Catalysing solutions for equitable global access and sustainable financing for novel tuberculosis vaccines for adults and adolescents: Landscape and evidence to date

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World Health Organization

Contents

Abbreviations

AAHI	Access to Advanced Health Institute
ADB	Asian Development Bank
AFDB	African Development Bank
AFRICA CDC	Africa Centres for Disease Control and Prevention
AMA	African Medicines Agency
AMC	advance market commitment
AVAREF	African Vaccine Regulatory Forum
BCG	Bacillus Calmette-Guerin
CHAI	Clinton Health Access Initiative
COGS	cost of good sold
COVAX	COVID-19 Vaccines Global Access
ECVP	Evidence Considerations for Vaccine Policy Development
EIB	European Investment Bank
EPI	Expanded Programme on Immunization
F&A WG	Finance and Access Working Group
GMP	good manufacturing practices
HICS	high-income countries
HPV	human papillomavirus
IGRA	interferon-gamma release assay
IP	intellectual property
LICS	low-income countries
LMICS	lower-middle-income countries
LSHTM	London School of Hygiene and Tropical Medicine
MI4A	Market Information for Access to Vaccines
MICS	middle-income countries
ML3	Global Benchmarking Tool Maturity Level 3
NITAG	National Immunization Technical Advisory Group
ODA	official development assistance
PAHO RF	Pan American Health Organization Revolving Fund
PCV	pneumococcal conjugate vaccine
PLHIV	people living with HIV
PPC	Preferred Product Characteristics
PQ	prequalification
R&D	research and development
SAGE	Strategic Advisory Group of Experts on Immunization
TAG	Treatment Action Group
TAG MVAC	Technical Advisory Group on Market Access for Vaccines
TB	tuberculosis
TPP	Target Product Profiles
UMICS	upper-middle-income countries
UNICEF	United Nations Children's Fund
WHO	World Health Organization
WHO AFRO	WHO Regional Office for Africa
WHO AMRO/ PAHO	WHO Regional Office for the Americas/ Pan American Health Organization
WHO EMRO	WHO Regional Office for the Eastern Mediterranean
WHO SEARO	WHO Regional Office for South-East Asia
WHO WPRO	WHO Regional Office for the Western Pacific

1 Introduction

1.1 BACKGROUND

The global tuberculosis (TB) epidemic is a serious threat to global health and development, requiring urgent action. Every year, at least 10 million people fall ill with TB, mostly adults and adolescents, and more than one million die from the disease. From 2000 to 2023, TB treatment and antiretroviral therapy for TB-HIV co-infection saved 79 million lives globally. However, progress is uneven across countries due to unequal access to healthcare, inadequate financing, conflicts, climate change and natural disasters. Today, TB accounts for approximately one-third of deaths among people living with HIV (PLHIV) and is a key driver of antimicrobial resistance. About a quarter of the world's population is infected with Mycobacterium tuberculosis, which increases the risk of developing TB disease.

Despite TB's devastating global impact, no new vaccines have been licensed in over a century. Safe, effective, affordable and accessible TB vaccines, particularly for adolescents and adults, are essential to accelerating reductions in TB incidence and mortality. The World Health Organization (WHO) TB Vaccine Accelerator was established in 2023 to catalyse global action towards this goal. The Finance and Access Working Group (F&A WG) was established in February 2025 to promote timely, equitable and sustainably financed access to affordable new TB vaccines for adults and adolescents, driven by public health need and fostering long-term sustainable supply. Since TB primarily impacts low- and middle-income countries (LMICs) and has limited market potential in high-income countries (HICs), a strategic approach to market shaping, access and financing is essential.

The F&A WG is co-convened by WHO, Gavi, the Vaccine Alliance, and the Government of South Africa. It is coordinating efforts across governments, partners, financing institutions, the private sector and civil society to propose strategic partnerships, financing and procurement mechanisms, and market access solutions, with a particular focus on speeding up vaccine availability and access for high-TB-burden countries.

In addition to the co-convenors, the F&A WG members include: African Development Bank (AfDB); Africa Centres for Disease Control and Prevention (Africa CDC); Asian Development Bank (ADB); Clinton Health Access Initiative (CHAI); Coalition Against TB, Indonesia; European Investment Bank (EIB); Global Fund to Fight AIDS, Tuberculosis and Malaria; Harvard T.H. Chan School of Public Health; London School of Hygiene and Tropical Medicine (LSHTM); MedAccess; Ministry of Health, Brazil; Ministry of Health, Indonesia; Research Institute for Tropical Medicine, Philippines; Treatment Action Group (TAG); United Nations Children's Fund (UNICEF); and Pan American Health Organization Revolving Fund (PAHO RF) for Access to Vaccines.

In 2025, the F&A WG worked towards developing an early understanding of anticipated barriers, bottlenecks, challenges and supply-demand dynamics relevant to country financing and access for novel TB vaccines. The outputs from the analyses conducted to develop this understanding are captured in this report via Chapter 2. These analyses help identify solutions and opportunities to incentivize equitable and affordable global access and sustainable financing, which is the overarching objective of the F&A WG in 2025.

1.2 INSTRUCTIONS FOR PUBLIC SUMMARY CONSULTATION

⚠ PLEASE READ BEFORE CONTINUING

We are pleased to share this working draft of the landscape and evidence to date as a public summary for consultation. Please note that it remains an interim version and will be finalized after receiving and reviewing collective comments. This landscape and evidence to date report will form part of a broader report that will include proposed solutions by the F&A WG to accelerate equitable access and sustainable financing to novel TB vaccines. The final report is expected to be published on 6 November 2025.

The purpose of the public summary for consultation is to gather feedback from key stakeholders as the work is finalized. By publishing this public summary in advance of the final report, WHO and its partners reaffirm commitments to inclusive engagement, transparency and accountability, ensuring that civil society and key stakeholders can inform the shared understanding that will shape the path to equitable access to novel TB vaccines.

Inputs on the insights and takeaways in this document will be especially valuable. To support consistent feedback collection, please submit comments within the accompanying Word document: *Public Summary – Feedback submission form*. The methodology for each section can be found in the Annex document: *Public Summary – Annexes*, but no feedback is requested on the Annexes.

FEEDBACK WINDOW

22–28 September 2025

Please submit the completed form with feedback by the close of business on 28 September 2025, by email to:

Tara Prasad
Department of Immunization, Vaccines and Biologicals, World Health Organization
prasadt@who.int

2 Landscape and evidence to date

In 2025, the F&A WG agreed to prioritize five key analyses (see sections 2.1–2.5). These aim to provide an early understanding of the current situation and stakeholders' plans, as well as to identify anticipated barriers, bottlenecks and challenges related to financing and access for novel TB vaccines. The analyses focus on four areas as outlined in Fig. 1.

FIG. 1

Focus areas for F&A analyses conducted in 2025

COUNTRY INSIGHTS

Consultations with high TB-burden countries to assess:

- demand for introducing and scaling new TB vaccines
- financial commitments for procurement
- barriers or conditions for access.

SEE SECTION 2.1

FINANCING INSIGHTS

Mapping of available and anticipated global financing (from countries and external partners) for procurement of novel TB vaccines to identify:

- needed funding using demand and price estimates
- potential gaps.

SEE SECTION 2.5

PRODUCT INSIGHTS

Review of TB vaccine candidates with potential for licensure and recommendations for use from 2030 to assess:

- target markets and pricing strategies
- manufacturing plans and licensing agreements
- investments and regional manufacturing opportunities.

SEE SECTION 2.3

MARKET INSIGHTS

TB vaccine market analyses to understand:

- low/medium/high demand-supply scenarios
- supply-demand balance and gaps in the first decade post-licensure.

SEE SECTION 2.2

SEE SECTION 2.4

Together, these five analyses capture both the current situation and projected future scenarios. This helps identify gaps, bottlenecks and potential solutions. The analyses are interdependent; thus, they also reveal root causes and cross-cutting strategies to address multiple barriers, which will guide proposed solutions needed to accelerate access.

Although the F&A WG's remit is global and long-term, the analyses also highlight early actions needed for first-to-market candidates and early-adopter countries in the first 10 years after licensure. As no product is yet licensed, uncertainty remains. To address this, the analyses identify risks, information gaps and areas where decisions cannot yet be made. They are designed to be dynamic and will evolve as new information and pipeline developments emerge. Establishing a shared understanding now is essential to enable early interventions, timely action and prepare the ground for equitable access.

2.1 COUNTRY ACCESS AND FINANCING PLANS

Introduction

This section provides an overview of current access and financing plans for novel TB vaccines in five high-TB-burden countries. Country perspectives on bottlenecks and needs are essential to shaping global solutions and ensuring solutions are both relevant and actionable at the country level.

Objectives

To gather country insights, strategic dialogues were organized by WHO with governments from five high-TB-burden countries (Brazil, Ethiopia, Indonesia, the Philippines and South Africa) to explore their vaccination strategy and demand, procurement plans and supply interdependencies, as well as potential domestic funding commitments and financing needs (see Box 1 for details on scope of country consultation and Annex A for more details). The consultations covered countries that collectively represent over 22% of the global TB burden and are likely to be early adopters of novel TB vaccines. Given their TB burden status, identifying barriers and potential solutions in partnership with these countries can support accelerating early access and contribute to public health impact. To complement national insights, consultations were also conducted with TB and immunization programme stakeholders from WHO regional offices,[1] recognizing the wide diversity among high-TB-burden countries globally.

