



Report to the GAVI Alliance Board

4-5 December 2012

KEY WORK AREAS AND DELIVERABLES: GAVI ALLIANCE 2013-2014 BUSINESS PLAN

- 1.1 The GAVI Alliance Business Plan aims to support GAVI's mission to save children's lives and protect people's health by improving access to immunisation in poor countries. The business plan is structured around the GAVI Alliance's four strategic goals: accelerating vaccine uptake and use, strengthening health systems to deliver immunisation, increasing predictability and sustainability of global and national financing, and shaping the vaccine market. The business plan also supports cross-cutting areas of GAVI's strategy: monitoring and evaluation; advocacy and communications; and policy development. Each of the strategic goals and cross cutting areas is underpinned by programme objectives, deliverables and targets, which are achieved through "critical path" activities, carried out by the GAVI Secretariat and Alliance implementing partners, including WHO, UNICEF, civil society and a technical assistance consortium for accelerating vaccine introduction (AVI-TAC). This document describes these critical activities and how they lead to achievement of the deliverables and targets set out by the Board.
- 1.2 There are some areas where the Alliance is falling behind on its annual targets including vaccine introductions, coverage, and equity. To tackle these areas, the Board endorsed a set of priorities which the Alliance partners have focused on:
 - (a) Increased in-country implementation and follow-through
 - (b) Accelerating progress on equity and coverage
 - (c) Sustaining coverage post-graduation
 - (d) Increasing the availability and use of operational data
 - (e) Strengthening of the HSS mechanism

2 Strategic goal 1: Accelerate the uptake and use of underused and new vaccines

- 2.1 Strategic goal 1, "the vaccine goal" aims to prepare and support countries in the successful introduction of new vaccines. Although GAVI should be able to catch up by 2015 in meeting its target, this is an area where currently the Alliance is behind achieving its yearly targets for the number of introductions per year due to both supply issues and country readiness delays.
- 2.2 The main areas of work in this area are improved country decision making, improving quality of applications and reporting, preparing countries for introduction, and ensuring uptake through appropriate behaviour change communication. There is also increased attention to sustainability as new vaccines are integrated into a country's routine programme. In the next two years, the Business Plan prioritises country readiness and ensuring uptake of vaccines. Depending on the nature of the activities, specific countries are

targeted for support through the Business Plan. Descriptions of the key deliverables and activities are provided below.

- 2.3 **Improve country decision-making structures, systems and processes:** By 2015, GAVI aims to ensure that 18 countries have functional national regulatory authorities (NRAs) and 50 countries have functional national immunisation technical advisory groups (NITAGs). At the beginning of 2012, there were 8 functional NRAs amongst GAVI countries and 43 functional NITAGs. WHO is proposing to focus NRA and NITAG support on 15 countries (see excel file on myGAVI with a tab of the list of focus countries for all activities), with particular focus to be given to GAVI graduating countries, as these structures will be critical when GAVI support ends.
- 2.4 GAVI is also supporting the **generation of data for decision making**, in particular around HPV (through demonstration projects), MenA and Yellow Fever (through risks assessments), and rubella. Further, WHO will also conduct preparatory activities for future introductions of Japanese encephalitis (JE), typhoid and malaria vaccines.
- 2.5 **Improve the quality of country planning, GAVI applications and performance reporting:** The key deliverables in this area relate to the quality of the applications and planning by countries, (which is reflected by the approval rate from the Independent Review Committee (IRC)) and the readiness of countries at the time proposed in their applications. To ensure sustainability of the technical assistance provided to develop the applications, a new deliverable has been included for 2014, namely: “30% of countries that submit an application by 2014, and which previously submitted an application in 2010-11 do so without externally funded technical assistance”.
- 2.6 WHO will support development of approximately 56 applications in 2013 (including 18 for rota, 13 for MR, 22 for HPV and 5 for PCV). In line with the focus on implementation, WHO is also proposing a new activity to provide support to countries to develop operational plans for the introduction of all new vaccines including those introduced through campaigns.
- 2.7 UNICEF will support WHO on these activities, especially for campaign-related activities, and for rubella and measles second dose routine immunisation programmes. This work funded by GAVI will be complemented by existing staff not funded by GAVI but who already provide technical support for measles/rubella/yellow fever/Meningitis A campaigns as part of the Measles-Rubella Partnership.
- 2.8 The Secretariat will coordinate the grant approval and review process through the Independent Review Committee structure (budgeted under the Monitoring and Evaluation (M&E) section of the business plan). In consultation with partners, the Secretariat will also undertake a significant redesign of the grant approval and monitoring process. The intention is to have a new process in place in 2013, with the objective to ensure more consistent and robust monitoring and performance review of GAVI grants to countries.

