

MEETING REPORT

Advancing a sustainable supply and demand ecosystem for monoclonal antibodies in Africa

On the sidelines of the
3rd World Local Production Forum

April 6, 2025

Abu Dhabi, United Arab Emirates

Co-convened by Africa Centres for Disease Control and Prevention
and IAVI, with support from Wellcome and Unitaïd

Acknowledgments

IAVI and the Africa Centres for Disease Control and Prevention would like to thank the meeting speakers and participants for their attendance and valuable contributions. IAVI gratefully acknowledges the funder of this initiative, Wellcome, for their sponsorship and overall support of the mAbs for Africa project. We also thank Unitaaid for their co-sponsorship of this meeting.

We thank the members of the IAVI project team, including Shelly Malhotra, Esther Mungai, Mina Adel, Katerina Chapman, Sana Johnson, and Sara Smyth; and colleagues at Africa Centres for Disease Control and Prevention, including Merawi Aragaw, Abebe Genetu Biyah, Wesley Rono, Kevin Irandagiye, and Jens Pedersen for their co-leadership of this project.



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Acronyms

Africa CDC	Africa Centres for Disease Control and Prevention
AI	artificial intelligence
AMA	African Medicines Agency
API	active pharmaceutical ingredient
APPM	African Pooled Procurement Mechanism
AUDA-NEPAD	African Union Development Agency New Economic Partnership for African Development
bnAbs	broadly neutralizing antibodies
DFIs	development finance institutions
EMLs	essential medicines lists
GMP	good manufacturing practice
IDs	infectious diseases
IP	intellectual property
mAbs	monoclonal antibodies
MoU	memorandum of understanding
NCDs	non-communicable diseases
NRAs	national regulatory authorities
R&D	research and development
RSV	respiratory syncytial virus
UHC	universal health coverage
WHO	World Health Organization

Executive summary

On April 6, 2025, Africa Centres for Disease Control and Prevention (Africa CDC) and IAVI, with support from Wellcome and Unitaid, convened a high-level meeting in Abu Dhabi to chart a pathway for advancing a sustainable monoclonal antibody (mAb) ecosystem in Africa. Despite their growing importance in global health, mAbs remain largely inaccessible across the continent due to a lack of affordable, equitable, and sustainable supply.

The convening brought together African manufacturers, regulators, researchers, funders, development finance institutions, and development partners to address systemic barriers and define a coordinated agenda for end-to-end mAbs development and access driven by the shared vision that mAbs must be treated as essential public health tools, not as luxury products.

Africa has a unique opportunity to develop a resilient, regional bio-manufacturing ecosystem to secure timely and equitable mAbs access. Key recommendations across six interconnected areas emerged from the convening:

1. **Research and development (R&D) and innovation** — Africa must move from reliance on imported innovation by expanding upstream R&D capacity as part of the manufacturing agenda. This entails aligning innovation pipelines with health priorities and leveraging artificial intelligence (AI) and platform-based strategies to lower costs and accelerate readiness. It also includes expanding public-private partnerships to support preclinical research and process optimization.
2. **Sustainable manufacturing** — Investments in scalable, modular infrastructure; platform diversification; regional manufacturing hubs with specialization in different stages of the value chain; and bolstering regional active pharmaceutical ingredient (API) supply chains are potential strategies to address capacity constraints, workforce shortages, and raw material constraints. Public-private partnerships will be critical to building resilient supply chains.
3. **Regulatory systems** — Harmonization through the African Medicines Agency (AMA) and the Cairo Memorandum of Understanding (MoU) offers a pathway to reduce duplication, accelerate approvals, and build confidence. Strengthened regulatory science capacity and reliance pathways are needed to support both biosimilars and novel platforms.
4. **Financing and market shaping** — High capital needs and weak demand visibility remain major barriers. Blended finance, extended repayment periods, pooled procurement, and advance market commitments can de-risk investment and create predictable markets for African mAbs.

5. **Policy and procurement alignment** — Faster integration of mAbs into treatment guidelines, essential medicines lists (EMLs), and universal health coverage (UHC) schemes is essential to signal demand and enable sustainable access. Product-specific access roadmaps and regional procurement agreements can improve affordability and uptake.
6. **Workforce development and technical capacity** — Expanding skilled human capital is foundational. Regional centers of excellence, standardized certification programs, and stronger partnerships between regional manufacturers and experts from industry and academia are needed to close gaps in bioprocessing, quality, and regulatory science.

The convening concluded with a strong consensus: Africa has the opportunity and capacity to leapfrog and lead in mAbs innovation and production. What is now required is sustained leadership, investment, and coordination to translate potential into action.

Introduction and meeting objectives

The meeting on *Advancing a sustainable supply and demand ecosystem for monoclonal antibodies in Africa* was convened on the sidelines of the World Local Production Forum in Abu Dhabi on April 6, 2025. This meeting brought together stakeholders from across the academic, private sector, advocacy, regulatory, and donor communities to explore how Africa can establish a sustainable and integrated ecosystem for mAbs development, production, and access. It marked the second in a series of consultative engagements, convened by Africa CDC and IAVI, aimed at accelerating the development of, manufacturing, and equitable access to mAbs across the continent, with the first held in December 2023 as an official side event to the 3rd International Conference on Public Health in Africa.¹ The objectives of the meeting included:

1. Identifying priority mAbs in the region and understanding market potential.
2. Highlighting opportunities to expand mAbs manufacturing in the region.
3. Fostering a sustainable mAbs supply and demand ecosystem in Africa.
4. Supporting collaboration for mAbs R&D, manufacturing, and access in Africa.

Jens Pedersen, Africa CDC, kicked off the gathering, highlighting the urgency of scaling up mAbs manufacturing in Africa to meet the continent's pressing health needs. He presented the meeting as a platform to validate key barriers, review the outcomes of a joint prioritization exercise conducted by Africa CDC and IAVI, strengthen regional collaboration, support innovative market-shaping strategies, and identify sustainable business models that reflect Africa's unique context. He noted that delivering on the promise of mAbs will require deliberate coordination, long-term investment, and shared ownership across public and private sectors.

