Unitaid
SAVE LIVES FASTER

43rd Executive Board Meeting
21-22 November 2023
Santiago Dantas room
Itamaraty Palace
Brasília, Brazil

Agenda item 13

Area for Intervention:
Enable access to monoclonal antibodies to treat and prevent infectious diseases in LMICs

Programmatic Priorities: *Long-acting and new technologies*
(Malaria; HIV and co-infections; global health emergencies; women and children's health)

Strategic Objectives: *Create systemic conditions for sustainable, equitable access*
(Foster inclusive and demand-driven partnerships for innovation)

For Information ☐ For Review and Advice ☐ For Decision ☒

Contents

1. Purpose and context of this document

This Area for Intervention (AfI) outlines opportunities to advance equitable access to monoclonal antibodies (mAbs), which apply innovative technology to treat or prevent disease, in low- and middle-income countries (LMICs), for Executive Board endorsement. The purpose of this document is to provide an overview of the relevance of mAbs to Unitaid's strategy, potential opportunities considering developments in the product landscape and stakeholder ecosystem, prioritization analysis, and proposed way forward.

2. Introduction

Engineered from living cells, mAbs can be developed to treat or prevent a wide range of diseases and are transforming modern medicine in high-income countries; mAbs also hold a great potential for the management of major public health conditions in LMICs.

Despite the promise, however, there is vast global inequity in access to mAbs. Very high prices, ill-suited formulations, and constrained production capacity compromises the use of mAbs in LMICs and perpetuates the lack of commercial interest in markets for infectious diseases.

Monoclonal antibodies are already dramatically improving outcomes for non-communicable and autoimmune diseases in high-income countries, importantly improving survival rates for people with cancer, and WHO has identified mAbs as an innovation with a very high potential impact[1].

A few mAbs have also recently been approved for infectious diseases, including respiratory syncytial virus (RSV), which causes severe respiratory illness in infants and toddlers. Other mAbs for infectious diseases are being actively explored, such as for malaria, HIV and most of the leading causes of death in LMICs (Fig.1).

Moreover, regarding epidemic and pandemic-prone pathogens, mAbs are one of the quickest medical countermeasures that can be leveraged during a health emergency due to their ability to be quickly isolated from those who have recovered from a disease and provide rapid protection against infection once administered to others. There are five mAbs that have been approved for the treatment of Ebola and COVID-19, and a further 37 are being developed for pandemic and epidemic-prone pathogens.

Figure 1: mAbs pipeline for top-leading causes of death in WHO Afro region (2019)

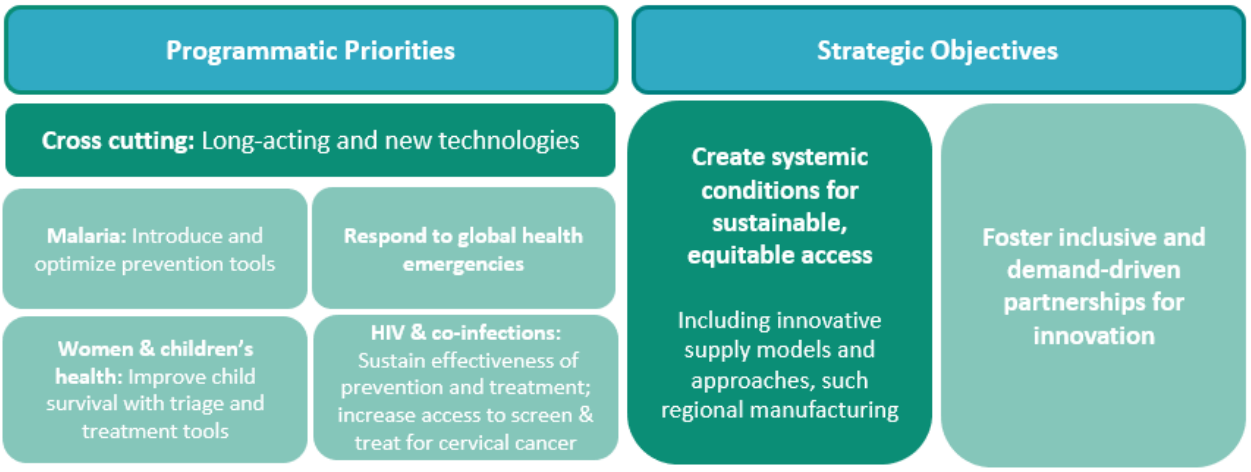
Cause of death	# mAbs in pipeline (# approved)	Fit with Unitaid portfolio
Neonatal conditions	3	+++
Lower respiratory infections	8 (2)	++
Diarrhoeal diseases	0	++
HIV/AIDS	21 (1)	+++
Ischaemic heart disease	1	…
Stroke	1	…
Malaria	4	+++
Tuberculosis	1	+++

