Report to the GAVI Alliance Board

16-17 November 2011

Report of the Chief Executive Officer

9 November 2011

Dear Board Members,

It is a great pleasure to provide you with this report, which combined with my board presentation, provide my perspective on the first GAVI Board meeting I will attend as CEO, as well as my first 100 days on the job.

I am grateful to the Government of Bangladesh for hosting this Board meeting. Around the meeting we will have the opportunity to see some of the Government's achievements in improving the health of the people of Bangladesh. I would particularly like to highlight and thank Faruque Ahmed as a former Board member and Director of the Health Programme of the Bangladesh Rural Advancement Committee (BRAC) which represents one of the best examples of the power of civil society in development in Bangladesh and around the world.

It is five months since GAVI's last Board meeting, and three months since I became CEO. Some of the papers that have been provided for the Board and the decisions that the Board will be invited to take are the result of processes that began many months before I became CEO, and so the perspective I offer here and at the Board meeting is in some respects still one of an outsider. Of course, I am fully engaged and so this is really the last time I will be able to say this…

GAVI has a strong business model, with a relatively small secretariat, and a large well-functioning Alliance, drawing on the strengths of each of the partners. Our model allows us to pool vaccine demand from countries and funding from donors, to create a significant market for vaccines appropriate for people living in the poorest countries.

This model has achieved some powerful results. Since GAVI's inception in 2000, WHO now estimates that the Alliance has helped countries prevent more than 5.5 million future deaths by immunizing 326 million additional children against hepatitis B, Haemophilus influenza type b (Hib), measles, pertussis, pneumococcal disease, polio, rotavirus diarrhoea and yellow fever.

I am particularly grateful to WHO for providing these figures. We are also working with our partners to strengthen the methodology behind them and the way we report results. An additional important challenge will be to capture our collective impact on morbidity. For many vaccines, Meningococcal A, Polio, and Rubella being good examples, the largest effects will be in reducing morbidity. We all know we are making a big difference in this area but we do not have an agreed way of measuring it.

