regional Office for Africa

Towards an enabling environment for sustainable manufacturing in Africa

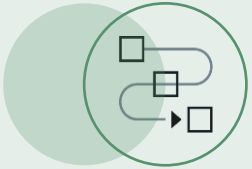
Perrer Tosso, Ph.D.

Our enduring 200-year old mission

Increase the supply of safe, effective **medicines, vaccines, and trusted diagnostics**. USP strengthens health systems at local, regional, and global levels and delivers end-to-end pharmaceutical services that champion **equitable access to quality medical products**.

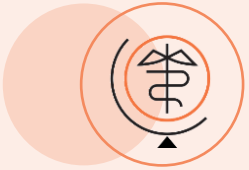
Why production of quality HIV products in Africa matters?

Localizing manufacturers of quality products according to **international standard** impacts the **patients**, **pharmaceutical industry**, and **health security**.



Improve supply resiliency

Allow manufacturers to participate in international tenders



Improved public health and wellbeing

Framework for sustainable manufacturing of HIV products in Africa

Sustainable manufacturing of HIV products in Africa requires an ecosystem

- Regulatory Systems
- Access to Affordable Finance
- Skilled Workforce
- Adequate Infrastructure
- Incentivizing Policies
- Access Technology and Innovation

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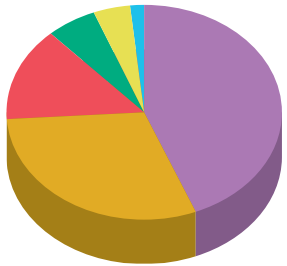
and Partnerships between various stakeholders to localize sustainable capacity

Our Impact in manufacturing in LMIC

USP provides technical assistance and capacity building to manufacture for API and finished products in: **cGMP**, **QMS**, **process and products developments**, **management and integration of big data**, **dossier preparation/filling**…**CM and PAT**

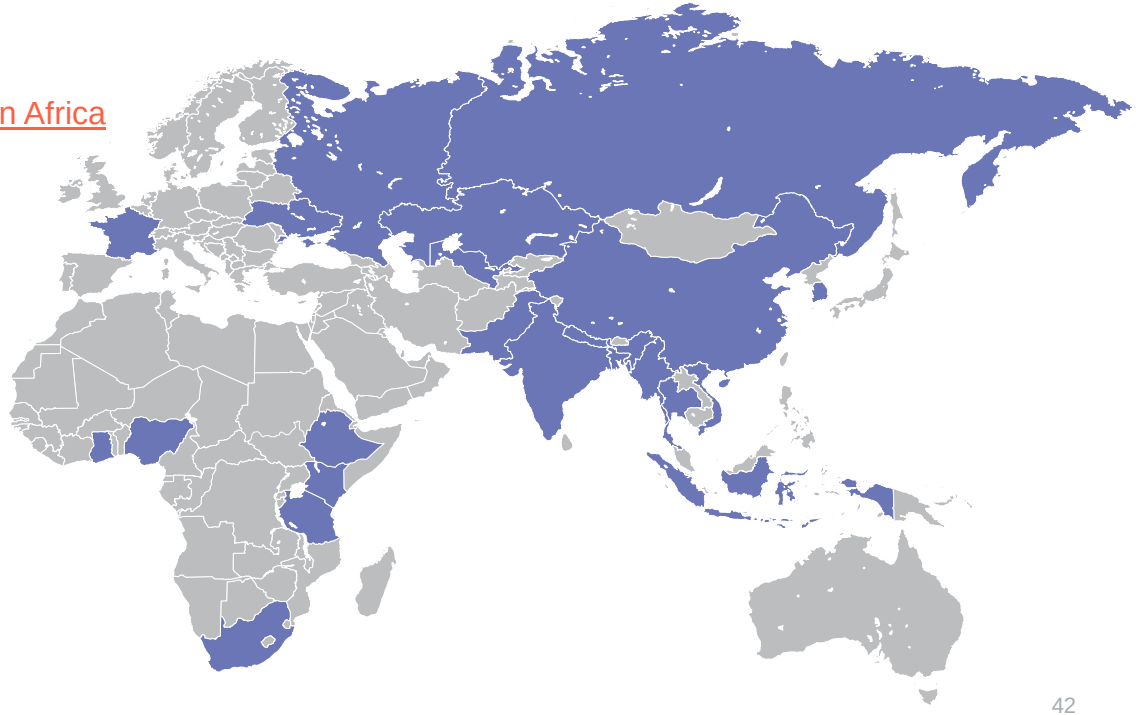
118 manufacturers supported globally, 39 in Africa

