

Measles-Containing Vaccines: Supply & Demand Outlook

UNICEF Supply Division

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Measles-Containing Vaccines (MCV): Supply & Demand Outlook May 2014

This update reports on anticipated 2014 MCV demand and supply availability. Unconfirmed 2014 MCV demand and supply may require extended lead times for delivery during 2H 2014. The availability of MMR vaccine with certain strains has been reduced.

1. Summary

- 2014 estimated requirements of measles vaccine could reach up to ~190 million doses (as of end April). UNICEF awarded an additional 54 million doses in January for a total of 163 million doses. Some additional quantities remain un-awarded as only 47% (90 million doses) of the demand is formally confirmed to date. Additional doses can be awarded should additional demand be confirmed during the year and to respond to unforecasted routine or supplementary immunization activities and emergency outbreak.
- Measles monovalent production capacity is sufficient to meet forecasted demand, but is fragile, as one manufacturer produces 80% of supply and also produces the only WHO pre-qualified measles and rubella (MR) vaccine.
- 2014 MR vaccine country requirements are estimated to reach 120 million doses, of which ~70% is planned for delivery during the 3Q and 4Q of the year. ~50% of MR demand is uncertain and subject to GAVI Board approval through 2Q 2014. Although annual supply awarded through UNICEF is sufficient to meet current forecasted demand, UNICEF will work with the sole manufacturer and countries to ensure that vaccine delivery schedules are accelerated to meet the programmatic requirements in 3Q and 4Q. Some country requirements may require extended lead times for delivery during 2H 2014.
- From 2014 onwards, the availability of measles mumps and rubella (MMR) vaccine is reduced in terms of different mumps strain. MMR vaccine with an Urabe mumps strain is no longer available. MMR vaccine with a Jeryl-Lynn mumps strain has limited availability, and the manufacturer is only offering this to countries that are using this vaccine. The changes from manufacturers come despite increased interest and demand driven by country preferences. UNICEF will continue to advocate for Jeryl-Lynn containing MMR to be more available. However, MMR vaccine supply with a Leningrad-Zagreb mumps strain is available at sufficient quantities to meet current forecasted country demand.

2. General Overview and Background

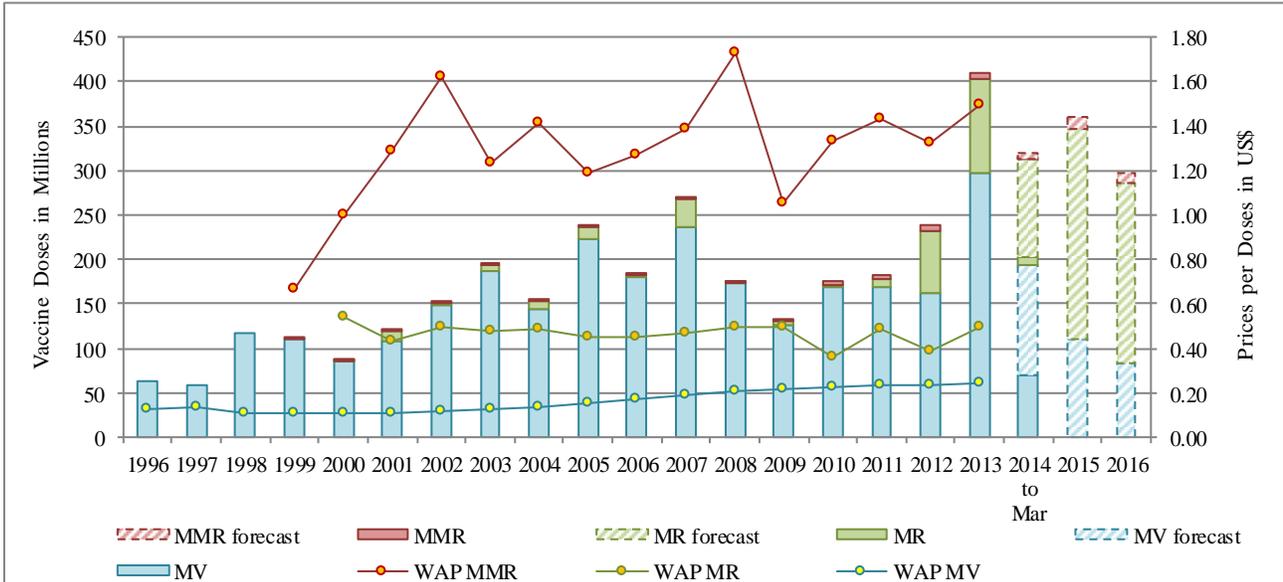
UNICEF's previous MCV Supply Update ([December 2013](#)) provides general market background and updates on changes in 2013 demand, which ultimately reached 410 million doses. Measles monovalent demand accounted for most of this increase, having doubled from an original forecast of 147 million doses to reach 297 million doses by year-end. Unforecasted routine demand from large countries, large outbreak response and an increased age group for supplementary immunization activities (SIAs) accounted for the increase (Figure 1). Some quantities procured in 2013 underwent delivery and programme implementation during 1Q 2014. Demand for MR increased to 106 million doses during 2013, primarily due to countries introducing the rubella vaccine with GAVI support.

