Catalysing solutions for equitable global access and sustainable financing for novel tuberculosis vaccines for adults and adolescents

World Health Organization

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Foreword

Tuberculosis (TB) is one of the world's deadliest infectious diseases. Despite global commitments to end TB by 2030, progress is fragile. Every year, more than 10 million people fall sick with TB and more than one million people die from the disease, mostly in low- and middle-income countries.

Global efforts to combat TB have saved an estimated 79 million lives between 2000 and 2023. However, drastic cuts in health financing, rising drug resistance and disruptions to health services due to conflicts, natural disasters and other shocks threaten this progress.

The World Health Organization (WHO) is committed to supporting science to find new solutions to fight TB. More than a century after the introduction of BCG, the only licensed TB vaccine, promising novel TB vaccine candidates have reached late stage development, offering the potential to alter the trajectory of the global TB epidemic.

WHO estimates that, over 25 years, a vaccine for adolescents and adults that is 50% effective could avert up to 76 million TB cases, 8.5 million deaths, 42 million courses of antibiotics and up to US$42 billion in costs faced by households affected by TB affected, especially for the poorest and most vulnerable (*1*).

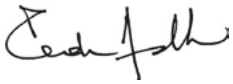
In 2023, WHO established the TB Vaccine Accelerator Council to facilitate the development, testing, authorization, and use of new TB vaccines. The Council convenes governments, partners, financing institutions, and civil society to coordinate global efforts across the vaccine value chain, from research and development through manufacturing and regulatory readiness to financing, procurement and country introductions. The TB Vaccine Accelerator provides a platform for collaboration to ensure that the next generation of TB vaccines translates rapidly into public health impact.

We know from prior experience that finance and access considerations are critical to accelerate vaccine rollout. As the science moves forward, pathways for ensuring equity and access must be included in early plans for manufacturing. In addition, ensuring sustainable financing for procurement and supporting the evolution of healthy TB vaccine markets will be vital for maximizing the speed and impact of introduction.

This report represents one of the first outputs of the TB Vaccine Accelerator's Finance and Access Working Group, reflecting insights from the group itself, as well as from high-burden countries and public and private partners. The report provides an analysis, with concrete solutions for how to prepare for country access to and financing of new vaccines.

New TB vaccines have the potential to save millions of lives faster and change the course of the epidemic. By harnessing the power of science, partnership and finance, we can realize our shared vision to end TB.

Dr Tedros Adhanom Ghebreyesus
Director-General, WHO



South Africa is a proud member of the TB Vaccine Accelerator and co-convener of the F&A WG. The Working Group brings together a remarkable assembly of expertise, commitment and shared purpose, reflecting the urgency and scale of the challenge before us, and the extraordinary opportunity we have to transform the future of TB prevention and control globally in a way that is sustainable, equitable and impactful. We are firmly committed to ending TB and have long been at the forefront of the global fight against TB, including hosting multiple clinical trial sites for promising TB vaccine candidates. As a result, we are now proactively preparing for TB vaccine candidates that are still in clinical trials.

Dr Aaron Motsoaledi
Minister of Health, Republic of South Africa;
Co-convener, F&A WG

The TB Vaccine Accelerator is a vital tool to ensure equitable access to novel TB vaccines, and Gavi, the Vaccine Alliance, is honored to play our part. As co-convener of the TB Vaccine Accelerator F&A WG, we bring decades of experience in vaccine market shaping and financing. In 2024, Gavi added novel TB vaccines to our vaccine portfolio, enabling us to accelerate our work to develop market shaping and financing strategies for low-income and middle-income countries. That work will continue throughout 2026 and beyond, as we work with WHO and other partners to unlock the potential of novel TB vaccines for all who can benefit.

Dr Sania Nishtar
Chief Executive Officer, Gavi, the Vaccine Alliance; Co-convener, F&A WG

Brazil strongly supports the WHO TB Vaccine Accelerator Council and the F&A WG, which aims to catalyze innovative and sustainable solutions for equitable global access and financing of novel TB vaccines for adults and adolescents. This multilateral effort reflects the shared understanding that science and solidarity must go hand in hand to achieve global health equity. The Government of Brazil considers the elimination of TB as a public health problem a national priority, which the Brazilian research and innovation ecosystem stands ready to respond to. Brazil believes that with advance planning, strategic investments, and strong partnerships, effective implementation of new technologies is achievable. Brazil remains firmly committed to international cooperation, scientific advancement, and equitable access, calling upon global partners to join us in transforming the promise of a new TB vaccine into a reality for all.

Dr Alexandre Padilha
Minister of Health, Brazil; Co-chair, TB Vaccine Accelerator Council

As one of the countries with the highest TB burden, ensuring the availability of a novel TB vaccine is a national priority for Indonesia. The country stands ready to lead global efforts to accelerate the development and deployment of a new TB vaccine through strong political commitment, regional collaboration and strategic investment in research and manufacturing capacity. Indonesia is demonstrating concrete leadership toward equitable access, turning innovation into availability and advancing the shared goal of ending TB worldwide.

Budi Gunadi Sadikin
Minister of Health, Indonesia; Co-chair, TB Vaccine Accelerator Council

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WHO thanks the F&A WG members for their contributions including through developing a shared vision; providing input to the methodology, findings, key takeaways, solutions and recommendations; and reviewing the report.

Members of the F&A WG are (listed alphabetically): Dinesh Arora (Asian Development Bank), Abebe Genetu Bayih (Africa Centres for Disease Control and Prevention), Grania Brigden (Global Fund to Fight AIDS, Tuberculosis and Malaria), Erlina Burhan (Coalition Against TB, Indonesia), Santiago Cornejo (Pan American Health Organization Revolving Fund for Access to Vaccines), Verena Damovsky (Clinton Health Access Initiative), Fernanda Dockhorn Costa Johansen (Ministry of Health, Brazil), Ana Liza Hombrado Duran (Research Institute for Tropical Medicine, Philippines), Eder Gatti Fernandes (Ministry of Health, Brazil), Mike Frick (Treatment Action Group), Dominic Hein (Co-convenor; Gavi, the Vaccine Alliance), Valeria Iansante (European Investment Bank), Andrew O. Jones (United Nations Children's Fund), Gillian Leitch (MedAccess), Marion Menozzi-Arnaud (Co-convenor; Gavi, the Vaccine Alliance), Nicolas Alan Menzies (Harvard T.H. Chan School of Public Health), Lindiwe Mvusi (Co-convenor; Government of South Africa), Norbert Ndjeka (Co-convenor; Government of South Africa), Cristina Niculescu (European Investment Bank), Murat Ozturk (Pan American Health Organization Revolving Fund for Access to Vaccines), Guy Pickles (MedAccess), Tara Lavanya Prasad (Co-convenor; WHO), Tiziana Scarna (formerly Gavi, the Vaccine Alliance), Dauda Foday Suma (African Development Bank), Bonanza Perwira Taihitu (Ministry of Health, Indonesia), Frauke Uekermann (Clinton Health Access Initiative), Eliud Wandwalo (Global Fund to Fight AIDS, Tuberculosis and Malaria), Richard White (London School of Hygiene and Tropical Medicine) and Matteo Zignol (Co-convenor; WHO).

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Abbreviations

AFRICA CDC	Africa Centres for Disease Control and Prevention
AMA	African Medicines Agency
AMC	advance market commitment
APPM	African Pooled Procurement Mechanism
AVMA	African Vaccine Manufacturing Accelerator
CEPI	Coalition for Epidemic Preparedness Innovations
CHAI	Clinton Health Access Initiative
CMC	chemistry, manufacturing and controls
COGS	cost of goods sold
CSOs	civil society organizations
DFIs	development finance institutions
ECVP	Evidence Considerations for Vaccine Policy
EIB	European Investment Bank
EPI	Expanded Programme on Immunization
F&A WG	Finance and Access Working Group
FAP	Ataulpho de Paiva Foundation
G6PD	glucose-6 phosphate dehydrogenase
GATES MRI	Gates Medical Research Institute
GDF	Global Drug Facility
GMP	good manufacturing practices
GNI	gross national income
GPEI	Global Polio Eradication Initiative
GSK	GlaxoSmithKline
GTB	Global TB Programme
HCW	healthcare workers
HHC	household contacts of TB patients
HICs	high-income countries
HIPC	Heavily Indebted Poor Countries
HPV	human papillomavirus
HRG	high-risk groups
HSIS	health systems and immunization strengthening
HSS	health system strengthening
IAVI	International AIDS Vaccine Initiative
IDA	International Development Association
IDFF	InnovFin Infectious Diseases Finance Facility
IFFIM	International Finance Facility for Immunisation
IFPMA	International Federation of Pharmaceutical Manufacturers and Associations
LICs	low-income countries
LMICs	low- and middle-income countries
LSHTM	London School of Hygiene and Tropical Medicine
MCMs	medical countermeasures
MDB	multilateral development bank
MDR/RR	multidrug-resistant/rifampicin-resistant
MI4A	market information for access to vaccines
MICs	middle-income countries
MTB	Mycobacterium tuberculosis
NITAGs	National Immunization Technical Advisory Groups
ODA	official development assistance
PAHO RF	Pan American Health Organization Revolving Fund
PBF	performance-based funding
PCV	pneumococcal conjugate vaccine
PEPFAR	President's Emergency Plan for AIDS Relief
PLHIV	people living with HIV
PMI	President's Malaria Initiative
POL	probability of licensure
PQ	WHO prequalification

R&D	research and development
RI	routine immunisation
RIF	resistance to rifampin
SAGE	Strategic Advisory Group of Experts on Immunization
SII	Serum Institute of India
TAG MVAC	WHO Technical Advisory Group on Market Access for Vaccines
TB	tuberculosis
UMICs	upper-middle-income countries
UNICEF	United Nations Children's Fund
USAID	United States Agency for International Development
VII	Vaccine Independence Initiative
WHO	World Health Organization

Executive summary

TB remains a global health challenge demanding urgent innovation

No new TB vaccine has been licensed in over a century beyond the Bacille Calmette-Guérin (BCG) vaccine. The BCG provides only partial protection against severe forms of TB in infants and young children and offers limited and inconsistent protection against pulmonary TB in adolescents and adults. Today, TB continues to kill more than one million people annually, with 10 million new cases each year, largely among adults and adolescents in low- and middle-income countries (LMICs). It is the leading cause of death among people living with HIV and a major driver of antimicrobial resistance. The persistent gap in prevention underscores the urgent need for coordinated global action to accelerate vaccine development, access and sustainable financing.

Purpose of this report

To support early access planning and ensure sustainable financing, F&A WG *(2)* of the TB Vaccine Accelerator Council *(3)* conducted a landscape analysis to assess the readiness of countries, suppliers, markets and financing systems for the equitable introduction of novel TB vaccines. This report outlines an integrated view of the evolving TB vaccine ecosystem encompassing different dimensions and providing key insights into gaps and bottlenecks to equitable access and sustainable financing. Based on the analysis and insights, key solutions are proposed to inform the pathway for action by governments, suppliers, civil society, donors and global health partners. A call to action identifies key roles and responsibilities of different stakeholders and next steps capture plans for the F&A WG to take forward needed solutions.

Key findings from analysis

Each analysis in the report identifies key findings, which are summarized below. In addition, the F&A WG's interpretation of the relevance of these findings and impact on novel TB vaccines is detailed in each chapter in Section 2 under 'Key takeaways'.

- **Country access to TB vaccines and financing is a key concern even as countries prepare for vaccine rollout.** National strategies for vaccine introduction, financing and delivery models vary widely. Countries require local evidence, cost-effectiveness data and WHO policy guidance to make informed decisions. Political support is strong, but no country has yet allocated domestic funds, pending clarity on product attributes, product supply and financing options.
- **Market challenges threaten equitable access.** The TB vaccine pipeline is advancing, with at least 16 candidates in development and six in Phase 3 trials. Manufacturers face uncertainty on country demand and financing and are seeking clearer commitments. Manufacturers are yet to share concrete access strategies and while manufacturing plans are under development, regional manufacturing is not yet planned in every high burden region for late-stage candidates.
- **Global demand for TB vaccines will outpace supply in the critical early years**. The global demand for novel TB vaccines between 2030 and 2040 is projected to exceed three billion regimens, with high-burden countries driving most of the demand. However, supply projections indicate a gap in the initial years after vaccine introduction (2030-2035), risking delayed access and reduced public health impact. Manufacturing capacity, especially in high-burden regions, is not yet assured, and supply of components could be a rate-limiting factor for mitigating this gap.
- **Global procurement of TB vaccines for all countries could cost US$5–8 billion between 2030 and 2040; however, no earmarked funding currently exists.** Countries have diverse pathways for procurement and financing. External financing will be needed to complement domestic financing, particularly in LMICs and low-income countries (LICs) facing fiscal constraints. However, countries and external donors face difficult trade-offs between novel TB vaccines, other vaccines and other TB interventions as they begin preparing plans for financing the vaccines.

Proposed solutions and way forward

Accelerating equitable access to novel TB vaccines will require early, coordinated and transparent global action. The F&A WG proposes six interlinked solutions that collectively address the anticipated barriers to access. These solutions are briefly explained in this section; further details can be found in Section 3 of this report.

Solution 1

Global catalytic instrument(s) that assure(s) funded demand from countries and donors to incentivize manufacturers to expand capacity and negotiate more affordable price(s).

Solution 2

Systematic and early generation of country-led evidence packages including demand forecasts, cost-effectiveness analyses and budget impact studies that enable governments to make timely and informed decisions.

Solution 3

Clarity on available domestic financing commitments and external support, supported by scenario modelling[1], that can help identify gaps and mobilize resources.

Solution 4

Coordination platform for supply and demand stakeholders to align, supported by shared roadmaps and regular dialogue that can help synchronize timelines between manufacturing, financing and country access.

Solution 5

Sharing of key information that is important for equitable access and is not commercially sensitive, to support country planning and trust building through market transparency.

Solution 6

Advocacy for licensing and technology transfer to at least one manufacturer in each high-burden region that can help strengthen supply security, regional ownership and vaccine acceptance.

Looking ahead

In 2025, the F&A WG mobilized to operationalize the vision of bringing together countries and partners across the global health architecture to address the identified challenges. The work ahead will focus on stakeholders committing to, designing, developing and advancing these solutions with the F&A WG serving as a global coordination mechanism.

Realizing the promise of novel TB vaccines will depend on joint commitment and collaboration among governments, donors, manufacturers, civil society and multilateral organizations. Only through such collective action can novel TB vaccines be positioned as global public goods that reach all who need them and contribute decisively to ending the TB epidemic.

1 An initial model has already been developed by WHO (see Annex 6) and can be used by the F&A WG in 2026 to take forward this analysis, which can be iterated as more information becomes available.

1 Introduction

1.1 Background

The global TB epidemic is a serious threat to global health and development and requires urgent action. Every year, more than 10 million people fall ill with TB, mostly adults and adolescents, and more than one million die from the disease *(4)*. Global efforts to combat TB have saved an estimated 79 million lives since the year 2000 *(5)*. However, progress is uneven within and across countries due to unequal access to healthcare, stigma, inadequate financing, conflicts and natural disasters. Today, TB is one of the leading causes of death of people living with HIV and is a key driver of antimicrobial resistance *(6, 7)*. About a quarter of the world's population has been infected with *Mycobacterium tuberculosis*, which increases the risk of developing TB disease *(8)*.

Despite TB's devastating global impact, no new TB vaccines have been licensed in over a century. The burden among adults and adolescents is particularly concerning. This age group constitutes both the most productive segment of society and the main driver of TB transmission. The BCG vaccine, the only licensed TB vaccine in use today, provides partial protection against severe forms of TB in infants and young children but offers limited and inconsistent protection against pulmonary TB in adolescents and adults, who account for the majority of transmission. As a result, the global TB epidemic continues to circulate widely, underscoring the urgent need for new vaccines that can protect older age groups and interrupt community transmission.

Current TB control efforts rely primarily on timely diagnosis and treatment, complemented by preventive therapy and social-protection measures that address the broader determinants of infection. The presence of safe, effective, affordable and accessible TB vaccines, particularly for adolescents and adults, is essential to accelerating reductions in TB illness, transmission and mortality, as was highlighted in the political declaration adopted by all countries at the 2023 United Nations General Assembly *(9)*. The TB Vaccine Accelerator was established by WHO with multiple partners to catalyse global action towards this goal.

1.2 A vision for equitable access to novel TB vaccines

In February 2025, the TB Vaccine Accelerator established the F&A WG to promote timely, equitable and sustainably financed access to affordably priced new TB vaccines for adults and adolescents. This was driven by public health need and by the goal of fostering long-term sustainable supply. Since TB primarily impacts LMICs and has limited market potential in high-income regions, a strategic approach to market shaping, access and financing is essential.

The F&A WG's mandate is to coordinate 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.

The F&A WG is co-convened by WHO, Gavi, the Vaccine Alliance, and the Government of South Africa. In addition to the co-convenors, the F&A WG members include the African Development Bank (AfDB); Africa Centres for Disease Control and Prevention (Africa CDC); Asian Development Bank (ADB); Clinton Health Access Initiative (CHAI); 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.

