MEETING REPORT

Advancing access to monoclonal antibodies in Africa: setting priorities, assessing feasibility, and enabling R&D and manufacturing

Side meeting of the International Conference on Public Health in Africa

Friday, December 1st, 2023
Lusaka, Zambia

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

AfricaCDC Centres for Disease Control and Prevention

iavi

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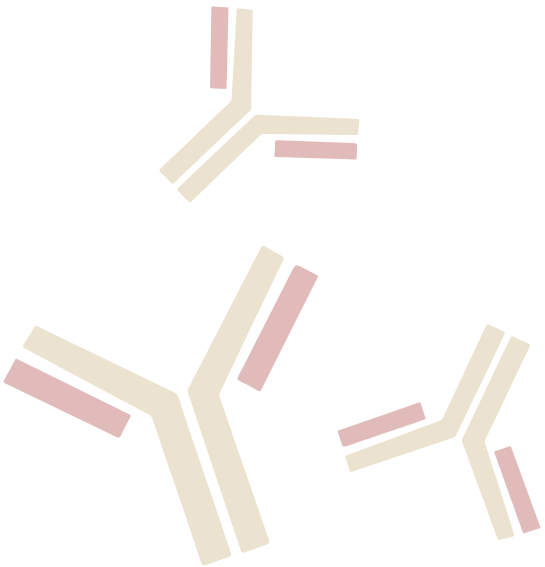
Contents



Acronyms

Africa CDC	Africa Centres for Disease Control and Prevention
COGS	cost of goods sold
CPHIA	International Conference of Public Health in Africa
CSIR	Council of Scientific & Industrial Research
EML	Essential Medicines List
IP	intellectual property
LMICs	low- and middle-income countries
mAbs	monoclonal antibodies
NCDs	noncommunicable diseases
PHAHM	Platform for Harmonized African Health Products Manufacturing
PPC	Preferred Product Characteristics
R&D	research and development
RSV	respiratory syncytial virus
TPP	Target Product Profile
WHO	World Health Organization

Executive summary

Monoclonal antibodies (mAbs) have transformed the treatment and prevention of many diseases from cancer to respiratory syncytial virus (RSV) over the last 30 years. However, their health impact is limited by their lack of access, especially in low- and middle-income countries (LMICs). Building on the progress made to strengthen local vaccine manufacturing capacities, strategies could be developed to ensure sustainable supply of other lifesaving biologics, including mAbs, which have a significant role to play in the prevention and/or treatment of non-communicable and infectious diseases.

On December 1, 2023, Africa Centres for Disease Control and Prevention (Africa CDC) and IAVI, with the support of Wellcome, hosted a workshop focused on advancing access to monoclonal antibodies in Africa. The workshop, which was held as an official side meeting of the 3rd International Conference of Public Health in Africa (CPHIA), focused on presenting evidence on a range of priority mAbs use cases and identifying regionally relevant criteria for prioritization of future monoclonal antibody investments for both infectious diseases and noncommunicable diseases (NCDs).

This workshop was the first in a series of consultative meetings. Its overall goal was to identify regionally relevant criteria for prioritizing future monoclonal antibody investments, considering disease burden, use case, technical feasibility, and demand. It aimed to build upon and leverage previous and ongoing regional and global prioritization processes and priority setting agendas.

During the workshop, speakers provided an overview of the mAb landscape in Africa and successfully developed a preliminary set of prioritization criteria. Beyond priority setting, participants also highlighted several enablers that will be critical to achieving the vision of expanded access to mAbs across Africa.

These preliminary criteria will be pressure-tested through a survey, to be conducted with a broader and more representative list of key regional and global stakeholders. A follow-up in-person consultative meeting with regional and global experts is planned for April 2025 to review the outcomes for prioritization efforts, support linkages with regional manufacturers, and outline key enablers to support the regional mAbs manufacturing agenda.

Introduction and meeting goals

In introducing the goals of the meeting and this broader effort, Akhona Tshangela, Partnerships for African Vaccine Manufacturing coordinator, now the Platform for Harmonized African Health Products Manufacturing (PHAHM), began by recognizing monoclonal antibodies as lifesaving interventions which should be made available on the continent. This effort aligns with the updated PHAHM strategy,[1] which seeks to expand the regional manufacturing agenda from its initial focus on vaccines to also include therapeutics and diagnostics. As the agenda for access to mAbs advances it will be important to garner political will to increase awareness of mAbs and ensure their access alongside other health interventions. In preparation for this meeting, Africa CDC identified a growing interest in mAbs from manufacturers across the continent and, in the current context of sub-optimal access, a potential opportunity to be a pioneer for mAbs research and development (R&D) and manufacturing across the continent and for LMICs more broadly. Consultative priority setting was highlighted as key to guide efficient use of resources.