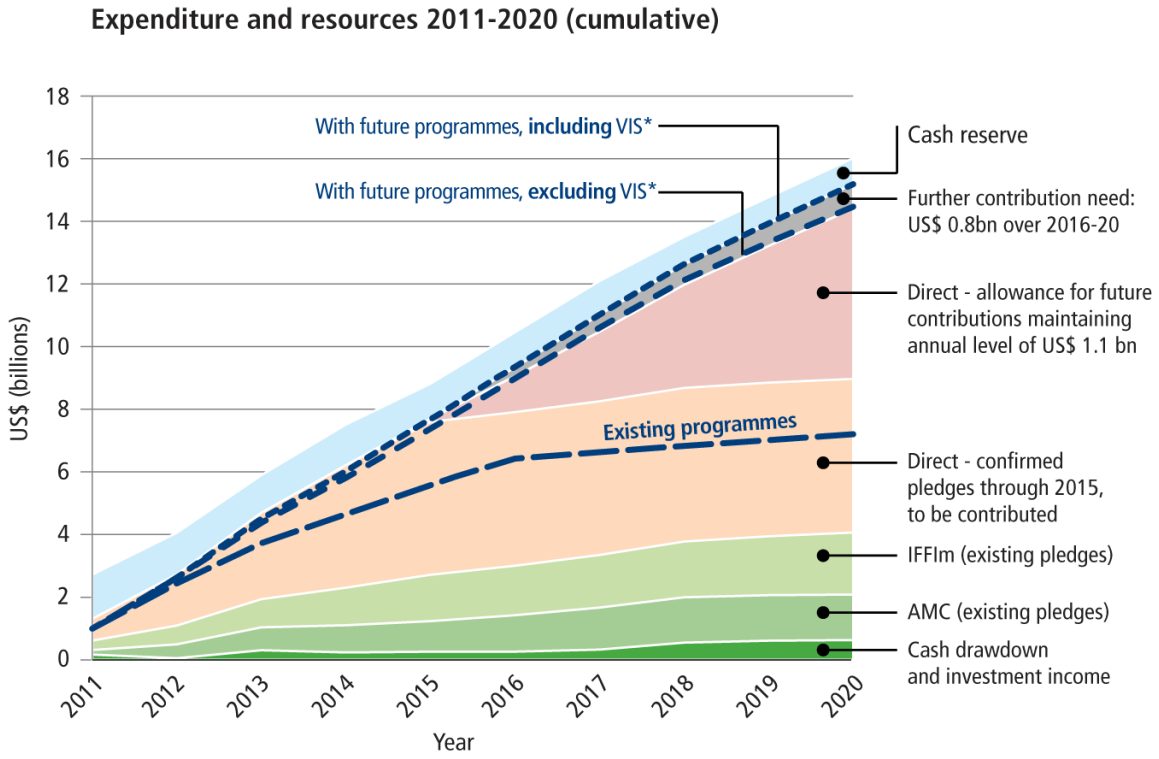
1. Opportunities and challenges

We aim to immunise almost a quarter of a billion children in the years up to 2015, contributing to preventing almost an additional four million future deaths and seeing dramatic reductions in morbidity. This will mean an unprecedented increase in the number of vaccine introductions which we think is challenging but achievable. We have seen country demand for pneumococcal and rotavirus vaccines grow at a much faster rate than historically for pentavalent vaccine, and program expenditure – on vaccines and cash-based programs - is expected to grow from $0.6bn in 2010 to $1.4bn in 2012, representing an increase of 123% in two years.

With all of the challenges in front of us, there are two that are far more important than the rest: delivering on our ambitious agenda, and maintaining confidence in GAVI's programs. To do this we need stronger immunization systems in countries sitting at the heart of well-functioning health systems, with clear roles for GAVI partners and the secretariat, providing robust and timely data so that programs are effective and risks are properly identified and managed. And we need, with the Board, to have the opportunity to take an overview of the global immunization landscape, so that, for example, benefit from synergies with those working on other vaccine efforts such as polio and measles; and we can follow developments in vaccine R&D and adjust our focus as new vaccines become available. In each of these areas the Alliance collectively and individually needs to up its game and the secretariat needs to play its role. In the following sections I begin to address how we can meet these challenges.

The starting point is that GAVI has a firm financial foundation, on the basis that we receive the pledges that were made in London and continue to proactively seek new contributions. With these resources we can fund the acceleration of demand that we have seen since the London pledging conference. If the Board approves the PPC's recommendation to start funding for HPV and rubella vaccines, and – once the vaccines are available and subject to further Board consideration – Japanese Encephalitis and typhoid, our finances still remain firm. As the chart below indicates, demand through 2020 can be met provided donors continue to contribute beyond 2015 with some annual increase (on the order of US$160 million) to the level set in London. I would stress that the chart is cumulative. The introduction of malaria or other new vaccines would require a more substantial additional increase of an order of magnitude of US$ 225 million a year from 2016-20. Details are provided in the Updated Long Term Financial Forecast paper, and the Board will have the opportunity to test the reasoning behind this statement during the meeting.

As one would expect, GAVI also receives suggestions for additional areas that should be funded, relating to existing or new vaccines, or to change policies in ways that have financial implications. Each time the Board is invited to make a decision, the Board rightly wants to know first that the individual decision is justified in its own terms, and second that taking that decision will not prevent future opportunities being seized. This requires a view of the landscape of possible decisions, and an analysis of the options, in as much as we can provide them given uncertainties, such as around price and efficacy of future vaccines. This should be a normal part of our planning process and we will discuss this at the meeting.



*VIS: Vaccine Investment Strategy covering the new windows for HPV, Japanese Encephalitis, Rubella and Typhoid accounts for US$ 0.7 billion of the demand through 2020. Demand for other vaccines represents the additional US$ 0.1 billion of the US$ 0.8 billion 'further contribution need' that arises in 2016-20.

At the last Board meeting, it was requested that we examine the case for reconsidering the Board's decision to set the GNI threshold for eligibility for GAVI funding at $1500, and look again at the option of raising it to $2000. The paper provided for the Board indicates that the health impact of making the change will be relatively small, and my view is that a better investment would be on making sure that graduating countries and other lower middle income countries (LMICs) have access to lower prices as discussed below.

The vaccine landscape

We conducted a formal planning process on new vaccines in 2008 where we consulted broadly with partners, experts and the Board in creating our Vaccine Investment Strategy. The current plans are to update the Strategy in 2013. In advance of this we will have a chance to discuss what new vaccines are on the horizon at the Board meeting and will then have a discussion on what further information might be useful as part of maximizing outcomes from GAVI investments. We will then take the information from this discussion into account when we plan for a more substantive discussion at the 2012 Board retreat. For this reason I would like to discuss a few of the potential areas below.

