

# Market & Supply Update

## Japanese Encephalitis (JE) Vaccine

### General Background

- Several types of JE vaccine in use and under development (differences in manufacturing technology used, presentation, # of doses required to be fully immunized, age-based indications, and WHO pre-qualification status).
- In 2011, the GAVI Board recommended opening a window for country applications for GAVI support, subject to the pre-qualification of a suitable JE vaccine.
- In 2013, WHO pre-qualified a JE vaccine for pediatric use.
- Following this pre-qualification, the Gavi Board initiated in 2014 the first round of applications to invite eligible countries to apply for support to introduce this vaccine through catch-up campaigns.
- Besides being WHO pre-qualified, the criteria set by Gavi on programmatic requirements for JE vaccine are: lyophilized, 5 doses per vial, for a target population aged 9 months up to 15 years of age.
- UNICEF concluded their 2015-2016 tender process mid-2014 and awarded one manufacturer a long-term arrangement (LTA). The delivery term is FCA China and prices are also being extended to mid income countries.
- First Gavi-supported JE vaccine campaign started in April 2015.

Illustration: JE countries or areas at risk



### Current Market Situation

#### Demand and Forecast

- Global market demand for JE vaccine - approx. 75-100M doses annually.
- Gavi’s current forecast anticipates campaign vaccine requirements could reach more than 45 million doses by 2020.

#### Supply

- JE vaccine supply is sufficient to meet Gavi forecast demand. However, current supply is dependent on one manufacturer and timely delivery is vulnerable to missed calendar schedules, which need to meet specific campaign seasonality.
- The vaccine has an 18 months shelf life, which is effectively reduced to 12 months by mandatory pre-release controls from the national regulatory authority (NRA).

### Issues and Challenges

Challenges That Could Affect JE Vaccine Supply Availability and Timing

Challenges	Considerations
Production	<p>Currently, the company’s production capacity is under pressure given change on requirements from Indian government.</p> <p>The JE vaccine has a shelf life of 18 months, of which 6 months are required for release authorization, including:</p> <ul style="list-style-type: none"><li>- End-product tests;</li><li>- Quality Assurance control;</li><li>- National authority-release processing time.</li></ul> <p>Upon release and shipment time, only 12 months vaccine shelf life remains. The manufacturer also shuts down its vaccine production facilities for two-months a year to carry out maintenance operations, which has an impact on the vaccine production and lead-time for release and delivery.</p>
Calendar timing	<p>Programme calendar timing depends on:</p> <ul style="list-style-type: none"><li>- Gavi applications and approval processes;</li><li>- Tender process and duration;</li><li>- Manufacturer production lead-time supply availability;</li><li>- National authority vaccine release duration;</li><li>- Campaign seasonality.</li></ul>
Country Readiness	<p>Country readiness to introduce JE vaccine is uncertain and can delay introduction timing and schedules due to:</p> <ul style="list-style-type: none"><li>- Staff training;</li><li>- Cold chain requirements.</li></ul>

### Way Forward

- Actively follow the development of additional JE vaccine market entrants acquiring WHO prequalification.
- Follow up with Gavi and WHO the possibility of considering alternative presentations suitable for programmatic requirements.
- UNICEF will review with Gavi JE vaccine demand and supply availability and assess the need to issue a tender during the 2H 2015.
- Actively follow the development of additional JE vaccine market entrants acquiring WHO prequalification.
- UNICEF will communicate with countries and promote awareness of JE vaccine’s short shelf life as well as implications and necessary considerations for programme campaign timings.

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