Pentavalent Market

UNICEF SUPPLY DIVISION
2018 Vaccine Industry Consultation
OUTLINE

- Historical demand and market overview
- Healthy Market
- Current Tender 2017-2019
- Evolving Market
- Hexavalent Vaccine
- Upcoming Tender
Penta vaccines (DTP-HepB/Hib) → Creating a healthy market

DONOR FUNDING:
Launch of GAVI (2000), and appointment of UNICEF as procurement agency to purchase Gavi-funded vaccines for eligible countries (including HepB-containing vaccines)

MULTIPLE SOURCE & SUPPLY AVAILABILITY:
New suppliers enter market and UNICEF able to increase awards from 2 to 4 penta suppliers (2008) easing supply constraint

NORMATIVE GUIDELINES ON USE:
WHO global recommendation on use of Hib-containing vaccines (2005)

APPROPRIATE (MORE CONVENIENT) PRODUCT PRESENTATION:
UNICEF awards supplier of newly launched liquid presentation (2006) followed by more rapid country introductions

APPROPRIATE (MULTI-DOSE) PRESENTATION:
UNICEF awards suppliers that have developed new 10-dose presentation (2011) at a significantly lower price per dose, also facilitating introductions in large countries including India.

COMPETITION & PRICE REDUCTIONS:
UNICEF multi-phased tender awards in a highly competitive market achieved significant price reductions and price-parity for Gavi and non-Gavi countries.
The Pentavalent vaccine market is considered **Healthy**, with sufficient supply from a diverse supplier base, though high concentration on one NRA.

**Supply meets demand, Country preferences and Buffer Capacity**
- Excess capacity, with multiple presentations

**Individual supplier**
- Mixed risk profile across manufacturers: sourcing of bulk antigens, production scale up, regulatory and legislative risks

**NRA risk**
- High concentration on Indian NRA

**Competition**
- Price premium required to ensure natural competition over the long-term

**Innovation**
- Multiple suppliers have hexavalent vaccines in their pipeline but the timing of product availability is unclear

**Total System Effectiveness**
- Potential need and opportunity to optimise presentation mix across and within countries
  - Establishing demand for low multi-dose presentations
  - Exploration of regional level presentation usage optimisation (i.e. country procurement of multiple presentations).
Pentavalent vaccine: Supply period 2017-2019

2016 UNICEF Tender

- Awards were made for 2017-2019
- 6 manufacturers were awarded: 5 awards for single dose, and 4 awards for 10 dose
- Awarded WAP across tender period: $0.84/ds, with price variation per presentation:
  - 1 dose: $0.80 - $1.40
  - 10 dose: $0.60 - $0.85

2017 ADJUSTMENTS

- Single dose additional demand and award increase by 18%:
- Awards were made, based on principle approach and with three objectives:
  I. Availability
  II. country preference
  III. health of the market.
- Application of UNICEF MFN clause on one of the single dose award

2018 ADJUSTMENTS

- Single dose additional demand, due to:
  - Failure to deliver full quantity on award; due to legislative changes in Labor Law
  - Increased forecast from countries
- Same principle approach was adopted for award increase
- Two awarded suppliers offered lower prices in response to national tender, raising the issue of application of MFN clause
MFN Clause – General Principles on How We Engage

• As per UNICEF mandate - to access lowest available prices, for poorest countries in the world, and taking into consideration UNICEF pivotal role in this market

• Contractual clause: ensuring fair and equal treatment

• Deliberation and analysis are made responsibly and in consideration of sustainability of the market
  • Consultation with suppliers, to obtain better understanding of the context and rationale for their offers
  • Internal analysis on comparative context (volume, presentation, duration of award etc.)
  • Explore legislative barriers
  • Partner consultation (Gavi, BMGF, PRG)
  • Additional financial and contractual analysis, of vaccine portfolios
Pentavalent vaccine: An evolving market

2019 ADJUSTMENT

- Awarded supplier request for price increase for 2019 supply period
  - Following has been taken into consideration:
    - Reason and justification
    - Price being within awarded range
    - Fairness of awarded volume vs. price level
    - Impact on other awards

2020+ EXTENSION

- UNICEF has been in one on one consultation with all awarded manufacturers on possibility for extension, and will organize a webinar in Q1 2019 to inform methodology of this extension

- Clarity on VIS outcome and Gavi Board decision on support for DTP booster and Hexavalent

- Opportunity for country consultation, and informed decision making
Pentavalent vaccine: Future consideration

**Working Group (wP-Hexavalent vaccine):**

- Analyse the parameters relevant to the potential value of wP-Hexavalent in the context of Gavi’s support to DPT booster dose (VIS 2018), and the global polio eradication initiative (GPEI).