2.9 Prepare countries for successful introductions of new and underused vaccines: The key deliverables in this area include: i) countries that introduced new vaccines reached their coverage targets in the first year after introduction (70% in 2013, 75% in 2014 and 80% in 2015) and ii) All GAVI supported countries have undertaken Effective Vaccine Management (EVM) assessments and 80% of them are on track in the implementation of their improvement plans.

2.10 Strong coordination at global, regional and country level is necessary to ensure successful roll out. To this end, the GAVI Secretariat, through the reinforced structure of the Country Programmes Department, will play a stronger role vis-a-vis appropriate stewardship of GAVI-related activities at country level. While the Country Responsible Officers (CROs) will work to ensure appropriate stewardship at country level, the Technical Support unit will ensure focus on health systems strengthening and country financing. The Vaccine Implementation team (formerly AVI), together with UNICEF Supply Division, will provide leadership on product-specific issues and aim to mitigate imbalances between supply and demand. They will also ensure countries have timely and accurate information on supply status and product availability. The team will provide enhanced coordination between the Secretariat and GAVI Alliance partners responsible for the multiple vaccine introductions before, during and after launch.

2.11 WHO will support over 40 countries with approved vaccine applications from 2012 with introduction activities including effective vaccine management assessments and improvement plans (EVMs), cold chain and logistics support, post introduction follow up activities and impact monitoring (as reflected in the Monitoring and Evaluation section). Support will also include activities to strengthen staff capacity around the introduction of a new vaccine, and vaccine management through provision of tools and training to accurately monitor in-country stock levels, follow up on EVM improvement plans, and focusing on integrated approaches to vaccine-preventable disease control in alignment with other preventive and curative services. Particular focus will be placed on support to implementation as opposed to assessments with specific countries identified for focused support (e.g. for implementation of EVM improvement plans), and clear assignment of lead entity between WHO and UNICEF in each country.

2.12 UNICEF will focus on vaccine management and cold chain and logistics (CCL). UNICEF will shift current emphasis from *assessment* of cold chain capacity and readiness alone to *implementation* of CCL strengthening activities as defined in EVM improvement plan recommendations. Given the Board's recognition that the Alliance will need to significantly *improve the quality and timeliness data*, UNICEF will help countries to implement vaccine stock and temperature monitoring systems that will provide programme managers in countries with *real-time data to reduce risks of vaccine stock outs and wastage*. To facilitate sustainability, UNICEF, along with WHO, will support training for logisticians to ensure optimal use of new data-generating systems in stock management.

- 2.13 In coordination with WHO and the Measles-Rubella Partnership, UNICEF is requesting funding to assist countries with campaign planning, incremental CCL strengthening, and demand creation activities for countries conducting MR catch-up campaigns as well as introducing rubella-containing vaccines into the routine schedule. This support is planned for four countries in 2013 and seven countries in 2014.
- 2.14 AVI-TAC will undertake advocacy activities in Nigeria, Democratic Republic of Congo, Ethiopia and Pakistan. It will support countries by proposing strategies, tools and develop in-country capacity to strengthen the political will around new vaccine introduction and optimal vaccine implementation, improved vaccine programme implementation and strengthened routine immunisation, and sustainable financing of immunisation programmes.
- 2.15 Strengthen national capacity for planning of behaviour change communication for new and underused vaccines within a country's disease control framework: Under the leadership of UNICEF, by end 2013, 15 countries will have developed and implemented coordinated communication plans and demonstrated impact on 1-3 priority targeted behaviours. UNICEF will accelerate the development of evidence-based communication plans through direct technical assistance, advocacy, and sharing lessons, materials and tools between countries. UNICEF will support countries to develop communication plans (four countries in 2013 and eight in 2014) and work with them on demonstrating the value of communications interventions (e.g. through targeted social research). In addition, UNICEF will build upon its experience in Communications/Social Mobilisation for polio eradication to ensure strategies for reaching excluded and hard-to-reach communities are also part of evidence-based communications efforts and work with partners in a selected number of countries (11 countries in 2013 and 8 in 2014) to increase GAVI's visibility around the launches of new vaccines.
- 2.16 Lastly, in order to ensure that there is adequate assistance with roll out of new vaccines, the Board has been asked to set aside funding to engage new partners in country as appropriate to support introduction activities. This will be managed by the Secretariat.

3 Strategic goal 2: Contribute to strengthening the capacity of integrated health systems to deliver immunisation

- 3.1 Strategic goal 2. “the health systems goal”, aims to identify and address health systems bottlenecks to improve coverage and equity. The interim deliverables of this goal have been substantially refined to better address the Board priorities, improve coverage and equity, reprogramme existing GAVI funding and better monitor implementation of existing grants. The main areas of work on which the 2013-2014 Business Plan and budgets are as follows:
- 3.2 Identify and address constraints to safe immunisation and service delivery in countries under 70% coverage. This programme objective focuses on countries with immunisation coverage below 70% or around the threshold. By

2015, at least 7 out the 12 countries¹ that were below 70% coverage in 2010 should have improved their immunisation coverage by minimum 10% from the baseline. The approach to support these countries is to understand the main reasons preventing these countries from increasing immunisation coverage and implement HSS programmes which are evidence-based through rigorous country analyses.

