

# Measles-Containing Vaccines: Supply Update

UNICEF Supply Division

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## Measles-Containing Vaccines (MCV) Supply Update – December 2013

### 1. Summary

- UNICEF's 2013 measles monovalent vaccine (MV) procurement will be double the originally forecasted demand of 147 million doses by the end of the year. A 33 million doses demand increase for routine immunization and a 98 million doses increase in supplementary immunization activities (SIAs) account for this trend. Increased quantities also include some outbreak emergency response requirements.
- Measles and rubella vaccine (MR) demand also increased due to countries introducing the vaccine with GAVI support. From 2011 to 2013, demand increased from 9 million to over 100 million.
- MV country demand will remain high for some time as follow-up campaigns take place at regular intervals. In addition, it is anticipated that countries will introduce a measles second dose (MCV2) prior to the introduction of MR.
- The MCV tender for 2013-2016 awarded four manufacturers a total of 1 billion doses and includes MV, MR and measles, mumps and rubella (MMR) vaccines. However, 80% of MCV supplied through UNICEF is dependent on one manufacturer, which is also the sole manufacturer for MR. No additional manufacturers are expected to substantially increase MCV supply capacity, or develop WHO prequalified MR vaccine before 2016.

### 2. Background & Procurement History

Measles is a highly infectious viral respiratory disease and one of the leading causes of mortality among children under the age of five. More than 150,000 people die from measles every year, mostly in low-income countries. Malnourished children (in particular those with vitamin A deficiency) and immuno-compromised children are particularly vulnerable. WHO recommends routine measles vaccination to reduce mortality in addition to supplementary campaigns in countries which do not achieve acceptable coverage rates.<sup>1,2</sup>

Rubella, while often mild in virulence, can lead to severe complications when pregnant women are infected. These complications can include foetal death and congenital rubella syndrome (CRS, affecting 110,000 babies annually), and can compromise hearing, sight, cardiovascular and endocrine health.<sup>3</sup> WHO recommends introduction of rubella vaccine within the context of measles immunization.

Six manufacturers currently produce WHO prequalified MCVs, including two combination vaccines: MV, MR, and MMR (Figure 1). UNICEF only procures 10 dose vials, though acknowledges some country demand for 5 dose vial presentations. However, 5 dose vials are currently not available through UNICEF due to the need to maximise production of MCV to meet increased demand.

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<sup>1</sup> WHO, *Measles*, WHO, Geneva, 2013 at <http://www.who.int/immunization/topics/measles/en/index.html>.

<sup>2</sup> WHO, *Measles Fact Sheet*, WHO, Geneva, February 2013 at <http://www.who.int/mediacentre/factsheets/fs286/en/>.

<sup>3</sup> WHO, *Rubella Fact Sheet*, WHO, Geneva, July 2012 at <http://www.who.int/mediacentre/factsheets/fs367/en/>.

Figure 1 Manufacturers with WHO Prequalified MCV<sup>4</sup>

Vaccine	Manufacturer	WHO Prequal.	Formul.	Sched.	Vial	Shelf Life	Cold Chain Capacity / ds
MV	Bio Farma (Indonesia)	1997	Lyophilised	2 ds	10 ds	24 months	1.3 cm
		2006	Lyophilised	2 ds	20 ds	24 months	0.75 cm
	GPO-MBP (Thailand)	2010	Lyophilised	2 ds	10 ds	36 months	2.13 cm
	Sanofi Pasteur (France)	2002	Lyophilised	2 ds	10 ds	36 months	2.46 cm
	Serum Institute of India Ltd	1993	Lyophilised	2 ds	1 ds	24 months	26.11 cm
		1993	Lyophilised	2 ds	2 ds	24 months	13.1 cm
		1993	Lyophilised	2 ds	5 ds	24 months	5.22 cm
1993		Lyophilised	2 ds	10 ds	24 months	2.611 cm	
MR	Serum Institute of India Ltd	2000	Lyophilised	1 ds	1 ds	24 months	26.11 cm
		2000	Lyophilised	1 ds	2 ds	24 months	13.1 cm
		2000	Lyophilised	1 ds	5 ds	24 months	5.22 cm
		2000	Lyophilised	1 ds	10 ds	24 months	2.611 cm
MMR	GlaxoSmithKline (Belgium)	2001	Lyophilised	1 ds	1 ds	24 months	9.6 cm
		2011	Lyophilised	1 ds	2 ds	24 months	4.8 cm
	Merck (USA)	2009	Lyophilised	1 ds	1 ds	24 months	15 cm
	Sanofi Pasteur (France)	2002	Lyophilised	1 ds	1 ds	24 months	12.66 cm
		2002	Lyophilised	1 ds	10 ds	24 months	2.46 cm
	Serum Institute of India Ltd	2003	Lyophilised	1 ds	1 ds	24 months	26.11 cm
		2003	Lyophilised	1 ds	2 ds	24 months	13.1 cm
		2003	Lyophilised	1 ds	5 ds	24 months	5.22 cm
2003		Lyophilised	1 ds	10 ds	24 months	2.611 cm	

