

# ACCELERATING ACCESS TO EBOLA VACCINES AND COUNTRY PERSPECTIVE

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BOARD MEETING

Seth Berkley, Robert Newman, Aurélia Nguyen  
10-11 December 2014, Geneva

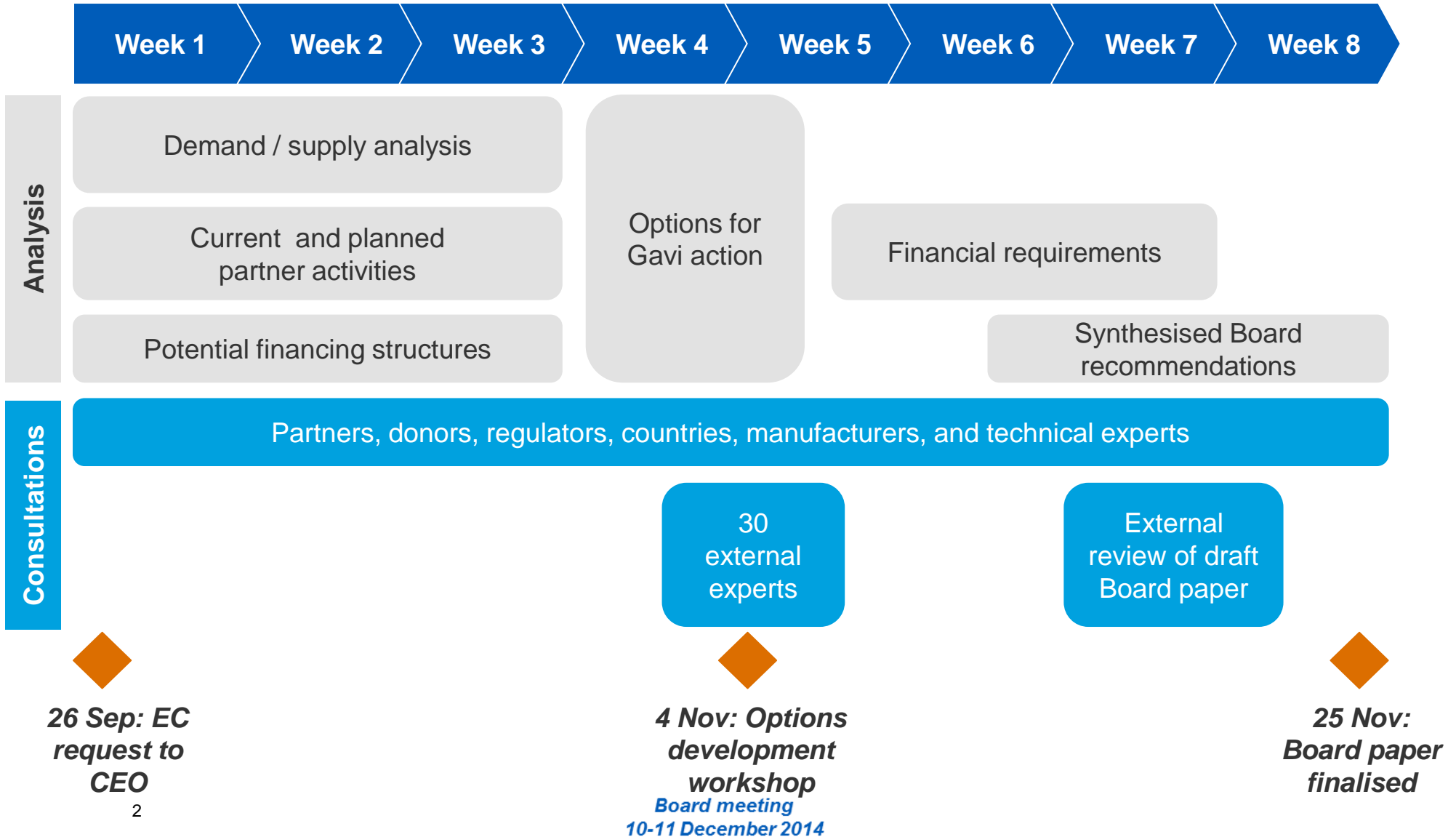


# AGENDA

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- ① **Process of generating Board recommendation**
- ② **Funding landscape and Gavi capabilities**
- ③ **Four recommended areas for Gavi action**
- ④ **Financial implications**
- ⑤ **Risks**

