



Report to the GAVI Alliance Board

12-13 June 2012

Subject:	Business planning process and risk management update
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Category:	For Decision
Strategic goal:	Affects all strategic goals

Section A: Overview

1. Purpose of the report

- 1.1 In November 2010, the Board approved a 5-year strategy and business plan with a 2-year budget (2011-2012). As the two-year period draws to a close the GAVI Alliance will refine the business plan building on lessons learned from 2011-2012 and develop a budget for the period 2013-2014. The purpose of this report is to present the priorities that will drive the definition of deliverables and associated activities for the 2013-2014 period.
- 1.2 This report is based on consultations including one-on-one interviews with Board members, workshops with technical staff from Board constituencies and discussions within the Secretariat.

2. Recommendations

- 2.1 The Board is recommended to:
 - a) **Endorse** the strategic priorities for the 2013-2014 business plan; and
 - b) **Request** the Secretariat and partners to take these priorities into account when preparing the business plan deliverables and budgets for 2013-2014.
- 2.2 The Board is also requested to review and discuss the GAVI risks and associated mitigation strategies.

3. Executive summary

- 3.1 While sustaining efforts accross all the strategic and cross-cutting goals as described in section C of this report, it is recommended that the GAVI business plan 2013-14 will focus on the following strategic priorities:

- a) **Improve implementation of vaccine introductions and roll out:**
GAVI's focus should go beyond the introduction process in order to ensure successful scale-up of the newly introduced vaccines. This requires better follow-through and sustained support for new vaccine introductions beyond the initial launch.
- At the country level, this will entail better assessments of country readiness prior to launch to identify country-specific support requirements and ensure they are in place. Wherever possible, the introduction itself should be coordinated with other relevant interventions (e.g. diarrheal control for rota, adolescent health for HPV) and leverage synergies with polio and other immunisation programmes in country. Furthermore there should be sustained follow-up throughout the first year of roll-out. In that period, GAVI should also encourage sharing of lessons learnt between countries. Along these steps, four specific areas will require particular focus: i) increasing political will in-country beyond the Ministry of Health; ii) improving cold chain and logistics; and iii) providing further training and management to health workers iv) Improving the quality and use of data.
 - At a global level, addressing and managing the short term supply constraints will be critical. The Alliance will have to simultaneously work with manufacturers to identify opportunities to increase supply, as well as build the right mechanisms to allocate the available supply in an optimal way.
- b) **Accelerate progress on improving vaccine coverage and equity:**
GAVI has made limited progress in improving coverage in underperforming countries and in narrowing the gaps in coverage between low and high wealth quintiles. Tailored-country approaches should focus on reaching the unreached and allow for a shift of focus from only the national level, to district level coverage and planning to achieve this. GAVI will also need to ensure that the coverage improvements are realised in a sustainable manner and not with a short term perspective. This is particularly important in underperforming countries, where plans for introduction of new vaccines should build on and strengthen routine coverage.
- c) **Ensure sustainability of programmes after graduation from GAVI support:** GAVI must work with manufacturers to secure affordable pricing for graduating countries while at the same time work with national governments to make sure that there is adequate "fiscal space" to support the immunisation programme, including delivery of new vaccines.
- d) In order to achieve the objectives above, GAVI will need to significantly **improve access to and use of quality, timely data** and link country programme reviews, planning and reporting to concrete implementation activities. As part of this, GAVI should create the appropriate incentives to countries to report and use the data for decision-making, and also

facilitate South-South collaboration to increase sharing of knowledge and lessons learned. The focus will be on the following:

- **Coverage data:** GAVI will need to support countries in strengthening their administrative coverage data and create the right incentives for countries to report quality data. As a new activity, GAVI should also fund independent verification of coverage estimates in some countries.
 - **Operational data:** GAVI will need to increase the availability and use of real-time, country-level operational data for programme management. In particular GAVI should better leverage and integrate the existing planning and analytical tools (e.g. cMYPs, EVMs, PIEs, EPI reviews etc.) to build a more comprehensive picture of a country's performance and needs. This will allow GAVI to better direct its technical assistance, allocate vaccine supply and inform the necessary reprogramming of HSS grants, without adding further to the extensive reporting requirement.
 - **Surveillance:** GAVI should ensure that its investments in surveillance and special studies result in the ability to monitor impact, effectiveness and safety.
- e) To achieve its 2015 objectives and targets, GAVI must improve the current **Health System Strengthening support mechanism**, ensuring that all the existing and future support focuses on strengthening immunisation in the context of integrated health systems. This will entail providing the relevant technical assistance to countries to re-programme their HSS grants and build national health plans that address the key bottlenecks to immunisation, including planning down to the district level. In particular, technical assistance for building these plans must be made available to countries with the weakest health systems.
- f) GAVI will also continue its work on market shaping and global resource mobilisation drawing on the existing strategies and processes developed for this purpose (e.g. Supply and Procurement Strategy, development of a Long Term Funding Strategy).
- 3.2 Through the Business Plan 2013-2014 GAVI will also explore whether some initial work will be required in 2013-14 in relations to the options discussed by the Board at the Oslo retreat in April 2012.
- 3.3 GAVI should also refine its **operating model** along the following dimensions:
- a) **Improve accountability for outcomes:** The business plan 2013-2014 will have a renewed focus on accountability for results. As such, business plan activities and deliverables should be focused on outcomes as opposed to outputs/processes.

- b) **Strengthen partnerships at country and regional levels:** GAVI should better leverage WHO and UNICEF resources at country and regional levels in particular with regards to ownership of GAVI Alliance policies and programmes. In-country partners should clarify roles, responsibilities and accountabilities between them, specifically with regard to supporting countries to address key bottlenecks to immunisation. To do this, Secretariat Country Responsible Officers (CROs) will prioritise stronger coordination and communication specifically with staff funded through the business plan at regional levels. They will also play a convening role in leveraging a wider set of partners at country level (e.g. donors, CSOs etc.).
- c) **Build the business plan on the basis of country needs:** The technical assistance funded through the business plan should be based as much as possible on needs identified at country level and strategically prioritised (e.g. large countries, fragile states, countries with stagnating or declining coverage). In the absence of formal country plans identifying these needs, GAVI should better engage with partners' regional offices during the business planning process.
- d) **Increase flexibility to respond to emerging priorities in countries:** the business plan model is perceived as rigid with regards to reacting to issues occurring in countries throughout the year. Building in 'flexibilities' would enhance the Alliance's ability to address key issues as they arise in-country by allocating resources as appropriate.
- e) **Recognise contribution by partners not funded through the business plan:** there are numerous partners contributing to GAVI's mission but not funded through the GAVI business plan. Discussions are on-going on how to capture their contribution into the GAVI business planning process to ensure better coordination.

4. Context

- 4.1 As per the process approved by the Executive Committee (EC), the Secretariat conducted structured consultations to review the progress to date and determine key areas of focus for 2013-2014 in order to ensure delivery on the strategy and associated targets and deliverables. These consultations included workshops with representatives from GAVI Board constituencies as well interviews with individual Board Members, conducted by the GAVI Secretariat Deputy CEO.

5. Next steps

- 5.1 Following the Board meeting, implementing partners and the Secretariat will develop detailed deliverables and associated activities and budgets based on priorities endorsed by the Board.

