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## The Market Shaping Goal

*Shape markets for vaccines and other immunisation products to achieve moderate or high levels of healthy markets dynamics.*

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# Supply and Procurement Roadmap *Measles-Rubella (MR)*

[Public Summary](#)

## Public Summary

Gavi, the Vaccine Alliance, engagement on measles dates to 2004 and rubella support began in 2011 through the measles-rubella (MR) vaccine. By the end of 2016, Gavi had supported 50 countries with measles and rubella programmes. However, challenges in the implementation of measles and rubella programmes, including stagnating measles-containing vaccine first dose (MCV1) coverage, led Gavi to adopt a new measles and rubella strategy in 2015. The goals are to provide a single coherent approach to measles and rubella, to increase routine immunisation coverage, and to put a strong focus on measles and rubella control, complemented as needed by higher quality, better-planned, more targeted and independently monitored campaigns. In line with the latest Strategic Advisory Group of Experts (SAGE) recommendations, Gavi also supports countries to include a second routine dose of measles-containing vaccine (MCV2) in national vaccination schedules.

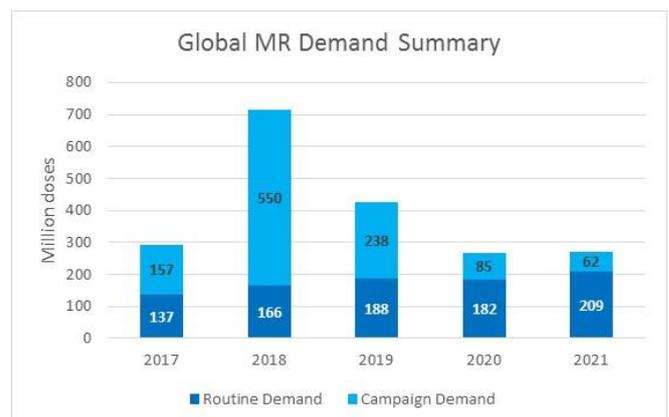
Gavi's measles and rubella engagement includes the following support:

- MR catch-up campaigns, when followed by or coincident with MR routine introduction, targeting children aged 9 months to 14 years;
- Measles as second dose, and MR vaccine as first and/or second dose introduction into routine immunisation;
- Measles and MR follow-up campaigns with a focus on children up to five years of age;
- Outbreak response fund managed by the Measles & Rubella Initiative to further support countries that cannot respond to significant outbreaks fast enough with local funding;
- In addition, as part of its specific India engagement strategy, Gavi has committed to supporting two out of four phases of India's national MR catch-up campaign being rolled out over 2017-2018, covering approximately 45% of the target population.

Gavi is further planning to continue its support for MR beyond the current strategic period 2016-2020 and therefore is committed to supporting a sustained supply of affordable MR vaccine by engaging in a number of market-shaping activities.

## Market Overview

The average forecasted global MR demand through 2021 is approximately 400 million doses per year, split between Gavi 71<sup>1</sup> countries (approx. 37%), India (39%), Indonesia (10%) and other non Gavi-countries. However demand is highly variable from one year to another as a result of country catch-up and follow-up campaigns as well as outbreak responses. For example, forecasted global demand peaks in 2018 at more than 715 million doses, comprising 166 million doses of routine



<sup>1</sup> Gavi 71 countries are the seventy-three countries eligible for Gavi support in 2003 based on a GNI/capita of ≤ USD 1,000, excluding India and Indonesia. They include currently eligible, transitioning and transitioned countries. Forecast source: Gavi base demand forecast v14 (to be updated with v15 in early 2018), GVMM March 2017, M&RI SIA forecast, WHO confidential reports

immunization demand and 550 million doses of campaign demand.

It is important to note that a large portion of Gavi demand has not yet been applied for by countries or approved by Gavi. In addition the timing of catch-up and follow-up campaigns is very uncertain and current forecasted demand could see significant variations in future years. Countries' future reliance on campaigns to achieve herd immunity in the face of routine immunisation coverage shortfalls is also unclear. This means that demand after 2021 is highly uncertain, especially in a possible context of a call for measles eradication.

Except for India which has already stated a preference for a 5-dose MR vial for routine use, other countries' preference and the cost effectiveness of presentations consisting of fewer doses are currently unknown in advance of price offers and the completion of in-country studies of real world wastage and potential coverage improvements.