In considering the landscape we need to make sure that GAVI is true to its original promise, which is to be the place where the whole vaccine community comes together to meet on our collective shared goals. However, I would stress that this is not necessarily about GAVI funding or even becoming engaged in additional areas of work.

Introduction of new vaccines is dependent upon strong systems. WHO reports that coverage across the GAVI-supported countries continues to improve with overall DTP3 coverage at 82% (although see below for my concerns about the robustness of some of the data). Measles coverage varies between regions – for example WHO's AFRO region has an average of 76%, while the Americas have a 93% average. However, these numbers hide the variance between countries and between areas within countries, meaning that measles outbreaks continue to occur.

This last year, measles outbreaks occurred in both industrialized countries such as France and developing countries such as DRC. Although measles is among the cheapest vaccines and countries are encouraged to procure their own vaccine, outbreaks in developing countries mean that children are dying or living with the sequela of a measles infection. Furthermore, given the transmissibility of measles, it is like the canary in the coalmine…a warning of the weaknesses in the immunization systems. More generally, continued outbreaks reduce confidence in our collective immunization system and the power of vaccines. Clearly in addition to the special immunization efforts, routine vaccine efforts in outbreak countries need to be strengthened. GAVI has funded 28% of the Measles Elimination Initiative (MEI) during 2000-2008 and is or will be funding eleven countries for measles second opportunity. If the Board approves the introduction of rubella vaccine, we will be involved both in measles and rubella elimination efforts since the rubella vaccine is combined with measles. We will also be looking at ways that we can further synergize our efforts with our partners and the measles elimination initiative before any potential measles-rubella roll outs occur.

New vaccines providing protection against high priority targets such as malaria, dengue fever, inactivated polio, cholera and conjugated typhoid may be coming to the market within a few years and we will have a chance to briefly discuss these at the Board meeting.

On polio we need to consider not just the new inactivated polio vaccine but also the infrastructure involved in eradicating this disease. As with measles, where there are polio outbreaks, this reflects weaknesses in the immunization system as a whole. And the polio eradication efforts mean that there are 3000 people, and a sophisticated laboratory and reporting system, in countries where there are potential synergies with our work. The good news on eradication is almost nine months without a case in India. However, new outbreaks in China, Uganda and DRC raise new challenges. Getting control in endemic countries (northern Nigeria, Afghanistan, Pakistan) means not only campaigns but strengthened routine delivery.

The Global Polio Eradication Initiative (GPEI) is considering a new strategy for bringing some of the changes that were expected post-eradication forward including adding a low-dose inactivated polio vaccine as a stand-alone at the time of DTP3 or even as part of a hexavalent vaccine. This would serve three functions: to increase protection; to allow coverage against type 2 as that gets removed from the oral vaccines used in the eradication program; and to prevent vaccine derived polio virus spread. We are obviously following this very closely including the discussion of WHO's Strategic Advisory Group of Experts on this topic. In the meantime, to work more closely with the GPEI, it makes sense to pick a country or two where we can practically explore how we can work better together to further each of our missions.

It has also been proposed that GAVI contributes to funding a cholera stockpile of a recently WHO pre-qualified vaccine to help with emergency response to outbreaks of this disease, such as in Haiti. We will watch with interest a recent decision by partners in health to introduce a pilot of cholera vaccine roll out in Haiti.

The big news in vaccines since the last meeting was around RTS,S, the malaria vaccine being developed in collaboration by GSK and the Malaria Vaccine Initiative, with support from the Gates Foundation. Preliminary results demonstrated a 50-56% efficacy against clinical malaria and a 45-47% efficacy against severe malaria in the 5-17 month age group. A first look at the combined younger age children (EPI age of 6-12 weeks along with older children) showed a lower efficacy of 35% against severe malaria and so we need to await more data to determine whether this vaccine will meet appropriate efficacy and duration of protection endpoints and be recommended for general use in high incidence malaria areas.

In describing these proposals, I am in no way recommending to the Board that GAVI should fund any of them at this time or at all; I am merely describing the landscape. During my presentation to the Board, I will present some very tentative numbers on the possible financial impact if the Board were to choose any of these proposals, and subject to the discussion, we will bring further information to the Board retreat or properly worked up options to the Board or EC. Obviously, any interest in further activities will need to take account of the impact on countries' and the Alliance's capacity, as well as financial considerations.

