GAVI UPDATE

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UNICEF VIC,
Copenhagen, DK
Gavi receives the 2019 Lasker-Bloomberg Public Service Award

Award given for saving millions of lives by providing sustained access to childhood vaccines around the globe

**Geneva, 10 September 2019** – The Albert and Mary Lasker Foundation announced today that Gavi, the Vaccine Alliance has received the prestigious 2019 Lasker-Bloomberg Public Service Award for providing sustained access to childhood vaccines in the world’s poorest countries, saving millions of lives and highlighting the power of immunisation to prevent diseases.

“It is a great honour for us to receive such a prestigious Award,” said Dr Seth Berkley, CEO of Gavi the Vaccine Alliance. “Since its creation in 2000 at Davos, Gavi has been making it possible for the world’s most vulnerable children to receive the vaccines they need to live healthy, successful lives. Our collective work as an Alliance has prevented more than 13 million deaths in developing countries while child mortality was halved largely thanks to immunisation. I couldn’t be prouder of what we have accomplished together.”
MARKET SHAPING METRICS
Progress on price reduction and product innovation; continued risks on supply

**Vaccine Price Reduction**
- 2015: $20
- 2016: $19
- 2017: $17
- 2018: $16
- 2020: N/A
(Cost of full course of Penta, PCV and Rota vaccines)

**Supply Security**
- 2015: 7/11
- 2016: 9/11
- 2017: 8/11
- 2018: 8/11
- 2020: 11
(Vaccine markets where supply meets demand)

**Healthy Market Dynamics**
- 2015: 1
- 2016: 2
- 2017: 3
- 2018: 3
- 2020: 6/11
(Vaccine markets classified with moderate or high healthy dynamics)

**Product Innovation**
- 2015: 0
- 2016: 3
- 2017: 5
- 2018: 7
- 2020: 10
(No. vaccines & immunisation products with improved characteristics)
# Market Shaping M&E Indicators: 2018

## 1 - SUPPLY
- **Behind target in 2018**
  - Drivers: HPV, Rota, IPV
- **On track for 2020 target**
  - =11 markets adequately supplied

## 2 - PRICE
- **WAP Penta + PCV + Rota 2017→2018**
  - From $16.63 to $15.90 (-4%)
- **Targets confidential**

## 3 - INNOVATION
- **On target in 2018**
  - Drivers: OCV CTC & 4d MDV PCV
- **On track for 2020 target**
  - =10 specified innovations

## 4 – HEALTHY MARKETS
- **Ahead of target in 2018**
  - 3 (Penta, YF, PCV) high/moderate
- **2020 target (6) at risk**
  - HPV/MenA/JE/OCV may not move
DOSE RENEWALS
The vaccine renewal process continues to increase scrutiny on requests to ensure efficient use of resources

--- Key objectives ---

Scrutinizing allocations and co-financing requirements

Efficient use of resources, including:
- Donor funding
- Supply
- Cold chain equipment
- Warehousing

Through more accurate forecasting of need and more country engagement in process

- Triangulation of 5-10 different data sources per country* to understand need for coming year. Analysing:
  - Vaccine consumption from shipments and country reported data
    - Focused on penta given long history and often more stable
  - Coverage trends from WUENIC, country, JRF
  - Country stocks and unshipped approvals

This is an ongoing approach but 2019 marked a significant increase in scrutiny over country requests. Historical over allocation of doses and in some cases overshipment has resulted in a decrease in allocations for some vaccines ranging from 5%-30%

* Top 15 countries by volume were analysed in this detail
Dose allocation renewals: What next?

• Diligence of doses in the chain is important
• Gavi MS is aware of the volatility this exercise has injected
• Short term intent to smooth the impact in collaboration with affected suppliers
• Long term fix to review our processes to reduce variability:
  • More frequent adjustments to avoid this shock
  • Country ownership review: assumptions around wastage, coverage, buffer stock etc need more scrutiny
Vaccine Manufacturer GS1 Compliance

Starting 1 October 2019, for vaccine tenders backed by Gavi financing issued by UNICEF, it will be a requirement to have GS1 barcoding on the secondary packaging by latest 31 December 2021.