- 5.2 In August, the GAVI CEO and Deputy CEO will review the consistency and relevance of the deliverables, activities and budgets submitted by all partners and seek clarification and modification where appropriate.
- 5.3 In early September, submission will be consolidated for review by an External Advisory Group (EAG) which will assess whether the proposed deliverables and associated activities are on the critical path for achieving GAVI's strategic objectives. The EAG will also review the extent to which priorities identified by the Board are appropriately addressed including whether a suitable implementing partner has been identified.
- 5.4 On 16th October (at the PPC meeting), the PPC and AFC will jointly review the business plan together with the recommendations from the EAG, and provide recommendations on changes to incorporate in the activities and budget. The Secretariat will then consult with partners and finalise the business plan and budget based on feedback received by the PPC and AFC.
- 5.5 On 9th November (at the AFC meeting), the revised activities and budget will be reviewed jointly by the PPC and AFC. The final two-year activities and budget will then be presented to the Board in December for final approval.
- 5.6 Of note, following the Board retreat in Oslo, the Governance Committee will clarify the roles and responsibilities of the EC and PPC in overseeing the business planning process.

Section B: Implications

6. Impact on countries

- 6.1 The Business plan process is intended to support delivery of GAVI's programmes in country. A more country-tailored approach to a subset of countries would allow for a better targeted technical assistance, recognising country specific strengths and weaknesses, and a strengthened Alliance presence at country-level.
- 6.2 With regard to country readiness to introduce new vaccines, strengthened partnerships at country level should help ensure appropriate feedback and follow-up on issues arising following the launch of new vaccines.

7. Impact on GAVI Stakeholders

- 7.1 The definition of priorities may result in different work being allocated to implementing partners as well as the potential engagement of additional implementing partners.

8. Impact on the Business Plan / Budget / Programme Financing

- 8.1 Per the guidance from the Board, the business plan budget envelope is expected to remain relatively stable in 2013. However, the Board interviews suggested that where there is a compelling case linked to priority deliverables, the Board would be prepared to consider additional targeted resources. For 2014, an indicative budget will be submitted to the Board in December 2012, and an updated, detailed version presented for final approval in December 2013.

9. Risk implications and mitigations

- 9.1 As of mid-2012, GAVI Secretariat and implementing partners have identified the following as key risks:
- (a) **Vaccine supply:** The risk of short-term shortages in pneumococcal and rota vaccines has increased due to external developments including production constraints. To minimise the impact, AVI partners have developed criteria for allocating vaccines in a supply-constrained environment. The AVI partners are also engaging manufacturers to increase supply, and are proactively monitoring demand, utilisation and vaccine uptake particularly in countries with large birth cohorts. With the support of AVI-TAC, the Secretariat is developing a communication strategy to ensure that countries are informed of existing and potential delays.
 - (b) **Country readiness to introduce new vaccines:** Because applications may be reviewed and recommended as much as two years in advance of roll-out of a new vaccine and real-time data systems are not in place at country level, there is a significant risk that country capability and infrastructure delay vaccine introduction or lead to unsuccessful roll-out.
 - (c) **Excessive “closed vial” wastage** resulting from poor stock management, including overstock. The Secretariat is currently conducting a review to ensure the appropriate number of doses is allocated to countries through the IRC process. However, it is worth noting that overly conservative estimates of the number of doses could result in stock-outs. This risk therefore requires careful mitigation and is closely linked with efforts to improve operational data quality and flexibility to quickly make changes if data shows a need.
 - (d) **Misuse of funds:** Two investigations were recently completed and another one launched. The Secretariat is implementing the mitigation measures endorsed by the Board in its July 2011 meeting, including hiring two additional TAP staff and more CROs. As of April 2012, more than 80% of GAVI countries had conducted a financial management assessment by GAVI. However, risk in this area has temporarily increased with the impending departure of the Internal Auditor. A search to find a replacement is currently underway.
 - (e) **Quality of data:** GAVI bases most of its programmatic and financial decisions on coverage data. The risk in this area ranges from incorrect quantity of vaccines ordered and delivered, to poor estimation of GAVI's

potential impact. GAVI is working to address this by revising the data quality assessment tool to improve administrative coverage data (new tool piloted in 2 countries) and reviewing innovative technologies to help assess coverage data (recruitment underway). The business plan 2013-14 will include new plans for forensic audits and surveys to verify coverage data. Further, in July WHO and UNICEF will launch a Grade of Confidence (GoC) system for their estimates of immunisation coverage. Even after these actions are taken, residual risk related to poor quality data will remain very high.