Source: WHO.

MV procurement rose substantially following the launch of The Measles (*and later* Rubella) Initiative (MRI) in 2000 by WHO, UNICEF, the United Nations Foundation, the American Red Cross and the United States Centres for Disease Control and Prevention (CDC). MRI targets the reduction of 95% in deaths from measles and rubella from 2000 levels by 2015. Additionally, MRI set a goal to eliminate measles and rubella from at least five WHO regions by 2020. A 71% reduction in measles deaths has been achieved through 2011.<sup>5</sup>

However, outbreaks in Africa since 2009 highlight the fragility of the gains made and the risk of fading governmental and financial support and higher demands from competing public health priorities.<sup>6</sup> Large measles and rubella outbreaks have occurred recently in many parts of the world with low immunity coverage and, in many instances, affect susceptible age groups above 5 years of age.<sup>7</sup>

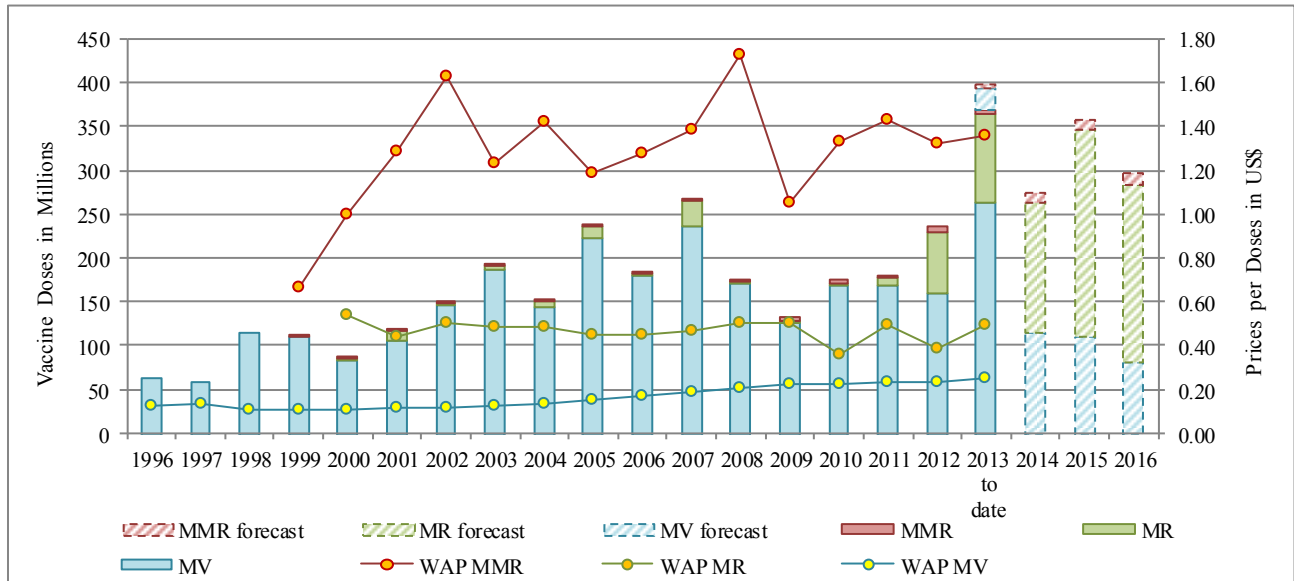
<sup>4</sup> WHO, *WHO Prequalified Vaccines*, WHO, Geneva, 2013 at [http://www.who.int/immunization\\_standards/vaccine\\_quality/PO\\_vaccine\\_list\\_en/en/index.html](http://www.who.int/immunization_standards/vaccine_quality/PO_vaccine_list_en/en/index.html).