- 3.3 WHO will lead the development and implementation of the country specific strategies and action plans in most countries. However, given the critical nature of this work, the fact that it is behind schedule and will require significant effort, the Secretariat is proposing that additional funding be set aside to engage additional partners to support this effort.
- 3.4 Improve immunisation systems in GAVI countries through implementation of national health strategies supported by well aligned and functioning GAVI HSS grants. The main deliverables for 2013 in this area are to ensure that 100% of countries facing HSS implementation issues have reprogrammed their grants and that a satisfactory monitoring mechanism has been put in place for HSS grants. The 2015 deliverable is *“100% of countries receiving GAVI HSS support demonstrate satisfactory implementation progress as assessed by the GAVI IRC, the Joint Assessment of National Strategies (JANS) or an equivalent independent mechanism”*.
- 3.5 To reach these deliverables, WHO will support countries to develop HSS applications, and reprogramme the existing grants. WHO will also build country capacity through peer-review sub-regional workshops, as well as country specific technical assistance. WHO will also support the Secretariat in the HSS grant review process through organising pre-assessments of HSS proposals prior to the IRC.
- 3.6 WHO and the Secretariat will establish and institutionalise more robust real time monitoring of the implementation of grants in countries. This includes greater emphasis on monitoring grant performance on programmatic parameters: achievement of intermediate results, implementation of the annual plan, etc. The real time monitoring system should enable the Alliance to detect in a timely manner implementation challenges, delays and risks, and react swiftly to prevent long-term interruption in the grant implementation. WHO will hire local consultants who will be responsible along with CROs for systematic monitoring of the grant implementation and development periodic grant implementation status reports (three times a year). They will also develop an online database for “live monitoring”.
- 3.7 To strengthen health information systems for immunisation, WHO will lead a cluster of activities aimed at improving the quality of country reporting on immunisation, through implementing data verification, service availability and readiness assessments. Analytical reports for immunisation and health progress reviews will be produced for ten priority countries. GAVI funding will be used to improve cause of death reporting which helps to increase the validity and accuracy of impact evaluation studies aimed at quantifying the

¹ Afghanistan, CAR, DR Congo, Chad, ,Haiti, Liberia, Mauritania, Nigeria, PNG, Somalia, Uganda and Yemen

impact of childhood immunisations on mortality. Finally, WHO and the Secretariat will support countries in developing more effective monitoring and evaluation frameworks for their HSS grants.

- 3.8 To improve the effectiveness of the HSS support model, the Secretariat will: (a) provide operational support to the Technical Advisory Group for Health System Strengthening (TAG-HSS); (b) simplify and improve HSS application mechanisms; (c) update and improve guidelines for countries and the IRC with regard to development and assessment of HSS programmes; (d) review GAVI's HSS support with the aim to make it more country tailored and relevant, effective, result oriented, and country focused.
- 3.9 The Secretariat, in collaboration with the World Bank Institute, will contract an academic partner to develop a one week training course on health system strengthening for immunisation. The aim of the training is to improve the capacity of countries and Alliance staff to analyse health system bottlenecks of immunisation programmes; develop log-frames, result chains, and M&E frameworks; understand and implement performance based financing; plan and budget for immunisation services and integration of services with the national health plans and budgets; and prepare proposals, including budgets, implementation workplans, etc. Following training, countries should be able to improve planning and implementation of HSS programmes. The training should also equip Alliance staff (including CROs) with the technical knowledge needed to more actively engage in health system work with countries.
- 3.10 Increase equity of routine immunisation. By 2015, four of the ten countries² with the highest inequity in coverage should have identified the main drivers of inequity, should be able to monitor inequities, and should have implemented equity action plans, using GAVI HSS grants to contribute to the funding of these plans. The countries have been identified on the basis of the analysis conducted by WHO in 2010 on the vaccine coverage by wealth quintile.
- 3.11 UNICEF will take the lead in this area, and place country staff in the ten most inequitable countries. Country staff will assess the key determinants of inequities and support the country to develop and implement strategies for reducing inequalities. Analytical/research activities will be complemented by policy dialogue, strategy development, implementation of innovative approaches and evaluation of effectiveness. Of note, out of the ten countries, four are also in the list of countries specifically supported for coverage improvement (see paragraph 3.2) and will require upfront coordination between UNICEF, WHO, the Secretariat and potential other partners.
- 3.12 In addition, WHO and AVI-TAC will work on global activities related to equity. WHO will study the determinants of low coverage in addition to geography and wealth, while AVI-TAC will support the Secretariat to develop and disseminate a global communication plan to promote GAVI Alliance efforts to achieve greater equity in vaccine implementation.

