

21-22 November 2013

Subject: GAVI engagement with graduating countries

Report of: Hind Khatib-Othman, Managing Director, Country Programmes

Authored by: Santiago Cornejo, Country Programmes; Aurelia Nguyen and

Melissa Malhame, Policy and Market Shaping;

Agenda item: 14

Category: For Decision

Strategic goal: SG3 - Financing & SG4 - Market shaping

Section A Overview

1 Purpose of the report

1.1 Following the discussion on graduation at the Board retreat held in March 2013, the purpose of this cover note is to present to the Board an approach for GAVI's engagement with graduating countries. The detailed report presented to the Programme and Policy Committee (PPC) is attached to this cover note.

2 Executive Summary – Update

- 2.1 Due to a scheduled joint meeting with the AFC, the PPC had insufficient time for a full discussion on the Secretariat recommendations in relation to support to be provided to graduating countries. Specifically, the PPC requested further time to discuss and understand the Secretariat recommendations on HSS support for countries with a DTP3 coverage below 90% and providing access to a graduation grant for graduating countries (recommendations 2.1 (a) ii and iii in the attached PPC report). The PPC therefore deferred a decision on those particular recommendations until its next meeting scheduled for 2014.
- 2.2 At the end of the meeting PPC members recognised that the PPC recommendation as agreed (see below in paragraph 3.1) only applied to countries who would enter the graduation track after 31 December 2013 and therefore countries that are currently on the graduating track would not have access to cash support to assist them in preparing for graduation. Since the PPC meeting, representatives of graduating countries have raised this as a strong concern with the Secretariat.
- 2.3 In view of the above concerns, the Chair of the PPC has requested that the PPC hold a teleconference to discuss these issues prior to the Board



meeting. The Chair of the PPC will be able to update the Board on those discussions at the meeting in Pnomh Penh. Section 4 of this report provides clarifying details not contained in the attached paper to the PPC on the financial implications of providing HSS support to countries currently in the graduation process with a DTP3 coverage below 90% until they graduate and of providing a graduation grant to all countries.

2.4 When discussing the attached report, PPC members commended efforts to establish a more strategic approach for graduating countries enabling them to maintain sustainably funded immunisation programmes when GAVI support terminates. PPC members stressed the importance of ensuring political will and engagement at the highest levels to ensure sustainability, which was not highlighted in the proposed approach. The Secretariat confirmed that the GAVI Alliance's high-level advocacy with ministries of finance and health, parliamentarians, and others to anticipate and address continuing weaknesses and financing of routine immunisation programs after graduation will be a priority. GAVI is supporting the Sabin Vaccine Institute and the African Development Bank to conduct these activities in nine graduating countries.

3 Recommendations

- 3.1 The PPC recommended, subject to AFC and EC endorsement for section (c) (which was subsequently provided), to the GAVI Alliance Board that it:
 - (a) <u>Approve</u> GAVI's strategic approach for graduation as set out in Section B.3 of Doc 13, by allowing countries to apply for new support (cash and vaccine support) until the end of the next calendar year after the date they have been informed of their expected graduation.
 - (b) <u>Request</u> the Secretariat to conduct analyses and consultations to develop and propose instruments to support access to affordable prices for all Lower Middle Income Countries (LMICs), including graduated countries and non-GAVI LMICs. Options would be brought to the Board for consideration in 2014.
 - (c) <u>Approve</u> an amount up to US\$ 2 million to be added to the 2014 Business Plan for the GAVI Secretariat and partners to scale-up engagement with graduating countries.
- 3.2 As outlined in Section 2 above, the PPC is anticipated to meet by teleconference before the November 2013 Board meeting to discuss other aspects of GAVI's engagement with graduating countries not addressed in the above recommendations and if the PPC recommendation changes as a result of this meeting, the Board will be updated at its meeting.

4 Content and Risk and Financial Implications – Update

4.1 Some countries currently on the graduation track still have areas that need improvement to ensure strong and sustainable immunisation programmes beyond graduation (see annex in MyGAVI for a summary of the findings



- from in-country graduation assessments). Additional resources will need to be invested to address these challenges.
- 4.2 The Secretariat envisaged making available two types of cash based support to graduating countries: 1) HSS support; and 2) a graduation grant. Each would address a different need. The current PPC recommendation to the Board, if adopted, would only enable countries that will enter the graduation track after the Board meeting to apply for HSS support.
- 4.3 Under the current PPC recommendation, countries that are currently in the graduation track would not be eligible to apply for HSS support. At its meeting in October, the PPC did not have the time to fully discuss the proposal for a graduation grant that would address specific needs highlighted in countries' graduation plans (formerly known as "transition plans"). Such graduation grants would be available to all graduating countries those that have already entered the graduation track and those that will do so in 2014 and beyond. The remainder of this Section will provide clarifying information regarding the Secretariat's original proposals to the PPC on the graduation grant and the provision of HSS support to currently graduating countries. This clarifying information will also be shared with the PPC in preparation of its discussion of these proposals before the Board meeting.

Graduation grants

Objective

4.4 The Secretariat had proposed that all graduating countries would be eligible to receive "graduation grants" from GAVI for the duration of the graduation process. Graduation grants would target the needs highlighted in the graduation plans and be modest awards (smaller allocations than the current HSS country allocation, see below for further details). It is expected that these grants will fund interventions that are linked to graduation and deliver "quick wins" to strengthen the capacity of immunisation programmes.

Scope of the graduation grants

- 4.5 The purpose of graduation grants would be to contribute to funding needs identified in the graduation plans. Therefore access to these grants would be limited to those countries that have a costed graduation plan. Taking into account that GAVI is phasing out funding in these countries, they would not fund recurrent expenditures (e.g. salary top-ups, per-diems, transportation costs to deliver vaccines, etc.). Graduation grants would be targeted specifically to **time-limited** in-country activities to support **catalytic investments**, such as capital investments or capacity building.
- 4.6 Some examples of the type of interventions that a graduation grant could support include:
 - investments in national regulatory authorities and laboratory capacity;



- technical assistance to design and improve procurement processes;
- technical assistance to set-up and train NITAG members;
- cost-effectiveness analysis for future vaccines to improve decision making processes;
- implementation of communication strategies to face the growing antivaccine challenge.

Process to access the grants

4.7 If the Board approves GAVI offering graduation grants to graduating countries, the Secretariat would develop a simplified process for accessing the grants. Given the nature of the graduation grants, it is proposed that only countries receiving GAVI vaccine support (i.e. not those countries who have access to GAVI prices, receive AMC funding or support for IPV) would be eligible to apply for a graduation grant. An eligible country could apply for a graduation grant once for an amount that could be spent during the period until the country graduates from GAVI support.

