



**Catalyzing solutions for equitable global  
access and sustainable financing for novel  
TB vaccines for adults and adolescents:  
Landscape and evidence to date**

***22 September 2025***

***Annexes for Public Summary for Consultation***

## Annex A: Country access and financing plans

### A1. Scope

This analysis provides an overview of high-TB-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 WHO consultations with stakeholders from five high-TB-burden countries and five WHO regional offices.

### A2. 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 Indonesia, Brazil, South Africa, and the Philippines. 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 WHO AFRO, WHO AMRO / PAHO, WHO EMRO, WHO SEARO, and WHO WPRO.

### A3. 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:

- 1) **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.
- 2) **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.
- 3) **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 distill 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 Finance and Access Working Group 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 B. Demand projections

### B1. Scope

The demand projection developed by Gavi quantifies the number of novel TB vaccine courses for adolescents and adults across all WHO member states and covers the 2030-40 period. The forecast is unconstrained and product-agnostic.

### B2. Consultations

In-depth interviews were conducted with country stakeholders in nine high-TB-burden countries accounting for 63% of global TB burden (Brazil, China, DRC, India, Indonesia<sup>1</sup>, Nigeria, Pakistan, South Africa<sup>1</sup>, and Viet Nam) and their consolidated inputs 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, immunisation programmes, other ministry of health divisions, regulatory agencies, National Immunisation Technical Advisory Groups, development partners, researchers, national procurement agencies, national treasuries and civil society organisations. 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 immunisation from global and regional organisations were consulted, including Gavi, the Gates Foundation, the London School of Hygiene and Tropical Medicine, UNICEF, the University of Cape Town, and WHO.

### B3. Methodology

The demand forecast has been developed using a standard population-based forecasting approach which aims to quantify the number of novel TB vaccine courses (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

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<sup>1</sup> Stakeholder consultations were conducted in collaboration with the London School of Hygiene and Tropical Medicine (LSHTM)

following paragraphs, the key elements of the demand forecasting methodology are described in more detail.

### **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)<sup>2</sup> are used to define the scope of potential target populations for vaccination.<sup>3</sup> 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 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 immunisation (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.
- High-risk groups (HRG) most susceptible to TB, reached via catch-up vaccination and routine immunisation, 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.

### **Coverage**

Country-specific coverage estimates for each target population and delivery strategy are based on analogues from existing vaccines or other health programmes. For routine immunisation, 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.

### **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 immunisation schedules, country financing constraints, and 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.

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<sup>2</sup> [WHO Evidence Considerations for Vaccine Policy Development for Tuberculosis Vaccines Intended for Adults and Adolescents](#) (2024)

<sup>3</sup> Travelers from low-burden countries to high/mid-burden countries added as additional target population

## 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<sup>4</sup>, 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
- **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

## 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 routine immunisation. Broad catch-up vaccination is expected to bring the highest and fastest public health impact in line with the goal of TB elimination.<sup>5</sup>

**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.

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<sup>4</sup> [WHO Global Lists of High-Burden Countries for TB, HIV-associated TB and Drug-resistant TB](#) (2021). 30 countries on each list, of this 20 countries with highest estimated number of incident TB cases/incident TB cases among people living with HIV/estimated number of incident MDR/RR-TB cases, plus the top 10 countries with highest estimated TB/TB-HIV/MDR-TB incidence rates not in the top 20 (threshold: >10,000 estimated incident TB cases per year/>1,000 estimated incident TB/HIV cases per year/>1,000 estimated incident MDR/RR-TB cases per year)

<sup>5</sup> [Portnoy et al.](#) (2023): The cost and cost-effectiveness of novel tuberculosis vaccines in low- and middle-income countries: A modeling study

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 (Figure 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.

**Figure 1: Demand scenarios differentiated by country archetype.**

		Max public health need <i>To vaccinate everyone and meet full public health need</i>	High demand <i>To accelerate impact on TB burden</i>	Medium demand <i>To achieve impact on TB burden in the long term</i>	Low demand <i>To protect those most at-risk for TB</i>
Target population & delivery strategy	High burden	Adolescents (15-yo)	RI		
		Adults (16-44-yo)	Catch-up nationwide <sup>1</sup>	Catch-up high-risk areas	
		High-risk groups		RI & catch-up (3 HRGs + HCW)	
	Mid burden	Adolescents (15-yo)	RI		
		Adults (16-44-yo)	Catch-up nationwide <sup>1</sup>	Catch-up high-risk areas	
		High-risk groups		RI & catch-up (3 HRGs + HCW)	
	Low burden	Adolescents (15-yo)			
		Adults (16-44-yo)			
		High-risk groups	RI & catch-up (PLHIV, HHC), RI (migrants, travelers)		RI (migrants, travelers)

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

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

## Annex C. Product licensing and access strategies

### C1. Scope

Currently, at least fifteen TB vaccine candidates are in clinical development, including six in Phase III trials (see Appendix 2 for novel TB vaccine pipeline). 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 these populations most at risk. Recognizing that scientific readiness alone is not enough, the 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 be leveraged to 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, mapping them to the key stages of the vaccine value chain and highlighting enablers that may accelerate progress along with bottlenecks, both of which will be critical to assess in order to ensure successful vaccine rollout.