To achieve this vision and mandate, the scope of the working group is:

i) To accelerate manufacturing, supply and access to quality-assured novel TB vaccines from a competitive and geographically diversified supply base and at adequate scale to meet country demand. This includes:

- ensuring sustainable supply and a balance between

commercial viability for suppliers and economic feasibility for countries;

- promoting vaccine manufacturing by at least one manufacturer in each high-burden region to ensure regional supply security; and

- reducing information asymmetries, promote transparency on price and on non-commercially sensitive manufacturing and access strategies, and ensure suppliers develop go-to-market strategies that centre access considerations.

ii) To accelerate the materialization of predictable and long-term demand from governments. This includes:

- expediting the procurement of vaccines by governments and other buyers (on behalf of high-burden countries); and

- accelerating the introduction and scale up of novel TB vaccines and optimizing the public health impact for their populations.

iii) To accelerate sustainable financing for the procurement of novel vaccines to meet country demand. This includes:

- promoting domestic financing from all countries and promoting financing from external sources to support countries in need; and

- ensuring funded demand for novel TB vaccines is quantified and shared with industry as a market signal.

iv) To promote the alignment of efforts and resources across stakeholders including governments, multilateral organizations, civil society organizations, and the private sector involved. The composition of the F&A WG has strengthened partnerships across countries, international agencies, philanthropy, multilateral banks, public-private collaborations, donors, civil society and experts.

The four key areas above are highly inter-dependent and achieving one objective requires the others to succeed. For example, for supply to materialize, concrete and funded demand needs to be signalled. For demand to materialize, available and affordable supply needs to be signalled. For funding to materialize, anticipated supply and estimated demand need to be projected to understand funding needs, vaccine prices and cost-effectiveness. This is why alignment of resources and coordination is key: to optimize timing and sequencing of decisions and actions by multiple stakeholders over different time horizons.

In 2025, the F&A WG prioritized the development of technical analyses to inform an early understanding of anticipated barriers, bottlenecks, challenges and market dynamics relevant to country financing and access for novel TB vaccines. In-depth consultations with multiple stakeholder groups (e.g. countries, suppliers and subject matter experts) provided foundational inputs to the analyses. These analyses were used to accelerate the identification of financing and access solutions to incentivize equitable and sustainably financed global access.

In 2026–2027, the F&A WG will foster the design, development and implementation of priority financing and access solutions based on priorities agreed through stakeholder engagement. The F&A WG will work in collaboration with the TB Vaccine Accelerator's activities on research and development (R&D), policy and country readiness, given interdependencies across the vaccine value chain.

Adolescent students hold up their hands to show they are vaccinated against cholera at a rural school in Kenya., 2023

© WHO / Billy Miaron

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 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 WG 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

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

- low/medium/high demand scenarios
- low/medium/high supply scenarios and comparison with demand to understand gaps in the first decade post-licensure

See Section 2.2

See Section 2.4

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

Together, these five analyses capture both the current situation and projected future scenarios. This helps identify gaps and potential solutions. The analyses are interdependent, revealing root causes and cross-cutting strategies that 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 inherently 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

2.1.1 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 that are both relevant and actionable at the country level.

2.1.2 Objectives

To gather country insights, strategic dialogues were organized 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 1 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 the acceleration of 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,[2] recognizing the wide diversity among high-TB-burden countries globally.

As the insights that follow are mainly representative of middle-income countries (MICs) 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.

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.

2.1.3 Key findings from country consultations

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

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

Countries unanimously 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 they await key evidence from clinical trials and confirmation of product availability. This includes national discussions about priority use cases, eventual financing, demand and supply planning, streamlining of policy and regulatory pathways, local manufacturing opportunities, integration with existing immunization and TB programmes and health system preparedness, including readiness assessments and vaccine acceptance. 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 offering new TB vaccines to high-risk groups; others may focus on high-burden regions. All must balance protecting the most vulnerable with minimizing stigma that could dampen demand.

2 Consultations were conducted with WHO Regional Offices for Africa, Americas, South-East Asia, Eastern Mediterranean and Western Pacific.

Remaining evidence gaps will be critical to inform introduction decisions

Several countries emphasized that generating local evidence through implementation studies will be critical to shaping large-scale rollout decisions, as informed by lessons learned from the RTS,S/AS01 malaria vaccine introduction. Consultations with countries and regional stakeholders 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, the pathway for new vaccine introductions by Ethiopia, a Gavi-eligible high-burden country, will be contingent upon WHO prequalification (PQ) and SAGE recommendations, and Gavi co-financing. Depending on the mechanisms used for novel TB vaccine, some or all of these steps may be needed.

Country introduction will be shaped by access and product attributes

Vaccine access (availability, affordability, acceptability and quality assurance), product characteristics (safety, efficacy, and supply chain and logistical needs), 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, or single-dose vials for community delivery). Without the complete information, some countries will develop multiple scenarios to inform early planning and potential future outcomes.

Countries with capacity prefer local manufacturing but will initially accept imports

Consulted countries with vaccine manufacturing capacity expressed a preference for nationally produced vaccines. However, all remain flexible and open to importing vaccines in the early stages and building fill-and-finish capacity as a transition to end-to-end domestic manufacturing capacity, including production of a drug substance. Overall, the country and regional consultations highlighted that regional manufacturing represents a growing priority. 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. For example, Indonesia highlighted its long-standing experience in producing the BCG vaccines through Bio Farma, which provides a strong foundation to support the production of new TB vaccines if technology transfer and licensing agreements are made available. This would ensure existing manufacturing capacity can be leveraged not only for national use but also for enhanced regional access and supply security.

Pooled and bilateral procurement expected across high-burden countries

MICs that are not Gavi-eligible or transitioning out of donor support are expected to self-procure. Some may be interested in leveraging pooled procurement agencies such as United Nations Children's Fund (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 WHO 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 designed for priority vaccines. Regional platforms like African Vaccine Regulatory Forum (AVAREF) and African Medicines Agency (AMA) will 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 WHO PQ as part of their regulatory and financing procurement pathways.

Political support exists, but it's too early for domestic budget decisions

While political support for introducing novel TB vaccines is strong, no country has yet allocated domestic funds, as it is still too early for a budget decision. Countries flagged the need for robust national cost-effectiveness and health impact data to support decision-making, and the need for global health partners to help bridge critical funding gaps for vaccine procurement in countries with resource constraints. Most of the global TB burden, over 60%, is present in MICs that are expected to self-finance new vaccines based on current financing patterns and substantial domestic financing commitments will be needed. Early advocacy to both the Ministry of Health and the Ministry of Finance in these countries is needed to ensure timely budget allocation for novel TB vaccines. Without early commitments, there is a high risk of delayed adoption in high-burden countries.

Country consultations highlighted that financing needs extend well beyond procurement. Countries also require resources

for enhanced infrastructure, delivery (logistics, distribution, storage and administration), healthcare workforce training and integration into immunization and national TB 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.

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. Consultations highlighted that a mix of delivery approaches could be deployed based on the population targeted. These could include routine immunization, campaign approach, school-based vaccination, PHC services and workplace channels. Countries plan to draw on experiences with COVID-19 and HPV vaccine rollouts and are actively exploring ways to build on existing platforms, leveraging systems in place from relevant disease programmes such as TB and HIV.

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 adolescent and adult populations that include high-risk and hard-to-reach groups. This will necessitate new delivery models, additional targeted investments and further workforce training. Technical support is needed by countries to ensure coordination between immunization and TB programmes.

Addressing vaccine hesitancy is key to ensuring uptake

Effective and proactive communication strategies will be critical to supporting trust, preventing the spread of misinformation and enabling vaccine acceptance. Early engagement with civil society, community, education 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 analysis to guide tailored approaches for overcoming hesitancy among adults.

2.1.4 Key takeaways from country consultations

These 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 product attributes (product access, country-level impact and cost-effectiveness modelling), potential supply 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 domestic financing can help create alignment on how the vaccine is expected to be used and ensure adequate financing. 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; and
- 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 or 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 (WHO/SAGE) policy, prequalification and programmatic guidance from WHO; and
- 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 global/regional solutions to ensure all high-burden countries can partake in demand aggregation approaches without having to commit to procuring through those same systems. Thus, countries can procure bilaterally or through pooled procurement mechanisms and use financing sources appropriate for them (whether domestic and/or external);
- countries to opt for procurement and financing channels suitable to their needs to maintain self-sufficiency, while benefitting from and supporting broader efforts; and
- equitable distribution of global supply (particularly if supply is constrained) through an equitable allocation framework, so that health impact and public health need drive access, rather than country purchasing power.

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;
- willingness from supply stakeholders (originators and licensees) to support regional manufacturing and technology transfer as needed, while avoiding market fragmentation;
- consideration of potential price implications of distributed regional supply; and
- political will within regions to foster regional vaccine manufacturing and ensure equitable regional distribution.

Early investments in immunization 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:

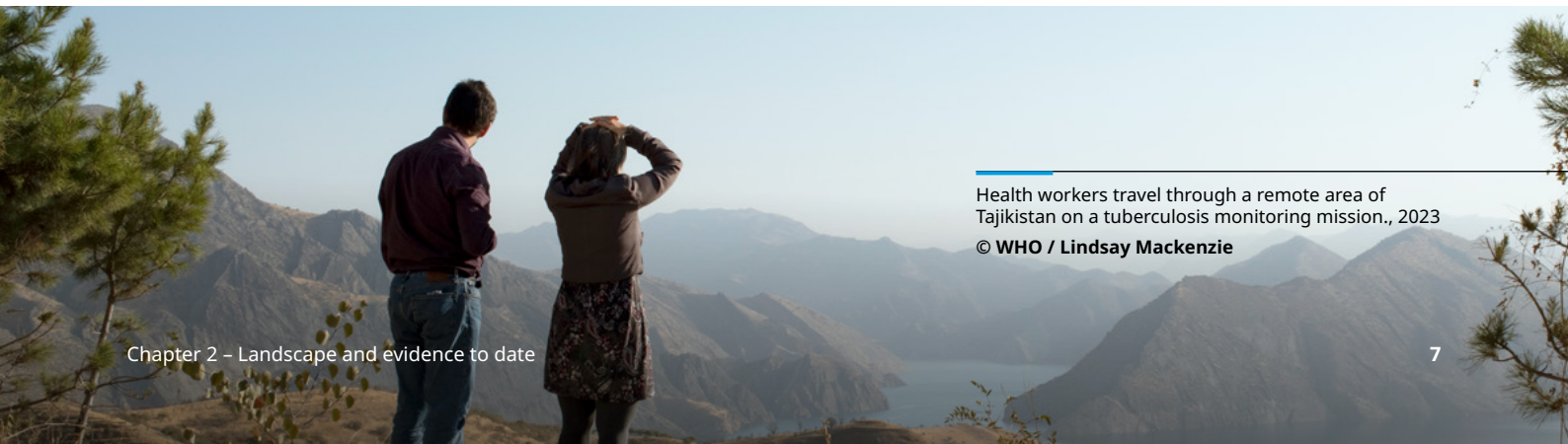
- funding allocated to country readiness and delivery, once relevant plans are developed;
- coordination between the Expanded Programme on Immunization (EPI), TB programmes, primary healthcare and education and workforce sectors;
- community engagement and partnerships with civil society; and
- dedicated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

Sharing clinical trial data on vaccine performance and safety, 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; and
- access to robust information systems to ensure the security and confidentiality of clinical trial data.

Implementation research is a critical enabler for broad and rapid policy recommendations and for setting up and optimizing delivery systems for adolescents and adults. It must be planned well in advance to ensure product introductions at scale are not unnecessarily delayed due to evidence gaps. 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 mobilisation plans;
- global actors to support and fund additional research that could be needed to inform policy recommendations;
- determination of areas/regions for research implementation, considering the highest TB burden; and
- strengthening of regional commitment to support vaccine research implementation.



Health workers travel through a remote area of Tajikistan on a tuberculosis monitoring mission., 2023

2.2 Demand projections

2.2.1 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) demand forecast methodology, which has been used to develop global demand forecasts by WHO for 13 antigens to date (*10*). 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).

2.2.2 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 clinical trial results (earliest end 2027) and their commercial availability and rollout (approximately 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.

2.2.3 Methodology

The global 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. More details on the methodology can be found in Annex 2 and online (*11*). It is premature at the global level to estimate demand per product, as it is not known which specific vaccine products will successfully achieve licensure, nor their performance characteristics. Hence, the projection is product-agnostic and includes projected country demand for any TB vaccine that meets the WHO Preferred Product Characteristics (PPCs) of greater than or equal to 50% efficacy against disease prevention.

The global 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, the 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 focused to specifically inform the demand projection. Further adaptations could be made in future iterations of the forecast following additional country consultations and more detailed information about fiscal and programmatic constraints.

2.2.4 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. These ranged from targeted introductions focusing on high-risk groups[3] to broad catch-up vaccination in adults, followed by routine immunization in adolescents. Accelerating the reduction of the TB burden requires vaccinating adults at scale, while routine immunization of adolescents provides

3 As defined in the WHO's consolidated guidelines on TB, high-risk groups for TB are defined as populations considered at highest risk of progression to disease and/or vulnerability to poor outcomes, namely people with HIV, contacts and other people at risk. In addition, populations in-scope for the forecast, including high-risk groups, were those defined in the WHO Evidence Considerations for Vaccine Policy (ECVP) for TB Vaccines Intended for Adults and Adolescents.

population immunity on a much longer time horizon and generates an impact on the TB burden in the long term (12). While an approach including large catch-up campaigns in adults brings the fastest reduction of TB burden, it is also a more costly and complex approach, as adult vaccination poses significant practical challenges.

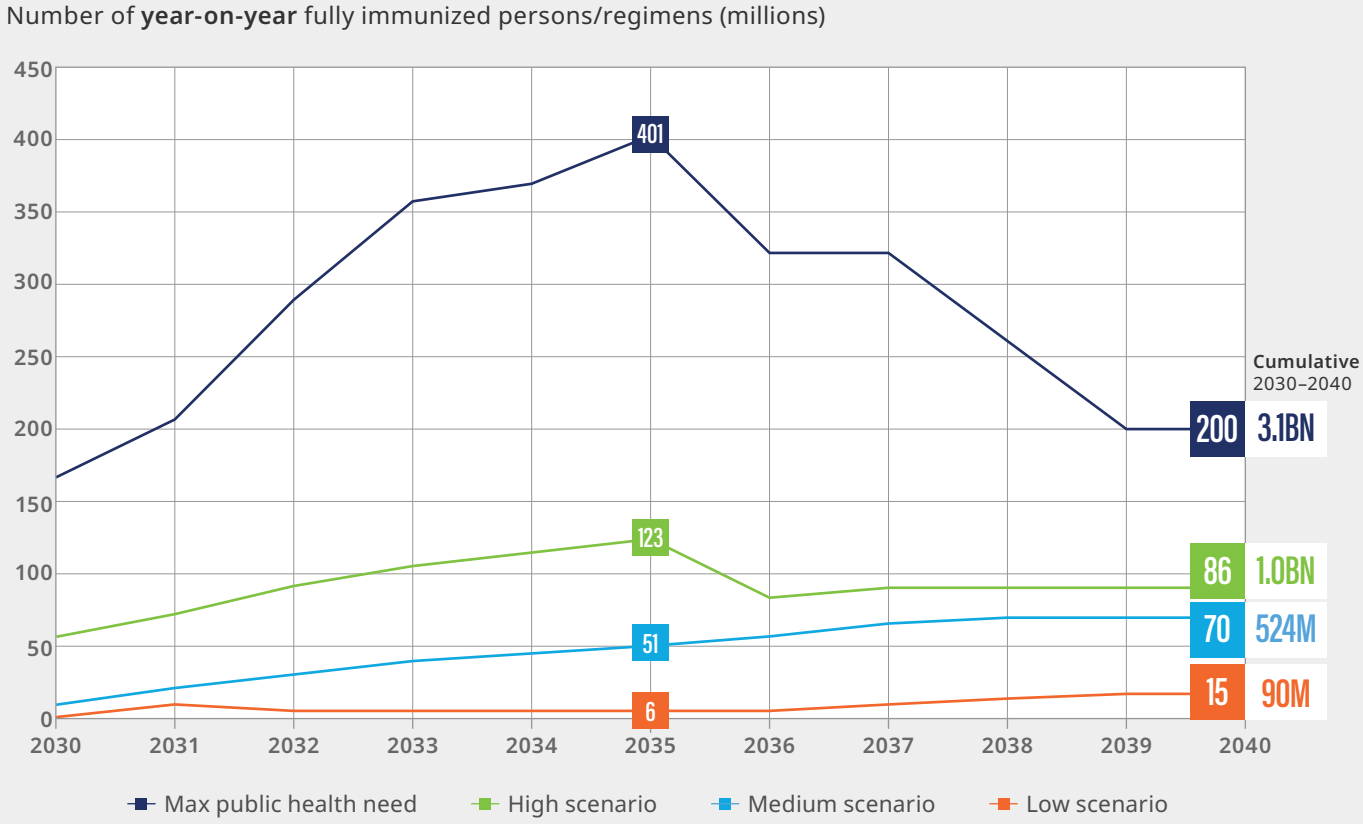
To address the uncertainties and reflect different levels of programmatic ambition shared by country stakeholders, four demand scenarios were developed: low, medium, high and maximum public health need (see Fig. 2). Each scenario reflects differences in the scope of target populations and delivery strategies, 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 ≥50% vaccine efficacy in line with the WHO PPC[4] (13). Across all scenarios, 52 countries are projected to introduce the vaccine during the 2030–2040 period. The scenarios and their assumptions are described in more detail in Annex 2.

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

4 Mathematical modelling studies suggest TB vaccines may be cost-effective at relatively low vaccine efficacy (VE). A preference for a VE at or above 50% is expressed, to better contribute to achieving the ambitious WHO End TB Strategy goals.

Fig. 2

Global demand (regimens) as projected under the four demand scenarios



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

Source: Gavi, the Vaccine Alliance

Maximum public health need scenario

- Catch-up vaccination volumes could be substantial in the first 5–7 years of vaccine availability.
- Populous 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 per year in year five 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.
- India comprises 40% of demand between 2030–2040 (~56% of demand between 2030–2035).

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 these are limited to high-risk groups and do not include broad population vaccination.
- India comprises ~33% of demand between 2030–2040 (~50% of demand between 2030–2035).

