Level setting: Establishing a common understanding of the assumptions, risks and potential use scenarios for new TB vaccines

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TB Vaccine Accelerator Forum

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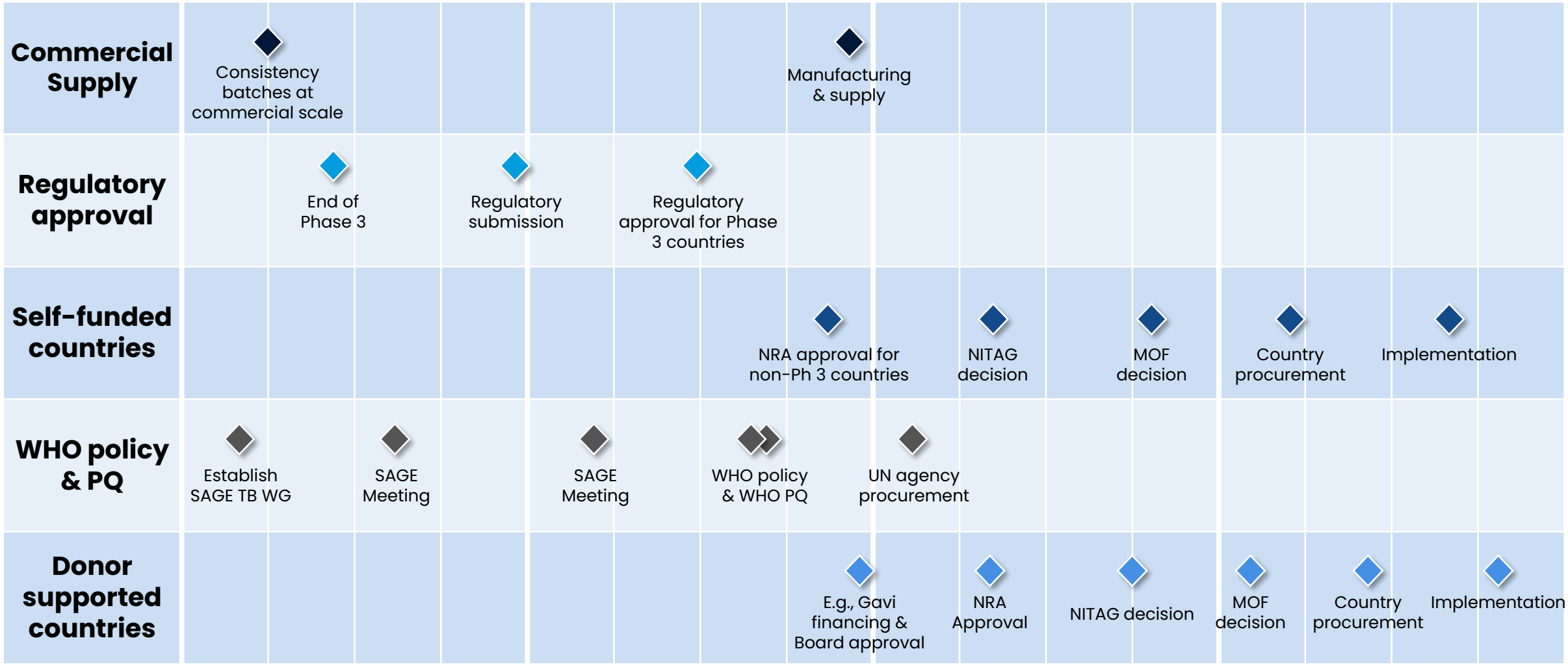
Overview of Pathway to Vaccine Policy & Uptake: Milestones & dependencies

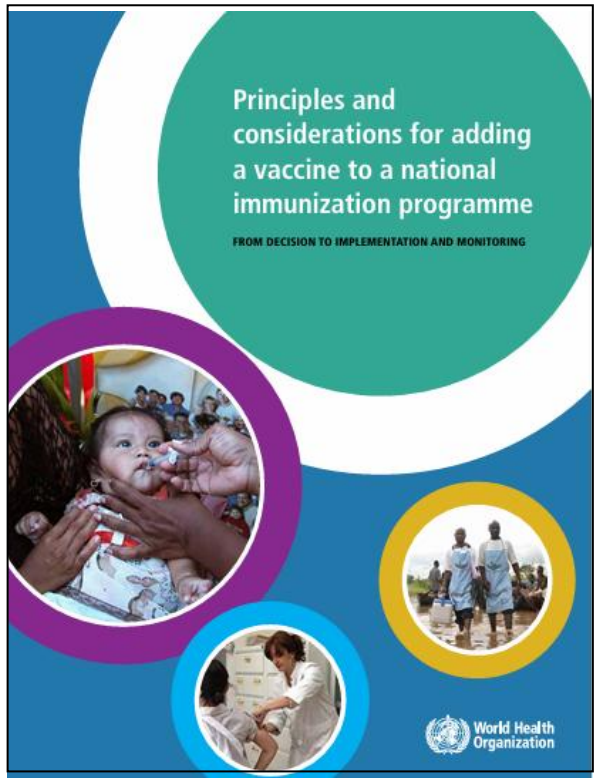


Note: Each vertical line represents one quarter, each thick vertical line represents one year. Note on Acronyms: MOF, Ministry of Finance. NITAG, National Immunization Technical Advisory Group. NRA, National Regulatory Agency. SAGE, Strategic Advisory Group of Experts on Immunization. TB, Tuberculosis. WG, Working Group. WHO, World Health Organization.

