Early Market Shaping Roadmap
Novel Tuberculosis Vaccines

PUBLIC SUMMARY
SEPTEMBER 2026

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Introduction

Context

Tuberculosis (TB) is the world's leading cause of death from an infectious agent, with 10.7 million cases and 1.2 million deaths in 2024, predominantly in low- and middle-income countries (LICs and MICs).[1] The World Health Organization (WHO) has identified 49 high-burden countries, which represent approximately 90% of the global TB burden.[2] In 2024, 77% of the deaths from TB occurred in Gavi-supported countries, with 46% in Gavi-eligible countries and 31% in Catalytic Phase countries, including 25% in India alone.[1,3]

WHO's The End TB Strategy includes targets for its Member States to reduce TB incidence by 90% and TB deaths by 95% by 2035 compared to 2015 rates.[4] However, since 2015, incidence has only reduced by 12%, and deaths by 29%.[5]

Vaccination is already an important prevention tool in the fight against TB: in 2023, approximately 250 million doses of the Bacille Calmette-Guérin (BCG) vaccine were administered[6] to protect children against TB. BCG vaccination provides up to 90% protection against severe forms of childhood TB. However, BCG protection wanes over time, providing limited protection in adolescence and adulthood (these groups play a central role in TB transmission).[7] Therefore, WHO Preferred Product Characteristics (PPC) for New Tuberculosis Vaccines prioritises development of vaccines to prevent pulmonary TB disease in adolescents and adults.[8]

New 2026 modelling from the London School of Hygiene & Tropical Medicine (LSHTM), drawing on an updated global demand forecast, suggests that a novel TB vaccine with 50% efficacy for adolescents and adults could avert up to 7.3 million deaths from 2030 through 2050 under a demand scenario targeting adolescents and adults in high-burden areas and high-risk groups.[9] The modelling also estimates that TB vaccines could generate up to US$ 135 billion in economic benefits for low- and middle-income countries by 2050.[10] With an estimated 5.8 to 20.8 deaths averted per 1,000 fully vaccinated individuals (depending on the demand scenario), modelling indicates that novel TB vaccines could have among the highest health impact in Gavi's vaccine portfolio – alongside human papillomavirus (HPV) and pentavalent/hexavalent.

Novel TB vaccines are anticipated to be introduced with, as well as complement, existing and innovative TB prevention, diagnostic and treatment tools. The health impact of novel TB vaccines is expected to be greatest when deployed as a broad immunisation intervention complementing other, more targeted TB prevention strategies focused on

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[1] WHO Global Tuberculosis Report (2025)
[2] WHO Global Lists of High-Burden Countries for TB, HIV-associated TB and Drug-resistant TB (2021).
[3] 'Gavi-eligible countries' refers to the 56 countries (as of 2026) that are under the threshold for eligibility for Gavi support which is US$ 2,300 GNI p.c. in 2026. 'Catalytic phase countries' refers to the 35 countries (as of 2026) supported under Gavi's catalytic phase that are not Gavi-eligible and whose GNI p.c. is equal to or below the World Bank's lower-middle income threshold, or if they are eligible to borrow from the International Development Association (IDA-eligible). 'Gavi-supported countries' is used as an umbrella term encompassing 'Gavi-eligible countries' and 'Catalytic phase countries'.
[4] WHO The END TB Strategy (2015)
[5] WHO Global Tuberculosis Report (2025)
[6] Global Vaccine Market Report (2024)
[7] Hatherill et al. (2022)
[8] WHO Preferred Product Characteristics for New Tuberculosis Vaccines (2022)
[9] Ellis et al. "Estimating the potential health and economic impact of novel TB vaccines: Summary of modelling results", June 2026. Preliminary results from modeling conducted by LSHTM with input from Gavi, using an updated global demand forecast developed by Gavi, Clinton Health Access Initiative (CHAI) and MMGH Consulting published in the WHO TB Vaccine Accelerator Finance and Access working group's 2025 report ; Assumes the 'High Demand' scenario endorsed by the working group
[10] Economic benefits are calculated as the sum of testing and treatment costs averted, non-medical costs averted, and productivity losses from disability and death averted.

high-risk groups. This will contribute to an amplified public health impact and, over time, reduce the need for treatment by lowering incidence and transmission.

The first vaccine candidate meeting the WHO PPC criteria could be licensed for use by a regulatory authority as early as 2030, highlighting the need for global stakeholders to already prepare for successful vaccine programme roll-out.