Financial implications

- 4.8 The Secretariat considered that the size of a graduation grant for each country would be based on needs identified through their graduation plans (bottom-up costing), rather than having a fixed formula to calculate country allocations. This approach accounts for the fact that it is not clear whether all graduating countries would request this type of support and that the cost of supported interventions could range significantly.
- 4.9 It would be expected that the amount requested for a graduation grant would be smaller than a country allocation for HSS support. The Secretariat has conducted a costing exercise of the graduation plans it has received to date. It was found that the costed graduation plans involved similar amounts as the levels of vaccine introduction grants for the relevant countries. The costs of the vaccine introduction grants were therefore used as a proxy for estimating the funding countries would require for a graduation grant.
- 4.10 Accordingly, the graduation grants were calculated as US\$0.80 per surviving infant per year. This number was then applied to the 20 graduating countries that would be eligible for a graduation grant (including the three countries that are anticipated to enter the graduation track next year). This gave a total estimate of a little more than US\$ 6 million per year to cover the graduation grants of 18 countries (approximately 1.5% of the projected cash envelope in GAVI's financial forecast). The Secretariat considered this number to be conservative as it assumes that all graduating countries will access funding for a graduation grant each year.

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¹ Ukraine and Cuba were not included in the calculations as they do not receive vaccine support and would not be eligible for a graduation grant as proposed. India was not included in these calculations either.

GAVI

Report to the GAVI Alliance Board

HSS support for countries currently in the graduation track with DTP3 coverage below 90%

Objective

4.11 The aim of providing currently graduating countries with a DTP3 coverage below 90% objective access to HSS support would be to address systemic issues in the delivery of primary health care services. The expected outcome of the extension of this support will be to increase DTP3 coverage by the end of graduation.

Scope of the support

- 4.12 As mentioned in Section 2 above, countries entering the graduation track from 2014 will be able to access HSS support for the duration of the graduation process because they will have 18 months to apply for it after they have been informed of their graduation. The Secretariat had proposed that currently graduating countries with a DTP3 coverage below 90% should also have the possibility to receive HSS support until the date of graduation.
- 4.13 The scope of HSS support for currently graduating countries with DTP3 coverage below 90% would be the same as the HSS support GAVI provides to other countries (clearly linked to immunisation outcomes). However, the activities that would be funded for these countries would need to be designed strategically to ensure sustainable impact on coverage while avoiding further dependency on external support after graduation.

Financial implications

- 4.14 Out of the 17 currently graduating countries, 5 countries have DTP3 coverage below 90%. Each of these countries have a current HSS grant that expires prior to the date they graduate. Under this proposal, country HSS grants could be extended until their graduation date. These countries are Azerbaijan, Bolivia, Honduras, Indonesia, and Papua New Guinea. To calculate the cost of continuing HSS support for these countries, the average annual grant amount for each country was multiplied by the number of years between the end of their current HSS grant and the termination of GAVI support. On that basis, the total cost for continuing the current HSS grants in these 5 countries until the time all of them have graduated is US\$20 million. Within that amount, the annual estimates will vary given that the sizes of the HSS grants and graduation dates of countries differ considerably.
- 4.15 Given that the proposed graduation grants and additional HSS support for selected currently graduating countries are cash grants, their financial implications (see paragraphs 4.8-4.10 and 4.14, respectively) would be dealt with under the Programme Funding Envelope mechanism. For 2014, the amounts involved would be relatively small and could be accommodated in the amount requested for the 2014 Programme Funding



Envelope as set out in Doc 06. For subsequent years, the estimated amounts would be included in future updates of GAVI's financial forecast and in the Programme Funding Envelope for each year.



9-10 October 2013

Subject: GAVI engagement with graduating countries

Report of: Hind Khatib-Othman, Managing Director, Country Programmes

Authored by:

Santiago Cornejo, Country Programmes; Aurelia Nguyen and

Melissa Malhame, Policy and Market Shaping;

Agenda item: 13

Category: For Decision

Strategic goal: SG3 - Financing: global predictability/national sustainability

Section A Overview

1 Purpose of the report

1.1 Following the discussion on graduation at the Board retreat held in March 2013, the purpose of this paper is to seek the endorsement of the Programme and Policy Committee (PPC) of the proposed GAVI's approach for graduation.

2 Recommendations

2.1 The PPC is requested to

Recommend to the GAVI Alliance Board that it:

- a) Approve GAVI's strategic approach for graduation as set out in Section B.3 of Document 13, by:
 - i. allowing countries to apply for new support (cash and vaccine support) until the end of the next calendar year after the date they have been informed of their expected graduation;
 - ii. allowing countries with a DTP3 coverage below 90% to apply for HSS support for the duration of the graduation process;
 - iii. providing also access to *graduation grants* to all graduating countries for the duration of the graduation process.

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b) Request the Secretariat to conduct analyses and consultations to develop and propose instruments to support access to affordable prices for all Lower Middle Income Countries (LMICs), including graduated countries and non-GAVI LMICs. Options would be brought to the Board for consideration in 2014.

GAVI

Report to the Programme and Policy Committee

2.2 The PPC is also requested to

Recommend, subject to endorsement by the Audit and Finance Committee, to the Executive Committee that it, in turn, recommend to the Board to approve an amount of up to US\$ 2 million to be added to the 2014 Business Plan for the GAVI Secretariat and partners to scale-up engagement with graduating countries.

3 Executive summary

- 3.1 In March 2013, the Secretariat presented a report to the Board Retreat summarising early lessons from the work with graduating countries. This paper follows upon that report by presenting a proposal to strengthen GAVI's strategic approach to graduating countries and includes the financial implications of such an approach.
- 3.2 GAVI's current engagement with graduating countries revolves around implementation of the co-financing policy to achieve financial sustainability of the vaccines introduced with GAVI support. The GAVI Alliance conducts many activities under Strategic Goal 3 of the Business Plan to support countries to achieve this important but narrow objective. GAVI needs to broaden its approach to graduation due to 1) the large number of countries currently in graduation status, and the pace at which additional countries will enter graduation phase; 2) graduating countries are experiencing a wider range of challenges than previously anticipated which will require additional focus and which cut across all of the Strategic Goals; and 3) the graduation phase representing the last opportunity that GAVI has to positively support countries, both financially and technically.
- 3.3 This paper proposes a strategic approach to graduation by expanding the scope and coordination of current activities being conducted in graduating countries (i.e. improving sustainability more broadly than financing GAVI-supported vaccines alone) and by intensifying engagement with graduating countries. The paper also recommends that graduating countries need to have access to cash support to fund activities to strengthen their programmes during the graduation phase. Currently nearly 60% of graduating countries do not have access to cash support from GAVI.
- 3.4 Linked to a comprehensive approach to graduation is the issue of access to affordable vaccine prices to sustain full financing of the immunisation programmes and the ability to introduce new vaccines after graduation. This paper reviews the considerations for identifying and evaluating potential solutions to support graduating countries. It is proposed to include non-GAVI Lower Middle Income Countries since this would improve GAVI's ability to develop economically viable instruments and to maintain tiered pricing principles within countries of similar income levels. While the other elements of the strategic approach to graduation are brought for Board approval, specific recommendations regarding access to affordable prices will not be brought to the Board for decision until 2014.