BOX 1

Scope of country consultations

The findings and takeaways presented in this section are based on consultations with five high-burden countries and selected regional stakeholders. Separately, nine country consultations and selected regional stakeholder consultations were conducted for demand analysis in the next section. While there is some overlap in themes (e.g. adoption, timelines and delivery strategies), the two consultation sets are independent and serve distinct analytical purposes.

As the insights that follow are mainly representative of middle-income countries that largely self-procure and self-finance their immunization programmes, the F&A WG will continue to explore the pathways and needs of lower-income and more donor-reliant countries in 2026–2027, noting the scope to ensure equitable access in all countries globally with demand.

1 Consultations were conducted with WHO regional offices for Africa, Americas, South-East Asia, Eastern Mediterranean and Western Pacific.

Key findings from country consultations

The key findings capture a summary of the views of stakeholders consulted.

Countries are preparing for TB vaccine introduction; target population strategies vary

Countries view adult and adolescent TB vaccination as a high priority, given the disease burden and potential for major health and equity benefits. The countries consulted indicated early efforts are under way to prepare for introduction while awaiting key evidence from completion of clinical trials and product availability. This includes national discussions about priority use cases, eventual financing, demand and supply planning, streamlining of policies and regulatory pathways, local manufacturing opportunities, health system preparedness, including readiness assessment and vaccine acceptance, and integration with existing immunization and TB programmes. This process is complex, involving multiple steps, stakeholders and interdependencies related to access, financing and national context.

Approaches to target population prioritization vary. Some countries plan to begin with high-risk groups; others may focus on high-burden regions. All must balance protecting the most vulnerable with minimizing stigma that could dampen demand.

Evidence gaps remain that will be critical to inform introduction decisions

Several countries emphasized that generating local evidence through implementation studies will be critical to inform large-scale roll-out decisions as informed by lessons learned from RTS,S/AS01 (RTS,S) malaria vaccine introduction. Consultations with countries and regional stakeholders further highlighted that other high-burden countries are opting for a measured approach, driven by the need to balance competing health priorities and secure political buy-in and financing commitments in large and complex health systems. These countries are therefore waiting for critical information on vaccine efficacy, target populations, product attributes, financing options, donor eligibility and WHO/Strategic Advisory Group of Experts on Immunization (SAGE) guidance before beginning planning. For example, vaccine introduction for Ethiopia, a Gavi-eligible high-burden country, is contingent upon WHO prequalification (PQ) and SAGE recommendations, and Gavi co-financing.

Country introduction will be shaped by access and product attributes

Vaccine access (availability, affordability, acceptability, quality assurance), product characteristics (safety, efficacy and supply chain and logistical needs), and cost-effectiveness and budget analyses were cited as key factors influencing countries' prioritization, introduction and scale-up plans. Product presentation will also influence introduction (e.g. thermostable vaccines in multi-dose vials to suit institutional settings, as well as single-dose vials for community delivery). In the absence of complete information, some countries will develop multiple scenarios to inform early planning and potential future outcomes.

Countries with capacity prefer local manufacturing but will accept imports initially

Consulted countries that have vaccine manufacturing capacity expressed a preference for locally produced vaccines; however, all remain flexible and open to importing vaccines in the early stages and building fill-and-finish capacity as a transition before they develop end-to-end domestic manufacturing capacity. Overall, the country and regional consultations highlighted that regional manufacturing represents a growing priority, especially in Africa, South-East Asia and Latin America. Investments in local production and technology transfer in countries such as Indonesia and South Africa aim to enhance long-term access and sustainability. Countries viewed this approach as vital for the long-term financial sustainability of the immunization programme, especially for countries that self-finance their vaccine procurement.

Pooled and bilateral procurement expected across high-burden countries

Middle-income countries (MICs) that are non-Gavi-eligible or transitioning out of donor support are expected to self-procure. Some may be interested in leveraging pooled procurement agencies such as UNICEF and PAHO RF, depending on supply and pricing. Regional consultations highlighted that countries eligible for donor support will likely leverage pooled procurement mechanisms, pending the addition of novel TB vaccines to relevant agencies' portfolios.

Self-procuring and self-financing countries use national processes, while others depend on WHO policy guidance and regulatory pathways

Some countries consulted will consider adopting the vaccine before SAGE recommendations or PQ by relying on local registration processes and National Immunization Technical Advisory Group (NITAG) recommendations. For most countries, early introduction will depend on accelerating regulatory approval for importing vaccines, which could require leveraging clinical data from other countries in the region. Countries such as Brazil and Indonesia can expedite approval under special access schemes or emergency pathways for priority vaccines. Regional platforms like African Vaccine Regulatory Forum (AVAREF) and African Medicines Agency (AMA) can also support joint reviews and fast-track approvals.

WHO policy recommendations, informed by SAGE discussions and WHO PQ, are important enablers to broad policy adoption and country introduction, particularly for countries that require both SAGE guidance and PQ as part of their regulatory and financing procurement pathways.

Political support exists, but too early for domestic budget decisions

While political support for eventually introducing novel TB vaccines is strong, no country has yet allocated domestic funds, as it is too early for a budget decision. Countries flagged the need for robust cost-effectiveness and health impact data to support decision-making, and also the need for global health partners to help bridge critical funding gaps for vaccine procurement in countries in need. The majority of the global TB burden, over 60%, is present in MICs that are expected to self-finance new vaccines based on current financing patterns – substantial domestic financing commitments will be needed.

Country consultations highlighted that financing needs extend well beyond procurement. Countries also require resources for infrastructure, delivery (logistics, distribution, storage, administration), healthcare workforce training and integration into immunization programmes. Regional consultations further highlighted that high-TB-burden countries that are graduating from donor support are particularly vulnerable to financial unpredictability and potential affordability challenges. High-burden countries reliant on donors are not yet sure what external funding will be made available.

↓ **Below**
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Delivering vaccines to adults and adolescents will necessitate new delivery models

Delivering novel TB vaccines to adolescents and adults presents distinct challenges, with countries noting that reaching adults at scale or within specific high-risk groups is significantly more difficult than reaching adolescents. Countries consulted are actively exploring ways to build on existing platforms, leveraging systems in place from relevant disease programmes such as HIV treatment to monitor vaccine coverage, efficacy and safety, as well as TB surveillance networks to support effective rollout. However, these systems have not been developed to reach non-routine populations such as adults and priority high-risk groups outside the traditional childhood immunization cohorts.

Integration of immunization and TB data systems is being explored to enable real-time tracking, with countries like South Africa and Indonesia interested in piloting school-based, workplace and community delivery models. While experiences from COVID-19 and human papillomavirus (HPV) vaccine campaigns offer helpful insights, TB vaccines will require tailored strategies given that vaccination must reach a broader and more diverse adolescent and adult population, including high-risk and hard-to-reach groups. This will necessitate new delivery models, additional targeted investments and further workforce training.

Addressing vaccine hesitancy is key to ensuring uptake

Effective communication strategies will also be critical to address misinformation and ensure vaccine acceptance. Early engagement with community and religious leaders and health professionals will be essential in risk communication, building public trust and accelerating uptake. One country highlighted that concerns around adult vaccine hesitancy, shaped in part by experiences during the COVID-19 pandemic, can be mitigated by embedding demand creation within primary health care. Readiness assessments should include evaluations of community trust and feasibility to guide tailored approaches for overcoming hesitancy among adults.

Key takeaways from country consultations

The key takeaways summarize the F&A WG's views on barriers and solutions at national, regional and global levels.

Accelerating countries' decision-making pathways to vaccine introduction and budget allocation requires clarity on supply (product attributes, product access, country-level impact and cost-effectiveness modelling), demand forecasts and alignment on priority use cases and immunization strategy. Likewise, country demand forecasts and introduction plans will influence scale, supply availability and price. To prevent delays and long lead times between product licensure and country introduction and scale-up, which can amount to multiple years, the following actions are needed:

Early discussions and advocacy among country stakeholders on country plans and needed domestic financing can help create alignment on how the vaccine is expected to be used and ensure adequate financing for this. This is also critical for providing suppliers with clear, reliable signals of funded demand. In the absence of complete information, scenario planning can help prepare for decisions to be made with final information. To support this, countries need:

- early engagement of communities and civil society to raise awareness of the TB burden, the potential impact and the priority of novel vaccines;
- cost-effectiveness, budget and health impact modelling at the country-level, in the context of existing TB interventions, to identify priority populations for use;
- Ministry of Health and Ministry of Finance alignment on budget needs and priorities;
- clarity on available external financing, including scope, eligibility and timing.

Demand projections and volume indications from countries (specifying how many doses a country would procure in what timeframe, if a vaccine meets a set of stated requirements) can support suppliers to establish and commit to

price points, which in turn can support country budget allocation. To support this, countries need:

- country forecasts of potential demand and national budget projections;
- clear guidance from donors on external funding availability;
- global (SAGE) policy, prequalification and programmatic guidance from WHO;
- technical assistance to support country readiness planning.