TB Vaccine Accelerator and Gavi engagement

In 2023, WHO established the TB Vaccine Accelerator Council to accelerate development, regulatory approval and equitable access to new TB vaccines. The Accelerator's Finance and Access Working Group (F&A WG),[11] established in 2025, is co-convened by WHO, the Government of South Africa and the Gavi Secretariat. It focuses on: accelerating manufacturing, supply and equitable global access to novel TB vaccines from a competitive and geographically diversified supply base at adequate scale; accelerating materialisation of predictable funded demand from governments and sustainable financing for vaccine procurement; and promoting alignment of efforts and resources across stakeholders.

The F&A WG published a report in 2025[12] with anticipated barriers, bottlenecks and market dynamics to provide a shared understanding of the current landscape and its possible evolution. The report stated that countries' access to TB vaccines and financing is a concern; market challenges threaten equitable access; global demand may outpace supply in critical early years; and from 2030 to 2040, funding needed to procure sufficient TB vaccines to meet demand could reach a value of US$ 5–8 billion. The F&A WG report proposed coordinated actions across demand, financing, supply and access. Building on the report, in 2026–2027, the F&A WG is working to develop and design prioritised solutions to accelerate finance and access for novel TB vaccines.

As an outcome of Gavi's Vaccine Investment Strategy (VIS) 2024, the Gavi Board approved support 'in principle' for TB vaccines for adolescents and adults, contingent on product availability, regulatory & technical review, and financial assumptions; and requested continued exploration of timely early market shaping interventions. Novel TB vaccines are also in scope for Gavi's Catalytic Phase support and a priority vaccine in Gavi's African Vaccine Manufacturing Accelerator (AVMA),[13] incentivising diversification of future supply to Africa.

This early market shaping roadmap is developed in the context of these mandates. Building on Gavi's role as co-convener of the F&A WG, this roadmap also aims to articulate the Alliance's specific contribution to complement and reinforce the F&A WG's collective efforts, including translation of the WG's global access and financing agenda into Alliance-specific priorities, decisions and interventions, with a focus on accelerating the impact of novel TB vaccines in countries eligible for Gavi support.

[11] The WHO TB Vaccine Accelerator Finance and Access Working Group aims to ensure timely, equitable and affordable access to new TB vaccines for countries with high public health needs, and includes country representatives from high-burden countries, global experts, civil society organisations, as well as finance and development partners.
[12] Catalyzing solutions for equitable global access and sustainable financing for novel tuberculosis vaccines for adults and adolescents
[13] A new era dawns for Gavi, as Board underlines strategic shift towards country ownership and increased support for the most vulnerable

Purpose and scope of the early market shaping roadmap

Early market shaping roadmaps are intended to align market shaping objectives and target outcomes across Vaccine Alliance partners. They focus on vaccines in development, with a greater emphasis on the uncertainties and risks that may prevent timely and successful implementation of a new Gavi vaccine programme.

This roadmap sets out the Alliance's early market shaping priorities for novel TB vaccines as of mid-2026, including target outcomes and interventions for the next three to five years, and a longer-term vision for successful programme implementation. It reflects the Alliance's unique position and capabilities within the broader vaccine ecosystem; and will both contribute to and complement activities and proposed solutions of the F&A WG.

The geographic scope of the roadmap includes demand forecasts for all LICs and MICs irrespective of Gavi eligibility, while strategic objectives, target outcomes and proposed interventions are focused primarily on Gavi-supported countries. This approach reflects the realities of the novel TB vaccine market, in which a significant share of the TB burden is concentrated in MICs, while recognising that Gavi's greatest leverage is in countries eligible for its core and catalytic support.

Vaccine pipeline and policy development

Clinical pipeline

A full overview of TB vaccine candidates in the pipeline is available here.[14] This section of the roadmap focuses on seven candidates in Phase 1, 2 and 3 clinical trials with a planned indication for prevention of disease in adults and adolescents, and with the potential to attain licensure between 2030 and 2040. These candidates align to varying degrees with WHO's PPC for new TB vaccines, which provide important reference points for future programme suitability.