- Broadening the approach of engagement to graduating countries as 3.5 proposed in this paper would enable the Alliance 1) to ensure that immunisation performance can be maintained or improved after graduation; 2) to help countries be in the best position to financially sustain their routine programmes and new vaccines; 3) to ensure affordability of new vaccines for graduated countries; and 4) to learn from country experiences in preparation for graduation. Such an approach is consistent with the expectations of a wide range of GAVI stakeholders and provides useful lessons to GAVI to assess potential future engagement with countries currently not eligible for GAVI support (e.g. LMICs). Some of the discussion presented in this paper suggests that the limited assistance for graduating countries implied by GAVI's eligibility policy and graduation procedures could in the future constrain the potential impact of the Alliance on vaccine-preventable child mortality. The paper is not requesting the PPC to reopen the discussion on GAVI's eligibility; however, the implementation of this approach will provide valuable lessons that will enrich the discussion of GAVI eligibility for next business plan cycle.
- 3.6 The implementation of this proposal would increase the workload of the GAVI Alliance. The workload to support the implementation of the cofinancing policy in eligible countries is already increasing as countries introduce more vaccines in addition to their existing need to pay for their traditional vaccines. Additional resources will be needed to implement this proposal.

4 Risk implication and mitigation

- 4.1 Without a specific comprehensive exit strategy, countries could graduate without a sustainably funded immunisation programme, a situation that is not aligned with GAVI's objective and expectations. With this in mind, the Secretariat has developed this strategic approach to graduation which outlines how the Alliance could support countries during the graduation phase.
- 4.2 There is a risk that the approach has not captured the relevant exceptional circumstances and/or that the suggested approach is not sufficient to address the problems within GAVI's mandate. The Secretariat has tried to mitigate this risk through an open and inclusive process taking into account lessons learnt so far from graduating countries.
- 4.3 It is important to recognise that the new comprehensive approach cannot ensure that all graduating countries will have high performing immunisation programmes after GAVI support ends. Some graduating countries are facing systemic issues that will require greater time and effort to be resolved. However, this approach aims to expand the support to these countries to improve their performance during the graduation phase and sets the foundations for work post-GAVI support.
- 4.4 Transparency, accountability and fiduciary risks will be assessed in accordance with the Transparency and Accountability Policy (TAP).



5 Financial implications: Business plan and budgets

- 5.1 It is foreseen that additional resources in the business plan would be required to support Alliance partners to implement this comprehensive approach to graduation. Within the current GAVI Programme Funding budget and forecast an additional US\$ 2 million was added in 2014 and its utilisation will be subject to future needs.
- 5.2 Individual country cash support would require additional resources for particular countries. These would come under the programme funding envelope and would be reported on in accordance with the amended Programme Funding Policy or be decided on by the Executive Committee of the Board where financial implications may set policy precedents.

Section B Content

1 Policy background

- 1.1 Since GAVI's creation in 2000 only three countries have graduated from GAVI support¹. However, these countries did not go through a graduation phase, because before 2011, graduation was regarded simply as the time when a country reached a certain income threshold and GAVI support ended. The graduation policy approved in 2009 changed this, introducing a five-year graduation period to provide countries with a "softer landing".
- 1.2 The GAVI Board approved the graduation policy and the revision of GAVI's eligibility policy, effective January 2011. GAVI's eligibility policy defines the criteria and the list of countries that are eligible for GAVI support. The eligibility threshold is adjusted annually to account for inflation and the current threshold for 2014 is US\$ 1,570 GNI per capita. GAVI's eligibility threshold is updated each July after the World Bank releases the latest GNI data. About a month after GAVI informs countries of the new eligibility changes, they have one last opportunity to apply for GAVI support. However, this timeline does not provide sufficient time for a productive policy dialogue with countries to decide what support the country should apply for in their last round. As of January 2014, 20 countries will be in the graduation phase, three of which enter graduation that same year². Based on the latest GNI per capita projections, it is expected that one to two additional countries will enter the graduation phase each year between 2014-2018 (see graph 1).

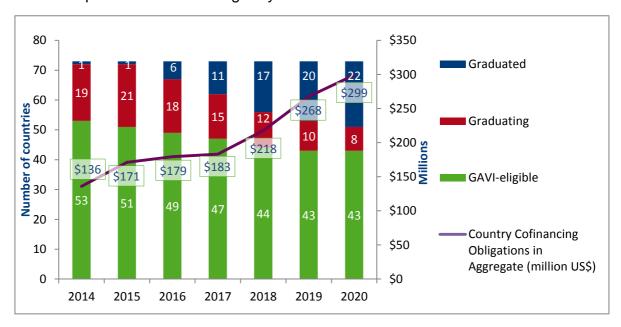
² Nicaragua, Papua New Guinea and Uzbekistan.

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¹ Bosnia & Herzegovina, China and Turkmenistan. Albania's final year of support is 2013





Graph 1: Evolution of Eligibility

- 1.3 The graduation policy only covers GAVI's operational procedures with the country during the graduation phase. According to the graduation policy, when a country enters graduation it can no longer apply for additional support for New Vaccines (NVS) or for Health System Strengthening (HSS). This policy and the co-financing policy specify that GAVI's graduation phase for vaccine support will last five years from entering graduation irrespective of the duration of the GAVI's vaccine approval. However, the policy is not the same for HSS. For some graduating countries, the original approval of NVS is extended after entering graduation to ensure the five years of support but this is not done for HSS support. Furthermore, after approving the graduation policy in 2009, the Board allowed graduating countries to apply one last time for NVS. This last round of applications occurred in 2011 and created a new cycle of support for NVS³, also not offered for HSS. These decisions resulted in a misalignment between the duration of support for HSS and support for new vaccines during the graduation phase.
- 1.4 Through the graduation period it is expected that countries will gradually prepare to take over responsibility for financing GAVI supported vaccines as the financial support from GAVI decreases. GAVI's co-financing policy is intended to support this transition offering countries that enter the graduation process a grace year to adjust their budgets for subsequent increases of their co-financing requirements (see graph 2). Co-financing contributions during graduation will rise linearly to reach the projected full GAVI price in five years, offering annual co-financing targets that countries need to achieve. Besides the co-financing policy, no other GAVI policy complements the graduation policy to allow different types of support, procedures and objectives during this phase. For example, HSS support