Early global coordination between anticipated supply and demand can minimize delays, incentivize actions by different stakeholders in parallel and help ensure data and evidence are generated and shared with all stakeholders. Given the mix of procurement and financing channels used by high-burden countries, there is a need for:

- flexibility in country inclusion criteria in global/regional solutions, ensuring high-burden countries can partake in aggregate solutions regardless of procurement mechanism (self- or pooled) or financing sources (domestic or external)
- ability for countries to opt for procurement and financing channels suitable to their needs to maintain self-sufficiency, while benefitting from and supporting broader efforts.

Regional manufacturing covering all high-burden regions can help strengthen equitable access, ensure regional supply security and increase acceptability of vaccines. To support this, countries need:

- prioritization of novel TB vaccines in the regional manufacturing agenda and financial incentive structures, with manufacturing hubs established across high-burden regions, to strengthen equitable and sustainable access;
- willingness from supply stakeholders (originators and licensees) to support regional manufacturing and technology transfer as needed, while avoiding market fragmentation;
- political will within regions to foster regional vaccine manufacturing and ensure equitable regional distribution.

Early investments in delivery systems tailored to adult and adolescent populations can help reduce delays in reaching target populations, increase vaccine acceptance and mitigate coverage gaps. To support this, countries need:

- funding allocated to country readiness and delivery, once relevant plans are developed;
- coordination between the Expanded Programme on Immunization (EPI) and TB programmes;
- community engagement and partnerships with civil society;
- dedicated efforts on public outreach to build awareness and foster acceptance.

Sharing clinical trial data and strengthening the monitoring of misinformation can help expedite country introduction pathways, increase trust in products and accelerate access. To support this, countries need:

- mechanisms for timely data sharing and regulatory recognition of comparable evidence across countries;
- robust information systems that can maintain the security and confidentiality of clinical trial data.

Implementation research is a critical enabler for setting up and optimizing delivery systems for adolescents and adults. It can help generate locally relevant evidence that accelerates national adoption and integration into programmes. To support this, countries need:

- inclusion of implementation research in early vaccine financing and resource mobilization plans;
- determination of areas/regions for research implementation, considering the highest TB burden;
- strengthening of regional commitment to support vaccine research implementation.

2.2 DEMAND PROJECTIONS

Introduction

Reliable and transparent demand estimates for adult and adolescent TB vaccines are essential to align the TB ecosystem early and to support timely, affordable and equitable access.

A global demand projection covering 2030–2040 was developed by Gavi for the F&A WG leveraging the WHO Market Information for Access to Vaccines (MI4A) methodology *(1)*, which has been used to develop global demand forecasts by WHO for 13 antigens to date *(2)*. The methodology was adapted to account for uncertainties surrounding novel TB vaccine candidates and endorsed by the WHO Technical Advisory Group on Market Access for Vaccines (TAG MVAC). More details on the methodology can be found in Annex B.[1]

Objectives

As described in Section 2.1, countries face multiple unknowns and uncertainties related to the potential products and their uptake. This presents challenges in deriving a precise demand forecast for a new class of TB vaccines several years ahead of the most optimistic timelines for their availability and roll-out (around 2030, assuming licensure by 2028). Hence, the projection herein provides an initial estimate of global demand for novel TB vaccines.

The projection provides a high-level aggregate summary to directionally provide market insights, including potential supply and financing needs. Eventual country-specific demand forecasts for operational procurement will depend on each country's programme and are not meant to be ascertained from this global estimate.

Methodology

The demand projection was approached from a programmatic perspective, focusing on whether and how countries would use the vaccine in different situations, without making specific product or price assumptions. It is premature to estimate demand per product, as it is not known which specific vaccine products will successfully achieve licensure. Hence, the projection is product-agnostic and includes projected country demand for any TB vaccine that meets the WHO Preferred Product Characteristics (PPCs) of over 50% efficacy.

The demand projection is based on extensive country and expert consultations, including in nine high-TB-burden countries, accounting for 63% of global TB burden (Brazil, China, Democratic Republic of the Congo, India, Indonesia, Nigeria, Pakistan, South Africa and Viet Nam). These country consultations are complementary to the country consultations described in the first section and more focused to specifically inform the demand projection.

Results overview

As these vaccines are still in development, variables such as product attributes, timelines for regulatory approval, anticipated use cases and national and global policy recommendations remain uncertain. With that in mind, different approaches were outlined by the consulted countries, which ranged from targeted introduction focusing on high-risk groups to conducting broad catch-up vaccination in adults, followed by routine immunization in adolescents.

1 Gavi will publish a separate document with more details on the demand analysis in October 2025.

Accelerating the reduction of TB burden requires vaccinating adults at scale, as routine immunization of adolescents provides population immunity on a much longer time horizon *(3)*. While an approach including large catch-ups in adults brings the fastest reduction of TB burden, it is also a more costly and complex approach, as adult vaccination poses significant challenges.

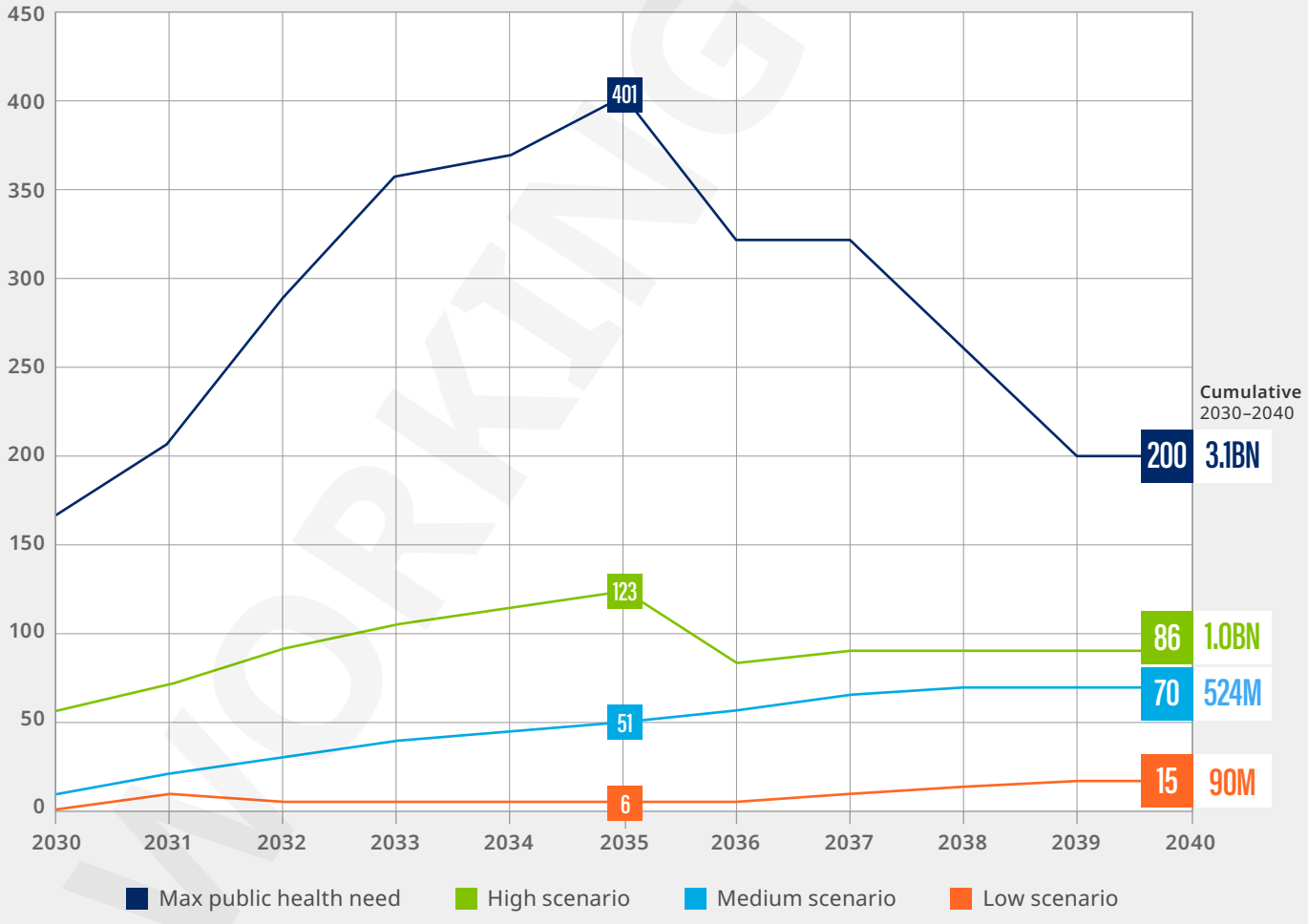
To address the uncertainties and reflect different levels of programmatic ambition shared by country stakeholders, four demand scenarios were developed: low, base, high and maximum public health need (see Fig. 2). Each scenario reflects differences in the scope of target populations and delivery strategies, accounting for a range of introduction approaches and different levels of programmatic ambition. Programmatic ambition reflects potential financial constraints, programmatic feasibility and readiness, and acceptability of vaccines. These scenarios assume vaccine efficacy of at least 50%, in line with the WHO Target Product Profiles (TPPs). Across all scenarios, 52 countries are projected to introduce the vaccine during the 2030–2040 period. The scenarios are described in more detail in Annex B.

