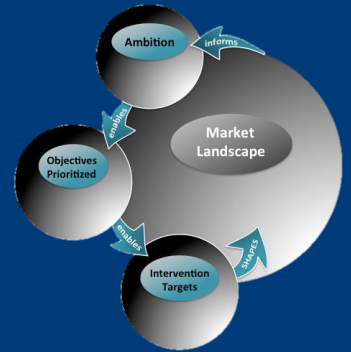


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The Market Shaping Goal

Shape vaccine markets to ensure adequate and secure supply of suitable, quality vaccines at appropriate and sustainable prices for developing countries.



Gavi Supply and Procurement Roadmap Japanese Encephalitis (JE) Vaccine

PUBLIC SUMMARY

Public Summary

Gavi, The Vaccine Alliance, supports Japanese Encephalitis (JE) vaccination campaigns in endemic countries. Gavi support is designed to drive the conduct of campaigns and support JE- routine immunisation. The objective of this engagement is to rapidly reduce JE cases in endemic Gavi countries.

In order to secure Gavi funding for campaigns, countries must commit to co-financing introduction of JE vaccine into routine immunisation programs following completion of campaigns.

Market Overview

- The global demand for JE vaccine is estimated at 80-100 million doses annually. Although market demand fluctuates due to campaigns, the majority of demand is steady and driven by routine immunisation in large countries, including China, India, Japan and South Korea. Other countries such as Thailand, Malaysia and the Philippines also contribute to global demand.
- Countries receiving Gavi support have begun to contribute to global demand first with campaign needs, followed by routine immunisation. The total contribution of demand from countries funded by Gavi is relatively small (<20% of doses).
- A small amount of global demand is driven by travel immunisation, military use, outbreak response, and private market purchases in India and 5 to 10 high-income countries.
- Several types of JE vaccine are available and have different characteristics such as number of required doses, pharmaceutical form and available presentations, resulting in limited flexibility to interchange vaccines. Globally there are more than 10 vaccines available. The following vaccines are prequalified by WHO:
 - Live attenuated vaccine (Chengdu Institute of Biological Products [CDIBP], China)
 - Live recombinant vaccine (Government Pharmaceutical organization – Bio Merieux, Thailand)
 - Inactivated vaccine (Biological E. Ltd, India)
- Global supply capacity across all manufacturers is sufficient to meet demand, however the limited number of prequalified vaccines and different vaccine characteristics may result in challenges managing demand and supply in years of peak demand.
- Development and manufacturing scale-up for CDIBP's JE vaccine was supported by PATH with a grant from the Bill & Melinda Gates Foundation. This support has resulted in supply of JE vaccine for low- and middle- income public markets, including Gavi-supported countries, and has also resulted in a low price creating an entry barrier to the low-income market for other potential entrants.

Healthy Market Framework Evaluation



The JE market currently meets one of the elements of a healthy market (highlighted green), and partially meets an additional four (highlighted amber). Of the four healthy market attributes that are partially met, two could have an impact on cost to Gavi and will require important trade-off decisions. Because of push funding investments and the resulting dominance of a single low cost manufacturer, the procurement trade-offs on purchasing from any other manufacturer will need to be weighed against benefits gained. These trade-offs should be considered over time with different considerations for the campaign vaccine use and the subsequent dominance of routine use.

Supply and Procurement Objectives

Balance of supply and demand

Maintaining supply from the primary manufacturer at full capacity will be critical to meet demand from Gavi funded campaigns and other countries.

- TARGET OUTCOME 1: Supply to countries is not interrupted.

Because total demand will likely exceed capacity in peak years, managing any supply gap will require interventions to meet campaign demand in peak years.

- TARGET OUTCOME 2: Address possible supply gaps and improve supply security of programmatically and financially suitable vaccine

Cost of vaccine to Gavi and countries

To minimise the costs of immunisation Gavi should concentrate supply to the manufacturer of preferred vaccine with the lowest total costs considering the cost per dose and required number of doses.

- TARGET OUTCOME 3: Achieve lowest possible weighted average price by maximizing supply from the lowest priced manufacturer.

In order to achieve the lowest possible cost to Gavi and countries, an alternative manufacturer should be engaged to provide lower priced vaccine to the Gavi-funded campaigns if needed to maintain country access to low priced vaccine.

- TARGET OUTCOME 4: Engage other manufacturers to offer lower priced, suitable vaccine for campaign and routine use.

Appropriate and innovative vaccines

Appropriate vaccines for use in Gavi-supported campaigns should have the following characteristics:

- Age indication of 9 months up to-15 years
- Available in multi-dose vials
- Single dose schedule
- Able to be used concomitantly with other vaccines

Innovation could be achieved by fully exploring the clinical profile of existing vaccines. The primary needs for data are in the following additional areas and would be required for all prequalified vaccines:

- Duration of protection sufficient to warrant single dose use in routine immunisation
 - Data in specific populations for all vaccines
- TARGET OUTCOME 5: Ensure that the duration of protection and need for a booster dose of all vaccines is identified by 2020.

Information

Information is a cross-cutting objective and enabler for all vaccines. Transparent communication with JE vaccine manufacturers by Gavi, UNICEF-SD, PATH and WHO is essential. This should include:

- Gavi policy regarding campaign and routine immunisation support.
 - Definition of population at risk in eligible countries and resulting demand forecasts
- TARGET OUTCOME 6: Clear communication with manufacturers on JE-specific policies, implementation, forecasts and ability to compete effectively in the tender process.

Supporting Stakeholder Action Plan

The following Action Plan between Gavi Alliance stakeholders will ensure optimized coordination, leading to the achievement of the above supply and procurement objectives.

- Facilitate technical assistance and oversight with the primary manufacturer
- Improve timing of demand approvals among partners
- Address supply gaps and ensure supply security by exploring procurement from at least one additional prequalified supplier
- Achieve lowest possible price through alternate contracting terms as needed
- Engage stakeholders to evolve the knowledge on duration of protection
- Clear communication with countries on implementation; with partners and suppliers on market requirements and tender processes