Review of landscape for mAbs and role in addressing public health challenges

Shelly Malhotra, Vice President of Global Access and External Affairs at IAVI, presented a summary of the current landscape for mAbs and key access considerations, to provide context on gaps in access to mAbs in Africa, building on work that was published in 2020 as a joint IAVI/Wellcome report.[2] The presentation outlined the case for expanding sustainable pathways for access to mAbs in Africa, highlighting the small proportion of globally licensed mAbs that are registered in Africa, the growing focus on mAbs for priority infectious diseases, and the increasing number of mAbs clinical trials that are taking place across the continent. Considerable progress has been made globally to optimize mAb products, and process improvements have reduced the costs of manufacturing, with potential for further biological and engineering innovation that could result in further cost reductions. It is vital to link these developments to the regional innovation and biosimilar manufacturing agenda, which could foster both affordability and regional supply sovereignty. Furthermore, growing inclusion of mAbs in World Health Organization (WHO) and national Essential Medicines Lists (EML) can help establish reimbursement and procurement pathways. Finally, understanding areas of highest prioritization and demand for mAbs regionally will be important to ensure adequate political will, investment, and demand to support a sustainable manufacturing and delivery ecosystem for mAbs. Overall, this work highlights the need to bring innovators and local manufacturers together early and the relevance of prioritization to identify high impact opportunities.

[1] https://africacdc.org/news-item/africa-cdc-spearheads-bold-move-to-secure-africas-health-future-by-creating-a-50-billion-dollar-medical-market/

[2] https://wellcome.org/sites/default/files/expanding-access-to-monoclonal-antibody-based-products.pdf

Disease-focused priority setting considerations

An expert panel brought together different perspectives on approaches to setting disease priorities from three organizations with diverse mandates and perspectives. Dr. Merawi Aragaw Tegegne, Acting Head, Division of Emergency Preparedness and Response, Africa CDC, outlined Africa CDC's process for risk ranking and prioritization, which is intended to support emergency preparedness and to guide investments in medical countermeasures and R&D.[3] For the Division's exercise, experts selected 19 criteria and developed a list of priority pathogens. Moving forward, this exercise will be carried out roughly every two years, to ensure that new gaps and priorities can be reflected in the regional agenda. Building on this first exercise, Africa CDC has conducted further work (in collaboration with UNICEF's Supply Division) to map availability of medical countermeasures and gaps. As an example, while both prevention and treatment tools are available for Ebola Zaire, the lack of interventions for Ebola Sudan highlights an important gap. In addition to products, an effective response depends on timely and adequate supply, workforce, and funding. Beyond formal pathogen prioritization processes, Dr. Aragaw Tegegne underlined the critical importance of routine efforts to monitor events and to conduct risk ranking exercises that are region-specific.

Dr. Erin Sparrow, Technical Officer with WHO's Immunization, Vaccines, and Biologicals (IVB) department, outlined a WHO initiative to prioritize key endemic pathogens,[4] established under the Immunization Agenda 2030 Strategy Priority Setting. This effort seeks to develop a global list of priority (endemic) pathogens for new vaccine R&D. The process consists of a landscape review and regional surveys using multi-criteria decision analysis intended to produce a global synthesis of priorities and tailored regional agendas. From Africa, pathogens such as Group B strep, neglected tropical diseases, Plasmodium falciparum (P. falciparum) malaria, RSV, and HIV were highlighted, all of which have mAbs in development. While the focus of this work is on vaccines, the discussion highlighted the potential complementarity between vaccine priorities and those for mAbs in specific use cases and target populations. In addition, given the time to protection (immediate in the case of mAbs) and efficacy in immunocompromised populations, mAbs may also provide key benefits over vaccines in certain scenarios—for example mAbs could provide immediate protection to neonates in an RSV outbreak. Finally, it is important to note that given the low total dose required for an infant indication it may be feasible to achieve vaccine-like prices.

Dr. Jacqueline Kirschner, Gates Foundation, began by highlighting the critical importance of health metrics and disease modelling to inform the strategic priorities of the foundation. These strategic priorities then guide the development of an interventional Target Product Profile (TPP), which is closely aligned with the WHO Preferred Product Characteristics (PPC). The TPP considers aspects such as the target population (including use cases, ages, and the potential needs of pregnant populations); efficacy thresholds; attributes such as duration of protection; prevention of transmission; safety profile; programmatic characteristics, including, for mAbs, concentration and volume as well as the number of health care touchpoints; thermostability; and cost of goods.

[3] https://africacdc.org/download/risk-ranking-and-prioritization-of-epidemic-prone-diseases/
[4] https://www.who.int/news/item/10-11-2023-accelerating-vaccine-development-for-global-health-impact---a-who-initiative-to-prioritize-key-endemic-pathogens

Considerations around cost are nuanced and the Gates Foundation assesses both cost per dose as well as cost effectiveness, including the potential impact of mAbs for key populations with unmet needs. Given that concentration and dose volume are important for both acceptability to patients and feasibility of delivery, the foundation prioritizes innovations that increase potency (thereby reducing dose amount and volume). Such innovations are also likely to increase acceptability and to reduce costs. Finally, previous experiences highlight the importance of competition and voluntary licensing with robust tech transfer support and early planning to support access.

