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| **SUBJECT:** | **GAVI'S MEASLES AND RUBELLA STRATEGY** |
| **Report of:** | Hind Khatib-Othman, Managing Director, Country Programmes |
| **Authored by:** | Khin Devi Aung, Stefano Malvolti |
| **Agenda item:** | 07 |
| **Category:** | For Decision |
| **Strategic goal:** | Affects all strategic goals |

## 1. Executive Summary

1.1 Gavi's involvement in measles has grown from 2004 to several different types of current support, with a total investment estimated to reach US$ 1.3 billion by 2020. Yet, given the evolving challenges of plateauing coverage and an increase in the incidence of measles outbreaks, and the new Gavi strategic vision for 2016-2020 which is focused on sustainable coverage and equity of all vaccines, it was deemed important by the Board in December 2014 to revisit Gavi's measles and rubella strategy.

1.2 The Gavi Programme and Policy Committee (PPC) in May was presented with several options for Gavi's future involvement in measles and rubella. The PPC considered Gavi's involvement in measles and rubella as critically important.

1.3 The Secretariat convened a Technical Working Group (TWG) receiving guidance from a high level Steering Committee (SC), who have met on several occasions to determine Gavi's future involvement in measles and rubella.

1.4 The PPC in October was presented with a proposed Gavi's measles and rubella strategy based on the principles of country ownership, financial and programmatic sustainability and be a central component of coverage and equity work. The PPC recommended the proposed strategy and noted the support as a priority spend for Gavi's remaining funds.

1.5 The PPC requested that the strategy takes into consideration Gavi's Fragility and Immunisation Policy when requiring countries to fully finance their own routine measles monovalent vaccine in order to receive Gavi support. The PPC also requested that the complementary roles and responsibilities with the Measles & Rubella Initiative (M&RI) be determined. Please find attached as Annex A a letter from M&RI outlining such complementarities.

1.6 The Audit and Finance Committee (AFC) in its meeting on 6 November confirmed the availability of the requisite resources for the measles and rubella strategy.

## 2. Recommendations

2.1 The Gavi Programme and Policy Committee recommended to the Gavi Board that it:

(a) **Approve** a comprehensive measles and rubella strategy for Gavi as set out in section B, 5.5-5.16 of Doc 10 to the PPC (the proposed "Measles and Rubella Strategy"), as amended by discussions at the PPC, and noting the additional funding for the current strategy period (2016-2020) amounts to approx. US$ 220 million.

(b) **Note** the importance of enhancing Gavi's approach to supporting countries for measles and rubella, and **request** the Secretariat and the Alliance partners to: (i) ensure Measles and Rubella Strategy is fully incorporated in the countries' immunisation programmes and plans, (ii) implement through the use of already existing mechanisms such as the Joint Appraisals and High Level Review Panel, with any necessary modifications; and (iii) put in place mechanisms that better leverage strengths in the Alliance, in order to improve the planning, efficiency and effectiveness of campaigns.

The Gavi Programme and Policy Committee requested that the Gavi Board:

(c) **Note** that the implication of the new strategy is that funding for the 2021-2025 period is estimated to be approx. US$ 500 million.

## 3. Changes brought in response to PPC feedback

3.1 Following feedback from the PPC in regard to taking Gavi's Fragility and Immunisation policy into consideration (Section B, 5.10 in PPC paper), it was further deliberated that for countries that fall under the policy where routine measles first dose (MCV1) is already funded by a third party, if such funders will continue financing MCV1, Gavi will consider providing measles and/or measles-rubella support upon discussion with such countries on the long term vision for measles financing.

3.2 In addition, Section B 5.11 in the PPC paper has been updated (in tracked changes) to clarify the language relating to the proposed co-financing approach.

## 4. Risk and Financial Implications - Update

4.1 In addition to the risks and implications presented in the PPC paper, an additional risk was noted by the PPC. As Nigeria enters accelerated transition phase in 2017, the country will no longer be eligible for Gavi support. With the current immunisation coverages in routine and campaigns in Nigeria, it is unclear when the country will be able to introduce MR

vaccines. This could potentially pose a risk of rubella infection for neighbouring countries who have already introduced rubella, even though the risk remains theoretical and unknown. Nevertheless, to mitigate this theoretical risk, neighbouring countries who introduce rubella must plan to achieve a high quality catch-up campaign and sustain homogeneous high coverage in routine immunisation.

MEASLES & RUBELLA INITIATIVE

Dr. Seth Berkley
Chief Executive Officer
Gavi, the Vaccine Alliance
2 Chemin des Mines
1202 Geneva
Switzerland

Dear Seth,

I am writing on behalf of the leaders of the five founding partners of the Measles & Rubella Initiative (M&RI) to let you know that we warmly welcome the ongoing review by Gavi, the Vaccine Alliance, of its measles and rubella strategy. Each of our institutions relates to Gavi, the Vaccine Alliance, in various ways; here we speak from our perspective as the leadership of M&RI.

This is an important moment for all of us to work together to address the challenges we face in reducing measles deaths, boosting routine immunization and meeting the goals of the Global Vaccine Action Plan. We all need a strong partnership between Gavi and M&RI that involves collaboration on programs and communications based on our complementary roles.

As partners of M&RI, we value and appreciate the Gavi emphasis on coverage and equity, a key goal shared by both Gavi and M&RI. We see the measles and rubella work of Gavi and that of M&RI to be complementary, and we thought it would be helpful to outline the current priorities of the Measles & Rubella Initiative:

- Continuing to leverage the assets and resources of the five M&RI founding partners to achieve country and regional goals for measles and rubella through strengthening immunization systems.
- Continuing to address these two diseases from a global perspective, working with Gavi and ministries of health in countries which still have a high burden of measles and rubella and actively supporting measles and rubella control activities in countries that are not Gavi-eligible.
- Working with ministries of health to vaccinate expanded age groups, particularly children over the age of five, when epidemiologically appropriate and necessary.
- Continuing to be on the front lines of measles outbreaks, employing our quick and flexible mechanisms for outbreak response and increasing our mitigation efforts related to outbreak prevention.
- Employing our repository of expertise to provide technical and programmatic assistance, surveillance and laboratory support, outbreak investigation and

response, community outreach and education as well as immunization policy development.