# 8-WEEK PROCESS TO GENERATE A BOARD RECOMMENDATION ON EBOLA RESPONSE

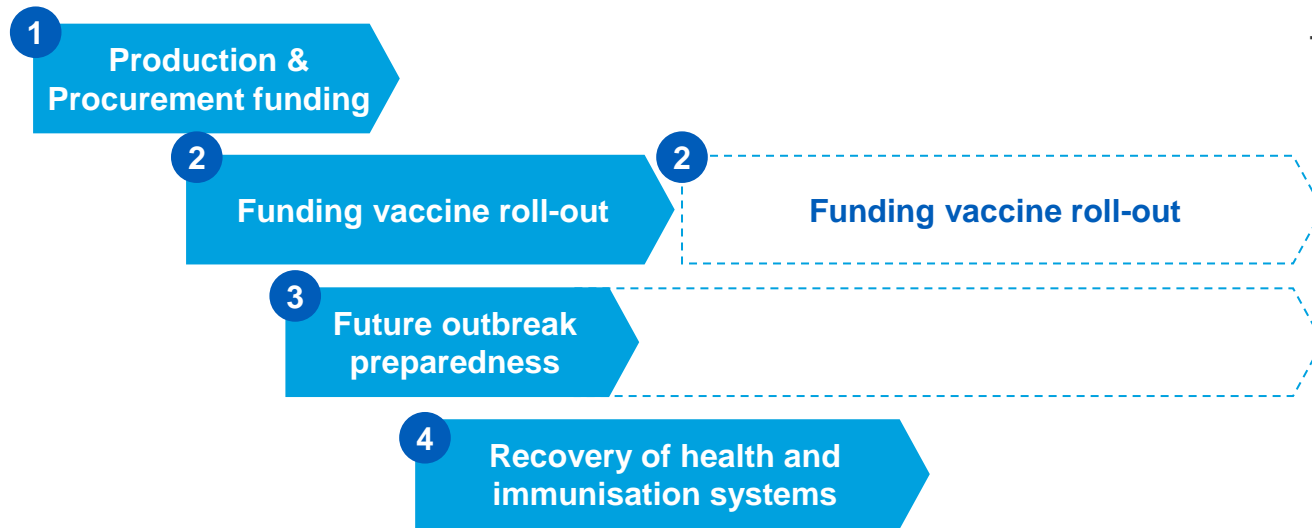
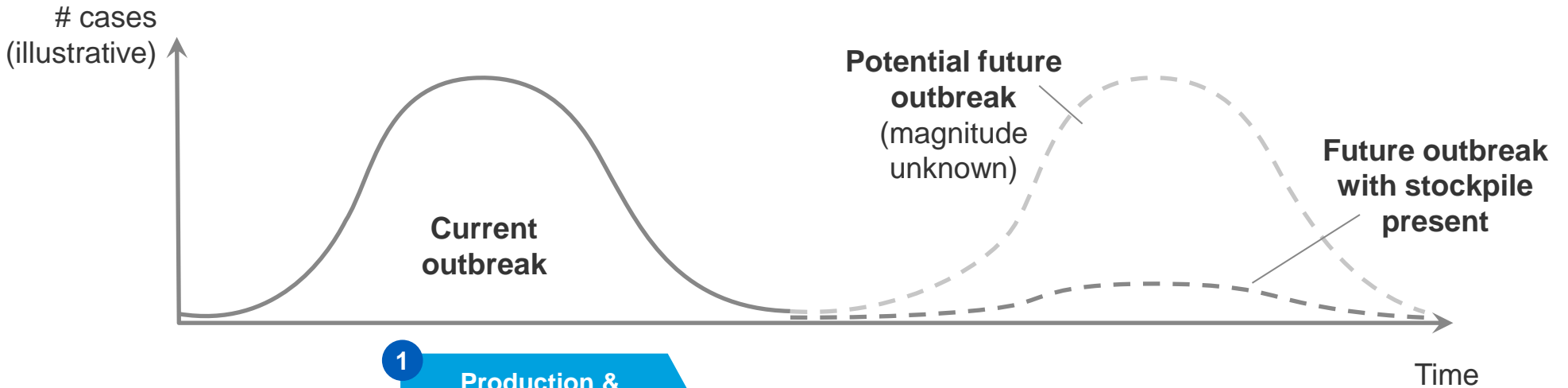