Use cases of monoclonal antibody products for infectious and non-communicable diseases

The second panel brought together disease experts from a range of fields, with the aim of presenting brief case studies of mAb products, to highlight relevant use cases. The panel kicked off with a video message from Dr. Anthony Fauci, describing the value of mAbs as an important tool for the prevention and control of disease, particularly infectious diseases. In his introductory comments, Dr. Pete Gardner, Wellcome, reflected on the relevance of mAbs to a range of recurrent themes in the third CPHIA meeting, including biosecurity, infectious diseases, NCDs, and African innovation. This highlighted the opportunity to link discussions around mAbs prioritization to diverse areas, and to contribute to advancing the ambition of local manufacturing. Each speaker presented an overview of both the opportunities and challenges in using mAbs to contribute to broader disease control efforts.

Prof. Kassoum Kayentao, Malaria Research and Training Center, International Center for Excellence in Research, University of Sciences, Techniques, and Technologies of Bamako, Mali—who recently led a Phase 2 trial in Mali of one of the most advanced malaria mAb candidates, CIS43LS—presented several potential use cases for malaria mAbs. He noted that studies to date suggest that one dose provides a high level of protection against *P. falciparum malaria* [5] in adults. Studies in Kenya are ongoing to understand whether 1-2 doses could provide 12 months' protection.[6] In considering malaria, it was important to highlight that despite a growing portfolio of tools, now including two vaccines with WHO Prequalification, there remain key periods of risk during the life course (e.g., among young children, among children who have recently been hospitalized with anemia, and during the first trimester of pregnancy) and targeted use of mAbs could address the significant morbidity and mortality associated with these periods. In addition, an effective mAb could also play a role in elimination campaigns and for travelers. The threat of drug resistance also highlights the value of diversifying tools for prevention and control of malaria.

Dr. Ameena Goga, WHO Child Health and Development, outlined the continuing burden of new HIV infections in infants (an estimated 130,000 infants were born with HIV in 2022) [7] despite major advances in prevention and treatment of HIV and the value of new tools to address vertical transmission in key populations during the critical post-natal period.

[5] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9881676/
[6] https://clinicaltrials.gov/study/NCT05400655?locStr=Kenya&country=Kenya&cond=malaria&term=phase%202&intr=L9LS&rank=1#study-overview
[7] https://data.unicef.org/topic/hivaids/global-regional-trends/

She argued that early prevention of infection should be assessed in terms of a substantial contribution to improved quality of life compared with a chronic disease over the life course. In terms of feasibility, the focus on neonates means subcutaneous delivery of a small dose in settings with high HIV incidence and prevalence could translate to a cost-effective intervention at 70% efficacy, at a product and delivery cost of $20/dose.[8] In addition, given that child health platforms are well established, a future program could leverage existing touchpoints to reach a broad population.

Dr. Pablo Rojo, Universidad Complutense de Madrid, highlighted both the promise and urgency of ensuring broader access to RSV mAbs for infants. In Spain, where nirsevimab has been given to every child at birth since October 1, 2023, there has been a reduction in the hospitalization of <6 months infants.[9] Given that RSV is most severe in the first six months of life, even a single dose could translate to substantial public health impact. Studies in cohorts of children living with HIV also demonstrate that they are at greater risk of hospitalization and death, highlighting the importance of exploring the potential of bnAbs for not only HIV prevention, but treatment and cure indications in children living with HIV. Efforts are ongoing to encourage much needed voluntary licensing and technology transfer for nirsevimab to widen access to it globally.

Prof. Sam Kariuki, DNDi, shared perspectives on how future development of mAbs could address unmet needs for new treatments for bacterial infections. He highlighted the example of cholera, a priority pathogen per the Africa CDC assessment. In terms of future risk, cholera is highly climate sensitive and samples of vibrio cholera in Nairobi show that it has acquired a mobile genetic element which is associated with an increase in drug resistance. An effective mAb as treatment for cholera and other bacterial pathogens could be a valuable tool in the context of multi drug-resistant disease. In addition, it is important to develop new tools that address the needs of neglected populations that may bear a disproportionate burden of infectious diseases, including so-called neglected diseases. This will also require early considerations of access, affordability, and increased efforts toward domestic resource mobilization.

Shifting away from infectious diseases, Prof. Paul Ruff, University of the Witwatersrand Faculty of Health Sciences, began by framing key challenges of prioritizing mAbs within the NCD space. NCDs refer to a heterogeneous group of diseases including cancer, heart disease, diabetes, and mental illness. Within the field of cancer, mutations of cellular proteins frequently occur with a need for complex varied therapeutic approaches, including monoclonal antibodies and signaling inhibitors. However, despite these challenges, there are also multiple opportunities to immediately address historic inequities that have limited access to these highly effective tools for critical diseases. The experience of trastuzumab in breast cancer, for example, highlights the need for early public/private dialogue to make these expensive medicines affordable.[10] Looking ahead to more innovative products including bi-specific monoclonals, antibody cocktails and antibody-drug conjugates, it will be important to be more proactive in ensuring broad access. Reducing the cost of clinical trials would also help to reduce overarching costs, especially in LMICs. New entrants to the market for anti-PD1/PDL-1 mAb inhibitor immunotherapy should increase competition, helping to reduce costs; however, access challenges are likely to persist as even newer innovative products become available. Beyond oncology, there are other areas such as rheumatology, gastroenterology, and blood disorders where access to novel mAbs is important for vulnerable populations, specifically individuals living in LMICs, who currently bear a disproportionate burden of mortality and morbidity. It will be important to

[8] https://onlinelibrary.wiley.com/doi/10.1002/jia2.26052
[9] https://www.eurosurveillance.org/content/10.2807/1560-7917.ES.2024.29.6.2400046
[10] https://resource-allocation.biomedcentral.com/articles/10.1186/s12962-019-0174-7

identify a set of critically important targets and work collaboratively with manufacturers, governments, and regulators to make these medicines more accessible.

