

GOVERNANCE, ORGANISATION AND STRATEGIC PRIORITIES OF THE TB VACCINE ACCELERATOR COUNCIL

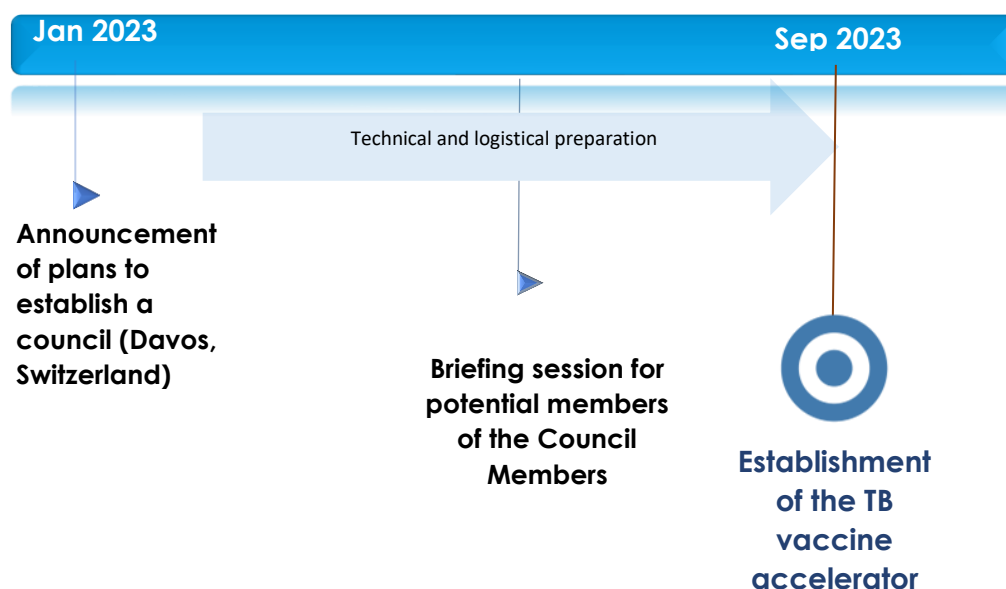
BACKGROUND

Tuberculosis (TB) is one of the leading causes of death from an infectious agent. The World Health Organization (WHO) End TB Strategy stipulates that to end the epidemic by 2030, major technological breakthroughs need to be introduced by 2025 to accelerate the rate of decline in disease incidence, such as a new TB vaccine that is effective both before and after infection. The only licensed TB vaccine, Bacille Calmette-Guerin (BCG), provides moderate to good protection against severe forms of TB in infants and young children (averting thousands of paediatric deaths annually), but it does not adequately protect adolescents and adults, who account for the majority of TB transmission. New vaccines that are effective in reducing disease transmission and mortality, among all age-groups are needed to end the TB epidemic. However, significant scientific challenges coupled with insufficient financing have slowed the pace of progress. A high-level coordination and commitment are needed to develop solutions to some of these pressing bottlenecks, drawing on lessons learnt from the response to the COVID-19 pandemic.

In January 2023, WHO's Director General proposed the establishment of a *TB Vaccine Accelerator Council* to create and catalyse high-level alignment between funders, global agencies, governments, and end users on the important challenges in TB vaccine development, and on actions to address them (Fig 1). Its vision is to boost the TB vaccine pipeline and to facilitate the licensing and use of effective novel TB vaccines to end the TB epidemic, as a matter of urgency.

This document outlines the potential governance, organisation and focus of the Council for the years 2023 and 2024.