It is important to note that the demand model outputs were calculated in regimens, not numbers of doses (e.g. for a vaccine with a regimen of two doses, the figures below would double).

FIG. 2

Demand as projected under the four demand scenarios

Number of **year-on-year** fully immunized persons/regimens (millions)



Note: For a 2-dose vaccine, these figures would double.

Maximum public health need scenario

Catch-up vaccination volumes could be substantial in the first 5–7 years of vaccine availability.

- Large high-burden countries such as India drive the projected demand up to around 400 million vaccination regimens by 2035.
- Over time, demand declines to approximately 200 million regimens annually.
- Catch-up campaigns account for most of the demand during the 10-year forecast period, while routine immunization would account for around 14% of demand in the same period.
- More than 90% of demand in the first decade is driven by 38 high-burden countries estimated to introduce vaccines between 2030 and 2040.

High scenario

- Catch-ups drive early demand, while routine immunization demand grows steadily.
- Demand peaks at approximately 120 million regimens in first 5 years of vaccine availability, driven by catch-up campaigns in high-risk geographical areas of high-burden countries.
- Global demand stabilizes at around 90 million regimens annually following the completion of catch-up vaccination in large, high-burden countries and the scaling-up of routine immunization programmes.

Medium scenario

- Annual demand is around 70 million regimens within the first decade of the vaccine uptake.
- The uptake curve is flatter, reflecting an approach that focuses on adolescent routine immunization alongside high-risk group vaccination.
- Catch-up demand is not substantial in this scenario as catch-ups are limited to high-risk groups and do not include broad population vaccination.

Low scenario

- Annual demand is less than 10 million regimens due to the sole focus on reaching high-risk groups through both routine and catch-ups. A small fraction of the population would get vaccinated even in large, high-burden countries.

Key findings from demand projections

The four scenarios span a broad range of possibilities, from an annual demand of around 10 million regimens all the way to several hundred million. Whether global ambition translates into real demand depends on country introduction choices. These will be shaped by:

Domestic and external funding availability

Countries highlighted financing – both domestic and from donors – as one of the most important factors that will influence demand materialization. Higher levels of financing would allow for broader vaccine use.

Vaccine efficacy

Countries also flagged that efficacy below the WHO PPC (i.e. less than 50%) would likely limit the use to high-risk populations.

↓ **Below**

Cost-effectiveness in the local context

While a higher product price would likely negatively influence cost-effectiveness and lead to targeted adoption, a lower price alone is unlikely to drive widespread adoption. Additional cost-effectiveness studies comparing the vaccine with other TB prevention measures will be required to inform country decisions about the trade-offs of different tools.

Policy recommendations for specific populations, e.g. PLHIV

WHO policy recommendations, regardless of previous exposure to TB infection, and especially for priority populations like PLHIV, have the potential to impact the broad adoption of novel TB vaccines, given the importance of HIV/TB comorbidity in several high-TB-burden countries.

Key takeaways from demand projections

The F&A WG discussed the various demand scenarios and trade-offs and reached consensus that the high-demand scenario best balances ambition to accelerate health impact with feasibility by limiting adult catch-up campaigns to high-risk areas. This scenario will require up to 120 million regimens annually in the first 5 years and 90 million annually in the 5 subsequent years.

The maximum public health need scenario was seen as aspirational as it would require resource mobilization and health system investments comparable to the COVID-19 pandemic response. Further, the low scenario would fall vastly short of reaching the full potential of the vaccines in terms of TB burden reduction.

To ensure demand materializes, several requirements are necessary:

- **Early financing commitments from donors and domestic budgets** from donors and domestic budgets, to enable timely investments for scaling up supply and in-country preparations.
- **Cost-effectiveness evidence** across a range of price and efficacy assumptions, comparing novel TB vaccines with other TB preventive measures, to inform prioritization and budget allocation.
- **Inclusive policy recommendations** for novel TB vaccines, supported by evidence now being generated, including safety data in PLHIV and interferon-gamma release assay (IGRA)-negative people, to ensure broad eligibility and avoid pre-screening.
- **Demand generation activities**, including partnerships with communities and civil society, to build awareness and support for vaccine introduction.

2.3 PRODUCT LICENSING AND ACCESS STRATEGIES

Introduction

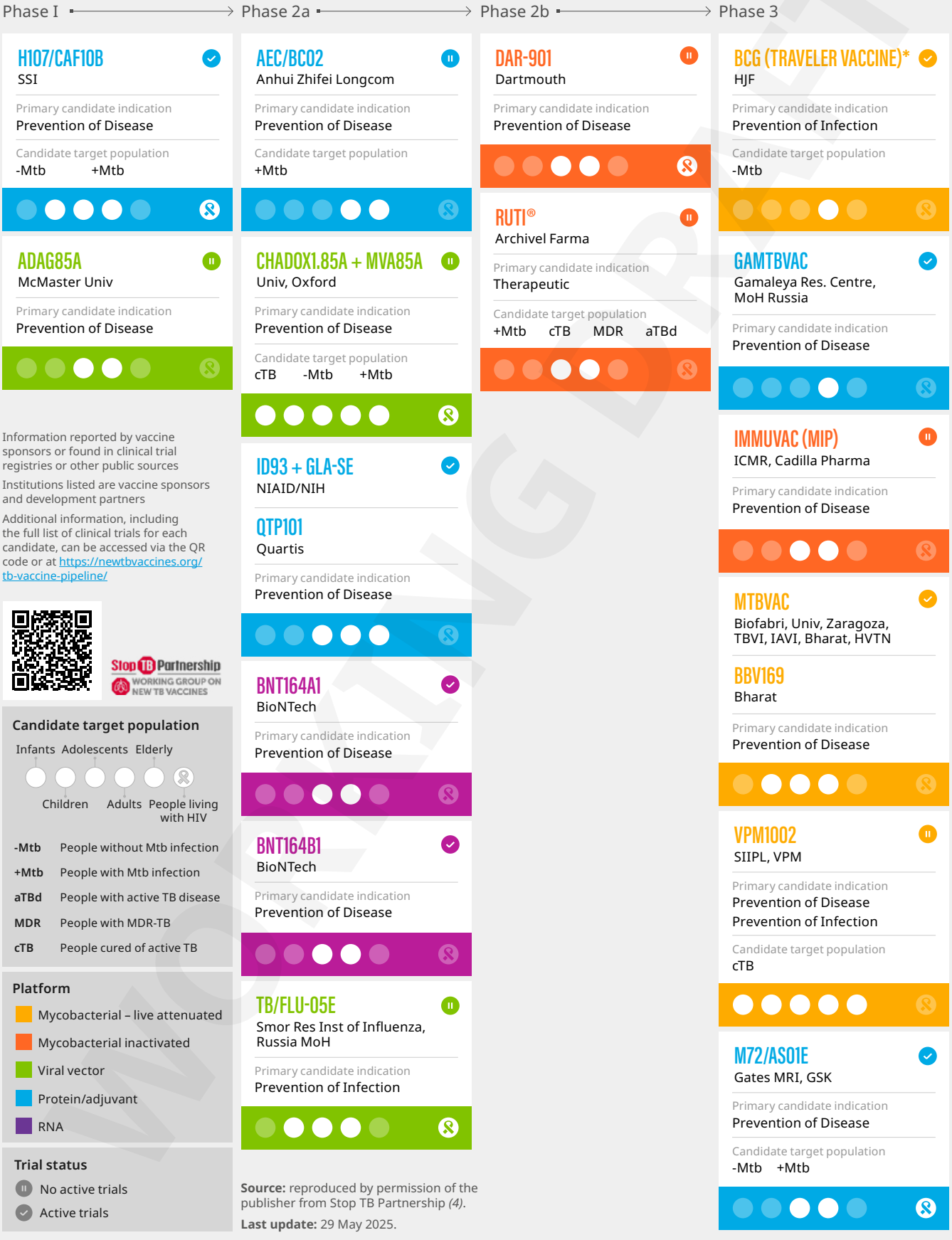
Currently, at least 15 TB vaccine candidates are in clinical development, including six in Phase 3 trials (see Fig. 3). Regulatory data for at least one vaccine candidate is expected within the next 3 years (2026–2028). Ensuring equitable and timely access to novel products once licensed requires early access planning by developers during the R&D phase. As demand for TB vaccines is projected to be significant, early plans to license products and scale manufacturing adequately are key to ensuring adequate and timely supply availability. Licensing and access strategies can also support geographically diverse manufacturing and foster long-term supply sustainability.

FIG. 3

TB vaccine pipeline

Vaccine candidates under clinical development

There are 16 vaccine candidates in the pipeline as of May 2025, of which eight are in active trials. The candidates are placed under the phase that corresponds to the most advanced ongoing or completed trial.