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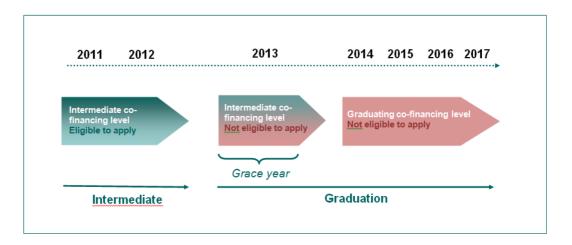
³ For vaccines approved in this last round GAVI approved the support for four years instead of five because a grace year was not required.



does not have specific requirements that differentiate graduating countries from other GAVI eligible countries. Furthermore, the co-financing targets used to monitor country's performance towards achieving financial sustainability of GAVI-supported vaccines are the only specific graduation targets for countries during this phase.

1.5 In summary, GAVI policies related to graduation are limited to an exit strategy to achieve financial sustainability of the vaccine support but lacks of a comprehensive and aligned approach for graduation.

Graph 2: Transition to graduation



2 GAVI's current engagement with graduating countries and lessons learnt

GAVI's current engagement with graduating countries

- 2.1 The Alliance designed activities and processes to support and monitor the implementation of the co-financing policy for countries to achieve financial sustainability of the GAVI supported vaccines during the graduation phase. These targeted efforts for graduating countries are mainly grouped under Strategic Goal 3 of the GAVI Alliance business plan, "Increase and sustain allocation of national resources to immunisation". Some of the key areas of work to support graduation include: monitoring co-financing performance, updating GAVI's fiscal space analysis, assessing potential bottlenecks to achieve financial sustainability of vaccines and developing transition plans, providing technical support to strengthen national capacity, and steering global, regional and country advocacy on financial sustainability. The Annex in myGAVI provides more details on these activities.
- 2.2 The GAVI Secretariat coordinates this work through the Immunisation Financing & Sustainability task team (IF&S). The IF&S task team reports to the Secretariat and comprises Alliance partners and independent organisations, including UNICEF and WHO, as well as the Bill & Melinda Gates Foundation (BMGF) and the Sabin Vaccine Institute. Even though the Alliance identified critical efforts to support graduating countries, the prioritisation, resourcing, scope and performance of these efforts have not



always been aligned with the importance of this issue. At global level the Alliance coordinates and provides technical support on issues regarding co-financing and graduation, with the primary focus being monitoring cofinancing payments and assessing financial sustainability issues. At regional level, regional focal points support immunisation financing issues including those related to graduation and co-financing, but not all regions have full-time staff supporting countries and even where they exist their time is not always prioritised for these issues. Furthermore, GAVI has not always been able to draw on the best expertise available across the Alliance. For example, while the World Bank was instrumental in shaping the Alliance's thinking on financial sustainability, they have not been involved in any GAVI activities since 2010 (i.e. since the advent of the new eligibility and graduation policies). Strategic Goals 1 and 2 of the business plan also provide resources to WHO and UNICEF to support areas that need improvements in graduating countries (e.g. NRA, HSS, NITAG, etc.). However, these resources have not always been prioritised to support graduating countries nor coordinated with the efforts undertaken within Strategic Goal 3.

- 2.3 There are additional areas of work within GAVI that also target graduating countries, but are not included in Strategic Goal 3 and therefore are not coordinated by the IF&S task team. One such area is GAVI's work to ensure access to affordable prices after graduation. The GAVI Alliance is securing commitments on prices for graduating countries directly with manufacturers. GAVI has negotiated stable prices for pentavalent and rotavirus vaccines for graduating countries when these vaccines were introduced with GAVI support. Stable prices are also guaranteed for all GAVI countries for pneumococcal vaccine under the pilot Advance Market Commitment (AMC), regardless of introduction status at the time of graduation. Prices for other GAVI supported vaccines (e.g. measles, MR, MenA and yellow fever) are already affordable across markets. In this sense, no additional negotiation is required from GAVI for countries who have already introduced those vaccines. These negotiations were successful but they were conducted individually rather than systematically.
- 2.4 The second area of work targeting graduating countries that is outside Strategic Goal 3 is the evaluation of the graduation policy and of graduated countries by GAVI's Monitoring & Evaluation (M&E) team. The Secretariat provided an M&E framework including a proposed set of indicators for the continuum from graduating to graduated countries to the Board Evaluation Advisory Committee. This framework is already being implemented with the evaluation of two graduated countries this year.

Lessons learnt from current engagement with graduating countries

2.5 The graduation policy is fairly new as it was introduced in 2011 and mainly focused on financial sustainability of vaccines introduced with GAVI support. The model of engagement with graduating countries focuses on the early detection of potential bottlenecks for achieving financial sustainability of the GAVI supported vaccines after graduation. The



assessments of bottlenecks lead to the development of plans that will guide activities at country level during the graduation phase. These plans are also used at global level to monitor country progress and to direct the provision of technical assistance and policy dialogue. The assessments and plans were however, designed mainly to ensure financial sustainability of vaccines post-GAVI support.

- 2.6 Despite the positive fiscal space prospects for these countries, there are still areas that can be improved in order to ensure strong performance of immunisation programmes beyond graduation. The assessments carried out beyond financing have so far identified that: a) countries (and local partners) need better information about the graduation process and about access to prices post-GAVI; b) countries could re-examine vaccine procurement approaches in order to improve competition and affordability; c) many of the graduating countries will need technical assistance to build up the capacity and functioning of their NRA (national regulatory authority): and d) some countries may need technical assistance to strengthen their National Immunisation Technical Advisory Groups (NITAGs) to help set priorities for future introductions. The main concern for all graduating countries was accessing affordable prices for vaccines introduced with GAVI support and also for future vaccine introductions. The Annex in myGAVI provides additional information on the key challenges identified through the assessments conducted in graduating countries in 2012.
- 2.7 While in some countries the assessments identified bottlenecks for performance on coverage (e.g. in Moldova anti-vaccine movements were identified as a key bottleneck), in most countries these issues were not assessed. Countries' economic development and fiscal capacity may not correlate with the level of health system strengthening. Accordingly some graduating countries have poorer vaccination coverage rates than nongraduating countries (e.g. Indonesia, Timor-Leste and Papua New Guinea). The next cohorts of graduating countries may be even weaker due to many country's' economic development outpacing institutional and health systems development. Poor immunisation coverage points to systemic problems in the health systems of these underperforming countries. While the assessments in graduating countries were intended to identify financial sustainability problems, there were missed opportunities to assess the sustainability of GAVI HSS support and to coordinate efforts to improve immunisation systems in graduating countries.
- 2.8 Based on early experiences with this process, it has become evident that despite some positive aspects of engagement with graduating countries and the fiscal space prospects of these countries, there are still areas that can be improved in order to ensure strong and sustainable immunisation programmes beyond graduation, such as procurement, regulatory oversight and priority setting. In a few graduating countries significant efforts are still needed to improve coverage and strengthen immunisation programmes performance. The revised approach will require additional focus that cuts across all business plan Strategic Goals because graduating countries are grappling with a wider range of issues than