² Nigeria, Yemen, Congo Rep (Brazzaville), India, Pakistan, Mozambique, Liberia, Vietnam, CAR, Madagascar

3.13 **Promote active engagement of Civil Society Organisations (CSOs):** Catholic Relief Services (on behalf of the GAVI CSO Constituency) will continue its work to support CSOs to be more involved in the Health Systems Funding Platform (HSFP) and the related policy dialogue. The work will focus on 14 countries in 2013. By 2015, at least 70% of countries will have actively engaged with CSO's in the development, implementation and the monitoring & evaluation of their GAVI HSFP grants, cMYPs and national health plans.

3.14 In addition the Secretariat is coordinating the implementation of the CSO policy, which explores how to engage CSOs, where appropriate, in service delivery(focus on hard to reach, post conflict, etc.).

4 Strategic goal 3: Increase the predictability of global financing and improve the sustainability of national financing for immunisation

4.1 With regard to increasing the predictability of global financing requirements, GAVI aims to expand and extend the public and private donor base and grow and develop its innovative finance product portfolio. The resource mobilisation priorities during 2013-2014 include (i) turning June 2011 pledges into actual and longer-term grants; (ii) accelerating outreach to new donors and partners; (iii) and building the case for a new long-term funding model and replenishment including a mix of financing instruments (direct, IFFIm, financial instruments in support of market shaping) that can best provide predictable and flexible funds needed to incentivise vaccine development and support sustainable immunisation programmes. Associated activities in support of these priorities are described in more detail below:

4.2 **Secure all pledges promised in June 2011 and extend pledges into multi-year commitments up to 2015:** In order to secure and protect signed commitments from current donors in a challenging fiscal context, and in order to extend shorter term maturity pledges to longer-term commitments, GAVI is enhancing its risk mitigation and outreach strategies through the following activities: (i) targeted and high-level visibility interventions and outreach with current donors with the different stakeholders in-country (solid CSO support, increased bi-partisan support, new champions); (ii) a successfully planned Mid-term Review, related positioning events and donor evaluations demonstrating results in donors areas of focus (value and impact, aid effectiveness, country work, HSS); and (iii) intensifying private sector outreach to complement governments efforts particularly through the GAVI Matching Fund (see IF contribution);

4.3 **Build up a donor diversification campaign:** Diversification will result from reducing concentration and building a core group of existing donors, accelerating private sector outreach and engaging new development partners. Activities will focus on building up presence and visibility through scaled up investment and demonstrating results in target markets; and strengthening in-house resource mobilisation expertise. Targets are: (i) to realise challenge

grants in the order of US\$ 200 million, which were pledged in June 2011, conditional upon these additional funds being raised from new sources; (ii) to scale up private sector participation, through the GAVI Matching Fund (see below).

- 4.4 The Innovative Finance (IF) plan for 2013-14 remains focused on delivering key components of GAVI's overall financial strategy. GAVI aims to achieve a capital structure that further diversifies its funding sources and helps optimise the Alliance business model. Some structures and funding partnerships that the Innovative Finance team will pursue are also meant to deliver a strategic value that goes beyond funding. The 2013-14 deliverables cover two major innovative finance mechanisms: IFFIm, which provides long-term, predictable and flexible funding, and the GAVI Matching Fund, which harnesses private sector resources and know-how. These deliverables will be supplemented by the team's continued efforts in innovative finance product development and active participation in selected sovereign positioning forums.
- 4.5 IFFIm's future role within GAVI will be defined as part of our long-term funding strategy, which will be presented to the GAVI Board in December 2012. For 2013, our objective is to secure agreement from the Board and key IFFIm donors on IFFIm's future role within GAVI's long-term funding strategy. Activities underlying this will include completing any processes necessary for IFFIm to continue its normal operations, including processes that support IFFIm's functioning as a non-AAA entity, engaging donors and prospects, and holding preliminary replenishment discussions with donors. The 2014 business objective is to have a meaningful replenishment of IFFIm as part of an overall GAVI replenishment. Activities in support of this effort would include exploring enhancements to the IFFIm structure, identifying new potential capital markets and sources of financing, and expanding the donor base.
- 4.6 In 2013-14, the Innovative Finance work will also continue to focus on expanding the GAVI Matching Fund through corporate and foundation partnerships that harness financial contributions, mobilise impactful advocacy initiatives and leverage competitive advantage and business skills to help us overcome programmatic challenges. As a result, GAVI aims to raise a cumulative US\$ 60 million in private sector commitments (financial and in-kind contributions) by 2013 and US\$ 100 million by 2014. These private sector commitments will be matched by DFID or the Bill & Melinda Gates Foundation.
- 4.7 With regard to co-financing, GAVI aims to increase country financing of routine immunisation costs using government resources, ensure fulfilment of co-financing requirements, and ensure graduating countries co-finance 80% of the 2016 projected vaccine price.
- 4.8 The three objectives for this programme area are listed below. These objectives reflect the priority areas considered as having the biggest impact on financial sustainability of immunisation programmes. The work in this area is coordinated through the Immunisation Financing and Sustainability Task Team (IF&S TT) and led and managed by the Secretariat.