<sup>5</sup> WHO, *Measles Fact Sheet*, WHO, Geneva, February 2013 at <http://www.who.int/mediacentre/factsheets/fs286/en/>.

<sup>6</sup> WHO, *Meeting of the Strategic Advisory Group of Experts on Immunization, November 2010 – Summary, Conclusions and Recommendations*, Measles and Rubella Initiative, Washington, November 2010, p.10 at <http://www.measlesrubellainitiative.org/wp-content/uploads/2013/06/SAGE-Nov-2010.pdf>.

<sup>7</sup> WHO, *Measles Case Distribution by Month and WHO Regions 2008-2013*, WHO, Geneva, November 2013, at [http://www.who.int/immunization\\_monitoring/diseases/big\\_measlesmonthlyregionaldistribution\\_PDF.pdf](http://www.who.int/immunization_monitoring/diseases/big_measlesmonthlyregionaldistribution_PDF.pdf).

**Figure 2 MCV Supply through UNICEF and Demand Forecast for 2013-2016**

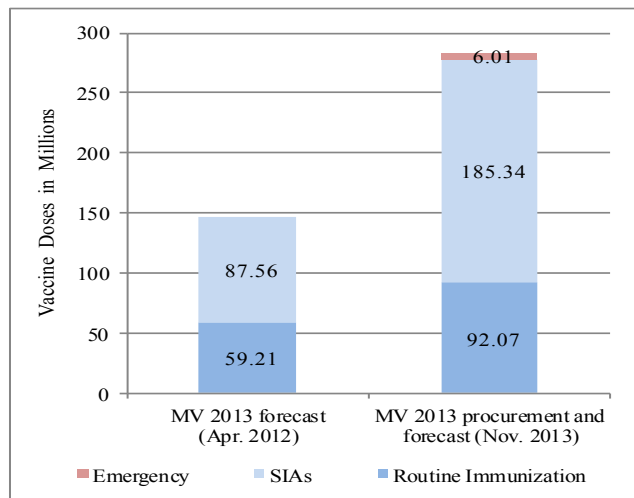


Source: UNICEF Supply Division.

### 3. Current Market Situation

#### 3.1. Demand

**Figure 3 MV 2013 Forecast and Procurement Development**



Source: UNICEF Supply Division.

Anticipated year-end 2013 MV procurement of 283 million doses is nearly double the original (April 2012) forecast of 147 million (Figure 3). Revised forecast demand for routine immunization increased by more than half as a result of increased country requirements (by an average of 43%), in addition to the un-forecasted demand from a number of countries. The un-forecasted Pakistan requirements account for 81% (~27 million doses) of the total increase in routine immunization demand.

Revised forecast demand for SIAs increased by 98 million doses as a result of increased revised country requirements, in addition to un-forecasted demand from additional countries. Demand from Sudan, DRC, Nigeria and Pakistan account for 83% of the total SIA increase. The epidemiological-driven need to increase age cohorts, in addition to follow-up and re-vaccination campaigns, has contributed to the increase. The demand for 6 million doses in response to large measles outbreaks in 7 countries has also added to the volume, of which 3 million doses were for the outbreak in Nigeria.