Sharonann Lynch, O'Neill Institute, listed the opportunities to advance access to mAbs and highlighted the need for a coherent approach, including advocacy, to advance this agenda. These opportunities include establishing cell line banks, engaging LMIC manufacturers to expand access to biosimilars, securing increased transparency on cost of goods sold (COGS), and the increased commitment of governments and philanthropies to work together to reduce COGS and accelerate product development. Breast cancer, which has a 90% survival in high-income countries but just a 40% survival rate in sub-Saharan Africa, exemplifies the profound inequities in access to diagnosis and to treatments by geography. Returning to the example of trastuzumab—which has been included on the WHO EML since 2015 and has WHO prequalified biosimilar options available—she highlighted the need to address these inequities with urgency and creativity.

Looking across a breadth of different diseases, several cross-cutting themes were highlighted as important considerations for mAbs, which would also be relevant for priority setting. These include vulnerable populations and unmet needs; the need for a nuanced discussion as to the role of mAbs in the context of existing interventions; the availability of relevant cost effectiveness data; the need for TPPs and PPCs; and private sector incentives to develop new product indications.

Perspectives on regional mAbs R&D, manufacturing, and regulation

Dr. Tsepo Tsekoa, Council of Scientific & Industrial Research (CSIR); Benedicta Durcan, Afrobodies; Dr. Rajesh Gupta, Vir Biotechnology; and Dr. Asmaa Ahmed, Egyptian Drug Authority, drew on their respective expertise in manufacturing, R&D, and drug regulation as they discussed priorities, opportunities, and risks to support a sustainable manufacturing ecosystem for mAbs.

Several themes emerged during the panel discussion:

MANUFACTURING

- Portfolio approaches for the development of antibody products could increase efficiency and sustainability by establishing a steady flow of routine production to keep facilities "warm," while ensuring agility in the event of sudden fluctuations in demand for specific products. This could also enable crossover production of products for infectious and non-communicable diseases.
- Manufacturers in Africa can leapfrog and install state of the art innovations on the continent (e.g., optimized platforms, proven cell lines and intensified processes), including leveraging end-to-end continuous manufacturing strategies. It was noted that efforts are underway to establish good manufacturing practice facilities for manufacturing mAbs on the continent for investigational clinical trial materials. Emerging technologies (e.g., RNA delivery processes), may also provide further opportunities.

INTELLECTUAL PROPERTY (IP) & TECH TRANSFER

- The importance of public health-oriented management of IP was noted. Several IP-related barriers were highlighted (e.g., lack of access to cell lines and limited freedom to operate for vector systems to establish proof of concept for a product).
- Noting the progress achieved through the WHO/Medicines Patent Pool mRNA Technology Transfer Programme, it was asked whether this model could be applied to other areas related to mAbs manufacturing.
- Biosimilars can provide opportunities serve the dual functions of addressing public health needs and improving product affordability, while building experience among regulators and manufacturers in mAbs technologies. Given the regulatory hurdles and challenges of proving biosimilarity, there was strong support for technology transfer.
- Regulatory harmonization provides an important pathway to addressing the challenge of product registration in multiple countries. In addition, regulators can play a key role in guiding mAb developers and manufacturers early in product development.

PRODUCT PRIORITIZATION AND SUSTAINABILITY

- Certain approaches may be more relevant to the continent because they take into consideration the use case and potential to scale. Afrobodies is a small South African biotech, which was established to focus on dual applications of nanobodies, the smallest functional single-domain antibodies known to be able to stably bind to antigens, for therapeutic and life science applications.
- Based on public health need there would likely be a regional market for mAbs, however targeted market shaping interventions may be needed to establish and sustain production until economies of scale are achieved.
- Dr. Gupta highlighted that it is important to think about future demand at both the health system and patient levels and to begin to build familiarity and trust in mAbs to manage future potential risks. This should include mapping the path to patients.
- As products advance, it will be important to build, and update, an investment case with assumptions on buyers and payers in different contexts. There may also be value in developing an exemplary case study which could outline the conditions for sustainable supply before producing mAbs at research and commercial scale on the continent. This may also help to better understand risks and determine which risks could be borne by different partners at key stages (including national governments, R&D funders, and health systems).

