Regional Procurement Updates

Vaccine Industry Consultation
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Africa CDC
The current reality of pharmaceutical manufacturing in Africa

**Therapeutics**

- Total demand volume produced locally:
  - Imports: 30-40%
  - Local: 60-70%

- Africa has limited manufacturing capacity, concentrated in a few countries that have a low level of integration along the value chain.

**Vaccines**

- The vaccines market is publicly driven and supply is concentrated to a small number of importers.

**Supply**

- **8** Countries contributing 80% of local production with over 600 manufacturers
- **<20%** Manufacturers producing APIs operating in Africa
- **<2%** Worldwide R&D projects in Africa

**Financing and procurement**

- **~40%** Financed through private sector
- **~25%** manufacturers belong to Multinationals

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Source: Fitch solutions (September 2020), IQVIA (September 2020), OCHA (United Nations Office for the Coordination of Humanitarian Affairs)
Health product manufacturing and innovation provides a sizeable opportunity on the African continent

Large health product market in Africa provides an attractive business case

- ~30 bn USD market in 2022 in Africa across health products (vaccines, therapeutics, diagnostics, etc.)
- Market has been growing 4% per annum (4bn USD increase) in the past 5 years
- Additional ~7 bn USD growth expected in the next 5 years

Additional benefits of localizing manufacturing and innovation

- Improve health security and capacity for emergency response
- Improves public health (DALY’s)
- Improves access and affordability
- Accelerate ongoing regional harmonization initiatives to facilitate trade
- Elevate technological expertise and capabilities
- Facilitate economic growth
Examples from developing countries that have successfully established a vaccine manufacturing industry

<table>
<thead>
<tr>
<th>Agenda-setting and Market design</th>
<th>Regulatory strengthening</th>
<th>Access to finance</th>
<th>Technology, IP, R&amp;D, and talent development</th>
<th>Infrastructure development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Export focused industry in high volume vaccine mostly run by private companies</td>
<td>Achieved status as functional vaccine regulatory system by WHO</td>
<td>Incentivized manufacturers through tax breaks</td>
<td>Climbed-up value chain from F&amp;F to R&amp;D over time</td>
<td>9 government funded biotech parks built since 2016 to support R&amp;D and production</td>
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<td>Focus on domestic and regional SA market and on highest volume vaccines in Brazil</td>
<td>Received certification by PAHO as a reference NRA in region allowing easier export within SA</td>
<td>Invested $50+m into public institutions e.g., Butanan, Fiocruz to receive complex tech transfers</td>
<td>Focused on tech transfers from MNC’s e.g., Sanofi for established modalities</td>
<td>Invested in sites with good manufacturing practices (GMP) for regional exports</td>
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<td>Modernized national regulatory agency to meet international standards (WHO PQ)</td>
<td></td>
<td>Dedicated investments in vaccines in the 5-year plan e.g., New National Vaccine Engineering Research Center</td>
<td>End-end focus with ambition for China developed vaccines</td>
<td>Focus on late-stage of value chain</td>
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Sources: PAHO.com, PubMed, Nature, Pharmaceutical Technology, Times of India,
The implementation of the New Public Health Order called for by the AU and Africa CDC is anchored on 5 pillars:

1. Strengthening African institutions for public health to represent African priorities in global health governance and that drive progress on key health indicators.
2. Strengthening the Public Health Workforce to ensure Africa has the workforce build capacity and capabilities that it needs to address health threats.
3. Expanding Local Manufacturing of Health Products across vaccines, diagnostics, and therapeutics, to democratize access to life-saving medicines and equipment.
4. Increasing Domestic Investment in Health including domestic mobilization of financial resources, human capital technical resources.
5. Promoting Action-Oriented and Respectful Partnerships to advance vaccine manufacturing, health workforce development, and strong public health institutions.
Pillar 6: Achieve Africa CDC’s mission through a clear ambition underpinned by 4 strategic priorities

Mission
To promote health security and self-reliance in Africa, by increasing its ability to develop, manufacture, and trade essential health products that help prevent, diagnose, alleviate, and cure local medical needs

Ambition
To increase manufacturing and innovation of health products (and raw material inputs) on African continent to meet 60% of demand by 2040

Strategic priorities

A. **Ensure healthy markets** for locally produced health products (incl., market design and intelligence)
B. **Strengthen the local R&D ecosystem** through increasing R&D capabilities and capacity
C. **Support capability building and talent development** to enable local manufacturing
D. **Incubate and scale capacity and infrastructure** of local manufacturing and supply chain

**+ Attract investments to drive delivery of above strategic priorities** through catalyzing strategic partnerships and resources
The 5-year roadmap for Pillar 6 aims to realize the AU’s public health order across health products, expanding from the current focus on vaccines.