Key findings from a comprehensive landscape analysis co-developed by IAVI and Impact Global Health, with support from Wellcome and Open Philanthropy, were presented.² The report highlights that the global pipeline for mAbs has grown substantially in recent years from roughly 570 candidates in 2020 to over 1,000 by 2024. While cancer still dominates, accounting for approximately 60% of mAb candidates, infectious diseases now represent a meaningful and growing share of the pipeline at 13%, with over 130 products in development. Despite this momentum, African countries remain largely underserved: access to approved mAbs is uneven and often nonexistent on the continent, particularly for infectious diseases.

Speakers highlighted the use case for mAbs across priority disease areas to illustrate their potentially transformative role in Africa. Alongside potential and/or current indications for HIV, malaria, and respiratory syncytial virus (RSV), mAbs are increasingly recognized as

¹ <https://www.iavi.org/wp-content/uploads/2025/03/Lusaka-mabs-meeting-report-2023.pdf>

² <https://www.iavi.org/features/access-to-monoclonal-antibodies-in-africa-a-call-to-action>

vital tools for epidemic preparedness, particularly in responding to pathogens such as Ebola Sudan, Marburg, and Crimean-Congo hemorrhagic fever, for which vaccines or treatments are lacking. Their ability to be rapidly deployed during outbreaks can reduce disease severity, preserve health system capacity, and limit socioeconomic disruption. Long-acting antibodies like CIS43LS and L9LS offer pre-erythrocytic malaria protection with strong trial efficacy.³ For HIV, broadly neutralizing antibodies (bnAbs) are being positioned as a potentially cost-effective, long-acting strategy for infant prophylaxis. These innovations are projected to reduce pediatric HIV acquisition by over 40% if implemented at scale.⁴ RSV prevention using infant-targeted mAbs (e.g., nirsevimab) presents a feasible, life-saving alternative in settings in which antenatal systems are less robust.⁵

This context set the stage for deep-dive discussions and emerging recommendations across six strategic pillars: R&D and Innovation, Sustainable Manufacturing, Regulatory Systems, Financing and Market Shaping, Policy and Procurement Alignment, and Workforce Development and Technical Capacity.

Strategic pillars for advancing mAbs access in Africa: barriers, opportunities, and recommendations

1. R&D and innovation

Africa's potential to lead in mAbs research is evident, but the translation of research into accessible, affordable therapeutics remains limited. The Abu Dhabi meeting underscored the need for regionally driven innovation, aligning scientific discovery with health priorities across infectious and non-communicable diseases.

Challenges for R&D and innovation

While Africa is a leader in disease surveillance and clinical trials, insufficient investment in upstream R&D such as cell line development, antibody engineering, and process optimization hinders local innovation. Stakeholders highlighted the potential for AI-enabled design and modular, adaptive technology platforms to reduce R&D costs and accelerate product readiness.

³ <https://pubmed.ncbi.nlm.nih.gov/36317783/#:~:text=Clinical%20Trial-,N%20Engl%20J%20Med,Epub%202022%20Oct%2031,-Safety%20and%20Efficacy>

⁴ <https://www.aidsmap.com/news/aug-2022/giving-antibodies-prevent-vertical-transmission-africa-would-be-cost-effective-or>

⁵ <https://www.who.int/news/item/30-05-2025-who-outlines-recommendations-to-protect-infants-against-rsv-respiratory-syncytial-virus#:~:text=In%20response%20to%20the%20global,system%2C%20cost%20Deffectiveness%20and%20anticipated>

Barriers to R&D and manufacturing innovation for mAbs in Africa were found to include:

- High costs and technical complexity of mAbs development.
- Limited capacity for innovation, translational research, and clinical validation in African settings.
- Intellectual property (IP) constraints and a lack of local manufacturing-ready candidates.

Progress and strategic opportunities

Stakeholders emphasized the need for investments in strengthening basic science, translational research, and overall R&D capabilities to reduce reliance on external innovation. Capacity in flexible technology platforms such as transgenic production systems, cell-free expression platforms, and modular bioprocessing units that can accommodate a range of mAbs and pivot rapidly during health emergencies is also critical. The transition to such adaptive systems requires parallel investment in innovation infrastructure, including pilot-scale facilities, tech transfer incubators, and bioprocess R&D centers.

Key priorities for R&D and innovation include:

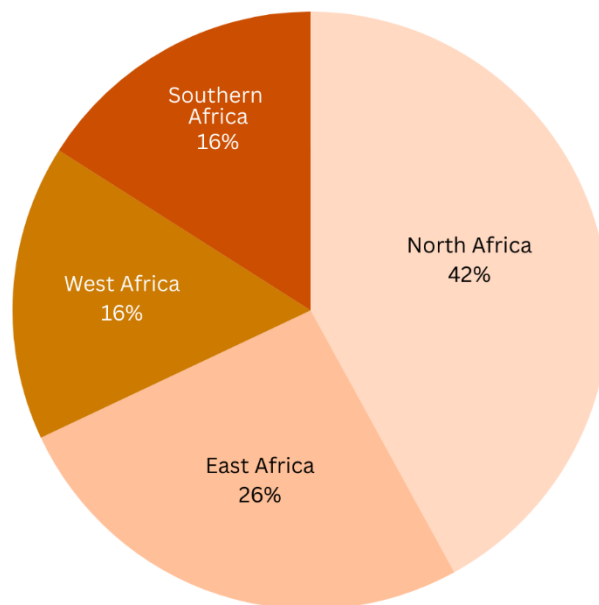
- Establishing regional R&D hubs that link academic institutions, biotech firms, and manufacturing partners.
- Aligning pipeline development with Africa's public health needs using robust prioritization frameworks.
- Promoting public-private partnerships to support preclinical research, pilot manufacturing, and downstream integration.
- Investing in flexible R&D platforms capable of pivoting during health emergencies.
- Strengthening data generation and modeling capacity to support product design.

Africa's R&D future for mAbs lies in ownership of its health priorities, innovation agenda, and product development strategies. Building that future requires structural investment, coordinated leadership, and a deliberate shift from participation to leadership in the global biologics ecosystem.

2. Sustainable manufacturing

Building a sustainable mAbs manufacturing ecosystem in Africa is essential for long-term health security, economic development, and equitable access. While several African manufacturers are actively investing in biologics production, the landscape remains fragmented, with uneven capacity, infrastructure, and regulatory maturity.

Geographic distribution of 19 manufacturers surveyed by region



A survey conducted as part of the Africa CDC/IAVI initiative assessed mAbs manufacturing capacity in Africa. Of the 33 manufacturers identified and contacted for participation in the study, 19 participated in an in-depth assessment. Their responses reveal an encouraging but nascent sector.