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 populous high-burden countries.

2.2.5 Key findings from demand projections

The four scenarios span a broad range of possibilities, from an annual demand of around 10 million regimens to several hundred million. Whether global public health need 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 to influence demand materialization. Higher levels of financing would allow for broader vaccine use.
- **Vaccine efficacy**
  Countries flagged that efficacy below the WHO PPC (less than 50%) would likely limit the use to high-risk populations.

A polio vaccinator makes her way through crop fields to administer polio vaccines in India, 2017

© WHO / Christine McNab, UN Foundation

- **Cost-effectiveness in the local context**
  While a higher product price would 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 addition of a vaccine into other TB programme measures at local level will be essential to inform country decisions about the trade-offs of different tools. At the same time, additional global or regional cost-effectiveness studies would be beneficial to guide broader policy prioritization and investment decisions. Acceptability, equity, community preferences and other factors also influence country decisions.

- **Policy recommendations for specific populations, such as people living with HIV (PLHIV) and those who have not been infected**
  WHO policy recommendations intend to include populations regardless of previous exposure to TB infection and PLHIV, given challenges of testing before vaccination and the importance of HIV/TB comorbidity in several high-TB-burden countries.

2.2.6 Key takeaways from demand projections

The F&A WG discussed the 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. Based on this, this scenario could be considered as the 'optimal demand' scenario and will require up to 120 million regimens annually in the first five years and 90 million annually in the five subsequent years. The materialization of demand will be contingent on factors cited above. Comparison of supply scenarios against the other three demand scenarios can be found in Annex 2.

As a comparison, the maximum public health need scenario 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.

A number of requirements are necessary to ensure demand materializes.

- **Early financing commitments 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 and other vaccines, 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 (i.e. uninfected), to ensure broad eligibility and to avoid pre-screening, which would otherwise be very challenging from a delivery standpoint.

- **Demand generation activities**, including partnerships with communities and civil society, engagement with education and workforce sectors, and training of health care providers, which builds awareness and support vaccine introduction and enables high vaccine uptake.

2.3 Product licensing and access strategies

2.3.1 Introduction

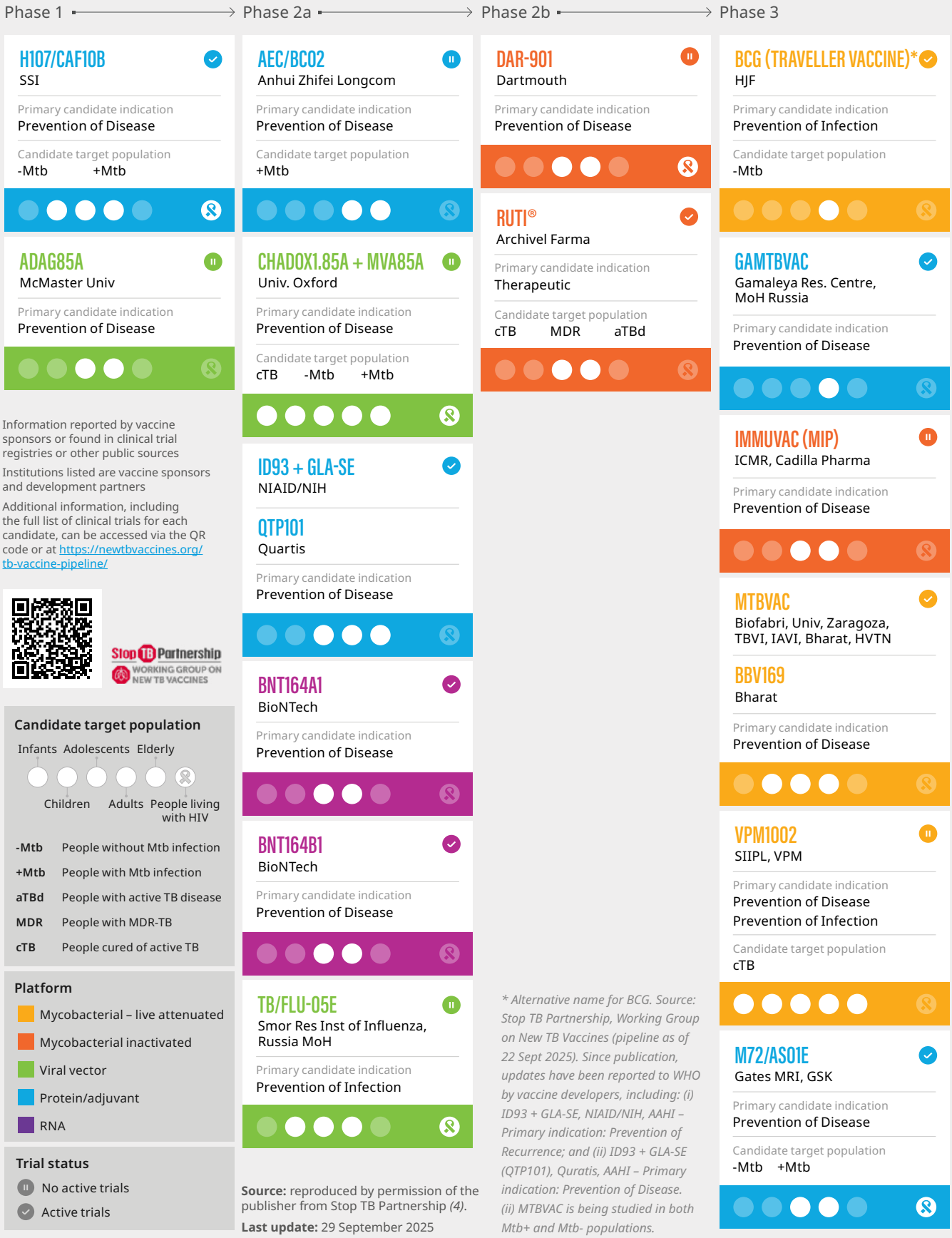
At least 16 TB vaccine candidates are in clinical development, including six in Phase 3 trials (see Fig. 3). Data is anticipated to support regulatory and policy assessment for at least one vaccine candidate within the next three years (2026–2028). Ensuring equitable and timely access to novel products 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, policy and access strategies can also support geographically diverse manufacturing, foster long-term supply sustainability and serve as a foundational pillar for sustained regional manufacturing.

Fig. 3

TB vaccine pipeline

Vaccine candidates under clinical development

There are 16 vaccine candidates in the pipeline as of September 2025, of which nine 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 September 2025

** Alternative name for BCG. Source: Stop TB Partnership, Working Group on New TB Vaccines (pipeline as of 22 Sept 2025). Since publication, updates have been reported to WHO by vaccine developers, including: (i) ID93 + GLA-SE, NIAID/NIH, AAHI – Primary indication: Prevention of Recurrence; and (ii) ID93 + GLA-SE (QTP101), Quratis, AAHI – Primary indication: Prevention of Disease. (ii) MTBVAC is being studied in both Mtb+ and Mtb- populations.*

2.3.2 Objectives

This section outlines key insights from desk research and consultation 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, ID93 + GLA-SE, BNT164a1 and BNT164b1 (see Annex 3 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.

2.3.3 Key findings from supply stakeholder consultations

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

The 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 LICs and MICs, which can help enhance trust and early adoption in these countries. However, most of the late-stage candidates lack the full required Phase 3 funding, which poses a risk to their advancement to licensure, in addition to any 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. 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 evidence that is expected to be needed to inform global policy for priority populations for novel TB vaccines *(14)*. However, product developers are uncertain which populations individual 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 many LICs and MICs creates ambiguity for regulatory approval *(15)*. In addition, early clarity on data requirements for global and national immunization policy and regulatory approval will be critical to reduce uncertainty and risks to manufacturers and to support timely access to products.

Equitable access strategies under consideration lack concrete plans at this stage

All suppliers stated they are actively considering strategies to ensure equitable access to novel TB vaccines, especially in high-burden countries. Supply stakeholders noted that 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. Some suppliers noted intent to use tiered pricing to differentiate across high-income countries (HICs), MICs and LICs. Some also noted that the pricing tiers would be built around cost-of-goods sold (COGS) and depend on the scale of manufacturing. Some R&D funders have 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. MTBVAC's partner coalition indicated that pricing will be anchored in principles of affordability, equity and sustainability, while Gates Medical Research Institute (Gates MRI) indicated that pricing for LMICs will ensure affordability, availability and equitable access, but will be dependent on factors such as manufacturing scale, efficiencies and volume commitments.

Manufacturing plans are 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. It was flagged that, 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. For some candidates, 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 are likely to come from separate supply chains and access channels.

Supply stakeholders shared the following information relating to candidate-specific manufacturing plans:

- 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 Fundação 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.

Regional manufacturing is 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 Latin America and South-East Asia, but none yet agreed for Africa. Quratis indicated interest in African-based manufacturing, although this is not currently part of the company's scope for this candidate. However, regional manufacturing in Africa is under consideration for at least one earlier-stage candidate and one late-stage candidate in the medium term.

Manufacturers flagged three risks related to manufacturing readiness

Risk 1: A lack of clear funded demand signals from countries and supranational funders, 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 2: 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 partners must be chosen carefully; they 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 *(16)*.

Risk 3: Fill-finish infrastructure across LICs and MICs may require further investment to establish adequate production capacity in line with antigen production and to achieve required volumes. Proven fill-finish models from the COVID-19 pandemic were highlighted as replicable in MICs.

Advance market commitments and pooled procurement seen as key to de-risking manufacturing

On procurement and financing, 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. Advance market commitments (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. For example, Quratis indicated it will pursue a tiered pricing model, considering affordability for LICs. It emphasized the importance of AMCs and volume guarantees to ensure affordability and sustainability.

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 investment 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 raised 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.

2.3.4 Key takeaways from supply stakeholder consultations

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

Accelerating suppliers' investments and the scale up 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, 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.

Several actions are needed to prevent delays and long lead times between country-funded demand signals and early manufacturing investments.

- **Demand certainty through volume and financing commitments from countries and/or partners** can incentivize suppliers to invest in manufacturing 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 covers 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 to support manufacturing de-risking, while ensuring equitable pricing and access terms from suppliers; and
    - global coordination between actors involved in supply and demand to minimize delays, incentivize actions by different stakeholders and help ensure risk is shared between manufacturers, donors and countries to maximize public health impact.
- **Accelerating equitable country access to supply** requires suppliers to make products available to all countries with a 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. Key challenges and areas for further action include:
    - advocating for public transparency regarding supplier access and pricing strategies, as well as licensing agreements to ensure concrete plans that promote equity materialize, reduce information asymmetries and help country planning. This can be supported by promoting early multi-stakeholder discussions on access planning;
    - supporting 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; and
    - increasing 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 a competitive and regionally diversified supplier base at market level. This needs to be balanced with the need to ensure long-term commercial viability and sustainability of the supply base. Key challenges and areas for further action include:
    - encouraging 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, currently only one global supplier produces the adjuvant for one of the advanced candidates, which could create 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. This needs to be done in parallel; and
    - encouraging regional manufacturing capacity in high-burden regions by advocating to originators and intellectual property (IP) holders of late-stage candidates for technology transfers, provided there are adequate demand signals that can ensure commercial viability. This needs to be paired with regional agreements that manufacturing countries will provide equitable access to the countries in the region. 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.

An adolescent Syrian refugee smiles after a health screening that helps her prepare for school in Turkey, 2019

© **WHO / Ozge Bayram**

2.4 Supply projections and comparison against demand

2.4.1 Introduction

A realistic supply projection for novel TB vaccines for adults and adolescents expected in the next 10 years is needed to align early.

2.4.2 Objectives

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

2.4.3 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 4. Consultations with the developers of five out of the six vaccine candidates of interest were conducted to inform these supply projections.

The supply projection for novel TB vaccines has been conducted approximately three years before the first potential licensure and, in some cases, before vaccine developers have fully established internal plans and manufacturing partnerships. 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.[5] 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 two-dose vaccine, numbers would double).

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

2.4.4 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.
- Supply 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.

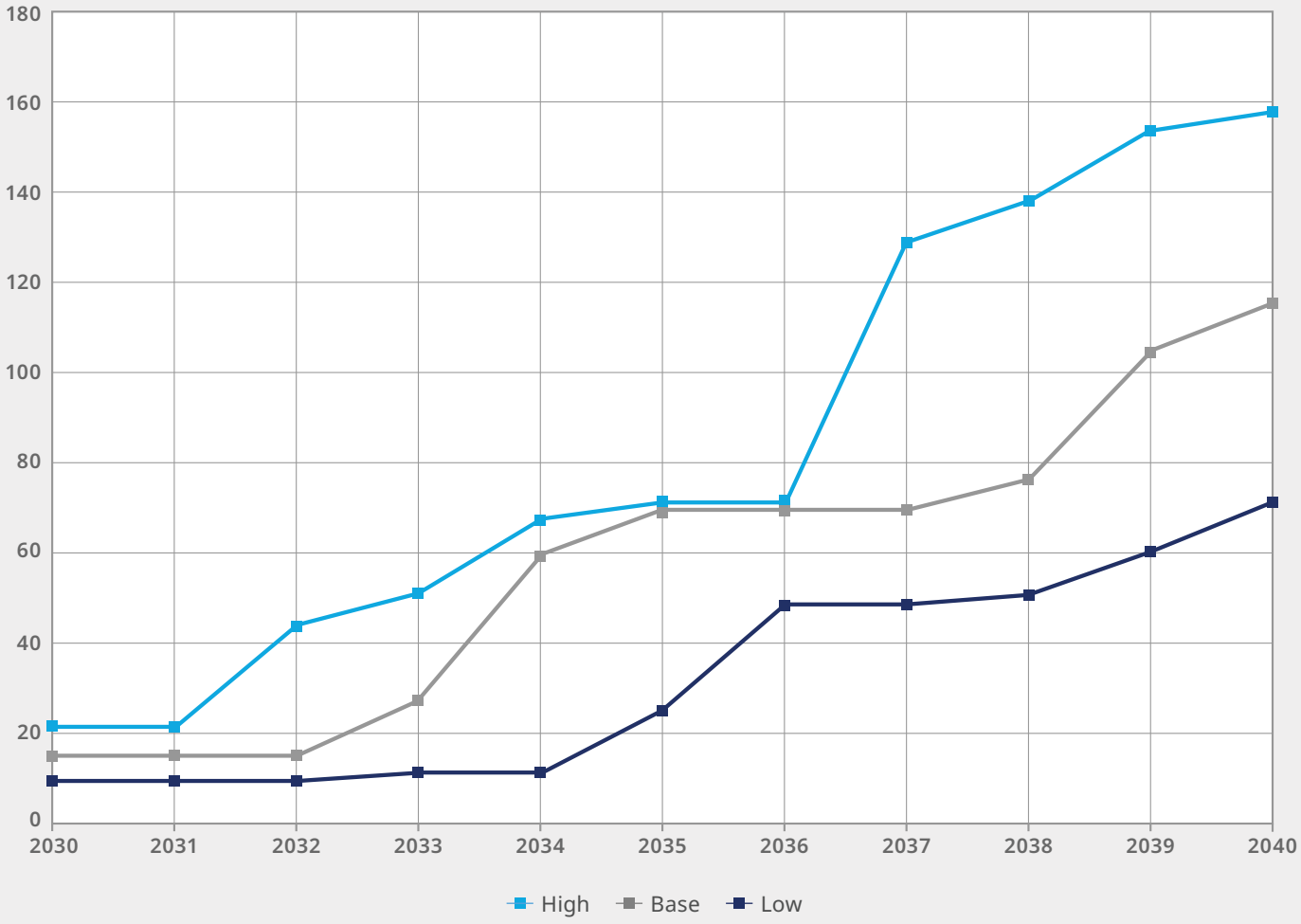
Low scenario

- 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 annual 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



Source: Gavi, the Vaccine Alliance

2.4.5 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 may be sufficient to meet projected demand.