Objectives along 5-year roadmap

2018 – 2022

PAVM set-up and start implementation

- **Set-up and mandated PAVM** to execute towards manufacturing 60% of local Vx demand
- **Develop continental strategy** and launch Framework for Action (FFA)
- **Install Secretariat** and launch implementation of priority bold program activities

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2023-2028

Step-change towards self-reliant continent with local development and manufacturing

- **Expand into broader health products/raw material manufacturing strategy** and implementation, while scaling bold programs
- **Build organizational capacity** for PAVM and Harmonized Africa Health Manufacturing Platform
- **Define innovation ecosystem foundation required to address** priority medical unmet needs
- **Continue cultivate partnerships and incentivize funding** across the health ecosystem

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1. Assessment of local Vx manufacturing raw material needs to enable manufacturing at scale
PAVM developed a continental strategy outlining the priority areas for local vaccine manufacturing

1. Potential disease prioritization

   Prioritized 22 diseases¹...

<table>
<thead>
<tr>
<th>Legacy</th>
<th>Expanding</th>
<th>Outbreak</th>
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<tbody>
<tr>
<td>Diphtheria</td>
<td>HPV</td>
<td>Ebola</td>
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<tr>
<td>Hepatitis B</td>
<td>Pneumococcal</td>
<td>Influenza</td>
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<tr>
<td>Measles</td>
<td>HIV</td>
<td>Chikungunya</td>
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<tr>
<td>Meningococcal</td>
<td>COVID-19</td>
<td>Lassa fever</td>
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<tr>
<td>Whooping Cough</td>
<td>Malaria</td>
<td>Rift valley fever</td>
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<tr>
<td>Yellow fever</td>
<td>Rotavirus</td>
<td>Disease X</td>
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<tr>
<td>Typhoid fever</td>
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<tr>
<td>Tetanus</td>
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<tr>
<td>Tuberculosis</td>
<td></td>
<td></td>
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<td>Cholera</td>
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2. Technology focus

   … requiring a breadth of technology platforms...

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<tr>
<th>Traditional</th>
<th>Innovative</th>
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<td>Live attenuated</td>
<td>Viral vector</td>
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<tr>
<td>Inactivated virus</td>
<td>RNA/DNA</td>
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<tr>
<td>Subunit</td>
<td></td>
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<tr>
<td>Virus-like particle</td>
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3. Potential value chain focus

   … along the different steps of the value chain

   **Fill & Finish (F&F)**
   *Fill & finish for all priority vaccines, enabling achievement of local production targets. Due to vaccine and modality agnostic nature, single plants could produce multiple vaccines, allowing for production of higher volumes that could lead to economies of scale, creating potential for Africa to become cost-effective against other DCVMs*

   **Drug Substance (DS)**
   *Expand drug substance mostly in established platforms where tech transfers are readily available; manufacturing will require developing a local raw materials industry*

   **R&D**
   *Expand R&D activities to develop new vaccines for Africa, support more efficient manufacturing and improve vaccine characteristics*

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1. The list will evolve over time based on ongoing scientific findings
The PAVM taskforce defined 8 bold programs to support the vaccine manufacturing ecosystem and continental strategy

**Market design and demand intelligence**
Achieving sustainable and reliable economies of scale by launching mechanisms that create demand certainty for manufacturers while facilitating country procurement

**Access to finance**
Stimulating a healthy market that result in sustainable and continuous investment in local manufacturing capabilities and broader ecosystem enablers

**Technology transfer and IP**
Establishing and accelerating technology transfer and intellectual property enablement to local manufacturers

**Regulatory strengthening**
Developing best-in-class National Regulatory Authorities (NRAs), regional harmonization and World Health Organization prequalification, to enable the export of products

**R&D and talent development**
Building the continent’s workforce by investing in the development critical manufacturing skills and capabilities and local R&D capabilities to develop new and improve existing products -- Considered as two bold programs: Talent and R&D --

**Infrastructure development**
Continuing and accelerating infrastructure initiatives including investment in mega-projects, innovative technologies etc.
An African pooled procurement mechanism (PPM) will help enable an efficient and sustainable African vaccine market.