Big picture assumptions

- New TB Vaccines for adults and adolescents will be used alongside existing TB interventions and new innovations, as they come to market.
- The TB and immunization programmes will need to work jointly to understand how vaccines could be used most effectively, relative to the TB and immunization programme.
- Depending on the use case (target population and delivery setting) and the country's health system, these vaccines could be delivered outside of the established immunization schedule.
- The immunization programme will be responsible for vaccine delivery and logistics to the point of administration.

Countries will have different use cases for new TB vaccines, depending on their context

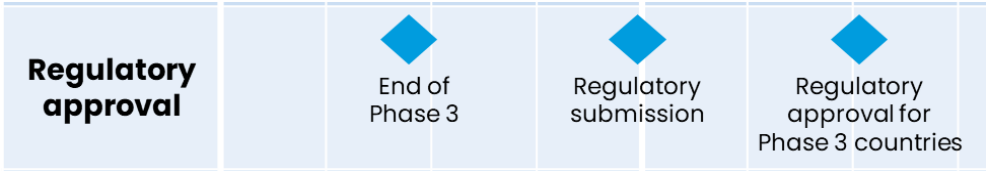


Principles and considerations for adding a vaccine to a national immunization program: from decision to implementation and monitoring

- The disease epidemiology: health and socio-economic burden, prevalence and incidence in different populations
- The attributes of the vaccines: efficacy, safety, duration of protection, cost-effectiveness, applicability and acceptability to priority populations for each country
- Strength of the immunization and health system

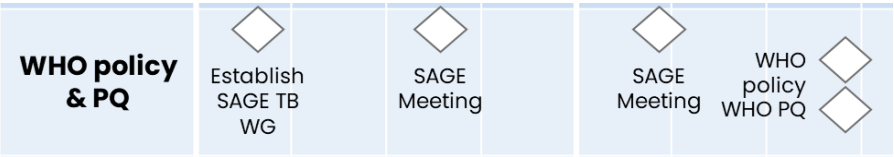
➢ Ultimately – is the vaccine perceived to be a PRIORITY need in the country, i.e., is it included in the National Immunization Strategy (NIS)?

Assumptions on regulatory approval timelines and strategy



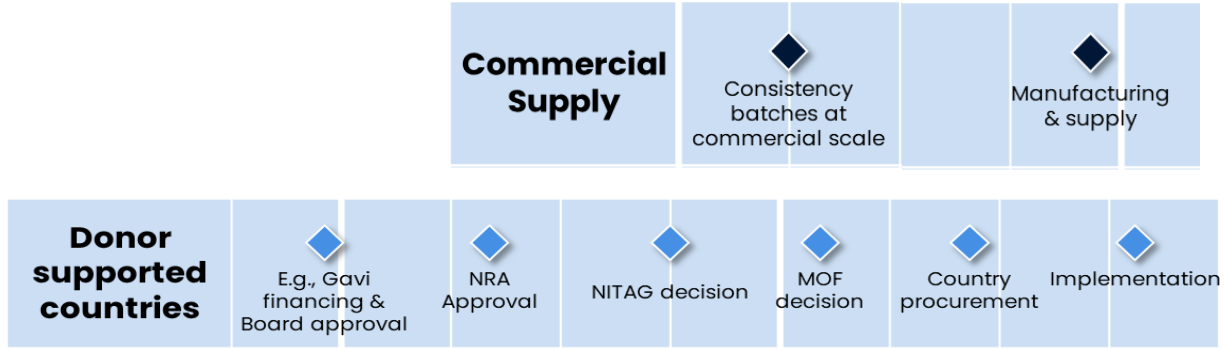
- Anticipated Indication: prevention of active pulmonary TB disease in adolescents and adults
- Demonstration of vaccine efficacy in IGRA-ve population (not previously sensitized to TB) is not feasible in a pivotal licensure trial
- From a programmatic perspective, IGRA testing prior to vaccination is unfeasible.
- Given the current pipeline, the earliest timeline for regulatory submission is 2028.
- Expedited approval timelines are anticipated to be around 6 months – TBC
- Countries involved in the phase 3 trials are likely to approve and introduce first
- Early engagement with reliance mechanisms (AVAREF, AMA, SEARN) can streamline regulatory review and approval by harmonizing across countries.