Although some mAbs have been recently included in the WHO Model List for Essential Medicines, mainly for cancer, several others have been rejected due to their prohibitively high price which, coupled with the high burden of cancer, would imply excessive resources being diverted from other priorities in health budgets. The WHO Expert Committee explicitly encouraged work to address the high price of mAbs to facilitate increased access[2].

[1] *2023 emerging technologies and scientific innovations: a global public health perspective*, WHO Science Division, 2023.
[2] *The selection and use of essential medicines 2023. Executive Summary of the report of the 24th WHO Expert Committee on Selection and Use of Essential Medicines,* WHO, July 2023.

Considering the severe access barriers affecting this growing class of therapeutics, Unitaid has identified opportunities to enable access to existing and forthcoming mAbs that would support multiple programmatic priorities (Fig. 2). Unitaid is very well positioned to apply strategies and achievements from its long-acting technologies portfolio to mAbs, as they are inherently long-acting products and share many of the same access barriers, from manufacturing complexity to use at the country level.

Figure 2: mAbs potential to support Unitaid's strategy and portfolio[3]



Following an analysis of possible interventions, their potential impact and fit for Unitaid (using the prioritization framework), the Secretariat proposes to position this opportunity under the 2024 funding in the Investment Plan, with potential further interventions in subsequent years depending on pipeline advances.

3. Public health challenge and key access issues

Why mAbs given the complexities? Global progress is off-track to meet 2030 targets of ending the AIDS, TB, and malaria epidemics, as well as preventable deaths of newborns and children under five. In addition, the world is increasingly vulnerable to health emergencies which in turn lead to further delays in meeting targets in main public health objectives. Moreover, 54 countries are off-track to meet under-five mortality targets by 2030[4], with lower respiratory infections being a leading contributor after preterm birth complications[5]. Therefore, innovative solutions are required to help meet the needs of the most vulnerable populations, enable the global response to efficiently advance on the targets, contribute to universal health care, and prepare for responding to emerging threats.

While a well-established formulary exists for leading infectious diseases, and new options have recently been added[6], persistent problems exist. Challenges are largely due to limited options for vulnerable populations[7], options with complex implementation requirements[8], and lack of vaccines for certain diseases[9]. Several mAbs that are in the pipeline or have been recently approved could overcome these issues.

[3] Unitaid Strategic Objective 1 (Accelerate the introduction and adoption of key health products) is not reflected as it relates to medium-term opportunities that will arise as products with a strong fit with Unitaid's mandate are nearer market entry.
[4] *Levels and Trends in Child Mortality Report 2022*, United Nations Inter-Agency Group for Child Mortality Estimation, 2023.
[5] *Global, Regional, and National Causes of Under-5 Mortality in 2000-19: An updated systematic analysis with implications for the Sustainable Development Goals,* Perin *et al*. *Lancet Child & Adolescent Health*, vol. 6, no. 2, 1 February 2022, pp. 106–115.
[6] Examples of recent additions to treatment and prevention: malaria vaccine and long-acting cabotegravir.
[7] Examples of populations left behind: babies and rural populations.
[8] Example of use cases where simplification is required: mass drug administration such seasonal malaria chemoprophylaxis.
[9] Example of diseases for which vaccines are yet lacking: HIV and key priority epidemic-and pandemic-prone viruses.