Table 1: African manufacturers engaged in or planning mAbs manufacturing initiatives

Region	Countries	No. of manufacturers (with mAbs prioritization)
North Africa	Algeria, Egypt, Morocco, Tunisia	8
East Africa	Ethiopia, Kenya, Rwanda, Uganda	5
West Africa	Ghana, Nigeria	3
Southern Africa	South Africa	3

The assessment revealed a manufacturing sector that is operational but uneven in maturity: while nearly 80% of surveyed manufacturers are already active, most are still in the process of building the infrastructure, workforce, and regulatory readiness needed to transition from partial operations to fully integrated, end-to-end mAbs production. Twelve of the respondents reported either current or planned capacity for both drug substance and drug product manufacturing, but critical gaps persist in areas such as lyophilization and upstream processing, which are currently present in only a handful of facilities.

Challenges for sustainable manufacturing

Five principal challenges emerged from the manufacturing landscape assessment:

1. Regulatory fragmentation, which delays approvals and limits harmonization across markets.
2. Workforce shortages, particularly in advanced bioprocessing and quality systems.
3. Infrastructure constraints, including limited access to good manufacturing practice (GMP)-grade facilities and API supply chains.
4. IP and technology access limitations, with few meaningful tech transfer partnerships.
5. Uncertain demand, deterring investment due to lack of offtake agreements and predictable procurement.

Progress and strategic opportunities

Despite these constraints, the manufacturing landscape is evolving, with several promising partnerships offering blueprints for scalable success:

- **Minapharm** in Egypt has demonstrated that sustained investment in vertically integrated biologics platforms including in-house cell line development and process optimization can deliver biosimilars at prices as low as 20% of the originator price. A licensing partnership with Alvotech now extends Minapharm's biosimilar portfolio, including monoclonal antibodies across 19 African countries, supported by scalable infrastructure for drug substance production, lyophilization, and fill-finish.
- **DEK Pharma** in Ghana is constructing an integrated biologics facility with modular design and isolator-based filling lines. By leveraging a reverse engineering platform that uses immune responses to design new monoclonal antibodies, DEK is prioritizing regionally relevant diseases such as malaria, mpox, and tuberculosis, aiming to bridge innovation with local public health needs.
- **Institut Pasteur de Tunis** exemplifies public-sector engagement in biosimilar R&D, including efforts to reduce reliance on high-cost biologics imports. However, the transition from scientific discovery to commercial-scale production is constrained by limited investment and infrastructure.
- **DEI Biopharma** in Uganda is scaling up mAbs production for oncology and autoimmune diseases, but like many others is challenged by capital constraints and limited access to enabling technologies. Early government support exists, but broader public investment in science remains critically low.

Several participants emphasized the need for long-term investment in Africa mAbs manufacturing and infrastructure that supports both pilot-scale and commercial production. Lessons from manufacturers on past challenges, such as Afrigen's early mAbs facility attempt, highlight the risks of launching without ecosystem readiness. Afrigen's pivot toward novel platforms like BioMilk™, which uses transgenic goats to produce mAbs and insulin, also highlights regional ingenuity in applying innovative and locally relevant solutions to tackle barriers to advancing mAbs innovation.

Several strategic entry points and opportunities were highlighted:

- Biosimilar manufacturing of licensed mAbs is widely regarded as the most feasible near-term entry point into mAbs manufacturing, offering lower technical risk and clearer regulatory pathways.
- Decentralized and regionalized production models were seen as especially relevant for Africa, where diversity in infrastructure, policy, and market size makes regional specialization in different stages of the value chain (e.g., API production, fill-finish, packaging, and quality control) more practical than every country building end-to-end facilities. This approach can foster economies of scale, encourage regional collaboration, reduce duplication of high-cost infrastructure, and align with continental trade frameworks such as African Continental Free Trade Area.
- Shared infrastructure platforms such as isolator-based lines or modular fill-finish units that can serve multiple products can enable flexible, responsive manufacturing and lower capital intensity.

Africa's mAbs manufacturing future will be defined by its ability to combine scientific ambition with infrastructure expansion, demand clarity, and long-term investment. The foundation is being laid; what is now required is investment and coordinated action.

Identified priorities for sustainable manufacturing include:

- Establishing regional hubs with diversified upstream and downstream capabilities to serve as an interlinked and complementary decentralized production network.
- Investing in modular, scalable infrastructure that allows for cost-effective manufacturing and rapid product changeovers.
- Promoting public-private manufacturing partnerships and expanding IP sharing and technology transfer mechanisms.
- Strengthening alignment between manufacturers, regulators, and product developers to accelerate licensing and reduce time-to-market.

3. Regulatory systems

A functional and harmonized regulatory environment is critical to the successful expansion of mAb development, manufacturing, and access in Africa. However, regulatory fragmentation, limited capacity, and inconsistent timelines across African countries continue to hinder product approvals and undermine investor confidence. Due to their complexity, biologics, especially biosimilars, require robust oversight. As such, the importance for strengthened, coordinated regulatory systems has grown.

Challenges in regulatory systems

African countries face several structural regulatory challenges in scaling access to mAbs:

- Fragmented frameworks across national regulatory authorities (NRAs) resulting in duplicate reviews and varying standards for biologics evaluation.
- Limited capacity to assess biosimilars and mAbs, which often demand specialized scientific and technical expertise in comparability studies, analytical method validation, pharmacovigilance, and GMP inspections.
- Lack of regulatory predictability for innovators and local manufacturers, who frequently encounter uncertainty regarding dossier expectations, approval timelines, and inspection criteria.
- Slow progression toward mutual recognition, which increases costs and delays multi-country product launches.

Progress and strategic opportunities

The African Union Development Agency New Economic Partnership for African Development (AUDA-NEPAD) is currently spearheading the African Medicines Regulatory Harmonization (AMRH) initiative aimed at streamlining and aligning regulatory processes across African countries to accelerate the approval and availability of quality-assured medical products, including biologics like mAbs. AMRH serves as a key implementation arm for the Pharmaceutical Manufacturing Plan for Africa, supporting the development of a robust regulatory environment that complements Africa's broader goals for local pharmaceutical production and health security.