Rationale for global (WHO) vaccine policy recommendation and prequalification (PQ)



- WHO vaccine prequalification ensures that vaccines used in immunization programmes are safe and effective.
- National regulatory approval is a prerequisite for WHO PQ., and approval by a regulator of maturity level 3 or 4 expedites WHO PQ and approval in LMICs.
- WHO PQ expedites regulatory approval in LMICs with less mature regulatory agencies
- Regulatory submission through the European Medicines Agency (EMA) M4all pathway engages and accelerates WHO PQ.
- Coordinated review by EMA with NRAs and regional reliance agencies (such as AVAREF and AMA) and WHO (both PQ and SAGE) could accelerate the first regulatory decisions
- WHO PQ is need for both are a requirement for Gavi financing and UN procurement , but will not take place without the expectation of a policy recommendation by WHO
- Self-financing and procuring countries will likely adopt first.

Vaccine manufacturing scale up and supply considerations



- Clinical trial material from the manufacturing consistency batches will need to be included in the pivotal phase III trial, or bridging to commercial batches post phase III will be required.
- Supply will be needed as soon as countries approve the vaccine for use and secure financing (either domestic or through other mechanisms such as Gavi).
- Gavi Alliance investment and board approval, and UN procurement process, can be prepared for at risk, conditional upon WHO policy and PQ.
- Accelerator F&A working group is leading work to position novel financing mechanisms *for all countries ahead* of vaccine approval to accelerate access

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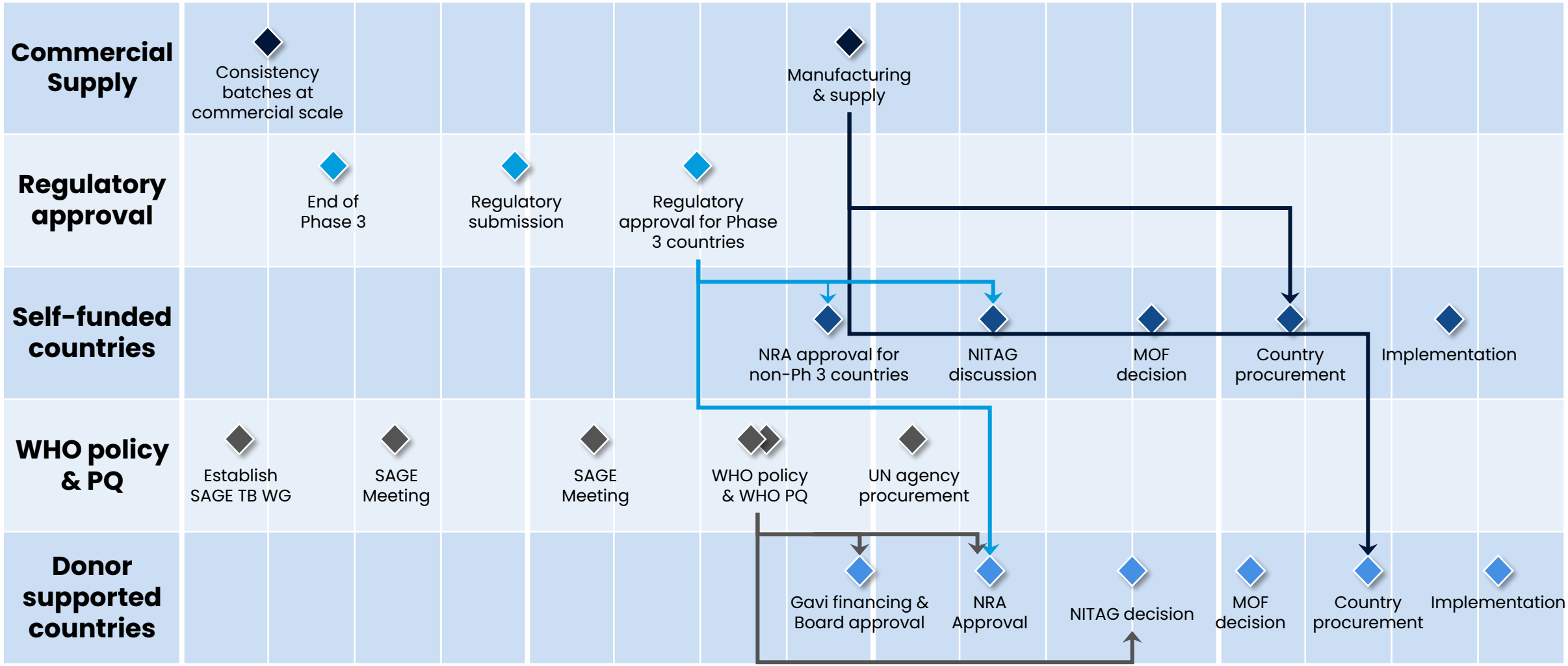

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Level Setting Panel

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