41 Products WHO prequalified of SRA approved



Product

- TB
- MNCH
- NTD
- Malaria
- COVID-19
- HIV/AIDS



Working with regulatory authorities

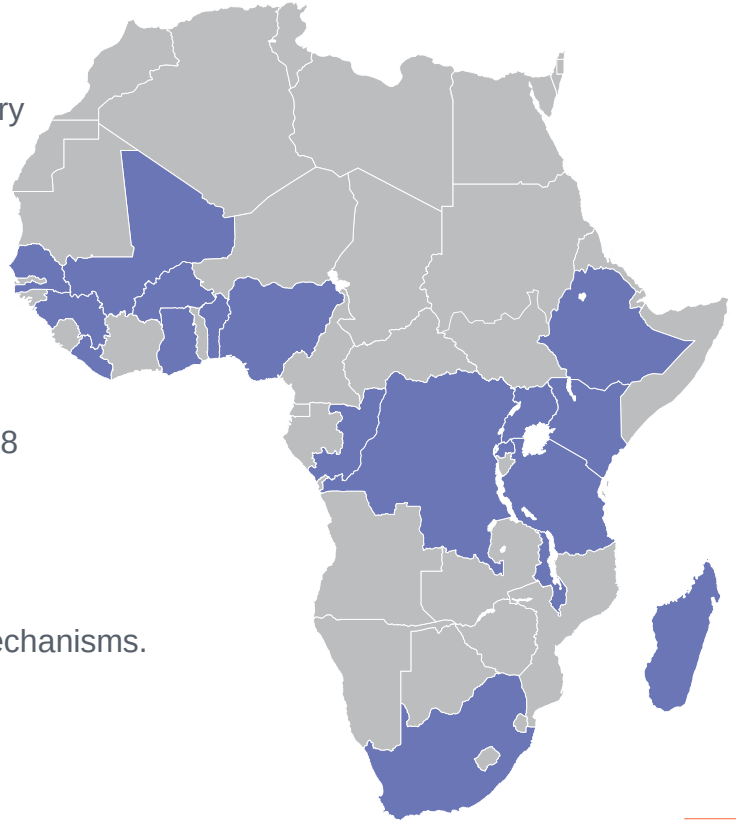
Collaborating with NMRAs to strengthen effective regulatory functions and systems. Developing capacity for:

- **Medicine dossier evaluation**
- **Registration/emergency use authorization**
- **Inspection, etc.**

Advancing regulatory maturity:

- WHO Global Benchmarking to advance maturity in 8 countries in Africa, including Rwanda.
- **Our work with the Ghana FDA allowed them to demonstrate they operate at Maturity Level 3.**

Supporting regional harmonization and mutual reliance mechanisms.



Summary of Our Impact

In the last 30 years, improved regulations, laboratories, medicines safety, and health system stewardship has resulted in:

50+

Programs in 50+ countries across 4 continents implemented by USP

100+

100+ manufacturers engaged with **41 products achieving WHO PQ or SRA approvals**

90+

90+ labs trained in global standards and best practices

Thank You

Empowering a healthy tomorrow

Expanding manufacturing capacity

Producing medicines closer to patients to advance health equity

Expanding manufacturing capacity is key to improving access to medical products, averting supply chain shortages, advancing health security, and assuring equitable responses during health emergencies. We work to strengthen **regional and local manufacturing of medicines, vaccines, personal protective equipment, medical devices, and other health products** to provide more equitable access for patients and communities worldwide.

