MARKET & SUPPLY UPDATE

Pentavalent and Hexavalent Vaccines

CONTEXT

Pentavalent global demand is estimated at ~300 million doses per year, of which UNICEF procures about 50% (2022 forecast). There are currently 6 active suppliers of WHO pre-qualified pentavalent vaccines, producing in fully liquid formulation in 1-, 2-, 5- & 10-dose presentations and liquid/yolk-hybrid formulation in 1-, 2- and 10-dose presentation. Of these, only the fully liquid formulation in 1 and 10 dose presentations are supplied through UNICEF.

A full Hexavalent Vaccine is considered a preferred immunization option to current schedule of 3 x Penta + 2 x IPV, based on less pressure on the health system, less vaccination sessions, assumptions of achieving higher coverage for IPV and finally prevention of premature withdrawal of IPV from countries immunization programs.

Accordingly, in November 2018 the GAVI Board approved (in-principle) support for Hexavalent vaccine, as an immunization option. All WHO pre-qualified pentavalent vaccine produces are developing Hexavalent (wp) vaccines. While no vaccine has achieved WHO prequalification yet, producers are progressing through different development stages which indicates a healthy pipeline for the vaccine.

Since 2001, strong collaboration on market shaping across GAVI Alliance partners, including the Bill & Melinda Gates Foundation, WHO and UNICEF, has achieved an affordable and sustainable Pentavalent vaccine supply for children in the world’s poorest countries. Similar collaboration will be required to achieve an affordable and sustainable Hexavalent supply while maintaining a healthy market for Pentavalent and IPV standalone vaccines.

SUPPLY & DEMAND

Following 2016 the UNICEF multi-phased tender awards and the highly competitive market situation which resulted in significant price reductions and price-parity for GAVI and non-GAVI countries, the subsequent years (2020 through 2022) brought about more price stability and equilibrium.

Pentavalent demand through UNICEF has been stable around +/-150 million doses per annum, since 2017. While the vaccine is fully introduced in all countries’ routine immunization program and there is good visibility on demand volume, the funding landscape is rapidly changing toward increased self-financed, as countries transition from GAVI support.

Demand projections for Pentavalent and Hexavalent vaccines for the coming years suggest an inversely proportional relationship in terms of demand development. As the Hexavalent market develops, subject to price viability within range of comparable immunization schedule (3xPentavalent + 2xIPV for primary series and a DTwP for booster in 2YoL) and a positive decision by GAVI Board to open a funding window, it is expected that a progressive uptake by GAVI-supported countries will start in 2024.

The assumption is that Hexavalent demand will reach 100 million doses by 2030, and that even after demand is fully realized, the DTwP/Pentavalent will continue to be used by countries that are using IPV in fractional doses (tIPV).

ISSUES & CHALLENGES

A key priority for UNICEF and partners is to ensure the long-term health of pentavalent vaccine market supply. The market will continue to be dependent on multiple manufacturers.

Increased country-specific vaccine registration requirements can challenge product user flexibility between vaccine manufacturers to meet country programmatic demands. UNICEF expects the demand for combination vaccines to include IPV to materialize during the upcoming tender period, particularly from MICs. UNICEF is following new IPV-containing combination vaccine innovation and is continually trying to anticipate changes to country product preferences, while also seeking to maintain a healthy pentavalent vaccine market with sufficient supply.

Sustainability of pentavalent market remains a focus for UNICEF and partners, as we anticipate that some countries would continue to use pentavalent, even after IPV containing wp Hexavalent becomes available and WHO pre-qualified.

STEPS FORWARD

A portfolio tender including DTwP standalone, Pentavalent and Hexavalent vaccines was issued during Q1 2022. This tender consists of two preliminary phases (I and II) and optional third phase.

Phase I concluded during Q3 2022 with awards for Pentavalent vaccine to four suppliers for the period 2023-2027. Hexavalent vaccine awards for phase II might be considered as vaccines become WHO pre-qualified. UNICEF is expecting to issue phase II of the tender within 2023, for awarding the remaining volume of demand.

It is expected that GAVI support for the Hexavalent vaccine will result in incremental increase of Hexavalent vaccine demand and an inversely proportional decrease of Pentavalent vaccine demand.

FURTHER QUESTIONS OR ADDITIONAL INFORMATION?

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