Priority setting—lessons from prior prioritization exercises

Results were presented from a scoping review that was conducted to identify criteria and approaches that could be leveraged from other prioritization exercises. The criteria reviewed included regional and global disease and product prioritization exercises, which focus on pathogen prioritization and prioritization of products such as vaccines and therapeutics.[11] The principles for prioritization used to determine products for inclusion in the WHO Essential Medicines List were also presented.

These existing priority-setting exercises have different goals, including disease prioritization, R&D priority setting, and decision-making to guide investment. Across these exercises, there were broadly similar categories of criteria, many of which would be relevant to priority-setting for monoclonal antibodies. Criteria identified addressed disease burden and epidemiology; social/economic impact; alternative interventions (both pipeline and licensed products); considerations related to R&D, technology, and breadth of innovation use; market shaping, procurement, and operational costs; product characteristics; availability of financing mechanisms; and considerations related to health system strengthening.

Results from a pre-meeting survey were presented. In this survey, participants were asked to rank the following draft criteria (not in order):

- Affordability of product
- Economic impact of disease
- Health impact (i.e., for prevention and/or treatment)
- Likelihood of R&D/manufacturing success
- Pathogen risk (e.g., epidemic or pandemic potential)
- Product suitability for eventual program implementation
- Regional commercial feasibility, including size of domestic/regional market(s)
- Unmet health need (including for special populations)

Based on the feedback received,[12] participants provided the following ranked list of criteria intended to be a starting point for further discussion:

1. Health impact (both treatment and prevention)
2. Product affordability
3. Likelihood of R&D/manufacturing success
4. Unmet health need
5. Economic impact of disease
6. Pathogen risk
7. Regional commercial feasibility
8. Product suitability for eventual program implementation

[11] Include list
[12] 13 responses, 11 complete

Breakout groups: mAbs considerations and recommendations on criteria

As part of group discussions, meeting participants were asked to make recommendations on lessons learned from other prioritization exercises, specific considerations that are unique to mAbs, and considerations for particular diseases (noting that many of the existing prioritization exercises address infectious diseases and associated interventions).

a) Learnings from other prioritization exercises, including those focused on alternative modalities to mAbs (e.g., vaccines)

During learnings from other prioritization efforts, participants recommended that prioritization approaches should:

- consider the benefits and tradeoffs of different modalities, including accounting for the full context and value chain per disease area, and what health needs are met by existing interventions vs. unmet needs where there are clear gaps that mAbs are well suited to address (e.g., considering RSV mAbs in the context of maternal vaccines).
- be tailored to different geographic regions and health system contexts.
- consider how global/regional prioritization can inform regional manufacturing priority-setting.
- understand how different organizations build approaches to prioritization in case there are synergies and opportunities for coordination.

b) Specific considerations or criteria that are unique to mAbs and relevant to a mAbs prioritization exercise

Participants recommended that:

- Approaches to assess the cost-effectiveness of mAbs should be nuanced given that products are relatively early in development, and new tools are often expensive upfront. Where possible, assessments should consider cost-effectiveness in terms of potential benefits accrued to health systems over time (e.g., long-term effectiveness over short-term affordability) and potential for future cost reductions, including from improvements in manufacturing processes leading to reduced COGS, as well as licensing to biosimilar manufacturers to diversify supply sources and create competition). It may be relevant to learn from previous introductions, for example, the WHO and UNAIDS 3 by 5 initiative which sought to provide ARVs to three million people in LMICs by 2005, and the global introduction of treatments for multidrug-resistant tuberculosis.
- There is a need to account for the fact that in practical terms existing interventions may have reached saturation in terms of coverage, and that new interventions may be needed to address unmet needs (considering arguments made for the incremental value of malaria vaccines, alongside insecticide-treated nets). Similarly, new products may be more favorable in terms of tolerability, feasibility, suitability, and time to impact. In terms of therapeutics, it was noted that mAbs may have advantages over small molecules and should not be considered purely as interchangeable products.

- As part of that effort manufacturers should consider the local disease/product priorities. mAbs might provide vaccine manufacturers with opportunities to expand their business models.
- Process alignment across mAbs areas could help de-risk manufacturing and manage ebbs and flows in demand by enabling production of a diverse portfolio of products (for example, by rotating production for NCDs, high burden infectious diseases, and niche smaller markets).[13]
- Looking at the demand side, it is important to consider scalability and future financing, procurement, and delivery mechanisms.
- Regulatory pathways for mAbs may differ by indication (treatment/prevention).
- Equity and the unmet needs of vulnerable populations (both acute and chronic suffering) must be considered.
- Time to impact (i.e., immediate protection vs. delayed protection pending immune response) is another key consideration for mAbs-based interventions vs vaccines.

c) Tailored considerations for infectious diseases and NCDs.