The 2025 Cairo MoU between Africa CDC, AUDA-NEPAD, and key Maturity Level 3 regulatory authorities was recognized as a key strategic opportunity. It lays the groundwork for mutual recognition of regulatory approvals and a shared African framework for mAbs oversight. Participants noted this MoU represents a rare convergence of political will, technical progress, and continental coordination — factors that are not always present in Africa's regulatory landscape.

Panelists emphasized the importance of the AMA as a vehicle for regulatory harmonization. While AMA's operationalization is still ongoing, it was seen as a critical regional mechanism to accelerate dossier assessments, facilitate pooled procurement, and support biosimilar approvals. However, AMA's success will depend on sustained

investment in capacity building and formal integration into country-level regulatory systems.

Several manufacturers shared lessons from engaging early with regulators. Afrigen Biologics emphasized how proactive consultation with regulators around novel platforms such as goat milk-based mAbs production systems, are helping to de-risk development and align expectations. DEK Pharma and Minapharm highlighted the value of joint site inspections and structured gap analyses in reducing surprises during GMP audits.

Stakeholders identified the need to standardize regulatory requirements for tech transfer, especially for dossiers involving biosimilars. The current lack of standardized protocols slows localization efforts and complicates relationships between licensors and local manufacturers. It was proposed that Africa CDC and AUDA-NEPAD work with AMA and the World Health Organization (WHO) to develop a reference dossier template and model comparability protocol tailored to mAbs, with an emphasis on method transfer validation and early facility readiness assessments.

Some identified priorities to strengthen Africa's regulatory systems in support of mAbs access include:

- Accelerating AMA integration by finalizing operational guidelines, clarifying country-level roles, and providing transitional support to NRAs.
- Scaling regional regulatory reliance and joint reviews, leveraging the Cairo MoU to streamline mAbs and biosimilar approvals across multiple countries.
- Investing in institutional capacity to evaluate biologics and biosimilars, including training programs, secondments, and regulatory science fellowships.
- Developing harmonized dossiers and comparability protocols, particularly for tech-transferred biosimilars, to enable smoother regulatory submissions.
- Adopting reliance-based regulatory pathways, such as abridged reviews for WHO-prequalified or Maturity Level 4 approved products, to accelerate access.
- Enhancing platforms for regulatory-manufacturer dialogue, fostering early engagement to resolve technical uncertainties and support innovation.

Stakeholders also called for stronger integration of regulatory planning into the mAbs product lifecycle — from clinical development to commercialization. Doing so would reduce development risks, increase investor confidence, and build momentum for timely and equitable rollout of mAbs across the continent.

4. Financing and market shaping

Financing emerged as one of the most persistent and cross-cutting constraints to scaling mAbs development, manufacturing, and access in Africa. Although several global and regional mechanisms exist to support vaccine and drug financing, equivalent systems for mAbs, particularly those produced or used in Africa, remain underdeveloped. Participants emphasized the need to simultaneously address capital barriers, procurement fragmentation, and market visibility to unlock sustainable investment in the mAbs ecosystem.

Challenges in financing and market shaping

Multiple financing bottlenecks were highlighted:

- High upfront capital requirements for building or upgrading biologics manufacturing facilities, with limited access to concessional or risk-tolerant capital.
- Lack of predictable demand and long-term offtake agreements, weakening the investment case for both local production and product developers.
- Fragmented procurement systems across African countries, each with small market volumes and variable purchasing capacity, deterring economies of scale.
- Low domestic health budgets and weak integration of mAbs into national financing frameworks, resulting in overdependence on donor grants and out-of-pocket spending.

A further challenge is the lack of robust data on disease burden, product pipeline evolution, and country-level demand, which undermines planning and investment. Proposed cross-cutting solutions include the development of regional demand forecasting platforms, integration of mAbs into Africa CDC's pathogen prioritization and health intelligence systems, and use of modeling tools to guide procurement and financing decisions. Better data is essential for shaping markets, guiding R&D priorities, and informing donor and government resource allocation.

Panelists from both the public and private sectors noted that while mAbs are increasingly included in clinical guidelines, their financing often remains ad hoc and piecemeal. This inconsistency in financing signals, combined with unclear pathways to reimbursement or pooled procurement, poses a major barrier to attracting manufacturers and developers.

Progress and strategic opportunities

Several proposals were presented to address these challenges and build investor confidence in the African mAbs market:

- Blended finance models were seen as critical to de-risking investment. Development finance institutions (DFIs), philanthropic investors, and global health donors were encouraged to co-invest in infrastructure and innovation alongside African governments and private investors. Such models could incorporate milestone-based disbursements, convertible grants, or concessional loans.

- Volume guarantees and advance market commitments were proposed to provide early-stage market assurance for priority mAbs. These tools would be particularly useful for manufacturers producing biosimilars, where upfront commitments can derisk investments in manufacturing scale up.
- Return-on-investment frameworks were recommended to build the case for mAbs investment in public health budgets. By demonstrating the cost-effectiveness and long-term savings associated with mAbs such as reduced hospitalizations, improved survival, and lower treatment failure, governments can make informed resource allocation decisions.

Proposed priorities to unlock financing and shape sustainable mAbs markets in Africa include:

- Operationalizing mAbs integration into regional pooled procurement platforms, starting with pilot products that have strong demand signals.
- Structuring blended financing packages that include investments from DFIs, donors, and public sources to support infrastructure development, R&D, and access programs.
- Developing investment cases that incorporate likely public health and economic returns to justify long-term procurement and donor funding.
- Promoting demand visibility tools, including multi-country forecasting and horizon scanning to guide developers and manufacturers.
- Creating mAbs-specific funding envelopes within existing mechanisms such as the Global Fund, Gavi, and the African Continental Free Trade Area health initiative, ensuring mAbs are integrated into broader health security and pharmaceutical manufacturing agendas.

Stakeholders emphasized that financing solutions must be integrated with policy, manufacturing, and regulatory planning to ensure the sustainability of the mAbs ecosystem. Without clear and coordinated market signals, even the most promising manufacturing and R&D efforts will struggle to translate into access.

5. Policy and procurement alignment

The successful introduction and sustained access to mAbs in Africa depends not only on manufacturing and regulatory capacity but also on the alignment of national policies, treatment guidelines, procurement systems, and reimbursement frameworks. While several mAbs are included in WHO and regional guidelines, their uptake at the country level remains uneven and they remain poorly integrated into EMLs, public procurement budgets, and universal health coverage schemes.