The continent suffers from vaccine procurement challenges that call for increased market shaping.

- **>90%**
  - Volumes of vaccines facilitated by Gavi and UNICEF in Africa

- **~150m doses**
  - Vaccines are from countries that are not Gavi supported

- **7 counties** Expected to transition from Gavi over the next 5 years representing ~170m doses

An African PPM can provide the unlock required to enable an efficient and sustainable Africa vaccines market through:

**Demand consolidation**
that enables increased purchasing power, economies of scale

**Demand forecasting and offtake certainty**
that enables ability to provide local manufacturers with long term supply agreements

**Centralised processes and platforms**
(e.g. negotiations and contracting) that reduce transaction costs and enable purchasing power to be leveraged effectively

**Ecosystem enablers**
e.g. financing, harmonization of relevant regulatory standards
There are four different collaboration models that improve efficiency and purchasing power

According to WHO guidelines on country pharmaceutical pricing policies

<table>
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<tr>
<th>Collaboration model</th>
<th>Description</th>
<th>Example of collaboration model</th>
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<td>Informed buying</td>
<td>Countries buy products individually based on the information they share with one another about prices, product quality and suppliers</td>
<td>SADC pooled procurement: intended to be a group contracting model, although currently limited to informed buying activities i.e., information sharing</td>
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<td>Coordinated informed buying</td>
<td>Participating countries conduct market research, share supplier performance information, and monitor prices in an organized way.</td>
<td>Valetta Declaration: a group of 10 EU countries that shares information (on new and mainly innovative medicines and therapies), and conducts horizon-scanning, assessments, and negotiations</td>
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<tr>
<td>Group contracting</td>
<td>Participating countries buy products individually but follow one process to select suppliers, negotiate price and award contracts to the winning suppliers</td>
<td>Gulf Joint Procurement Program (GJPP): Issues joint tenders on behalf of the six Gulf Cooperation Council (GCC) states, which pay the manufacturers directly</td>
</tr>
<tr>
<td>Central contracting and procurement</td>
<td>All processes and purchasing are conducted through an established procurement agent acting on behalf of participating countries</td>
<td>PAHO RF: Provides member states with demand forecasts, pools demand, performs centralized negotiations and contracting, pays suppliers through a revolving fund that countries and donors pay into</td>
</tr>
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Learnings and observed impact for existing PPMs on sub-national, national and international levels

WHO PPM definition

A formal arrangement where financial and other resources are combined across different purchasing authorities, to create a single entity for procuring health products on behalf of individual purchasing authorities

Observed impact:

- Increased access
- Reduced operating costs and administrative burdens
- Improved quality assurance
- Reduction in procurement corruption
- Increased equity between members
- Improved forecasting and supply management


Long standing successful PPMs such as PAHO RF (>40 years operational) provide evidence that PPMs can be financially and operational sustainable over the long term.
Considerable progress has been achieved to date, with a focus this year on market shaping instruments

Progress on Market Design and Demand Intelligence Bold program

In 2024, the focus will shift towards:
- validation of the technical PPM design and draft of pilot PPM implementation playbook
- implementation of the legal instrument which will help facilitate mostly the PPM
- further development of required market shaping instruments both for Vx (incl. financing model for PPM premiums) and broader health products
Initiating and implementing a PPM is a robust and complex process that requires significant commitment.

PPMs are complex, multicomponent systems that require...

- Sustained political will and commitment from member states
- Effective stakeholder integration
- Support from multiple partners
- A fitting enabling environment

Pooled procurement ultimately relies on co-operation and co-ordination between all relevant stakeholders to be successful. The Africa CDC is committed to advancing market shaping activities, including a pilot PPM. It calls for continued collaboration and cooperation between stakeholders to drive a unified and collective effort.