- (f) **External reporting on GAVI:** Negative press can harm political and financial support to GAVI. The Secretariat continues to employ a proactive and reactive strategy to mitigate this risk and continues to strengthen internal protocols around crisis communications. At the end of 2011, the Secretariat communicated proactively to the Board and donors on the repayment of funds by Mali and responded, with UNICEF and WHO, to the inaccurate and negative press stories about GAVI in Pakistan. There is also active monitoring of the press in India, where the anti-vaccine lobby remains strong.

- 9.2 The risks highlighted here are those identified as top risks for the organisation, however there are a number of other risks that have been identified and for which mitigating actions are being implemented. The second tier of key risks includes: countries not fulfilling their co-financing requirements and not sustaining investments in vaccines after graduation; quality assurance of vaccines; the impact of the continuing global financial crisis on GAVI's ability to raise adequate resources; and the downgrading of IFFIm. A more detailed update on risk register is available every quarter on the myGAVI site.

10. Legal or governance implications

- 10.1 The recommendations in this report do not have any legal implications at this stage.

11. Consultation

- 11.1 The workshops described above allowed for input from a range of stakeholders and included representatives from all Board constituencies. In parallel, the Deputy CEO conducted one-on-one interviews with most Board members to get their input.
- 11.2 A meeting between senior staff from UNICEF, WHO and the GAVI Secretariat was also held to identify and review key risks.

12. Gender implications / issues

- 12.1 GAVI's implementation of the gender policy is currently being evaluated. Results and recommendations, including for the business plan and business planning process, will be presented to the Board at its next meeting.

13. Implications for the Secretariat

- 13.1 The priorities identified through this process will better inform the Secretariat focus, structure and resources for the period 2013-2014.

Section C:

14. Priorities per strategic goal/cross-cutting area

- 14.1 The main priorities for GAVI have been highlighted in Section A. This section outlines in more detail the focus areas for each strategic goal/cross-cutting area as well as the areas where GAVI could scale back its investment, shift focus and/or make efficiency gains.
- 14.2 Of note, all workshop participants and the majority of Board members interviewed noted the need to ensure that the goals were seen as closely linked and viewed as interdependent, rather than treated as separate silos.
- a) **The Vaccine Goal (SG1):** The priorities in SG1 have been highlighted in Section A. These priorities include improving the implementation of vaccine introductions and confirming country readiness by providing sustained country-specific support to ensure new vaccine introductions go beyond the initial launch and improving access and use of quality, timely operational data. As most countries have already made a decision to introduce, focus for the coming two years should shift from strategic objective 1.1 (*"Increase evidence based-decision making by countries"*) to focus on strategic objective 1.2 (*"Strengthen country introduction to help meet demand"*). More specifically, the following areas have been identified as opportunities for GAVI to work differently:
- Strategic objective 1.1: Increase evidence based decision-making by countries: Support to decision-making should extend to creating political will beyond the Ministry of Health (Ministries of Finance and Education, national leadership, drawing on the experience of other countries in the region, community advocacy, etc.). This may evolve expansion of activities that could be contracted externally.
 - Strategic objective 1.2: Strengthen country introduction to help meet demand: There should be greater clarity on a country-by-country basis between WHO and UNICEF on the roles and responsibilities regarding technical assistance. Furthermore there should be dedicated resources through the business plan for technical assistance to countries with specific needs (e.g. large countries, underperforming etc.), more clarity on who amongst the partners is accountable for these resources and more flexibility to address unforeseen issues. Opportunities to strengthen routine systems, integrate immunisation with other interventions and leverage vaccine introductions for system-wide long-term gains need to be identified and pursued. GAVI will also work on developing introduction

strategies for the newly supported vaccines (HPV and MR) and engage with other partners to ensure coordination with other health interventions (e.g. cancer control with HPV vaccine). Particular focus by WHO and UNICEF will be dedicated to cold chain and logistics and training of health workers and ensuring that countries are ready to introduce new vaccines.