Challenges for policy and procurement

Participants identified key barriers to policy and procurement integration:

- Delayed incorporation of mAbs into national treatment guidelines and EMLs, leading to weak demand signals and procurement hesitancy.
- Limited coordination between national policy-setting bodies, procurement agencies, and regulatory authorities resulting in misaligned priorities and timelines.
- Lack of structured product-specific access pathways, particularly for biosimilars and pipeline mAbs that may not yet have WHO prequalification.
- Inadequate budget allocation for mAbs in national health financing plans, compounded by siloed donor funding streams that prioritize vaccines and small molecules.

These challenges contribute to underutilization of available mAbs and undermine private sector interest in developing or producing regionally relevant biologics.

Progress and strategic opportunities

To address policy and procurement misalignment, stakeholders discussed the development of product-specific access roadmaps, linking upstream clinical development to downstream procurement and financing mechanisms. These roadmaps can include defined pathways for inclusion in national formularies and EMLs; budget impact and cost-effectiveness analyses to support reimbursement decisions; and standardized procurement templates for biosimilars and innovator mAbs.

Pooled procurement was also highlighted as a powerful tool to consolidate demand across countries. The African Pooled Procurement Mechanism (APPM) aims to establish a coordinated platform for purchasing regionally relevant therapeutics and vaccines. If effectively implemented for mAbs, the APPM could support demand aggregation, improve negotiating power, and offer guaranteed volumes to manufacturers — thereby providing stronger market incentives for local production.

The Africa CDC is committed to supporting countries in aligning national procurement strategies with disease burden data and regional mAbs prioritization exercises. Stakeholders also proposed using pooled demand forecasts to inform national quantification and procurement planning, reducing variability and improving predictability for suppliers.

The session emphasized the importance of embedding mAbs within UHC frameworks. While mAbs are often perceived as high-cost therapeutics, the cost-benefit analysis of certain products such as RSV prevention in infants or long-acting HIV prophylaxis, demonstrates their potential to reduce overall treatment costs and improve patient outcomes. Aligning these interventions with UHC financing models would improve affordability and uptake.

Proposed priorities to strengthen policy and procurement alignment for mAbs access include:

- Fast-track inclusion of high-priority mAbs into national treatment guidelines and essential medicines lists, building on WHO guidance and regional consensus.
- Develop product-specific access roadmaps that integrate regulatory approval, policy endorsement, and procurement planning.
- Strengthen national procurement planning capacity, linking disease prioritization, cost-effectiveness data, and market forecasts.
- Embed mAbs into national health insurance and reimbursement schemes, particularly for products with proven long-term public health impact.
- Promote cross-border procurement agreements and integration of mAbs into the APPM, enabling smaller countries to participate in regional tenders and benefit from economies of scale.

Panelists underscored that procurement systems must not only follow clinical priorities but also actively shape markets by sending clear, sustained signals to developers and manufacturers. Aligning policy and procurement processes is essential to unlock access and accelerate the integration of mAbs into routine care across Africa.

6. Workforce development and technical capacity

The expansion of mAb development, regulation, and manufacturing in Africa is constrained by critical shortages in specialized human resources. While there has been considerable investment in manufacturing infrastructure, progress is undermined by technical skill gaps across key domains, particularly upstream bioprocessing, quality control, regulatory science, bioanalytical testing, and basic science capabilities.

Challenges for workforce development and technical capacity

Stakeholders cited multiple workforce-related gaps impeding the scale-up of Africa's mAbs ecosystem:

- Shortage of trained personnel in core areas such as cell culture, process development, fill-finish operations, and analytical characterization.
- Lack of institutionalized training programs in biologics manufacturing, particularly outside of South Africa and Egypt.
- Insufficient regulatory science expertise, particularly in biosimilar evaluation, GMP auditing, and pharmacovigilance.
- Fragmented training initiatives, often project-specific, donor-driven, and not integrated into national human capital strategies.
- Limited academic-industry collaboration, leading to outdated university curricula and a mismatch between graduate training and industry needs.

- Gaps in basic science, translational research, and overall R&D capacity on the continent, hindering the growth of a regional innovation ecosystem.

These gaps create bottlenecks across the entire value chain — from R&D to manufacturing and regulatory oversight. They also increase the cost and duration of technology transfer partnerships, as licensors are often required to provide extensive, customized technical support. Effective technology transfer remains a cornerstone of regional mAbs production. However, many African manufacturers face persistent barriers due to limited readiness, lack of robust and tailored training, and misaligned expectations between licensors and licensees.

Progress and strategic opportunities

A harmonized framework for technology transfer covering due diligence, documentation standards, and post-transfer support, was proposed to improve standardization and strengthen the quality of technology transfer. Facilitating “fit-for-purpose” technology transfer approaches tailored to the maturity of local manufacturers was seen as essential to ensure effectiveness and maximize long-term impact.

Several promising programs were referenced during the convening. IAVI’s longstanding research capacity strengthening program, the Institut Pasteur de Dakar, and the South African Health Products Regulatory Authority are piloting training courses for regulators and manufacturers. Africa CDC’s regional health workforce strategy, which includes pharmaceutical manufacturing and regulation as a priority area, were highlighted, although implementation is at an early stage.

Participants emphasized the need for expanded investment in strengthening regional capacity and for R&D to bolster the African innovation ecosystem. They argued for regional centers of excellence that go beyond short-term training and offer structured certification pathways in areas such as biologics process engineering, cleanroom operations, GMP compliance, and bioanalytics. These centers could also support practical internships, mentorship, and continuous professional development.

The establishment of continental training frameworks, recognized by both regulatory authorities and employers, was proposed as a way to harmonize skills standards across countries and improve workforce mobility. This approach would also facilitate south-south exchanges and collaborative capacity development across national borders.

Academic institutions were encouraged to modernize curricula in biotechnology, pharmacy, and engineering, integrating hands-on training with support from local manufacturers. Public-private partnerships were recommended to co-design training modules, leveraging industry expertise to ensure relevance and uptake.