Participants highlighted the following considerations for infectious diseases and NCDs:

- Across multiple disease areas and even if existing products are available, many patients continue to face gaps in addressing prevention and treatment. These should be well defined as part of a deep-dive technical assessment.
- For NCDs, mAbs provide enormous possibilities given the increasing burden over the last 10 years and the fact that the product landscape for mAbs for NCDs is significantly more mature than for mAbs for infectious diseases.
- For infectious diseases, low hanging fruit include prevention of HIV, malaria, acute and chronic respiratory illness (e.g., RSV). Beyond infectious disease prevention, there may be value in long-lasting treatments which would provide relief from taking regular medication for chronic infectious diseases, such as HIV. For certain infectious diseases, positive end-user perception of products may increase public health impact if associated with increased uptake and coverage. For example, mAbs may have advantages with respect to acceptability and stigma reduction over daily pills. Finally, it is important to recognize that Africa is genetically, ecologically, economically, and culturally diverse and there is a huge variation in disease burden across different regions. It cannot be assumed that drugs will work similarly in different populations, highlighting the need for more clinical studies, including in endemic regions.

[13] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC11216602/

Identifying criteria to support future mAbs priority-setting

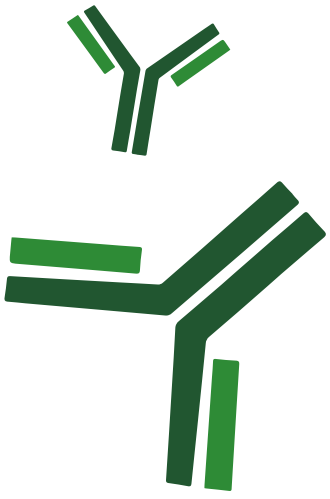
Regarding considerations for future prioritization, participants were broadly in agreement with the preliminary ranked criteria. However, the discussion highlighted several additional criteria and further considerations that could serve to differentiate between use cases.

In terms of additional criteria, some participants recommended that efforts could begin by focusing on a subset of existing mAbs for infectious diseases which could be ready for programmatic implementation within a predefined timeframe to establish mAbs delivery within regional health systems. It might also be relevant to focus on products that would facilitate replacement of outdated technologies such as blood-derived immunoglobulins (e.g., horse-derived antitoxin for diphtheria, antibodies for rabies, or RSV mAbs for which newer and more potent antibody-based options are available).

For health impact (prevention and treatment), several disease-specific considerations were highlighted:

- For NCDs, potential increases in survival rates
- For infectious diseases, the potential to prevent or reduce the burden of drug-resistant infections.
- The potential to increase coverage overall or to address gaps not met by current interventions. Gaps could be defined in terms of access, immune gaps, tolerability, delivery feasibility, safety profiles, and suitability for populations for pregnant, infant, or neonatal populations. Many participants felt that the focus should be on serving populations whose needs may be unmet or underserved by currently available products.

One group proposed a set of criteria, including weighting, differentiating between infectious diseases (assuming initial focus on prevention for pipeline) and NCDs (assuming primary focus on treatment for licensed products). These are summarized in the table below:



Proposed criteria for infectious diseases and NCDs:

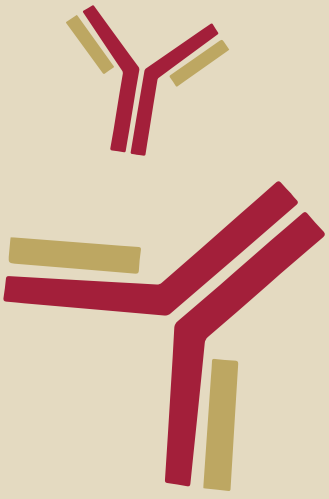
CRITERIA	COMMENT	DISEASE AREA	PRELIMINARY WEIGHTING
Health impact	Need indicators (DALYS): Individual level morbidity and mortality	Infectious diseases NCDs	5
	Population level impact	Infectious diseases NCDs	
	Long-term burden of disease	NCDs	
Pathogen risk	Risk of pathogen/outbreak	Infectious diseases	2.5
Acceptability	Patient and health care provider demand and preferences	Infectious diseases NCDs	4
Probability of regulatory and technical success	Existing regulatory pathway (including for biosimilar entry)	Infectious diseases NCDs	Infectious diseases: 4 NCDs: 5
Suitability-improved use case	Improving patient and health care delivery experience	Infectious diseases NCDs	Infectious diseases: 5 NCDs: 3
	Improving delivery pathways	Infectious diseases NCDs	
	Feasibility	Infectious diseases NCDs	
	Infrastructure to deliver and monitor	NCDs	
Market feasibility	Financing	Infectious diseases	Infectious diseases: 2.5 NCDs: 4
	Procurement ecosystem	Infectious diseases	
	Sustainability/regional commercial feasibility	NCDs	
Cost effectiveness	Defining target product profiles to identify parameters Defined differently in NCD space: Lack of affordability means that we should focus on it in NCD space and define an access pathway	Infectious diseases NCDs	5
Unmet need (that can uniquely be fit with mAbs technology)	Availability of prevention tools, therapeutic tools, and burden in vulnerable populations	Infectious diseases	5
	Potential to increase coverage overall or address gaps not met by current interventions (gaps could be defined as access, immune gap, tolerability, delivery feasibility, safety profiles, and suitability for populations for pregnancy, infants, or neonates).	NCDs	
Safety	Risk/benefit ratio for the local context	NCDs	2.5

Conclusions and next steps

Overall, there was strong support for the aims of the meeting and an appetite to make progress on a regional manufacturing and access agenda for mAbs in sub-Saharan Africa, recognizing the relevance to the new PHAHM strategy. Additionally, mAbs present an opportunity for African researchers to lead on developing innovative approaches for production and patient management to secure improved local/regional supply, while also meeting global demand.

