Vaccine Industry Consultation – Gavi update 2017

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Agenda

- Gavi progress in 2016
- Supply and Procurement Strategy (SUPPRS) 2016-20
- SUPPRS Implementation - Update
- Vaccine Investment Strategy 2018 - Update
- Engagement and information sharing
2016–2020 INDICATORS
MISSION PROGRESS

1. Children immunised
   - TARGETS: 300 million
   - 2015: > 65 million

2. Future deaths averted
   - 2015: > 1.2 million
   - TARGETS: 5–6 million

3. Under-five mortality rate
   - 2015: < 64 per 1,000
   - TARGETS: 58 per 1,000
   - 10% reduction in rate from 2015 baseline by 2020

4. Future disability-adjusted life years (DALYs) averted
   - 2015: > 56 million
   - TARGETS: 250 million

5. Vaccines sustained after Gavi support ends
   - 2015: 100%
   - TARGETS: 100%

**Estimate as of mid-2017: 100 million**

Projected on track, based on assumed continued improvement over last report (latest available data shown)

On track, based on data available year to date
In 2016-20, Gavi 4.0 more introductions planned than during the previous period

- The new Measles strategy means Gavi funds routine as well as M “follow up” programs. Gavi now also funds routine MenA and JE routine.

- HPV Multi-age-cohort programs are not included in these graphs

* The 270 number of introductions includes the count of follow up activities, the upper range of ~300 includes the count of HPV multi-age-cohorts programs, but m-a-c is not reflected in the chart.
SUPPLY AND PROCUREMENT STRATEGY 2016-2020

**MISSION 2**

**PRIORITIES**
- Healthy Markets
- Long-term View
- Innovation

**SCOPE**
- Gavi supported countries (including transitioning countries)
- Vaccines for Board-approved antigens
- Other immunisation products (focus on cold chain equipment)

**OBJECTIVES**

**CREATE HEALTHY MARKETS IN SUPPORT OF GAVI COUNTRIES’ IMMUNISATION NEEDS**
- Sufficient and secure supply
- Appropriate and sustainable prices
- Suitable and quality products

**ENABLERS**

**ACTORS**
- Countries as Customers
- Industry
- Market shaping intermediaries

**APPROACHES AND TOOLS**
- Roadmaps
- Coordination and accountability
- Data collection and analytics
- Forecasting (strategic and operational)
- Healthy Markets Framework
- Tailored procurement
- Manufacturer engagement

**MONITORING AND EVALUATION**
- Outcome Indicators
- Process indicators
- Market Shaping externalities
- Evaluation of strategy outcomes and impact

**OUTCOMES BY 2020**

- 11 vaccine markets have sufficient and uninterrupted supply
- Decrease in Weighted Average Price (per child) to fully immunise with pentavalent, pneumococcal, and rotavirus vaccines
- 10 new products procured by Gavi with improved characteristics

**6 VACCINE MARKETS HAVE MODERATE OR HIGH ‘HEALTHY MARKET DYNAMICS’**
In 2016, we made progress on the three strategic priorities of the Supply and Procurement Strategy

**Healthy markets**
- Delivering on healthy markets
  - The Alliance will move beyond singular objectives to advance the overall healthy market dynamics of its vaccine markets

**Long-term view**
- Taking a long-term view of markets
  - The Alliance will shape markets with a view to longer-term impact and the role of countries as increasingly independent financiers of immunisation programmes

**Innovation**
- Driving innovation to better meet country needs
  - The Alliance will pursue a common agenda on product innovation to inform product choices and support Alliance goals on immunisation coverage and equity
Externalities of market shaping

Monitor the unintended consequences of Gavi market shaping activities in Gavi and non-Gavi countries

Monitor the positive and negative externalities of its market shaping activities on the market place, i.e. on manufacturers, Gavi and non-Gavi countries and partners, including the weighting of risks and consequences against the potential benefits.

Gavi will also work with manufacturers to determine which information provide insight into the impact of market shaping on innovation and research and development.

Status
• Public consultation on externalities of market shaping concluded
• External consultancy retained
• Identification and prioritisation of externalities ongoing
Support for informed, country-owned decisions

Under the strategic goal on sustainability, Gavi will support countries towards successful transition

Support country governments to make well-informed introduction and product decisions by sharing with them the full set of trade-offs to consider in evaluating the options.

Support countries by sharing key information, tools, methodologies that can help strengthen the forecasting and product strategy development capabilities.

Support clarification of the roles of partners in supporting continued country transition post Gavi support.