In addition, in the case of pandemics, mAbs can address critical needs complementing vaccines. First, mAbs can serve as the primary prophylaxis option during the time required for vaccines to be made available in a pandemic and can reinforce vaccination until the vaccinated person is able to mount an effective response. mAbs also offer an option for prophylaxis for populations who cannot benefit from vaccines such as people with immunodeficiencies, the very young, and the elderly. Finally, mAbs can play a key role in decreasing viral load to contain spread in the communities[10] and potentially avoid lockdowns. Due to their high relevance for pandemics, the 100 Days Mission[11] includes mAbs as target antivirals to be developed for WHO-priority pathogens (25 antivirals to be developed by 2026).

Globally, mAbs have enormous potential to address unmet needs in infectious diseases in LMICs by providing a faster, more tolerable, and highly efficacious response, and can complement other ongoing strategies using small molecules and vaccines. However, mAbs are more complex than small molecule medicines and face a unique set of access barriers that contribute to stark global inequity.

Critical access issues hinder use in LMICs. With currently available mAbs being ill-adapted for LMICs, and prohibitively expensive, the entire African region makes up only 1% of the current mAbs global market[12]. Severe challenges for access to current and forthcoming mAbs include a lack of research and development beyond the most profitable therapeutic areas, high-cost manufacturing and prohibitive prices, a geographically concentrated manufacturing base, regulatory hurdles, and a lack of suitability for LMICs health systems.

The access barriers affecting mAbs include:

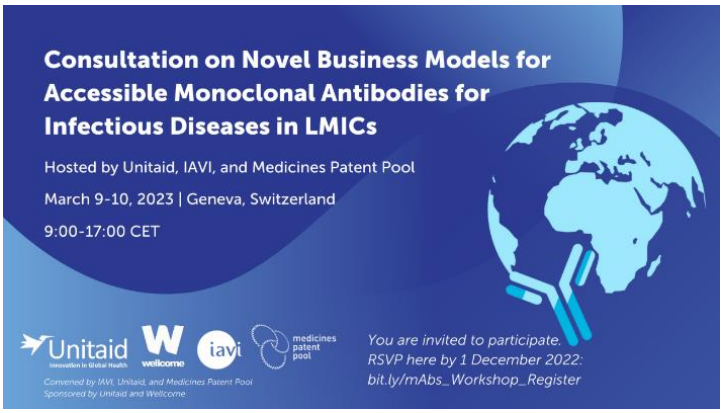
- **Innovation and availability:** The lack of commercial incentive in LMICs renders the infectious disease mAb pipeline very fragile. There are currently 14 mAbs approved for bacterial and viral infections, including COVID-19, compared to over 100 for non-infectious diseases. Current formulations typically require an IV infusion or injection and cold chain.
- **Affordability:** The current mAbs market (mainly for non-communicable diseases) is typically high-price and low-volume, targeting high-income countries. For example, cancer monthly treatment costs often exceed US$10,000, and even where biosimilars[13] exist, prices remain high (≈US$500 per month), due to complex and costly manufacturing, lack of demand, and regulatory requirements.
- **Quality:** Despite recent simplifications, regulatory pathways for mAbs remain complex. There is limited capacity for mAb approvals in LMICs, burdensome and unharmonized guidance for biosimilars[14], and a lack of expedited processes for use in emergencies.
- **Supply and delivery:** Global manufacturing capacity is limited and highly concentrated, primarily in high-income countries, affected by a high upfront capital investment, manufacturing complexities, complex intellectual property and trade secrets landscape, and lack of market visibility in LMICs.
- **Demand and adoption:** There is little to no awareness or treatment literacy about mAbs in LMICs and a lack of evidence on user preferences, cost-effectiveness, and programmatic suitability and feasibility in real-world settings.