Fig 1: Roadmap towards the establishment of the Council



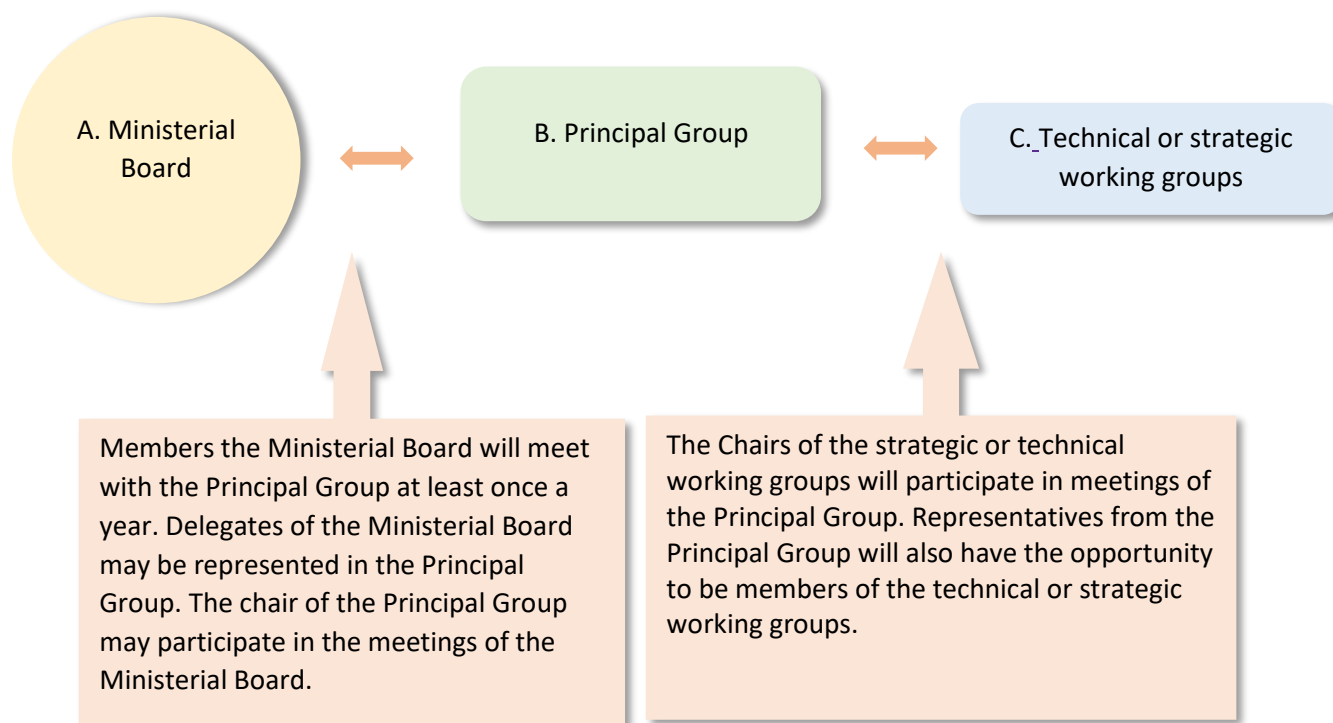
I. GOVERNANCE AND ORGANISATION

The Council is comprised of a Ministerial Board and a Principal Group and will be supported by working groups (Fig 2). The Ministerial Board, comprising of mainly Ministers of Health is the political and strategic force of the Council, while the Principal Group, comprising of leaders of research and funding institutions, international organizations and civil society helps shape the strategic work of the Council. Individual subject matter experts from research and funding institutions, regulatory agencies, international organizations, immunization partners, industry and civil society are organized to form technical or strategic working groups to support decision-making by the Principal Group and the Ministerial Board.

Status

The TB vaccine accelerator council is a WHO initiative, an informal voluntary network for Participants to exchange views, share information, and enhance technical and political co-operation. It is not a distinct legal entity, and it derives its legal status from WHO. Thus, it shall be administered by WHO, which provides its Secretariat.

Fig 2: Architecture of the TB vaccine accelerator council



A. The Ministerial Board: The objective of the Ministerial Board is to provide strategic direction and political advocacy, building upon political commitments and existing initiatives in vaccine development and access, including resolutions of the World Health Assembly, and United Nations General Assembly.

The members of the Ministerial Board will include Ministers of Health or equivalent officials from Member States.

The Ministerial Board will make evidence-based and actionable recommendations to the WHO Director-General and other relevant stakeholders, drawing on scientific evidence and strategic dialogue with relevant bodies of the Council. Members will initially serve for a period of two years.

Proposed way of working

- *Meetings:* The Ministerial Board will also have one face to face meeting and will also meet as a Council together with the Principal Group, once a year, annually.
- *Chair:* Two members of the Council will chair/co-chair the Council, on a rotating basis, every two years, with due consideration to gender and geographic balance.
- *Facilitation:* The WHO Assistant Director-General for Universal Health Coverage/Communicable and Noncommunicable Diseases will facilitate the convening of the Ministerial Board on behalf of the WHO Secretariat, with support from the Chief Scientist.
- *Consultations:* The Ministerial Board may engage in consultations and dialogue with a broad range of stakeholders including UN entities, regional and sub-regional organizations, international and regional financial institutions, civil society, academia, and the private sector.
- *Materials:* The Ministerial Board body will rely on existing materials in the public domain and request/commission additional research on issues relevant to its goals. It will also be informed by technical reports from, and strategic dialogue with the Principal Group and technical working groups of the Council, as relevant.
- *Reporting:* A comprehensive annual public report that includes summary of activities by the Ministerial Board will be made available by the Secretariat.

B. The Principal Group: The members of the Principal Group will include leaders of research and funding institutions, international organizations, representatives of civil society and Chairs of the Council's technical working groups that collectively represent a broad range of knowledge associated with development of, and access to vaccines in low- and middle-income countries. Members will initially serve for a period of two years.

Proposed way of working

The Principal Group's work will initially rely on the following modalities:

- *Meetings:* The Principal Group will have quarterly virtual meetings, and one face to face meeting (annually) as part of the meeting of the Council.