- 4.9 Countries successfully mobilise resources required in their annual plans and budgets: In order to strengthen domestic funding for the routine immunisation programme, GAVI will now support countries to implement cMYPs (as opposed to supporting all countries to develop their plans). Activities are focused on monitoring actual country expenditures (amounts and sources) on immunisation programmes in relation to the planned costs and budgets, and providing tailored support to countries where the share of external financing of routine immunisation is large with the aim to increase government funding of routine immunisation programmes.
- 4.10 In this context, WHO, with the support of UNICEF, will lead the activities to assist countries with customised support. WHO will provide tailored support to make sure that budgets are funded and executed. AVI TAC will develop the advocacy tools and messages to facilitate the advocacy activities. However, standardised workshops will still be used in some circumstances such as the dissemination of new cMYP guidelines and tool.
- 4.11 To measure the degree of success of this strategic goal (improving/sustaining allocation of national resources to immunisation), there is a need to strengthen the global reporting mechanism, the capacity to track the flows of resources, and the knowledge base on the actual immunisation costing and financing at country level. To this end, the UNICEF/WHO Joint Reporting Form (JRF) will continue to be used for data collection, however with a stronger emphasis on data-quality assurance. UNICEF will lead the piloting and implementation of a new global system to track immunisation resource flows on global and country levels with support from WHO. This activity will be harmonised with the Decade of Vaccines (DoV) so the DoV technical working group will define the specifics of the design of the tracking system. Recent analytical work, including the DoV costing exercise, showed that there is limited accurate and precise data on the delivery cost of immunisation programmes and introducing new vaccines. The Bill & Melinda Gates Foundation is conducting eight in-country case studies on immunisation costing and financing to overcome this gap and the Secretariat will build on the lessons learned from these studies to carry out two case studies per year.
- 4.12 Implement the co-financing policy and secure domestic funding for all other routine vaccines: This objective was refocused to government vaccine financing, including non-GAVI routine vaccines and co-financing. The activities aim at ensuring that 100% of countries meet their co-financing requirements and a gradual increase of government resources for the other routine vaccines.
- 4.13 Monitoring and reporting on country co-financing performance remain critical elements of the implementation strategy. The Secretariat will continue to coordinate the monitoring and reporting on country performance and also track countries that finance traditional vaccines with domestic resources. Those activities will be accompanied by strengthened global advocacy for financial sustainability and co-financing in order to increase high-level awareness and support among countries and partners to sustain political commitment. In

addition, as the next revision of the co-financing policy is expected in 2014, appropriate preparatory analytical work will be carried out in advance.

- 4.14 As some countries that successfully co-finance are not funding other routine vaccines (non-GAVI supported), the focus of this objective was widened to include funding of vaccines as a whole (beyond co-GAVI financing only). The IF&S Task Team will finalise the list of underperforming countries, which will include countries that are not funding their non-GAVI routine vaccines. These countries will receive tailored support, including mapping of financing flows, delays and shortfalls, in order to identify country-tailored solutions to strengthen their capacity to plan and budget appropriate domestic resources for vaccine financing. WHO will lead the tailored support of twelve underperforming countries and UNICEF in five countries. Also UNICEF will explore in two countries the creation of new, or utilisation of existing revolving funds (and/or other mechanisms of collaborations with partners/donors) to identify and address issues of poor mobilisation or untimely release of national funds in experiencing regular stock-outs.
- 4.15 Support graduating countries in sustaining investment in immunisation. The level of preparedness of countries to graduate will be assessed through the following criteria: (a) the extent to which health sector budgets adequately reflect the next year's vaccine and vaccination financing needs; (b) one year before graduation, countries have the right processes and capacities in place for successful graduation, and they consistently fulfil the co-financing requirements.
- 4.16 During 2012, the GAVI Alliance partners have planned to carry out country assessments aimed at developing transition plans in six of the 16 currently graduating countries. This work will continue and WHO will lead the assessment in four additional priority graduating countries over the course of 2013-2014, which will mean that at least ten graduating countries will be assessed at least one year before graduation.
- 4.17 An appropriate monitoring methodology will be implemented to ensure countries execute their transition plans and stay on track towards graduation. WHO will lead the monitoring and provision of tailored assistance in four of these countries in which assessments were conducted and are experiencing challenges in the implementation of their transition plan and/or will require support in adjusting the set of required activities to achieve financial sustainability. The Secretariat through the engagement of the Sabin Vaccine Institute will lead the monitoring and same type of support for the execution of transition plans in three additional countries.
- 4.18 A comprehensive 'training for graduation' will be designed and several training courses will be carried out over the next two years. The Secretariat will coordinate the development of the curriculum and partners with the appropriate comparative advantage will follow up with the selected countries that require support across all Strategic Goal areas.
- 4.19 Furthermore, noting that engagement with graduating countries should ideally happen well in advance of the countries actually passing the eligibility

threshold WHO will also lead the engagement with three selected countries, identified as 'soon to graduate' countries, to increase awareness about the upcoming requirements, inform about the available support and ways to successful graduation, and support advocacy for mobilisation of domestic resources.