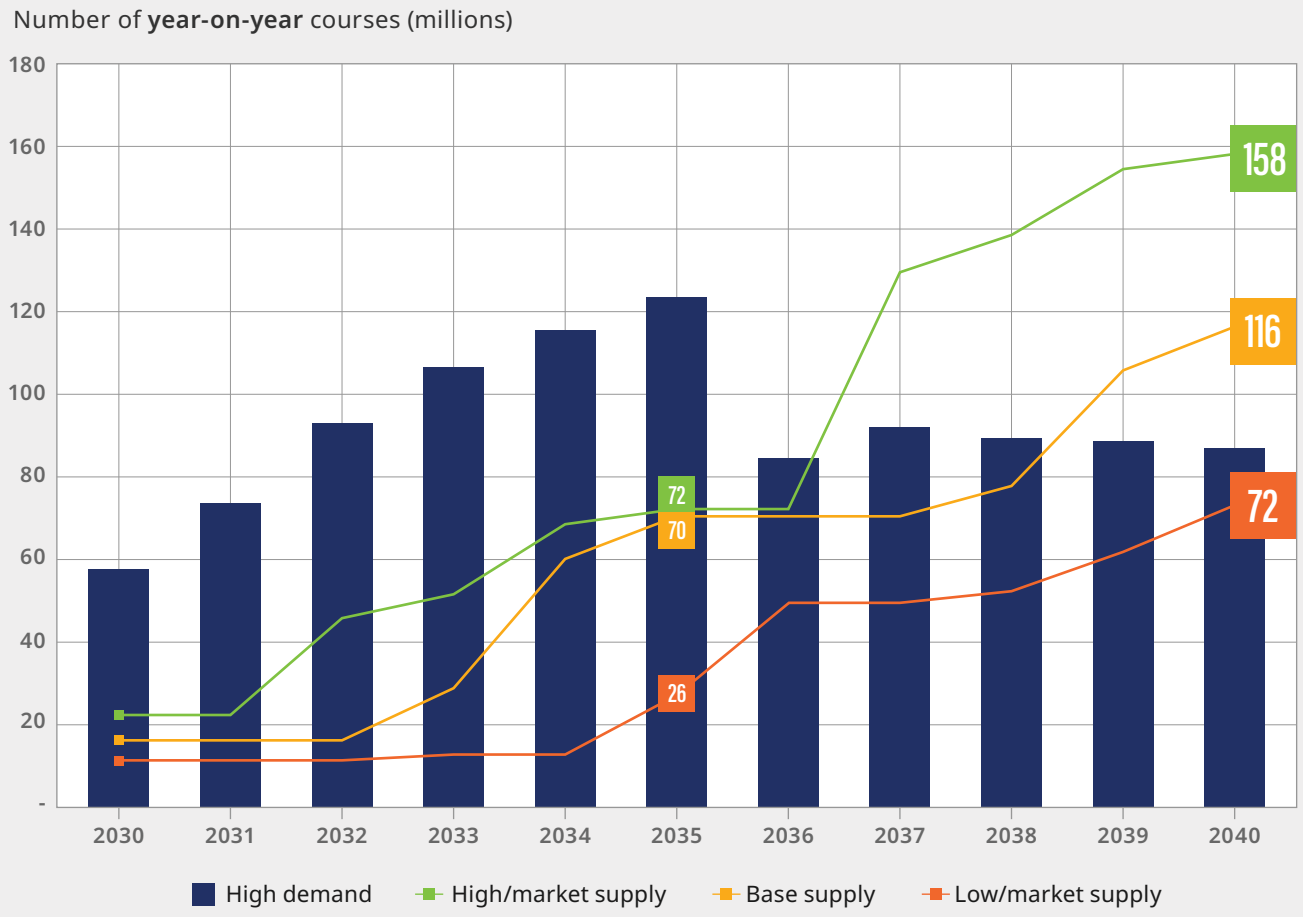
2.4.6 Results overview

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 may 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 could meet demand under the high supply scenario, and by the end of the decade, also under the base supply scenario, but may 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.

While there is a risk of supply being insufficient to meet demand until the mid-2030s across all three supply scenarios, it is important to acknowledge the challenge in managing supply availability over time in market with catch-up vaccination, requiring close communication and global cooperation to achieve a sustainable balance.

Fig. 5

Demand-supply comparison as projected in high demand and all supply scenarios



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

Source: Gavi, the Vaccine Alliance

2.4.7 Key findings from comparison of demand and supply projections

Under the high-demand scenario, and comparing to the base supply scenario, a projected supply-demand gap in the initial years after vaccine introduction is anticipated (2030–2035). The supply gap may amount to about 360 million regimens during this period or an average yearly gap of 60 million regimens. It should be acknowledged that this is an average and demand and supply are not constant in this period.

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 choices about which groups and areas to prioritize for vaccination and could require global partners, regional partners and countries to develop transparent 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. In addition, if there is demand, but supply is insufficient, the experience of people seeking vaccination that have to wait for supply to be available could have a detrimental impact on trust, vaccine hesitancy and long-term demand.

Additionally, the demand forecast is unconstrained and, in the real-world, if demand materializes at levels similar to the high scenario and this results in supply constraints, the prediction that supply could meet demand in the late 2030s under the high- and base- supply scenarios could be optimistic.

2.4.8 Key takeaways from comparison of demand and supply projections

Key market-shaping interventions are needed to prevent a potential supply gap as anticipated under the high-demand scenario.

- **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 that supports 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**. This could 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.
- **Development of an equitable allocation framework.** This should be developed by WHO in collaboration with core partners and key stakeholders to inform manufacturer and procurement agency decisions on fair allocation should supply constraints arise.

Two adolescent boys play in a field in Cambodia, 2017
© WHO / Yoshi Shimizu

2.5 Financing landscape

2.5.1 Introduction

Vaccines are among the most cost-effective public health interventions, with an estimated return of US$22–51 for every dollar invested *(17)*. Yet many LICs and MICs are facing challenges with existing immunization programmes and constraints on the introduction of new vaccines, given existing and required levels of government expenditure *(18)*. The global TB response already faces a significant financing gap *(19)*. 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.

2.5.2 Objectives

01 Estimate funding requirements for novel TB vaccines, based on demand and price projections (see Annex 5 for further details).

02 Identify funding sources and financial commitment towards novel 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 novel TB vaccines and does not estimate financing gaps across the full immunization value chain (e.g. for product development or delivery).

2.5.3 Key findings from financing landscape

The key findings capture a summary of the results of the analysis on financing undertaken, including through modelling and input captured from stakeholder consultations (see Box 2 for details on scope of analysis and Annex 5 for details on the methodology and stakeholder consultations).

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

Under the high-demand scenario in Figure 2, global demand between 2030 and 2040 is projected to exceed three billion regimens. Procuring these vaccines would cost an estimated US$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).

Fig. 6 shows the breakdown across country income groups and by Gavi eligibility.

BOX 3

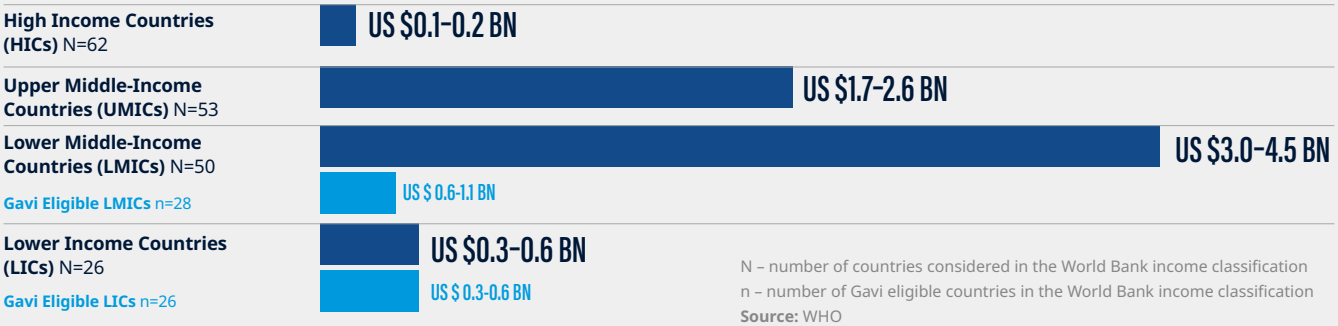
Funding needs go beyond vaccine procurement

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 US$7.7 billion, bringing the total cost across procurement and delivery to US$12.9–15.5 billion *(20)*. In addition, there are existing funding gaps for clinical trials for candidates in development. There is also likely to be funding needed for evidence generation following licensure to drive broad policy optimization in all high-risk groups.

Source: Based on estimates from COVAX Working Group[6] on delivery costs *(20)*.

Fig. 6

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



N – number of countries considered in the World Bank income classification
n – number of Gavi eligible countries in the World Bank income classification
Source: WHO

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 US$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 US$600 million (2012–2025) and $4.6 billion respectively (2009-2020) *(21, 22)*.

The funding requirement for novel TB vaccine is significantly higher than the global BCG vaccine market value, which was estimated to be US$153 million in 2024 *(23)*. It will add to the existing global annual vaccine market, estimated to be nearly US$46 billion in 2023, excluding COVID-19 vaccines *(24)*.

There is an existing TB funding gap of US$16.3 billion in 2024. 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 some extent *(25)*.

6 COVAX Working Group is a multi-organizational working group including WHO, Gavi and UNICEF established in early September 2020 with the task of estimating the costs of delivering COVID-19 vaccines in the 92 AMC countries. The cost estimates were developed to facilitate planning, budgeting and fundraising at global level.

2 There is 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 5. WHO has categorized TB vaccine procurement financing into two main categories: external funding and country financing, which includes loans, liquidity support and domestic funding.

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 official development assistance (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** (Financing tools such as bridge financing, concessional loans or blended finance which need to be repaid through the national budget)	• Loans and liquidity support can be made available for vaccine procurement, based on country needs and priorities. • Historically, not a key source of financing for vaccine procurement. • Ideally further supported by de-risking approaches like blended financing, co-financing and volume pooling. • While not an ideal solution, depending on a country's specific liquidity needs and financing capacity, countries may choose to access this type of financing. • Debt swaps can also help reduce a country's debt burden.
	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 NITAG. • These decisions will require data on cost-effectiveness, budget, impact and pricing, which is not yet available. • Countries with limited budgets may need external support or co-financing, especially amid competing health priorities[7].

To date, no earmarked funding has been allocated to novel TB vaccines across any of the traditional 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 ODA for health and the need to balance investments across multiple priorities (*26*). In addition, there is additional uncertainty about how the funding landscape will evolve in the next three to five years when TB vaccines may become available to countries.

Countries have diverse pathways for procurement and financing. Although some countries are eager 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.

7 Currently 54 countries are eligible to receive Gavi support for immunization and 108 countries are eligible to receive Global Fund support for TB products.

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 US$5.2–7.8 billion. Assuming countries have demand for available vaccines when licensed, whether this funding need is met will depend on domestic allocations, donor commitments and broader ODA, geopolitical and economic trends. The Gavi Board's 2024 approval of its Vaccine Investment Strategy includes in-principle approval to support novel TB vaccines to inform early market shaping and planning efforts, which is a positive step in the path towards funding support for low- and middle-income countries *(27)*.

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.

2.5.4 Key takeaways from financing landscape

The key takeaways capture a summary of the views of the F&A WG 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.

The following actions are needed to increase clarity on funding availability and reduce the potential funding gap.

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 health taxes *(28)* to raise funds for public spending on vaccination procurement and delivery.
- Leverage proven financing models for vaccines and health products for TB as well as other infectious disease areas to catalyse resource mobilisation for novel TB vaccines (refer to Annex 7), while considering applicability to novel TB vaccines.
- Encourage countries and partners to explore new approaches as part of wider global health financing efforts, including goals of the Lusaka Agenda *(29)*.

Negotiate more affordable pricing and increase 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, considering funding gaps for R&D, delivery costs and procurement and delivery of other TB interventions.

3 Solutions and roadmap

This section outlines the solutions identified by the F&A WG to accelerate equitable access and sustainable financing and reduce risks, delays and gaps in achieving the vision that is strived for. The accompanying call to action highlights different stakeholder roles and responsibilities in taking forward these solutions. The next steps outline F&A WG plans and timeline to collaborate with key stakeholders and take this work forward.

This section builds on the key takeaways from the landscape and evidence to date (Section 2), and a review of historic mechanisms (Annex 7), capturing efforts to date.

3.1 Summary of key identified gaps

Against the scope and vision (outlined in Section 1.2), gaps have been identified in novel TB vaccine access and financing, including existing or anticipated bottlenecks as well as areas where acceleration, coordination or early action is needed to prevent delays.

These are organized into three categories from the vision in 1.1. Relevant solutions identified in 3.2 are mapped to relevant risks.[8]

1. Manufacturing, supply and access to quality-assured novel vaccines

Requirement	Risk	Relevant solutions
Optimized supply timing and volume to meet demand projections	The global supply does not meet global demand and supply constraints occur	• (1), (4), (6)
Market competition and related dynamics	A monopoly and/or oligopoly emerge after first product(s) are licensed resulting in constrained supply and other access barriers	• (1), (6), (5)
Predictable funded demand to incentivize manufacturing	Lag time and potential delays arise from final clinical trial data availability and product licensure to the finalization of country-level demand and funding commitments	• (2), (1), (3)
Geographic diversification and tech transfer of supply to promote regional supply security	Plans for ensuring manufacturing capacity in high-burden regions are not uniformly available. Partnerships have been agreed for some candidates in Latin America and South-East Asia, but none yet agreed for Africa	• (6), (1), (4)
Sufficient adjuvant access to enable supply expansion	Heavy reliance on imported critical inputs, including adjuvants, could be a determining factor in the establishment of regional supply chains. There is a single supplier of adjuvant for at least one late-stage candidate	• (4), (6), (1)
Concrete supplier plans on equitable access, pricing and distribution of supply	Lack of certainty to what extent suppliers will centre as access considerations in their commercial strategies. This planning should start during R&D late stage	• (5), (1), (4)
Transparency on developer/supplier licensing, access and pricing strategies to help countries plan and identify potential access gaps	Lack of public transparency on supplier licensing, manufacturing, access and pricing strategies	• (5), (1)

8 This mapping is non-exhaustive and illustrative. Each solution may address multiple risks, and multiple solutions can contribute to mitigating a single risk. The mapping is intended to guide coordinated implementation planning rather than prescribe exclusive actions.

2. Materialization of predictable and long-term demand and procurement of vaccines

Requirement	Risk	Relevant solutions
Concrete global and country-level demand and volume commitments for procurement	Early global demand projections have been completed by Gavi, but this needs to be translated into country-level forecasts	• (2, (3), (1)
Clarity on eventual product availability, characteristics and price which will influenceability to secure supply for national TB control needs	Early signals are needed to help countries and donors plan. This is not available yet	• (5), (1), (4)
Timely development of required evidence for countries that is needed to drive country decisions and actions	Potential gaps anticipated, including delays in lead times from product licensure to country decision-making on prioritization, regulatory authorization and policy on vaccine introductions	• (2), (3), (1)
Health system preparedness	Complexity is anticipated in immunization programmes for novel TB vaccines related to platforms for vaccine implementation, subnational population prioritization and community engagement, among others	• (2), (4)
Vaccine confidence and acceptance	Potential risks particular to TB vaccines due to stigma associated with TB and the high-risk populations that will be prioritized for vaccination, along with more general issues on trust, confidence and acceptance of a new vaccine	• (2), (4)

3. Sustainable financing for vaccine procurement adequate to meet country demand

Requirement	Risk	Relevant solutions
Country budget planning and domestic financing availability, timing and scale. This ensures funded demand signals	Not available yet. This is needed early to send meaningful signals to manufacturers	• (1), (2), (3), (4), (5)
External financing availability, timing and scale	Not available yet. This is needed early to send meaningful signals to manufacturers and countries	• (1), (3), (4), (5)
Evidence to inform trade-offs between introducing novel TB vaccines and other health priorities. Important for countries and donors with financial constraints and competing priorities	Risk of delays in evidence generation needed to inform country decision-making. Risk of major shifts in global health roles leading to uncertainty on responsibilities when key decisions need to be taken.	• (2), (3), (4)

3.2 Proposed solutions and mechanisms

To address the identified barriers and accelerate equitable access and sustainable financing of novel TB vaccines, WHO and the F&A WG have identified the need for the following solutions. These build upon the key takeaways throughout Section 2 and prioritize the most urgently needed actions related to financing and access.

Beyond the urgent actions, there are many other actions and activities identified in the key takeaways that will continue to be tracked by the F&A WG in the coming years to mitigate gaps or risks identified.

A nurse travels to villages on horseback to administer measles vaccinations in Mexico, 2024
© WHO / Felix Marquez

Solution 1

Global catalytic instrument(s) to guarantee demand which will boost supply and drive down prices

Why is this needed?

One of the central gaps identified in the landscape analysis is the lack of predictable and long-term demand signals, combined with the absence of reliable financing commitments. At this stage, projected country public health-driven need has been estimated, but to establish programmatic demand and translate this into funded demand requires additional efforts by multiple stakeholders. Without this clarity, developers and manufacturers have indicated they are reluctant to scale up production capacity 'at-risk', i.e. in advance of licensure. As a result, and given the high anticipated demand globally, supply shortages and inequitable access may result once vaccines are approved a nd recommendations for use are issued. Future suppliers of novel TB vaccines have identified the need to deploy such mechanisms early (while candidates are in development), so they can invest in needed manufacturing capacity (see Section 2.3).

Historical lessons from the introduction of other novel global health interventions show that uncertainty on demand and funding can lead to delays in suppliers scaling up manufacturing, which can result in delays in country access, the need for allocation mechanisms for the constrained supply and high initial prices. In the case of novel TB vaccines, this risk is exacerbated by the fact that most of the demand is expected to come from LMICs, so manufacturers cannot rely on HICs for funded demand, which has typically been the source of more predictable early adopter vaccine use, absent a funding mechanism. At the same time, a funding mechanism should reduce or prevent competition for limited supply between countries with disparate ability to pay.

What would this solution entail?

Global catalytic instrument(s) could aggregate demand for high-burden MICs and LICs. The aim is to provide visibility into aggregated demand from multiple countries, as well as to aggregate financing to de-risk supplier investments and facilitate access and price commitments from suppliers (e.g. commitments to expand supply, affordable prices, priority registrations, etc.). This could directly address multiple gaps such as de-risking manufacturing investments, creating production at scale to lower vaccine costs and providing governments with more affordable and predictable supply.

Donor and development finance institution (DFI) capital will be critical. But governments should also commit domestic financing as a crucial component of ownership and to ensure sustainability. The instrument(s) thus provides a platform not only for demand aggregation but also to incentivize resources pooling between MICs, LICs and donor partners, strengthening collective buying power and reinforcing equity. The instrument(s) also support global coordination between actors involved in supply and demand to minimize delays and help ensure risk is shared between manufacturers, donors and countries, and to maximize public health impact.