- Strengthening measles and rubella surveillance and data quality, with robust linkages to a strong WHO Global Measles and Rubella Laboratory Network (LabNet) to enable tracking the spread of virus genotypes and supporting countries and regions to verify interruption of endemic transmission.
- Continuing our efforts to strengthen immunization systems at the country level -- including through catalytic contributions such as the development of a second year of life platform to provide vaccinations, reduce missed opportunities and link with other health interventions -- in recognition of the critical importance of strengthening routine immunization, the strong role that Gavi and other organizations and actors play, and the need for strong coordination and cooperation.
- Working with the Global Polio Eradication Initiative in its legacy planning related to the transition of GPEI knowledge and assets to benefit national immunization programs, including for measles and rubella.

The decline in deaths from measles has plateaued in recent years and the global 2015 milestone of 95% reduction in measles mortality will not be met. The Measles & Rubella Initiative recognizes that it will be extremely difficult to reach the 2020 WHO regional elimination goals. We are committed to taking measures to work with partners and countries to improve the implementation and quality of proven strategies that are predicated on a strong immunization system to achieve and maintain high levels of population immunity, monitor disease, and prepare and respond to outbreaks, as well as to ensuring sustainable financing and conducting needed research and development. Therefore, we have embarked on a Mid-Term Review of the Global Measles and Rubella Strategic Plan 2012-2020. The review will be conducted by recognized independent programmatic experts. We are confident that the results from this review will strengthen our efforts and our collaboration with Gavi.

Our vision is for a world without measles, rubella and congenital rubella syndrome. We support the goals of the Global Vaccine Action Plan and the targets of the WHO regions to move toward regional elimination and eventual global elimination. We recognize that Gavi's approach is to support measles mortality reduction in Gavi-eligible countries, and we strongly support Gavi's mission to build sustainable programs and save children's lives by increasing equitable use of vaccines. We see our roles as highly complementary as our respective efforts move along the control-elimination continuum in the years ahead.

On behalf of the five founding partners, I want to emphasize the importance of our close collaboration. We look forward to a constructive working relationship with the Gavi Secretariat at all levels, as well as to our ongoing relationships with other key partners. After the Gavi Board approves its new measles and rubella strategy, we would like to work with you to establish an effective and efficient balance of mandates, responsibilities and labor, in addition to the already agreed upon regular meetings between our senior leaders. We would like to propose that a joint communique be issued by Gavi and M&RI to explain the complementarity of our roles.

Countries, working with global immunization partners, have achieved a 75% reduction in measles mortality since the year 2000. Governments, M&RI, Gavi and many other stakeholders should be proud of all of the work over the last 15 years that has resulted in

the reduction of measles deaths being the single most important contributor to child mortality reduction under Millennium Development Goal 4. We look forward to working closely with you to benefit the world's children.

Sincerely,

Kathy Calvin
President and CEO
United Nations Foundation

Signed on behalf of:

Margaret Chan
Director-General
World Health Organization

Thomas R. Frieden
Director
U.S. Centers for Disease Control and Prevention

Anthony Lake
Executive Director
United Nations Children's Fund

Gail J. McGovern
President and Chief Executive Officer
American Red Cross

**UPDATED FOR THE BOARD**

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## Section A: Overview

### 1. Executive Summary

1.1 In December 2014, the Gavi Board noted that one coherent Gavi strategy on measles and rubella was needed, given that Gavi's involvement in measles has grown from 2004 to several different types of support currently, with a total investment estimated to reach US$ 1.3 billion by 2020.

1.2 The Gavi Programme and Policy Committee (PPC) in May 2015 was presented with several options for Gavi's future involvement in measles and rubella. The PPC considered not desirable the options of no more Gavi involvement in measles or the pursuit of measles elimination; the latter due to the absence of donor commitment to finance this. The PPC requested the Secretariat to develop further options 3 (strengthening routine immunisation) and 4 (measles and rubella control) for submission to the PPC in October 2015 for its recommendation to the Board for decision in December 2015.

1.3 The Secretariat convened a Technical Working Group (TWG) receiving guidance from a Steering Committee (SC), who have met on several occasions to determine Gavi's future involvement in measles and rubella.

1.4 The SC and the TWG agreed that measles control is on the continuum towards elimination, and that Gavi support should be to contribute to countries in their efforts along this continuum. They determined that Gavi's future engagement should be based on the principles of country ownership, and financial and programmatic sustainability. Based on its unique co-financing model, Gavi was also considered best placed to ensure financial sustainability. The SC also supported Gavi to use its investment in measles to contribute further to strengthened routine immunisation (RI) coverage

and equity and to improved quality of Supplementary Immunisation Activities (SIA).

1.5 To satisfy these principles, the SC and TWG considered it important that countries: a) **self-finance the first dose of measles vaccine** in their national immunisation programme; and b) have a **long term budgeted plan** for measles and rubella activities, consistent with the epidemiology of the disease requiring periodic campaigns that need to be routinised, for financial and programmatic sustainability.

1.6 Hence the most appropriate option for Gavi to support countries was considered the one providing comprehensive measles and rubella vaccination support as part of a mandatory 5 year rolling plan, aligned with the comprehensive multiyear plan (cMYP). In terms of scope, this proposed option includes:

(a) Extending the current measles SIA support to all Gavi eligible countries that still need to conduct measles SIA before they are able to introduce measles-rubella vaccine (MR);
(b) Continuing to provide the 9 month-14 year old wide age initial MR catch-up campaigns;
(c) Starting to provide support for the needed periodic M or MR follow up campaigns[1];
(d) Requiring that countries co-finance routine measles second dose (MSD) or MR vaccines ensuring that country funding is not replaced by Gavi funds; and
(e) Continuing to fund outbreak response.

1.7 The proposed strategy is estimated to require an additional investment of approximately US$ 130 million over the original forecasted expenditure included in replenishment ask of US$ 700 million[2], and approximately US$ 219 million above the forecasted expenditure of US$ 600 million[3] presented to the Board in June 2015 for its measles and rubella programmes for 2016-2020 period. This investment would avert an additional 320,000 future deaths, totalling more than 1 million future deaths averted from measles and Congenital Rubella Syndrome (CRS) in this 5 year period alone, one of the top 'best-buys' in terms of impact, behind pentavalent vaccine. This is also consistent with the central role that measles coverage plays in the new Gavi's coverage and equity strategy.

