Hepatitis B Vaccine (HepB)

CONTEXT

- A vaccine against Hepatitis B has been available since 1982. The vaccine is 98% effective in preventing infection, the development of chronic disease and liver cancer due to Hepatitis type B.

- Hepatitis B vaccination of infants is considered one of the key components of Global Health Sector Strategy on Viral Hepatitis 2016 - 2021 endorsed by WHO and supports achieving the UN Sustainable Development Goal of eliminating viral hepatitis as a major public threat by 2030.

- WHO recommends that all infants should receive their first dose of Hepatitis B vaccine as soon as possible after birth, preferably within 24 hours. The birth dose should be followed by 2 or 3 doses to complete the primary series.

- In June 2023 Gavi recommended to proceed with the funding, design and roll-out of the HepB birth dose programme, which was approved in principle in 2018 and paused since 2020. The timing for the programme launch is currently being discussed by the partners.

- Hepatitis B vaccine is available for infants and adults, and it is WHO pre-qualified in 1 and 10 dose presentations. It is available in monovalent formulations that protect only against Hepatitis B and also in combination formulations with other vaccines.

- Hepatitis B pediatric vaccine is a relatively affordable vaccine with a 2023 projected WAP for the 10-dose vial of $0.25/dose. The WAP for the 1-dose is significantly higher, projected at $0.49/dose for 2023. The WAP for HepB adult vaccine is $0.33/dose for the 10-dose presentation and $0.7/dose for the 1-dose presentation.

SUPPLY & DEMAND

- There are currently 4 manufacturers of WHO prequalified Hep B pediatric vaccine, of which only 2 actively supplied through UNICEF.

- As the vaccine is bulk to Pentavalent, there is ample market capacity and availability. However, the bulk is mainly allocated to formulation in combination vaccines and there is a strong prioritization towards direct market outside of UNICEF for Hep B vaccine as finished product.

- As per forecast received from countries, demand for Hep B pediatric vaccine through UNICEF is expected to be stable at around 15-20 million doses per year for the next 5 years. However, demand is highly driven by one country.

- Once the demand forecast and the funding mechanism for the Hep B birth dose programme are defined, UNICEF will work with manufacturers to understand the production capacity and timing to cover these additional requirements.

- For Hep B adult there are currently 2 manufacturers of WHO prequalified vaccines and UNICEF has arrangements with one of them. The demand for the adult vaccine through UNICEF is relatively low and influenced by specific programmatic vaccination campaigns of adult populations.

ISSUES & CHALLENGES

- Hep B standalone supply can at times be constrained due to manufacturers decision on prioritization of production lines and resources toward more profitable markets, as well as the use of bulk for combination vaccines.

- Demand for Hep B pediatric vaccine through UNICEF is highly driven by one large population country, hence forecasting accuracy and country’s decision on volume, timing and channel of procurement largely affects UNICEF overall forecast accuracy.

- Demand through UNICEF is fully self-financed by governments with no donor support, and therefore achieving and maintaining affordable and sustainable prices continues to be a focus in this market.

LOOKING AHEAD

- UNICEF will collaborate with partners on the design and implementation of the Hep B birth dose programme, including working with manufacturers to ensure sufficient supply to support the program without disrupting the regular supplies.

- In 2023 UNICEF made awards for supply of the full demand of Hep B vaccine during 2023-2025 and 50% of the demand of 2026-2027. The awards for the remaining 50% will be made in 2024 once there is more visibility on countries decision to introduce the birth dose.