previously anticipated. Further, the graduation phase represents the last opportunity that the GAVI Alliance has to positively support countries, both financially and technically. The proposed new approach is timely due to the large number of countries currently in graduation status and the pace at which additional countries will enter the graduation phase.

2.9 This paper describes a comprehensive and strategic approach for GAVI's graduating countries. The objectives of this approach are: 1) to ensure that immunisation performance can be maintained after graduation; 2) to help countries be in the best position to financially sustain their routine programmes and new vaccines; 3) to ensure affordability of new vaccines for graduated countries; and 4) to learn from country experiences in preparing for graduation. This approach will require adjusting the misalignments from previous policy decisions and prioritising and better coordinating resources to intensify the engagement with graduating countries.

3 Request for Board decisions

Allowing countries to apply for new support

- 3.1 The proposal to strengthen GAVI's approach to graduation relies on improving the policy dialogue at country level. Findings from the assessments in some graduating countries indicated a desire to introduce additional vaccines with GAVI support but applications were not made because of misunderstandings about the implications of graduation. Ideally GAVI would engage with these countries before they pass the eligibility threshold. However, GNI projections are estimates that tend to fluctuate and this complexity does not provide a favourable environment for a productive policy dialogue with countries.
- 3.2 As such the Secretariat recommends the Board to adjust the terms of the graduation policy to align with the co-financing grace year to allow countries to apply for new support for one additional year. The proposed adjustment would imply that a country had until the end of the year following GAVI's updated eligibility threshold (i.e. countries would have approximately an 18-month window to submit an application for new support).
- 3.3 The adjustment in the graduation policy would apply to countries that entered graduation from 2014 onwards⁴. The policy adjustment would not be grandfathered to the first 16 countries that entered the graduation phase as they already had a one year period to apply for support⁵. The proposed adjustment would require minor additional resources to the GAVI financial forecast, given the existing inclusion of planned introductions from graduating countries. This adjustment in the graduation policy would provide valuable additional time to facilitate the policy dialogue and would

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⁴ In 2014 it would apply to three countries only.

⁵ This proposal is enshrining what was already offered to the first set of graduating countries.



ensure countries have the best information/data available to make an informed decision whether or not to introduce a new vaccine.

Access to cash support during the graduation phase

3.4 Some graduating countries still have areas that need improvement to ensure strong and sustainable immunisation programmes beyond graduation. They will need to invest additional resources to address these challenges. These are countries who also need to increase their budgetary allocations significantly to fulfil their co-financing requirements and who have mostly been phased out by other immunisation donors. Additionally, there is a lack of alignment in the approval of HSS support and the duration of the graduation phase with, about 60% of graduating countries with no HSS support. Furthermore, almost all HSS support to graduating countries will end before vaccine support ends, Timor-Leste being the only exception⁶. This lack of alignment limits the options for graduating countries to address weaknesses and gaps as they are not eligible to apply or renew HSS support when they enter the graduation phase.

Graduation grants

- 3.5 The paper recommends to the Board that through accessing "graduation grants" countries would be eligible to receive cash support from GAVI for the duration of graduation. Graduation grants would target the needs highlighted in the graduation plans and as such would be expected to be modest awards (smaller country allocation than the current HSS country allocation). Section 4 describes the process for countries to access these grants.
- 3.6 The purpose of graduation grants would be to contribute to funding needs identified in the graduation plans. Therefore access to these grants would be limited to those countries that have a costed graduation plan in place. Taking into account that GAVI is phasing out funding in these countries. graduation grants should not increase the dependency on external partner support for the routine delivery of immunisation services and thus they should not fund recurrent expenditures (e.g. salary top-ups, per-diems, transportation costs to deliver vaccines, etc.). Instead graduation grants should be targeted to time-limited in-country activities to support catalytic investments, such as capital investments or capacity building. The findings of the assessments conducted in graduating countries recommends this type of investment, including: implementation of communication strategies for immunisation to face growing anti-vaccine challenges; investments in national regulatory authorities and laboratory capacity; covering cold chain gaps; or conducting disease burden studies and cost-effectiveness analysis for future vaccines to improve decision making processes.

 8 Graduation Plan is the new term for the current Transition Plan (see Section 4).

⁶ Potentially it could be aligned in Uzbekistan but it is pending the submission and approval of the application.

⁷ To be eligible a country must receive vaccine support from GAVI. A country just benefitting from access to GAVI prices, AMC funding or IPV support will not be entitled to cash support. The graduation phase last for as long as they receive vaccine support.



The exact need for each graduating country cannot be defined until the 3.7 country conducts a graduation assessment and plan. Also the cost of the potential interventions for support could range significantly and it is not clear if all graduating countries would demand this support. It is therefore proposed that funding for each country is based on needs identified through their plans (bottom-up costing), rather than having a fixed formula to calculate country allocations. The total amount for graduation grants would be included as part of the 15-25% cash support envelope approved by the Board in 2011 in Kigali. Since graduation grants would be funded from the current cash envelope (already factored into GAVI's future financial projections), this Board decision would not have additional cost implications to GAVI's existing financial forecast. In addition, as the execution of cash support is not yet meeting the 15-25% commitment, new graduation grants would not be taking away funding from poorer GAVI eligible countries.