[10] *Pandemic preparedness strategies must go beyond vaccines.* Gupta R., Purcell L., Cort D., Virgin H. April 2023. *Sci. Transl. Med.,* 15 (690), eadd3055.
[11] *100 Days Mission. First Implementation Report*. International Pandemic Preparedness Secretariat, 2021.
[12] *Expanding access to monoclonal antibody-based products: A global call to action*. Wellcome, IAVI, 2020.
[13] "Biosimilars" refer here to "generic" versions of biologic products, including mAbs.
[14] Whereas generic small molecules must demonstrate bioequivalence to the reference product, biosimilar mAbs must demonstrate high similarity to the reference product.

4. Partner engagement

Unitaid started exploring the area of mAbs, with a focus on HIV, in 2018[15] by engaging with various partners such as **WHO, IAVI, Welcome**[16], the **Medicines Patent Pool**, and **civil society actors**[17] to anticipate access needs for the then-nascent pipeline of mAbs for infectious diseases. The COVID-19 pandemic further highlighted the importance, and challenges, of access to mAbs in LMICs[18], as identified by Unitaid and partners in the **ACT-A** (Access to COVID-19 Tools Accelerator) Therapeutic Pillar. In November 2022, Unitaid joined WHO, the Korean government, and many other countries and organizations in the Seoul declaration, launched at the inaugural World Bio Summit co-hosted by the Republic of Korea[19].

In March 2023, Unitaid and partners co-convened a consultation[20] with a broad range of over 100 stakeholders. The consultation engaged infectious and emerging disease experts, innovator and biosimilar companies, product development partners, funders, regulators, the public sector, civil society and community representatives on recommendations for increasing access to mAbs. The success of this consultation illustrated the high level of interest in mAbs for LMICs from across sectors given their potential for impact. The recommendations emerging from the consultation have largely informed Unitaid's approach to this AfI.



Following this consultation, Unitaid has continued to engage with multiple partners to validate findings and ensure alignment and complementarity of initiatives, including i) **those advancing the pipeline** for infectious diseases for LMICs (e.g. Bill and Melinda Gates Medical Research Institute, PATH, IAVI, the HIV Vaccine Trials Network); and several public or private groups developing mAbs for pandemic-prone pathogens, ii) **funders** supporting development of various key infectious diseases mAbs (BMGF, NIH, CEPI), regional capacities (WHO, Republic of Korea), and innovation (including BMGF, RIGHT, Wellcome, LifeArc); iii) **industry,** including from Republic of Korea, Brazil, and South Africa, having demonstrated potential and interest to expand their capacity and portfolios to include mAbs, and iv) **civil society and communities** who need to be engaged from the design phase to ensure mAbs target the needs and preferences of end-users.

5. Opportunity for Unitaid investment

The prominence and importance of mAbs for LMICs are rapidly increasing. The percentage of biologics in the pharmaceutical pipeline has doubled in the past two decades, with mAbs being the largest class. Recent breakthroughs in mAbs have been approved, with others on the close horizon that could have a great impact in LMICs. However, the promise of mAbs in infectious diseases cannot be fulfilled if access is not equitable. Waiting until an increased number of products within Unitaid's disease portfolio are nearer to market entry will be too late and lead to vast inequalities in LMICs. **Now is therefore the time to anticipate challenges and address systemic issues that hinder access and can enable LMICs to benefit from this paradigm change.**

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[15] *Disease Narrative for HIV*, Unitaid, 2019.
[16] *Expanding access to monoclonal antibody-based products: A global call to action***,** Wellcome, IAVI**,** 2020.
[17] *Antibodies for HIV prevention: the path forward.* S Malhotra, R Baggaley, S Lynch, C Pérez-Casas, Y Raphael, L Stranix-Chibanda. Journal of the International AIDS Society 26: 5. May 2023.
[18] *Monoclonal Antibodies For COVID-19 Are A Potentially Life-Saving Therapy.: How Can We Make Them More Accessible?* A Sitlani, S Malhotra, P Aggarwal, C Pérez Casas, L Keir. Health Affairs Forefront. 2021.
[19] *Seoul Declaration*. 2022, https://worldbiosummit.kr/kor/bbs/board.php?bo_table=en_notice
[20] The *Consultation on Novel Business Models for Accessible Monoclonal Antibodies for Infectious Diseases in LMICs*, March, 2023.

