



## Report to the GAVI Alliance Board

11-12 June 2013

<b>Subject:</b>	<b>Risk Management Update</b>
<b>Report of:</b>	Helen Evans, Deputy CEO
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<b>Agenda item:</b>	15
<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 regular reporting to the Board and the Executive Committee on the risks faced by the GAVI Alliance in fulfilling its mission. This risk report is based on the regular risk assessment conducted at the end of the first quarter 2013, and made available to the Board on myGAVI in May 2013.
- 1.2 As requested by the Board, key risks identified by the new proposal and monitoring Independent Review Committees (IRCs) have also been integrated into this report.

#### 2 Recommendations

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

#### 3 Executive summary

- 3.1 Of note, the Internal Auditor is currently conducting an audit of the risk management process, which he expects to complete before the November 2013 Board meeting. His findings could result in changes to how the process is conducted and reported to the Board.
- 3.2 As of the end of the first quarter 2013, the following items were identified as **the highest risks** for the Alliance as part of the risk review process.
  - (a) **Low data quality on immunisation coverage, leading to ineffective decision making by the GAVI Alliance:** The Secretariat convened a Data Summit in Q1 2013 to review current efforts of the GAVI Alliance and partner agencies working in the area of immunisation coverage

data quality and develop a high level action plan to address the urgent need for improvement. The Action Plan was finalized and focuses on: (a) Strengthening country systems and capacities jointly with WHO and Global Fund (e.g. monitor data quality, reward accurate reporting, use HSS for data quality improvement); (b) improving survey design, frequency, methods and content (e.g. frequency of household survey); and, (c) advancing innovation in use of biomarkers, technology and triangulation (e.g. use biomarkers and mobile technologies to assess coverage data discrepancies and impact, develop approaches to address discrepancies of various data sources). The risk is rated as high and stable.

- (b) **Misuse of funds and/or perception of misuse in cash-support programmes:** In the past quarter, media interest in misuse of funds cases has increased with corruption-related arrests taking place in two countries that had faced misuse of GAVI funds. These arrests have attracted media and political commentary in country and have highlighted the potential confusion on the nature of the misuse (i.e. 'misuse by GAVI' vs 'misuse of GAVI programmes by country'). GAVI communicated pro-actively to avoid confusion and the GAVI CEO regularly updates the Board on the latest developments of on-going investigations. As part of a mitigation strategy on misuse, two new types of transparency and accountability (TAP) missions were initiated in Q1 2013 - Cash Programme Audits (CPA) and Monitoring Reviews. The primary objective of a CPA is to undertake a substantive examination of the controls in place in-country to manage GAVI cash programmes, and to examine and validate the appropriate use of GAVI-disbursed funds consistent with the approved proposal and any Aide-Memoire signed with the recipient Government. The objective of a Monitoring Review is to enable TAP to assess the management of cash programmes in-country and particularly the implementation of enhancements identified through previous TAP work, and internal or external audits. In addition, joint monitoring reviews in country have led to enhanced collaboration between TAP officers and country responsible officers (CROs). The risk is rated as high and stable.
- (c) **Shortage of 2-dose schedule rota vaccines in the period 2013-2016:** There is inadequate rotavirus supply to meet country demand. Discussions with manufactures and countries have therefore been a priority activity by the Secretariat, UNICEF and other partners. The Secretariat met with development and private sector partners to identify potential solutions including addressing programmatic challenges associated with the 3-dose schedule vaccine (primarily the absence of vaccine vial monitor (VVM) and the large cold chain footprint). Discussions with existing and new manufacturers on the development of new vaccine presentations adapted to low-income country needs also continues. The risk is rated as high and stable.
- (d) **Failure to sustain impact after graduation:** There are 2 aspects of this risk: (1) the continuous need for financial investment in

immunisation; and (2) the performance of the immunisation programme after graduation. On the financing aspect, the report provided by UNICEF in Q1 showed that Angola and Congo Republic, both graduating countries, defaulted in their 2012 co-financing requirements. For both countries the main problem was not the availability of fiscal space but weak budgetary and planning capacity. A strategy paper is under development and will be presented to the Board at its November meeting to propose options on how the Alliance can better support countries in this transition, as well as how the Alliance can work with industry to on pricing related issues. With regards to performance of the immunisation programme after graduation, the Board discussed at its retreat in Q1 broadening the scope of engagement with graduating countries, including increasing focus on programmatic aspects of sustainability, and possibly providing cash support to graduating countries. They agreed that the Secretariat would develop a more detailed plan of broadened engagement with graduating countries for further discussion and ultimately inclusion in the GAVI strategy 2016-2020. This risk is rated as high and stable.

