Creating a sustainable vaccine landscape for Typhoid Fever

Vinita Vishwanarayan I Clinton Health Access Initiative (CHAI)

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Agenda

- The elusive TCV vaccine
- Drivers of low manufacturer interest
- Supporting a healthy vaccine market for Typhoid Fever

In spite of huge need and pledged donor support in 2008, as of today still no Typhoid Conjugate Vaccine has been pre-qualified

High disease burden in Gavi and LMICs

- High burden¹ of typhoid fever:
 - Incidence rate of 21·7 M and ~217,000 fatalities annually
- Children aged 2-14 bear greatest burden
- High prevalence of resistance to first-line multidrug treatments



Strong rationale for Gavi VIS decision in 2008 to support Typhoid Conjugate Vaccine

- Low cost² for TCV ~\$12 per case averted
- Suitable for children < 2 yrs.
- Gavi budget² for TCV vaccine in 2008 VIS ~\$0.5B between 2009-2020
- WHO PQ'd TCV initially expected in 2010-2011
- Introduction delayed as no available PQ'd TCV suppliers during 2008 Gavi VIS

Long lag in TCV suppliers getting to market with earliest WHO PQ approval expected by Q4 2017

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Estimated WHO PQ Timelines	2017	2018	2019	2020	2021	2022	2023	2024	
BIO-MED Promise for healthier life			Lice	nsed in India, WI	HO PQ timelines	TBD			
中国生物技术股份有限公司	Submitted for NRA licensure, WHO PQ timelines TBD								
å pi									
Bharat Biotech Lead Innovation	Licensed								
Zvdus									
Zy <mark>d</mark> us Cadila	NRA expected								
BE		Anticipate 1-2 suppliers to get WHO PQ'd by							
SK chemicals	next Gavi VIS in 2018								
biorarma									

Source:

- 1. Dougan, G and Baker, S. Salmonella enterica serovar Typhi and the pathogenesis of typhoid fever. Annu Rev Microbiol. 2014; 68: 317–336
- 2. Gavi Vaccine Investment Strategy 2008, Typhoid Analysis
- 3. Estimated WHO PQ timelines based on current development status of TCV candidate

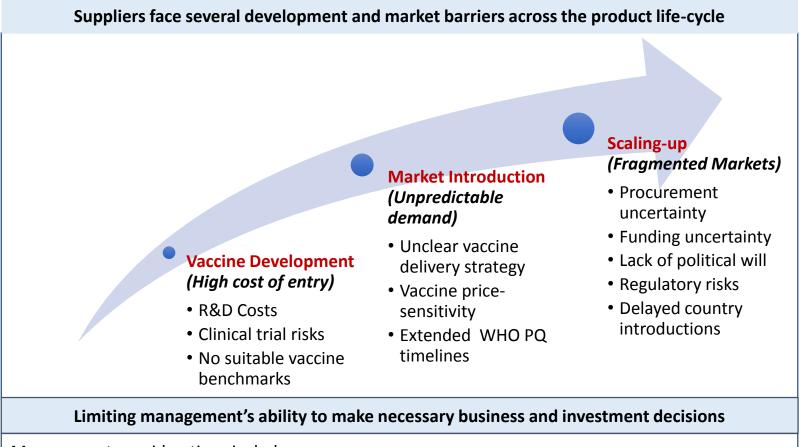
Typhoid market is characterized by poor market dynamics, leading to internal de-prioritization of TCV development by suppliers and longer time to market

Typhoid Market Dynamics



Limited supplier interest due to low potential margins and demand uncertainty

These market dynamics affect various stages of the product life-cycle and can negatively influence management's decision to invest in TCV market



Management considerations include:

- Allocation of limited resources based on expected returns
- Budgeting for investments required in manufacturing capacities/capabilities
- Prioritizing markets and creating market entry strategy
- Aligning with broader company strategy

Framework for prioritization of vaccine pipeline

Expected return = A Potential return X B Probability of realizing return

B Probability of capturing return

High

Probability of realizing return depends on:

- Development risks
- Political & funding support
- Manufacturing & delivery needs
- Competitive dynamics Low

Low potential return, high feasibility

"Quick wins"

Lower market opportunity, low feasibility

"Long shots"

High potential return, high feasibility

"Top priority"

High market opportunity, low feasibility

"High-risk/High-return"

Small

Large

Potential return

Potential return depends on:

- Potential revenue: Need for vaccine, population size
- Potential margin: Geography, competition

The global community can help suppliers overcome these barriers and accelerate their time to market through a number of activities

Global Community can support suppliers in expediting development of new vaccines

Role for Global Community Demand Forecast Country Liaison Policy and funding Partner support Share country Share early Share ideal Highlight feedback on estimates of vaccine TPP and partnership potential need potential opportunities potential and introduction vaccine demand delivery across the timelines strategies with with suppliers product development suppliers life-cycle Provide **periodic** Share countryspecific issues updates on Clarify price findings from around targets and Support surveillance programmatic funding DCVMNs with studies and suitability availability **WHO PQ implications** applications

Expedite development of new and neglected disease vaccines

Asante kwa mawazo yako

Thank you for your attention

Merci de votre attention

Obrigado pela sua atenção

여러분의 관심에 감사드립니다

感谢您的关注

உங்கள் கவனத்திற்கு நன்றி

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Joshua Chu Vice President



Sheldon Xie

Director



Nine Steensma

Director



Sourabh Sobti Manager



Kartick Kumar Senior Manager



Yanfeng Lin Senior Technical Advisor



Kevin Ho *Associate*



Lily Zeng Senior analyst



Contact for follow-up queries:
Vinita Vishwanarayan
Senior Associate
Clinton Health Access Initiative (CHAI)
vvishwanarayan@clintonhealthaccess.org

Backup

CHAI's vaccines program works with manufacturers to ensure affordable, adequate supply and with MoHs to improve immunization services

CHAI complements efforts by other global stakeholders across the vaccines value chain

Research and development

- · Basic vaccine R&D
- New immunization technologies, delivery models, evidence-based policy changes

Manufacturing, quality, WHO PQ

- Technical assistance
- Support for WHO PQ

Funding and procurement

- Global demand forecasting
- Funding for vaccines, infrastructure, CCE
- Tendering, procurement

In-country delivery

 In-country delivery, logistics, data gathering

CHAI role

Other global stakeholders



Manufacturer support

- LMIC commercial strategy, business planning
- Volume guarantee and other deal making

MoH support

- New vaccine introduction
- Long-term planning, budgeting
- · Cold chain logistics























Manufacturers