Projected supply capacity is expected to meet demand, however demand peaks may stress buffer capacity and supply will need to be closely monitored in periods of high campaign activity over 2018-2019.

Serum Institute of India (SII) remains the only supplier of a WHO prequalified MR vaccine. Other manufacturers are expected to gain WHO-prequalification for their vaccines in the near to mid-term.

SII's price for MR in a 10-dose vial remained effectively the same between when it started supplying UNICEF in 2002 at \$0.48 per dose through 2010 at \$0.484 per dose. It subsequently raised its prices at an annual growth rate close to 5% reaching \$0.606 in 2017.

### Healthy Markets Framework Evaluation

The MR market is currently in a low state of health; meeting only one of the healthy market attributes (highlighted in green), partially meeting four (highlighted in yellow), while three attributes remain unmet (highlighted in red).

The major market need is to diversify the supply base and reduce the **Individual supplier risk** as well as improve **Long-term competition**. Both attributes are expected to move towards partially met as new suppliers enter the market.

Supply Meets Demand: **Met**. Total market supply is currently sufficient. This is unlikely to change considering SII supply capacity and the pipeline of new entrants.

Country presentation preference: **Partially met**. Country preference is partially met as only one presentation has been available until recently and country preference is unclear. Availability of the 5 dose presentation is expected to improve in the near term, however its impact on the total supply capacity will need to be monitored. India has already communicated preference for a 5 dose presentation for routine use while other countries' preferences remain to be determined.

Buffer capacity: **Partially met**. Buffer capacity will be low during peak campaign years but should improve with supply capacity from new entrants.

Individual supplier risk: **Unmet**. The market is currently entirely relying on the supply capacity of SII, which should improve with the current product pipeline.

National Regulatory Authority (NRA) risk: **Unmet**. NRA risk is high with reliance on a single manufacturer and NRA. New entrants are not expected to contribute to NRA diversity as they mostly emerge from India.

Total System Effectiveness	Long Term Competition	Product Innovation
Buffer Capacity	Individual Supplier Risk	NRA Risk
Meet Country Preferences		
Supply Meets Demand		
Inadequate Supply		

Long-term competition: **Unmet.** Reliance on a single supplier carries significant risk although the pipeline of new entrants should improve long-term competition.

Product innovation: **Partially met.** Emerging new technology such as microarray patches may have a role in delivery of MR vaccine, but this will require further scoping on market opportunities.

Total system effectiveness (TSE): **Partially met.** TSE is partially met in a context where only the 10-dose vial presentation is in use. Cost-effectiveness of other presentations will have to be determined, including the monitoring of wastage in different settings and different uses, i.e. routine immunisation vs. campaigns.

## Supply and Procurement Objectives and Target Outcomes

The supply and procurement objectives were analysed resulting in the following target outcomes:

### 1<sup>st</sup> Objective: Balance of MR supply and demand

- Reduced dependency on single supplier for routine and campaign demand by 2022
- At least three manufacturers offer prequalified products to UNICEF by 2022
- UNICEF supply from at least two NRAs by 2022
- MR demand forecasting is improved as an aide to managing peak demand and improve suppliers' production planning, reducing risk for the supplier and achieving more long term, sustainable affordable price

### 2<sup>nd</sup> Objective: Cost of vaccine to Gavi and countries

- MR WAP is maintained at less than *target value (confidential)* through 2020 and at less than *target value (confidential)* through 2025
- 5-dose vial presentation is made available to Gavi supported countries by 2019 at less than *target value (confidential)*, if cost effective based on improved wastage and increased coverage

### 3<sup>rd</sup> Objective: Appropriate and innovative vaccines

- Role of microarray patches to contribute to a healthier market is established

## Supporting Stakeholder Action Plan

An action plan ensures the coordination between Gavi, the Vaccine Alliance stakeholders and is designed to facilitate the achievement of the above supply and procurement target outcomes. The action plan includes the following items:

- Support at least two pipeline manufacturers to obtain WHO-prequalification for MR vaccines
- Investigate mechanisms for improving forecast accuracy of campaign requirements
- Engage existing and pipeline manufacturers to identify appropriate activities that support reaching the Gavi Alliance targets
- Based on the pace of new supplier entries, explore the value of procurement tactics to control potential price movement
- Establish 5-dose vial presentation pricing commitment as part of additional supplier's supported entry investment
- Review evidence based studies to understand the value of microarray patches