Why it matters

While pharmaceutical supply chains have become increasingly complex, the supply of many essential health products is constrained by a limited number of producers from a handful of major manufacturing hubs. The challenge extends beyond limited sources of finished products, but includes few sources for starting materials, raw materials, and active pharmaceutical ingredients (APIs) as well.

Over-consolidation of the pharmaceutical market makes supply chains vulnerable *to disruptions and impedes access to essential medicines for millions of patients.*

Our Impact

40+ technology transfers facilitated
including 10 fill/finish programs.

40+ products approved
by the WHO's prequalification program or other stringent regulatory authority, including APIs and finished products.

100+ pharmaceutical companies engaged
to strengthen good manufacturing practices.

4,000+ people trained
in good manufacturing practices from 24 countries.

OUR WORK IN ACTION

Facilitated technology transfer between Gilead Sciences Inc. and Pakistan manufacturer Ferozsons to expand the supply of essential COVID-19 treatment remdesivir to 16 countries.

In Nigeria, we worked to establish new local sources for five essential medicines for maternal and newborn health.

In Indonesia, Kazakhstan, Philippines, and Uzbekistan, we helped 10 manufacturers produce medicines to combat drug-resistant TB, including the first locally produced anti-TB medicine to receive WHO-prequalification in Indonesia.

Learn more about our work on the USAID PQM+ program and our other programs on our website.

OUR EXPERTISE

Manufacturing Quality

- Quality system development
- GMP, GLP, GCP, and other GxPs
- Bioavailability/bioequivalence
- Corrective and preventive actions
- Quality control/lot release

March 2022

Technology Transfer

- Feasibility analysis
- Product and process knowledge transfer
- Skills transfer for workforce development

Regulatory Advisory Services

- Dossier preparation/filing
- Product registration
- Mock inspections/audits

Process Optimization

- Capital improvement projects
- Facility design/expansion
- Material sourcing/selection
- Traceability/barcoding
- Advanced manufacturing technologies

Pharmaceutical Sector Strategy

- GMP roadmaps
- Market intelligence
- Predictive analytics

The standard of trust

Creating an enabling ecosystem for regional COVID-19 vaccine production

Expanding vaccine production in isolation is insufficient to expand access to COVID-19 vaccines. That is why our efforts are focused on creating an enabling ecosystem for sustainable production that includes collaborating with the following:

- Regulators to advance and optimize regulatory review, emergency use, and full approval processes.
- Local manufacturers to explore sustainable models of expansion, including feasibility studies and backward integration.
- Pharmaceutical innovators to address and bridge capacity gaps for successful technology transfer.
- Development and finance institutions to de-risk investments through strategic and technical insights and guidance.

Learn more about our work

https://www.usp.org/global-public-health

Strengthening medicines regulatory systems

Bolstering national and regional authorities to improve access to medicines

Medicines regulatory authorities (MRAs) help people access safe, effective, and quality-assured medical products and guard against harmful substandard and falsified products. We work to support national MRAs to **strengthen regulatory functions and achieve advanced regulatory maturity**. We also work with regional regulatory authorities to build capacity for **regulatory cooperation, reliance, convergence, and harmonization**.

Why it matters

Strong regulatory systems are fundamental to resilient health systems. With effective oversight and greater efficiency, MRAs can help new products reach patients faster and foster an enabling environment for expanded manufacturing capacity. A critical link in the supply chain, strong MRAs promote health security and improve equitable responses during health emergencies.