Regardless of any additional new vaccines, what we have in the pipeline for the next few years will take us a good way towards meeting our business plan targets. To achieve success, we need to ensure that countries are in a position to effectively deliver these new vaccines.

Health systems

Vaccine delivery depends upon strong health systems, and immunization is also a key part of health systems – indeed it is often the backbone – particularly in places where other parts of the system are weak. Where treatment is not an option, prevention becomes even more important; and immunization is used as a tracer of health system performance because all of the elements of the health system – financing, service organization, human resources, governance, information and technologies – have an immediate impact on immunization.

In conversations I had before and since becoming Chief Executive, the issue where I have found the most intense and widest range of opinions is in relation to cash based support. The Board meeting in Kigali reached a settled position that we should be devoting a proportion of our resources to using cash to support health systems, and that this funding should have a strong link to immunization outcomes. We have chosen indicators for the Health Systems Goal in the GAVI strategy which reflect this policy. However, in my view, we are not where we need to be in implementing our cash based programs. We have limited heath systems expertise in the secretariat, partner support has not been able to fully compensate and one of our main partners in the Health Systems Funding Platform, the Global Fund to Fight AIDS, Tuberculosis and Malaria, has been focused on other issues.

We are in transition between two funding systems. The Board has also rightly introduced stronger fiduciary controls. Disbursements have been slowed, meaning that in this year so far we are not at the average proportion of spending that the Board requested (we are currently around 10% of overall program spending compared to the 15-25% average up to 2015 requested). It will be a priority for me to increase this average so that we are in line with the Board's decision, but only if we can do so with programs of sufficient quality, with strong links to immunization, and at a risk level that makes sense.

The way we work with countries to help them strengthen their immunization systems of course needs to be different in Rwanda and in Somalia, India and DRC. Until now GAVI has largely operated with the same business model for all countries. In other words, we have been a wholesale operation. Of course there has been some variation but the aim has been to have tailoring for country circumstances done by countries – by submitting applications for vaccines or cash-based support that are relevant to their circumstances – or by in-country partners. This model has virtues – it avoids duplication and means that the GAVI secretariat has remained small. However, if we are to achieve the ambitious objectives that we have set, we need to make some changes, while understanding that we cannot have 73 different operational models. UNICEF has taken a new strategy under their relatively new leader, Tony Lake, to take a deep dive in a limited number of countries and look at immunization coverage at the district level assuring that we are reaching the "fifth child". We welcome this enhanced effort on equity which aligns well with a closer look at country challenges and we are already in the planning stages of working together on this.

GAVI needs to differentiate between fragile countries – where our practice is already different in some cases, for example in Somalia GAVI's programs are largely managed by UNICEF and WHO – underperforming countries (like Uganda or Papua New Guinea where special attention is required), and large countries (where there are enormous coverage differentials between regions and provinces and political strategies are particularly critical). Drawing on advice from Alliance members, we will come back to the PPC and Board with more developed ideas on how programs should be systematically differentiated. In the following section I provide my initial thoughts on how we can manage risk, and I also present here some thoughts on the Performance Based Funding proposal below.

Managing risk

Mitigating risk needs to drive how we tailor our programs, while recognizing when we are working in the poorest countries in the world where fiduciary controls are often not as strong as they should be, we cannot eliminate risk entirely. This includes fiduciary risk and implementation risk in our cash-based programs as well as risks concerning vaccine program implementation and commodities.

On cash-based programs, Helen Evans kept the Board up to date with investigations that were proceeding into the potential misuse of funds in Mali, Côte d'Ivoire, Niger, Cameroon and Zambia. In October I informed the Board that the Government of Mali had repaid all misused funds, and we have recently agreed with the Government measures to strengthen the oversight of funds. Because of the insecure situation in Côte d'Ivoire, it has not been possible to start an investigation but this will begin shortly. A long standing investigation is also underway in Zambia, primarily into

misuse of non-GAVI funds; the government has committed to repay all misused funds. Investigations are proceeding in Niger and Cameroon and I will inform the Board as soon as they have concluded. It is already clear, however, that the situation in both these countries is more serious than GAVI has previously experienced, and I have written to both Ministers of Health to ask that they do everything they can to bring the investigations to a rapid conclusion. Subject in part to the discussion with the Board about the 2012 business plan budget, we are following up on the recommendations by the Director of Internal Audit to the Board in July to strengthen our control activities and will report on progress at the upcoming meeting. I want to emphasize that the Internal Auditor and I are completely aligned on the challenges in hand and our need to mitigate them as much as possible.