*Geneva, 9 September 2019* – Gavi, the Vaccine Alliance is supporting countries to improve vaccine visibility and traceability from manufacturer to beneficiary, contributing to our efforts to secure quality assured vaccines delivered to the right place, in the right quantities, at the right time to all children and adolescents.

UNICEF and the World Health Organization (WHO) have recognised the benefits of the use of harmonised global or international identification and serialisation standards on vaccines to improve visibility and traceability. Since 2015, UNICEF has recommended the use of GS1 standards on the secondary package of vaccines. Gavi, the Vaccine Alliance is planning to require GS1 data and barcode standards on the secondary package to improve product identification, labeling, and data exchange within the immunisation supply chain. Starting 1 October 2019, for vaccine tenders backed by Gavi financing issued by UNICEF, it will be a requirement to have GS1 barcoding on the secondary packaging by latest 31 December 2021. An implementation roadmap will be developed in consultation with partners in the coming months.
HPV Vaccine Supply

Resetting expectations

• Supply in 2019 and 2020 lower than expected
  • Significant step-up in supply from previous years, but below Gavi requirements
  • Manufacturers with pipeline HPV vaccines are engaged to ensure expected PQ timelines (2021 earliest) are met

• Programme adaptation & implications
  • Alliance partners have agreed to continue prioritizing single age cohorts and delay multi-age cohort (MAC) implementation
  • 2019 introductions will reduce from 18 to 15, with further introductions in 2020 unlikely under current supply outlook
HPV supply constraints continue to delay vaccine scale-up

Demand forecast at time of December 2016 board decision
Routine Multi-Age Cohort

Latest supply forecast

Million doses
IPV Vaccine Supply

Enough supply to cover 1 routine dose in 2018, catch-up delayed

- Improving supply, rising prices
  - Supply secured for 1-dose schedule in countries procuring through UNICEF → IPV now (re)introduced in all countries*
  - Price increase in UNICEF tender 2019-22 due to scale-up investment costs
  - Supply & pricing expected to improve during tender period based on new entrants

- Catch-up immunization
  - 43 million children** globally in need of catch-up immunization
  - Catch-up immunization could begin in high risk countries starting Q3 2019
  - Catch-up in all other countries expected starting 2020 based on supply availability

(*): Mongolia and Zimbabwe were the last countries to introduce IPV in April 2019
(**): including 33 million children in 32 Gavi supported countries
Rotavirus Vaccine Supply

Several challenges overcome in 2018, delayed intro’s in 2019

- **Supply issues in 2018**
  - Reduced allocations of Rotateq (Merck) → 4 impacted countries in Africa
  - Manufacturing issue with Rotarix (GSK) → introduction delays in 9 countries
  - Extensive Alliance collaboration to mitigate impact and support countries in evaluating alternative vaccines

- **Improved market resilience**
  - WHO PQ of vaccines from 2 manufacturers and a new presentation from an existing manufacturer in 2018
  - Further presentations expected to be PQ by 2020 (2 → 9 presentations in total)
VIPS background and goal

2016 – 2020: Innovation as one of the Alliance priorities for shaping markets

The Alliance aims to pursue a common agenda of driving vaccine product innovation to better meet country needs and support Alliance goals

Prioritise innovations in vaccine delivery attributes to provide greater clarity to manufacturers and immunisation partners to make investment decisions

VIPS
VIPS is a close Alliance-wide collaboration effort
VIPS will be delivered through two prioritisation phases by end Q1 2020

**Phase I: Initial prioritisation of innovations**
- 24 innovations assessed
- Innovations’ characteristics and potential public health value;
- Potential ‘breadth of use’ (applicability to several vaccines)

**Phase II: Final prioritisation of innovations paired with vaccines**
- 9 innovations prioritised for Phase II
- 9 prioritised innovations analysed with 17 priority vaccines
- AIM: Prioritise ~ 3 - 4 innovations

• Short-listed innovations paired with priority vaccines

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1 Purpose is to prioritise innovations “themselves”, “as platforms”, however it will be signaled for which individual vaccines or types of vaccines the innovation is seen to be most valuable.
Under Phase I, 9 innovations have been short-listed.

