Market & Supply Update
Japanese Encephalitis (JE) Vaccine

Summary

• 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. Since then, two additional JE vaccines acquired WHO pre-qualification.
• First Gavi-supported JE vaccine campaign started in April 2015 in Laos PDR and followed by supported campaigns in Cambodia and Nepal.
• UNICEF concluded a tender process mid-2014 and awarded one manufacturer a long-term arrangement (LTA) which is currently valid till end 2017. The delivery term is FCA China and prices are also being extended to mid income countries. However, given that there are now two other WHO pre-qualified products in the market, UNICEF SD is not automatically using the LTA if/when UNICEF is requested to procure JEV but is also issuing tenders to the other manufacturers and will offer the countries all the possible options available in the market.

General Product Information

• All fifteen JE vaccines currently in use or under development are based on genotype 3 virus strains.
• JE vaccines fall into 4 classes: inactivated mouse brain-derived vaccines, inactivated vero cell-derived vaccines, live attenuated vaccines, and live recombinant (chimeric) vaccines.
• All WHO prequalified vaccines use the SA 14-14-2 JE vaccine strain; though they differ in production platform, formulation and immunization schedule. At present, there are three WHO prequalified JE vaccines.

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Platform Strain Type</th>
<th>WHO PQ</th>
<th>Present.</th>
<th>Formulation</th>
</tr>
</thead>
<tbody>
<tr>
<td>CDIBP (China) [tradename: RS.JEV]</td>
<td>Primary Hamster Kidney SA 14-14-2</td>
<td>2013</td>
<td>1 dose</td>
<td>Lyophilized</td>
</tr>
<tr>
<td></td>
<td>Live Attenuated 1 dose</td>
<td>2013</td>
<td>5 dose</td>
<td>Lyophilized</td>
</tr>
<tr>
<td>Biological E (India) [tradename: JEV]</td>
<td>Vero cell culture SA 14-14-2</td>
<td>2013</td>
<td>1 dose</td>
<td>Liquid</td>
</tr>
<tr>
<td></td>
<td>Inactivated 2 dose**</td>
<td>2014</td>
<td>2 dose</td>
<td>Liquid</td>
</tr>
<tr>
<td>Sanofi Pasteur (France) [tradename: IMOEJEV]</td>
<td>Vero cell culture SA 14-14-2</td>
<td>2014</td>
<td>4 dose</td>
<td>Lyophilized</td>
</tr>
<tr>
<td></td>
<td>Live recombinant 2 doses*</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(*) Note: In February 2015, after careful review of the immunogenicity data and advice from SAGE, WHO redefined programmatic suitability of live recombinant JE vaccine and now recommends only one dose regardless of age of recipient and the manufacturer’s recommendation of 2 dose schedule (paediatric).

Illustration: JE countries or areas at risk (WHO, 2012)

Demand and Forecast

Demand quantification and forecast accuracy have been a challenge. In summary the main challenges are:

• Uncertainties associated with country interest in introducing JE vaccine with Gavi support (and subsequently any plans of potentially procuring doses for routine immunization through UNICEF (via Procurement Services).
• Major driver of demand definition is country applications for Gavi support. However applications from countries have been slower than expected by Gavi.
• Demand impacted by availability of pre-purchased JEV doses for donation to countries by one partner (PATH).

➢ UNICEF SD will revise the demand forecast numbers every 6 months and continue communication with UNICEF Country Offices and partners in order to clarify any eventual future demand.

Supply

• Global market demand for JE vaccine - approx. 75-100M doses annually.
• Currently, there are three WHO pre-qualified JE vaccine for infant use. The price aspect may influence countries decisions in product selection (potentially resulting in high dependence to the product supply by one manufacturer).

➢ SD will continue to work with Gavi and WHO on the possibility of considering alternative presentations as suitable and programmatically adequate in the near future. UNICEF SD will issue tenders based on specific country requirements (for WHO prequalified JE vaccine) and offer the countries all options available.

For further questions or additional information, please contact:
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