These instrument(s) – framed as catalytic and time-bound – should be designed to incentivize early supply availability and to evolve as the market matures. The structure of the global instrument(s) could include:

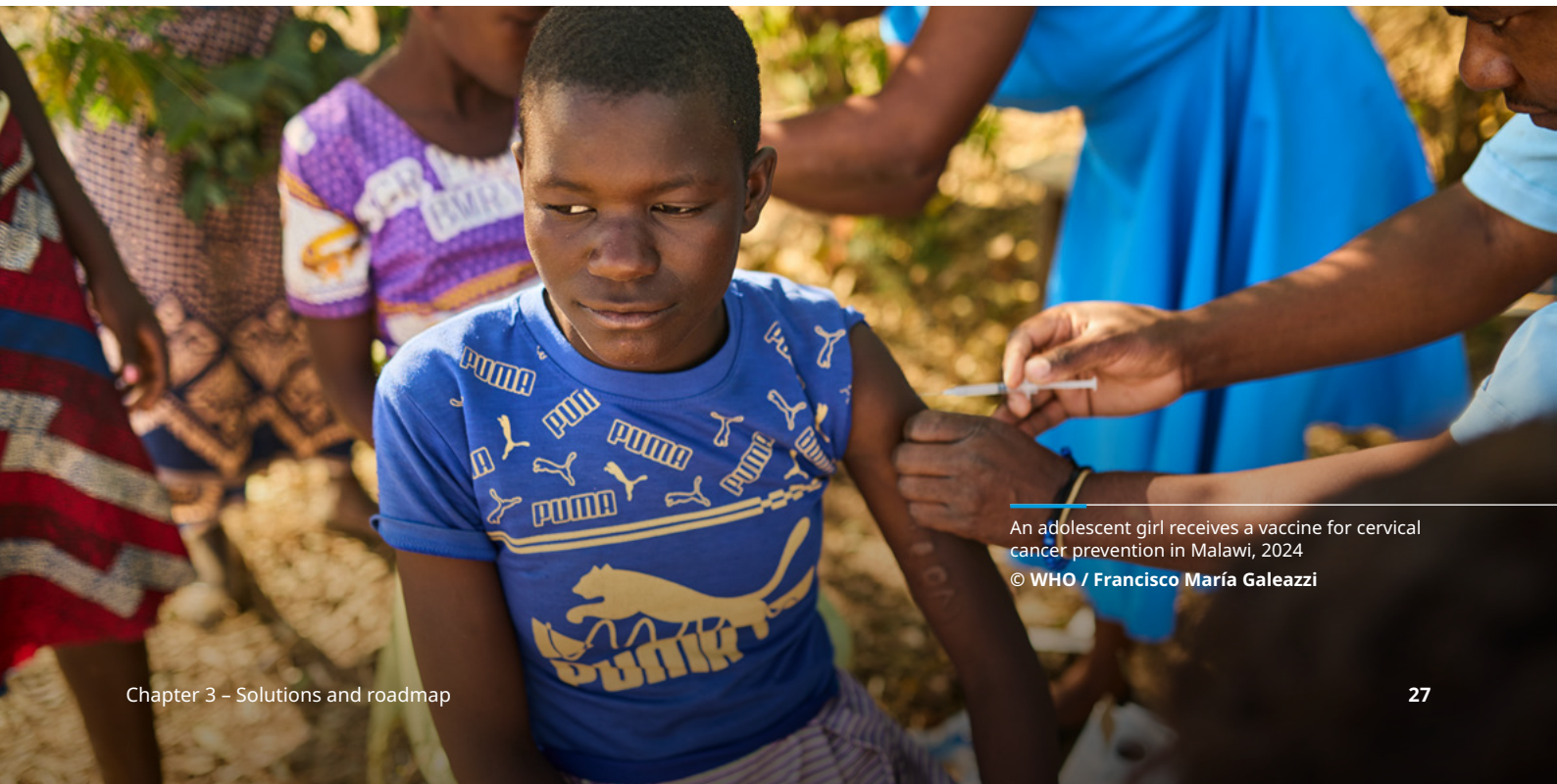
- volume guarantees for products that meet required characteristics to provide predictable demand signals and allow manufacturers to invest confidently in scaling up production at-risk, helping to de-risk these investments and ensure adequate scale of supply to meet country demand[9];
- a mechanism to accelerate and pull core funding early to demonstrate funded demand to manufacturers, based on country and donor commitments and estimated volumes. This could reduce perceived risk on funded demand materialization; and
- entry incentives for the first two suppliers to bring vaccines to market, ensuring rapid availability of initial doses. By design, the instrument should cover at least two vaccine products to avoid a "winner-takes-all" dynamic and to stimulate a competitive market.

The global instrument(s) could seek to secure:

- more affordable pricing incentivized through reduced COGs and greater manufacturing scale. Price evolution mechanisms, including periodic reviews of COGs and opportunities for adjusting pricing as demand expands, to ensure affordability over time;
- sunset and transition criteria to ensure that, once a competitive and sustainable market is shaped, the instrument(s) neither creates distortions or dependency, nor locks up the market to early suppliers. Instead it aims to ensure healthy market competition in the medium to long term. Review of the mechanism could be based on time horizons, market milestones or volume-based milestones;
- inclusive country scope to include all high-burden countries regardless of their procurement and financing channels. i.e. demand and funding could be aggregated under the instrument no matter whether countries will choose to procure themselves or use pooled procurement mechanisms and/or if they pay for vaccines through domestic or external financing. This would ensure aggregation of volumes with the relative market weight of MICs while supporting self-sufficiency and country-driven pathways; and
- specific considerations for access, equity and affordability for LICs.

Multiple mechanisms may be required (e.g. innovative financing, market shaping and/or pooled procurement – refer to Annex 7.3, which lists types of mechanisms) to meet the above needs. Critical to any mechanism(s) developed by relevant partners is to ensure country self-sufficiency is strengthened and MICs buying power leveraged.

9 As outlined in 'high' demand projection in Section 2.2, which is demand including adult catchups to accelerate impact on TB burden.



An adolescent girl receives a vaccine for cervical cancer prevention in Malawi, 2024

© WHO / Francisco María Galeazzi

Adolescent boys play soccer at a school in Argentina, 2013

© WHO / Camila Eugenia Vargas

Solution 2
Early evidence generation

Why is this needed?

This is needed to prevent delays in vaccine adoption by countries. A recurring challenge in vaccine introduction is the lag between product licensure, policy recommendations and country adoption if data is insufficient, including to generate required country-level evidence (e.g. cost-effectiveness, health impact and target populations). In addition, for TB vaccines, trials are likely to focus on narrower populations than their intended use, leaving gaps in data for high-risk groups such as PLHIV, adolescents, occupational cohorts or uninfected populations. Without required evidence, countries may be hesitant to prioritize TB vaccines over other health interventions, especially in constrained fiscal environments.

What would this solution entail?

This solution calls for the systematic generation of country-led evidence packages to accelerate national decision-making and budget planning. This is in addition to global policy recommendations that provide guidance to countries. By producing country-level demand forecasts, cost-effectiveness analyses (with other TB preventive measures and other vaccines) and budget impact estimates, countries would be better equipped to assess prioritization of novel TB vaccine introduction, integrate novel TB vaccines into health budgets and secure domestic and external financing. In the absence of final information (e.g. on vaccine efficacy, impact, safety and price, etc.), countries can leverage methodologies for scenario-planning through modelling, based on a range of assumptions. Countries can be supported and equipped with technical assistance and tools to accelerate evidence generation, ensuring capacity is built locally rather than externally driven. Early evidence can also support early engagement of communities and civil society to raise awareness of the TB burden, and the potential impact and priority of novel vaccines.

Comprehensive evidence packages will also be important in supporting demand and financing risk assessments for Solution 1. In this way, evidence generation will ensure that individual and public health need for novel TB vaccines translates into funded demand, enabling governments and donors to make timely, evidence-based decisions.

Through the landscape, the F&A WG identified the need for additional evidence in the form of real-world acceptability data. This could broaden the evidence base beyond trial populations, feeding into global policy bodies and forums such as SAGE and the ECVP, and informing readiness planning covered by other working groups in the Accelerator. Expanded target populations will also have implications on demand and the resulting market size, so needs to be considered in the F&A WG.

A group of adolescents at school wait to receive a vaccine against cervical cancer in Fiji, 2023
© WHO / Faizza Tanggol

Solution 3
Clarity on domestic and external funding

Why is this needed?

To ensure early actions and accelerated access, an understanding of available financing, both domestic and external, is essential to clarify potential funding gaps and need for innovative financing mechanisms. This is also essential for the catalytic instrument(s) named in Solution 1, to provide signals on funded demand to industry to promote at-risk manufacturing at scale.

Given the large share of TB burden in MICs, there is a key opportunity to drive the novel TB vaccine market through MICs financing and to promote country self-sufficiency. However, it is expected that domestic budgets may be insufficient to finance novel TB vaccine introduction in all high-burden countries. Without external support, the global instrument could remain under-capitalized, and suppliers may not receive credible demand signals. At the same time, reliance solely on external funding would undermine long-term sustainability and leave countries vulnerable to volatility and expected decreases in external funding.

What would this solution entail?

A blended financing approach is therefore essential, combining external catalytic funds with country financing. The goal would be to 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. In parallel, the goal is to ensure early donor commitments for countries requiring external support, with clarity on scale, eligibility and timing. For domestic funding to materialize, governments need to prioritize novel TB vaccines and make decisions on introduction and budget allocation. To ensure early access once country-level national demand is projected, early financing commitments from governments will be important. This is needed for Solution 1. Multilateral, global and regional financiers should complement, not replace, domestic funding, and should promote co-financing.

External financiers need to clarify potential available funding envelopes, eligible country scope and any conditions or parameters, to help countries plan and to identify any funding gaps. Key financiers should consider supporting the catalytic instrument(s) to help accelerate early access to novel TB vaccines.

Given the lack of clarity on available external and domestic financing, the F&A WG identified funding need, but not funding availability or gaps. As a next step, scenarios should be modelled to identify what level of funding may be available from different sources to understand potential funding gaps and areas for action. An initial model has already been developed by WHO (see Annex 6) and can be used by the F&A WG in 2026 to take forward this analysis. This can be iterated as more information becomes available.

There are additional financing gaps that need to be addressed but are outside the scope of the F&A WG. Included in this category are costs beyond vaccine procurement including delivery and workforce costs that will need to be considered to ensure sustainability of novel TB immunization country programmes. Also included in this category are gaps in funding for Phase 3 trials which could delay product entry and competition, reducing supply scale.

A community health volunteer prepares to provide TB screenings in a rural village in Cambodia, 2023

© WHO / Tytaart

Solution 4
Coordination between demand and supply

Why is this needed?

Lack of coordination can delay introduction if supply distribution, financing arrangements, procurement processes and country readiness move on misaligned timelines. For novel TB vaccines, such misalignment could delay public health impact once vaccines are successfully licensed. Coordination is therefore essential to align decision-making across all stakeholders. In addition, coordination can promote synergy, alignment and shared accountability in the implementation of key solutions, ensuring a holistic approach to facilitating access to novel TB vaccines.

What would this solution entail?

A structured coordination platform that links supply- and demand-side stakeholders, including a shared roadmap with clear sequencing of activities, should be developed. In addition, develop an equitable allocation framework, as has been done for numerous other novel vaccines, in case supply is constrained in the years immediately following licensure. Regular multi-stakeholder roundtables should be convened to monitor and align expectations regarding access. Coordination should be institutionalized as the backbone of an equitable vaccine access strategy, ensuring that no track operates in isolation and that bottlenecks are addressed early. The F&A WG will aim to serve this purpose in 2026–2027.

A vaccinator is driven to a community health post to administer vaccines in Kenya, 2023

© WHO / Ethnovision / Billy Miaron

Solution 5
Market transparency for key access information

Why is this needed?

Countries and funders often lack visibility on suppliers' licensing and manufacturing plans (i.e. who will manufacturer the product, where will the manufacturing take place and which countries can buy from these manufacturers), and access and pricing strategies (i.e. how will suppliers ensure equitable access to all countries in need, how will they distribute and allocate supply, at what price and to which countries or mechanisms). This information gap can delay national planning, funding availability and create uncertainty for procurement. Information asymmetries can result in inequitable access.

What would this solution entail?

Establishing minimum standards for transparency for information that is important for equitable access and is

not commercially sensitive is a core aspect of achieving the necessary visibility to achieve access. Suppliers would be requested to disclose such information as it becomes available. This could include pricing strategies and eventually price corridors, licensing terms including geographic scope and royalty structures, and access and distribution plans for different countries and regions. This approach balances the need for transparency with feasibility, while building trust and accelerating country-level decision-making. The global instrument(s) in Solution 1 could support in securing commitments from suppliers.

Vaccines are manufactured at a technology transfer hub in South Africa, 2022

© Medicines Patent Pool / Rodger Bosch

Solution 6

Licensing and technology transfer to at least one manufacturer in each high-burden region

Why is this needed?

Regional manufacturing capacity in every high-burden region can help strengthen equitable access, ensure regional supply security and increase acceptability of vaccines. If global supply is constrained, there may be delays in access in countries and regions without manufacturing capacity. Regional manufacturing builds resilience and strengthens political ownership and regional self-sufficiency.

What would this solution entail?

Based on current manufacturing and licensing plans, advocacy with relevant supply stakeholders should aim to secure manufacturing capacity to produce at least one vaccine in each high-burden region (i.e. Africa, Asia and Latin America). This will require technology transfer and IP-sharing agreements, ensuring regional manufacturers can produce at scale and to required quality standards. The global instrument(s) recommended in Solution 1 could support securing such agreements from originators. This capacity could start with supporting fill-finish before transferring know-how and full manufacturing. It would need to build on credible demand and financing signals, require appropriate regulatory capacity in countries and should ideally be built early for first licensed vaccines in order to support commercial viability of manufacturers.

Ensuring manufacturing in a region translates into regional access and supply security requires agreements between manufacturers and countries. Regional manufacturers would need to commit to supply regionally. Likewise, relevant country governments and regional bodies would need to commit to buy regionally and ensure equitable regional distribution. Existing manufacturing hubs could be leveraged in Africa, Asia and Latin America, led by regional institutions such as Africa CDC, PAHO, ASEAN and supported by global partners. National governments in the region can also support through investments in manufacturing and public-private partnerships. Regional manufacturing should be accounted for in global supply and demand considerations, to prevent market fragmentation and ensure overall alignment. The aim would be a diversified, resilient global manufacturing base that reduces risks of shortages and inequities.

3.3 Call to action

WHO and the F&A WG call on key stakeholders to play their part in ensuring equitable access and sustainable financing for novel TB vaccines:

- WHO has a central coordinating role in fostering global collaboration and accountability among all stakeholders.
- Governments in high-burden countries have a key role to play in translating political will into funded demand via purchasing commitments, and ensuring early planning and investments for country readiness and vaccine introduction.
- HICs can support the global reduction of TB incidence by providing external funding to countries in need and to the relevant funding agencies.
- Through the G20, key governments can affirm responsibility and commitment to ensuring that equitable access to novel TB vaccines is prioritized and safeguarded across all regions, based on public health need and impact.
- Civil society has a key role to support accountability from governments and global partners, to shape demand and to support community engagement for successful product rollout.
- Supply side stakeholders have a key role by providing transparency on access plans, to invest in manufacturing capacity to meet demand, to ensure equitable distribution of supply and to ensure affordability for MICs and LICs.
- Global funding partners and financiers have a key role to provide external funding and loans that support countries' procurement of novel TB vaccines, based on country needs and public health impact.
- Global procurement, innovative financing and market shaping partners have a key role in providing technical expertise for the design and implementation of proposed instrument(s). Partners, including Gavi, The Global Fund, MedAccess and PAHO RF, among others, may have roles to support the financing approaches and instruments for introduction and scaling access of novel TB vaccines in low- and middle-income countries.

3.4 Next steps

The development and implementation of financing and access strategies by countries is an essential step in the planning and equitable access to new TB vaccines once they become available.

All the members of the F&A WG will continue to actively engage and collaborate with all other key stakeholders (including supply side stakeholders, global funders, civil society and other areas of the TB Vaccine Accelerator). **In 2026–2027**, the F&A WG will prioritize efforts to develop most urgently needed solutions, and additional analyses needed to support these, so that they can be launched as rapidly as possible. Recognizing that in the short-term, TB vaccines first coming to market and early adopter countries may have more advanced plans, the F&A WG may need to target efforts to support them. There will be a need to consider long-term equitable access to all countries and a healthy and competitive supplier base. Hence, the F&A WG will also consider medium-long term solutions that may be needed as the vaccines come to market. The F&A WG will aim to ensure that solutions across countries offer benefits to all stakeholders, while optimizing public health impact.

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Annexes contents

Purpose of this annex

This annex provides supporting information for the *Catalysing solutions for equitable global access and sustainable financing for novel tuberculosis vaccines for adults and adolescents* document. It includes scope, consultations and methodology information for each analysis from the landscape and evidence to date section of the main report. It also includes additional data tables and other materials that expand on topics summarized in the main report.

Methods for developing main report

To support early access planning and ensure sustainable financing, the Finance and Access Working Group (F&A WG) of the tuberculosis (TB) Vaccine Accelerator Council conducted a landscape analysis to assess the readiness of countries, suppliers, markets and financing systems for the equitable introduction of novel TB vaccines. Based on the analysis and insights, key solutions are proposed in the main report to inform the pathway for action by governments, suppliers, civil society, donors and global health partners. A call to action identifies key roles and responsibilities of different stakeholders, and next steps capture plans for the F&A WG to take forward needed solutions.

Annex 1: Country access and financing plans

A1.1 Scope

This analysis provides an overview of high-tuberculosis-burden countries' current perspectives on readiness, challenges, and opportunities related to the introduction of novel TB vaccines. Country access and financing plans, along with key bottlenecks and needs related to vaccine introduction, are presented to inform global calls to action. Given the interconnected nature of national, regional and global decision-making, these insights help ensure efforts are both relevant and actionable at the country level. The analysis draws on World Health Organization (WHO) consultations with stakeholders from five high-TB-burden countries and five WHO regional offices.