HSS support for graduating countries with a DTP3 below 90%

It is important to highlight that the graduation grants are not intended to 3.8 address issues of low coverage. Low immunisation coverage in underperforming countries is due to systemic issues in the delivery of primary health care services. These systemic issues can be resolved with longterm solutions that require strategic and larger investments, such as those offered through GAVI HSS. It is worth noting that only four of the six graduating countries with DTP3 coverage below 90% have access to HSS support, and only one has HSS support for the duration of the graduation phase⁹. The Board is therefore recommended to extend access to HSS support for countries with a DTP3 below 90% for the duration of the graduation phase. The financial implications of extending HSS support in those five countries for the graduation phase would be of around US\$ 20 million¹⁰. A key assumption in this cost estimate is that HSS support to future graduating countries (beyond the current 20 countries) would be aligned for the duration of their graduation phase and therefore within the 15-25% cash support envelope. If the Board approves the extension of HSS support in these low-performing countries activities would need to be designed strategically to ensure sustainable impact on coverage while avoiding further dependency on external support after graduation.

Scaling-up technical support in programmatic areas to graduating countries

3.9 The current agenda with graduating countries is already ambitious and resources are scarce, so expanding the scope of work to include this broader engagement would require additional resources through the business plan. Graduation grants would help fund some of the technical assistance needs and efficient planning and coordination with other activities of the business plan would produce economies of scale.

⁹ This does not included Ukraine with a DTP3 lower than 90% but not receiving vaccine support.

¹⁰ This amount does not include a potential extension for India as the country uses a different allocation.



Nevertheless additional resources will be required to expand the scope of the assessments and to intensify the technical assistance and monitoring of graduation strategies. The Board is requested to approve US\$2 million of additional funding to support the new activities and needs of the GAVI Secretariat and partners in 2014.

GAVI to conduct the required analyses and consultations to develop and select instruments to support access to affordable prices in GAVI graduates and non-GAVI Lower Middle Income Countries. These instruments would be brought to the Board for consideration in 2014.

3.10 At its retreat in April 2012, the GAVI Alliance Board requested that GAVI explore the potential for GAVI to assist graduating and Lower Middle Income Countries in gaining access to affordably priced vaccines. ¹¹ The Secretariat proposes to pursue the development of procurement instruments for a number of its currently supported vaccines for all GAVI graduates and all non-GAVI Lower Middle Income Countries. It has identified a number of potential instruments and identified a preliminary structure for evaluating the different options. Research and consultations are now required to refine the needs of countries and thus inform the selection of the most relevant instrument, leading to a recommendation to the Board in 2014.

4 Implementation of the new approach to graduation

4.1 This section of the paper describes the framework to implement GAVI's comprehensive approach to graduation.

Scaling-up engagement with graduating countries

GAVI has pro-actively engaged with graduating countries through an ongoing policy dialogue which has enabled to identify bottlenecks and country mitigation. The proposed approach goes a step further by formalising and expanding the assessments to comprehensive graduation plans which include stronger support and monitoring. Graph 3 displays the four elements of the proposed approach:

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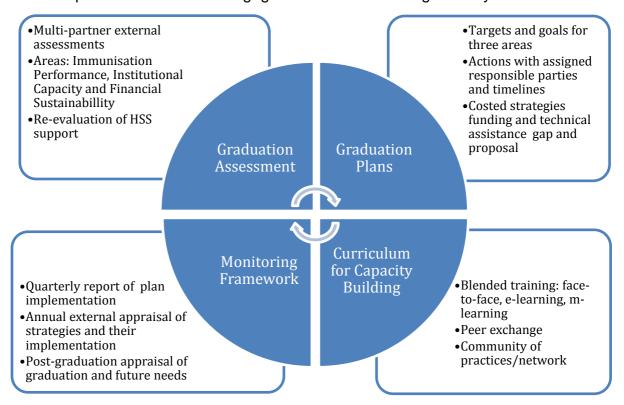
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¹¹ GAVI Alliance Board Retreat. Note of discussions, 16-17 April 2012.

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Graph 3: Framework for Engagement with Graduating Country



- 4.2 The first element of the framework is the graduation assessment. Assessments follow agreed guidelines in order to ensure consistency within all countries. This proposal expands the scope of the guidelines in order to ensure that the following dimensions are assessed in all graduating countries:
 - A. Immunisation Performance:
 - i. Coverage of new and underused vaccines
 - ii. Equity in immunisation coverage
 - iii. New vaccines introduction
 - B. Institutional Capacity:
 - i. National Regulatory Agency (NRA)
 - ii. NITAG
 - iii. Planning and budgeting
 - iv. Procurement
 - v. Legislation
 - C. Financial Sustainability:
 - i. Availability of fiscal space for vaccines



- ii. Predictable and secured funding for vaccines
- iii. Predictable and secured funding for delivery of immunisation
- 4.3 In addition, for countries entering graduation and still receiving GAVI HSS support, the assessments would be an opportunity to re-evaluate the GAVI HSS support and assess the sustainability of these investments, and whether critical needs are targeted in the new context of graduation. This process would be the occasion to ensure that GAVI HSS support is aligned with the graduation priorities of the country and to re-programme if required.
- 4.4 The results of the graduation assessments feed into the development of transitional plans (now called graduation plans). The graduation plans would formulate mitigation actions to the gaps and/or weaknesses found in the assessments. The new graduation plans would not only focus on financial sustainability of new vaccines but on all three dimensions of the graduation framework. An improvement from the current transition plans is that the graduation plans would be costed. One of the weaknesses in the current plans is that governments do not have additional funding to finance the new unplanned activities and the investments required to improve their immunisation programmes. If the Board approves this proposal the graduation plans would be costed and would be used to access GAVI's new graduation grants.
- 4.5 The multi-partner technical experts providing support to develop graduation plans would review and validate the priorities and budgets to be funded with the graduation grants. After the in-country endorsement of the requests, the graduation grants would be submitted to the GAVI CEO for final approval. This process would ensure that graduation grants are country-based, responsive and flexible but also targeted to the graduation needs. Since access to graduation grants would be based on the costed graduation strategies this would create incentives for graduating countries to conduct the assessments and implement their graduation strategies. These plans would also be the basis for the policy dialogue with countries to ensure programmatic and financial sustainability post-GAVI support. The in-country dialogue on graduation would continue to be expanded to a wide range of stakeholders: MoF, MoH and partners, including CSOs as they play an active role in the delivery of health services.
- 4.6 Expanding the scope of engagement beyond the financial sustainability of vaccines will require a well-structured and a more comprehensive programme for technical support to graduating countries. The outcomes of these graduation plans might include intensive institutional capacity building, in which south-to-south cooperation could play an important role. A new curriculum for capacity building is being piloted this year, which will serve as a platform for capacity building in graduating countries. The proposed capacity building would be a process whereby organisations and individuals in a country are supported through strengthening knowledge and skills.