- b) **The Health Systems Goal (SG2):** As mentioned in Section A, focus should be on increasing coverage and equity via sustainable systemic approaches. This requires putting in country a streamlined and more effective HSS programme, both in terms of grants and technical assistance. Health system strengthening, more than anything else, requires tailored approach to countries. Special needs of underperforming states will be prioritized. This will mean more intensive support to them (in terms of funding as well as technical assistance) and more careful application of risk management measures. Re-programming of the existing grants will be more actively pursued specifically in underperforming countries. Furthermore, GAVI will need to move forward on the implementation of the approved performance-based funding (PBF) mechanism. Recognising that this mechanism does not suit every context, it should be targeted to the relevant countries to minimise the risk exposure and harness the benefits from such a mechanism. GAVI will also explore ceasing its funding through the business plan of waste management and injection safety activities as these funds have had their intended catalytic impact (most countries have developed appropriate policies whose implementation could be addressed through the HSS funding window). GAVI should also shift its support to countries from developing national health plans in a broad sense to supporting countries link their plans to immunisation-specific deliverables including to the subnational level.
- c) **The Financing Goal (SG3):**
- With regard to co-financing, as highlighted in Section A, GAVI should adopt a more comprehensive view to sustainability, including securing affordable pricing for graduating countries ensuring adequate “fiscal space” to support the immunisation programme in the long run. The following areas have been identified as opportunities for GAVI to work differently:
 - Prioritise the support to countries to develop cMYPs, as opposed to systematically supporting all countries to develop their plan every year Tracking and providing technical assistance to countries with low performance on financing of traditional vaccines.
 - Earlier engagement with future graduating countries to ensure that they are able to sustain vaccine financing when GAVI support ends.

- Engaging additional partners on co-financing and expanding the scope from exclusively focusing on GAVI vaccines to other aspects of immunisation financing.
- With regards to global resource mobilisation, in December 2012, the Secretariat will present plans for a long-term funding strategy to the GAVI Board. This strategy will propose a new model, including the mix of financing instruments (direct, IFFIm, financial instruments in support of market shaping) that can best provide the more predictable and flexible funds needed to incentivise vaccine development and support sustainable immunisation programmes. To achieve Strategic Goal 3, the short-term resource mobilisation priorities during 2013-2014 include the following:
 - **Secure all pledges promised in June 2011 and extend pledges into multi-year commitments up to 2015.** Whereas GAVI was able to turn 81% of the pledges into signed agreements as of February 2012, the effort to deliver on and extend the pledges in time is complicated by prolonged fiscal challenges in Europe and North America. In order to secure pledges and protect signed commitments from current donors in this context, GAVI is addressing this challenge through: (i) bipartisan engagement of donor country stakeholders; (ii) adequate visibility for donors and demonstrated results; and (iii) private sector outreach particularly through the GAVI Matching Fund. Significant efforts will also be deployed to extend shorter-term pledges to longer-term commitments, particularly for donors who had only pledged until 2013 and need to extend pledges to 2015. A successful Mid-Term Accountability Review in 2013 will be key to achieving the above objectives.
 - **Build up a multi-year donor diversification campaign.** Given the current economic context, the related risk to the delivery of some of the pledges and the need to continue fundraising, a donor diversification strategy could target the following objectives: move from a highly concentrated donor base (3) to a critical mass or core group of existing donors (12) taking into account risk mitigation, growth potential and key donors' priorities; scale-up innovative finance mechanisms including IFFIm, private sector participation through the GAVI Matching Fund and the development of new innovative mechanism. The GAVI Matching Fund has demonstrated early success to date, however, private sector fundraising is very resource intensive. Although reaching the US\$ 260 million by 2015 is a challenging target, it is one that GAVI is committed to reach. The GAVI Matching Fund offers important non-financial strategic benefits, including gaining new powerful champions for GAVI, enhancing the advocacy base, and bringing to bear business skills on some of the challenges that face GAVI.