Status
• Background and in-country research to identify country needs
• Draft stakeholder plan to support product decision-making and procurement by countries
Support product innovation to better meet country needs

Accelerating product innovation to better meet country programmatic needs and improve coverage and equity

“Product innovation’ refers to completely new products or to adaptations to existing products that provide measurable financial or programmatic benefits

Develop **common principles** to make the assumptions underpinning the value proposition explicit for **long-term product innovations**

Convene a platform to articulate a **clear and aligned perspective on how and what to prioritise. Communicate these priorities** in a non-binding manner

Understand **countries’ needs** by leveraging countries’ and technical partners’ field experience to consider financial and non-financial impact of innovations

**Status**
- Common principles developing in TSE (next slides)
- Draft proposal for a platform complete
The healthy markets framework assesses the attributes of a ‘healthy market’

<table>
<thead>
<tr>
<th>Total System Effectiveness</th>
<th>Long Term Competition</th>
<th>Product Innovation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Buffer Capacity</td>
<td>Individual Supplier Risk</td>
<td>NRA Risk</td>
</tr>
</tbody>
</table>

Meet Country Preferences

Supply Meets Demand

Inadequate Supply

The highest level achieves positive system features such as the effect of the market on immunization system effectiveness, long term competition and product innovation.

A more healthy market has additional supply security attributes.

A healthy market meets country preferences for specific vaccine characteristics.

The minimum of a healthy market is supply meets demand.

Markets without adequate supply are not healthy.

Developed jointly by BMGF, Gavi and UNICEF
Total Systems Effectiveness (TSE) initiative

The Total Systems Effectiveness (TSE) initiative is a multi-stakeholder effort (WHO, UNICEF, Gavi, PATH, CHAI, JSI & Gates), initiated in March 2016, but really kicked off in March 2017.

More to follow: Internal consultations are organised within partners as part of the socialization of the concept and to inform the ‘Go/No go’ decision.

The Issues

1. The innovation conundrum
   - The supply of innovations is not always met with country level demand for it

2. The decision making bias
   - Country decisions to introduce a non-vaccine innovation is often guided by purchase price without understanding of:
     - Potential savings on service delivery costs, or from a safety perspective, or in terms of wastage
     - Benefits in terms of coverage and health impact (reduction in disease) that could be achieved

3. The coverage equity plateau
   - Countries are often limited by procuring a single vaccine product for nationwide use when using a mix of presentations adapted to different in-country settings and delivery strategies could help break the coverage plateau
TSE is an analytical ‘end-to-end’ framework

The Solution

1. By helping to understand the **trade-off** across a core set of components and make the **value proposition of new innovations (and assumptions) explicit** and **much earlier** in the vaccine and technology product development process.

2. By paving the way for a **future-state** where countries:
   - Have the choice of **multiple product presentations** for different programmatic adaptations
   - Can comprehensively evaluate the **tradeoffs** of each **beyond just the purchase price**
   - Can apply **“Systems” thinking** to product decision-making with the context of coverage and equity improvements
The vaccine investment strategy:

An evidence-based approach to predictable programming

Enabling predictable vaccine programming and investment decisions by the Board (rather than first-come-first-serve vaccine investment decisions)

Ensuring predictability of Gavi programs to help long-term planning by countries, industry and donors

Implementation of future vaccines dependent on resource mobilisation, vaccine development outcomes and WHO normative guidance
The Vaccine Investment Strategy (VIS) sets new vaccine priorities, aligned with Gavi’s strategic cycle and replenishment

**VIS #1**
MenA, JE, HPV Rubella, Typhoid conjugate

**VIS #2**
YF mass campaigns, Cholera stockpile, Rabies/Cholera studies, Malaria – deferred

**VIS #3**
Mid 2017: Vaccine ‘long list’
Oct 2017: Methodology
Jun 2018: Vaccine shortlist
Dec 2018: Investment decisions
# Preliminary overview of candidates in VIS 2018