One dose of rubella and two doses of measles vaccine in country routine immunization programmes are currently recommended by WHO. WHO’s Strategic Advisory Group of Experts on Immunization (SAGE) recommends that:¹

- Countries are to introduce or use a rubella containing vaccine (RCV) as a first dose measles combination vaccine (MR or MMR) (MCV1). A first dose MR or MMR will ensure a higher coverage rate for both rubella and measles.
- Countries that introduce a combination vaccine (MR or MMR) as MCV1 into routine immunization should carry out catch-up campaigns to reach all children between 9 to >15 years of age to ensure coverage of all susceptible age groups according to national epidemiology.
- Countries that use different MCVs for their first and second dose measles vaccine should use the same combination vaccine (MR or MMR) for both routine doses.

3. Current Market Situation

Figure 1 MCV Supply through UNICEF and Demand Forecast for 2014-2016

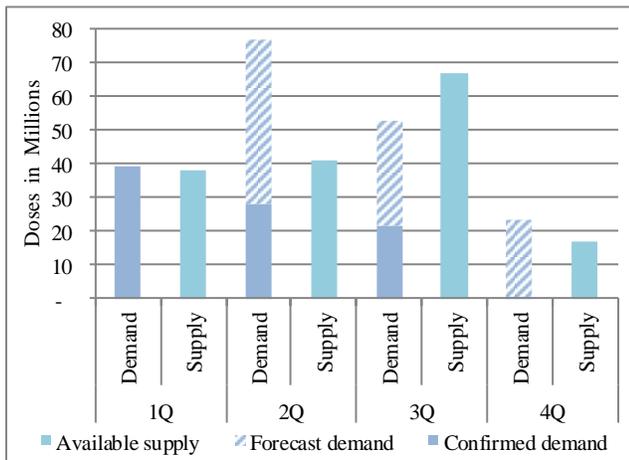


Source: UNICEF Supply Division.

2014 measles monovalent requirements may reach up to ~190 million doses (as of end April). Potential increases to this number may be driven by responses to outbreaks reported in Central Africa Republic, Guinea, Ethiopia and South Sudan, as well as the demand for increased age-group SIAs. To date only 47% of the total forecasted quantities has been confirmed, with ~2/3 of anticipated 2Q 2014 still remaining un-confirmed to date. Supply availability will not be sufficient to meet country requirements during 2Q 2014 should the quarterly estimates be confirmed with little warning, given the lead-time required (Figure 2).

