



**7<sup>TH</sup>** GLOBAL FORUM  
ON TB VACCINES

8-10 October 2024  
Rio de Janeiro, Brazil

Driving innovation from discovery to access

# Introduction of TB Vaccines, what should we consider?

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# Requirements for Implementation

## 1. Regulatory Agency Approval

- Safety studies
- Efficacy Studies

## 2. Incorporation criteria

- **Epidemiological:** relevance of the disease (morbidity and mortality);
- **Immunological:** the vaccine's ability to confer high immunogenicity and safety;
- **Technological:** incorporation of production technology into the public national park;
- **Socioeconomic:** compensatory cost/benefit for public health purposes;
- **Logistics:** storage capacity, inventory and conservation of products.

## 3. CONITEC/SUS

- Health Technology Assessment
- Incorporation by CONITEC into the Unified Health System - SUS

# Product Suitability Considerations

## Supply chain in Brazil

### Presentation

Ideal: 5 doses vial.

Today: 20 doses vial.



### Stability

Storage Ideal: 2° to 8°C.

Shelf life after opening: 18h to 24h

Today: 2° to 8°C

Shelf life after opening: 6h

### Production

Ideal lead time: 3 to 6 months

# Post-marketing pharmacovigilance

## Monitoring the safety and assessing the benefit-risk of vaccination

### Passive surveillance

- Universal and decentralized type
- Serious AEFI: Immediate compulsory notification (within 24 hours)
- Non-serious AEFI and immunization errors: Not mandatory notification
- Online information system: e-SUS Notifica (MedDRA)

### Active surveillance

- Different methodologies (depending on the scenario and need)
- Big Data sentinel units (Linkage)
- Adverse Events of Special Interest (AESI): international and/or national list

### Security sign surveillance

- Qualitative analysis: rare and/or unexpected events
- Quantitative analysis: Observed vs. Expected
- Disproportionality of notifications

### Pharmacovigilance committees

- Interinstitutional Committee (CIFAVI)
- State Committees (CEFAVI)

### Communication

- Crisis and risk situations
- Technical and scientific publications
- “Saúde com Ciência”: prebunking and debunking

# Global/Regional Level Actions

- Monitoring of the Technological Horizon - MHT of vaccines under development
- Monitoring of the actions developed at partner institutions
- Articulation with tuberculosis technical groups

# Conclusion and next steps

- Vaccination is important for disease control
- New technologies and strategies are welcome
- We are constantly evaluating and evolving to offer the best to the population





# Thank you!

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