FULL VALUE OF VACCINE ASSESSMENT

GROUP B STREPTOCOCCUS VACCINE

FINANCIAL ANALYSIS

World Health Organization

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Executive summary

As part of the development of a value assessment for a group B streptococcal (GBS) vaccine, an assessment was conducted on the return on investment and financial sustainability for vaccine manufacturers of developing and commercializing a GBS vaccine.

The assessment indicated that the development of a GBS vaccine could be finalized by 2028 with a total cost of some US$ 226–378 million for completion of the clinical development and building a dedicated manufacturing plant. After achieving the first registration and WHO prequalification the vaccine could be rolled out globally as of 2029 based on countries' burden of disease, strength of immunization programme and maternal immunization platform.

Subject to different assumptions on vaccination schedules and target populations, the number of introducing countries and the strength of competition, the vaccine could generate up to US$ 8 billion in sales over the period 2029–2040. This turnover could increase to US$ 16 billion with a two-dose schedule with priming in adolescence and boosting during pregnancy or could be lowered to US$ 1.9 billion if two competitors are in the market.

As a result, the net present value (NPV) of the initiative is US$ 742 million in the base case, providing vaccine manufacturers with a significant return on the initial investment and hence making the vaccine development enterprise financially viable. The NPV can range up to US$ 1.6 billion for two-dose scenarios. Importantly, the NPV remains positive under the most aggressive competition or most conservative clinical development scenarios. Of all pessimistic scenarios (lack of Gavi support, higher COGS, stronger competition, need for full efficacy trial) the NPV turns marginally negative (US$ -34 million) only under the most conservative clinical development scenario (i.e. the need for a full efficacy trial). The results of these more pessimistic scenarios are evidence of an acceptable level of risk of the initiative that can absorb most unexpected deterioration of the assumptions of the base case.

On the basis of the simulated plan and market forces, the business case for the development of a GBS vaccine can be considered financially sustainable. It is likely to guarantee a sizeable return on investment without the need for any incentive beyond the market. These results should encourage manufacturers to focus their efforts on the development of a GBS vaccine that can have not only a solid public health value assessment but also a commercial one. Nonetheless, the role of donors or financers can still prove very important in de-risking the development of the GBS vaccine that, especially at this stage, is still affected by many levels of uncertainty.