Information reported by vaccine sponsors or found in clinical trial registries or other public sources

Institutions listed are vaccine sponsors and development partners

Additional information, including the full list of clinical trials for each candidate, can be accessed via the QR code or at https://newtbvaccines.org/tb-vaccine-pipeline/

Stop TB Partnership
WORKING GROUP ON NEW TB VACCINES

Candidate target population

Infants, Adolescents, Elderly, Children, Adults, People living with HIV

-Mtb	People without Mtb infection
+Mtb	People with Mtb infection
aTBd	People with active TB disease
MDR	People with MDR-TB
cTB	People cured of active TB

Platform

- Mycobacterial – live attenuated
- Mycobacterial inactivated
- Viral vector
- Protein/adjuvant
- RNA

Trial status

- No active trials
- Active trials

Source: reproduced by permission of the publisher from Stop TB Partnership *(4)*.

Last update: 29 May 2025.

Objectives

This section outlines key insights from desk research and consultation led by WHO with seven supply stakeholders involved in the development and eventual commercialization of five mainly late-stage candidates expected to reach the market starting from 2030; namely: MTBVAC, M72/AS01E, IDP3+GLA-SE, BNT164a1, and BNT164b1 (see Annex C for details on methodology). The consultations aimed to understand stakeholders' plans to ensure equitable access in high-burden countries, licensing agreements, pricing commitments, manufacturing partners and related investments. The consultations also explored potential barriers that supply stakeholders anticipate in regulatory and policy pathways, manufacturing and commercialization strategies and/or operational challenges, noting that some candidates are being developed for global use while others are intended for domestic markets.

Key findings from supply stakeholder consultations

The key findings capture a summary of the views of stakeholders consulted. Where supply stakeholders have agreed, candidate-specific information has been included.

Late-stage pipeline is advancing

In recent years, the TB vaccine pipeline has advanced several late-stage candidates designed to meet WHO's preferred product characteristics for preventing disease in adolescents and adults. Late-stage candidates in this analysis include candidates currently undergoing or about to initiate Phase 3 trials, as well as candidates in Phase 2a/b with a planned accelerated clinical development programme timeline. The pipeline includes diverse technology platforms, ranging from adjuvanted protein subunit to messenger RNA-based (mRNA) candidates, which, if successful, could enable more rapid manufacturing scale-up. There are also multiple clinical trials and emerging implementation research studies in high-burden low-income countries (LICs) and MICs, which can help enhance trust and early adoption in these countries. M72/AS01E has secured full Phase 3 funding. However, the majority of late-stage candidates lack the full required Phase 3 funding, which poses a risk to their advancement to licensure, in addition to scientific risks. Quratis highlighted that while clinical approvals and study sites are in place for ID93+GLA-SE, Phase 2b/3 trials remain unfunded, creating a critical bottleneck. Additionally, MTBVAC is yet to secure full funding for Phase 3 trials.

Barriers exist for some candidates to reach licensure

The WHO Evidence Considerations for Vaccine Policy Development (ECVP) for TB vaccines provides early guidance on priority populations for novel TB vaccines *(5)*. However, product developers are uncertain which populations countries will prioritize (e.g. adults, adolescents, PLHIV), which creates barriers to advancing candidates. Without clinical efficacy data for the target population, countries may be unable or unwilling to introduce the vaccine, limiting access. This uncertainty also has a direct impact on suppliers' ability to predict demand and plan corresponding manufacturing and supply. This report seeks to help clarify some of these uncertainties and provide a more informed basis for product development and planning.

Policy and regulatory pathways will differ across countries

Developers expect LICs and some LMICs to use WHO PQ to support their national regulatory approval. While MICs may not require global policy and regulatory processes, the lack of regulatory harmonization, requiring suppliers to submit multiple filings and, in some cases, generate additional evidence for country-specific requirements, was cited as a factor that could cause delays in regulatory approvals. The lack of adult immunization policies in multiple LICs and MICs creates ambiguity for regulatory approval.

Equitable access strategies under consideration, lack of concrete plans at this stage

All suppliers stated they are considering strategies to ensure equitable access to novel TB vaccines, especially in high-burden countries. Supply stakeholders noted it was too early to share concrete plans while candidates are in development, but noted that global access considerations are part of their planning. They cited the need for demand and volume assumptions to inform access planning. Suppliers noted intent to use tiered pricing to differentiate HICs, MICs and LICs. Some noted that the pricing tiers would be built around cost of goods sold (COGS) and depend on the scale of manufacturing. Some research and development (R&D) funders included equitable access clauses in commercialization agreements, but these are not publicly available. Suppliers, meanwhile, expressed interest in engaging with innovative financing partners at later stages to help enable equitable access.

In terms of candidate-specific pricing strategies shared by supply stakeholders:

- MTBVAC's partner coalition indicated that pricing will be anchored in principles of affordability, equity and sustainability.
- Quratis indicated it will pursue a tiered pricing model, considering affordability for LICs. It emphasized the importance of advanced market commitments (AMCs) and volume guarantees to ensure affordability and sustainability.
- Gates MRI indicated that pricing for LMICs will likely follow a cost-plus or similar approach to ensure affordability, dependent on several factors such as manufacturing scale, efficiencies and long-term volume commitments..

Manufacturing plans in development with varying degrees of licensing partnerships planned

Several suppliers noted plans to scale up production to meet concrete demand for their products, once known, and to help address the large unmet public health need for these vaccines. Some suppliers plan to build manufacturing capacity through licensing agreements with other manufacturers, while other suppliers have existing manufacturing capacity to leverage. In some instances, regionally exclusive licensing deals or originator-controlled supply may limit global supply flexibility. Some suppliers highlighted the need to ensure licensing agreements do not result in market fragmentation, which may drive prices upwards. Manufacturing also requires sufficient adjuvant capacity, not only antigen capacity. Although supply stakeholders confirmed that adjuvant volumes should be sufficient to meet projected demand, adjuvanted vaccines may still require coordination between their respective producers, since the antigen and the adjuvant come from separate supply chains.

In terms of candidate-specific manufacturing plans, supply stakeholders shared the following information:

- Quratis confirmed it holds exclusive rights to manufacturing ID93 + GLA-SE in 44 countries via the Access to Advanced Health Institute (AAHI) but is open to regional licensing and tech transfer to expand equitable access. Quratis stated its good manufacturing practices (GMP) facility can already produce around 100 million doses annually and is scaling up fourfold.
- Biofabri, Bharat Biotech and Fundacao Ataulpho de Paiva (FAP)/Fiocruz will lead manufacturing for MTBVAC in specific geographies. Access clauses are embedded in all partnership agreements to ensure affordability and equitable distribution of vaccines.
- Gates MRI noted plans to provide a technology transfer of the antigen to a lead manufacturer, with planned regional expansion over time. The AS01 adjuvant will be solely supplied by GSK. GSK noted it intends to supply the AS01 adjuvant to meet expected global demand for the M72 candidate.

↓ **Below**
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Regional manufacturing not yet planned in every high-burden region

Plans for ensuring manufacturing capacity in high-burden regions are not uniformly considered and vary depending on the licensing plans of originators. There are regional manufacturing partnerships agreed in the Latin America and South-East Asia regions, but none yet agreed for the Africa region. Quratis indicated interest in African-based manufacturing, although this is not currently part of the company's scope for this candidate. In addition, the supplier of one of the late-stage candidates noted consideration of an Africa-based manufacturer for the future.

Manufacturers flagged three risks related to manufacturing readiness

RISK 01 A lack of clear funded demand signals from countries, which prevent the early and at-risk investments needed to scale manufacturing capacity and ensure rapid access. Manufacturers require clarity in demand signals to plan their manufacturing capacity.

RISK 02 High costs of tech transfer, both financial and operational, can increase final vaccine prices. They also add complexity to the supply chain, creating additional risks and expenses. Further, manufacturing partner(s) must be chosen carefully: partners must comply with global GMP and operate in countries with sufficient regulatory maturity, preferably WHO Global Benchmarking Tool Maturity Level 3 (ML3) or higher, to facilitate WHO PQ for vaccine production *(6)*.

RISK 03 Fill-finish infrastructure across LICs and MICS may require further investment to establish adequate production capacity in line with antigen production and achieve required volumes. Proven fill-finish models from the COVID-19 pandemic were highlighted as replicable in MICs.

AMCs and pooled procurement seen as key to de-risk manufacturing

On the procurement and financing side, self-financing MICs with a high burden of disease and high expected volumes of procurement are seen as a key market opportunity from a financial value standpoint. Gavi-eligible high-burden countries also represent a key market opportunity from a volume perspective. AMCs, volume guarantees and pooled procurement were frequently cited as foundational tools for creating predictable demand and to de-risk investments by manufacturers in scaling production capacity. Suppliers generally view volume-based AMC models favourably, particularly when they are initiated early enough in the product development cycle. Suppliers noted that AMCs have previously been introduced too late and after major manufacturing decisions have been made, which limits their influence on supply planning.

Suppliers flagged expectations that self-procuring MICs will fund TB vaccine procurement through domestic funds, noting uncertainty on external support. Concerns were also flagged regarding the current fiscally constrained environment and the need for clear funding signals from countries and global partners who will finance the procurement of vaccines. Suppliers emphasized that global actors and donors are critical to closing access gaps by convening buyers, aggregating volumes and sending early demand signals.

Key takeaways from supply stakeholder consultations

The key takeaways capture a summary of the views of the F&A WG on barriers and solutions.