Anticipating mAbs for infectious diseases directly relevant to Unitaid's mandate, Unitaid interventions can help establish a proof of concept for market viability, access and adoption of mAbs in LMICs. This will position Unitaid to help facilitate rapid access to priority products as they get approved and to mAbs as medical countermeasures when health emergencies arise. Moreover, defining models for sustainable and viable markets could catalyze investments from partners for access at scale.

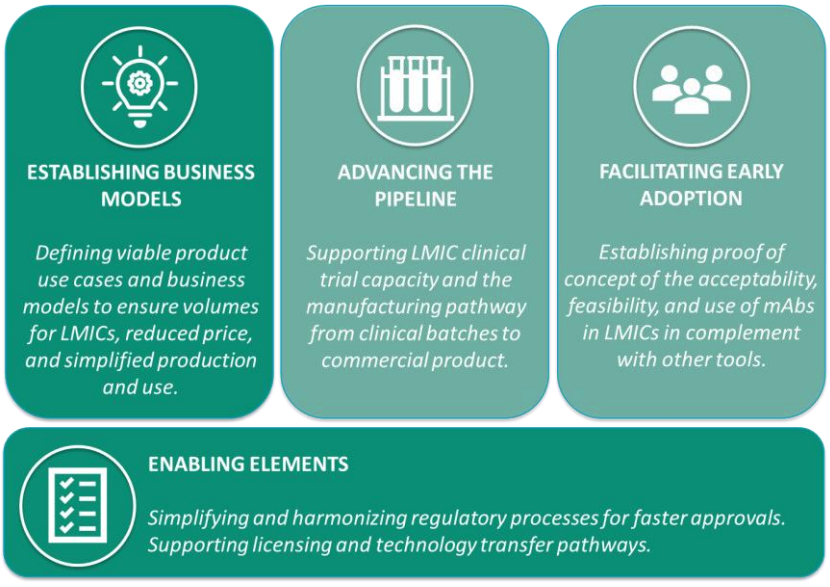
The following questions are key considering the unique access barriers for mAbs:

- How can we minimize the time gap between research and access to resulting products?
- How can technological innovations be harnessed to lower the cost of producing mAbs and make products more adapted to LMICs? How can manufacturers be incentivized to use them?
- What are promising access mechanisms, novel business models, partnership opportunities, and enabling elements required to improve access to mAbs for infectious disease in LMICs?
- What products will have viable use cases conducive to commercial launch, market creation, and scaled use in LMICs?
- Where viable use cases can be established, how can product introduction and scale be de-risked for mAbs for diseases primarily in LMICs (e.g. malaria), mAbs for diseases with higher prevalence in LMICs (e.g. HIV), and mAbs for emerging infectious diseases and pandemic threats?

Unitaid has identified immediate- and medium-term opportunities to address these questions and enable equitable access to mAbs for LMICs (Fig. 3).

- In the immediate term, Unitaid has identified cross-cutting opportunities to support the definition of product use cases and viable business models that ensure sufficient mAbs volumes for LMICs, reduce their price and simplify their production and use. Likewise, enabling elements such as expedited regulatory processes and licensing and technology transfer pathways must be addressed in the short term.
- In the medium term, Unitaid is very well positioned to advance the late-stage pipeline of priority mAbs and facilitate early adoption for those that are approved.