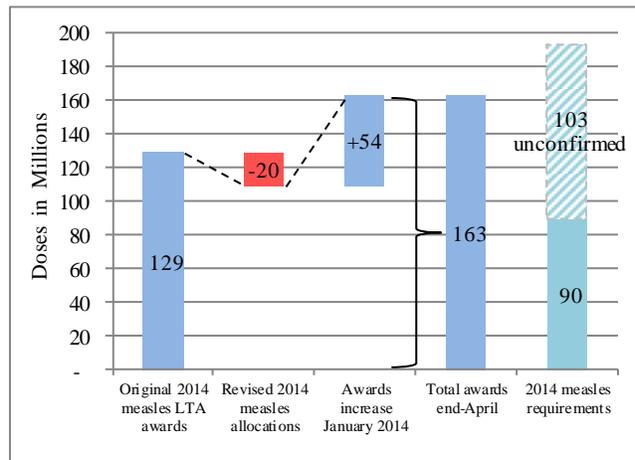
¹ World Health Organization, *Meeting of the Strategic Advisory Group of Experts on Immunization, November 2013: Conclusions and Recommendations*, WHO, Geneva, January 2014, p.12 at <http://www.who.int/wer/2014/wer8901.pdf>.

Figure 2 UNICEF Measles Supply Availability versus Demand Forecast 2014



Source: UNICEF Supply Division.

Figure 3 Measles Supply (Awards) versus Requirements 2014

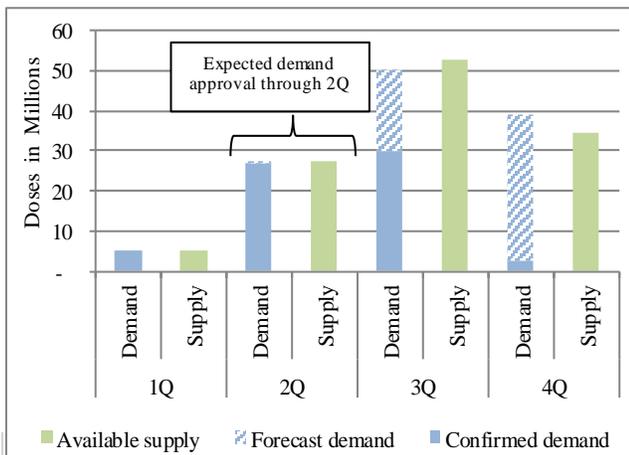


Source: UNICEF Supply Division.

UNICEF awarded an additional 54 million doses to its original 2014 allocation in order to secure 163 million doses of availability. The award is in anticipation of increased demand confirmation and in compensation for the loss of 20 million doses of supply due to the exit of one manufacturer from the market (Figure 3).

New country introductions continue to be the main driver for 2014 MR demand, which could reach 120 million doses, but will ultimately remain dependent upon GAVI Board approval expected through 2Q 2014 (Figure 4). The Board’s decision will determine support for EPI introductions of rubella vaccine through catch-up campaigns for children between 9 months to 14 years of age.² MR country demand would be adjusted and communicated to manufacturers.

Figure 4 UNICEF MR Supply Availability and Timing versus Demand Forecast 2014



Source: UNICEF Supply Division.

Despite adequate *awarded* supply for the entirety of the year, much of the unconfirmed 2014 MR demand is concentrated during 2H 2014. Normal lead time from order placement to delivery is 5-6 weeks, but due to high demand, longer lead times are currently required extending up to 10-13 weeks. As most 2H 2014 demand remains unconfirmed (to-date), extended lead times may start to occur particularly during 2H 2014 as previous demand materialises and following GAVI approvals during 2Q 2014. Supply availability is only confirmed upon the issuance of purchase orders. As currently planned, little margin exists during 2H 2014 to ensure that such a

