

4 The Market Shaping Goal

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

Supply and Procurement Roadmap

Japanese Encephalitis (JE) Vaccine

Public Summary

May 2018 addendum to the 2016 Roadmap:

Since the completion of the 2016 roadmap, UNICEF-SD extended the LTA with the only supplier of JE vaccine to Gavi-supported countries twice, currently covering the period until the end of 2018. In order to inform procurement beyond 2018, UNICEF SD decided to update the procurement strategy, which should be informed by an updated Gavi supply and procurement roadmap. This updated version of the 2016 roadmap reflects the evolution of the JE vaccine market since 2016 and the resulting supply and procurement objectives for the Alliance.

Public Summary

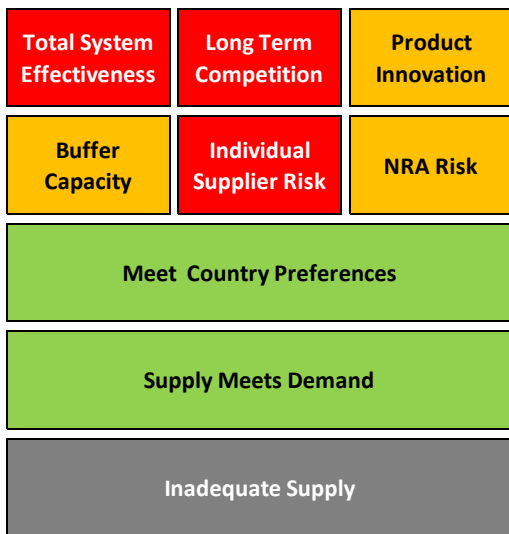
Gavi, The Vaccine Alliance, supports Japanese Encephalitis (JE) vaccination in endemic countries and this support is designed to drive the conduct of catch-up campaigns and support the introduction of JE vaccine into the routine immunisation schedule. The objective of this engagement is to rapidly reduce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

In order to secure Gavi funding for campaigns, countries must demonstrate plans to introduce and co-finance 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, a large portion of demand is steady and driven by routine immunisation in large countries, including China and India. Other countries such as Japan, South Korea, Thailand, Malaysia, Myanmar, Vietnam and Nepal 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 (<10% 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 two of the elements of a healthy market (highlighted green), and partially meets an additional three (highlighted amber). 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 and Target Outcomes

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 sufficient and not interrupted.

Because total demand may exceed capacity in peak years, managing any supply gap will require interventions to meet campaign demand in peak years. Moreover, because of Gavi reliance on a sole supplier, supply security needs to be managed.

- TARGET OUTCOME 2: Address risk of 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 ensure availability of supply 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 offered 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 to-15 years or above
- 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.

Supporting Stakeholder Action Plan

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

- Facilitate technical assistance and oversight with the primary manufacturer
- Ensure timely communication with manufacturers to manage risks associated with volatile demand, as well as to assess and manage risks of possible supply interruption
- Engage non-prequalified manufacturers to explore opportunities to increase overall quality and programmatic suitability of JE vaccines available in the market
- 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 ensure timely updates on the duration of protection and need for a booster dose