Accelerating suppliers' investments and the scale of vaccine manufacturing requires clarity on the funded demand from countries and global buyers. Likewise, supply volumes, availability and price will influence country demand forecasts and introduction plans. Given the interlinked dynamics and risk of delays and long lead times in the absence of two-way information flow, global stakeholders could play a critical role in fostering transparency and coordination. To prevent delays and long lead times between country-funded demand signals and early manufacturing investments, several actions are needed.

- **Demand certainty through volume and financing commitments from countries and/or partners** can incentivize suppliers to invest in manufacturing at-risk and ensure supply is scaled up early and adequately. To support this, suppliers need:
  - concrete volume commitments from countries and global buyers backed by financing that cover the needs of countries that have demand for products in the first years after product licensure;
  - AMCs, volume guarantees or other market-shaping and financing instruments activated early enough can support manufacturing de-risking, while ensuring equitable pricing and access terms from suppliers;

- global coordination between actors involved in supply and demand to minimize delays, incentivize actions by different stakeholders in parallel and help ensure risk is shared between manufacturers, donors and countries, and maximize public health impact.

- **Accelerating equitable country access to supply** requires suppliers to make products available to all countries with demand, prioritize allocation to high-burden countries and ensure affordability. This needs to be balanced with ensuring long-term commercial viability and the sustainability of the supply base. The following are key challenges and areas for further action.

  - Advocate for public transparency on supplier access and pricing strategies, licensing agreements and plans to ensure concrete plans that promote equity materialize, reduce information asymmetries and help country planning.

  - Support the affordability of products through predictable, aggregated and at-scale demand and purchasing commitments (e.g. AMCs, volume guarantees), which incentivize manufacturing at scale and reduce the level of risk factored into product pricing.

  - Increase affordability through strengthened buying power while ensuring commercial viability. Tiered pricing does not guarantee affordability, particularly when MICs face heterogeneous pricing depending on their buying power. Instruments that aggregate volumes and secure advance price agreements across tiers – for example, by setting a predictable price for MICs – can strengthen buyer power. They also support funding and demand planning while improving affordability for countries (e.g. through AMCs or volume guarantees).

- **To accelerate equitable country access to supply** requires that, at the market level, there is a competitive and regionally diversified supplier base. This needs to be balanced with the need to ensure long-term commercial viability and sustainability of the supply base. The following are key challenges and areas for further action.

  - Encourage a competitive market with multiple suppliers to prevent monopoly dynamics and promote supply security by ensuring volume and financing tools are offered to more than one supplier, including pipeline suppliers (e.g. candidates in late-stage development). The current pipeline indicates monopoly and oligopolistic dynamics when the first products enter the market. In addition, only one global supplier produces the adjuvant for one of the advanced candidates, which creates a risk of supply bottlenecks in the future. Supporting first-licensed products is key to ensuring rapid access, while long-term sustainable access will rely on competition and supporting the evolution of the pipeline to ensure multiple products are available.

  - Encourage regional manufacturing capacity in high-burden regions by advocating to originators and intellectual property (IP) holders of late-stage candidates when necessary, provided there are adequate demand signals. Manufacturing plans in multiple regions do not exist for all candidates, and no confirmed late-stage partnerships covering Africa have been established to date. However, regional manufacturing in Africa is under consideration for at least one early-stage and one late-stage candidate

↑ **Above**
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2.4 SUPPLY PROJECTIONS AND COMPARISON AGAINST DEMAND

A realistic supply projection for adult and adolescent TB vaccines expected in the next 10 years is needed to align the TB ecosystem early.

Objectives

This supply projection, developed by Gavi, is a strategic instrument to inform early demand-supply comparison and understand likely supply gaps and the need for potential interventions to address such gaps.

Methodology

All vaccine candidates with the potential to be licensed before 2040, likely to be indicated for adults and adolescents, and developed for global or regional use, were considered in scope. (These vaccines are detailed in Annex D.) Consultations with the developers of five out of the six vaccine candidates of interest were conducted to inform these supply projections.

Typically, supply projections are generated at programme launch, once vaccines are licensed and attributes known. In the case of novel TB vaccines, the supply projection has been conducted approximately 3 years before the first potential licensure and, in some cases, before vaccine developers have fully established manufacturing partnerships, so the methodology has factored in these associated uncertainties. Low, base and high scenarios shown in Fig. 4 were developed to reflect differences in the probability of licensure, doses per regimen, use of the vaccine in PLHIV and available supply volumes. The assumptions have been tested and aligned with a dedicated Expert Group.[1] A critical assumption is that the vaccine is approved for use without the need for screening for previous exposure to TB infection.

Dosing regimens vary across candidates; thus, supply is reported in regimens (e.g. for a 2-dose vaccine, numbers would double).

1 The Expert Group included members with expertise covering TB vaccine development, general vaccine development, vaccine regulation and vaccine manufacturing.

Results overview

High scenario

- This scenario reflects optimistic licensure timings and earlier and higher supply availability based on early scale-up investments.
- Supply levels out in the second half of the 2030–2040 period.
- The annual number of regimens starts at around 20 million and increases to around 160 million regimens.

Base scenario

- This scenario reflects less optimistic licensure timings and increased supply later than under the high scenario, based on post-licensure capacity investments.
- Demand is estimated at 15 million annual regimens in 2030, gradually increasing to about 115 million regimens by 2040.
- The base scenario increase is more gradual than in the case of the high scenario due to investments made later.

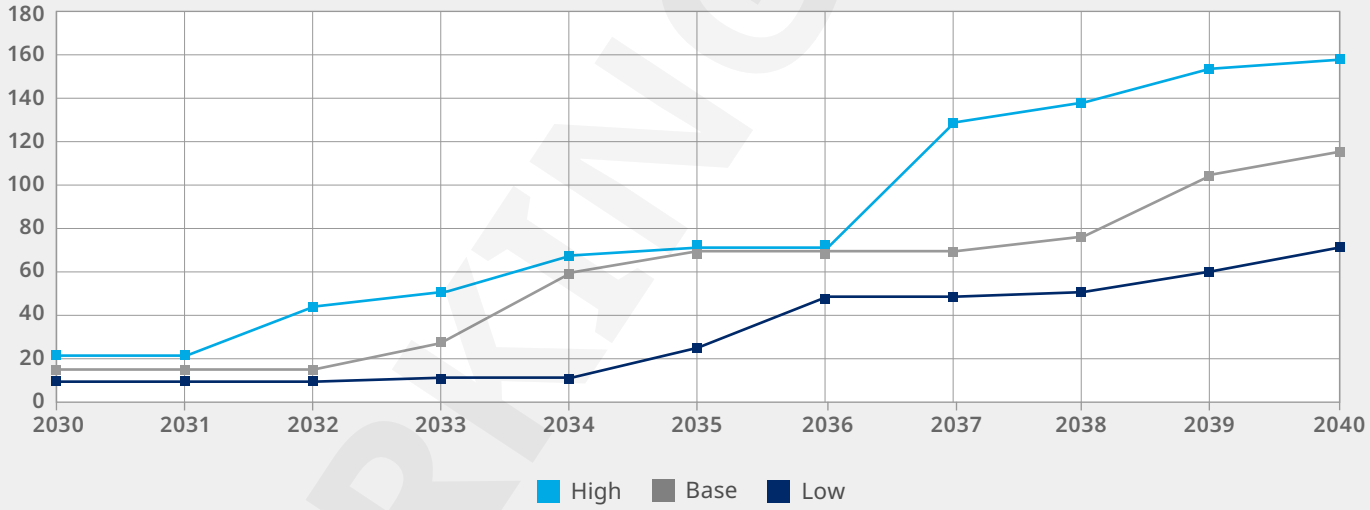
Low scenario

- This scenario reflects licensures later in the 2030–2040 period with a supply increase resulting from post-licensure capacity investments kicking in after 2040.
- Supply starts at around 10 million regimens and increases to around 70 million.

FIG. 4

Supply as projected under the three supply scenarios

Number of **year-on-year** courses (millions) by supply scenario



Comparison of demand and supply projections

The high-demand scenario was used per F&A WG guidance to compare with the three supply scenarios and assess whether projected supply will be sufficient to meet projected demand.

