GAVI’S ENGAGEMENT IN EBOLA VACCINE

BOARD MEETING
Aurélia Nguyen
4-5 December 2019, Delhi, India
# Gavi’s engagement in Ebola to date: impact and lessons learnt

<table>
<thead>
<tr>
<th><strong>Impact</strong></th>
<th><strong>Lessons learnt</strong></th>
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</table>
| • US$ 390 m committed, US$ 100 m available funds, US$ 20 m fundraised  
• Support recovery in W. Africa  
• Support response in DRC/neighbours | • Flexible support to Ebola-affected countries |
| • Incentivised development & licensure  
• >250,000 doses for current outbreak  
• Close monitoring of regulatory progress, supply and price | • Importance of COGS transparency  
• US$ 5 m prepayment: limited leverage on strategic decisions |
| • Strengthened collaboration across Alliance  
• New collaborations | • Manage expectations as to future support to investigational products |

**Ebola Funding envelope (2014)**

- APC for Merck V920 (2015)

- Partnerships

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Board meeting  
4-5 December 2019
## Ebola vaccine pipeline: range of vaccine types and potential use cases

<table>
<thead>
<tr>
<th>Phase I</th>
<th>Phase II</th>
<th>Phase III²</th>
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<tbody>
<tr>
<td><strong>2 candidates</strong></td>
<td><strong>5 candidates:</strong></td>
<td><strong>1 candidate:</strong></td>
</tr>
<tr>
<td>- Inovio</td>
<td>- CanSino¹</td>
<td>- Merck</td>
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<tr>
<td>- Novavax</td>
<td>- Gamelaya¹</td>
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<tr>
<td></td>
<td>- Janssen</td>
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<tr>
<td></td>
<td>- Rspotrebnaezor¹</td>
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<td></td>
<td>- Sabin</td>
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**Vaccines meet one or both of WHO TPP use cases:**
- Reactive and preventive vaccination in an outbreak settings
- Preventive vaccination in non-outbreak settings, targeting high risk individuals

¹ Licensed in country of origin
² Clinical efficacy and effectiveness

Licensed by the EMA and WHO prequalified in November 2019
Focus of programme would be emergency vaccine stockpile for outbreak response

Vaccination approach and stockpile characteristics

- SAGE guidance: 500,000 doses
- Informed by Alliance analysis: epidemiology, demand scenarios, risk factors, public health goals
- Includes preventive vaccination (HCWs/FLWs) in affected areas and neighbouring countries

Policy considerations and stockpile management

- Access to stockpile and vaccine funding in line with current stockpiles
- However, tailored operational support given unique delivery requirements
- ICG-like mechanism tailored for Ebola, as part of broader disease control strategy

Programme likely to evolve given future demand (and impact on supply), deployment experience, updated SAGE recommendations and availability of new vaccines
With highly-targeted preventive programme to protect high-risk individuals before outbreaks

**Vaccination approach**

- Pending SAGE recommendation
- **High-risk groups** (e.g. HCWs at highest risk of occupational exposure) in non-outbreak settings
- Indicative size of target population (HCWs): ~25-40k doses
- Indicative country scope: ~6-10 based on different risks

**Policy considerations and management**

- **No co-financing** given highly targeted use, but reassess after 2 years
- **Tailored operational support** given new contact point / targeted approach
- Vaccine access to non-Gavi-countries (without support)
- **Mechanism to review requests** to be defined

Board meeting 4-5 December 2019
# Financial projections

<table>
<thead>
<tr>
<th>Category</th>
<th>2020</th>
<th>2021-2025</th>
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<tbody>
<tr>
<td>Vaccine procurement</td>
<td>~ US$ 8 million</td>
<td>~ US$ 133 million</td>
</tr>
<tr>
<td>Operational cost support*</td>
<td>-</td>
<td>~ US$ 32 million</td>
</tr>
<tr>
<td>Secretariat and Alliance partner costs</td>
<td>~ US$ 1 million</td>
<td>~ US$ 4 million</td>
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<tr>
<td>Total</td>
<td>~ US$ 9 million</td>
<td>~ US$ 169 million</td>
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* For interim period before licensed vaccine is available and stockpile is fully operational, HSS/operational cost support window from 2014 Ebola envelope (US$ 52.4 million currently remaining) to be used to support operational support for use of WHO-recommended investigational vaccine (e.g. ongoing outbreak)
Recommendation (1/4)

The Gavi Alliance Programme and Policy Committee recommends to the Gavi Alliance Board that it:

a) **Approve** the opening of a funding window for the establishment of an Ebola programme for licensed vaccines used for i) reactive and preventive vaccination in an outbreak setting through an emergency stockpile and ii) preventive vaccination in a non-outbreak setting, both\(^1\) contingent on WHO prequalification of vaccine and SAGE recommendation, in line with Board-approved policies and decisions with adjustments laid out under b), c) and d);

\(^1\)This edit to the decision point reflects the recent licensure and prequalification of the Merck Ebola vaccine in November 2019, subsequent to the PPC meeting in October 2019.
Recommendation (2/4)

b) **Approve** Gavi support for vaccines for preventive use without a co-financing obligation for Gavi eligible countries with the co-financing policy for Ebola vaccine subject to review after two years from start of programme;

c) **Approve** Gavi operational cost support for both reactive and preventive vaccination that is tailored to each country based on context;

d) **Approve** the principle of providing non-Gavi eligible countries access to vaccines for preventive vaccination, where possible. These countries would bear the cost of the vaccine;
Recommendation (3/4)

e) **Note** the financial implications associated with the above approvals for vaccine procurement, operational cost support and Secretariat and partner resources for 2020 is expected to be approximately US$ 9 million and for 2021-2025 is expected to be approximately US$ 169 million. Gavi will seek to absorb the Secretariat and PEF-related components in the 2020 estimated costs within the 2020 budget submission;
f) **Note** that the Secretariat will work with partners to further develop processes to enable allocation of vaccines and operational cost support for both reactive and preventive use;

g) **Approve** retaining the operational cost and health system support component of the 2014 Ebola envelope for the interim period before a licensed vaccine is available in order to provide operational support for use of investigational vaccines and closing the remainder of the 2014 Ebola envelope; and

h) **Note** the remaining balance of the operational cost and health systems support component of the 2014 Ebola envelope of US$ 52.4 million.
THANK YOU