Participants identified the following priorities to strengthen workforce development and technical capacity for the African mAbs ecosystem:

- Support and strengthen existing Regional Capability and Capacity Networks to serve as regional hubs for hands-on biomanufacturing and regulatory training, leveraging partnerships with African governments, academia, and industry to scale training pipelines and foster cross-border knowledge exchange.
- Develop continent-wide certification frameworks, enabling standardization and recognition of technical qualifications across borders.
- Integrate biologics-specific content into university curricula, with emphasis on mAbs development, GMP standards, regulatory science, and quality systems.
- Foster academic-industry partnerships, including internships, apprenticeships, and research fellowships linked to active manufacturing sites.
- Map existing workforce supply and demand across the mAbs value chain, and align national strategies to anticipated manufacturing and regulatory expansion.

Participants agreed that building a sustainable pipeline of skilled professionals is foundational to the success of Africa's ambitions in mAbs production and access. Without targeted investments in human capital, infrastructure and policy advances will struggle to deliver their full impact.

Cross-cutting recommendations

A few cross-cutting themes also emerged from the convening, highlighting systemic enablers necessary to support the full lifecycle of mAbs development, manufacturing, regulation, and access in Africa. These themes intersect all six strategic pillars and underscore the need for coordinated, ecosystem-wide interventions.

Diagnostics and health system integration

The clinical utility of mAbs particularly for non-communicable diseases (NCDs) depends on the availability of timely, accurate diagnostics and integration into routine care pathways. Stakeholders highlighted the need for diagnostics scale-up alongside mAbs rollout, particularly for oncology, HIV, and autoimmune conditions. Investments in decentralized testing capacity, clinical decision-support systems, and patient referral networks were seen as critical to achieving real-world impact.

Coordination and matchmaking mechanisms

There was strong support for establishing a formal coordination platform to facilitate matchmaking between African manufacturers, global developers, regulators, funders, and policy stakeholders. This structure would help align priorities, reduce duplication, and accelerate the path from R&D to access. Participants proposed that Africa CDC, in collaboration with key partners, play a convening and stewardship role to ensure coherence across initiatives, projects, and funding mechanisms.

These cross-cutting themes emphasize that progress in any single domain — be it R&D, manufacturing, regulation, or financing — must be reinforced by systemic alignment. Building a resilient mAbs ecosystem in Africa will require strategic coordination, integrated planning, and co-investment across multiple domains of the health and innovation landscape.

Conclusion

Monoclonal antibodies offer enormous potential to address Africa's burden of infectious and non-communicable diseases yet remain largely out of reach due to a lack of regional availability and affordability. The April 2025 convening in Abu Dhabi affirmed that Africa has the foundational infrastructure, political will, and regional commitment to build a resilient mAbs ecosystem, provided action is coordinated and strategic.

The continent stands at a pivotal moment to design a greenfield mAbs architecture that avoids legacy inefficiencies. Countries including Egypt, Tunisia, Morocco, Ghana, Uganda, and South Africa are already advancing programs in biosimilar development, manufacturing scale-up, and regulatory engagement. The challenge now is to move from fragmented progress to a cohesive, continent-wide strategy that addresses supply and demand side requirements in an integrated manner.

Participants identified several persistent barriers like fragmented supply chains for API and other materials, market uncertainty, regulatory delays, workforce limitations, and barriers to securing required co-investments, that must be addressed in an integrated manner. A set of initial actions were proposed to systematically address these barriers (see Table 2).

Table 2: Summary of key recommendations by stakeholder

For policymakers and regulators:

- Policy, regulatory, and procurement alignment: Accelerate AMA operationalization and fast-track national guideline updates. Enable pooled procurement mechanisms and ensure product-specific access roadmaps are integrated into national systems.
- Coordination and matchmaking: Create platforms led by Africa CDC for connecting developers, regulators, funders, and manufacturers. Support regional centers of excellence as convening points for training, partnership-building, and innovation sharing.
- Market intelligence and shaping: Develop a prioritization framework linking local disease burdens with market-viable products. Harness Africa CDC leadership through the APPM to consolidate demand and generate actionable data to guide investment and procurement.

For donors and financing bodies:

- Innovative financing: Deploy blended finance tools, concessional loans, and equity to de-risk local production. Align DFI terms with industry needs and leverage public health funding to subsidize priority mAbs.

For innovators and Africa-based manufacturers:

- Technology transfer and manufacturing ecosystems: Strengthen regional hubs through voluntary licensing and platform-based manufacturing strategies. Shift toward full-spectrum capabilities, including upstream R&D capabilities and drug substance production, while institutionalizing workforce development for sustainable tech transfer.

Africa has an opportunity to lead in shaping a sustainable, accessible biologics ecosystem. The foundations are in place. What is needed next is decisive investment, regional leadership, and collective commitment to transform this promise into impact.

APPENDIX 1. Summary of key takeaways from breakouts

Breakout group	Key considerations and learnings	Recommendations
1. Sustainable business strategies for mAbs manufacturing and access	Africa is uniquely positioned to develop mAbs manufacturing from a “greenfield” status, allowing the continent to leapfrog to innovative models without legacy constraints.	- The time is ripe to move beyond dialogue to implementation of tangible manufacturing projects and product development initiatives. - An opportunity exists to leverage regional R&D, including Africa’s academic and research institutions that can support early-stage innovation, target selection, clinical trials, and platform optimization.
	Manufacturing systems must serve both high-income (e.g., oncology) and public health (e.g., infectious diseases) markets to support sustainability.	- Seek portfolios to balance both mAbs for infectious diseases (IDs) and NCDs, using shared manufacturing platforms, to balance public health needs and commercial viability. - Implement tiered pricing and dual market models, using profits from NCD-related mAbs to subsidize production and access for ID-focused products.
	Harness learnings, including from India’s generic pharmaceutical industry, as a blueprint for how Africa can become a global and regional supplier and build self-sufficiency.	Foster aligned planning across African regions to avoid duplication, promote resource sharing, and enable continental procurement and regulatory strategies.
2. Optimal partnership approaches to catalyze regional innovation	Low demand uptake despite high clinical need yields low volumes, high production costs, and high cost of goods sold.	- Robust market intelligence and forecasting tools can help assess real-world demand and guide investment decisions. - Companion diagnostic capabilities must be bolstered to support identification of treatment populations to support market uptake.
	Weak procurement systems, fragmented demand, and underfunded national programs hinder commercial viability.	- Regional pooled procurement and harmonized manufacturing strategies can help achieve scale and sustainability. - Ensure government partnership in harmonizing regulatory systems, policy alignment, and public-private procurement frameworks.
	Divergent product business cases across mAbs demand different partnership structures.	- Design deliberate and structured partnerships: - Establish formal mechanisms to connect product developers with capable manufacturers. - Ensure licensing and tech transfer focus on capacity-building and absorptive capability, not just technology handover.