4.20 Finally, in order to secure the best possible support to the graduating countries, new partners to support advocacy and other activities strengthening financial sustainability of immunisation at country level, will be further engaged, including the Sabin Vaccine Institute, the World Bank and regional development banks (African Development Bank and the Asian Development Bank).

5 Strategic goal 4: Shape vaccine markets

5.1 Strategic goal 4, "the market shaping goal", aims to ensure adequate supply of appropriate, quality vaccines at low and sustainable prices for developing countries. The main areas of work include strategic demand and supply forecasting, ensuring efficient and effective vaccine procurement and supply chain management; developing instruments for lowering price to GAVI and countries; and encouraging the development of appropriate products. The Supply and Procurement Strategy, adopted at the end of 2011, guides the work in this area.

5.2 Strategically forecast the demand and supply for all the vaccines in the GAVI portfolio: Forecasting will be fully transitioned from AVI-TAC to the Secretariat from January 2013. Activities include the production of twice-yearly demand forecasts and yearly supply forecasts for all current and future vaccines. The Secretariat will validate the forecasts with partners and use them as a basis for communication to industry, countries donors and for internal financial planning and forecasting.

5.3 Ensure efficient and effective vaccine procurement and supply chain management: For the majority of GAVI countries procurement is conducted by the UNICEF Supply Division³. Working together, the GAVI Secretariat and UNICEF develop procurement strategies, convene Procurement Reference Groups when appropriate, agree on award strategies, manage financial and programmatic implications of supply issues and conduct regular consultations with manufacturers.

5.4 Key areas of UNICEF's work as GAVI's procurement partner include contract management; relationships with industry; market influence; innovative financing; risk mitigation; and supply security. It also arranges complex transport and supports supply chain optimisation, develops monitoring indicators, manages cash, budgets and financial reports and oversees strategic management and non-financial reporting.

5.5 WHO also contributes to this work area by providing risk mitigation solutions to minimise interruption of supply. This will be done through working with the

³ The PAHO revolving fund procures vaccines for countries in the PAHO region.

National Regulatory Authorities (NRAs) of the producer countries for specific vaccines, and/or specific suppliers, in order to map the identifiable technical risks and make the information available to the procurement agencies.

- 5.6 WHO will support stringent enforcement and implementation of quality standards in domestic vaccine manufacturers to meet WHO/GAVI expectations for assured quality global supply. More specifically, a time-limited catalytic activity is proposed to accelerate the excellent progress being made by the NRA of China (SFDA) to enforce and implement the appropriate quality standards in domestic manufacturers expected for supply to GAVI countries. An international staff position in the WHO Country Office, dedicated to support specific activities designed to stimulate development of appropriate quality vaccines by domestic manufacturers is proposed. This position and related funding for activity is additional to and synergistic with the support to SFDA already being provided by WHO through a BMGF grant. Separate funding is being requested from BMGF for additional support to the NRA of India.
- 5.7 Develop instruments for lowering price to GAVI and countries and/or encouraging development of appropriate products: The Secretariat is developing roadmaps for each GAVI supported vaccine. The roadmaps inform the procurement strategy and engagement with manufacturers in line with the prioritised objective for a given vaccine. Roadmaps include: i) an analysis of the market including current and future products and of product characteristics and considerations of cost and price drivers; ii) considerations of how GAVI should start engaging in the market; iii) prioritisation of objectives; iv) definition of options for supply-side interventions and signalling to manufacturers; and v) timeframe for engagement with the various stakeholders, including action plan and indicators.
- 5.8 The Secretariat, UNICEF and other Alliance members such as the Bill & Melinda Gates Foundation will implement the initiatives identified in the roadmaps. Examples are: extending volume guarantees or pre-payments to secure price decreases; working with partners and manufacturers to bring new suppliers to market sooner for vaccines where only one or two manufacturers currently exist; exploring portfolio-wide issues for potential barriers to new entrants such as IP and technology transfer.
- 5.9 To inform GAVI's medium term strategy, WHO will define product characteristics for future vaccines, and assessing the feasibility of accelerated evaluation and licensure pathways for second generation vaccines.
- 5.10 WHO will contribute to build international consensus on quality assurance (QA) so that products can be made consistently over time by the same manufacturer and, crucially, enable multiple manufacturers to make vaccines to a specific and acceptable standard of quality. This activity will yield instruments (international QA guidance's) that will help accelerate development of specific products identified as priorities by the GAVI Board. The approach for this will be two-fold:

- (a) *Defining product characteristics for future vaccines:* WHO will embark on such an exercise for second-generation malaria vaccines. This activity comes timely as in parallel to the final clinical evaluation of the RTS's malaria candidate vaccine, multiple efforts are underway to improve upon this product.
- (b) *Assess feasibility of accelerated evaluation and licensure pathways for second generation vaccines:* A most effective way of reducing vaccine prices comes with product competition. The work would focus on HPV vaccines, where the conventional development pathway has been very lengthy, and where opportunities for placebo controlled studies will cease to exist.