# WHERE CAN GAVI CONTRIBUTE?

## PARTNER LANDSCAPING AND GAVI CAPABILITY ASSESSMENT

Cost category		Critical funding area	Est. funding coverage	Fit with Gavi capabilities? (based on past experience, partner input)
Clinical trials		Phase I	High	X
		Phase II	High	X
		Phase III	High	X
Production & procurement	Production scale up	Production at clinical trial scale	High	X
		Scale up / scale optimisation	Medium	✓
		Commercial scale mfg	Low	✓
	Procurement	Vaccine procurement	Medium	✓
	Risk mitigation	Indemnification	Medium	X
	Diverted manufacturer resources	Diverted manufacturer resources	Low	✓
Vaccine roll-out		Planning & coordination, social mobilisation, IEC, training, HR, transport /logistics/cold chain, waste management, surveillance and monitoring of AEFI, etc.	Medium	✓
Future outbreak preparedness		Clinical trials	Low	X
		Production scale up	Low	✓
		Procurement	Low	✓
		Vaccine roll-out	Low	✓

# 4 RECOMMENDED AREAS FOR GAVI ACTION



# 1 VACCINE PRODUCTION AND PROCUREMENT

## ENVELOPE DRIVEN BY LEVEL OF UNCERTAINTY AND EVOLVING LANDSCAPE

### Procurement-related principles

- 1 Plan for high vaccine demand
- 2 Focus on alleviating bottlenecks to vaccine availability
- 3 Prioritise solutions that are candidate-agnostic
- 4 Avoid prematurely locking into a market that is not fully understood

### Recommendation:

Envelope signaling Gavi potential spend

- ✓ Utilises Gavi's multilateral mechanism to aggregate and coordinate funding
- ✓ Signals a market for Ebola vaccine and related supplies
- ✓ Allows addressing of different demand scenarios in an evolving environment
- ✓ Enables tailored agreements with individual manufacturers
- ✓ Enables support of multiple manufacturers

# 1 VACCINE PRODUCTION AND PROCUREMENT

## DETERMINATION OF ENVELOPE SIZE

### Key drivers of size of US \$300 million envelope

Volume of vaccine required to combat current outbreak	Up to 12M courses
Number of manufacturers	2-3 manufacturers (with different economics)
Manufacturer costs	Marginal costs of production and unsubsidized scale up costs

### Key drivers of uncertainty around spend within envelope

Actual demand versus "high demand" scenario	Actual demand anywhere from <100K to >12M courses
Manufacturer from which vaccines are ultimately procured	Different cost structures, vaccine technologies
Level of subsidy for each manufacturer	Funding discussions still evolving

**Funding structures within this envelope will be subject to EC approval**

## 2 FUNDING VACCINE ROLL-OUT

BASED ON CURRENT DATA – DETAILED COUNTRY-LEVEL COSTING UNDERWAY

### A Standard campaign categories with Ebola-specific cost multiplier assigned

- Social mobilisation, IEC<sup>1</sup>, advocacy
- HR and training
- Vehicles and transportation
- Waste management
- Surveillance, including for AEFI<sup>2</sup>
- Evaluation

US\$ 38 M<sup>3</sup>

### B Additional cost categories for Ebola vaccine roll-out

- Emergency Operations Centres
- Cold chain and logistics
- Security and crowd control
- Increased infection control measures

### C Stockpile cost categories

- Management of stockpile
- Operational costs for use of stockpiled courses in future outbreaks

US\$ 7 M

US\$ 45 M

1. IEC: Information, education, and communication 2. Adverse Events Following Immunisation 3. Assuming target population of 12M individuals



### 3 FUTURE OUTBREAK PREPAREDNESS

#### Recommendation 1: Stockpile of first- generation vaccines

- Relatively small stockpile required
- To be maintained until 2nd generation vaccine becomes available

#### Gaps remaining

- Profile of first generation vaccine(s) expected to be suboptimal for longer-term application:
- Monovalent vaccine
  - Thermostability concerns

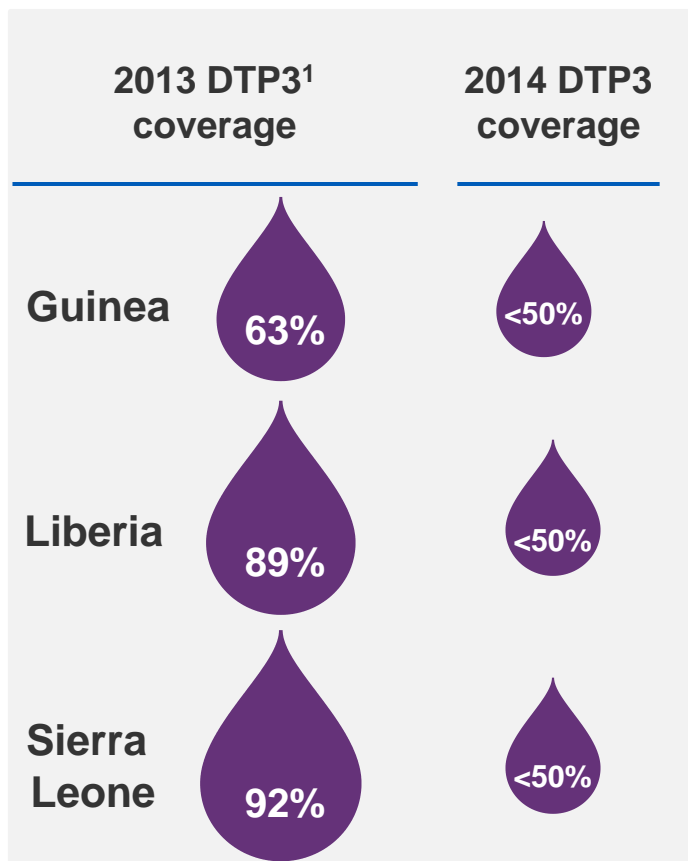
#### Recommendation 2: In-principle commitment to 2nd-generation stockpile