[1] Although follow-up campaigns are needed less frequently for rubella than for measles because of the lower infectivity of rubella, SAGE recommends that once MR has been introduced into a country it replaces single-antigen measles in all strategies. This helps to reduce potential programmatic errors.
[2] Based on Strategic Demand Forecast (SDF) v9.0
[3] Revision in forecasted expenditure largely due to revision on forecast of country introduction (Nigeria MR campaign excluded)- SDF v 11.0

## 2. Recommendations

2.1 The PPC is requested to:

(a) **Recommend** to the Board that, subject to confirmation by the Audit and Finance Committee that sufficient funding is available, it approve a comprehensive measles and rubella strategy for Gavi as set out in section B, 5.5-5.16 of Doc 01 (the "Measles and Rubella Strategy"); and

(b) **Recommend** to the Board that it note the importance of enhancing Gavi's approach to supporting countries for measles and rubella, and **request** the Secretariat and Alliance partners to: (i) implement the Measles and Rubella Strategy through the use of already existing mechanisms such as the Joint Appraisals and High Level Review Panel, with any necessary modifications; and (ii) put in place mechanisms that better leverage strengths in the Alliance, in order to improve the efficiency and effectiveness of campaigns.

## Section B: Content

## 3. Background

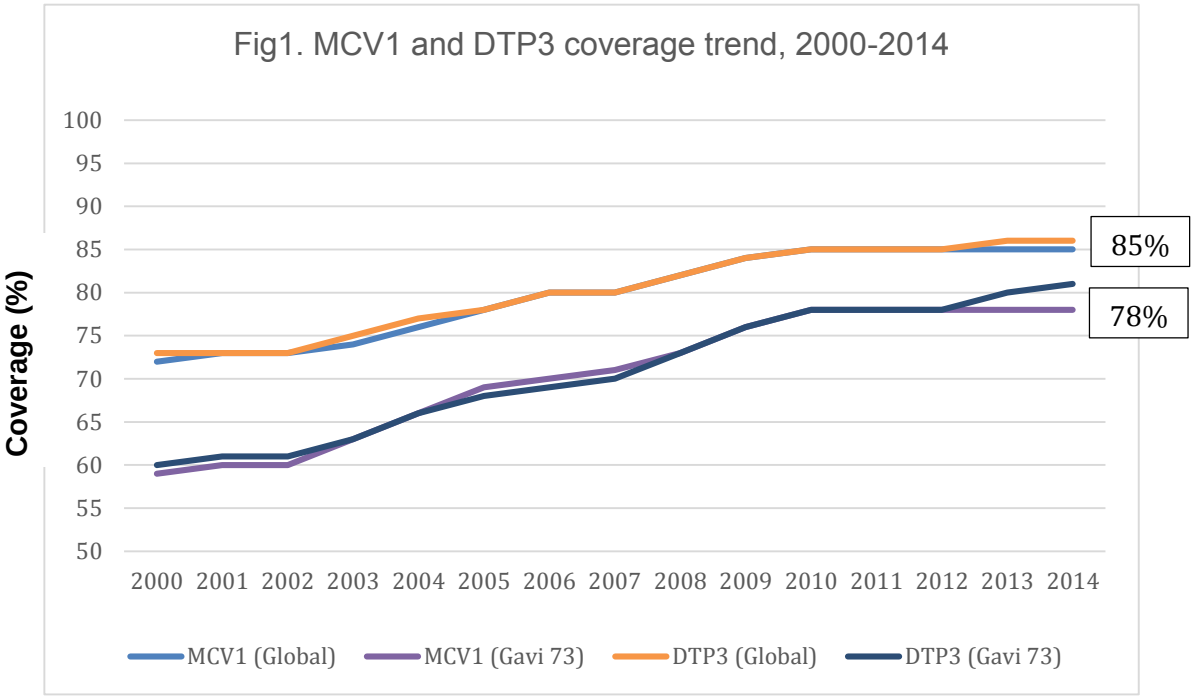
3.1 Gavi's involvement in measles efforts started in 2004, with a mortality reduction goal, when Gavi provided funding to the Measles Initiative (later renamed the Measles & Rubella Initiative -M&RI) for measles SIAs. Currently, four streams of Gavi support exist for measles and rubella: routine measles second dose for a period of 5 years, measles-rubella catch-up campaign for children 9 months-14 years of age, measles SIAs for 6 large countries at high risk of measles outbreaks, and funding until 2017 to the M&RI for outbreak response. Based on the current windows of support, Gavi's engagement in measles and rubella would have concluded by the early years of the next decade, after an investment totalling almost US$ 1.3 billion[4].

3.2 With Gavi support for measles and rubella being limited in time and scope, the Gavi Board in December 2014 noted that a single Gavi strategy was needed and that this would be considered by the PPC before being brought to the Board.

3.3 In May 2015, the PPC was presented a situational analysis including Gavi's contributions and achievements, challenges, lessons learnt and opportunities, and options for Gavi's future support for measles and rubella efforts. The PPC expressed support for further work to be carried out on developing options 3 (strengthening routine immunisation) and 4 (measles and rubella control). Please see Annex A for the various options provided to the PPC in May. It was also agreed that the options outlined in the paper are illustrative and that alternative combinations can be pursued.

[4] Disbursed by the end of 2014: approximately US$ 555 million. Forecasted expenditure 2015-2020: US$ 700 million. As per v11.0Fa. cash flow basis

3.4 Of relevance, later in June, the Gavi Board approved indicators for Gavi's 2016-2020 strategy. These included in the 'Aspiration 2020' disease dashboard the '*number of countries reporting an annual incidence of less than 5 measles cases per million population'; and for* Strategic Goal 1: accelerate equitable uptake and coverage of vaccines, monitoring and development of a target (to be proposed in a separate PPC paper) for '*first dose of routine measles vaccine coverage'.* This highlights the importance of measles as one of the central components of coverage and equity work of Gavi's 2016-20 strategy period; MCV1 coverage has stagnated over the past 5 years at 85% globally and 78% in Gavi 73 countries[5], showing the need to improve routine immunisation coverage. Please see Figure 1 on MCV1 coverage relative to DPT1 coverage.




## 4. Process of developing Gavi's measles and rubella strategy

4.1 Since the May 2015 PPC meeting, the Gavi Secretariat convened a Steering Committee (SC) composed of immunisation experts and interested PPC members, to guide the work of the Technical Working Group (TWG) comprising technical experts from partner organisations, such as WHO, UNICEF, U.S. Centers for Disease Control and Prevention (US-CDC), Bill & Melinda Gates Foundation (BMGF), as well as independent experts. Please see Annex B for the Terms of Reference and list of members of the SC and the TWG.

4.2 The SC and TWG discussed on several occasions the principal questions of 1) what makes sense for Gavi to support in measles and rubella; 2) ideal pre-requisites for a country to introduce rubella containing vaccine (and measles second dose) in a programmatically and financially sustainable

[5] WHO/UNICEF immunisation coverage estimates, released July 2015

manner; and 3) how to encourage and support countries to integrate measles supplementary activities into routine long term and short term planning and budgeting.