		○ Tailor financing models/structures to reflect the different risk profiles of NCD vs. ID mAbs. • Establish flexible manufacturing infrastructure — platform-agnostic systems capable of producing a range of biologics. • Launch cross-cutting regional innovation hubs and centers of excellence to support: ○ Translational R&D ○ Regulatory readiness ○ Technology transfer ○ Cell bank development
3. Regional prioritization	• Complex prioritization landscape must consider several factors, including commercial viability, platform compatibility, portfolio balance, regulatory pathways, and IP landscapes.	• Improve data systems to inform portfolio balance: ○ Gather granular, sub-national disease burden and mortality data. ○ Map market readiness and timelines to inform selection of near-term, feasible mAb candidates as part of portfolio strategies. • Leverage cross-sector infrastructure: ○ Explore overlaps with vaccine manufacturing platforms to accelerate mAb production capacity and reduce costs. • Balance portfolio considerations: ○ Across NCDs and infectious disease (established markets with targeted impact vs. infectious diseases such as malaria and HIV with broad global health impact). ○ Factor in future risk scenarios, considering climate-sensitive and outbreak-prone diseases, where mAbs can play a rapid-response role.
	• Misalignment of stakeholders and lack of prioritization can fragment efforts and delay progress.	• Create multi-stakeholder coordination structures: ○ Establish formal working groups that include funders, buyers, researchers, and manufacturers to define shared priorities and hybrid models of prioritization that accommodate both high-need and high-impact products. • Consider market drivers: ○ Potential buyers such as governments and global procurement organizations need to be considered from the outset and are key stakeholders in prioritization discussions.
	• Foster sustainable, end-to-end manufacturing systems regionally.	• Support early-stage development: ○ Bring African manufacturers into product development earlier, during discovery and preclinical development. ○ Build capacity for regulatory and tech transfer readiness. • Where possible, adopt platform thinking and invest in shared technologies that allow rapid development of multiple mAb products.

4. Sustainable financing for regional mAbs supply resilience	Funding contraction with donor retreat increases risk sensitivity/aversion and requires stronger alternative financing models.	- Frame mAbs as essential medicines to shift political perceptions and unlock public financing. - Transition to innovative financing models, including exploring: - Blended finance, combining public funds, donor capital, and concessional loans. - Sovereign wealth funds and philanthropy, engaging non-traditional investors and African high-net-worth individuals. - Return-on-health investment framing, positioning mAbs as essential investments that drive health and economic development outcomes, not luxury interventions. - Cultivate cross-sector coalitions that span industry, academia, finance, and policy. - Public investment in local research and universities are needed to strengthen Africa's research ecosystems by integrating universities into R&D value chains, from early discovery to clinical development. - Embed cost-reduction strategies in all manufacturing models from the outset.
	Lack of demand visibility/market uncertainty deters investment.	- Local and regional institutions must play a more active role in demand forecasting and signaling. - Harness the government as a market maker: African states must take on greater responsibility by subsidizing essential biologics, allocating health budgets more strategically, and improving fiscal governance to absorb loans and grants. - Africa CDC and APPM should build market intelligence and supply-demand platforms that: - Aggregate cross-border needs. - Provide procurement visibility. - Serve as trusted information hubs for manufacturers and funders.
	Efforts needed to avoid abrupt transitions from global suppliers.	- Advance a phased localization strategy: - Develop phased manufacturing blueprints with realistic timelines and scalability benchmarks. - Develop gradual capacity-building plans that maintain continuity while expanding local production. - Initially focus on already-licensed "trailblazer" products with established markets to mitigate commercial risk and scale them up quickly to inform African manufacturing scale-up strategies.

APPENDIX 2. List of meeting participants

Muhumuza Abdullcharim	Afya na Haki
Mina Adel	IAVI/Africa CDC consultant
Nadia Sam Agudu	Institute of Human Virology
Simon Agwale (virtual)	Innovative Biotech
Zitto Alfayo	African Export-Import Bank
Alex Asamoah Ankomah	Impact Global Health
Merawi Aragaw (virtual)	Africa CDC
Vijay Badekar	Macleods Pharmaceuticals Ltd.
Menghis Bairu	Bio USAWA
Bianca Baluta	European Commission
Shaheer Bardissi	Minapharm Pharmaceuticals
Linda-Gail Bekker (virtual)	Desmond Tutu Health Foundation
Henk den Besten	Consultant
Eluemuno Blyden	Avril Pharma, Inc.
Luigi Bonfatti	Regionalized Vaccine Manufacturing Collaborative
Tiwa Braimoh (virtual)	Medicines Patent Pool
Janet Byaruhanga	AUDA-NEPAD
Beatriz Castro	Fiocruz
Katerina Chapman	IAVI
Rachel Chikwamba (virtual)	Council for Scientific and Industrial Research
Adrian Kivumbi Ddungu	DEI Biopharma Ltd.
Stephanie Diagne	African Export-Import Bank
Vito Di Cioccio	mAlbe S.r.l.
Oluranti Doherty	African Export-Import Bank
Makram Essafi	Institut Pasteur de Tunis

Sayeh Ezzikouri (virtual)	Institut Pasteur de Maroc
Pete Gardner	LifeArc
Shongandh Ghosh	Theertha Biopharma
Julia Hochberger	WEMOS
Pierre Hugo	Medicines for Malaria Venture
Kevin Irandagiye	Africa CDC
Ike James	Medicines Patent Pool
Samuel Kariuki	Drugs for Neglected Diseases Initiative
Kassoum Kayentao	Mali International Centers for Excellence in Research (ICER)
Holm Keller	kENUP Foundation
Andre Pascal Kengne (virtual)	South Africa Medication Research Council
Farhan Ahmad Khan	DEK Vaccines Limited
David Klutse	Atlantic Lifesciences Ltd.
Farrah Losper	Biovac
Colleen Loynachan (virtual)	100 Day Mission
Michael Lusiola (virtual)	Regionalized Vaccine Manufacturing Collaborative
Julie Makani	Muhimbili University of Health and Allied Sciences
Shelly Malhotra	IAVI
Faith Mangwanya	Unitaid
Robert Matiru	Unitaid
Sébastien Morin	Medicines Patent Pool
Moses Mulumba	Afya na Haki
Esther Mungai	IAVI
Miriam Mutebi (virtual)	Aga Khan University Hospital
Olivia Ngou	Impact Sante
Kofi Nisah-Poku	DEK Vaccines Limited
Everest Okeakpu (virtual)	Biovaccines Nigeria Limited