Figure 3: Summary of opportunities for Unitaid investment in near- and medium-term



5.1 Establishing business models for accessible mAbs in LMICs

With limited manufacturing capacity and prohibitively high prices, supply and demand challenges both contribute to the current lack of market for mAbs in LMICs. A paradigm shift in the business model for mAbs in LMICs is essential to enable availability, affordability and acceptability. **Unitaid can support the development of viable models through further definition of product use cases, demand size, production capacity, cost-saving opportunities, and sustainable product portfolios.**

The realization of such sustainable business models will require reducing the price and simplifying production and use of mAbs. This can be achieved through both product and manufacturing optimization. Unitaid can advance product optimization by supporting work, and leveraging advances supported by other partners, to extend the half-life of mAbs for less frequent dosing, increase the potency for smaller dose requirements and improve formulations for ease of administration. At the manufacturing level, Unitaid can facilitate lower COGs by leveraging higher-yielding technologies already in use by a limited number of manufacturers and providing visibility on funded demand to increase the scale of operation. Both product and manufacturing optimization can enable Unitaid to contribute to meeting the objective of reducing the cost of producing mAbs to less than $25 per gram[21], a fourth of the current status quo.

Establishing use cases for mAbs in infectious diseases in LMICs is also critical for developing viable business models. While the rich pipeline of mAbs for infectious diseases advances, efforts are needed now to investigate which products will have a use case most conducive to scaled use in LMICs, especially in the context of other tools (vaccines, small molecules) that may be available or emerging. Unitaid interventions can support the analysis and evidence collection required to establish viable product use cases, which in addition to informing business models may help partners coalesce around the advancement of the most promising products.

The viability and sustainability of business models can be enhanced by establishing a strategic portfolio of mAbs with different disease profiles. For example, production of priority mAbs that have limited and unpredictable commercial markets, but target populations in need in LMICs, could be bundled with mAbs that have more established markets. Unitaid can support further definition of optimal product portfolios based on regional priorities to build a viable business case for mAbs in LMICs.

Unitaid can also provide catalytic support to expand existing biomanufacturing capacity in LMICs for vaccines or other biologics to include mAbs production. While the long-term objective of the international community to establish brand new manufacturing capacity would require very high-magnitude investments, Unitaid can use targeted support to existing manufacturers in LMICs to optimize manufacturing, ensure volumes for LMICs and reserve capacity for responding to pandemics.

5.2 Enabling elements for faster access in LMICs

Simplification of regulatory processes for mAbs is making progress, with more weight being placed on analytical comparability and reduced clinical evidence requirements. However, these efficiencies are yet to be broadly adopted and there is a lack of harmonization across regulatory authorities.

Unitaid can support the enhancement of regional regulatory capacity and harmonization of guidance for mAbs in LMICs through targeted investments in collaboration with the WHO Prequalification program and other entities. Unitaid can also provide incremental investments specific to mAbs to increase regulatory capacity for mAbs, such as specific training or equipment requirements.

[21] *100 Days Mission. First Implementation Report*, International Pandemic Preparedness Secretariat, 2021.

Regulatory efficiencies are also critical for pandemic preparedness to enable rapid access during health emergencies. Unitaid has an opportunity to support the establishment of expedited approval mechanisms that can be leveraged in response to pandemic situations.

Licencing and technology transfer requires specific considerations for mAbs. Unitaid can make targeted investments to further boost and support licensing and technology transfer models for mAbs to expedite the pipeline and the market entry of biosimilars.

5.3 Advancing the pipeline

To help guide the development of fit-for-purpose products, WHO has published Target Product Profiles for malaria[22] and HIV[23] mAbs and has plans to develop Preferred Product Characteristics that are applicable to mAbs broadly. In the medium term, Unitaid will monitor opportunities to support targeted investments in clinical trials to advance priority products in alignment with this guidance, as well as continued community engagement to ensure end-user preferences are considered at all stages of development. Supporting targeted clinical trial capacity in LMICs is also an opportunity to contribute to pandemic preparedness as they could be quickly leveraged to test new candidates in the instance of a health emergency.