A1.2 Consultations

In determining which countries to consult, the WHO selected countries that were: (1) high-TB-burden countries; and (2) part of the TB Vaccine Accelerator Council. These criteria resulted in initial consultations planned with Brazil, Indonesia, the Philippines and South Africa. Given the diversity of economies across the African region, the WHO decided to consult a lower-income country to gain a more representative perspective, resulting in Ethiopia being added to the consultation list. Overall, these consultations allowed the WHO to explore countries' vaccination strategies and demand, procurement plans and supply interdependencies, and domestic funding commitments and financing needs.

The WHO also complemented these national-level insights with regional perspectives, recognizing the wide diversity among high-TB-burden countries in different regions. Thus, consultations were also conducted with the WHO Regional Office for Africa, the WHO Regional Office for the Americas/Pan American Health Organization, the WHO Regional Office for the Eastern Mediterranean, the WHO Regional Office for South-East Asia and the WHO Regional Office for the Western Pacific (WHO.

A1.3 Methodology

A detailed questionnaire was sent to countries and regional offices in advance of the consultations that outlined the topics to be discussed, which included:

- **vaccination strategy and demand:** assessing national priorities, vaccine profile preferences and anticipated immunization plans (including target populations and rollout strategies) to understand demand and ensure readiness for continuous delivery once the vaccine is approved;
- **access and delivery:** assessing the procurement and supply plans and interdependencies, country policy and regulatory environment, as well as infrastructure needed to introduce and scale up novel TB vaccines for adults and adolescents once approved; and
- **financing:** exploring financial commitments and potential financing mechanisms for TB vaccine procurement and vaccination, including domestic funding, donor contributions and alternative financing options to ensure sustainable support for the vaccine rollout.

The insights gathered in the consultations were validated by each of the stakeholders. These insights informed the development of case studies for each country and were used to distil key takeaways and identify priority actions needed to ensure an equitable and accelerated rollout of TB vaccines.

As the insights captured are mainly representative of middle-income countries that are expected to largely self-procure and self-finance, 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.

Annex 2: Demand projections

A2.1 Scope

The demand projection developed by Gavi quantifies the number of novel TB vaccine regimens for adolescents and adults across all WHO member states and covers the 2030–2040 period. The forecast is unconstrained and product-agnostic.

A2.2 Consultations

In-depth interviews were conducted with country stakeholders in nine high-TB-burden countries accounting for 63% of global TB burden (Brazil, China, Democratic Republic of the Congo, India, Indonesia[1], Nigeria, Pakistan, South Africa[1] and Viet Nam). Their consolidated inputs were used to inform the assumptions and scenarios in the forecast.

Country-level interviews included a broad range of stakeholders to capture a holistic view of each country's ambition for novel TB vaccination. Depending on the country context, participants included representatives from national and subnational TB programmes, immunization programmes, other ministry of health divisions, regulatory agencies, National Immunization Technical Advisory Groups (NITAGs), development partners, researchers, national procurement agencies, national treasuries and civil society organizations (CSOs). In total, more than 120 stakeholders were consulted across the nine high-burden countries through individual interviews and workshops.

In addition to country-level stakeholders, leading experts on TB and immunization from global and regional organizations were consulted, including Gavi, the Vaccine Alliance, the Gates Foundation, the London School of Hygiene and Tropical Medicine (LSHTM), United Nations Children's Fund (UNICEF), the University of Cape Town and WHO.

A2.3 Methodology

The demand forecast has been developed using a standard population-based forecasting approach, which aims to quantify the number of novel TB vaccine regimens (rather than doses, given the product-agnostic nature of this demand forecast) required for a complete primary vaccination series (i.e. no booster doses assumed) over the 2030–2040 period, represented through different scenarios.

The estimate is based on the size of the target population in each scenario, the assumed delivery strategy to reach each target population, the attainable coverage of the vaccine, timelines for country adoption, vaccine wastage and buffer, where relevant. Country archetypes are used to make assumptions about novel TB vaccine adoption in different epidemiological settings. In the following paragraphs, the key elements of the demand forecasting methodology are described in more detail.

A2.3.1 Target population and delivery strategy

In the absence of a global policy recommendation on target populations for novel TB vaccines, WHO's Evidence Considerations for Vaccine Policy (ECVP) *(1)* are used to define the scope of potential target populations for vaccination.[2] The target populations that were determined to be both identifiable (i.e. no screening required) and reachable by the health system (i.e. existing touchpoints with the population) through consultations with global experts and country stakeholders were included in the demand forecast.

As such, the demand forecast includes three categories of target populations:

- adolescents (15 years old), reached via routine immunization (RI), to provide population immunity in the longer term;
- older adolescents and adults (16–44 years old), reached via large-scale catch-up vaccination either nationwide or in high-risk areas, to ensure rapid population-wide coverage; and
- high-risk groups (HRG) most susceptible to TB, reached via catch-up vaccination and routine immunization, to ensure rapid and continued protection. High-risk groups include people living with HIV (PLHIV), household contacts of TB patients (HHC), healthcare workers (HCW), miners, prisoners, people diagnosed with diabetes, migrants and travellers.

1 Stakeholder consultations were conducted in collaboration with the London School of Hygiene and Tropical Medicine (LSHTM).
2 Travellers from low-burden countries to high/mid-burden countries added as additional target population.

A2.3.2 Coverage

Country-specific coverage estimates for each target population and delivery strategy are based on analogues from existing vaccines or other health programmes. For RI, the forecast assumes that countries will take three years to reach this coverage estimate, modelled with a linear ramp-up. For catch-up vaccination, the forecast assumes that countries will conduct these in a phased approach over three to six years, depending on their population size.

A2.3.3 Introduction year

The number of introductions per year assumed in the forecast is based on historical adoption patterns for new vaccines and takes into account the current context of crowded immunization schedules, country financing constraints and the need for balance with other new vaccines and health interventions. Each country's introduction year is determined through a combination of relative TB incidence, financial status and past vaccine adoption behaviour, with adjustments made based on country-specific inputs. The earliest year of introduction is assumed to be 2030.

A2.3.4 Country archetypes

The forecast builds on three country archetypes based on differences in TB epidemiology across countries. The target populations described in the previous sections are varied across country archetypes to reflect different programmatic goals in different epidemiological contexts.

- **high-burden countries:** 49 countries on WHO's high-TB-burden list*(2)*[3], accounting for 67% of the world's population and 91% of TB incidence;
- **mid-burden countries:** 49 countries with TB incidence above 50 cases per 100,000 population, accounting for 9% of the world's population and 6% of TB incidence; and
- **low-burden countries:** 98 countries with TB incidence below 50 cases per 100,000 population, accounting for 24% of the world's population and 3% of TB incidence.

A2.3.5 Demand scenarios

To reflect different levels of ambition influenced by potential financial constraints, potential product characteristics, programmatic feasibility considerations and the acceptability of vaccines as shared by country stakeholders, the forecast includes four demand scenarios, reflecting a range of introduction approaches that emerged in the consultations.

The maximum public health need scenario represents the upper bound of demand, assuming all adolescents and adults for whom the vaccine is likely to be indicated are vaccinated in high- and mid-burden countries through catch-up vaccination and RI. Broad catch-up vaccination is expected to bring the highest and fastest public health impact in line with the goal of TB elimination*(3)*.

The high-demand scenario reflects the goal of **accelerating impact on the TB burden** by vaccinating all eligible adolescents and adults in high-burden geographic areas and high-risk groups through catch-up vaccination, achieving fast reduction in TB cases and deaths, while routinely vaccinating adolescents to provide population immunity in the longer term.

The medium-demand scenario reflects a **longer-term approach to reducing TB burden**. This scenario assumes high-risk groups most susceptible to TB are vaccinated first through catch-up vaccination, while routinely vaccinating adolescents, providing population immunity in the longer term.

The low-demand scenario represents the **lower bound of demand** in which only high-risk groups, most susceptible to TB, are vaccinated through catch-up and routine vaccination.

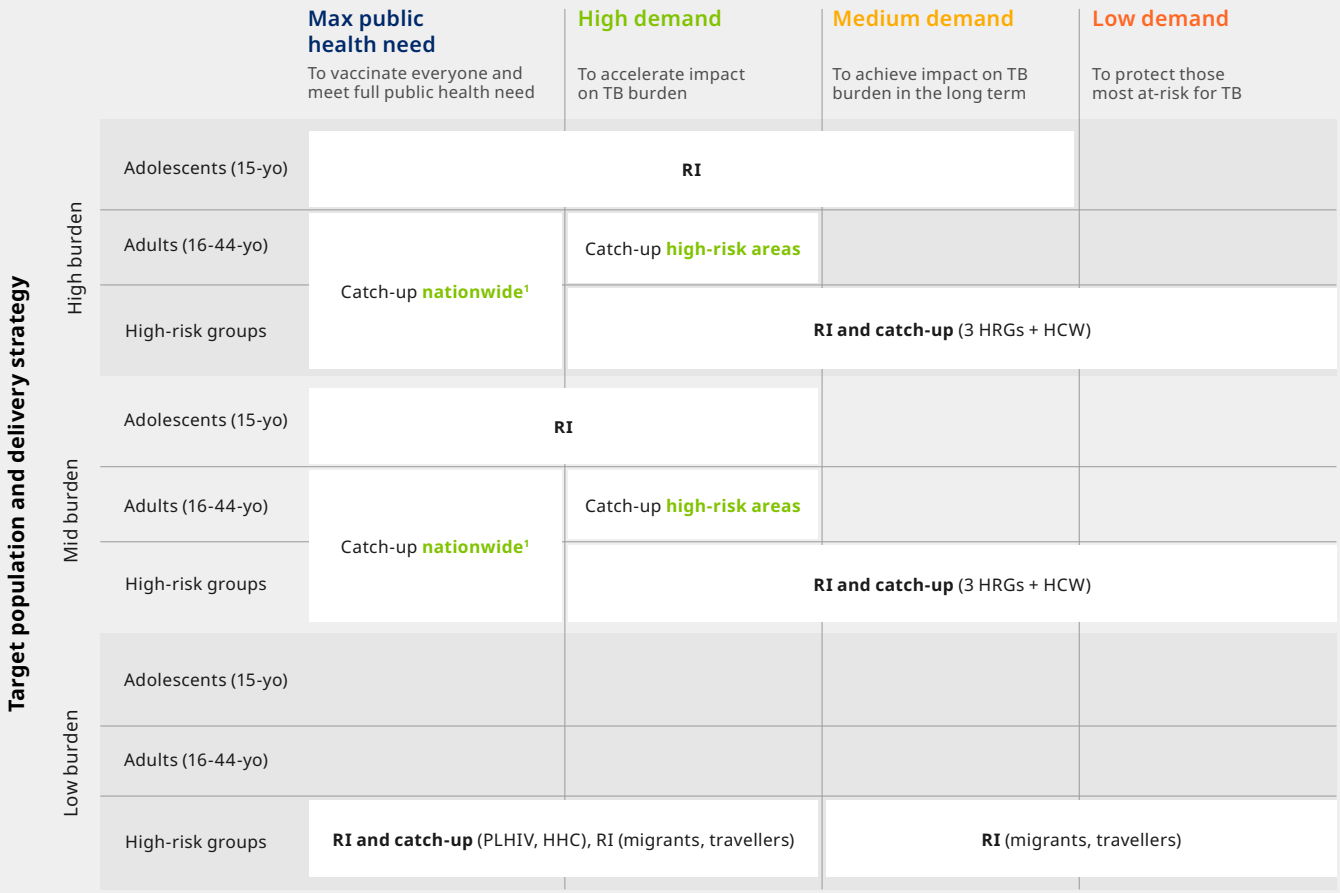
Assumptions in each scenario were varied by country archetype (Fig. A2.1). High-burden countries are assumed to take the most comprehensive approach to vaccination, while low-burden countries are assumed to only vaccinate a subset of potential high-risk groups across all scenarios.

Where required, these scenarios have been further adapted based on country-specific inputs for the nine countries interviewed.

3 Each list includes 30 countries: the 20 with the highest estimated number of incident TB, TB/HIV or multidrug-resistant/rifampicin-resistant (MDR/RR)-TB cases, plus the 10 with the highest incidence rates not already in the top 20 (thresholds: over 10 000 TB, over 1 000 TB/HIV or over 1 000 MDR/RR-TB cases per year).

Fig. A2.1

Demand scenarios differentiated by country archetype.



1 Including the elderly (65-year-olds) in China

Note: Correction will be made to adjust for risk of double counting in scenarios which assume both sub-national and national catch-up vaccination of specific high-risk populations

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Annex 3: Product licensing and access strategies

A3.1 Scope

Currently, at least 16 TB vaccine candidates are in clinical development, including six in Phase 3 trials. While these new TB vaccine candidates are progressing through late-stage clinical trials, there is an urgent need to ensure that, once approved, these vaccines can reach populations most at risk. Recognizing that scientific readiness alone is not enough, WHO engaged directly with suppliers to understand the operational, regulatory and financial hurdles that could delay or limit vaccine rollout, as well as the enablers at each stage of the value chain that can support a successful rollout and accessibility.

The objective of this analysis is to present a structured synthesis of the insights gained from these supplier consultations and mapping them to the key stages of the vaccine value chain. It highlights both the enablers that may accelerate progress and the bottlenecks that must be addressed to ensure a successful vaccine rollout.

A3.2 Methodology

WHO screened the global TB vaccine pipeline to identify the relevant TB vaccine candidates. Selection of the candidates focused on three criteria, those being: (1) clinical maturity, meaning that candidates in Phase 2b or later were prioritized; (2) target population relevance and vaccine efficacy, with an emphasis on vaccines designed to prevent TB in adolescents and adults; and (3) regulatory outlook, prioritizing candidates expected to produce pivotal clinical results by 2030 in line with WHO's End TB Strategy. Table 1 outlines the selected vaccine candidates.

Between March and June 2025, WHO conducted structured consultations with the selected supply stakeholders. The consultations included a detailed questionnaire followed by interviews with clinical, regulatory, manufacturing and commercial leads on topics across the immunization value chain, including enablers, barriers and future plans.

Insights generated from these conversations were then synthesized across the five critical vaccine value chain stages, which include:

1. research and development (R&D) – clinical evidence and Phase 3 financing;
2. policy and regulatory pathways;
3. manufacturing and technology transfer;
4. procurement and financing models; and
5. delivery and administration readiness.

A3.3 Consultations

WHO identified key stakeholders to include in consultations based on whether the stakeholders were: (1) primary developers of prioritized candidates; (2) manufacturing partners involved in current or planned tech transfer; or (3) entities with commercialization ambitions in low- and middle-income countries (LMICs). Table A3.1 shows the selected stakeholders and their rationale for inclusion as well.

Table A3.1

List of shortlisted stakeholders and candidates

Stakeholder	Associated candidate	Justification for consultation	Consultation status
GlaxoSmithKline (GSK)	**M72/AS01E**	Initial developer and provider of the AS01E adjuvant	Conducted
Gates Medical Research Institute (Gates MRI)	**M72/AS01E**	Current sponsor of the vaccine's clinical development – licensee for LMICs	Conducted
BioNTech	**BNT164a1 & BNT164b1**	Leading the development and clinical evaluation of the BNT164 programme*	Conducted
FioCruz	**MTBVAC**	Technical support partner to Ataulpho de Paiva Foundation (FAP), which is the licensee for Latin America	Conducted
International AIDS Vaccine Initiative (IAVI)	**MTBVAC**	Development partner focused on activities supporting an adult and adolescent indication, providing expertise in chemistry, manufacturing and controls (CMC), clinical development and regulatory, and leading global access planning activities	Conducted
Bharat Biotech	**MTBVAC**	Licensee for India and Sub-Saharan Africa (SSA)	Conducted
Serum Institute of India (SII)	**VPM1002**	Leading large-scale manufacturing and advanced clinical trials	Outreach on-hold**
Quratis	**ID93 + GLA-SE**	Leading clinical trials and regulatory submissions	Conducted
Gamaleya	**GAMTBVAC**	Leading development and clinical evaluation	No response

Phase 1 Phase 2a Phase 2b Phase 3

**Included in consultations due to accelerated development plans, with Phase 3 results projected before 2030.*

***Until Phase 3 conclusion*

Note: Reflects the development stage at the time of conducting consultations.

Annex 4: Supply projections and comparison against demand

A4.1 Scope

The supply projection developed by Gavi quantifies the vaccine supply expected to be available in the 2030–2040 period. Depending on the anticipated indication of the vaccine candidates in scope, the forecast also quantifies the vaccine supply expected to be available for special populations (e.g. PLHIV). The analysis also estimates the anticipated cost of each vaccine candidate.

A4.1.1 Vaccine candidates included in the forecast

The forecast sought to include all novel TB vaccines under development that are intended to prevent TB disease in adolescents and adults with the potential to be licensed before 2040 anywhere in the world.

Candidate vaccines were identified through a mixed methods approach, including analysis completed by other groups, expert knowledge and a literature search. Several critical sources included:

- Treatment Action Group's 2024 Pipeline Report on *Tuberculosis Vaccines*;
- ClinicalTrials.gov; and
- Clinical Trials Registry - India.

Six vaccine candidates were shortlisted for inclusion in the forecast:

1. **M72 + AS01E**, developed by the Gates Medical Research Institute;
2. **GamTBVac**, developed by the Gamaleya Research Institute of Epidemiology and Microbiology;
3. **MTBVAC**, developed by BioFabri, in partnership with Bharat Biotech International Limited and the Institute of Technology in Immunobiologicals (Bio-Manguinhos), an institute of the Foundation Oswaldo Cruz (Fiocruz) and IAVI;
4. **BNT164a1/b1**, developed by BioNTech;
5. **ID93/GLA-SE**, developed by Quratis; and
6. **AEC/BC02**, developed by Anhui Zhifei Longcom.