The candidate vaccines employ a range of technologies, including adjuvanted protein, live-attenuated and mRNA platforms; and, if successfully licensed, may exhibit significant differences in effectiveness and programmatic characteristics:

- M72/AS01E is an adjuvanted protein-based candidate being developed by the Gates Medical Research Institute (MRI) that demonstrated 50% efficacy in a Phase 2b efficacy trial and an acceptable safety profile for people living with HIV (PLHIV) in a Phase 2a trial,[15,16] which together justified initiation of a Phase 3 efficacy trial with results expected in mid-2028, followed by licensure by 2029–2030, if successful.
- GamTBvac is an adjuvanted protein-based candidate being developed by the Russian Gamaleya Federal Research Centre. A Phase 3 clinical trial evaluating the efficacy of GamTBvac against respiratory TB not associated with HIV infection is expected to be completed in 2026.[17]

[14] Stop TB Partnership Working Group on New Vaccines (WGNV) – TB vaccine pipeline
[15] https://www.thelancet.com/journals/lanhiv/article/PIIS2352-3018(25)00124-9/fulltext
[16] https://www.nejm.org/doi/full/10.1056/NEJMoa1909953
[17] https://clinicaltrials.gov/study/NCT04975737

- MTBVAC is a live attenuated candidate being developed by a Biofabri-led international consortium of academic and global health partners, which has initiated a Phase 2b efficacy trial with results expected in 2028.[18]
- BNT164 is an mRNA candidate being developed by BioNTech undergoing a Phase 2a dose- and regimen-ranging clinical trial, with results anticipated at the end of 2026.[19]
- H107e/CAF10b is an adjuvanted protein-based early-stage candidate being developed by Statens Serum Institut (SSI). It is currently in Phase 1 clinical development.
- QTP101 is an adjuvanted protein-based candidate developed by Quratis currently in Phase 2a. It consists of a recombinant protein ID93 and the GLA-SE adjuvant.
- AEC/BC02 is an adjuvanted protein-based candidate being developed by Anhui Zhifei Longcom Biopharmaceutical. It was undergoing a Phase 2a study, which has been suspended.

Policy development

Future guidance from global or national authorities on the use of novel TB vaccines will be essential, based on clinical trial results and other available evidence. The WHO Technical Advisory Group on Evidence for Clinical and Policy Considerations for New TB Vaccines is supporting early scenario-planning to identify the evidence needed for future policy recommendations. This work aims to support timely recommendations and avoid delays to access, while informing the future role of WHO's Strategic Advisory Group of Experts on Immunization (SAGE), which is ultimately responsible for issuing global vaccine policy recommendations.

Demand and supply overview

In 2025, Gavi, Clinton Health Access Initiative (CHAI) and MMGH Consulting developed global demand and supply forecasts to inform the F&A WG. They can be found in the 2025 F&A WG report; and details on the global demand forecast and methodology can be found here. The F&A WG reached consensus that the "high-demand scenario" best balances the ambition to accelerate health impact with implementation feasibility. This scenario is grounded on extensive consultations with high-burden countries; and assumes catch-up vaccination in high-burden areas and high-risk groups, with routine adolescent vaccination to provide population immunity in the longer term.

The Alliance's analyses and early market shaping interventions build on the high-demand scenario endorsed by the F&A WG and the supply forecast developed in 2025, with the following adjustments:

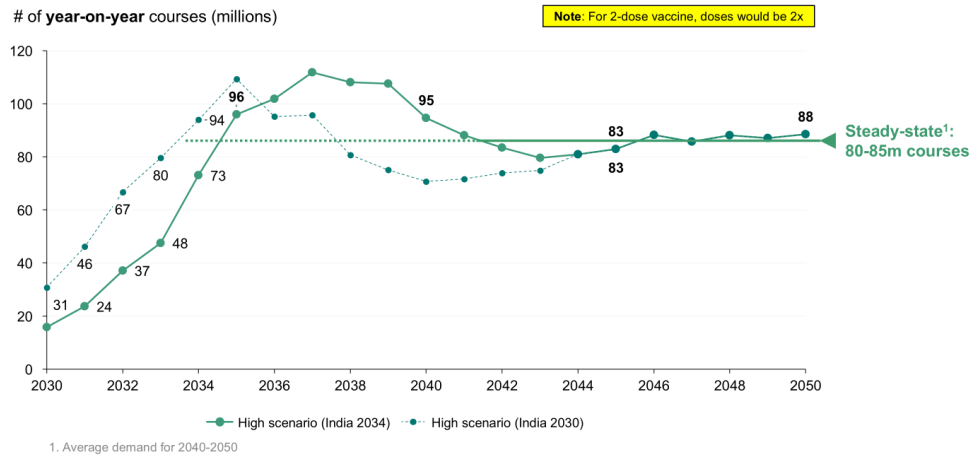
- On demand: analyses focus on LICs and MICs, where the burden of TB and expected demand for novel TB vaccines are concentrated. Demand from countries expected to rely on locally developed or regionally supplied vaccines, as well as high-income countries, is excluded from the analysis. India is considered separately – given its large share of potential demand, and uncertainty in terms of introduction strategy and timelines.