WHO recommendations encourage countries to vaccinate children with 2 doses of MCV and to introduce rubella in combination with the first dose of MCV (MCV1) using MR or MMR. Since 2011, MR demand through UNICEF has increased from 9 million doses to an anticipated 100 million doses in 2013, and is expected to exceed 200 million by 2016. The MRI Strategic Plan 2012-2020 target of achieving high MCV and rubella coverage in 68 priority countries is driving this trend. GAVI is supporting the MRI's Strategic Plan 2012-2020 and MR introduction in 49 GAVI countries. GAVI supports catch-up campaigns for children aged 9 months to 14 years up to 2020 in order to catalyse the replacement of MV with MR in routine immunization programmes.<sup>8</sup>

The introduction of a second dose of MCV (MCV2) requires  $\geq 80\%$  coverage MCV1. To date, 11 countries have introduced MCV2 with GAVI support and an additional 20 will introduce MCV2 by 2015, subject to  $\geq 80\%$  coverage of MCV1. WHO's Strategic Advisory Group of Experts on Immunization (SAGE) reviewed in its November meeting whether countries using a combination vaccine (MR or MMR) as a first dose should adopt a second dose using the same combination vaccine. The recommendations from the SAGE are expected to be released in the January Weekly Epidemiological Record (WER).

### 3.2. Manufacturer Base

UNICEF currently procures MCV from four manufacturers:

- More than 80% of MCV supply is sourced from Serum Institute of India (SII). SII is also the only current manufacturer with WHO prequalified MR. WHO prequalification of new MR entrants is only expected from 2016 at the earliest.
- Bio Farma and SII have been able to substantially increase production of MCV based on UNICEF forecast requirements in order to meet some additional demand.
- GSK provide quantities of MMR in 2-dose presentation to UNICEF.

Figure 4 UNICEF LTA Awards for 2013-2016

Vac.	Company	Duration	Present.
MV	Bio Farma	LTA – 4 years	10 ds
	Sanofi Pasteur	LTA – 4 years	10 ds
	Serum Institute of India Ltd	LTA – 4 years	10 ds
MR	Serum Institute of India Ltd	LTA – 4 years	10 ds
MMR	GlaxoSmithKline	LTA – 4 years	2 ds
	Sanofi Pasteur	LTA – 4 years	10 ds
	Serum Institute of India Ltd	LTA – 4 years	1, 5, 10 ds

Source: UNICEF Supply Division.

<sup>8</sup> The GAVI Alliance, *Measles Vaccine Support*, The GAVI Alliance, Geneva, 2013 at <http://www.gavialliance.org/support/nvs/measles/>.

#### 4. Issues / Challenges

- For 2013, MCV supply has been sufficient to meet all country requirements (72 countries supplied to date), however, overlapping requirements in the timing have constrained supply. Demand for MCVs is again anticipated to remain high going forward. As most of the supply is sourced from one manufacturer, vaccine security for MCV will remain fragile.
- WHO's SAGE has yet to release its recommendation whether countries using a combination vaccine (MR or MMR) as a first dose should also adopt a second dose using the same combination vaccine. The cost and logistics implications of using two different vaccines, a combination vaccine as a first dose and a monovalent measles vaccine as a second dose, is not clear for some countries, and contributes to uncertainty in MV and MR demand.
- In 2013, SAGE highlighted an increased proportion of measles cases occurring in older children and adults and the need to consider modifying SIA design to ensure the coverage of all susceptible age groups according to national epidemiology, which would also affect MCV demand moving forward.
- Country-level plans for MR introduction have not yet been concluded. The limited visibility for MR creates uncertainty in forecasts, which in turn creates planning uncertainty for manufacturers, particularly as it relates directly to interchangeable MV and MR volume demand. Any postponed demand for MR in turn will increase MV demand.

#### 5. Steps Forward

- UNICEF is working with partners to develop a more accurate and timely demand forecasts, particularly for SIAs.
- UNICEF and its partners continue on-going discussions with manufacturers in developing and planning different MCV demand scenarios.
- UNICEF will increase the dialogue with potential new MCV manufacturers and encourage acceleration into the market.
- The information in this note is accurate as of the date of its publication. However, demand and supply are rapidly evolving. This note will be updated should there be significant changes to the market.

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