MARKET & SUPPLY UPDATE

Pentavalent & Hexavalent Vaccines

CONTEXT

• UNICEF procures and supplies approximately 50% of global pentavalent demand, which has been stable at approximately 150 million doses a year since 2017. Global production capacity of prequalified vaccines is estimated at approximately 480 million doses per year, with 5 active suppliers of WHO pre-qualified vaccines. UNICEF supplies whole-cell pertussis pentavalent vaccine in fully liquid formulation in 1 and 10 dose presentations.

• The whole-cell pertussis hexavalent vaccination represents an immunization alternative to current schedules of pentavalent and standalone IPV, with less vaccination sessions and potentially higher coverage. In October 2021, WHO’s SAGE working group meeting on immunization recommended the use of the hexavalent vaccine in a four-dose schedule, and that the Hexavalent vaccine could fit in any of the existing primary series of IPV schedule.

• Following GAVI Board approval of the investment on hexavalent vaccine in June 2023, a funding window will be opened for countries to apply and switch over from Pentavalent and IPV. All WHO pre-qualified pentavalent vaccine producers are developing hexavalent vaccines. While no vaccine has achieved WHO prequalification yet, producers are progressing through different development stages which indicates a healthy pipeline for the vaccine.

• In June 2023 Gavi recommended to proceed with the funding, design and roll-out of the DTwP booster dose vaccination in the second year of life (2YL), which was approved in principle in 2018 and paused since 2020. The timing for the programme launch as well as the recommended DTwP-containing vaccines are currently being discussed by the partners.

• Pentavalent is currently a relatively affordable vaccine with a 2023 projected Weighted Average Price (WAP) of $0.83 per dose for the 10-dose presentation and $1.24 per dose for the 1-dose presentation.

SUPPLY & DEMAND

• UNICEF anticipates that total demand for routine immunization of pentavalent vaccine will reach approximately 632 million doses during 2023-2027, which is manageable considering UNICEF supplied annual volumes since 2017.

• On the one hand, pentavalent demand projections for routine immunization show a progressive decline as the market for hexavalent develops, which will be subjected to its price viability in comparison with the cost for the immunization schedule of 3 doses of pentavalent and 2 doses of IPV for primary series, and a DTP-containing booster in the second year of life.

• On the other hand, ongoing catch-up and recovery plans may result in a significant increase of pentavalent demand in the short term.

• The assumption is that hexavalent demand will reach 100 million doses by 2030 and that, while pentavalent will continue to be used by some countries, especially those that are using IPV in fractional doses (fIPV).

• Once the demand forecast, the funding mechanism and the DTwP-containing vaccine of choice, that are required to support the DTwP booster (2YL) programme, are defined, UNICEF will work with manufacturers to understand the production capacity and timing to cover these additional requirements.

ISSUES & CHALLENGES

• A key priority for UNICEF and partners is to ensure the long-term health of pentavalent vaccine market.

• While pentavalent vaccine is fully introduced in all countries’ routine immunization programme and there is good visibility on demand volume, funding landscape is rapidly changing toward increased self-financed as countries transition from GAVI support which will require improved accuracy on pentavalent demand forecasting.

• Increasing country specific registration requirements of pentavalent can challenge product user flexibility between vaccine manufacturers to meet country programmatic demands.

• The Indian NRA releases over 70% of pentavalent vaccines procured through UNICEF. Therefore, the pentavalent market depends on a continued functional and effective Indian NRA to help monitor and minimize any risks to the disruption of supply.

LOOKING AHEAD

• Phase I of the portfolio tender including DTwP standalone, pentavalent and hexavalent vaccines was concluded in Q3 2022 awarding 4 Pentavalent suppliers for supply during 2023-2025. UNICEF is expecting to issue phase II of the tender in Q3 2024.

• UNICEF will continue working with partners on the development and implementation of Hexavalent programme to ensure a suitable balance of demand and supply during the early years, as well as to ensure the long-term health of the pentavalent and IPV standalone markets.

• UNICEF will collaborate with partners on the design and implementation of the DTwP booster dose (2YL), including working with manufacturers to ensure sufficient supply to support the program without disrupting the supply of DTwP-containing vaccines for routine programmes.

FURTHER QUESTIONS OR ADDITIONAL INFORMATION? PLEASE CONTACT: Luis Ortega
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