## 5. Gavi's Measles and Rubella Strategy

### A. Deliberations of the Steering Committee and the Technical Working Group

5.1 The SC noted that measles control is on the continuum towards elimination, and Gavi support should contribute to countries' efforts along this continuum. The SC also strongly supported that measles be one of the central components of any strategy aimed at improving coverage and equity. The SC also noted that Gavi should play a role in sustainability by using a strong co-financing model and creating correct incentives, using its distinctive advantage of high level political engagement.

5.2 The main principles for Gavi's support to measles and rubella were determined: 1) central component of coverage and equity; 2) country ownership; and 3) programmatic and financial sustainability.

5.3 Several comparative advantages were identified with respect to the role that Gavi can play in supporting measles and rubella: its commitment to push the coverage and equity agenda, its established governance structure providing legitimacy, its ability to influence countries at political level, high visibility in immunisation globally and in countries, its strong role in helping to strengthen countries' capacities, central role in market shaping and signalling, its strong mandate for financial sustainability, its co-financing model, and its ability to set norms and expectations and to operationalise the global goals and recommendations.

5.4 Some potential areas identified for improvement were: being perceived by countries as only for new vaccines, not for traditional vaccines such as measles, and being seen only as a financing body, incompatibility with speed needed for activities such as outbreak response, sometimes confusing and complicated policies and processes, and currently perceived misalignment of goals (mortality reduction versus elimination). However, Gavi is working to address these, and its increasing involvement in measles and rubella, together with partners, through the proposed strategy would help to improve global measles and rubella control efforts and send a strong message that Gavi is about immunisation, not only new vaccines.

### B. The proposed measles and rubella strategy

5.5 The Gavi Secretariat and the TWG recommend the option set out below based on guidance from the SC that Gavi's future engagement in measles and rubella be based on a comprehensive support, requiring a rolling 5-year measles and rubella plan. This option comprises the following components:

(a) Extend the current measles SIA support from 6 large countries, to all the Gavi eligible countries that require measles SIA at national or subnational levels before introducing MR, focusing on children up to 5 years of age;
(b) Continue to provide 9 month-14 year old wide age initial MR catch-up campaigns for all Gavi eligible countries;
(c) Include follow up M or MR campaigns for all Gavi eligible countries, noting that the timing, scope and geographical distribution of follow-up campaigns will be driven by measles epidemiology;
(d) Continue the support for measles second dose, extending beyond the current limited 5 years, requiring countries to co-finance routine measles second dose and MR vaccines using a specific co-financing policy, without replacing the current government funding; and
(e) Continue to provide an outbreak response fund.

5.6 As part of a rolling 5 year- measles rubella plan, countries are to review on an annual basis all the key activities with the elements of the target age groups, frequency/timing and geographical scope of campaigns being supported by strong epidemiological models. Within the financial limits of those plans, there will be flexibility for countries to revise the key parameters of their activities if supported by strong epidemiological evidence.

5.7 This option represents a modest increase in financial support due to modification in forecasting for MR introduction date for countries. This coherent Gavi support would have an additional cost implication to Gavi of approximately US$ 130 million [6] for 2016-2020 over the forecasted expenditure in replenishment ask of approximately US$ 700 million for all Gavi measles and rubella programmes (and US$ 219 million[7] over the forecasted expenditure presented to the Board in June 2015) and will help to avert additional 320,000 future deaths, totalling over 1 million deaths averted from the support during this period.

[6] **Does not include India, Indonesia or Nigeria**. Nigeria forecasted to introduce MR in 2021, but phase 2 starts in 2017, hence not eligible. If Nigeria is included, additional US$ 35-100 million (30 million if measles SIA in 2019 or 100 million if MR catch-up in 2019) would be needed.
Assumption: M follow ups for <5 yo, MR catch-up for <15 year old. MR follow ups for<5 yo, but every 4th MR follow up is for children <15 yo. Latest UN Pop released August 2015. Price forecast v12.0, **follows normal Gavi eligibility and transition policy, and latest co-financing policy**. Does not include countries who have received measles second dose support before 2015.
[7] Revision in forecasted expenditure largely due to revision on forecast of country introduction (Nigeria MR campaign excluded)

**Table 1**. Comparison of forecasted expenditure and impact between different selected vaccines and the proposed future Gavi support for measles and rubella, 2016-2020.

| Replenishment ask (2016-2020)[8] | | |
|---|---|---|
| | Expenditure in US$ millions | Deaths averted |
| Pneumococcal | 2,852 | 600,000 |
| Penta | 1,297 | 3,000,000 |
| Rota | 962 | 200,000 |
| HPV | 371 | 600,000 |
| MSD and MR | 682 | 700,000 |
| Yellow Fever | 350 | 300,000 |
| Typhoid | 294 | 20,000 |
| Cholera | 89 | |
| Meningitis | 124 | 60,000 |
| Japanese Encephalitis | 96 | 8,000 |
| **Proposed Gavi's measles and rubella strategy (2016-2020)** | | |
| Measles and Rubella | 812 | 1,020,000 |

5.8 From a strategic standpoint the new investment is accompanied by an underpinning paradigm shift from thinking of one activity at a time and having an artificial barrier of planning, budgeting and implementation between campaigns and routine, towards thinking holistically for a coherent set of interventions for a longer period of time. Hence a rolling 5 year measles rubella plan will be required as part of the cMYP. This would encourage better budgeting, and commitment from countries, which until now has been a weakness of measles and rubella activities. This long term planning would also facilitate understanding of the long term implications of rubella vaccine introduction which include raising routine coverage as well as increasing budget needs. This recommended option would allow flexibility for countries to use the most cost-efficient strategies, such as targeting for wide age subnational campaigns and focal follow up activities targeted to areas with high number of susceptible children rather than a blanket wide age nationwide campaigns, within a limited amount of funds provided by Gavi based on the five year plan.

5.9 This would also provide an opportunity for the Alliance partners to use Gavi's leverage to strengthen routine immunisation such as through improving application guidelines. Countries will be required to include in their long term plans the strategies to strengthen the routine immunisation system, including learning from the methods by which campaigns reach the

[8] version: v9.0Fa (as input to Replenishment Investment Opportunity document), Programme year basis

unreached to increase the equity and effectiveness of routine vaccination, and budgeting and funding for these activities. If MSD is part of the EPI schedule, they must also include concrete activities to increase the second dose coverage. Plans must also include details of monitoring and surveillance activities and how data will be used to guide future action to consistently reach all populations.