### C2. Methodology

The 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 IIb 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 below outlines the selected vaccine candidates.

Between March and June of 2025, the 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, which were enablers, barriers, and future plans.

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

- 1) R&D - clinical evidence and phase III financing
- 2) Policy and regulatory pathways
- 3) Manufacturing and technology transfer
- 4) Procurement and financing models
- 5) Delivery and administration readiness

### C3. Stakeholders consulted



## PUBLIC SUMMARY FOR CONSULTATION - WORKING DRAFT

The 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 LMICs. Table 1 below shows the selected stakeholders and their rationale for inclusion as well.

Table 1. List of shortlisted stakeholders and candidates

Stakeholder	Associated Candidate	Justification for Consultation	Consultation Status
<b>GSK (GlaxoSmithKleine)</b>	<b>M72/AS01E</b>	Initial developer and provider of the AS01E adjuvant	Conducted
<b>Gates MRI</b>	<b>M72/AS01E</b>	Current sponsor of the vaccine's clinical development – licensee for low- and middle-income countries (LMICs)	Conducted
<b>BioNTech</b>	<b>BNT164a1 &amp; BNT164b1</b>	Leading the development and clinical evaluation of the BNT164 programme*	Conducted
<b>FioCruz</b>	<b>MTBVAC</b>	Licensee for Latin America	Conducted
<b>IAVI (International AIDS Vaccine Initiative)</b>	<b>MTBVAC</b>	Assisting in trial design, funding, and global health integration	Conducted
<b>Bharat Biotech</b>	<b>MTBVAC</b>	Licensee for India, SSA	Conducted
<b>Serum Institute of India (SII)</b>	<b>VPM1002</b>	Leading large-scale manufacturing and advanced clinical trials	Outreach on-hold*
<b>Quratis</b>	<b>ID93 + GLA-SE</b>	Leading clinical trials and regulatory submissions	Conducted
<b>Gamaleya</b>	<b>GAMTBVAC</b>	Leading development and clinical evaluation	No response

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

\*\*Until Phase III conclusion

Phase
Phase I
Phase IIa
Phase IIb
Phase III

## Annex D. Supply projections and comparison against demand

### D1. Scope

The supply projection developed by Gavi quantifies the vaccine supply expected to be available in the 2030-40 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. people living with HIV). The analysis also estimates the anticipated cost of each vaccine candidate.

#### Vaccine candidates included in 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 Pipeline report on Tuberculosis Vaccines ([2024\\_pipeline\\_TB\\_vaccines\\_final.pdf](#))
- ClinicalTrials.gov ([Home | ClinicalTrials.gov](#))
- Clinical Trials Registry-India ([Clinical Trials Registry - India \(CTRI\)](#)).

Six vaccine candidates were isolated 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
6. **AEC/BC02** developed by Anhui Zhifei Longcom.

### D2. Stakeholder consultations

Consultations were conducted by Gavi 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.

## Vaccine Developers

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

1. **Gates Medical Research Institute** 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**
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.

## Vaccine development and regulatory experts

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

### D3. 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 were combined into an estimate of supply volume at a global market level.

Because the candidates are in different stages of development, with varying probability of achieving licensure and with different dosing schedules, 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.

## Forecast assumptions and scenarios

Assumptions on the future supply availability of vaccine 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 (detailed below), that included:

1. **When and if 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 were identified. For each scenario, the probability of each candidate achieving licensure (POL) and the associated year of licensure was 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. **For whom each vaccine will be indicated.** Because the vaccines have different compositions and manufacturing methods and are being tested differently, the indications for the specific populations for each vaccine candidate could differ 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. **How much supply will be available.** Because of the stage of development of most candidates, 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 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 5 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. **At what price will the vaccine 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.

### 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 has a 60% POL and that 100 million doses could be available, then the resulting estimate is adjusted to 60 million doses for the first five years after licensure and thereafter adjusts to 100%.
2. POL adjusted supply (expressed in doses) was divided by the number of doses per vaccination course (i.e., one, two or three doses) to arrive at the number of estimated available vaccination courses.