3.3 In addition to the high 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 1 2013, there were a number **new risks** that were identified by the Secretariat that, although not high will be added to the register. They are as follows:

- (a) **Functionality of National Regulatory Authorities (NRAs) in vaccine producing countries:** Sustaining the NRA functionality in vaccine producing countries with prequalified vaccines is one of the highest priorities for the NRA work by WHO. Failure in producing countries (India, Indonesia) may have a serious impact on the global supply of assured quality vaccines. In order to control the risk and anticipate capacity failure close monitoring of the NRA functionality is conducted during updates of Institutional Development Plans (IDP) and continuous feedback on regulatory function status is conducted by WHO during follow up visits. Dedicated funds for this activity are channelled through the GAVI business plan. This risk is rated as low.
- (b) **Lack of epidemiological data to guide investment decisions:** This risk relates to GAVI's ability to design its programmes and investments using the most relevant epidemiological data, and to monitor the impact of GAVI vaccines on the epidemiology of diseases (e.g. serotype replacement), or when target age groups change (e.g. measles Supplementary Immunisation Activities (SIAs)). This risk was particularly acute in Q1 with the review of the applications for measles SIAs in DRC and Pakistan, and in the context of a potential contamination of a laboratory in the African region supported by WHO, which could have invalidated results of some of the surveillance conducted so far. The risk mitigation strategy focuses on continuous targeted investments into evaluations, effectiveness assessments, and epidemiological surveillance. GAVI partners are also exploring whether

current surveillance investments should be restructured to detect the evolution in epidemiology and to establish baseline information prior to introduction of the new vaccines. This risk is rated as low.

- (c) **Lack of supply continuity support for planned campaigns:** In addition to their effect on countries, campaigns can place a significant burden on manufacturers because they require meeting a surge in demand at specific points in time. They can also have a significant impact on cold chain capacity which is already limited in some GAVI countries. This risk has been raised in Q1, with the start of implementation of measles rubella campaigns and upcoming measles SIAs, as well as and the start of the yellow fever campaign in Nigeria. On the latter, yellow fever supply continues to be challenging, with demand higher than supply availability. On the supply risk, regarding short term mitigation, UNICEF is working together with manufacturers, GAVI, and WHO to develop the tender strategy in order to bring more security to the market. For the longer term, the Secretariat has recently completed “road maps” for measles rubella and yellow fever to address this issue. On the supply chain, the Secretariat is working with partners to develop an Alliance wide strategy which will be brought to the Board in the fall. This risk is rated as medium.
- (d) **Unforeseen challenges in implementation of Grant Application, Monitoring and Review (GAMR):** This risk relates to operational issues that may impede the implementation of the GAMR process, scheduled for full roll out in 2014. The risk mitigation strategy focuses on early identification of possible implementation challenges; development of detailed plan to address operational issues; regular consultation and brainstorming with major stakeholders; and refining/building on lessons learned. The risk is rated as low.
- (e) **Measles SIAs (campaigns):** There are two components to this risk. First, measles SIAs can detract from routine immunisation activities; and second, GAVI systems and procedures are not adapted to the characteristics of campaign work when they require urgent implementation or where the epidemiological data are not clear. With regard to the first, countries have been required to state in their applications how the campaign will contribute to strengthening routine immunisation services. This is intended to help proactively avoid campaigns undermining routine immunisation. Implementation support to the campaigns, including the systems strengthening aspects, is provided by WHO and UNICEF, who are present on the ground. With regard to the second point, the time horizon of GAVI’s application and approval process is designed to support planned campaigns. However, changes or outbreaks sometimes arise requiring rapid decision making. To accommodate the timeframe on measles SIAs, the Executive Committee has held extra-ordinary meetings to review IRC recommendations and advise on age groups eligible for GAVI support. GAVI has also committed US\$ 55 million from 2012 – 2017 to the

Measles & Rubella Initiative to help respond to outbreaks or rapidly evolving situations. This risk is rated as medium.

### **Section B Implications**

#### **1 Impact on countries**

- 1.1 The risk assessment and management process is a critical component in ensuring the successful delivery and full impact of GAVI's programmes in-country.
- 1.2 The risks rated above as high, if realized, would have a dramatic impact on GAVI programmes

#### **2 Impact on GAVI stakeholders**

- 2.1 Following Internal Auditor's suggestions, WHO, UNICEF have started in Q1 2013 to identify and report on risks related to their programme areas. This reporting does not include country-specific risks on GAVI programmes but rather high level risks in each programmatic areas funded through GAVI business plan.

#### **3 Impact on Secretariat**

- 3.1 Each team in the Secretariat is required to provide 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.

#### **4 Legal and governance implications**

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

#### **5 Consultation**

- 5.1 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 identifying, monitoring and managing risks.

#### **6 Gender implications**

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