5.10 In addition, countries will be required to fully finance their own routine measles monovalent vaccine in order to be able to receive Gavi support for measles second dose and/or MR.

**Structuring the financing of Gavi's measles and rubella strategy**

5.11 **Co-financing of routine vaccines:** ~~The current co-financing policy excludes MR vaccines and MSD (~~Gavi currently does not support ~~from Gavi for~~ routine MR vaccines, and for MSD, Gavi pays full MSD[9] for a period of 5 years~~)~~. The price of MR vaccines has in the past been considered low enough to ~~justify a deviation from the co-financing policy by~~ require~~ing~~ countries to fully finance the routine vaccine (following a Gavi supported campaign). The TWG however considered that the cost of including MR vaccines in the routine schedule, while less expensive than new vaccines, still provides a hurdle for many countries in their constrained fiscal space especially given the cumulative effect of co-financing for several vaccines. Providing support to countries to start using a largely underused MR vaccine through co-financing was therefore considered important. Based on the guidance provided by the Steering Committee that all countries should be financing their monovalent measles routine first dose as an inexpensive vaccine providing high impact, the TWG recommended[10]:

(a) For countries adding a routine measles[11] second dose: Countries would pay US$ 0.40 for 2 doses, while Gavi pays the rest (approximately US$ 0.14-US$ 0.20)[12]. Note that very few countries are expected to introduce MSD without introducing MR.

(b) For countries adding MR[13] vaccine (switching from one dose M to one dose MR vaccine): countries would pay US$ 0.30 (comparable to the current Weighted Average Price-WAP-of measles vaccine) and Gavi would pay for the rest (approx. similar amount).

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[9] If a country wishes to use MR also as a second dose, Gavi pays for theoretical measles component (WAP) and country pays for theoretical rubella component.

[10] This will apply for countries at all phases for equity. For Phase 1 countries: increases 15% per year (not linked to prices). For Phase 2 countries: 5 year phasing out.

[11] The fully-loaded WAP of measles in 2016 is approximately US$ 0.33 per dose based on unloaded vaccine pricing available at http://www.unicef.org/supply/files/Measles.pdf and cost of freight, syringes and safety boxes of approximately $0.08 per dose. The fully loaded WAP of MR vaccine is US$ 0.67 per dose based on unloaded vaccine pricing available at http://www.unicef.org/supply/files/MR.pdf and cost of freight, syringes and safety boxes of approximately US$ 0.06 per dose. These prices are subject to changes.

[12] Countries would, in theory, be co-financing the 2 routine doses of measles. However, the US$ 0.40 the country will co-finance is more than the equivalent of a measles monovalent one dose, and operationally, is less complex than just applying a co-financing for the second dose.

[13] See footnote 4

(c) For countries adding 2 doses of routine MR vaccines: countries would pay US$0.60 (comparable to WAP of 2 doses of measles vaccine) and Gavi would pay the rest (approximately similar amount).

5.12 **Co-financing of campaign vaccines:** While catch-up campaigns would be fully funded, the TWG considered it important to require co-financing measles or MR vaccines for follow-up campaigns to avoid perverse incentives for countries to do campaigns rather than strengthening routine, and to encourage country ownership. The amount and mechanism needs to be further determined during the preparatory year (2016). Currently, Gavi's support includes all vaccines for campaigns and an operational cost support of US$ 0.65/target (an average of 80% of operational cost needs).

5.13 In order to ensure good quality, high and equitable coverage campaigns are conducted, potential incentives based on performance could be explored, as part of the policy review on direct financial support, to be submitted to the Board in June 2016. It is also equally important to minimise perverse incentives that may exist from frequently conducting campaigns, and this should also be looked into by the policy review.

5.14 **Routine immunisation strengthening:** To ensure that countries plan holistically towards long term measles and rubella control, countries and partners should include activities for routine immunisation strengthening, providing linkage to HSS funding support, and for Joint Appraisals and review of support to ensure such linkage.

5.15 **Grandfathering:** Recognising that some Gavi countries have already or are currently benefiting from Gavi support for MR campaign and MSD support under previous policy, based on the **principle of Gavi not replacing government funding or what the countries had committed to fund**, the TWG recommended that the previous policy[14] be applied for support for these countries. However, due to the substantial cost of follow up campaigns, these countries should receive MR follow up campaign support from Gavi, noting that these countries have high MCV coverage and will not need frequent follow-up campaigns. Please see Annex C for countries that will receive support under previous policy and the year in which they will need to start financing the two routine vaccine costs.

5.16 While Gavi's measles and rubella strategy would only financially support vaccination activities, the strategy would require additional supporting efforts for routine immunisation strengthening, for surveillance and for modeling to help with programme planning. Countries and partners are to leverage other Gavi funding platforms such as the Health Systems Strengthening (HSS), Performance Based Funding (PBF), Partnership Engagement Framework (PEF) as well as funds available from other donors such as US-CDC, BMGF, and bilateral donors. There also needs to be strengthened mechanisms to ensure efficiency and effectiveness of campaigns to accompany this increasing investment.

[14] no support from Gavi for routine MR vaccines, and for measles second dose, Gavi pays full measles second dose[14] for a period of 5 years

## C. Other options considered

5.17 The proposed strategy was considered far more favourable against other options:

(a) Option 2: to fund the same activities as in the proposed strategy but without the flexibility to respond to changing epidemiology. While this would cost Gavi the same amount as the proposed option, and would be simple to implement since this requires no changes in how things currently function, it would not allow for country needs and tailoring, such as when a country wishes to conduct a subnational campaign that would make higher impact than a blanket nationwide campaign, or when a country needs to conduct SIAs more frequently, in narrow age groups, in areas that have very low coverage. This option would also not be sufficient to shift the thinking from business as usual, nor for the use of new tools.

(b) Option 3: to fund campaigns but not routine MR vaccines- while this would cost Gavi only an additional investment of US$ 60 million on top of the forecasted expenditure included in the replenishment ask (and US$160 million above the forecast presented to the Board in June 2015), this would not be aligned with Gavi's emphasis on routine immunisation, and also may send the wrong message to countries- that campaigns are important and routine is not. In addition, Gavi will not be able to make use of its leverage on routine immunisation or on financial sustainability through co-financing of the vaccines.

