

Terms of Reference: Finance and Access Working Group for New TB Vaccines

[FINAL Feb 2025]

In May 2024, Members of the Tuberculosis (TB) Vaccine Accelerator Council requested the WHO Secretariat to establish working groups to accelerate the achievement of goals aligned to its mission. Four working groups are being established in a phased approach: i) research and innovation; ii) product development, manufacturing & policy; iii) finance & access; and iv) country readiness.

The Finance and Access Working Group (F&A) is established to promote timely, equitable and sustainably financed access to affordably priced new TB vaccines in all countries where there is demand for these vaccines, driven by public health need.

Since TB primarily impacts low- and middle-income countries and has limited market potential in high-income regions, a strategic approach to market shaping and financing is essential. The F&A working group will coordinate efforts across governments, partners, financing institutions, 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.

GOALS

- Develop an early understanding of anticipated barriers, bottlenecks, challenges, and supply-demand dynamics relevant to country financing and access for novel TB vaccines
- Accelerate the identification of financing and access solutions and opportunities to incentivize equitable and affordable global access
- Develop a financing and access options framework, outlining mechanisms that enable countries to have timely and sustainable access to novel TB vaccines
- Coordinate efforts across governments, partners, financing institutions, private sector, and civil society to propose strategic partnerships and financing and access mechanisms with global applicability, while maintaining a particular focus on speeding up vaccine availability and access for high TB-burden countries
- Foster the development and implementation of financing and access strategies that enable countries to have timely and sustainable access to safe, effective, and affordably priced TB vaccines

GUIDING PRINCIPLES OF THE WORKING GROUP

The principles outlined below serve as a guiding framework for the F&A working group. Each principle reflects a core priority that proposed visions, approaches, and solutions should strive to align with or address. While not all activities of the working group may fully align with every principle, those that are broadly consistent with relevant principles will be given priority for further consideration.



- ***Sustainability***: Facilitate the sustainable, long-term accessibility and affordability of new TB vaccines-by promoting balance between the commercial viability for suppliers and economic feasibility for countries, incorporating measures such as technology transfer to enhance production and distribution capacities, where relevant.
- ***Equity***: Strive to provide countries, particularly those with high TB burden, with equitable and sustainable access to safe, effective, and affordably priced new TB vaccines that meet WHO's anticipated evidence requirements for SAGE recommendations and WHO prequalification standards.
- ***Innovation***: Foster innovation, competition, and capacity building through sustainable market-shaping, financing, and procurement models as well as through technology transfer, as appropriate.
- ***Inclusive partnership and transparency***: Strengthen partnerships across countries, multilateral banks, international agencies, public-private collaborations, industry, donors, civil society, and experts to align on procurement strategies, financing, and access solutions.
- ***Complementarity and building on lessons learnt***: Develop financing and access strategies aligned with existing push funding for R&D, pull mechanisms for late-stage investment in new TB vaccines, and other incentives provided by public, philanthropic, and multilateral entities, and building on lessons learnt from past effort (e.g., the development and rollout of malaria or COVID-19 vaccines), to maximize the collective public health impact of timely supply and equitable, affordable access to TB vaccines.

PRIMARY FUNCTIONS OF THE WORKING GROUP (2025-2030)

- **Propose a comprehensive vision** for a successful access and finance strategies for new TB vaccines (goal, objectives, milestones, risks, and opportunities etc). Include a focus on the short-term early suppliers and country adopters, with medium-long term focus on access to additional products in more countries for sustainable and equitable global access.
- **Assess country-specific demand, financing and access needs for 5 high-burden countries**: Conduct in-depth consultations with governments and key actors to gain insights into country-specific demand for introducing new TB vaccines and scaling up demand over time, financial commitments to new TB vaccines, and potential barriers or conditions for access. Use the country-specific insights to understand demand, financing and access needs from a global perspective.
- **Assess supply specific challenges and opportunities**: Review emerging TB vaccine candidates (with potential for licensure before/by 2030) and assess their commercial financing and access attributes such as product characteristics, efficacy, pricing, licensing agreements, financing requirements, supply constraints, and explore stakeholder interest to address these challenges, including possibility of local manufacturing opportunities in high-burden regions.
- **Assess global financing sources challenges and opportunities**: Review available and planned domestic and external financing sources for novel TB vaccines for all countries where there is demand for TB vaccines and identify potential gaps and solutions.
- **Conduct market landscape analyses and develop unified demand and supply scenarios**: Conduct TB vaccine market analyses as necessary to create a unified understanding of short,



medium and long term scenarios related to global and regional demand and supply dynamics, as well as supply-demand balance and anticipated gaps.

- **Promote collaboration to facilitate timely and equitable access to new TB vaccines:** Promote alignment of efforts and resources across governments, multilateral organizations, civil society organizations, and the private sector involved in financing immunization and primary health care to develop solutions that enable timely and equitable access to new TB vaccines, drawing on lessons learnt from the response to malaria, COVID-19 pandemic, and other comparable diseases.
- **Address where possible trade, financial, and political risks:** Map and propose solutions (where possible) to overcome potential trade, financial, and political barriers that may impact new TB vaccine access, where relevant.
- **Monitoring of progress:** Establish a monitoring plan to track progress against the strategic objectives and milestones. Identifying areas for improvement and adapt as necessary to evolving challenges and opportunities.