- Integrate programmatic, financial and supply considerations related to wP-Hexavalent, and present to the Board for decision making in November.
Pathway to define Hexavalent Support

- Consistent with SAGE recommendation and WHO position paper
- WHO prequalified
- Reliable supply base**
- Estimated cost should account for any increased procurement costs that are commensurate with evidence-based benefits
- Respond to country demand and preferences

(*): VIS 2018 is considering a potential Gavi investment in 3 boosters as per the WHO recommendation. wP-hexavalent would specifically be considered alongside options of DTwP and pentavalent for the first booster in the 2nd year of life.

(**): Development of the standalone IPV remains the main priority Gavi Alliance and any Hexavalent development should not adversely impact the availability of IPV standalone vaccines
Next round of Penta tender

- Extension of current tender by one additional year; through 2020

- Tender strategy to take into consideration:
  - Clarity on VIS outcome and Gavi Board decision on DPT booster, and Hexavalent; support and recommended strategy

- Extension will provide opportunity for country consultation, and informed decision making

UNICEF will issue tender for Pentavalent Vaccine in end-2019 / Q1 2020, for duration **2021-2023**
In summary ....

- Pentavalent vaccine remains the corner stone of immunization program
- Pentavalent vaccine is still an evolving Market, despite stabilized and predictable demand
- Increased transparency on the Cost of Goods is needed to realize a sustainable, and affordable price for pentavalent vaccine
- UNICEF and Alliance partners will continue to work closely with the industry, to ensure sustainability of the health of this market
- Next contracting exercised expected end-2019 / 1Q2020 for 2021-2023 needs
DPT Vaccines

OUTLINE

- DTP Historical, current demand - market overview
- Future Consideration for booster dose
DwPT Vaccine: demand through UNICEF

Until 2005, DTP standalone vaccine demand fluctuated between 81-136 mil ds per year, but declined rapidly, upon introduction of combination vaccines, to reach approximately 5-7 million ds per year.

In 2016-2017 demand increased to over 10 mil doses, but returns to +5 mil ds in 2019-2021.
80% of the demand is from 6 large population MICs, using DTP booster dose.

- New tender covers 3-year period
- Two suppliers have been awarded to support vaccine security objective

Sources: UNICEF Supply Division
DTwP Vaccine: future consideration

• After introduction of DTwP in combination vaccines, demand for standalone vaccine has been historically low despite SAGE recommendation on the 4th booster dose during the 2nd YL

• Support to countries is included as part of Gavi Vaccine Investment Strategy (VIS)

• Options for investment include DTwP standalone, pentavalent or Hexavalent vaccine

• Decision by the board will be made in the upcoming meeting in November 2018

• Subject to board approval for support and ultimately, based on countries’ decision on type of vaccine, UNICEF will update manufacturers if there are any changes in demand forecast.

Sources: UNICEF Supply Division
Hepatitis B

OUTLINE

- Historical demand and market overview
- Upcoming Tender 2019 -2021
DEMAND from 26 countries mainly driven by Nigeria and Philippines representing ~50% of demand

DEMAND TREND: demand for HepB paediatric started to decline from 2009 as countries increasingly introduced pentavalent vaccine. Annual demand has stabilized at ~20mds

AMPLE AVAILABILITY: There is ample market capacity and availability of HepB vaccines from a stable supply base.

WHO PQ: 6 WHO Pqed suppliers, of which only 3 offer HepB to UNICEF
HepB vaccine: vaccine investment strategy

- Support for operational cost of administration of Hep B birth dose is included in Gavi VIS 2018, for board decision in Nov. 2018

- If approved, funding support is expected to moderately increase demand upwards, from currently at -/+ 20 mil ds annually, to 30-40 mil ds, by 2027.

- As part of Gavi VIS implementation strategy for outreach, cPAD is considered to be piloted in some specific districts

- UNICEF tender for HepB will be issued in Oct: duration 2019 – 2021

- Tender strategy supports UNICEF’s Strategic Plan to ensure that every child survives and thrives
THANK YOU