(c) Option 4: to fund measles follow up campaigns, MR catch-up campaigns and co-finance routine vaccines, but not MR follow up campaigns. This would require no additional investment over the forecast included in the replenishment ask, but this option does not provide clear visibility on who will finance the needed follow up MR campaigns. In addition, long term planning and budgeting, which are the desired outcomes of Gavi support, will not be achieved through this option.

## D. Pre-requisites for countries to introduce MR vaccines in a programmatically and financially sustainable manner

5.18 The 2011 WHO position paper on rubella states that countries should achieve and maintain immunisation coverage of ≥80% with at least one dose of a rubella containing vaccine delivered through routine services OR regular SIAs, or both, to avoid a potential increased risk of CRS. From a programmatic and financial standpoint, the TWG considered several options for criteria and the implications regarding which countries would not meet the criteria. Please see Annex D for data on MCV1 routine and SIA coverage and DTP3 coverage that allowed assessment of a number of different potential options. The TWG and SC considered that since the WHO position paper was based on modelling which showed that 80% is a conservative (risk-averse) requirement, Gavi should continue to align with the WHO rubella position paper in terms of coverage criteria, but add an additional filter that Gavi uses to demonstrate programme strength. Hence, countries who meet the following coverage criteria in addition to demonstrating

country financing for monovalent measles first dose, would be able to apply for Gavi support for MR: MCV1 ≥80% (WUENIC[15] estimates) OR measles SIA coverage ≥80% (by a high quality coverage survey) , AND DTP3 coverage ≥70%[16].

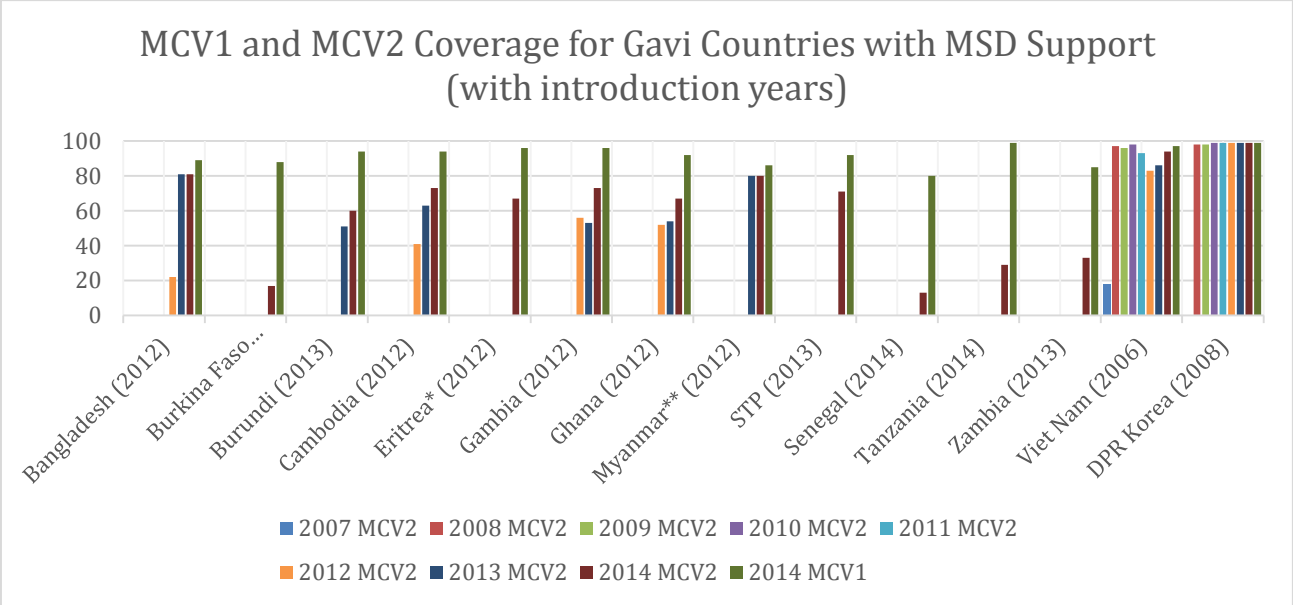
## E. MSD criteria and rationale for support

5.19 The 2009 WHO position paper on measles recommends introducing a routine MSD only when a country has had MCV1 coverage ≥ 80% for three consecutive years. The SC recommends that Gavi application criteria remain aligned with the policy. It also highly recommended continuing to support introduction of routine MSD into the EPI schedule, to introduce a new platform in the second year of life for other vaccines such as booster doses and other health interventions.

5.20 This may also facilitate providing a first dose of measles to children >12 months of age, contributing towards reducing the number of measles susceptible children. As coverage increases, the immunity gain would help to increase the length of time between campaigns.

5.21 Analysis of MSD introduction supported by Gavi shows that countries have been able to reach a reasonably high coverage within 3-4 years of introduction. In addition, ten out of 20 of Gavi's priority countries have a routine MSD and this provides opportunity for coordination among partners to help countries increase coverage.

**Figure 2:** MCV2 coverage (and year of introduction) for 14 countries which received Gavi funding support compared to MCV1 (WUENIC 2014) coverage




* Eritrea: JRF data
** Myanmar: From 2008 to 2011 the vaccine was introduced in some parts of the country. The first year in the graph corresponds to the first year of full country introduction

[15] WHO/UNICEF immunisation coverage estimates
[16] To be revised if WHO position paper or Gavi filter is revised.

5.22 It was acknowledged, however, that more evidence needed to be generated on whether this was providing a second dose or a second opportunity for children who missed the first dose in their first year of life, and studies for this should be incorporated into the PEF by Alliance technical partners. There are also opportunities to conduct programmatic studies to address bottlenecks.

### F.Surveillance

5.23 Since measles, being the '*canary in the coalmine'*, can signal where routine immunisation is faltering, improvement in measles surveillance is important to identify areas of low coverage, improve immunisation coverage in those areas and to control outbreaks. Better surveillance data is a cross-cutting aspect that needs to be funded for countries' programme planning and impact analyses. As many surveillance activities are supported by polio assets and US-CDC, there is concern that measles surveillance will diminish once polio is eradicated. At the global level, there is an estimated funding gap of US$ 2-4 million/year for Global Measles and Rubella Laboratory Network. Other mechanisms of support for MR surveillance activities, such as the Global Health Security (GHSA) and CDC Africa, may develop in the future. However, at present, surveillance quality is far from optimal at the country level. Surveillance quality, assessed using surveillance quality indicators, should form part of Joint Appraisal, and improvements and technical assistance should be provided through HSS funding and PEF where needed.