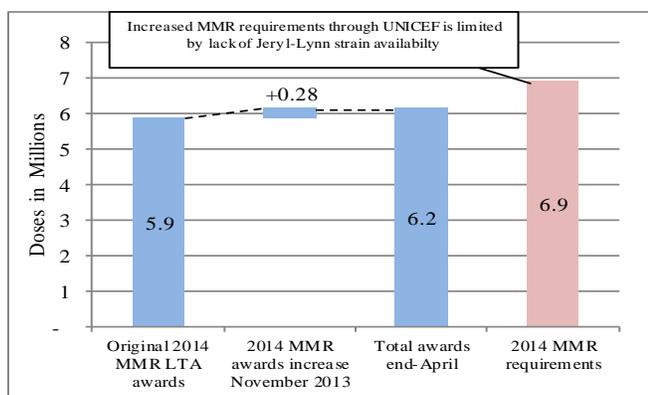
² The GAVI Alliance, *Measles-rubella Vaccine Support*, The GAVI Alliance, Geneva, 2014 at <http://www.gavialliance.org/support/nvs/measles-rubella/>.

high volume of purchase orders for all country requirements can be met with standard MR delivery lead times. UNICEF is working with the manufacturer and countries to facilitate planning to meet country programmatic requirements.

At present, MR and measles monovalent are supplied in 10-dose vials. Some countries are requesting supply in a 5-dose vial presentation to reduce wastage rates. However, 5-dose vials are not supplied by manufacturers on account of finite manufacturing capacity. Filling a 10 dose vial with a 5 dose volume would produce half the volume and reduce the manufacturer’s capacity to meet global demand. UNICEF, together with the Measles and Rubella Initiative (MRI) partners, will work with countries to quantify demand for 5-dose vials and secure possible availability in the future, without jeopardising overall MCV supply. UNICEF will seek to secure availability by 2017.

Additionally, the largest measles manufacturer also produces the only WHO prequalified MR vaccine. Even though the manufacturer’s MR production capacity is sufficient to meet all current country requirements, the production facilities for measles and MR are shared. As a result, any increase in MR production could affect measles monovalent production capacity and vice versa, demanding accurate planning with adequate lead-times for both products.

Figure 5 MMR Supply (Awards) versus MMR Requirements 2014



Source: UNICEF Supply Division.

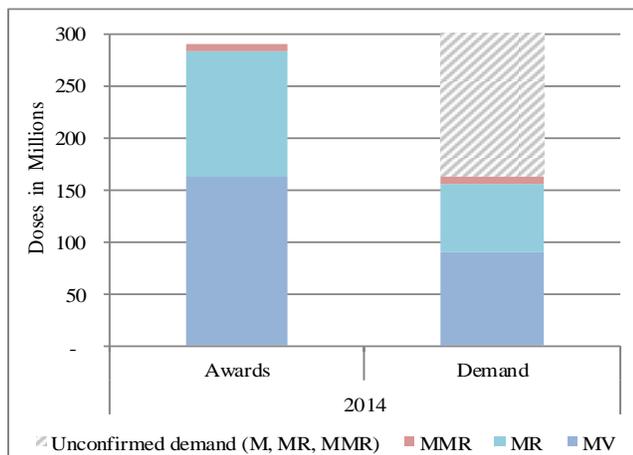
An additional 280,000 doses of MMR were awarded in 4Q 2013 (Figure 5) for 2014. Some MMR vaccine availability in terms of the different mumps strain through UNICEF has been reduced. The MMR vaccine with an Urabe mumps strain is no longer available from 2014 onwards. The MMR vaccine with a Jeryl-Lynn mumps strain is only available to countries that have a forecasting and procurement history with UNICEF. Demand for Jeryl-Lynn-containing MMR vaccine has increased on account of country product preference and Urabe-containing

MMR vaccine no longer being available. Incremental demand cannot be met due to the currently limited availability. Only MMR vaccine with a Leningrad-Zagreb mumps strain production capacity and supply availability is sufficient to meet all MMR country demand requirements and can meet possible increased demand.

