



## Report to the GAVI Alliance Board

21-22 November 2013

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| <b>Subject:</b>        | <b>Risk Management: Risk Management Update</b>                                 |
| <b>Report of:</b>      | Helen Evans, Deputy CEO  |
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| <b>Agenda item:</b>    | 11a  |
| <b>Category:</b>       | For Guidance   |
| <b>Strategic goal:</b> | Affects all strategic goals  |

### Section A: Overview

#### **1 Purpose of the report**

- 1.1 This report is part of the quarterly risk monitoring process based on the GAVI 'risk register' to track the evolution of the key risks faced by the GAVI Alliance in fulfilling its mission. This risk report is the regular update to the Board and is based on the assessment conducted at the end of the third quarter 2013.

#### **2 Recommendations**

- 2.1 The Board is requested to give guidance on the key risks outlined in this paper and the mitigation strategies put in place as well as identify additional risks, as appropriate.

#### **3 Executive summary**

- 3.1 As of the end of the third quarter 2013, the following items were identified as **high risks** for the Alliance as part of the risk review process (i.e. the residual level risk was high after the mitigation strategy had been implemented).
- (a) **Vaccine management in country:** Owing to the constraints in vaccine supply and the relatively expensive cost of the vaccines that GAVI supports, it is critical that all efforts are applied to ensure effective management of the vaccines in GAVI countries, and most importantly minimising misuse. National governments are ultimately responsible for vaccine management; however, under the business plan the GAVI Alliance provides resources to WHO and UNICEF to support the mitigation strategies (e.g. Effective Vaccine Management assessments, support to cold chain refurbishment etc.). In addition,

given the evolution in value, volume and types of vaccines being supplied to countries, GAVI is strengthening its monitoring systems and increasing the number and skillset of Country Responsible Officers. This was also taken into account in the revision of the transparency and accountability policy (TAP) will be reviewed by the Board during this meeting (see Doc 02j). Although the TAP team will continue to focus on cash grants, their scope will expand to also include vaccine audits. Lastly, GAVI is developing an end-to-end supply chain strategy to improve supply chain performance and management. A draft options paper was discussed at the PPC in October 2013, and will be brought to the Board in June 2014.

This risk is noted as high but stable.

**(b) Capacity to oversee and manage programmes and grants and to minimise misuse of funds:**

One of the key risks for GAVI relates to grant performance. The main mitigation strategy for this risk is the oversight and support performed by the Alliance partners. In particular, the Country Responsible Officers (CROs) in the GAVI Secretariat are tasked with monitoring the programmes, provide guidance on implementation and play a convening role as necessary for GAVI partners in country. In the past 12 months, the team has been scaled up and the expectation with regards to monitoring and oversight has increased although it should be noted that CRO's still have responsibility for multiple countries which puts restrictions around the depth of engagement possible with any one country.

The following activities are also aimed to improve oversight and stewardship of GAVI grants:

- **The Grant Application and Monitoring Review (GAMR):** The new process to improve the monitoring and renewal process of the GAVI grants will be launched in 2014. It includes a more integrated approach to monitoring and renewal and a stronger and more explicit focus on risks in country, with differentiated approaches for each country.
- **A whistleblowing facility** has been included in the Business Plan to allow third parties anywhere in the world to report concerns to GAVI anonymously or confidentially (e.g. concerns on operation of and potential misuse of GAVI-supported cash or vaccine programmes, the execution of GAVI contracts, etc.)

The risk is rated as high and stable.

**(c) Poor data quality on immunisation coverage informing GAVI decision making:**

Related to the previous risks, the poor quality and limited availability of real time coverage data significantly hampers the ability to measure

impact and to manage the roll out of vaccines. This risk is potentially heightened by the need for such information to implement the Performance Based Financing (PBF) mechanism for all new HSS grants.

In Q3, the Secretariat developed a detailed implementation plan as follow up to the data summit conducted in January. A data quality advisory group (DQAG) made up of partner institutions and independent experts now meets regularly to track implementation of the action plan and other data quality improvement investments and activities. As examples of these activities:

- WHO and GAVI are integrating the immunisation data quality assessment tool (IDQA) and WHO's Service Availability and Readiness Assessment (SARA) tool. GAVI, WHO and the Global Fund have jointly launched a competitive RFP to conduct this work. This joint approach leverages funds from multiple agencies to enable scale up in a larger number of countries. Findings will be summarized in country-specific report cards.
- The Secretariat has also mapped countries with serious data discrepancies and gaps in availability of surveys and revised the HSS and NVS guidelines adding clear recommendation for 2 household surveys every five years (one with full birth history).so that HSS funds can contribute to filling gaps where needed.

The risk is rated as high and stable

**(d) Failure to sustain investment in vaccines and impact after graduation:**

This risk comprises the on-going need by countries to financially invest in immunisation and related health system capacity, to ensure the continuing performance of the immunisation programme after graduation. Sustainability is a key pillar of GAVI's model.

As of January 2014, 20 countries will be in the graduation phase, three of which enter graduation that year.

At the beginning of 2013, there were 2 graduating countries in default of their co-financing requirement. Through intensive efforts by Alliance partners at country level, these countries had fulfilled their 2012 arrears at the end of Q3.

In November, the Board will consider a paper on how GAVI can enhance its support for graduating countries (see Doc 14). The proposed approach includes intensified engagement, technical assistance for programme support and exploring access to tiered pricing.

The risk is rated as high and stable.

### (e) Vaccine supply shortages

GAVI is monitoring closely the supply availability and risk of shortage across the vaccines in its portfolio. The risk is particularly acute for the pneumococcal and rotavirus vaccines. As of quarter 3 2013, the latest situation for these vaccine is described below.