***Globally, less than 30% of national regulatory authorities have full capacity** to assure the safety, efficacy, and quality of medical products.*

Our Impact

50+ national regulatory authorities strengthened

25+ countries supported with strengthened post-marketing surveillance for safety and/or quality

3 national regulators supported that achieved Maturity Level 3

OUR WORK IN ACTION

Developed and implemented an integrated regulatory information management system —one of the first in the region— with the Drug Regulatory Authority of **Pakistan**.

Reduced registration times by up to 40 percent in **Ethiopia** and streamlined review procedures to eliminate a backlog of dossier applications.

Built capacity for remote inspections in **Kazakhstan** which enabled the inspectorate to conduct 28 remote inspections for medical devices and medicines, in a major step toward Pharmaceutical Inspection Co-operation Scheme (PIC/S) membership.

Developed legislation and supported establishment of the **Liberia** Medicines and Health Products Regulatory Authority, allowing for national regulatory oversight for the first time.

Learn more about our work on the USAID PQM+ program and our other programs on our website.

OUR EXPERTISE

Regulatory maturity advancement

- Global benchmarking support
- Risk-based approaches
- PIC/S ascension process
- Integrated information management systems

National legislation, policies, and plans

- Pharmaceutical laws
- Strategic planning
- Quality assurance policies
- Resource allocation
- Fee schedules

Health security

- Pandemic preparedness
- Emergency use procedures
- Product safety and quality monitoring

Regional cooperation and harmonization

- Joint review processes
- Regional surveillance
- Mutual recognition procedures
- Convergence

Advancing health security through regulatory guidance and thought leadership

The COVID-19 pandemic laid bare long-standing vulnerabilities in health systems and pharmaceutical supply chains, particularly in low- and middle-income countries, where regulators were ill-prepared to address the onslaught of challenges brought on by the pandemic.

To support regulators in preparing and responding to the pandemic, USP issued a pandemic preparedness paper and, through the USAID-funded PQM+ program, issued guidance for streamlined emergency use authorization procedures for vaccines and diagnostics.

We also supported a number of countries in establishing or strengthening post-market surveillance and pharmacovigilance programs to monitor vaccines quality and safety.

Learn more about our work
www.usp.org/global-public-health

Updates from South Africa: API Cluster Program

13 February 2023

Prof Richard Gordon

API Cluster

The cluster concept

A cluster: A **collaborative multi-stakeholder and autonomous vehicle** geared to identify and achieve common objectives in a coherent manner

TIA's/DSI goal focus on the technology development value chain (TRL 4-8) makes the Clusters a unique model that can……

- facilitate, catalyse and enable industries in South Africa in a coordinated manner closing the gap in technology transfer from HEIs and SCs to the market.

Criteria for an Innovation Cluster

- **High-impact**, with technology solution applied at a national, provincial, municipal and/or international level
- High relevance to industry and the potential to address a **critical economic or social issue**
- **Strong RDI competence** across private and public institutions which when integrated **amplifies the outcome**
- Excellence along a technology development value chain to give rise to **a multi-disciplinary programme** with **multi-stakeholders** fulfilling different functions
- Consortium-led approach characterised by **resource pooling**, collaborative RDI effort, and knowledge exchange
- Potential to create **new commercial and research opportunities** as well as to develop competitive Intellectual Property
- **Human capital and capacity development** component to ensure continued skills development, especially in emerging areas.