In aggregate, UNICEF has LTAs with 4 manufacturers to supply 289 million doses of MCV during 2014. Some supply has been left un-awarded and will be subject to subsequent country demand confirmation. Current MCV award allocations are sufficient to supply all confirmed country requirements of ~162 million doses, which may ultimately reach ~320 million doses if all demand materialises (Figure 6). UNICEF’s MCV supply is reliant on one manufacturer, which accounted for 86% of the total 2013 volume. While the manufacturer has met all demand requirements, such high reliance on a single manufacturer presents a risk to supply security, particularly in an increasing demand environment (Figure 7). Arrangements are in place to secure a portion of MCV supply ready for shipment within 72 hours for outbreak response.³

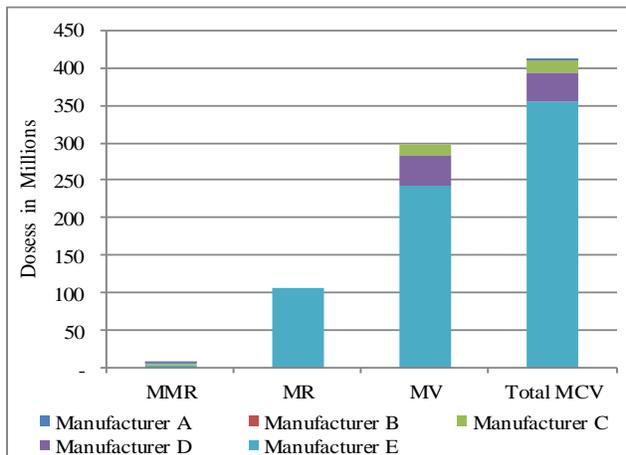
³ 1 million doses of measles monovalent and 100,000 doses of MR can be ready for shipment within 72 hours.

Figure 6 Aggregate 2014 MCV Awards



Source: UNICEF Supply Division.

Figure 7 2013 MCV Manufacturer Supply Share



Source: UNICEF Supply Division.

4. Issues and Challenges

- MCV supply continues to be broadly sourced from just one manufacturer, perpetuating a fragile supply base.
- Demand for MCV vaccine supply in 5-dose vials cannot be met at present on account of manufacturer production capacity concerns, which would reduce capacity to meet global demand. UNICEF and MRI partners will work with countries to quantify demand for 5-dose vials and secure possible availability in the future, without jeopardising overall MCV supply.
- Total 2014 measles supply availability depends upon measles monovalent and MR country demand confirmation, as both vaccines share the same production facilities. To date, 63% of measles monovalent country demand has yet to be confirmed and ~50% of country plans for MR introduction have not yet been concluded. MR introduction is dependent on the GAVI Board's approvals expected through 2Q 2014. A 2H 2014 concentration of delayed demand may not allow sufficient time to ensure the timely delivery of supply compared to current plans.
- Increased interest and demand for MMR Jeryl-Lynn vaccine as a product preference cannot be met due to limited product availability through UNICEF.
- Demand for measles monovalent is subject to the persistent threat of measles outbreaks and subsequent emergency vaccination response requirements, which may potentially affect planned deliveries.
- Despite clear WHO SAGE recommendations for the use of measles combination vaccines (MR or MMR) as a measles first and second dose, uncertainty remains in the demand and countries' readiness to introduce MCV2 using the same combination vaccine as the first dose.

5. Steps Forward

- Countries should communicate confirmation of MCV demand as soon as possible.
- The GAVI Board approval decisions through 2Q 2014 will determine the support and definitive list for rubella and MCV2 country introductions.

- UNICEF will work with manufacturers and countries to ensure that vaccines meet 2014 programmatic requirements. UNICEF may request flexibility on some vaccine shipments in order to meet the priority needs of some countries.
- UNICEF will work together with programme, partners and countries to identify the 5-dose vial quantities required and ensure that cost effectiveness and cold chain capacity considerations are taken into account and communicated to manufacturers.
- UNICEF will communicate to industry the need to increase Jeryl-Lynn strain MMR vaccine availability in order to meet country product preferences.
- UNICEF is continuing its efforts with partners and manufacturers to develop more accurate demand and planning forecasts with different MCV demand scenarios.
- Dialogue with global partners on potential new MCV manufacturers and encourage acceleration of new manufacturers into the market.
- MCV market dynamics may be subject to rapid change. The note will be updated should there be significant changes to the market.

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