The above will be undertaken in collaboration with the Accelerator's working groups on *product development, policy and manufacturing*, as well as *country readiness, advocacy, and community partnerships*.

PRELIMINARY LIST OF DELIVERABLES for 2025

These deliverables will be modified in discussion with Group Members

- Define the **vision and milestones** for the working group. Include a focus on short term early suppliers and country adopters and medium-long term focus on global equitable access.
- **Undertake analysis of licensing and access provision** agreements for TB vaccine candidates in Phase II/III development including possibility of local manufacturing options in high burden regions
- **Map country specific plans**, requirements, opportunities and challenges in TB vaccine introduction and scale up, with a focus on five high TB burden countries and one country in SSA.
- Propose 10-year **demand forecast** (with 3 scenarios) based on country uptake, epidemiological changes, and funding constraints.
- Develop a 10-year **supply forecast** (with 3 scenarios) taking into account the TB vaccine R&D pipeline, manufacturing capacity, and potential incentives including the availability of funding.
- **Map available/anticipated vaccine financing sources** in countries (including domestic and external financing), particularly in high TB burden countries, and identify potential gaps based on pricing and demand scenarios.
- **Map demand scenarios against supply forecasts** to identify potential supply/demand gaps following a product-agnostic yet pragmatic approach.
- **Propose options of financing and access strategies (including strategic partnerships, financing and procurement mechanisms, and market shaping solutions)** to enhance TB vaccine availability, affordability, and equitable access globally, while addressing funding requirements and potential risks.
- **Undertake TB vaccine summit preparation:** Prepare policy briefs and advocacy messaging for the Q4 2025 TB Vaccine Financing & Access Summit.

WAY OF WORKING

- **Decision making:** The working group will strive to achieve consensus in its decision-making processes. Members are encouraged to collaborate openly and constructively, ensuring that diverse perspectives are considered.
- **Communication:** The working group will maintain regular communication through scheduled meetings, email exchanges, and collaborative platforms. Members are expected to participate actively and contribute to the timely delivery of agreed-upon action points.
- **Transparency:** The working group is committed to transparency in all its activities. All members will have access to relevant documents, discussions, and decisions. Relevant reports and updates will be shared regularly with members, and minutes of meetings will be made available.
- **Confidentiality:** Due to the sensitive nature of some financial, strategic, and country-specific information, members must agree to handle confidential information responsibly at all times. and may be requested sign non-disclosure agreements (NDAs) where necessary.
- **Delegation of representation:** The working group members may delegate representation to specific members for particular tasks, external meetings, or presentations. Delegates will be



empowered to represent the group's interests in such settings and will report back to the group following the engagement. Any delegation of representation will be clearly outlined and agreed upon by the group, ensuring that the representation aligns with the group's objectives and values.

- **Technical support:** The working group may receive support from independent technical consultants engaged by the Secretariat and co-leads or other group members. Sharing of workload by various group members and their respective agencies is encouraged for resource pooling and fast progress. Additionally, the working group may draw on input from WHO's strategic and technical advisory groups to support its activities as needed.
- **Term:** The working group members will initially serve for a term of two years.
- **Reporting:** The Co-leads will provide Council members with a quarterly report summarizing the group's activities.
- **Frequency of meeting:** The working group will initially meet on a monthly basis and will adjust the frequency as needed. Co-leads will meet on a bi-weekly basis.

Convening:

The working group will be co-convened by three co-leads:

- **South Africa:** South Africa is a member of the TB Vaccine Accelerator Council and a key champion of the working group, both as a high-TB burden country and a leading R&D hub for TB vaccines. In its role as G20 President in 2025, South Africa will prioritize advancing multilateral discussions on global health, particularly TB vaccine access, through the G20 Health Working Group.
- **GAVI, the Vaccine Alliance:** Gavi is an international organisation bringing together public and private sectors with the shared goal of saving lives and protecting people's health by increasing equitable and sustainable use of vaccines. Gavi, a member of the TB Vaccine Accelerator Council, will support a TB vaccine programme for Gavi-supported countries and will contribute its vaccine market shaping expertise.
- **WHO:** WHO is the directing and coordinating authority for health within the United Nations system. In the context of the End TB Strategy (WHA67.1) and the Global Strategy for TB research and innovation (WHA73.3), it coordinates global efforts to end the TB epidemic through universal access to people-centered prevention and care, multisectoral action and innovation. The TB vaccine accelerator council is a WHO initiative, and as such it derives its legal status from WHO, which provides its Secretariat.

The Co-leads will initially serve for a term of two-years.

Function of the Co-leads:

- Provide strategic direction for the working group.
- Facilitate working group meetings, ensuring chairing, productive discussions, consensus-building, and timely decision-making on prioritized issues.
- Oversee technical deliverables.



- Report progress to the Council and other relevant bodies.

This work is carried out with full contribution of each working group member and assistance from the Secretariat. The way of working will be reviewed periodically to ensure it remains effective and adaptive to evolving circumstances. Members will have the opportunity to propose adjustments or improvements to the processes based on their experiences and the group's progress.