[18] https://clinicaltrials.gov/study/NCT06272812
[19] https://clinicaltrials.gov/study/NCT05547464

- On supply: analyses focus on late-stage vaccines expected to achieve global licensure and WHO prequalification before 2040.

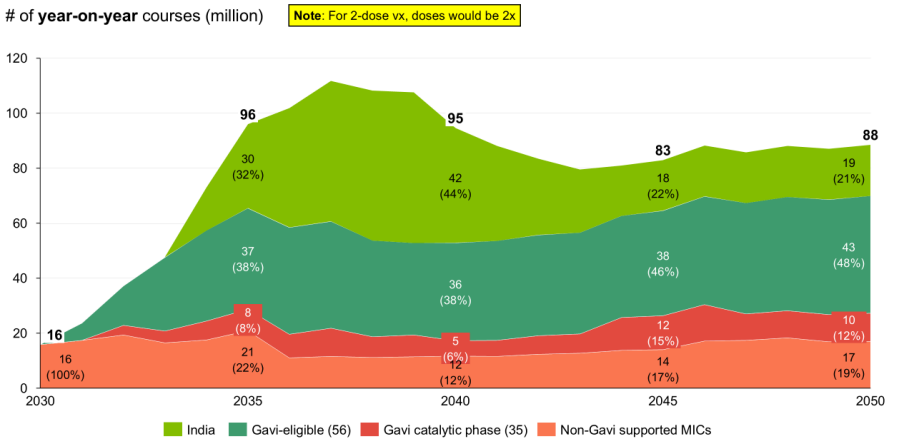
Under a scenario in which India introduces in 2034, demand over the first five years would average around 49 million courses per year, before reaching a peak of approximately 110 million courses per year in 2037. If India introduces as soon as 2030 in high-risk groups and high-risk areas, demand over the first five years increases to approximately 70 million courses per year, with demand peaking in 2035 at 110 million courses. In both scenarios, demand gradually levels out and stabilises over the longer term at around 86 million courses per year from 2040 onwards (see Figure 1).

Figure 1. Demand forecast for Gavi market shaping analysis with 'India introduction 2034' or 'India introduction 2030'



When the high-demand scenario is broken down by country group, Gavi-supported countries (including countries in Gavi's Catalytic Phase, excluding India) contribute approximately 50% of the long-term demand (2030–2050) under both India introduction scenarios (see Figure 2). And India contributes to approximately 30% of the 2030–2050 demand.

Figure 2. Demand forecast breakdown with India assumed to introduce in 2034



4 4 Note: India not included in Gavi catalytic category given its special Board-approved strategy
Note: Bangladesh, Côte d'Ivoire, Djibouti, PNG not included in 'Gavi' eligible countries as expected to transition from Gavi before TB vx introductions

Key insights emerging from the analysis of demand and supply forecasts:

- Candidate vaccines align with WHO PPC to varying degrees, which may have implications for future country preferences and programme suitability.
- Early supply of novel TB vaccines may be insufficient to support timely and equitable introduction across countries if countries seek to pursue both routine immunisation and catch-up campaigns for high-risk groups and high-burden areas, in line with their ambitions. This gap is expected to be most acute in the first years after licensure, when only one product may be available.
- Meeting expected demand will therefore require manufacturing scale-up of the first vaccine, as well as at least two additional candidates to reach licensure and WHO prequalification – underscoring the importance of continued investment in the late-stage development.
- Further Vaccine Alliance work is needed ahead of the next roadmap update to estimate credible funded demand from countries.
- Strong and credible demand signals, early commitments and clarity on financing will be critical to incentivise sufficient supply, improve affordability, and avoid delays in the future launch and country roll-out of novel TB vaccines.
- India's introduction timing, scope and product choice will be a key factor in understanding the scale and timing of any demand/supply imbalance.