- Assure availability of effective vaccines for future outbreaks
- Vaccine availability dependent on timing of vaccine development and optimisation

**Lack of longer-term availability of an effective Ebola vaccine could result in a repeat of the current situation**

# 4 RECOVERY OF HEALTH AND IMMUNISATION SYSTEMS

## Ebola has crippled health and immunisation systems



## Recommendations to support recovery *(Upon country request)*

Vaccines and related injection safety devices and programmatic support	up to US\$ 12.5 M
Reprogramming of currently approved HSS grants	No additional costs
Increase of HSS funding	up to US\$ 30.5 M
Waiving of 2014-15 co-financing requirements	up to US\$ 2 M
<b>Total</b>	<b>up to US\$ 45 M</b>

1. Coverage with 3rd dose of a DTP-containing vaccine

# FINANCIAL IMPLICATIONS OF APPROVING RECOMMENDATIONS

Recommendation per Board Paper	US\$ million
<b><u>Ebola Programme Funding Envelope (2015-2020)</u></b>	
Ebola vaccine production and procurement	300
Ebola vaccine roll-out	45
Recovery of health and immunisation systems	45
<b>Sub-total: Ebola Programme Funding Envelope</b>	<b>up to 390</b>
<b><u>Addition to Business Plan budget (2015-2016)</u></b>	
Secretariat costs	3.5
Support to WHO & UNICEF	7.0
Support to Civil Society Organisations	0.5
<b>Sub-total: Addition to Business Plan Budget</b>	<b>up to 11.0</b>
<b>Total cost of funding the recommendations</b>	<b>up to 401</b>
Less: <b><u>Already provided</u></b> in Gavi expenditure forecast for 2014-2015	(100)
<b>Additional resources required</b>	<b>up to 301</b>
Deduct: <b>Resources from other funding agencies / donors</b>	TBD
<b>Balance to be funded through Gavi</b>	<b>TBD</b>

# RISKS ASSOCIATED WITH RECOMMENDATIONS

Risk	Potential mitigation(s)
<b>Vaccine safety &amp; acceptability not fully evaluated</b>	<ul style="list-style-type: none"> <li>• Regulatory advice, WHO recommendation for use</li> <li>• Information to countries</li> </ul>
<b>Gavi investments have no impact on current outbreak</b>	<ul style="list-style-type: none"> <li>• Gavi investments contingent on WHO recommendation for use</li> </ul>
<b>Gavi enters into sub-optimal agreements with manufacturers</b>	<ul style="list-style-type: none"> <li>• Short-term agreements guided by WHO recommendations</li> <li>• Allow adjustments as situation evolves</li> <li>• Manufacturer transparency</li> </ul>
<b>Vaccines do not reach target populations</b>	<ul style="list-style-type: none"> <li>• Support health system recovery efforts</li> <li>• Plan carefully for vaccine roll out, commit sufficient funding for critical activities</li> </ul>
<b>Gavi ill-suited to engage in emergency response</b>	<ul style="list-style-type: none"> <li>• Leverage existing Gavi mechanisms wherever possible</li> </ul>
<b>Human resource diversion hinders performance of other Gavi efforts</b>	<ul style="list-style-type: none"> <li>• Reprioritise current staff workloads</li> <li>• Hire dedicated staff to manage Ebola-related activities</li> </ul>
<b>Financial resource diversion hinders performance of other Gavi efforts</b>	<ul style="list-style-type: none"> <li>• Seek incremental funding for Ebola activities from donors who have already pledged resources for Ebola response</li> </ul>

1. See Section 4.2 of Board Paper for more details

**THANK YOU**

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[www.gavi.org](http://www.gavi.org)