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The Market Shaping Goal

Shape vaccine markets to ensure adequate supply of appropriate, quality vaccines at low and sustainable prices for developing countries.



Supply and procurement roadmap

Meningococcal vaccine

PUBLIC SUMMARY

Public summary

Gavi, the Vaccine Alliance is engaged in meningococcal vaccination to eliminate serogroup A meningococcal meningitis (MenA) epidemics as a public health problem in Africa.

Over the past ten years, the Meningitis Vaccine Project (MVP) and PATH, with support from the Bill & Melinda Gates Foundation (BMGF) collaborated with and provided funding for Serum Institute of India (SII) to develop a MenA conjugate vaccine (MenAfriVac) and to build sufficient production capacity to meet Gavi-supported demand, at an affordable price. Available and prequalified by the WHO since 2010, MenAfriVac has allowed the Gavi strategy to be implemented.

Gavi's current meningococcal engagement: Gavi committed to fund in 26 Gavi-eligible countries in the "meningitis belt" of Africa, (1) preventative vaccination campaigns, (2) routine immunisation, (3) catch-up vaccination campaigns to immunise the children born between the start of campaign vaccinations and the start of routine immunisations, and (4) maintenance of a vaccine stockpile for emergency response.

Progress and timing:

- At the end of 2014, countries of the African meningitis belt conducted approximately 74% of the planned Gavi-supported campaigns. The completion of remaining campaigns is planned in 2017. In countries where conjugated MenA campaign vaccination was rolled out, the overall number of cases of meningococcal meningitis has decreased significantly (by up to 94%), MenA cases have almost disappeared, MenA carriage was eliminated, and there is no evidence of serogroup replacement.
- Gavi-supported routine immunisation is starting in 2015 following the prequalification in January 2015 of a MenA conjugated vaccine formulation indicated for children 3 to 24 months of age in a 1-dose schedule.
- Gavi-supported catch-up vaccinations are planned to take place between 2015 and 2017.
- The need for stockpile is expected to reduce as MenA epidemics disappear.

Gavi's future meningococcal exit strategy: Gavi support to campaign vaccination is planned to end when all 26 target countries will have rolled out routine immunisation and when meningococcal meningitis epidemics are eliminated as a public health problem in Africa. If current epidemiological trends continue, this will occur in 2018 after which routine immunisation is expected to keep MenA disease under control. Thereafter, Gavi funding for meningococcal routine immunisation will continue to be made available to eligible countries requesting such support.

Market overview

- One manufacturer, SII, supplies a MenA conjugated vaccine (MenAfriVac) prequalified by the World Health Organization (WHO). SII's supply capacity is expected to continue to meet the demand in Gavi-supported countries short, mid and long-term.
- Peak annual demand for MenA conjugated vaccines in Africa will be 78 million doses in 2016. From 2017, demand for African countries is projected to reduce to 30 million doses per year on average.
- Two conjugated MenACW₁₃₅Y vaccines are WHO prequalified and two conjugated MenA-containing vaccines are locally registered but not prequalified. These MenA-

containing conjugated combination vaccines have a 2-dose or 3-dose schedule in children less than 24 months of age.

- No new pipeline conjugated MenA vaccine is expected on the market before 2019.
- The price of MenAfriVac will increase from USD 0.60/dose in 2014 to 0.63/dose in 2016.
- The global market for conjugated MenA-containing vaccines reached USD 1.3 billion in 2014, of which USD 40 million was for the Gavi/UNICEF market.
- The demand for emergency response and stockpile varies from year to year in volume and in nature so that it is tailored to the responsible meningococcal serogroup and to each local outbreak. Between 2008 and 2013, annual demand was 5-9 million doses, 67% MenAC polysaccharide, 25% MenA conjugate, 6% MenACW₁₃₅ polysaccharide, 2% MenACW₁₃₅Y polysaccharide. If epidemiological trends continue, likely demand will be reduced to 0.5-1.5 million doses of MenAC + MenACW₁₃₅/ACW₁₃₅Y, ideally all W₁₃₅-containing. Prices range from USD 0.60/dose for the conjugated MenA to USD 5.0/dose for the highest priced W₁₃₅-containing polysaccharide.

Prioritised supply and procurement objectives

The supply and procurement objectives were analysed and weighted according to timeframe, to potential market shaping impact and to Gavi's potential capacity to influence the market.

1st priority objective: Cost of vaccine to Gavi and countries. It is critical to ensure that Gavi-supported countries access a sustainable price after Gavi's exit from campaigns. As such, the target outcome for this area is:

- The weighted average price (WAP) is reduced or stabilised from 2016.

2nd priority objective: Balance of supply and demand. Supply has been reliable since 2010 and has capacity to meet demand now and in the future. As there is only one supplier of MenA, the target outcome for this area is:

- Gavi defines in 2016 its supply-risk mitigation plan and initiates implementation where applicable.

Objective related to outbreak control: Availability and cost of vaccines for outbreak control. Annual procurement of vaccines for outbreak control and stockpile is ineffective at providing quantities and sustainable prices for multivalent meningococcal vaccines in Africa (polysaccharide or conjugated). Potential target outcomes for this area are the responsibility of the International Coordinating Group for outbreak response (ICG).

Supporting stakeholder action-plan

An action plan between Alliance stakeholders is defined to ensure optimised coordination leading to the achievement of the above supply and procurement objectives.

- Engage the supplier to minimise costs taking into account improvements of the production costs, inflation related adjustments, and any other relevant parameters.
- Ensure that the 2013 supply agreements are met, and optimise procurement activities mid and long-term. This is led by UNICEF Supply Division with support from the Gavi Secretariat from 2015-2020+. In particular UNICEF Supply Division and the Gavi Secretariat will:

- ❖ Ensure that supply performance is in line with effective demand during peak demand in 2015 and 2016, and ensure supply of the 5mcg formulation to meet the requirements for implementation of routine immunisation from 2015.
- ❖ Prepare and implement the next tender to be issued for MenA-containing conjugate vaccines supply.
- Analyse and quantify the risk of supply interruption; review options for mitigation and propose a recommendation for decision.
- Propose and implement optimised options to improve the procurement performance for emergency outbreak response with the objective of securing the needed volumes at predictable and sustainable prices. Led by the ICG with UNICEF Supply Division: 2015.

Meningococcal vaccines
Summary visual roadmap
Gavi Supply & Procurement Strategy