<table>
<thead>
<tr>
<th>Disease Category</th>
<th>Candidate Vaccine</th>
<th>Likely Vaccination Strategy</th>
<th>Currently supported by Gavi?</th>
<th>Licensure Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Planned Preventative Immunisation for Endemic Diseases</td>
<td>Diphtheria</td>
<td>Routine Diphtheria-containing Booster</td>
<td>✓</td>
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<tr>
<td></td>
<td>Tetanus</td>
<td>Routine Tetanus Toxoid-containing Booster</td>
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<tr>
<td></td>
<td>Pertussis</td>
<td>Routine Pertussis-containing Booster</td>
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<tr>
<td></td>
<td>Hepatitis B</td>
<td>Birth Dose</td>
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</tr>
<tr>
<td></td>
<td>Oral cholera vaccine</td>
<td>Preventive Campaigns in Endemic Settings</td>
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<td>Licensed</td>
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<tr>
<td></td>
<td>Meningitis C, Y, W, X</td>
<td>Multivalent Conjugate Vaccines in Routine &amp; Campaigns</td>
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<td>Licensed</td>
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<tr>
<td></td>
<td>Group B streptococcus</td>
<td>Routine Maternal Immunisation</td>
<td>✘</td>
<td>Under Development (Phase 2)</td>
</tr>
<tr>
<td></td>
<td>Hepatitis E</td>
<td>Campaigns in Humanitarian Settings</td>
<td>✘</td>
<td>Licensed</td>
</tr>
<tr>
<td></td>
<td>Hepatitis A</td>
<td>Routine Immunisation</td>
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<td>Licensed</td>
</tr>
<tr>
<td></td>
<td>Dengue</td>
<td>Routine Immunisation</td>
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<td>Licensed</td>
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<tr>
<td></td>
<td>Influenza</td>
<td>Routine Maternal Immunisation</td>
<td>✘</td>
<td>Licensed</td>
</tr>
<tr>
<td></td>
<td>RSV</td>
<td>Routine Maternal Immunisation</td>
<td>✘</td>
<td>Under Development (Phase 3)</td>
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<tr>
<td></td>
<td>RSV mAb</td>
<td>Prophylactic Neonatal Use in High-risk Populations</td>
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<tr>
<td></td>
<td>Rabies</td>
<td>Post-exposure Prophylaxis</td>
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<td>Licensed</td>
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<tr>
<td></td>
<td>Rabies Ig/mAb</td>
<td>Post-exposure Prophylaxis</td>
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<td>Licensed (mAb in development)</td>
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<tr>
<td></td>
<td>Malaria (RTS,S)</td>
<td>Implementation Pilot Phase 2; Future Routine Use</td>
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<td>Licensed (Implementation pilots)</td>
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<td></td>
<td>PCV</td>
<td>Catch-up campaigns for 2-4 Additional Cohorts</td>
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<tr>
<td>Public Health Risk Reduction</td>
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<td>Outbreak Response</td>
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<tr>
<td></td>
<td>Zika virus</td>
<td>Outbreak Response</td>
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<td>Ebola</td>
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<td>Flu/IVP</td>
<td>IPV post-eradication</td>
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<tr>
<td></td>
<td>Influenza</td>
<td>Pandemic Response</td>
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* Further analyses and information might shift this list over the course of the next few months
Industry engagement moving forward

Gavi will engage with industry in a deliberate and partnership-minded way with sensitivity to the different business needs of individual manufacturers and mutual transparency.

- **Give visibility over longer time horizons** for product development and adapting product strategies where needed to recognise the varying constraints of individual manufacturers

- **Communicate priorities and opportunities** for vaccines and other immunisation products as early as is feasible through the VIS and the product roadmaps

- **Coordinate and align their communications** to ensure that market-shaping goals are clearly articulated (‘one voice’)

- **Engage in regular dialogue**, both formal and informal

- **Convene informal bilateral meetings** (mirrored at CEO level when possible) to review individual and joint business priorities
Each vaccine market has specific attributes and needs – strategies are aligned to individual markets
## Supply and procurement roadmap availability

<table>
<thead>
<tr>
<th>Roadmaps</th>
<th>First version</th>
<th>Second version</th>
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<tr>
<td>HPV</td>
<td>2012</td>
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<td>Pentavalent</td>
<td>2013</td>
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<td>Yellow Fever</td>
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<td>2016</td>
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<tr>
<td>Rotavirus</td>
<td>2013</td>
<td>2016</td>
</tr>
<tr>
<td>IPV</td>
<td>2013</td>
<td>2017</td>
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<tr>
<td>Measles-Rubella</td>
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<td>2017</td>
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<tr>
<td>Pneumococcal</td>
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<td>2017</td>
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<tr>
<td>Japanese encephalitis</td>
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<td>2016</td>
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<tr>
<td>Meningococcal A</td>
<td>2015</td>
<td>2017</td>
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<td>Meningococcal Stockpile</td>
<td>2017</td>
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<tr>
<td>Cholera</td>
<td>2014</td>
<td>2018</td>
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<tr>
<td>Typhoid</td>
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**KEY**
- **Year**: Current roadmap
- **Year**: Update ongoing
- **Year**: Update planned

Available at: [http://www.gavi.org/about/market-shaping/supply-and-procurement-roadmaps/](http://www.gavi.org/about/market-shaping/supply-and-procurement-roadmaps/)
Market Shaping information for public use on Gavi website

http://www.gavi.org/about/market-shaping/

- Supply and Procurement Strategy
- Gavi Base Demand Forecast
- Public roadmap summaries
To receive strategic demand scenarios, email: forecast@gavi.org

### Strategic Demand Scenarios (SDS) forecasting calendar

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>2017Q1</th>
<th>2017Q2</th>
<th>2017Q3***</th>
<th>2017Q4</th>
<th>2018Q1</th>
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<tr>
<td>PCV</td>
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<td>Rota</td>
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<td>JE</td>
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<tr>
<td>Mening C, W, etc.</td>
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<tr>
<td>TCV</td>
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<td>Penta</td>
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**v14 base forecast**

**v15 Base forecast**
THANK YOU