Key market risks

Market risks associated with the novel TB vaccine market inform the roadmap's strategic objectives, target outcomes and market shaping interventions:

Policy risk: Lack of adequate evidence for policy recommendation at licensure could result in a narrow policy recommendation – for example, limited to high-burden settings or high-risk groups, delaying uptake and impact of novel TB vaccines.

Supply risks:

- Potentially limited early supply and uncoordinated procurement could lead to inequitable and delayed access of novel TB vaccines across countries.
- Delayed financing for late-stage development or manufacturing scale-up; and/or clear demand signals could constrain timely and adequate supply, especially in the early years.
- Failure or delay of late-stage candidates would reduce the number of licensed vaccines and increase dependence on fewer products.
- Limited regulatory coordination across global, regional and country-level authorities could delay licensure and country access.
- "Successful" – i.e. licensed – products may not meet the PPC that align with country preferences, including dosing, storage, use in high-risk groups and affordability.
- Lower-than-expected funded demand increases production costs, and could weaken the commercial attractiveness of vaccine supply and reduce affordability.

Demand risks:

- Insufficient predictability and materialisation of demand resulting in lower health impact due to:
  - uncertainty around India's future demand and policy choices;
  - limited country readiness, local evidence and cost-effectiveness data, which could delay introduction decisions; and

- inadequate global and domestic financing, including uncertainty on how novel TB vaccines will be integrated into Gavi's vaccine budgets, could limit routine introduction and catch-up campaigns under the high-demand scenario.
- Uneven demand across products due to different product profiles could challenge supply allocation and market sustainability, and exacerbate the supply/demand gaps.

Novel TB vaccine market shaping vision and strategic objectives

The strategic objectives, target outcomes and proposed interventions outlined in this section are defined to align with, contribute to and reinforce the broader agenda of the F&A WG. They focus primarily on Gavi-supported countries, where the Vaccine Alliance has a mandate and the greatest leverage.

This section includes a long-term vision statement for a future novel TB vaccine market, consistent with the F&A WG's vision. The underlying strategic objectives break down how the Alliance's long-term vision will materialise, while target outcomes and interventions focus on the short- to medium-term actions needed to realise these objectives.

An updated roadmap, anticipated in mid-2027, will refresh these objectives, outcomes and interventions based on information available at that time.

Vision statement
A novel TB vaccine market in which a diversified supplier base delivers several affordable and suitable vaccines, with predictable and sufficient supply to enable timely, equitable and sustainable access in low- and middle-income countries over 2030–2040.

The early market shaping roadmap for novel TB vaccines includes three strategic objectives:

1. **Objective 1:** Ensure sufficient, timely, affordable and sustainable supply of novel TB vaccines to meet the demand of Gavi-supported countries, while contributing to global access in line with the TB Vaccine Accelerator F&A WG.
2. **Objective 2:** Support materialisation of the high-demand scenario to ensure accelerated health impact from novel TB vaccines through routine immunisation and targeted catch-up campaigns.
3. **Objective 3:** Encourage a competitive and geographically diverse pipeline of novel TB vaccine candidates, ensuring products meet country preferences.

Each strategic objective is underpinned by target outcomes that the Alliance aims to achieve through a set of interventions shared among Gavi's market shaping partners.

Objective 1: Ensure sufficient, timely, affordable and sustainable supply of novel TB vaccines to meet the demand of Gavi-supported countries, while contributing to global access in line with the TB Vaccine Accelerator F&A WG.

Target outcomes and interventions

Outcome 1: Potential demand/supply imbalances are understood, and market shaping and financing options for Gavi are defined and ready to be implemented as soon as

clinical trial results are available to de-risk manufacturing and ensure sufficient, timely and affordable supply for Gavi-supported countries (including Catalytic Phase countries), in alignment with the F&A WG's global efforts.