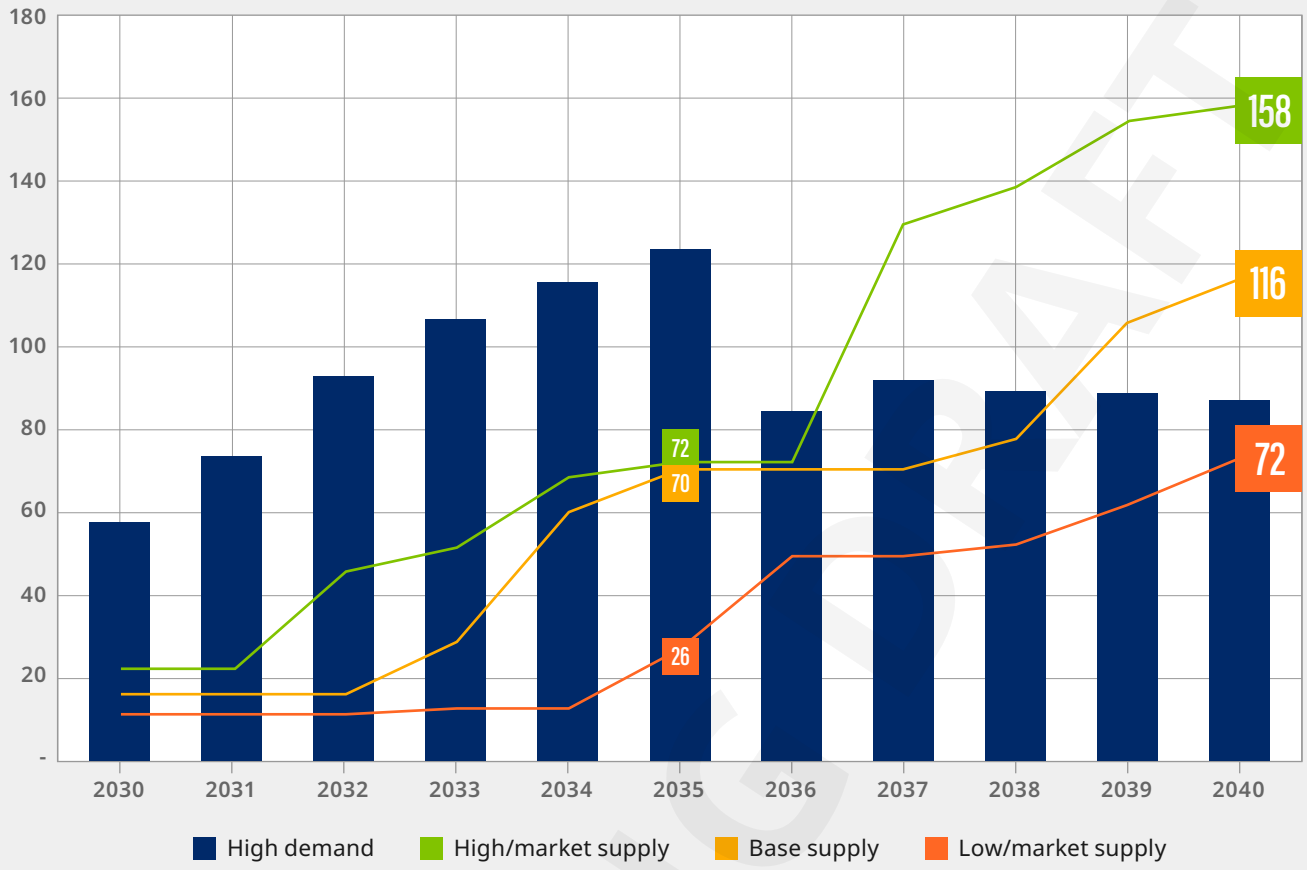
Results overview

Fig. 5 presents a comparison of the high-demand scenario and the three supply scenarios for novel TB vaccines. Under the level of programmatic ambition agreed by the F&A WG to accelerate impact on disease burden (high-demand scenario), supply is projected to be insufficient to meet demand until the second half of the 2030s across all three supply scenarios. From the second half of the 2030s onward, supply is expected to meet demand under the high supply scenario, and by the end of the decade, also under the base supply scenario, but would remain insufficient under the low supply scenario. It is important to note that meeting demand in these scenarios assumes the availability of at least two global vaccine products.

FIG. 5

Demand-supply comparison as projected in demand and supply scenarios

Number of **year-on-year** courses (millions)



Note: For a 2-dose vaccine, these figures would double.

Key findings

Under the high-demand scenario, a projected supply-demand gap in the first 5 years after vaccine introduction is anticipated. The supply gap may amount to about 360 million regimens during this period or an average yearly gap of 60 million regimens.

This gap may limit early access and impact. In this scenario, broad catch-up vaccination for adults in high-risk areas would not be feasible. It would necessitate countries making difficult choices about which groups and areas to prioritize for vaccination and could require global partners and countries to develop allocation frameworks that ensure fair distribution of limited supply. It would mean that people at risk of TB would be made to wait to receive the protection offered by new TB vaccines or seek potentially less desirable alternative preventive interventions. If demand materializes ahead of supply availability, the experience of people seeking vaccination only to be made to wait could have a detrimental impact on long-term demand or contribute to vaccine hesitancy.

Key takeaways

To prevent a potential supply gap as anticipated under the high-demand scenario, several key market-shaping interventions are needed:

- **Early financing commitments and innovative financing mechanisms to ensure funded demand and supply availability at programme launch**. Providing early and solid signals on funded demand is key to incentivize suppliers to make early and at-risk investments to ensure supply availability to support catch-up vaccination from the get-go.

- **Continuous funding of several candidate vaccines**. It is critical to ensure Phase 3 clinical trials of the candidates of global interest are funded to increase the likelihood of at least two global vaccines being licensed, as well as ensuring that studies to enable regulatory authorization and policy recommendations for use are also funded.

- **Continuous information sharing and dialogue with suppliers** (e.g. to support rapid decision-making on capacity investments as new clinical data emerges).
- **Empowering civil society and affected communities to shape demand and purchasing commitments**, monitor vaccine availability, generate demand for new TB vaccines, and monitor the vaccine information landscape for signs of misinformation or hesitancy that may be linked to difficulties accessing new TB vaccines due to supply constraints.

2.5 FINANCING LANDSCAPE

Introduction

Vaccines are among the most cost-effective public health interventions, with an estimated return of $22–51 for every dollar invested *(7)*. Yet many LICs and MICs are facing constraints to continue to support the introduction of novel vaccines, given existing and required levels of government expenditure *(8)*. The global TB response already faces a significant financing gap *(9)*. Limited resources force countries to make difficult trade-offs – between vaccines, and between vaccines and other health interventions. In a constrained funding environment for governments and donors, ensuring adequate and sustainable financing for novel TB vaccines is critical to ensure successful long-term immunization programmes.

Objectives

01 Estimate funding requirements for novel TB vaccines, based on demand and price projections (see Annex E for further details).

02 Identify funding sources and financial commitment towards TB vaccine procurement from domestic and external sources.

03 Assess potential financing gap for countries to procure novel TB vaccines in the first 10 years of product availability.

BOX 2

Scope of financing gap analysis

Please note that this analysis focuses exclusively on the financing gap for procuring TB vaccines and does not estimate financing gaps across the full immunization value chain (e.g. for product development or delivery).

Key findings from financing landscape

The key findings capture a summary of the results of the analysis on financing undertaken by WHO including through modelling and input captured from stakeholder consultations. (see Box 2 for details on scope of analysis and Annex E for details on the methodology and stakeholder consultations).

1

Procurement of TB vaccines for all countries globally could cost $5–8 billion between 2030 and 2040

Under the high-demand scenario in Fig. 2, global demand between 2030 and 2040 is projected to exceed 3 billion regimens. Procuring these vaccines would cost an estimated $5.2–7.8 billion.

The range reflects differences in expected vaccine prices across countries, based on donor eligibility and income classification. (see Box 3 for estimates on funding needs beyond vaccine procurement).

BOX 3

Funding needs go beyond vaccine procurement

It is important to recognize that funding needs for novel TB vaccines extend beyond procurement, which was the focus of this assessment. Using estimates from COVAX (COVID-19 Vaccines Global Access), vaccine delivery costs across the same volumes would add an additional $7.7 billion, bringing the total cost across procurement and delivery to $12.9–15.5 billion *(10)*.

Source: Based on estimates from COVAX Working Group on delivery costs *(10)*.

FIG. 6

Estimated TB vaccine procurement funding requirement of countries segregated by World Bank income classification

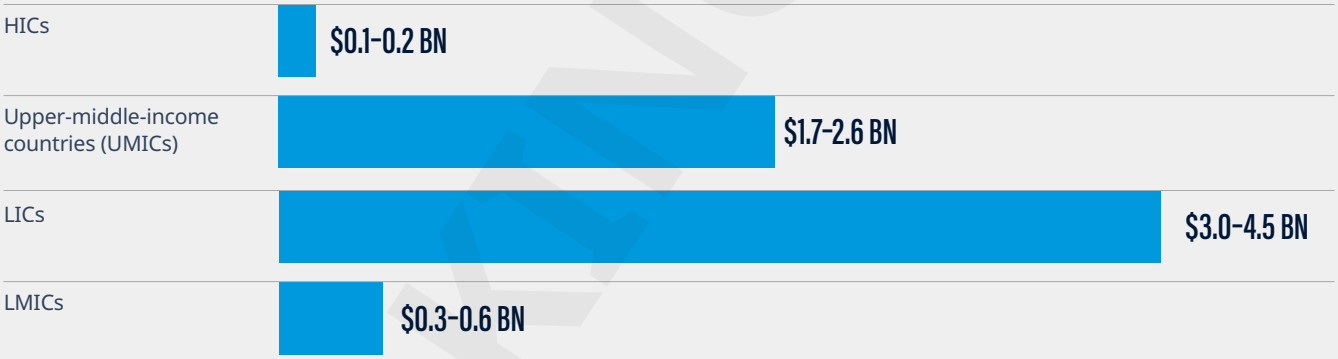


Fig. 6 shows the breakdown across country income groups. MICs account for the largest share of the funding requirement, due to their high TB burden and large populations. For Gavi-eligible countries, the total funding requirement for the procurement of the TB vaccine is estimated to be $0.9–1.6 billion. By comparison, Gavi's total financial support for the HPV vaccine and pneumococcal conjugate vaccine (PCV), including procurement, delivery and health system strengthening costs, across even longer time horizons has been approximately $600 million (2012–2025) and $3.3 billion (2009–2020), respectively *(11,12)*.