Beyond priority setting, participants also highlighted several enablers that will be critical to achieving the vision of expanded access to mAbs across sub-Saharan Africa. These include harmonized regulatory pathways; strong access terms and conditions; market shaping, e.g., a continental pooled procurement facility; demand mobilization, noting that acceptability and demand rely on health care literacy; political will; and pharmacovigilance and monitoring capability. Previous vaccine manufacturing landscaping assessments have shown that African vaccine manufacturing capacity is heavily concentrated on fill/finish. Plans to significantly and rapidly increase this capacity introduce the risk that not every manufacturing project would be sustainable and commercially viable. There was strong support among participants for an approach that linked the access to mAbs agenda with the efforts to develop sustainable regional manufacturing capacity and a recommendation that this be integrated into activities going forward.

The suggested prioritization framework will be incorporated into a revised list of potential criteria. This list will be pressure-tested through a survey, to be conducted with a broader and more representative list of key regional and global stakeholders and applied to a range of infectious disease and NCD mAbs. A manufacturing landscape will be completed to further determine the baseline capabilities and interest of regional manufacturers in potential mAbs production, with a focus on prioritized mAbs. Additionally, a technical assessment will be conducted exploring potential use cases and feasibility. A follow-up in-person consultative meeting with regional and global experts is planned for April 2025 to review the outcomes, support linkages with regional manufacturers, and outline key enablers to support the regional mAbs manufacturing agenda. While the December 2023 meeting in Lusaka focused primarily on the infectious disease space, the follow-up workshops in 2025 will focus on the infectious disease/NCD split and the areas of overlap between the two spaces.



APPENDIX 1. List of participants

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List of participants
December 1, 2023
Lusaka, Zambia

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Ayesha Sitlani (virtual)	IAVI	United States
Benedicta Durcan	Afrobodies (Pty) Ltd	South Africa
Carol Nawina Nyirenda	CITAMPLUS	Zambia
Colleen Loynachan	Wellcome	United Kingdom
Erin Sparrow	World Health Organization	Switzerland
Ethel Makhila	IAVI	Kenya
Greg Perry	International Federation of Pharmaceutical Manufacturers & Associations	Switzerland
Hani Kim (virtual)	RIGHT Foundation	South Korea
Jacqueline Kirchner	Gates Foundation	USA
Kassoum Kayentao	Malaria Research and Training Center, International Center of Excellence in Research, University of Sciences, Techniques and Technologies of Bamako, Mali	Mali
Ken Ondeng'e	Africa CDC	Ethiopia
Lindsey Wu	World Health Organization	Switzerland
Lisa Gieber (virtual)	IAVI	United States
Maureen Awuor	AMREF Health Africa	Kenya
Marcus Olasupo	Africa CDC	Ethiopia

Maxwell Mumba	Communities Delegation, UNITAID	Zambia
Merawi Aragaw	Africa CDC	Ethiopia
Michelle Mulder (virtual)	South Africa MRC	South Africa
Mumun Gencoglu	International Federation of Pharmaceutical Manufacturers & Associations	Switzerland
Neville Kisalu (virtual)	PATH	United States
Ngozi Erondu	O'Neill Institute	United Arab Emirates
Pablo Rojo	PENTA	Spain
Paul Ruff	University of Witwatersrand	South Africa
Pete Gardner	Wellcome	United Kingdom
Rajesh Gupta	Vir Bio	United States
Sébastien Morin	Medicines Patent Pool	Switzerland
Sam Kariuki	DNDi East Africa	Kenya
Sharonann Lynch	O'Neil Institute	United States
Shelly Malhotra	IAVI	United States
Sophie Mathewson	IAVI	United States
Suzanne Majani	Roche	Kenya
Thandi Onami	Gates Foundation	United States
Tiwadayo Braimoh	Medicines Patent Pool	Switzerland
Tsepo Lebiletsa Tsekoa	Council of Scientific and Industrial Research	South Africa
Wim Vandevelde	Communities Delegation, Unitaid	South Africa

APPENDIX 2. Meeting agenda

Advancing access to monoclonal antibodies in Africa: setting priorities, assessing feasibility, and enabling R&D and manufacturing

December 1, 2023
Protea Hotel Lusaka Tower, Lusaka, Zambia
8 a.m. – 5 p.m.

Meeting Objective: The overall goal of this project is to define a priority agenda for monoclonal antibody (mAb) interventions in Africa. The objective of this first consultation is to provide an overview of the mAb landscape and to identify regionally relevant criteria for prioritization of future monoclonal antibody investments, taking into consideration disease burden, use case, technical feasibility, and demand. It is anticipated that this will lead to focused efforts in research and development (R&D), manufacturing, access interventions, and support efforts to sustain the innovation and manufacturing ecosystem.