A4.2 Consultations

Gavi conducted consultations with vaccine developers to verify or receive information on the vaccine candidates. A group consultation was held with vaccine development and regulatory experts to validate and/or adjust assumptions on each candidate made following the developer consultations. Each of the consultations were conducted by the Gavi Secretariat with observers from partner organizations invited to participate as observers.

A4.2.1 Vaccine developers

Consultations were requested from all vaccine developers and conducted with five of the six developers of the vaccines in scope. These developers included:

1. Gates MRI and partner GSK;
2. BioFabri with partners Bharat Biotech International Limited and the Institute of Technology in Immunobiologicals (Bio-Manguinhos), an institute of the Foundation Oswaldo Cruz (Fiocruz) and IAVI;
3. BioNTech;
4. Quratis; and
5. Anhui Zhifei Longcom.

Consultations were held virtually and were focused on product development and regulatory plans, demand and policy plans, supply plans, pricing and affordability.

A4.2.2 Vaccine development and regulatory experts

An additional consultation was conducted with a group of five experts who covered the following areas: vaccine development, including for TB, HIV, malaria, influenza, dengue fever, Ebola and COVID-19 vaccines, vaccine regulation and vaccine manufacturing. The consultation focused on the following topics: assumptions for each vaccine candidate, validation of the methods used to develop supply forecasts for individual vaccine candidates, scenarios, and methods for combining individual forecasts into a market forecast.

A4.3 Methodology

The forecast first established assumptions across different scenarios for each vaccine candidate. These assumptions were translated into a numeric supply estimate for the vaccine candidate, and each of the individual candidate supply estimates was combined into an estimate of supply volume at a global market level.

The candidates are in different stages of development, with varying probabilities of achieving licensure and different dosing schedules. Therefore, the assumptions for each individual vaccine candidate were standardized to create a market perspective that accounts for the different characteristics and probability of licensure of each candidate.

A4.3.1 Forecast assumptions and scenarios

Assumptions on the future supply availability of vaccines were developed for each vaccine candidate based on independent desk review research, consultations with each developer, the vaccine development expertise of the forecasting team and the expertise of the expert panel of vaccine development and regulatory experts. Assumptions were made across four critical categories, varying by scenario, as follows.

1. **If and when each vaccine candidate will be licensed**. Because the candidates are in different development stages and are employing different regulatory strategies, a range of possible outcomes was identified. For each scenario, each candidate's probability of licensure (POL) and the associated year of licensure were estimated. Vaccine candidates in later-stage development were generally assigned a higher POL than those in earlier stages of development. Plans for the use of untested regulatory licensure pathways were assigned a POL lower than those using more traditional regulatory licensure pathways. The assumptions were monitored to ensure that they represented both the best estimate in an absolute sense and relative to each other. These assumptions were made for pessimistic, base and optimistic scenarios and differed across the three scenarios for most vaccines. Probability of licensure assumptions ranged from 20% to 70% and year of licensure assumptions ranged from 2027 to 2036.
2. **Populations for which each vaccine will be indicated**. Differences in composition, manufacturing methods and testing approaches among the vaccine candidates mean that their target populations may vary in terms of age range, inclusion or exclusion of special populations and whether any pre-screening requirements are necessary (e.g. testing for previous TB infection). These assumptions were static for each vaccine candidate across the scenarios. Age range assumptions were between 14 and 85.

3. **Amount of available supply**. The early development stage of most candidates means that developers have not finalized their manufacturing strategies, and estimates of future supply availability were made based on expert knowledge of the vaccine candidates and developers. Supply was estimated as the number of doses. Assumptions were based on future developer activity in the absence of third-party incentives or interventions. It was assumed that an increase in volume would occur five years after the first licensure for all candidates, reflecting greater investment in manufacturing capacity following a successful pivotal trial result. Assumptions were made for low, base and high supply volume scenarios. Supply estimates for individual vaccine candidates in doses per year ranged from 10 million to 200 million.

4. **The price at which each vaccine will be offered**. Estimating the financial needs of future TB vaccination requires estimating the price at which each vaccine candidate will be offered. Prices were estimated per dose and were assumed to have an inverse relationship with the supply for each candidate (i.e. the same candidate can offer a lower price at a higher volume). Low, base and high estimates for price were made.

Three scenarios were developed for each vaccine candidate, reflecting the range of possible future outcomes.

1. **Low/pessimistic:** This scenario reflects pessimistic, longer development times and therefore later licensure, combined with a low estimate of potential volume availability and high price.

2. **Base:** This scenario reflects the best estimate of what is expected on the timeline of licensure, estimate of available volume, and price and uses the base version of all assumptions.

3. **High/optimistic:** This scenario reflects optimistic, shorter development times and, therefore, earlier licensure, combined with a high estimate of potential volume availability and low price.

A4.3.2 Individual candidate volume forecast

Individual candidates differed significantly in their assumed POL per scenario and dosing schedule. To ensure a comparison of candidates that equalizes those dimensions and provides a view of the most likely future market situation, the supply volume of candidates was adjusted in two ways.

1. Supply (expressed in doses) was adjusted by the POL for each candidate in each scenario to arrive at a probability-adjusted estimate of available supply. For example, if it was estimated that a candidate had a 60% POL and that 100 million doses could be available, then the resulting estimate was adjusted to 60 million doses for the first five years after licensure and thereafter adjusted to 100%.

2. POL-adjusted supply (expressed in doses) was divided by the number of doses per vaccination regimen (i.e. one, two or three doses) to arrive at the number of estimated available vaccination regimens.

A4.3.3 Market volume forecast

The POL-adjusted supply estimates in regimens for each candidate and each scenario were then added together to form a market perspective on the range of supply availability. The base scenario represents the simple sum of the base available supply for each vaccine candidate in scope. Low and high market supply scenarios were developed to recognize that it is unlikely that all candidates would simultaneously arrive at the low/pessimistic scenario (or the high/optimistic scenario). These scenarios therefore adjust the absolute scenario volumes of the high and low scenario estimates for each individual candidate by one-third (i.e. the low numbers are increased by one-third and the high numbers are decreased by one-third). The market scenario forecasts follow a methodology similar to that used in WHO's Market Information for Access to Vaccines (MI4A) analysis reports.

This results in three market-level supply scenarios:

1. **low/pessimistic:** the sum of individual candidate low/pessimistic scenarios that have been increased by one-third;

2. **base:** the sum of the individual candidate base scenarios; and

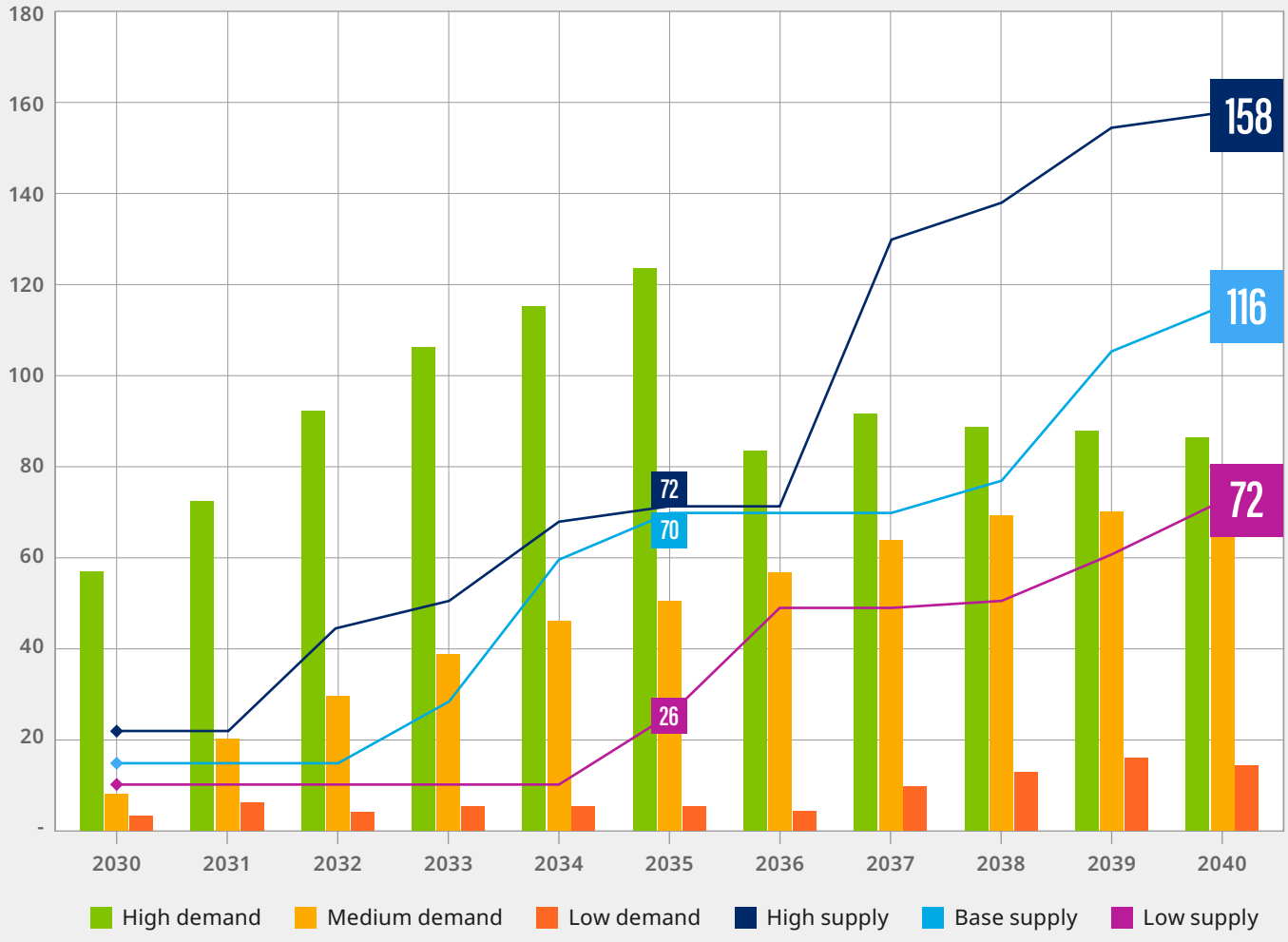
3. **high/optimistic:** the sum of individual candidate high/optimistic scenarios that have been decreased by one-third.

The results of the comparison between all demand scenarios and supply scenarios are presented in Fig. A4.1.

Fig. A4.1

Comparison of all supply and demand scenarios

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



Source: Gavi, the Vaccine Alliance

Annex 5: Financing landscape

A5.1 Scope

To support the objectives of the F&A WG, an analysis of the anticipated financing requirements and availability for novel TB vaccines targeting adults and adolescents was conducted.

Objective 1
Estimate funding requirements for novel TB vaccines, based on demand and price projections.

Objective 2
Identify funding sources and financial commitment towards TB vaccine procurement from domestic and external sources.

Objective 3
Assess potential financing gap for countries to procure novel TB vaccines in the first 10 years of product availability.

This section details the methodology and findings from the analysis.

A5.2 Methodology

Separate methodologies are used to estimate the anticipated financing requirement and funding availability for the procurement of novel TB vaccines over a timeframe of 2030–2040. However, it is important to recognize that the global TB architecture continues to evolve, and the funded demand by 2030 will be influenced by country-level optimization and prioritization decisions, which in turn affect financing needs and resource availability. The following methodology has been applied to generate estimates, acknowledging these considerations.

A5.2.1 Financing requirement

To calculate the funding requirement per country for TB procurement, the following formula was employed:

Funding requirement $ per country	=	Vaccine demand in courses	X	Average price per course

Vaccine demand in regimens

A Gavi-led demand assessment was conducted to understand potential vaccine uptake globally, considering disease burden, delivery feasibility and competing priorities. For the purpose of this analysis, the **high scenario** is considered to estimate country-level vaccine demand in regimens. It was found to balance ambition with feasibility while sending a strong market signal to manufacturers.

Average price per regimen

A price corridor for novel TB vaccines segregated by donor eligibility and income groups based on World Bank classification was defined by WHO using benchmarks of analogue vaccine doses, such as the human papillomavirus (HPV) vaccine, pneumococcal conjugate vaccine (PCV) and malaria vaccine. The pricing corridor benchmarks reflect the pricing needs of Gavi-supported low-income countries (LICs), advance market commitment (AMC)-eligible middle-income countries (MICs), and self-financing MICs. It should be noted that this approach is structured to support future procurement models (e.g. AMCs and pooled procurement) and inform country-level financial planning, but it is not supposed to be guidance for manufacturers or suppliers.

The details of the justification of analogues, pricing corridor benchmarks and the resulting novel TB vaccine pricing corridor are provided in tables A5.1 and A5.2.

Table A5.1

Rationale for analogue selection

Analogue	Justification for inclusion
HPV	Adolescent target, tiered pricing track record, MIC rollout precedent
PCV	High cost of good sold (COGS), multi-dose, similar delivery challenges
Malaria RTS,S	AMC precedent, protein/adjuvant-based, relevant for Africa

Source: WHO

Table A5.2

Price corridor of analogues

Category	HPV	PCV	Malaria
Gavi-eligible countries	$2.90–5.18	$2.75–3.30	$3.90
Non-eligible LMICs	$2.9–11.4	$4.0–14.18	$3.90
Upper-middle-income countries (UMICs)	$4.5–14.14	$4.0–16.0	$3.90
High-income countries (HICs)	$26.75–33.25	$25.0+	$9.30

Source: WHO

Dose per regimen assumption

Given the early nature of this work and the lack of clear product characteristics, it can be assumed that the product that reaches the market can be either a single-dose or a double-dose vaccine and hence, 1.5 is taken as the estimated dose per regimen (Table A5.3).

Table A5.3

Price corridor of novel TB vaccines

Category	Per dose price corridor	Per regimen price corridor
Gavi-eligible countries	$2.00–3.50	$3.50–5.25
Non-eligible LMICs	$3.50–5.00	$5.25–7.50
UMICs	$5.00–7.50	$7.50–11.25
HICs	$10.00–15.00	$15.00–22.50

Source: WHO

A5.2.2 Financing availability

The financing availability was determined through stakeholder consultations with 18 key financing and access stakeholders for insights related to TB vaccine financing availability. The stakeholder categories consulted were:

1. immunization and TB funders to provide insights into available external funding for immunization programmes;
2. development banks, procurement agencies and innovative financiers to provide insights into the availability of loans and liquidity support for novel TB vaccine procurement; and
3. country-level stakeholders and WHO regional offices to provide insights into national health budget planning for novel TB vaccine procurement.

A5.3 Consultations

The list of stakeholders consulted across various groups is outlined below:

1. immunization and TB funders: Gavi, The Global Fund;
2. development banks, procurement agencies and innovative financiers: Asian Development Bank, European Investment Bank, African Development Bank, MedAccess, PAHO Revolving Fund (PAHO RF) and UNICEF; and
3. country-level stakeholders and WHO regional offices: Brazil, Ethiopia, Indonesia, the Philippines, South Africa, WHO Regional Office for Africa, WHO Regional Office for the Eastern Mediterranean, Pan American Health Organization, WHO Regional Office for South-East Asia and WHO Regional Office for the Western Pacific.

The consultation focused on the following main topics:

- prioritization of TB in the existing funding portfolio;
- availability of funding and potential financing mechanisms for TB vaccines; and
- learnings from financing other vaccines.

Annex 6: Financing gap modelling

A6.1 Scope

The section aims to inform the solution proposed by the F&A WG to clarify the availability of domestic and external funding available to countries for the procurement of novel TB vaccines. Understanding the financing flows is critical for identifying potential funding gaps and the need for innovative financing mechanisms. It is also closely linked to the development of a global catalytic instrument that can provide clear signals on funded demand to industry, thereby enabling at-risk manufacturing at scale. This financing gap model can be used in the years to come to clarify financing gaps through further validation and consultations with key stakeholders and countries.

A6.2 Methodology

The financing gap analysis is based on a framework for analysing country financing models by defining archetypes and developing scenarios to analyse a series of projections.

A6.2.1 Country archetype mapping

Countries adopt diverse financing models to fund health and development priorities, reflecting differences in economic structures, policy choices and institutional capacity. A set of country archetypes was developed to categorize similarities in how countries mobilize and allocate resources, as a basis for exploring potential future financing pathways.

Each country was mapped to one of four archetypes based on TB incidence rates and gross national income (GNI) per capita. The archetypes and their defining characteristics are mapped in Table A6.1 and Fig. A6.1 shows how countries are grouped into the archetypes.