- *Chair:* The Chief Scientist is the chair of the group. A member of the Principal Group will co-chair for a term of one year, and on a rotating basis.
- *Facilitation:* The Chief Scientist will facilitate the convening of the Principal Group on behalf of the WHO Secretariat, with support from WHO Assistant Director-General for Universal Health Coverage/Communicable and Noncommunicable Diseases and the WHO Assistant Director-General for Universal Health Coverage and Life Course, as appropriate.
- *Interaction with the Ministerial Board:* Members the Ministerial Board will meet with the Principal Group at least once a year. Representatives of the Ministerial Board may be represented in the Principal Group. The chair of the Principal Group may participate in the meetings of the Ministerial board.
- *Materials:* The Principal Group may rely on existing materials in the public domain and materials generated by the technical or strategic working groups. The Principal Group may request/commission additional research on issues relevant to its goals, in consultation with the working groups, as relevant.
- *Reporting:* A quarterly meeting report summarizing activities of the Principal Group will be made available.

C. The working groups: The members of the technical or strategic working groups may include scientists from various organizations, individual experts in vaccine product development and regulatory science, public health agencies, policy makers, experts in human rights and international law, civil society representatives, the private sector and other stakeholders that represent a broad range of knowledge associated with development of, and access to vaccines in low- and middle-income countries. Members will initially serve for a period of two years. These working groups could be existing groups within WHO, or those working with WHO. New working groups may be established per recommendation by the Ministerial Board or the Principal Group.

Proposed way of working

- *Meetings:* The working groups will meet virtually on a monthly basis, or as often as required.
- *Interaction with the Principal Group:* The Chairs of the technical or strategic working groups will participate in meetings of the Principal Group. Representatives from the Principal Group will also have the opportunity to be members of the technical or strategic working groups.
- *Materials:* Members of the working groups may produce technical reports, manuscripts, policy briefs or other materials on issues relevant to the technical work area and in consultation with the WHO Secretariat to support the work of the Principal Group or the Ministerial Board.
- *Reporting:* A meeting summary will be produced to facilitate the technical work of the working groups.

II. THE ROLE OF WHO

WHO will provide secretariat support to the Council. Specifically, the Ministerial Board and the Principal Group will be supported by the WHO Global TB Programme under the leadership of the Chairs and facilitators described above. The strategic and technical working groups will be supported by cross-functional teams in the Global TB Programme and the Department of Immunization, Vaccines and Biologicals.

III. STRATEGIC PRIORITIES

The overarching strategic objectives of the Council for the next two years include the following:

Goal 1: Identify needs for, and types of innovative sustainable financial solutions, as well as partnerships between the public, private and philanthropic sectors that can expedite the translation of science into TB vaccines and ensure their equitable access once available.

The Council's way of working to deliver on this goal:

- a) advocate for, and support investments to accelerate the development of novel TB vaccines that meet WHO guidance on preferred product characteristics;*
- b) strengthen regulatory capacity in countries, particularly in low- and middle-income countries with high-TB burden to ensure timely testing and equitable access to vaccines of assured quality, once available;*
- c) align efforts with other actors/initiatives focused on resolving inequities in access to vaccines, considering that ensuring timely access to vaccine globally, particularly in low-and-middle income countries, requires the coordinated action of multiple stakeholders across sectors: governments, multilateral organizations, civil society, and the private sector;*
- d) streamline and align partnerships that provide immunisation or primary health care/integrated financing, and ensure effective global collaboration where the roles, responsibilities and accountability of all partners are clearly defined for the delivery of new TB vaccines, once available.*

Goal 2: Identify market solutions to incentivize TB vaccine development, and to ensure that the R&D ecosystem is positioned to rapidly manufacture and distribute vaccines equitably and at scale, once they are available.

The Council's way of working to deliver on this goal:

- a) initiate engagement with manufacturers, member states, international organizations and other relevant actors on market-shaping to support the development of a healthy market and affordably priced vaccines;*
- b) support tech transfer and manufacturing scale-up, if capacity and resources are available, the establishment of sustainable manufacturing capacity in regions, with support to overcome intellectual related barriers where needed;*
- c) Strength engagement with relevant actors and institutions that have the power to resolve trade, financial, and political issues affecting access to vaccines;*

- d) *leverage industry knowledge and capacity to accelerate regulatory pathways, demand forecasting, procurement and supply planning.*

Goal 3: Advocate with decision makers in the public, private, philanthropy and other relevant sectors to strengthen commitment and concerted action to develop and expand access to novel effective TB vaccines, including through political platforms such as the African Union, ASEAN, BRICS, G20, G7, and others.

The Council's way of working to deliver on this goal:

- a) *strengthen engagement with political platforms to boost commitment and action required to close funding gaps for the development, and delivery of vaccines, and to ensure greater impact from the roll-out of vaccines once available, for example by ensuring that they are introduced in a timely manner, and are priced affordably.*

Reporting on progress

A comprehensive public annual report on the Council's activities will be published by the Secretariat. The Ministerial Board, Principal Group and the working groups may publish white papers, manuscripts in peer-reviewed journals or meeting reports, as relevant and in consultation with the Secretariat.