Jens Pedersen	Africa CDC
Martina Penazzato (virtual)	WHO – Global Accelerator for Pediatric Formulations Network (GAP-f)
Gary Pierce	Sevare GMP
Katja Pohlmann	Federal Ministry of Economic Cooperation and Development
Julien Potet (virtual)	Médecins sans Frontières
Pablo Rojo	Hospital Universitario 12 de Octubre
Wesley Rono	Africa CDC
Samia Rourou (virtual)	Institut Pasteur de Tunis
Padmashree Gehl Sampath	African Pharmaceutical Technology Foundation
Heather Sherwin (virtual)	Elma Philanthropies
Paramdeep Singh	PurLab Sarl
Petro Terblanche	Afrigen
Tsepo Tsekoa	Council for Scientific and Industrial Research
Rosalind Turkie	NCD Alliance
Cecilia Wanjala	BioVax
David Woo (virtual)	WHO Local Production Assistance Unit
Ghada Abu Zaid	African Development Bank
Timothy Zungwe (virtual)	Innovative Biotech

APPENDIX 3. Meeting agenda

Advancing a sustainable supply and demand ecosystem for monoclonal antibodies in Africa

April 6, 2025

Abu Dhabi, United Arab Emirates

Convened by Africa CDC and IAVI, with support from Wellcome and Unitaid

Time	Agenda items	Intended outcome(s) and objectives
8:30 – 9:00	Registration	
9:00 – 9:10	Welcome, introduction and meeting objectives	To discuss meeting objectives and intended outcomes. Confirmed speaker: Jens Pedersen, Africa CDC
9:10 – 9:25	Presentation: Setting the scene	To present outcomes of the mAbs Access in Africa and prioritization survey reports. Examine current gaps in mAbs availability and usage for both NCDs and IDs and propose targeted areas for development and investment. Confirmed speaker: Shelly Malhotra, IAVI
9:25 – 10:30	Panel Discussion: Understanding mAbs pipeline priorities and potential demand	Outcome: Define key mAbs priority areas for NCDs and leading Infectious diseases. Objectives • Share evidence on the product profile, use case, and relative prioritization of mAbs addressing leading infectious diseases and NCDs, considering their effectiveness, feasibility, and potential demand in the region to set the stage for the subsequent discussions. Moderator: Jens Pedersen, Africa CDC Confirmed speakers: • Merawi Aragaw, Africa CDC • Kassoum Kayentao, University of Sciences, Techniques and Technologies of Bamako • Shelly Malhotra, IAVI • Rosalind Turkie, NCD Alliance • Pablo Rojo, Hospital Universitario 12 de Octubre

10:30 – 10:45	Presentation: mAbs manufacturing assessment	Highlight status of mAbs manufacturing in the region based on a landscape assessment. Confirmed speaker: Mina Adel, IAVI
10:45 – 11:05	Coffee break	
11:05 – 12:20	Panel Discussion: mAbs manufacturers panel	Outcome: Identify a roadmap for strengthening mAbs manufacturing in Africa by addressing key enablers, needs, and challenges. Objectives • Highlight the capabilities and plans of African manufacturers in mAbs production. • Discuss key enablers and barriers for scaling up mAbs manufacturing in Africa. • Explore collaborative opportunities to advance local mAbs manufacturing. Moderator: Jens Pedersen, Africa CDC Confirmed speakers: • Shaheer Bardissi, Minapharm Pharmaceuticals • Farhan Ahmad Khan, DEK Vaccines Ltd. • Makram Essafi, Institut Pasteur Tunis • Petro Terblanche, Afrigen • Adrian Kivumbi Ddungu, Dei BioPharma
12:20 – 1:20	Lunch	
1:20 – 2:20	Roundtable discussion: Creating an enabling ecosystem to support regional mAbs manufacturing and access	Outcome: Key initiatives to help create a sustainable financing, procurement, and manufacturing ecosystem for African biologics manufacturing. Objectives • Define a clear vision for enabling local mAbs production and access. • Identify financing models to support regional manufacturing capacity. • Strengthen regulatory and policy frameworks to accelerate approvals and market entry. • Explore strategic procurement mechanisms to create a predictable market. • Leverage licensing and technology transfer and partnerships for regional supply sovereignty and capacity building. Moderator: Ester Mungai, IAVI Confirmed speakers: • David Woo, WHO Local Production and Assistance Unit • Janet Byaruhanga, NEPAD • Ike James, Medicines Patent Pool • Wesley Rono, Africa CDC • Faith Mangwanya, Unitaid

2:20 – 3:20	Panel Discussion: Funder and investor panel	Outcome: Discuss and strategize key funders investments to support mAbs ecosystem in Africa. Objectives • Discuss current or future investment strategies and opportunities to support the mAbs ecosystem in Africa. • Highlight synergies across funding priorities and specific needs identified to support local mAb production and infrastructure. Moderator: Shelly Malhotra, IAVI Confirmed speakers: • Alex Asamoah Ankomah, Impact Global Health • Pete Gardner, LifeArc • Oluranti Doherty, African Export-Import Bank • Ghada Abu Zaid, African Development Bank • Padmashree Gehl Sampath, African Pharmaceutical Technology Foundation
3:20 – 4:30	Coffee break & breakout sessions	Participants break into small working groups to discuss the key barriers and required enablers to support a sustainable regional mAbs supply and demand ecosystems in Africa.
4:30 – 5:20	Report back & discussion	Rapporteurs report back from breakout group discussions.
5:20 – 5:30	Wrap up & summary	To provide a summary of key takeaways from the meeting. Confirmed speaker: Shelly Malhotra, IAVI
5:30 – 5:40	Meeting closing	Jens Pedersen, Africa CDC
6:00 – 8:00	Networking reception & snacks at the Andaz Capital Gate	