Unitaid can also complement late-stage clinical trials by supporting smaller proof of concept studies for particular use cases, such as for specific high-risk populations. Addressing such evidence gaps provide an opportunity for Unitaid to improve equity and build the value proposition for emerging products.

Importantly, early consideration of the manufacturing pathway is required, for both clinical batches and potential scale up. Unitaid will monitor opportunities to support the early identification of a commercial manufacturer so that clinical research can quickly transition to real-world access.

On the longer horizon, breakthrough innovations are expected that can further simplify the antibody-based therapies, and Unitaid will continue to monitor the innovation pipeline in this space.

5.4 Preparatory activities now to facilitate early adoption later, especially as increasingly relevant products emerge from the pipeline

Without real-world evidence on the acceptability and feasibility of mAbs in LMICs, use at scale will not be possible. Engaging with affected communities, increasing awareness, and supporting treatment literacy will be essential to support the uptake of this new class of medicines.

Building off lessons learned from the long-acting and new technologies portfolio, Unitaid will monitor opportunities to support community engagement and facilitate early adoption of mAbs in LMICs. Establishing proof of concept of LMIC adoption with approved mAbs (e.g. RSV) can pave the way for accelerated adoption of future mAbs as they emerge from the pipeline (e.g. malaria). In addition to determining feasibility and acceptability, implementation studies will be critical to determine how mAbs can best be used in complement to other tools in real-world settings.

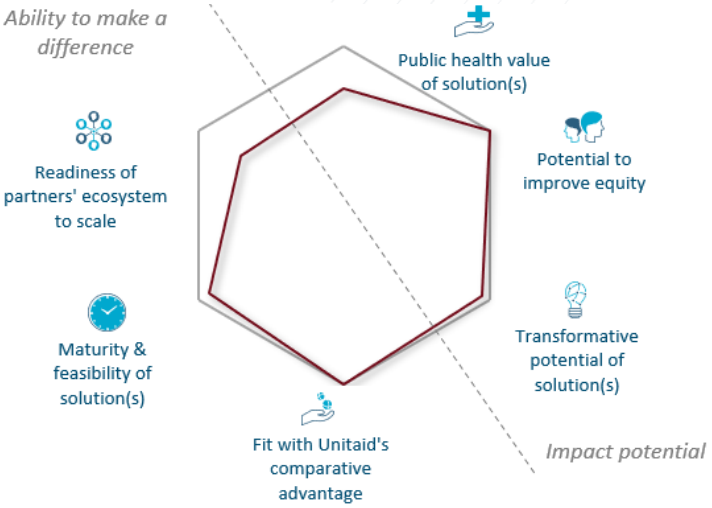
[22] *WHO meeting on preferred product characteristics for monoclonal antibodies for malaria prevention*, WHO,2021.

[23] *Preferred product characteristics for monoclonal antibodies for HIV prevention*, WHO, 2022.

6. Assessment of the opportunity

6.1 Impact potential, including the public health value of the solution, the potential to improve equity and the transformative potential of the solution (NB: scoring reflects assessment of opportunities outlined in Section 5 that are possible now, even as some of the more Unitaid-relevant applications of mAbs in LMICs are in earlier stages of development)

Unitaid interventions in mAbs have the potential to help establish a proof of concept for LMIC access and use of mAbs that are more affordable and better adapted to LMIC contexts. In addition, Unitaid interventions can establish viable business models that ensure sufficient volumes of mAbs for LMICs, and regulatory efficiencies that expedite access. The public health value of this impact is significant as mAbs can address gaps that cannot be met by other tools or can replace existing, complicated options. This value has been demonstrated by the paradigm change in cancer treatment outcomes. In addition, mAbs could be a key tool in minimizing mortality during a pandemic with high severity of disease, for which other options may be unavailable.



This opportunity has great potential to improve equity as there will be a huge lag in access to mAbs between high-income countries and LMICs in the absence of interventions. In addition, mAbs could improve equity by meeting the needs of populations for which other solutions may not exist or may be complex, such as pregnant women and infants. In the case of a pandemic, mAbs could also provide immediate protection for those who are immunocompromised, such as people living with advanced HIV disease.