- Microarray patches (MAPs)
- Combined Vaccine vial Monitor (VVM) and Threshold Indicator (TI)
- AD sharps-injury protection (SIP) syringes
- Solid-dose implants
- Dual-chamber delivery devices
- Freeze damage resistant liquid formulations
- Heat stable/controlled temperature chain (CTC) qualified liquid formulations
- Compact prefilled auto-disable devices (CPADs)
- Barcodes / Radio Frequency Identification (RFID)

Note: Innovation pictures are just examples of innovations.
MARKET SHAPING IN GAVI 5.0
The next strategic period will be critical for the Alliance’s new 2030 aspiration

**Vision**

Leaving no-one behind with immunisation

**Mission**

To save lives and protect people’s health by increasing coverage and equitable use of vaccines

**Goals**

1. Introduce and scale up vaccines
2. Strengthen health systems to increase equity in immunisation
3. Improve sustainability of immunisation programs
4. Ensure healthy markets for vaccines and related products

**Set of principles**
Limitations of the HMF

- HMF focuses on market considerations for Gavi supported countries, and may not apply to other markets.

- Market health is viewed from the perspective of Gavi and the countries it represents; manufacturers may have a different perspective.

- HMF approaches each vaccine market separately— it does not consider the effects of one market on another.

- The determination of how much achieving each attribute is worth requires judgement.

- The attribute of Total Systems Effectiveness is not currently well understood but will be a focus area to strengthen.
Healthy market framework

**Healthy market dynamics**

**Supply**
Sufficient and secure

**Innovation**
Suitable and quality products

**COST**
Appropriate and sustainable prices

**Healthy markets**
Moderate or high levels of ‘healthy market dynamics’

**Demand quality?**

**Environmental impact?**

**Price volatility?**

**Distinguish outbreak / routine / regional?**
MICS engagement – Board recommended to ‘institutionalise’ this support with a more deliberate approach in Gavi 5.0

Leveraging the ‘Power of the Alliance’ through three levers of support

**Advocacy & political will building**
- Technical assistance to support to strengthen countries’ political commitment to immunisation and new vaccine introductions

**Market shaping**
- Pooled procurement - tender mechanism pooling countries’ demand
- **Limited catalytic funding** support for new vaccine introductions (i.e. 6-9 months of a birth cohort)

**Technical assistance**
- Support to strengthen decision-making and regulatory processes - a prerequisite for success of the model
- Strengthen countries programme management & immunisation know-how to prevent backsliding

Support to former Gavi-eligible MICs to be catalytic only, helping countries **maximise the impact of domestic investments**;
Countries will continue to fully finance their vaccine programmes
Board-recommended engagement with former eligible MICs could be extended to some never eligible MICs

Proposed approach to support former Gavi-eligible MICs

Board recommended to ‘institutionalise’ this support with a more deliberate approach in Gavi 5.0 (2/2)

Power of the Alliance in three key levers of support

- Advocacy & political will building
  - Technical assistance to support to strengthen countries’ political commitment to immunisation and new vaccine introductions

- Market shaping
  - Pooled procurement - tender mechanisms pooling countries’ demand
  - Limited catalytic funding support for new vaccine introductions (i.e. 6-9 months of a birth cohort)
  - Benefits for countries
    - More attractive vaccine prices
    - Catalytic funding to prompt new introductions
    - Simplified procurement

- Technical assistance
  - Support to strengthen decision-making and regulatory processes - a pre-requisite for success of the model
  - Strengthen countries' programme management & immunisation knowledge to prevent backsliding
  - Benefits for manufacturers
    - Risk reductions through predictability of volumes & ensure country payments
    - Pooled and harmonised procurements
    - Access to new markets

Support to former Gavi-eligible MICs to be catalytic only, helping countries maximise the impact of domestic investments; countries will fully finance their vaccine programmes

Engagement would be part of a learning agenda

- Model of support to former Gavi eligible MICs could be extended to a number of never Gavi-eligible MICs with GNI pc below $6k with missing introductions
- Support to focus on introducing key missing vaccines and not on supporting coverage improvement; however, work towards vaccine introductions may have an effect on coverage
- Engagement to be catalytic and help countries make better use of and leverage domestic resources allocated to immunisation
- Engagement could be sequential, focusing first on a subset of countries
THANK YOU