5.24 As much of the surveillance activities and funding depend on polio legacy planning, it was acknowledged that uncertainty remains and may magnify in the future. Hence, greater engagement by Gavi in the polio legacy planning process currently underway will be essential going forward. Polio assets in Gavi eligible countries are involved in many activities important to Gavi – routine immunisation, campaigns, and surveillance – and just how these assets are transitioned beyond polio is a conversation in which Gavi must play a role.

## 6. Gavi's other workstreams relevant to the measles and rubella strategy

6.1 The PPC in May was requested for guidance on Gavi investment in data and measurement as part of the Gavi Alliance Strategy 2016-2020. The PPC was supportive of including **vaccine-preventable disease (VPD) surveillance** as one of the three suggested areas of focus for potential investments. The PPC noted that work is ongoing to see how to leverage some existing work in the context of one of the key legacies of the polio eradication initiative being the global network for surveillance and outbreak monitoring.

6.2 **Review of Gavi's direct financial support to countries**: this review, to be brought to the Board in June 2016, aims to optimise the design and allocation of Gavi's direct financial support to countries so that it aligns with and supports the goals of the 2016-2020 strategy. The review will also look

into optimising the structure of Gavi's direct financial support windows, which includes synergies and other sources of improved efficiency across the direct financial support windows (HSS, operational cost for campaigns, vaccine introduction grant), and funding levels. This review may wish to consider creating the right incentives in campaign support for high sustained coverage and country ownership.

6.3 **Market shaping:** Currently, only a 10-dose vial presentation of M and MR vaccines is available for Gavi countries, most of which is provided by a single supplier. There is anecdotal evidence of strong interest in 5-dose vials to be used in routine settings to reduce wastage and increase timely coverage by encouraging health workers to open the vials even for small session sizes; however, when countries have routine 2 dose schedules, session sizes will increase. The overall decision by Gavi on offering alternative presentations would need to consider security of supply, cost and programmatic implications.

## 7. Other opportunities in support of Gavi's measles and rubella strategy

7.1 The BMGF provided a grant to WHO and US-CDC in late 2013 to help improve **campaign effectiveness**- to develop a pre-campaign planning checklist, intra and post campaign monitoring guidelines, measles and rubella sero-survey guidelines, and for training and deployment of consultants to assist countries to plan, implement and monitor campaigns, and for improved data access and information sharing. Systematic use of these tools will be important to help improve campaign quality.

7.2 A grant was also made by BMGF for **modeling to guide programme decision making** for optimal age range, interval and geographic scope of catch-up and follow up campaigns and optimal approach to outbreak response. BMGF has also made two grants to **improve MR vaccine affordability and supply** through two additional manufacturers, as currently there is only one supplier of WHO pre-qualified MR vaccines which is also the major supplier of measles vaccines.

7.3 There are also **potential new areas** in which BMGF is interested: improvements in data and development of new tools, most notably for **modeling** as well as involvement of additional modelers, and **improved use of mapping** to be used in concert with currently collected data and expanded modeling work.

7.4 The John Snow, Inc. (JSI) has also developed in collaboration with WHO, a guide for countries to strengthen immunisation and surveillance using measles activities (UMASIS).

## 8. Results Framework

8.1 Results Framework for the proposed Measles and Rubella Strategy, attached as Annex E is available on myGavi.

## 9. Implementation Plan

9.1 Due to the paradigm shift and the need to familiarise all stakeholders including updating the application guidelines for 2017, a year of intensive preparation is needed. Hence, Gavi's strategy, subject to recommendation by the PPC and approval by the Board in December 2015, will come into effect in January 2017, with the requirement of countries funding for monovalent measles first dose to come into effect in 2018 to adapt to the new requirements. In 2016, countries who have been forecasted to conduct follow up measles SIAs may be supported if needed, and this will be done in coordination with the M&RI. The detailed implementation plan, attached as Annex F, is available on myGavi.

## Section C: Risk implication and mitigation and Financial implications

## 10. Risk implication and mitigation for the strategy

10.1 Extension of support may put Gavi in the difficult position of being asked to provide funding for measles and rubella elimination activities even though Gavi's support is to contribute to countries along the control-elimination continuum. This would be mitigated by clear communication on Gavi's support.

10.2 Gavi's support may not stop measles transmission as the support is not for elimination, but new tools and requirement for more frequent review would encourage countries to consider the most cost effective strategies to reduce mortality, as they move along the continuum.

10.3 The quality of campaigns and/or of routine immunisation may also fail to improve in all countries, with resultant measles outbreaks. To mitigate this, all the Alliance partners and countries must have increasing ownership of measles and rubella control, and enabling support must be provided to ensure as much as possible that a very high coverage is achieved and inequities are reduced and that zero dose children missed by routine services are reached.

10.4 With increasing focus on long term planning and budgeting encompassing improvement in the quality and coverage of both routine and campaigns, there will need to be strengthening of the Secretariat to ensure success at every stage. Lack of strengthening of the Secretariat's capacity, both human and technical could pose a major risk for efficiency and effectiveness of Gavi's increasing investment in this field.

10.5 Countries and partners may face difficulties in long term planning and budgeting. Gavi and technical partners will need to well prepare for the rolling out of the strategy, and support should be provided at this stage.

10.6 Roll-out of the proposed measles and rubella strategy may not be sufficient to focus on the need to strengthen routine immunisation systems, an essential pillar for sustained measles control and elimination. However,

measles as one of the central focus of Gavi's coverage and equity work would reinforce both workstreams.

10.7 The funding policies may appear to be complex, but this is outweighed by the benefits of country ownership and equity.

10.8 The potential paradoxical effect of increased CRS is minimised by following WHO recommendations and applying an additional filter for programme strength for countries' application to Gavi for support for introduction of MR vaccine.

10.9 With only one supplier of MR vaccine, there is supply security risk, particularly if there are shifts in the timing of campaigns for large countries. Expansion of the number of manufacturers is a priority to address the risk, and at least one or two new entrants are expected in both the measles and MR vaccine markets prior to 2018, which would ease this risk.

10.10 There is a risk of changes in forecast in terms of country introductions of MR and measles second dose (most likely if SAGE changes its recommendations in terms of criteria for measles second dose introduction), and this will lead to a corresponding change in forecasted expenditures, as is the case for other vaccines.