6 Monitoring and evaluation (M&E)

- 6.1 The cross-cutting M&E section of the Business Plan seeks to ensure that valid, reliable and useful measures of performance are available and used to support organisational and stakeholder learning, management of strategy, improvement of programmes, mitigation of risk and reporting of performance. The areas identified by the Board in 2012 are addressed in the M&E section of the 2013-2014 business plan as follows:
- 6.2 Ensure effective routine programme monitoring that links decision making to performance: The key deliverable in this area for 2013 is the redesign and deployment of a systematic routine grant monitoring system. The main activity will consist of the redesign of the current new proposal and monitoring review process (See SG1, paragraph 2.8). In support of this, the Secretariat will take to scale a grant monitoring scorecard tool that it has developed in consultation with partners. It will also ensure that all new policies and initiatives have a robust M&E framework in place from inception; and improve on data systems including its data warehouse and the "e-platform" through which the Secretariat receives data and information from countries. As the lead entity responsible for these items in the Business Plan, the Secretariat conducts this work in close consultation with WHO and UNICEF.
- 6.3 Coordinate and conduct targeted studies to address key questions and meet critical information needs: Three categories of targeted studies are included in the Business Plan for 2013-2014: targeted studies to be conducted by AVI-TAC, following Board approval in June 2012; additional targeted studies to be commissioned starting in early 2013; and Board and Committee requested evaluation studies to be commissioned starting in early 2013. AVI-TAC is the lead entity in two pneumococcal vaccine effectiveness studies (PCV10 in Kenya and PCV13 in South Africa); two rotavirus vaccine effectiveness studies (Ghana and Rwanda) and a fifth study, on risk of intussusception due to rotavirus vaccination. Additional targeted studies to be commissioned in 2013 as part of the Business Plan were identified based on the recommendations of the research expert group convened in April 2012. One is a combined study on pneumococcal vaccine effectiveness and the risk of pneumococcal vaccine failure due to serotype replacement in Asia. The second is the aforementioned assessment of validity of coverage data through biomarkers.

6.4 Evaluation studies included in the Business Plan for 2013-2014 include the effectiveness and sustainability of GAVI support to graduated countries (2013), and the AMC impact evaluation (2014). The Secretariat will commission all of these evaluations, as well as the pneumococcal vaccine study and the assessment of validity of coverage estimates, through transparent and competitive processes. Pending agreement from the PPC, specific thematic reviews will be conducted instead of large backward-looking HSS evaluation (e.g. changes in content and orientation of new proposals submitted for HSS support from GAVI).

6.5 Evaluate the impact and cost-effectiveness of GAVI support to countries. WHO and the GAVI Secretariat will evaluate the impact and cost-effectiveness of GAVI support to countries. WHO uses data from surveillance, targeted studies and evaluations to improve the models used to estimate the number of future deaths averted resulting from vaccination in GAVI supported countries. WHO also develops tools and methods to estimate the cost-effectiveness of vaccination and the broader economic impact of vaccines to assist GAVI eligible countries in their decision making process vis-à-vis new vaccine introduction and provides evidence on value for money of vaccines. Activities in 2013 will also include technical consultation to develop methods to document the impact of HPV vaccination.

6.6 The Secretariat is responsible for two activities. The first is a continuation of a process which began in 2011, in which the Secretariat and the Gates Foundation jointly convened an expert modelling group to project the future impact of vaccination in GAVI supported countries to 2020. In the 2013-2014 period this work will continue with additional vaccines and outcomes included in the modelling process. The second relates to the implementation of full country evaluations. These are five year prospective evaluations to be conducted in five countries. The purpose of these evaluations is to generate information and learning regarding the relevance, effectiveness, impact, and efficiency of GAVI support to countries and the sustainability of country programmes receiving such support. The scope of the evaluations will include GAVI's support for new and underused vaccines, as well as GAVI's cash based support to countries. The findings from the full country evaluations will be used to refine models used to model the impact of GAVI support to the full range of countries it supports. In 2012 a contractor was selected and the inception phase is underway. If the inception phase is successful, the core phase will commence in 2013.