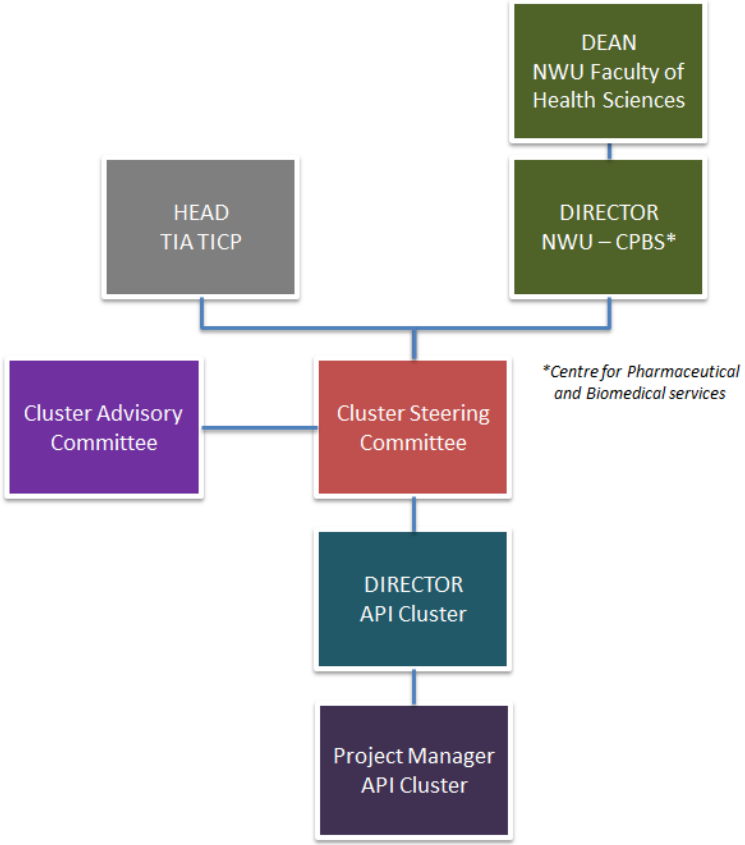
Goals (selected)

1. …….
2. ….support key actions to accelerate commercialisation and facilitate transfer to industry
3. Facilitate opportunities for local manufacturing
4. Promote collaboration and networking among private sector industry, SMMEs and academia to leverage local expertise and other resources
5. Leverage funds both local and international
6. ……..

To demonstrate South Africa's potential self-reliance on establishing small-molecule API manufacturing capabilities

- Underpinned by **realigning current capabilities** at various HEIs, research institutes and commercial companies towards a focused API process synthesis and engineering programme.
- **Combined strategy of home-developed and in-licensed technology process** development which can be used to **lever collaboration and partnerships** within the pharmaceutical sector.
- ……..

Governance


DEAN
NWU Faculty of Health Sciences
DIRECTOR
NWU – CPBS*
HEAD
TIA TICP
Cluster Advisory Committee
Cluster Steering Committee
*Centre for Pharmaceutical and Biomedical services
DIRECTOR
API Cluster
Project Manager
API Cluster

So, how are we doing: Phase 1

- 6 projects funded at local universities:
  - 2 projects Wits, looking at currently used ARV and TB drug API
  - 1 project with UP for anti-helminth project
  - 1 project at UWC for green chemistry
  - 1 project at NMU for Flow chemistry for antimalarial
  - 1 project at CSIR for capacity development
- Mixed success
  - Several cases where technology has leapfrogged older technologies
  - Exciting data on several “green” chemistry projects
- Market analysis report commissioned
  - Generic and importers
  - Look at opportunities for import substitutions.

API+ Laboratory

Pilot-Scale laboratory at CPT Pharma

18 NOV CPT PHARMA CELEBRATES GIANT LEAP FOR PHARMACEUTICAL MANUFACTURING

Posted at 12:25h in 2020, Press Releases • Share

News Provided by: Chemical Process Technologies Pharma (Pty) Ltd

WALTLOO, PRETORIA, Nov 2, 2020 — Chemical Process Technologies Pharma (CPT Pharma), a relative newcomer to the field of generic active pharmaceutical ingredients (API) production, has been granted a licence by the South African Health Products Regulatory Authority (SAHPRA) to manufacture APIs for human medicine on 28 August 2020.

API+ Laboratory

API Cluster Projects

- 5 API projects with local and international partners that include.
  - 2 ARV API’s
  - Next generation Malaria API with MMV
  - Next generation AMR drug with GARD-P
  - Next generation Covid drug with GIZ
- Open source project with M4All