

Market & Supply Update

Rotavirus Vaccine

Summary

There are currently two WHO prequalified suppliers in the Rotavirus market, GlaxoSmithkline (GSK) and Merck. The vast majority of UNICEF contracted supply for GAVI is for GSK's vaccine: in the current tender 2012-2016, 93% of awarded courses (83 million courses) are for this vaccine. In the short term, there is a supply shortage driven by limited availability of the vaccine GAVI countries overwhelmingly prefer. This will continue to result in delays in introduction of rotavirus immunisation programmes through 2016. In the mid-term (2016-2020), supply is expected to continue to be constrained given rapid growth in worldwide demand. Two of seven rotavirus vaccines currently in development are expected to gain pre-qualification between 2017 and 2018; one developed by Bharat Biotech and one developed by Serum Institute of India.

General Background

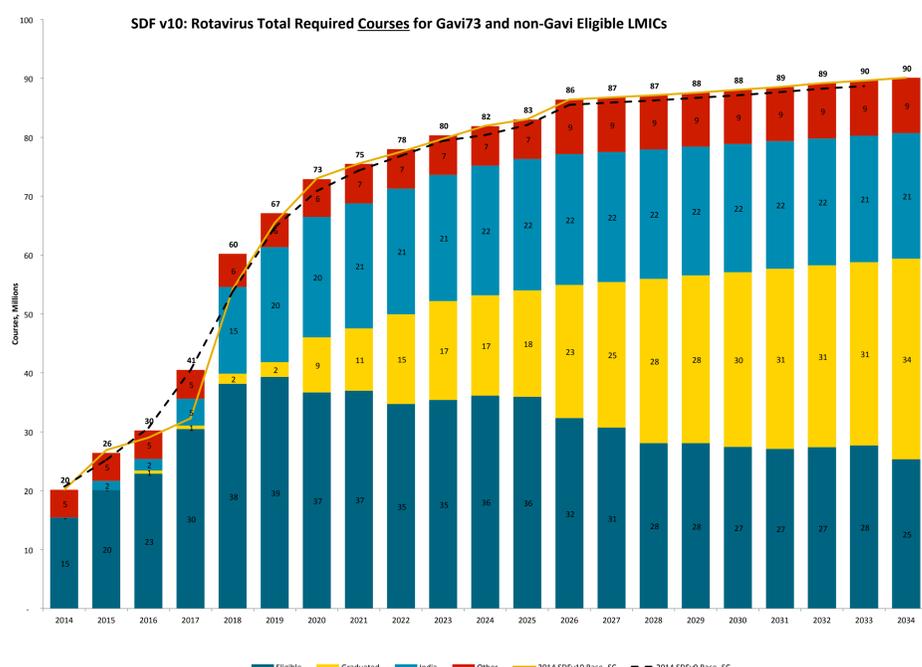
- GAVI-supported countries' share of global demand will grow to 48% in 2016 from 20% of volume in 2012.
- The Weighted Average Price (WAP) of rotavirus vaccines purchased by UNICEF for GAVI decreased 33% between 2011 and 2012
- WAP as at 2014 is \$2.75 and \$3.81 per dose for the two and three dose presentations respectively.
- The two WHO prequalified presentations have the below volumes
 - Rotavirus , 3 dose vaccine, by Merck in 2ML per dose (packs of 10 or 25 single-dose tubes, lowest cold chain requirements per dose 46 cm³)
 - Rotavirus , 2 dose vaccine by GSK in 1.5ML per dose (packs of 1, 10 or 50 single-dose tubes, lowest cold chain requirement per dose 17 cm³)

Current Market Situation

Demand and Forecast

By the end of 2015, a total of 43 GAVI countries are expected to have introduced Rotavirus, bringing total demand to 26 mio courses . SDFv10 anticipates supply constraints to lift in 2018, with possible entry of either a more programmatically suitable 3 dose formulation, a new supplier or both.

India plans a phased introduction into the public sector using local product with the demand expected to exceed 20 mio courses by 2020. A new manufacturer Bharat introduced Rota into the Indian private market in March of 2015.



Non-Gavi Country Supply

GAVI demand is expected to level off at 50% by 2020. UNICEF currently procures on behalf of the Philippines. As countries graduate GAVI demand will reduce by 2020. In terms of volumes Non GAVI country demand is expected to increase up to 10mio courses. Tender for requests by MIC are on ad hoc basis and is done as demand materialize.

Issues and Challenges

- Near monopoly with 93% of demand from one supplier
- Current demand exceeds supply for above presentation
- Delayed timelines for new manufacturers and or improved presentations by current manufacturers
- Delays in planned introductions due to programmatic requirements prior to introduction causing inaccuracies in forecasting
- New entrants targeting the local Indian market, with the demand expected to exceed 20 mio doses by 2020. Extra capacity will be offered to GAVI and other markets.

Step Forward

Together with partners in GAVI Alliance, UNICEF is developing the tender strategy for the tender to cover the period 2017 onwards.

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