- The IF&S task team is coordinating the implementation and monitoring of 4.7 the assessment and plans. Progress in the implementation of country plans is being reported to the IF&S task team but not on a timely and systematic manner. It is therefore critical to strengthen the monitoring framework to intensify engagement with graduating countries. The new proposal suggests that the IF&S task team reviews quarterly reports on progress made on all graduation plans. Also, multi-partner annual incountry appraisals would be conducted to review progress and, if needed, strategies would be updated to ensure continuous relevance. Finally, a multi-partner appraisal on the end of graduation would be conducted in countries where GAVI support has ended. This appraisal would review the support provided, would evaluate the progress achieved and would identify future needs to further strengthen the immunisation programme. The end of graduation appraisal could potentially be used to guide further engagement of development partners in these LMICs.
- 4.8 The annual appraisals would be built into GAVI's Grant Application Monitoring and Review (GAMR) process. As intended in GAMR, the appraisals would be in-country multi-partner exercises putting the country at the centre, while progress on the implementation of the graduation plans would be reviewed and future priorities redefined. In this sense, these appraisals could also be an opportunity to review and monitor all the requirements of the new GAMR approach. The reports of these appraisals would be one of the many documents submitted, according to GAMR, to the internal panel for final review. The introduction of these appraisals actually enhances the implementation of GAMR by also prioritising incountry reviews in graduating countries. The end of graduation appraisals would supplement the independent external evaluation overseen by GAVI's M&E team. The objective of the independent external evaluation is to evaluate and obtain a retrospective of GAVI's support in the country. The end of graduation appraisals are more forward-looking and policyoriented as they identify future needs/gaps, and logically would be conducted by the organisations supporting the countries to overcome those gaps.
- 4.9 In order to effectively manage the available Secretariat and Alliance resources, the IF&S task team would continue to coordinate and monitor all efforts with graduating countries. The actual implementation of some areas of the approach would be conducted by experts outside the IF&S task team (e.g. NRA, NITAG, etc.). If the Board approved this new approach, an IF&S meeting would be hosted immediately after the Board in order to plan its roll-out.
- 4.10 It is important to acknowledge that it would be ambitious to expect all graduating countries to overcome all barriers before the end of graduation. In some of these countries, barriers to achieving high coverage are deep systemic problems that require more time to overcome. However, having a monitoring framework that tracks in-country progress towards these objectives would help the GAVI Alliance to focus its efforts on addressing these bottlenecks. The end of graduation appraisals would provide the



GAVI Alliance with evidence of future needs in LMICs that could be used if the Board decided that GAVI should continue to engage with these countries.

Access to affordable prices is another key element in support of graduation.

- 4.11 The goal is to develop an instrument supporting graduated countries to sustain immunisation programs begun with GAVI support and to enable both GAVI graduates and non-GAVI eligible LMICs to have the financial ability to introduce new vaccines. As countries graduate out of GAVI support, they are seeking to gain visibility and access to the lowest prices possible for vaccines for which they have previously received GAVI funding or for other new vaccines in GAVI's portfolio. Visibility enables countries to budget their fiscal space and assess the cost-effectiveness of interventions using vaccines paid for with government funds.
- 4.12 GAVI and UNICEF SD have secured commitments from specific manufacturers for continued access to GAVI prices by graduated countries for a number of vaccines, but this list is not comprehensive and does not cover non-GAVI eligible LMICs. The Secretariat will continue to engage with manufacturers with the aim to provide GAVI graduates with access to the GAVI price for all vaccines for five years after they begin fully financing, irrespective of whether they started the introduction of a given vaccine with GAVI financing or not.
- 4.13 Beyond these commitments, graduates must eventually pay prices that are distinct from GAVI prices. GAVI supports tiered pricing principles whereby countries pay different prices based on their varying levels of national income or other measures. Instruments to secure affordable prices for graduates and non-GAVI LMICs should be based on tiered pricing principles.
- 4.14 The scope proposed would be in line with the GAVI Board discussion in April 2012 to explore GAVI's potential role in facilitating access to lower vaccine prices for all LMICs, including both graduating countries and non-GAVI eligible LMICs. [1] Including non-GAVI LMICs would add 14 countries and increase the addressable birth cohort by over 80%, from 7.7 million to 14.1 million^[2], delivering both a potential wider public health impact and a sufficient size of demand to create an economically viable opportunity for pooled procurement based on country income levels. Inclusion of non-GAVI LMICs would also help to bring parity: non-GAVI-eligible LMICs have national incomes that are in the same range as GAVI graduates. The scope of vaccines covered would include GAVI portfolio vaccines such as pneumococcal pentavalent. conjugate, rotavirus papillomavirus vaccines. For example, 7 of the 17 graduating countries will not have introduced rotavirus vaccine with GAVI support and could benefit

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^[1] GAVI Alliance Board Retreat. Note of discussions, 16-17 April 2012.

Based on World Bank income tiers updated July 2013 and UN Population Division estimate of 2013 birth cohort.



from help to access an affordable vaccine price. Furthermore, none of the graduating countries will have introduced HPV vaccine with GAVI support. These are the vaccines that are the most expensive for countries to continue with or introduce. Other vaccines in the portfolio (e.g., measles, measles-rubella, yellow fever vaccines) are largely competitively priced and GAVI prices do not differ significantly from prices offered to non-GAVI countries^[3]. Additional new vaccines could be considered as they become supported by GAVI (e.g. Inactivated Polio Vaccine).

- 4.15 Within any instrument designed to give countries access to affordable vaccine prices, a variety of tools can be deployed. GAVI's level of engagement within each potential instrument varies on a spectrum ranging from minimal involvement to full ownership and creation of a bespoke mechanism. Tools that could be deployed to lower prices include:
 - A. Working with UNICEF SD to negotiate with vaccine manufacturers individually to gain commitments for appropriately priced vaccines for graduated and non-GAVI eligible LMIC countries as a component of their long term supply agreements for GAVI demand. This option is similar to the proposal under the UNICEF Middle Income Country (MIC) tender of having a "reference price" for a given vaccine. The difference is that the negotiations would also involve GAVI, and GAVI would use its reputation and buying power to potentially influence manufacturers.
 - B. Minimisina the risk premium applied to prices bv manufacturers where an uncertainty of demand or payment exists. Demand could be guaranteed through GAVI's existing demand, GAVI's balance sheet or by existing (e.g. IFFIM) or new financing instruments. GAVI could use its balance sheet to guarantee a percentage of demand from graduates and LMICs and negotiate lower prices based on that demand guarantee. This could be executed through the UNICEF MIC tender. If the guaranteed quantity for purchase is not met, GAVI would fund the "gap" doses either for use in GAVI-eligible countries or pay for the value of the doses if the doses cannot be used elsewhere. GAVI engagement would require an assessment and acceptance of the risk involved in the demand guarantee and require some operational oversight in the event of needing to purchase those doses.
 - C. Minimising payment default risk through building on an existing or establishing a liquidity fund where countries benefit from short term liquidity provided by the fund, or by seeking "insurers" of the payment who bear the risk of a default.
- 4.16 Tools that are most effective at reducing prices aim at reducing the risk premium manufacturers would otherwise place on purchases from graduates or other LMICs (examples (b) and (c) above). In other words,

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^[3] For measles-rubella and yellow fever vaccines, lowest GAVI price within 20% of lowest public market price. The lowest procurement price for each of these vaccines is well below \$1 per dose.