The transformative potential of this opportunity is high as it could establish the viability of a sustainable market for a new class of medicines for infectious diseases in LMICs and incentivize continued innovation in mAb products and manufacturing, thereby advancing a functional pipeline. The opportunity to address access barriers proactively could minimize the lag in availability and uptake for LMICs and accelerate progress towards global targets for infectious diseases, childhood mortality, and pandemic preparedness. Given the cross-cutting nature of access interventions, this opportunity could also result in positive externalities of increasing LMIC access to mAbs for other indications such as cancer.

6.2 Ability to make a difference, including fit Unitaid's comparative advantage, maturity and feasibility of the solution and readiness of partner ecosystem

This opportunity shows a close fit with Unitaid's comparative advantage in establishing systemic conditions for sustainable, equitable access, including innovative supply models and approaches. In addition, in the medium-term Unitaid could accelerate late-stage development and country adoption of new products. An investment in mAbs would strategically complement Unitaid's current investments in long-acting and new technologies, as well as malaria, maternal and child health, and HIV and co-infections, and support Unitaid's growing role in the fields of pandemic preparedness and regional manufacturing.

As the pipeline is quickly evolving, the opportunity to prepare for equitable access is timely. Specific interventions vary in terms of their maturity and feasibility, with cross-cutting opportunities to establish viable business models and enable access being ready for investment and product-specific interventions being monitored for the medium-term. Direct interventions for responding to pandemics could be deployed sooner, depending on need.

While Unitaid-relevant applications of mAbs for LMICs are in earlier stages of development, there is strong momentum gathering with key partners already preparing to develop and launch activities to advance the use of mAbs for infectious diseases in LMICs.

6.3 Risk

With the high impact potential of this opportunity comes an increased level of risk. A key risk is the ability to meaningfully address the main access barriers for mAbs, namely feasibility and cost-effectiveness in LMICs. The latest developments suggest that such improvements are possible. For example, some companies have already reached a cost per gram that indicates compatability with cost-effectiveness for certain doses or use cases; decreased complexity of regulatory pathways for both mAbs and biosimilars is reducing the time and cost of product development; and mAbs for oncology indications have been approved with subcutaneous formulations. In parallel, learnings on similar challenges are emerging from Unitaid's long-acting technologies portfolio. There are therefore opportunities to leverage these developments to benefit mAbs for infectious diseases.

Despite these advancements, however, a risk remains that the industry will continue to prioritize mAbs for non-infectious diseases that are profitable in high-income countries. Unitaid interventions to establish a viable business case and strategies to incentivize companies to engage in infectious diseases, and collaboration with partners that share this interest, aim to mitigate this risk.

As interventions to proactively prepare for equitable access to future products will be made at risk, there is an additional risk that the pipeline will not deliver the expected products, or will deliver products that fail to meet all preferred product characteristics. The Secretariat will continue to be actively engaged with partners and industry in this dynamic area to monitor progress and mitigate the evolving risk profile of investments.

6.4 Cost and level of effort

Identified near-term opportunities within this AfI are expected to be delivered within US$ 25M, in line with the Investment Plan for 2024. Unitaid estimates that targeted investments will be required in the near term to address enabling elements (e.g., to support regulatory and licensing activities specific to mAbs). Further targeted investments are expected to be required to identify and establish viable business models for accessible mAbs in LMICs. This can include outlining subsequent investments in product and manufacturing optimization and increased manufacturing capacity. Such work to establish proof of concept for access to mAbs in LMICs are intended to be catalytic to enable scaled-up manufacturing and deployment of mAbs in LMICs.

While initial investments are required now to proactively mitigate access barriers, subsequent potential investments to advance the pipeline and facilitate early country adoption will continue to be explored as the pipeline and global architecture for mAbs evolves.