6.7 Ensure availability and use of high quality programmatic and epidemiological data: The key deliverable in this area is the implementation of the coverage improvement plans in eight countries in 2013 and 16 in 2014. WHO, UNICEF and the Secretariat all contribute to this work area. WHO's business plan submission covers the traditional approaches, including supporting countries with data quality self-assessments, refining their estimates of the target population and conducting coverage surveys. WHO has not included in its submission a more 'game changing' approach, since funding for such an approach is being sought from another donor.

- 6.8 In addition to supporting WHO on global level estimates, UNICEF will develop a web interface to improve data collection quality for a range of programmatic immunisation indicators, using edit and logic checks in real time.
- 6.9 The Secretariat is leading on a sub-set of activities related to implementation of the revised immunisation data quality assessment (IDQA) tool, which is an independent assessment of data quality with a strong focus on the accuracy of the numerator of children vaccinated with the last recommended dose.
- 6.10 Meet established quality indicators for surveillance of diseases preventable by new and underused vaccines. The deliverable in this area is that countries have the ability to conduct adequate surveillance activities for most GAVI vaccines. WHO is the lead entity in strengthening country, regional and global capacity to conduct surveillance of vaccine preventable diseases. Their submission includes a continuation of previously funded sentinel site surveillance for rotavirus and invasive bacterial diseases. The rotavirus surveillance is producing good results that are being used for decision-making and for monitoring impact of vaccination. Surveillance for invasive bacterial disease has been more of a challenge. Recent support for improving data management as well as laboratory capacity and the addition of rapid diagnostic tests and PCT have resulted in a substantial improvement in detection of pneumococci. WHO is currently conducting site assessments and will discontinue sites that do not meet established criteria. In addition to the ongoing work on rota and invasive bacterial diseases, the WHO submission includes funding for new activities related to surveillance for epidemic meningitis in the African meningitis belt; surveillance for Yellow Fever; and limited funding for surveillance for typhoid and JE in a few select countries in Asia.

7 Advocacy, Communications and Public Policy

- 7.1 GAVI's advocacy, communications and public policy activities seek to develop awareness of the value of vaccines leading to a strengthening of the political will of decision-makers to invest in and expand access to immunisation. The Secretariat's advocacy and communications approach is focused on the following 2013-2014 priorities:
- 7.2 The value of immunisation, new vaccines, and GAVI is understood amongst key influencers and stakeholders: The deliverable for this area is to increase stakeholders awareness and increase the diversity of media coverage. In order to achieve this, GAVI will demonstrate results and increase visibility, especially in selected key donor and potential donor markets, and evolve the GAVI brand and its messaging. In 2013, the work will focus on i) increased media support for donors and diversified outreach beyond health and development media; ii) strengthened partnerships with advocacy groups and VIP champions; iii) new campaign-type approaches that empower partners and new allies, iv) an increased presence in social media v) a strengthened brand to help better leverage GAVI's assets, expand supportive constituencies and enhance visibility.

- 7.3 AVI-TAC will support this area by generating scientific communications materials, providing scientific support to reputational risk management, and helping generate field and human interest stories especially in the lead up to the Mid-Term Review.
- 7.4 Mobilised and empowered advocates to inform GAVI's policies, support fundraising and help achieve its strategic goals: The deliverable in this area is to increase the number of advocates engaged in key processes. To achieve this GAVI will strengthen its stakeholder network by including faith-based groups and the private sector while developing further synergies among partners' advocacy and communications activities. In addition GAVI will aim to strengthen southern voices and in-country advocacy to ensure that the voice of developing country advocates resonates in global forums, and in new and emerging donor markets.
- 7.5 Increased influence in development aid policy settings: To attract new development partners and reposition itself in a changing public policy environment, GAVI will lead on several activities to advance this deliverable. GAVI will focus on encouraging G20 and BRICS countries to become champions of immunisation, and will pursue priority dialogues among advocates and replenishment partners including ministers of finance, parliamentarians and southern networks (with equity and sustainability as core themes).
- 7.6 In order to maintain prominence on the policy agenda and strengthen the evidence base for investment, GAVI will advocate for health and equitable access to immunisation to remain at the core of the post-Millennium Development Goal (MDG) agenda, and will demonstrate the economic benefits of immunisation.

8 Policy

- 8.1 GAVI's policy development activities seek to ensure that GAVI adapts and develops policies that are aligned to the evolving environment and further the four strategic goals. The main policy review for 2013 will be the Vaccine Investment Strategy (VIS), covering the period 2014-19. The VIS will provide the Board with the ability to understand and take decisions about vaccine investments across a portfolio of options. The aim of the VIS is to pre-empt one-off decisions and help the Board understand the opportunity costs associated with decisions, and to support planning by countries, industry and partners. The Strategy will be developed in light of GAVI's existing commitments. The process will build upon the rigorous approach endorsed by the Board in 2008.
- 8.2 The Secretariat will also review the prioritisation mechanism, the gender policy and the TAP policy in 2013. The co-financing policy will be reviewed in 2014. The GAVI Secretariat will also respond to Board requests for new or revised policies as they evolve.