### Market Volume Forecast

The POL adjusted supply estimates in courses 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' Market Information for Access to Vaccines (MI4A) market 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

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

## Annex E. Financing Landscape

### E1. Methodology

The WHO aimed to understand the global financing requirement, availability and gap for procurement of novel TB vaccines over a timeframe of 2030-2040.

#### E1.1. Financing requirement

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

$$\text{Funding requirement \$ per country} = \text{Vaccine demand in courses} \times \text{Average price per course}$$

#### *Vaccine demand in courses*

Gavi led a demand assessment aimed at understanding potential vaccine uptake globally, considering disease burden, delivery feasibility, and competing priorities.

Based on the review of demand scenarios in Gavi's demand forecast, the '**High Scenario**' is considered in this document to estimate country-level vaccine demand in courses as it was found to balance ambition with feasibility while sending a strong market signal to manufacturers. The findings from the detailed demand analysis can be read in Section 2.2.

#### *Average price per course*

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

The details of the justification of analogs, pricing corridor benchmarks and the resulting novel TB vaccine pricing corridor are provided below:

#### Rationale for analog selection

Analog	Justification for inclusion
HPV	Adolescent target, tiered pricing track record, MIC rollout precedent
PCV	High COGs, multi-dose, similar delivery challenges
Malaria RTS,S	AMC precedent, protein/adjuvant-based, relevant for Africa

**Price corridor of analogs**

Category	HPV	PCV	Malaria
<b>Gavi-eligible countries</b>	\$2.90-\$5.18	\$2.75-\$3.30	\$3.90
<b>Non-eligible LMICs</b>	\$2.9-\$11.4	\$4.0-\$14.18	\$3.90
<b>UMICs</b>	\$4.5-\$14.14	\$4.0-\$16.0	\$3.90
<b>HICs</b>	\$26.75-\$33.25	\$25.0+	\$9.30

**Dose per course assumption**

Given the early nature of this work and lack of clear product characteristics, we assume the product that reaches the market can be either a single-dose or a double-dose vaccine and hence take 1.5 as estimated dose per course.

**Price corridor of novel TB vaccines**

Category	Per dose price corridor	Per course price corridor
<b>Gavi-eligible countries</b>	\$2.00-\$3.50	\$3.50-\$5.25
<b>Non-eligible LMICs</b>	\$3.50-\$5.00	\$5.25-\$7.50
<b>UMICs</b>	\$5.00-\$7.50	\$7.50-\$11.25
<b>HICs</b>	\$10.00-\$15.00	\$15.00-\$22.50

**E1.2. Financing availability**

The WHO conducted stakeholder consultations with 18 key financing and access stakeholders for insights related TB vaccine financing availability. The various groups of stakeholders consulted included

- 1) Immunization and TB funders to provide insights into available external funding for immunization programs
- 2) Development banks, procurement agencies and innovative financiers to provide insights into availability of loans and liquidity support for novel TB vaccine procurement
- 3) Country-level stakeholders and WHO regional offices to provide insights into national health budget planning for novel TB vaccine procurement

**Stakeholders consulted**

The list of stakeholders consulted include:

- 1) Immunization and TB funders: Gavi, Global Fund
- 2) Development banks, procurement agencies and innovative financiers: Asian Development Bank, European Investment Bank, African Development Bank, MedAccess, PAHO Revolving Fund and UNICEF



- 3) Country-level stakeholders and WHO regional offices: Brazil, Ethiopia, Indonesia, Philippines, South Africa, WHO Regional Office for Western Pacific, PAHO, WHO Regional Office for Africa, WHO Regional Office for South-East Asia and WHO Regional Office for the Eastern Mediterranean

### Discussion topics

The consultation focused on the following main topics:

- Prioritization of TB in existing funding portfolio
- Availability of funding and potential financing mechanisms for TB vaccines
- Learnings from financing other vaccines

### E1.3 Financing gap

#### Methodology

The WHO conducted a financing gap analysis to understand potential financing gaps by modelling various funding availability scenarios for each country.

#### Scenario modelling

Given the early nature of this analysis, there is no earmarked or committed amount to novel TB vaccine procurement funding. Consequently, at this point, all of the financing requirement can be treated as a financing gap.

Three scenarios were modeled to reflect varying levels of funding availability across funding sources which could be used to estimate the potential financing gaps in 2026.

- Scenario 1 (Strong Domestic Leadership with Support): The baseline scenario for a strong TB vaccination roll-out which assumes a higher percentage of domestic funding availability in the range.
- Scenario 2 (Externally Catalyzed 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 a constrained funding availability across all funding sources.