GAVI or its donors would assume some of the financial risk in order to ensure that the price available to LMICs using these tools would be within an appropriate range of the GAVI price.

- 4.17 In designing an instrument for lowering prices, challenges related to feasibility of the procurement mechanism and payment terms required should also be considered, recognising that the relative importance of each of these factors is highly variable from country to country. With regards to contracting and procurement:
 - A. Individual pricing and contracting between a country and a manufacturer would be the most flexible structure for countries (and minimise GAVI involvement) but would create complexity in applying many of the tools for accessing the lowest prices.
 - B. Establishing a pooled procurement mechanism based on country income levels through UNICEF SD would build on existing tools and relationships. Further work is required to understand and address whether, this could exclude some countries from participation due to local procurement regulations.

From the country perspective, short and medium term issues related to liquidity should be considered. Currently, when purchasing through UNICEF, countries must provide a prepayment for vaccine in hard currency. As some countries face difficulties with this, UNICEF has established the Vaccine Independence Initiative (VII) that allocates approximately US\$ 10 million across the countries that seek use of the fund. For several countries this fund has been successful during a transition period. In its current form, the limited size of short-term credit available to each country limits its utility for large countries or expensive vaccine purchases. Managing the timing of order placement and repayment, as well as recapitalization of the fund, could help address this and expand the utility of this mechanism. Alternatively, GAVI and UNICEF have been exploring whether UNICEF's requirement for funds being in place prior to procurement could be waived if the purchase is backed by a third party, like GAVI, allowing additional countries to participate.

4.18 To evaluate the relative strengths and weaknesses of potential instruments, a number of criteria should be assessed, including: level of GAVI engagement required and impact on GAVI; ability to secure lowest prices for countries; participation of manufacturers; and feasibility and attractiveness for countries with regards to both procurement and payment requirements. Consultations with Alliance partners, manufacturers and countries would enable the Secretariat to refine this list of criteria, perform a robust trade-off assessment across potential options and develop evidence-based recommendations. For example, discussions with Alliance partners could support the identification of potential tools to lower prices; manufacturer engagement would inform our understanding of the extent to which those tools reduce the risk premium; and country engagement is critical to clarify the feasibility and attractiveness of options with regards to factors such as procurement mechanisms and payment terms.

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Section C Implications

1 Impact on countries

1.1 As proposed in this paper, to broaden the scope of engagement with graduating countries would enable the Alliance to strengthen the long-term sustainability of achievements made in graduating countries through GAVI support. The aim of this work is to better respond to graduating countries and to situations that limit access to or optimal use of GAVI support. It involves an increased level of engagement, dialogue and co-ordination with the country and Alliance partners. It further contains an increased reliance on in-country and global processes for the coordination of support. This proposal therefore involves the requirement of additional staff time in graduating countries to engage in this intensified approach.

2 Impact on GAVI stakeholders

2.1 The suggested approach would also require closer collaboration with various partners both within and outside of the GAVI Alliance. At both national and international level, and in order to support graduating countries, the new approach would involve intensified coordination with implementing partners including WHO, UNICEF, other international organisations, civil society organisations and relevant partners. WHO and UNICEF in particularly would need to increase their efforts in graduating countries. These requirements would increase the workload of our partners in a context where there is already a greater need to support the implementation of the co-financing policy in non-graduating countries. Also, as mentioned before, GAVI would seek the participation of additional partners with the technical expertise required to support the different needs of graduating countries. In particular, the reengagement of the World Bank would be critical.

3 Impact on the Secretariat

3.1 The GAVI Secretariat would need to increase its engagement with graduating countries mainly through the Country Responsible Officers (CROs). The additional needs for CROs to support the graduating countries are included in the GAVI Secretariat's 2014 work plan. The Secretariat's Immunisation Financing team would support CROs by providing technical assistance on specific multi-partner visits. The team would also continue to coordinate all activities in relation to the IF&S task team and the capacity building curriculum for graduating countries. The Secretariat's Immunisation Financing team is very small, and also, responding to an increased workload on co-financing. It is therefore proposed that an additional staff member would be needed to support CROs with technical support in appraisal activities and to facilitate the policy dialogue in graduating countries. This request is included in the adjusted 2014 business plan and budget. Additional funding to support capacity building activities would be included in the individual graduation grants and addressed through the business planning process, but more

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- resources in the business plan would be required to support Alliance partners in their supplementary efforts.
- 3.2 Any implications for the market shaping team on access to affordable pricing will be put forward in a more detailed proposal on instruments to be brought to the Board in 2014.

4 Legal and governance implications

4.1 This paper is not requesting the Board to reopen the discussion on GAVI's eligibility policy and only proposes minor adjustments to the graduation policy, allowing countries to apply for new support during the grace year and aligning cash support with the introduction of graduation grants. Where necessary, GAVI's grant arrangements for graduating countries would be adjusted.

5 Consultation

- 5.1 This proposal is based on extensive input and feedback from graduating countries. The proposal used the recommendations and lessons learnt from the country assessments conducted in six graduating countries in 2012. At the end of 2012, a meeting brought together country representatives from six graduating countries from the EURO region and from Mongolia to discuss these issues. An additional three countries were also consulted during the in-country visits in 2013 (Angola, Indonesia and Uzbekistan). The Secretariat also consulted delegations at the WHO Regional Committee meetings for EURO and PAHO on the recommendations of the paper. The paper hence summarises feedback from 85% of graduating countries and it is only missing feedback from Sri Lanka, Kiribati and Papua New Guinea (not a graduating country at the time of starting development of this paper).
- 5.2 The contribution of the IF&S team was also instrumental in the development of this report. The Secretariat had initial discussions with manufacturers on the issues on access to pricing for graduating countries and other LMICs.

6 Gender implications

Each graduation assessment is expected to include an analysis based on existing data of the country situation with regards to gender and immunisation from both the service delivery and access perspectives.