- d) **The Market Shaping Goal (SG4):** At the end of 2011 the GAVI Alliance adopted a new supply and procurement strategy. Efforts in 2013-2014 will focus on the following:
- Employing innovative procurement mechanisms and supporting entry of new manufacturers to ensure **low and sustainable prices**.
 - Facilitating **access to pricing** for graduating and lower middle income countries.
 - Proactive engagement on manufacturer capacities to ensure **security of supply** especially with regard to pentavalent, pneumococcal, rotavirus, and measles-rubella vaccines.
 - Signalling desired product characteristics to stimulate **innovation for products** suitable to GAVI countries.
 - Monitoring developments of vaccines that have been identified as priorities by the GAVI Board (JE, malaria, dengue, hexavalent, typhoid and cholera vaccines).
 - Ensuring appropriate quality of vaccines procured with GAVI funding
- e) **Advocacy, Communication and Public Policy:** GAVI's advocacy and communications activities seek to strengthen the political will of decision-makers in donor and developing countries to invest in and expand access to immunisation. The following priorities have been identified for 2013-2014:
- Broadening and strengthening the **GAVI stakeholders' network** including faith-based groups and the private sector, while expanding collaboration with cancer and women's groups.
 - Adjusting focus to **new priority dialogues among replenishment partners** including parliamentarians and southern networks.
 - Repositioning GAVI in a **changing public policy environment** with a focus on G20 and BRIC countries.
 - Developing a **strengthened evidence base** for investments in GAVI, including demonstrating the economic benefits of immunisation.
 - **Demonstrating results and increasing visibility**, especially in selected key donor and potential donor markets.
 - **Evolving the GAVI brand** and its messaging to help better leverage GAVI's communication assets, find its supportive constituency and enhance visibility.
 - Encourage country-to-country and country-to-donors advocacy based on sharing experiences and messages on the benefits achieved by countries that have already rolled out new vaccines.

- f) **Monitoring & Evaluation:** Moving forward, special studies and surveillance will be considered as part of the cross-cutting effort on monitoring and evaluation. In the 2013-2014 time frame, efforts will focus on:
- **Strengthening country data platforms:** A priority area will be to support the generation and use of high quality, relevant and timely data. GAVI will explore ways to incentivise countries to improve quality of administrative coverage data; support countries to implement additional methods to assess coverage; and fund independent verification of coverage estimates in strategic countries.
 - **Fill key knowledge gaps:** including vaccine impact, safety and effectiveness, and the broader benefits of immunisation. Another aspect of this work will be to ensure integration of information and efforts of routine monitoring, surveillance, targeted studies and evaluations.
 - **Ensure analysis and use of data for better management decision:** focusing on disseminating knowledge from surveillance, targeted studies and evaluations across countries and strengthen country capacity to analyse and use data for decision-making.
 - **Optimising investments in surveillance:** by focusing on higher quality studies of new vaccines in specific countries rather than broader surveillance in many countries. GAVI should also ensure that its investments in surveillance and special studies result in the ability to monitor impact, effectiveness and safety.
- g) **Policy Development.** A number of GAVI policies are scheduled for review or development in 2013-2014. These include:
- Vaccine investment strategy. Last reviewed in 2008, this policy will look at vaccines which could be available in the 2015-2019 time period and provide a framework for decision-making for potential GAVI investment.
 - Engagement with lower middle income countries. GAVI will explore policy options for engaging with this group of countries.
 - Review of the co-financing policy, scheduled for review in 2014.
 - Gender policy: pending the outcome of the evaluation, which will be completed in 2012, this policy may require a review or redesign.
 - Other policies as mandated by the Board.