**(i) Rotavirus:** The supply of the 2-dose schedule vaccine, preferred by GAVI-supported countries continues to be limited, although there are encouraging developments in Q3. In 2014, thanks to accelerated production, one manufacturer will be able to deliver 10% more than the original estimated amount (an additional 4 million doses). However, despite this increase, the supply of the 2-dose schedule vaccine will remain constrained until 2015, when supply capacity is expected to double. Dialogue with the manufacturer on further Rotarix supply estimates is ongoing. The 3-dose schedule vaccine remains available for earlier introduction, but demand has so far been limited.

**(ii) Pneumococcal:** The availability of supply of the pneumococcal vaccine remains a challenge to fulfil country demand. In particular, the production issues that resulted in a decrease in the available supply of PCV 10 for the latter half of 2013 and the first half of 2014 continue to impact the timing of the introductions in Bangladesh and Nigeria who are re-planning their introductions for Q4 2014. The Secretariat and partners are working on optimising the allocation of available supply and procuring additional doses of both pneumococcal vaccines (PCV 10 and PCV 13). In Q3, the third tender of PCV under the Advance Market Commitment (AMC) was concluded for 50 million annual doses in long term supply agreements plus 42 million additional doses in the short term, easing supply constraints for both products. All of the 51 currently approved countries are expected to receive PCV supplies by the end of 2014.

The risk is rated high and decreasing

### (f) Inability to sustain current low pricing of vaccines for GAVI eligible countries:

The major event following the close of Q3 was a resolution passed by PAHO's Directing Council in October. The resolution reaffirmed the most favoured nation clause (MFN), a contractual condition that the PAHO Revolving Fund establishes with manufacturers that requires suppliers to sell to PAHO at the lowest price offered globally. To date PAHO had agreed with GAVI to grant exceptions to the MFN in relation to the PCV and HPV vaccines, and for other vaccines PAHO works bilaterally with manufacturers on exceptions. This has allowed GAVI and UNICEF to negotiate lower prices for GAVI eligible countries. If PAHO decides to enforce the MFN clause without any exceptions, this could severely threaten GAVI's efforts as GAVI may

have to pay significantly higher prices than it currently pays or may be unable to access certain vaccines. GAVI is engaging with PAHO leadership and other stakeholders to try to resolve this issue.

This risk is rated as high and increased.

- 3.2 **New risk:** In addition to the risks mentioned above, there are a number of other risks tracked through the risk register (available on myGAVI or on request from the Secretariat). In quarter 3 2013, there was one new risk, related to **GAVI Secretariat staff**. The quarter saw the departure and pending departure of several senior staff members, leading to a loss of critical experience and erosion of institutional memory. In addition, while the results of the staff survey showed a high level of engagement and commitment to GAVI's mission, there was only moderate levels of staff satisfaction with professional development opportunities that might have consequences for staff retention. While the volume of programme expenditure is growing rapidly -- by 280% in the four years from 2010 to 2014 -- and expectations on the depth of grant oversight have increased significantly, Secretariat staffing is growing at a much lower rate and workloads are heavy. There are three approaches to mitigating this risk:

- (a) Prioritisation: A dedicated effort was launched in the executive team to ensure that teams prioritise their work and focus on the most critical activities.
- (b) Staff development: The Secretariat is working to improving staff development by proactively engaging with managers on identifying, nurturing and recognising high performers; and encouraging talent management through management trainings and other professional development opportunities.
- (c) Succession planning: The Secretariat is working to improve succession planning by leveraging and growing internal talent, identifying and mobilising external talent and working to ensure timely replacement of vacant positions.

This risk is rated high.

- 3.3 Of note, the Internal Auditor conducted an audit of the risk management process, which was completed before the November 2013 Board meeting. His recommendations will be taken forward in 2014 around the 4 following areas:

- (a) Developing a risk policy covering key elements of GAVI's risk management approach.
- (b) As part of the Strategy 2016-20 process, explore a small number of critical risks which might be considered to be potentially mission-challenging.
- (c) Review and document the key operational risks of the organisation.

- (d) Establish a process of risk assessment covering the risks that GAVI incurs in supporting countries, differentiated by country. The Secretariat will take this forward through the new Grant Approval and Monitoring Review (GAMR) to be introduced in 2014.

### **Section B: Implications**

#### **4 Impact on countries**

- 4.1 The risk assessment and management process is a critical component in ensuring the successful delivery and full impact of GAVI's programmes in-country. The risks rated above as high, if realized, would have a significant impact on GAVI programmes to countries.
- 4.2 The GAMR process will explore further country-specific risks and their impact on the GAVI grants.

#### **5 Impact on GAVI stakeholders**

- 5.1 Identification of the risks triggers specific mitigation activities by GAVI Secretariat and implementing partners funded through the business plan.

#### **6 Impact on Secretariat**

- 6.1 Each team in the Secretariat provides a quarterly update of their risks highlighting the evolution of the risks over the quarter, detailing mitigation strategies and highlighting new potential threats to the organisation. The risk register is then discussed by the Executive Team to ensure appropriate mitigation strategies are in place. Where a risk increases in a particular quarter it can require additional attention and resources over and above routine management which may, in turn, restrict the capacity available for other deliverables.

#### **7 Legal and governance implications**

- 7.1 The Secretariat, in consultation with external legal counsel where appropriate, prepares for and addresses any legal consequences of risks identified.

#### **8 Consultation**

- 8.1 The risk management framework has been developed by the Performance Management Unit in consultation with the Internal Auditor and the Executive Team. WHO and UNICEF are consulted on and encouraged to contribute to identifying, monitoring and managing risks.

#### **9 Gender implications**

- 9.1 There are no matters in this risk review that have implications on gender.