## 11. Financial implications

11.1 As part of Gavi's replenishment ask, Gavi had forecasted approximately US$700 million in support of its measles and rubella programmes for the period 2016-2020. As per the last forecast presented to the Board in June 2015, this support had been revised to approximately US$ 600 million reflecting updates to forecasts of country introductions and campaigns (e.g. Nigeria MR campaign excluded). The new strategy being proposed would add approximately US$ 219 million to the forecasted expenditure presented to the Board in June 2015 (approximately US$ 130 million incremental to that forecasted in replenishment ask). See Annex G for comparison between forecasted expenditures of replenishment ask, June 2015 Board meeting and the proposed measles and rubella strategy. In addition, continuing this support beyond 2020, it is estimated that US$ 500 million would be required to support the countries from 2021-2025.

11.2 As per the Annex to the CEO report issued in June 2015 to the Board, Gavi's Replenishment Investment Case included a provision of US$ 500 million to ensure the Board had the flexibility to approve new investments in support of the 2016-20 strategy in addition to fully funding projected country demand for vaccines. In addition, the latest financial forecast indicates that due to recent cost savings, Gavi could have a further US$ 450 million available through 2020 (if all donors honour their existing Berlin pledges and those who have not yet pledged for the entire 2016-2020 period extend at projected support levels).

11.3 There will also be a need for additional strengthening of the Secretariat in terms of human resources, considering that without these resources to

oversee this strategic investment, there is a risk in the ability to maximise the impact. Additional resources may also be needed for adaptation of the review processes, and together, this is estimated to cost approximately US$ 2 million over 2016-2020.

## Section D: Implications

### 12. Impact on countries

12.1 Gavi's comprehensive support for measles and rubella will provide countries with predictable financing as well as strengthen country ownership. Requiring a 5 year rolling plan as part of the cMYP that is to be assessed annually and flexible in use will put measles to the forefront as one of the main antigens central to coverage and equity, and encourage greater focus on measles. However, this can potentially be burdensome and countries will require technical assistance from experts as well as support in modelling and risk assessment for programme modification.

12.2 Gavi/country co-financing of both first and second doses of measles and rubella vaccines would relieve the fiscal space constraint the country would find itself in, on top of the obligations for other vaccines.

12.3 Some countries will require time to adapt to the requirement that they meet the funding for routine measles first dose. In this regard, Gavi and partners' advocacy with the ministries of finance and others will be critical.

### 13. Impact on Gavi stakeholders

13.1 Gavi and its technical partners will need to engage with countries and provide technical assistance in a different way. More intense engagement and further mainstreaming and integration with routine immunisation would be necessary.

13.2 Partnership Engagement Framework, including its components such as foundational support for partners may need to reflect the increasing emphasis on measles control as an indicator of programme strength, long-term commitment to rubella control/elimination, additional need for long term planning, annual assessment and review of plans, strengthening of routine immunisation and surveillance.

13.3 Gavi and partners such as the BMGF will need to bring on board other organisations with comparative advantage in providing the required needs, such as technical assistance on routine strengthening prior to and after campaigns, modelling for disease outbreaks, and risk mapping for programmatic needs.

13.4 Gavi requiring countries to fund the first dose of monovalent measles vaccine would free up the funding provided by UNICEF and other donors in this regard. M&RI could also use their existing funds for non-Gavi countries and other needs such as surveillance. Gavi and M&RI will need to further strengthen coordination around funding to maximise impact, technical

assistance, communication, and advocacy and will also need to discuss future collaboration mechanisms.

## 14. Impact on Secretariat

14.1 Gavi's comprehensive support will require a corresponding increase in the need to oversee the strategy to ensure success at every stage. As such, there will be a need to increase the human and technical capacity of the Secretariat to oversee and monitor this investment; the following additional resources are foreseen: one measles and rubella programme manager and one monitoring and evaluation manager dedicated to measles and rubella. In addition, continued strengthening of the country mechanisms is desired, as without it, it will be impossible to drive planning at local level. Further investments in improving campaign may also be required. There may need to be a cross-Alliance team overseeing campaign investment specifically, considering Gavi's investment in vaccines used in campaigns such as measles, rubella, yellow fever, meningitis A, and cholera.

14.2 With guidance from Gavi, country applications for MR SIAs should include a budgeted plan to strengthen RI stating how the country plans to use the measles activities strategically and deliberately to strengthen the routine immunisation system before, during and after the campaigns, and also to clarify roles and assign responsibilities for follow-up actions with timelines.

14.3 The special needs of measles and rubella also mean that committees and groups reviewing countries' proposals (such as the Independent Review Committee) and annual reviews (joint appraisals and High Level Review Panel) will need to be further strengthened to include experts on measles and rubella.

14.4 The Secretariat will need to ensure that funding is disbursed at least 6 months ahead of the planned campaign to facilitate adequate time for preparation for the campaign, and this will in turn depend on the country's early planning. The Secretariat will need to balance this need with the increasing need for oversight of funding disbursed to countries. The Gavi application process (Application to IRC approval to Decision Letter to disbursement) will need to be monitored systematically, streamlined and identified bottlenecks will need to be addressed in a timely fashion.

14.5 As measles disease surveillance is important for programmatic purposes and as it is also closely linked to polio funding, it would be crucial for Gavi to be involved in high level discussions around polio legacy planning in this regard.

## 15. Legal and governance implications

15.1 Subject to the PPC recommending to the Board the approval of the measles and rubella strategy, appropriate legal arrangements will be put in place with relevant partner organisations to implement the strategy and with M&RI in respect of the outbreak response fund.

## 16. Consultation

16.1 Consultations with stakeholders including some country representatives, technical experts, Alliance technical partners and the M&RI were done through formal involvement in SC who provided guidance to the TWG or bilaterally. Please refer to points 4.1 to 4.2 on the process of consultation.

## 17. Gender implications

17.1 The recommendation for Gavi's measles and rubella strategy will bring continuing benefit to future women through protection at a young age against rubella infection, and preventing Congenital Rubella Infection in babies born to these women. In addition, vaccination of the children will have indirect benefits for women due to fewer chances of infection transmission and thus helping to prevent CRS.

## Annexes *(available on myGavi)*

Annex A: Options for Gavi's measles and rubella strategy presented to Gavi's PPC meeting in May

Annex B: Terms of Reference and List of members of Steering Committee and Technical Working Group on Gavi's measles and rubella strategy

Annex C: Countries for whom Gavi will apply previous policy of support

Annex D: Options considered by the TWG for criteria for MR introduction to be able to apply for Gavi support

Annex E: Results Framework for Gavi's measles and rubella strategy

Annex F: Detailed Implementation Plan

Annex G: Comparison of forecasted expenditures between replenishment ask, version 11 presented to the Board in June 2015 and the proposed measles and rubella strategy