The funding requirement for novel TB vaccine is significantly higher than the global Bacillus Calmette-Guerin (BCG) vaccine market value, which was estimated to be $153 million in 2024 *(13)*. It will add to the existing global annual vaccine market, estimated to be nearly $46 billion in 2023, excluding COVID-19 vaccines *(14)*.

This funding requirement will also add to the existing TB funding gap of $16.3 billion in 2024, at least partially, as vaccines are expected to generate savings for governments through prevention and lack of subsequent treatment and care expenses, thereby reducing the existing TB funding gap to an extent *(15)*.

2 No earmarked funding yet available for TB vaccine procurement

Extensive consultations with key financing and procurement stakeholders informed insights related to the availability of financing for novel TB vaccines, as detailed in Annex E. WHO has categorized TB vaccine procurement financing into two main categories: external funding and country financing, which includes loans and liquidity support and domestic funding (Table 1).

TABLE 1

Summary of insights on funding sources for procurement

EXTERNAL FUNDING (External grants provided to countries and payments made for vaccine procurement without the need for repayment by countries)		• Overall availability of external funding could be reduced given major ODA reductions in 2025. • Current external funding for novel TB vaccines is uncertain. • Funders anticipate eligible countries need to prioritize novel TB vaccines among other interventions, should external support become available.
COUNTRY FINANCING (Country financing for procurement of vaccines, either allocated from existing national health budget or loans/liquidity that need to be repaid)	**Loans and liquidity support** (Debt and financing tools such as bridge financing, concessional loans or blended finance which need to be repaid through the national budget)	• Historically, not a key source of financing for vaccine procurement. • Loans and liquidity support can be made available for vaccine procurement, based on country needs and priorities. • Ideally further supported by de-risking approaches like blended financing, co-financing and volume pooling.
	Domestic funding (Budget allocated from a country's existing national health budget)	• Countries stressed that domestic funding depends on national decisions to introduce and fund novel TB vaccines, including consideration of recommendations from WHO and NITAGs. • These decisions will require data on cost-effectiveness, budget, efficacy and pricing, which is not yet available. • Countries with limited budgets may need external support or co-financing, especially amid competing health priorities.

To date, no earmarked funding has been allocated to novel TB vaccines across any of the funding sources. While existing funding could be leveraged, countries and external donors face difficult trade-offs between novel TB vaccines, other vaccines and other TB interventions. These challenges are further compounded by projected reductions in official development assistance (ODA) for health and the need to balance investments across multiple priorities *(16)*.

Countries have diverse pathways for procurement and financing; although some countries such as South Africa are aiming to become early adopters, budget allocation is considered premature for most given the lack of a licensed product, as well as limited efficacy and cost-effectiveness data.

3 Financing gap will hinge on country and donor prioritization of novel TB vaccines

In the absence of currently earmarked financing commitments, the estimated funding need for 2030-2040 is $5.2–7.8 billion. Whether this funding need is met will depend on domestic allocations, donor commitments and broader ODA, geopolitical and economic trends.

Further, if higher demand and higher prices were to materialize compared to the forecasted figures and proxies used, this would increase the funding need, and vice versa. Finally, vaccine procurement costs are a part of the total funding countries need to support sustainable immunization programmes.

Key takeaways from financing landscape

The key takeaways capture a summary of the views of the Finance and Access Working Group on barriers and solutions.

Ensuring the timely and adequate availability of funding for the procurement of novel TB vaccines requires financing commitments from countries and external donors. This will ensure funding signals incentivize manufacturing at-scale and at-risk, and more affordable pricing can be negotiated. To increase clarity on funding availability and reduce the potential funding gap, several actions are needed:

Early commitments and clarity on funding

- Secure early commitments from early adopter countries to indicate intent to purchase novel TB vaccines, followed by accelerated budget decision pathways, in line with national processes.
- Ensure early donor commitments for countries requiring external support, with clarity on scale, eligibility and timing.

Innovative financing mechanisms

- Develop innovative financing mechanisms, such as social impact or vaccine bonds, to raise funding from non-traditional actors and explore using tools such as sin taxes to raise funds for public spending on vaccination procurement and delivery.

Negotiations for more affordable pricing and increased budget efficiency

- As products reach licensure, leverage aggregated demand to negotiate more attractive prices and volume-based discounts to maximize budget efficiency.
- Strengthen demand forecasting to reduce procurement uncertainty, minimize buffer stock needs and reduce wastage.

Mapping and evidence for decision-making

- Iteratively map funding availability from different sources, and funding needs as price and volume dynamics evolve, to enhance clarity on the funding gap.
- Generate evidence to inform prioritization and decision-making for countries and donors with competing priorities for limited funds.
- Maintain a holistic view of vaccine procurement funding gap, in light of funding gaps for R&D, delivery costs and procurement and delivery of other TB interventions.

Below
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References

1. Vaccine markets. In Immunization, Vaccines and Biologicals [website]. World Health Organization; n.d. (https://www.who.int/teams/immunization-vaccines-and-biologicals/vaccine-access/mi4a, accessed 16 September 2025).

2. MI4A Market Studies. In Immunization, Vaccines and Biologicals [website]. World Health Organization; n.d. (https://www.who.int/teams/immunization-vaccines-and-biologicals/vaccine-access/mi4a/mi4a-market-studies, accessed 16 September 2025).

3. Clark RA, et al. The impact of alternative delivery strategies for novel tuberculosis vaccines in low-income and middle-income countries: a modelling study. Lancet Global Health. 2023;11(4): e546-e555.

4. TB Vaccine Clinical Pipeline. In: Stop TB Partnership [website]. Stop TB Partnership (https://newtbvaccines.org/tb-vaccine-pipeline/clinical-phase/, accessed August 2025).

5. WHO Evidence Considerations for Vaccine Policy Development for Tuberculosis Vaccines Intended for Adults and Adolescents. Geneva: World Health Organization; 2024 (https://iris.who.int/handle/10665/376907), accessed August 2025).

6. List of National Regulatory Authorities (NRAs) operating at maturity level (ML3)1 and maturity level 4 (ML4) (as benchmarked against WHO Global Benchmarking Tool (GBT). World Health Organization; 2024 (https://cdn.who.int/media/docs/default-source/medicines/regulatory-systems/wla/list-of-nras-operating-at-ml3-and-ml4.pdf, accessed August 2025).

7. Sim SY, et al. Return On Investment From Immunization Against 10 Pathogens In 94 Low- And Middle-Income Countries, 2011–30. Health Affairs. 2020;39(8) (https://www.healthaffairs.org/doi/10.1377/hlthaff.2020.00103, accessed September 2025).

8. Espinal C, Becerra-Posada F, Torres JR. Improving Middle-Income Countries Access to Vaccines. A Blueprint to Overcome Current Challenges. Ann Glob Health. 2023;22:89(1):80. doi: 10.5334/aogh.4151.

9. Financing for TB prevention, diagnostic and treatment services. In Global Tuberculosis Report 2024. Geneva: World Health Organization; 2024 (https://iris.who.int/handle/10665/379339, accessed August 2025).

10. Costs of delivering COVID-19 vaccine in 92 AMC countries. COVAX Working Group; 2021 (https://www.who.int/docs/default-source/coronaviruse/act-accelerator/covax/costs-of-covid-19-vaccine-delivery-in-92amc_08.02.21.pdf, accessed August 2025).

11. Human papillomavirus (HPV) vaccine market shaping roadmap. Gavi, the Vaccine Alliance; 2024 (https://www.gavi.org/news-resources/knowledge-products/human-papillomavirus-hpv-vaccine-market-shaping-roadmap, accessed August 2025).

12. Pneumococcal vaccine support. In Gavi, the Vaccine Alliance vaccine support [website]. Gavi, the Vaccine Alliance; 2025 (https://www.gavi.org/types-support/vaccine-support/pneumococcal, accessed August 2025).

13. Bacillus Calmette-Guérin (BCG) Market and Supply Update. UNICEF Supply Division; 2024 (https://www.unicef.org/supply/media/22761/file/BCG-Market-update-october-2024.pdf, accessed August 2025).

14. Global vaccine market report. World Health Organization; 2024 (https://iris.who.int/bitstream/handle/10665/380367/B09198-eng.pdf, accessed August 2025)

15. Financing for TB prevention, diagnostic and treatment services. In Global Tuberculosis Report 2024. World Health Organization; 2024 (https://iris.who.int/handle/10665/379339, accessed August 2025).

16. Cuts in official development assistance. Organisation for Economic Development and Co-operation; 2025 (https://www.oecd.org/en/publications/cuts-in-official-development-assistance_8c530629-en/full-report.html, accessed August 2025).