- Identify risks and bottlenecks driving potential demand/supply imbalances, and understand the need for de-risking.
- Understand and regularly update development funding gaps to bring late-stage candidates to licensure, and engage developers and funders to advocate for timely financing solutions to fill the gaps.
- Update supply and demand forecasts as new information becomes available.
- Understand access agreements in place, including access terms across Gavi and non-Gavi-supported countries to inform affordability assessments, funding needs and potential roles for intervention.
- Define options (including timing of implementation) for Gavi's role in potential market shaping and financing mechanism(s) to ensure equitable access (i.e. sufficient, timely and affordable supply for Gavi-supported countries), in alignment with the F&A WG's design of catalytic instrument(s).
    - Working with the F&A WG and other partners, explore participation of interested non-Gavi-supported MICs in above mechanism(s), to improve supply and affordability for participating MICs through market efficiencies.
    - In line with the F&A WG, explore global and regional pooled procurement frameworks that enable coordinated purchase mechanisms across Gavi-supported countries and potentially non-Gavi-supported MICs, with the aim of reducing fragmentation, improving affordability through economies of scale and mitigating the risk of inequity.

Outcome 2: Accelerated Gavi Board approval, and accelerated regulatory, policy and procurement pathways, are planned ahead of first licensure to ensure countries can introduce the vaccine as soon as available.

- Plan for coordinated regulatory pathways at global, regional and country level through the Technical Advisory Group on Evidence for Clinical and Policy Considerations.
- Plan and ensure steps are in place for Gavi Board approval and UNICEF procurement processes to have concluded ahead of and conditional on WHO prequalification, to ensure countries can introduce as soon as the vaccine is available.
- Monitor policy pathway to understand implications for demand, timelines and scope for future Gavi programme launch following SAGE recommendation.
- Identify evidence gaps for policy decision-making at global level and advocate to address them through Technical Advisory Group on Evidence for Clinical and Policy Considerations.

Objective 2: Support materialisation of the high-demand scenario to ensure accelerated health impact from novel TB vaccines through routine immunisation and targeted catch-up campaigns.

Target outcomes and interventions

Outcome 3: The Vaccine Alliance and the Government of India are engaged in an ongoing dialogue on novel TB vaccine introduction to remain informed of respective plans.

- Leverage the Gavi-India partnership to share perspectives on novel TB vaccine introduction plans to inform global demand and supply outlook.

Outcome 4: Demand from Gavi-supported countries is understood, with clear pathways for financing (domestic and global) defined to provide a credible demand signal.

- Update demand forecast as new information becomes available.
- Align assumptions underpinning cost-effectiveness analyses across stakeholders (i.e. WHO and the Global Fund) to ensure consistency in the assessed value of novel TB vaccines supporting financing global and domestic decisions.
- Fund cost-effectiveness analyses for the high-demand scenario: (i) to inform the Gavi Board; and (ii) for use by the F&A WG.
- Anticipate how novel TB vaccines will be assessed in Gavi's vaccine budgets: as a programme funded through discretionary or guaranteed budget.

Outcome 5: Coordination is in place between Gavi and the Global Fund to align on country financing and support modalities for novel TB vaccines in LICs and lower middle-income countries.

- Establish and work through a joint Gavi-Global Fund project team to:
  - Align how novel TB vaccines will be integrated in country-level planning alongside other TB interventions; and
  - Align on implications of how Gavi and the Global Fund will support countries and understand the potential impact on demand.

Outcome 6: Gavi-supported countries are ready for introduction and scale-up as soon as vaccines are available.

- Advance country planning/readiness through early engagement through TB Vaccine Accelerator Working Group on Country Readiness, Advocacy and Community Partnership.
- Design Gavi-supported programme and country guidelines 'at risk', conditional on WHO prequalification.

Objective 3: Encourage a competitive and geographically diverse pipeline of novel TB vaccine candidates, ensuring products meet country preferences.

Target outcomes and interventions

Outcome 7: Plans and incentives are in place to support **regional diversification of supply**.

- Contribute to the F&A WG's taskforce on regional manufacturing to map and regularly update developers' regional manufacturing plans, and promote regional diversification;
- Leverage Gavi's African Vaccine Manufacturing Accelerator (AVMA), including TB vaccines' priority status, to incentivise African manufacturing; and
- Explore additional incentives including through future AVMA course correction to further incentivise regional manufacturing of novel TB vaccines.

Outcome 8: A diverse portfolio of novel TB vaccines is available to meet various country and programme needs.

- Leveraging WHO PPC, communicate and regularly update priority product characteristics if needed, based on country use cases, policy considerations and delivery constraints.

- Engage developers to communicate demand expectations, country preferences and desired product attributes, helping ensure products in the pipeline meet key country requirements, including suitability for high-risk populations, shorter schedules to enable large campaigns, and simplified storage and delivery requirements.