TIME	AGENDA ITEMS	INTENDED OUTCOME(s)	SPEAKERS
08:00	**Welcome, introduction and setting the scene** • Meeting objectives (10')		• Dr. Abebe Genetu Bayih, Africa CDC • Shelly Malhotra, IAVI
08:10	**Opening remarks: Africa CDC leadership**		• Akhona Tshangela, Africa CDC
08:25	**Review of landscape for mAbs and role in addressing public health challenges; challenges related to mAbs access and potential solutions**	• To frame these discussions within the context of the mAbs pipeline • To level set in terms of current barriers to mAbs accessibility and availability in Africa • To build on and link to the broader portfolio of mAbs-related work led by IAVI and partners, including Wellcome, Unitaid, Medicines Patent Pool, Policy Cures Research, and Gates Foundation	• Shelly Malhotra, IAVI
08:45	**Disease priorities and strategic priorities in Africa and other considerations relating to prioritization** • Africa CDC risk ranking and prioritization of epidemic-prone diseases (15') • WHO, Priority Pathogen Initiative/AFRO region to summarize prioritization initiative (10') • Roundtable discussion (10') • Discussion (15')	• To provide an overview of regional prioritization efforts • To discuss other prioritization considerations	• Dr. Merawi Aragaw Tegegne, Africa CDC • Dr. Erin Sparrow, WHO • Dr. Jacqueline Kirchner, Gates Foundation • **Moderator:** Dr. Abebe Genetu Bayih, Africa CDC

TIME	AGENDA ITEMS	INTENDED OUTCOME(s)	SPEAKERS
09:35	COFFEE BREAK		
09:55	**Panel discussions: mAbs for emerging, re-emerging, and endemic infectious diseases** **mAbs for non-communicable diseases** • Discussion/ Q&A with audience (15')	• Ground the discussion with some specific examples of mAbs products and to highlight the relevant use case to inform subsequent priority-setting	• **Infectious diseases: introductory comments** o Dr. Pete Gardner, Wellcome • **Discussants:** o Dr. Ameena Goga, WHO o Prof. Kassoum Kayentao, MRTC, Mali o Prof. Sam Kariuki, DNDi o Dr. Pablo Rojo, Hospital 12 de Octubre • **NCDs: Introductory presentation on Africa CDC NCD strategy,** Dr. Mohammed Abdulaziz (Africa CDC) • **Discussants:** o Prof. Paul Ruff, University of Witwatersrand o Dr. Sharonann Lynch, O'Neill Institute • **Moderator:** Dr. Pete Gardner, Wellcome
11:00	**Breakout groups: 40 mins**	• Based on use case panels, discussion on factors shaping prioritization criteria for NCDs and IDs and implications for mAbs	• **Three groups with designated moderators and rapporteurs**
11:40	**Reporting back to the larger group**	• Capture takeaways from breakout discussions	
12:00	LUNCH		
13:00	**Regional regulatory perspective on mAbs (20')** • Presentation (15') • Q&A (5')	• Perspective on how changes to regulatory ecosystem could inform regulatory pathway and access to mAbs	• Chimwemwe Chamdimba, AUDA-NEPAD
13:20	**Perspectives on monoclonal antibodies and regional manufacturing (30')** • Discussion (20') • Q&A (10')		• **Manufacturers, industry, R&D, regulatory** o Dr. Raj Gupta, Vir Bio o Dr. Benedicta Durcan, Afrobodies o Dr. Asmaa Ahmed, Egyptian Drug Authority o Dr. Tsepo Tsekoa, CSIR • **Moderator:** Ethel Makila, IAVI

TIME	AGENDA ITEMS	INTENDED OUTCOME(s)	SPEAKERS
13:50	**Preliminary presentation on potential criteria for future mAbs prioritization with a focus on regional needs**	• Review a preliminary list of potential criteria for mAbs prioritization, including reflecting feedback to date • To level set and answer any questions before going into breakout groups	• Sophie Mathewson, IAVI
14:20	**Breakout groups: 60 min** • Break into smaller groups to develop draft criteria for prioritising ID/NCD mAbs, with a focus on regional needs, for discussion in plenary	• To define six top criteria for IDs/ NCDs • To surface other programmatic, feasibility, economic, or health system considerations	• Invited rapporteurs to summarize any key decisions, points of clarification, and conclusion.
15:20	**BREAK**		
15:35	**Reporting back to the larger group** **Synthesis and building consensus**	• To identify key areas of alignment and divergence across the groups • To foster collective dialogue and debate with an aim of working toward identification of a set of criteria where there is some consensus	• Shelly Malhotra, IAVI
16:30	**Wrap up and closing** • Summary of meeting • Next steps for this work. Explain how these will then be linked to the list of priority diseases, mAbs suitability, and critical implementation considerations in the subsequent phases of the project, including a deep drive into different disease types opportunities to remain engaged and future outreach • Official closing of meeting	• To provide key summary takeaways • To indicate how this work will be taken forward	• Dr. Abebe Genetu Bayih, Africa CDC • Ethel Makila, IAVI
16:50	**Group Photo**		
17:00	**END**		