Table A6.1

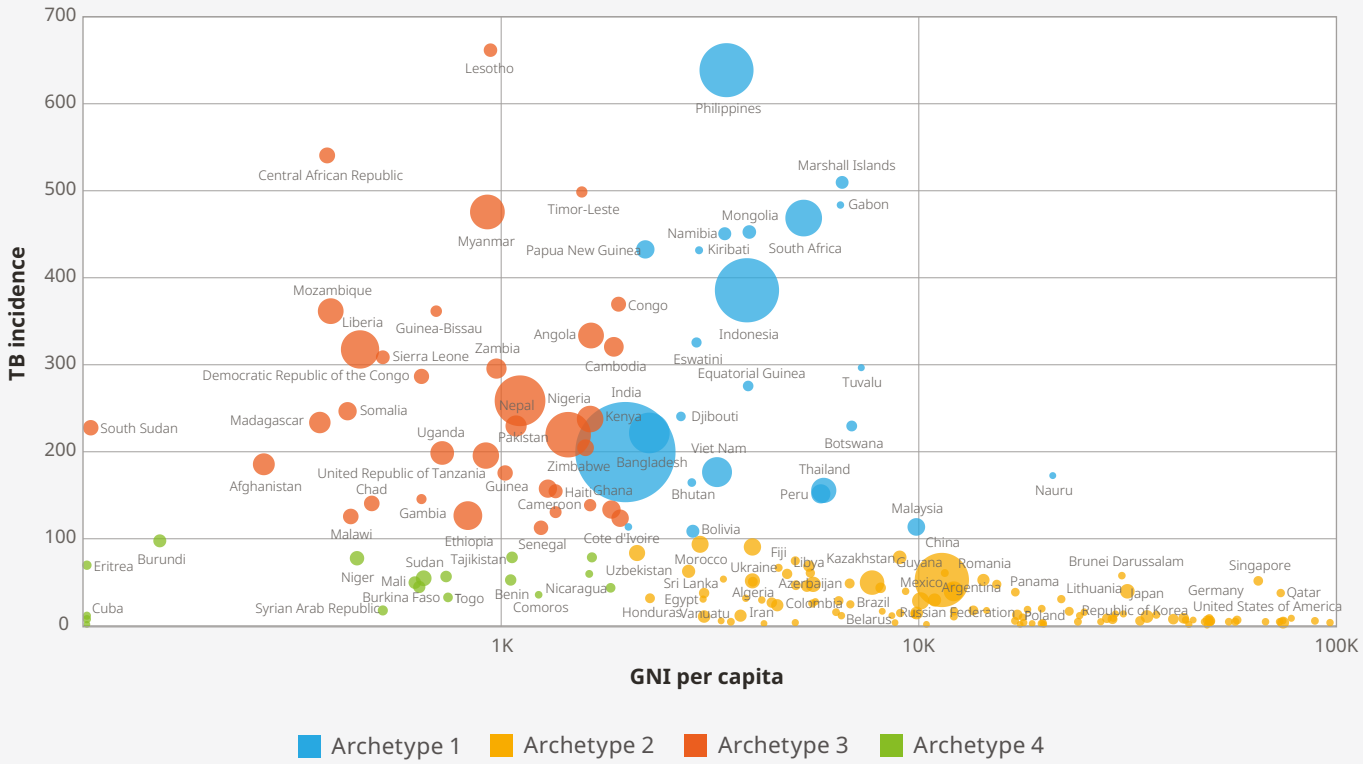
Criteria definition for country archetypes

Country archetype	GNI (US$)	TB incidence rate (per 100 000 population)
Archetype 1	>=2 500	>=100
Archetype 2	>=2 500	<100
Archetype 3	<2 500	>=100
Archetype 4	<2 500	<100

Source: WHO

Fig. A6.1

Segregation of countries into archetypes



Source: WHO

Archetype characteristics

To predict the funding behaviour of each archetype, benchmarks of historical government vaccine expenditure as a percentage of total vaccine expenditure were analysed (Table A6.2).

Table A6.2

Historical benchmark for average government vaccine expenditure across archetypes

Country archetype	Government vaccine expenditure as a percentage of overall vaccine expenditure	Non-government vaccine expenditure as a percentage of overall vaccine expenditure
Archetype 1	78%	22%
Archetype 2	96%	4%
Archetype 3	37%	63%
Archetype 4	30%	70%

Source: WHO Immunization Data for the year 2022/2023 (using latest data before 2022/2023 if unavailable). https://extranet.who.int/tme/generateCSV.asp?ds=budget.

Based on the benchmarks, funding availability across domestic funding, external funding, and loans and liquidity support for each archetype was estimated as outlined in Fig. A6.2.

In addition, the estimated funding availability across sources was further adjusted for each country based on its donor eligibility, historical TB-related expenditure from external funding and coverage from large financing institutions.

Fig. A6.2

Projected available financing across country archetypes for each funding source based on historical benchmarks

Domestic funding		External funding		Loans and liquidity support	
Archetype 3 20–40%	Archetype 1 70–80%	Archetype 3 30–50%	Archetype 1 5–15%	Archetype 3 10–20%	Archetype 1 5–10%
Archetype 4 10–30%	Archetype 2 90–95%	Archetype 4 20–50%	Archetype 2 1–3%	Archetype 4 1–10%	Archetype 2 1–5%

Source: WHO

A6.2.2 Scenario modelling

Scenario analysis can be used to estimate the financing gap by predicting the financing trajectory of each country within different archetypes. Multiple scenarios can be developed to account for uncertainty in financing trajectories, capturing a range of possible funding levels and structures that could materialize. This approach enables the estimation of potential outcomes across different contexts, providing evidence to guide strategic decision-making and prioritization of future actions.

The following illustrates three possible scenarios reflecting different levels of funding availability across funding sources, which could be used to estimate the potential financing gaps for 2030–2040.

- **Scenario 1: Strong domestic leadership with support**. This is a baseline scenario for a strong TB vaccination roll-out, which assumes a higher percentage of domestic funding availability in the range.
- **Scenario 2: Externally catalysed action**. This scenario assumes a constrained domestic funding availability, with external funding actors playing a critical role in supporting the novel TB vaccines.
- **Scenario 3: Constrained fiscal space**. This scenario assumes constrained funding availability across all funding sources.

Scenario modelling can provide insights into different levels of potential financing gaps in novel TB vaccine procurement across archetypes. The scenarios suggested above, if applied, can illustrate potential outcomes under varying macroeconomic conditions.

The above financing gap modelling framework will be further refined through stakeholder consultations and review of key information as it becomes available in the coming year(s). The framework is intended to provide an evidence base for clarifying the potential financing gap for the procurement of novel TB vaccines.

Annex 7: List of mechanisms

A7.1 Scope

This section presents a non-exhaustive compilation of past and current financing and access mechanisms led by organizations that are represented on the F&A WG. The list includes finance and access mechanisms that have been used either for vaccine or TB and other infectious-disease-related health products.

The analysis informs the solution proposed by the F&A WG to establish global catalytic instrument(s) to guarantee demand, boost supply and drive down prices. Further evaluation of these types of mechanisms will be undertaken in 2026 for applicability to novel TB vaccine access and financing barriers.

A7.2 Overview of mechanisms

Table A7.1 lists selected mechanisms, organized with key details such as their name, type, leading partner(s), scope and year of implementation.

Table A7.1

Detailed list of mechanisms

Name of mechanism	Focus			Stage of value chain			Mechanism type	Partners	Description	Recent year of use
	I	TB	O	V1	V2	V3				
African Vaccine Manufacturing Accelerator (AVMA) *(1)*	✓			✓			Performance-based funding (PBF)	Gavi, African Union, Africa Centres for Disease Control and Prevention (Africa CDC) regional vaccine manufacturers	Time-bound milestone and per-dose payments to African manufacturers (e.g. on WHO PQ) to crowd in investment and build sustainable local capacity	2025
InnovFin Infectious Diseases Finance Facility (IDFF) *(2)*	✓		✓	✓			Loans and liquidity support, matching fund	European Investment Bank, European Commission	Financing including standard debt and equity-type instruments to innovative players active in developing or manufacturing vaccines, medicines, medical and diagnostic devices, and research infrastructure to combat infectious diseases	2023
RTS,S malaria vaccine innovative financing arrangement *(3)*	✓			✓			Procurement payment risk mitigation	MedAccess, Gavi, GSK, vaccine manufacturers	Provided de-risked bridge financing from Gavi to maintain vaccine production capacity while awaiting policy decisions. If the programme proceeded after WHO's positive recommendation, funded costs would be credited towards dose procurement; if not, most costs would be reimbursed to Gavi by MedAccess.	2021
PAHO RF *(4)*	✓		✓		✓		Pooled procurement, loans and liquidity support	PAHO Member States	Aggregates regional demand for vaccines and medicines across the Americas, pools purchasing, negotiates lower prices, ensures supply stability and offers working capital	2025

I = Immunization **T** = TB **O** = Others **V1** = Product R&D and manufacturing **V2** = Procurement and market access **V3** = Delivery and HSS

Name of mechanism	Focus			Stage of value chain			Mechanism type	Partners	Description	Recent year of use
	I	TB	O	V1	V2	V3				
Vaccine Independence Initiative (VII) *(5)*	✓				✓		Loans and liquidity support; Procurement guarantee	UNICEF, MedAccess	Capital fund to allow UNICEF Supply Division to initiate procurement on behalf of countries, which needs to be paid back by the countries in 30 days once the vaccines are received and invoiced; supports LMICs purchasing essential medical supplies with domestic budgets	2025
International Finance Facility for Immunisation (IFFIm) vaccine bonds *(6)*	✓				✓		Vaccine bond	IFFIm, donor governments, World Bank, Gavi	Converts long-term donor pledges into immediately available cash via bond issuance to accelerate immunization and outbreak response	2025
Surge Financing Initiative for Medical Counter-measures (MCMs) *(7)*	✓		✓		✓		Loans and liquidity support	DFIs, MedAccess, European Investment Bank, International Finance Corporation	Fund to provide surge financing for procurement, production and distribution of vaccines, therapeutics, diagnostics and other medical countermeasures during future pandemics	Announced in 2024; not operational
COVAX Facility (inactive) *(8)*	✓				✓		Pooled procurement	Gavi, WHO, Coalition for Epidemic Preparedness Innovations (CEPI), UNICEF	Pooled purchasing and equitable allocation of COVID-19 vaccines, prioritizing LMICs	2023
Gavi COVAX AMC (inactive) *(9)*	✓				✓		AMC	Gavi, WHO, CEPI, UNICEF, donor governments, foundations	Donor-financed mechanism within COVAX providing subsidized COVID-19 vaccine doses to 92 LMIC	2023
Gavi Risk Sharing Facility for COVID-19 vaccines (inactive) *(10)*	✓				✓		Procurement payment risk mitigation	MedAccess, Gavi, Open Society Foundations	Provides financial guarantees to de-risk COVAX procurement by covering shortfalls between ordering and country payments	2022
COVAX Cost-Sharing Mechanism (inactive) *(11)*	✓				✓		Loans and liquidity support	Gavi, World Bank, Asian Development Bank, European Investment Bank	Flexible purchasing option for AMC countries to buy additional doses beyond their donor-funded allocations, using domestic or low-cost financing from multilateral development bank (MDB) partners	2021
COVID-19 supplies volume guarantee (inactive) *(12)*	✓		✓		✓		Procurement guarantee	MedAccess, UNICEF	MedAccess provided a guarantee of up to US$ 50 million enabling UNICEF to secure essential products from supplier	2021
PCV AMC *(13)*	✓				✓		AMC	**Funders:** Canada, Italy, Norway, Russia, UK, Gates Foundation **Key partners:** Gavi, World Bank, UNICEF	Guaranteed a viable market at affordable prices to spur PCV R&D/manufacturing and supply for Gavi-eligible countries	2020
Polio International Development Association (IDA) financing results-linked buy down *(14)*	✓				✓		Debt relief fund; PBF	Gates Foundation, World Bank, Gavi, USAID	Support to Pakistan through an innovative buy-down mechanism that allows partial conversion of IDA credit into a grant if certain objectives of polio immunization are met	2015
Polio Performance Programme *(15)*	✓					✓	PBF	**Funders:** Gates Foundation, European Investment Bank (EIB), European Commission **Partners:** WHO, UNICEF	Financial contribution to the Global Polio Eradication Initiative (GPEI) that is frontloaded by EIB and repaid by the European Commission or Gates Foundation based on pre-defined key performance indicators	2025

I = Immunization **T** = TB **O** = Others **V1** = Product R&D and manufacturing **V2** = Procurement and market access **V3** = Delivery and HSS

Name of mechanism	Focus			Stage of value chain			Mechanism type	Partners	Description	Recent year of use
	I	TB	O	V1	V2	V3				
Gavi's health systems and immunization strengthening (HSIS) framework *(16)*	✓		✓			✓	PBF	Gavi (with alliance partners and countries)	Funds delivery infrastructure, training, cold chain and system bottlenecks to improve routine immunization; performance-based elements introduced and later integrated under HSIS	2016
Unitaid Solidarity Fees on Premium Airline Travel *(17)*		✓	✓		✓		Solidarity levy	Governments of France, Brazil, Chile, Kenya and several other countries in coalition with Unitaid	Earmarked airline-ticket levy that finances Unitaid market-shaping interventions; has enabled access to health innovations for more than 300 million people in LMICs	2025
Global Drug Facility (GDF) *(18)*		✓			✓		Pooled procurement	The Global Fund	Pooled procurement entity for TB drugs for The Global Fund's member countries, which helps countries gain access to high quality second-line anti-TB medicines at concessionary prices along with technical assistance	2025
TB preventive therapy volume guarantee (inactive) *(19)*		✓			✓		Procurement guarantee	MedAccess, Clinton Health Access Initiative (CHAI), Unitaid, Macleods Pharmaceutical	MedAccess provided a volume guarantee to Macleods Pharmaceutical, agreeing to make up any shortfall in the agreed sales volumes allowing reduction of price	2021
Drug-resistant TB treatment volume guarantee *(20)*		✓			✓		Volume guarantee	MedAccess, Viatris, TB Alliance	Volume guarantee agreement for pretomanid, which helped reduce its price by 34% in more than 130 LMICs	2022
Wambo.org *(21)*		✓	✓		✓		Pooled procurement	The Global Fund	Digital procurement platform to provide The Global Fund grant implementers with access to competitive prices, increased transparency and reliability in the supply of quality health products	2016
Xpert Mycobacterium tuberculosis (MTB)/ resistance to rifampin (RIF) Test Buy-down *(22)*		✓			✓		Grant, tiered pricing	Gates Foundation, United States Agency for International Development (USAID), Unitaid, Cepheid	10-year buy-down agreement to reduce GeneXpert TB test costs to US$9.98 per unit and negotiated reduced prices for the different instrument configurations in 145 high-burden countries	2012
The Global Fund Country Grants *(23)*		✓	✓		✓		Grants	The Global Fund	Financing based on burden and capacity to support national HIV, TB and malaria programmes through grants tailored by country consultations and approved via Technical Review Panel	2025
The Global Fund Country Matching Funds *(24)*		✓	✓		✓		Matching Fund	The Global Fund	Offers additional funds to countries if they budget and commit to strategic priority interventions (e.g., HIV prevention in key populations, TB case-finding, health system strengthening)	2025
The Global Fund Strategic Initiatives *(25)*		✓	✓		✓		Grant	The Global Fund	Funds cross-cutting or high-impact programmes not feasible through country grants but is a strategic priority, such as community systems strengthening, removing gender barriers, regional diagnostics, emergency response funding	2025
Debt Swaps (Debt2Health) *(26)*		✓	✓		✓		Debt Relief Fund, PBF	The Global Fund	Allows creditor and debtor countries to convert – or swap – part of their debt into lifesaving health investments	2024

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Name of mechanism	Focus			Stage of value chain			Mechanism type	Partners	Description	Recent year of use
	I	TB	O	V1	V2	V3				
AMR Action Fund *(27)*			✓	✓			Loans and liquidity support	International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) and its member biop-harmaceutical companies, World Health Organi-zation, European Investment Bank, Wellcome Trust	Nearly US$1 billion investment initiative to invest in clinical-stage companies that are pursuing both traditional small-molecule compounds and innovative modalities, such as bacteriophages and antibody treatments	2020
African Pooled Procurement Mechanism (APPM) *(28)*			✓		✓		Pooled procurement	Africa CDC	Pooled procurement mechanism to improve the affordability, availability and equitable access to essential medical supplies across the continent	2025
Heavily Indebted Poor Countries (HIPC) Initiative *(29)*			✓		✓		Debt Relief Fund; PBF	Inter-American Development Bank, African Development Fund, International Monetary Fund, World Bank	Allows countries that meet certain criteria, commit to policy changes to reduce poverty and demonstrate a record of doing so to receive 100% relief on eligible debts	2025
Edible oil fortification volume guarantee *(30)*			✓		✓		Volume guarantee	MedAccess, dsm-firmenich	Volume guarantee to establish a ceiling price for edible oil fortification in LMICs	2025
Radiotherapy Volume Guarantee and Pay-per-use Model *(31)*			✓		✓		Volume guarantee, PBF	MedAccess, Elekta, CHAI	Pay-per-use model financing of radiotherapy equipment covered by a volume guarantee to cover potential shortfall in number of patients using radiotherapy machines in Kenya and the United Republic of Tanzania	2025
Introduction of next-generation bed nets (inactive) *(32)*			✓	✓	✓	✓	Product development support, volume guarantee, product subsidy	MedAccess, BASF, Gates Foundation, The Global Fund, Unitaid, President's Malaria Initiative (PMI), CHAI	The Gates Foundation provided grant funding to support development of new nets. MedAccess provided a volume guarantee to BASF, allowing BASF to introduce the mosquito nets at a significantly reduced rate in LMICs. The Global Fund and PMI provided a short-term co-payment for the price differential between standard of care nets and new nets	2019
Glucose-6 phosphate dehydrogenase (G6PD) testing volume guarantee *(33)*			✓		✓		Volume guarantee	MedAccess, SD Biosensor, PATH	MedAccess provided a volume guarantee to SD Biosensor to be able to produce and supply its G6PD testing devices and test strips globally, and offer both products at a reduced price in LMICs	2022
Dual rapid test for syphilis and HIV volume guarantee *(34)*			✓		✓		Volume guarantee	MedAccess, SD Biosensor, CHAI, The Global Fund, President's Emergency Plan for AIDS Relief (PEPFAR), African Society for Laboratory Medicine	MedAccess provided a volume guarantee to SD Biosensor while The Global Fund and PEPFAR indicated they would increase procurement if the price was below US$1 allowing SD Biosensor to decrease the price for the diagnostic test	2021
HIV viral load testing all-inclusive pricing model (inactive) *(35)*			✓		✓		Volume guarantee	MedAccess, Hologic, CHAI, Unitaid, African Society for Laboratory Medicine	MedAccess provided a volume guarantee to Hologic, agreeing to make up any shortfall in agreed sales volumes, allowing Hologic to introduce viral load testing to national government testing programs at a significantly reduced rate	2018

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