The Board has received a paper and will have a discussion on Performance Based Funding (PBF); as I note below, it will be important that any new program design not only makes improvements in programmatic delivery but also reduces fiduciary risk. Leaving aside PBF and considering the health systems funding platform more broadly, there are some countries where a combination of the quality of country systems and the level of in-country oversight by partners will mean that we can provide pooled or budget support cash funding in support of a well-developed national health system plan, and easily provide an element of performance based funding. But at this stage my view is that this will not be possible in some GAVI-eligible countries for some time. We need to recognise this and determine how we proceed.

Although to date GAVI has focused mainly on risks related to cash grants, from my perspective, the potentially larger and more financially and programmatically significant risk is that vaccines might not be managed properly. We currently have insufficient understanding of the logistics systems country by country. One of the consequences is that we do not have sufficiently robust information about whether countries have the cold chain capacity at all levels necessary to introduce new vaccines. The WHO estimates that two thirds of GAVI countries have sufficient capacity to introduce either pneumococcal or rotavirus vaccines, while half would have capacity to introduce both vaccines over the coming years. Capacity is harder to assess at the sub national level. As new vaccines are introduced, the combination of underperforming information systems coupled with higher capacity utilization of cold chain space could potentially lead to increased wastage and stock outs and therefore reduced vaccine coverage. Given the cost of the new vaccines and how important they are in protecting people's health, both of these should give us serious cause for concern.

We are fortunate that there is no evidence of a secondary market in vaccines, and that the risk of fraud in relation to vaccines is small. But this does not mean that vaccines are not sometimes wasted because they are not properly managed or that there are stockouts and we have missed opportunities for vaccination. Our knowledge has improved considerably in recent years as, working closely with WHO, we have introduced Effective Vaccine Management reports as part of the application process for new support; the challenge now is to ensure that these reports accurately represent reality on the ground.

This risk was highlighted by the GAVI task team on large countries, which found that in Nigeria there had been a major stock out in the first half of 2011 of basic vaccines

(DTP, and BCG against tuberculosis). This is a problem in itself given the issues it reveals in the GAVI-eligible country with the second largest birth cohort and because the GAVI secretariat and WHO and UNICEF headquarters did not know about it until the task force visited the country. As additional vaccines are introduced, the stress on the logistics system will increase as will the risk of stock-outs. This is an area where we need to do much more work with countries and partners.

There are some important differences between the risk profiles of GAVI and the Global Fund - most notably 85% of GAVI's program funds are spent on vaccines which represent a low risk of fraud, as compared to the commodities that the Global Fund supports or cash-based programs; and we have already been taking steps to strengthen our management of fiduciary risk. But the Report of the High Level Independent Review Panel on Fiduciary Controls and Oversight draws similar conclusions in terms of the need for intelligence about what is happening in countries at the field level. The challenge will be to do this without becoming so risk adverse that we stifle the innovation GAVI is built upon.

Better data

To manage all of these risks we need better intelligence about what is happening in countries; and systematically better data.

We need to strengthen our data systems, so that the Secretariat, partners, country implementers and the Board get timely and robust information to base decisions upon. To take one example, Ethiopia, UNICEF and WHO have estimated DTP3 coverage in Ethiopia to be around 86%. The preliminary results of the 2011 DHS survey are that DTP3 coverage is 36.5%. Differences of this order of magnitude cannot be put down to sampling error. UNICEF and WHO are working with the Government of Ethiopia to investigate levels of coverage, and the Government and the Gates Foundation have been looking at the feasibility of a biomarker study in Ethiopia, which would provide biological information about vaccine-induced immunity would help clarify the correct level of coverage. Subject to investigation into feasibility and cost, my view is that the immunization world should pursue an ambitious agenda on using biomarkers and other innovative survey methodologies to allow more accurate data for planning. I have recently mentioned this at my presentation at WHO's Strategic Groups of Experts meeting. I have also been surprised as to the lack of real time data used for managing vaccine roll-outs. We need to work with our partners taking advantage of new readily available digital technologies. I am pleased by the focus UNICEF is putting on getting real time operational data from sub-district level.

In addition to having more staff to liaise – from Geneva - better with countries and partners, we need to hold our Secretariat staff more accountable for stewardship of the GAVI investments and better empower them to do the tailoring necessary at country level. At present the cycle of IRC recommendations and monitoring does not empower staff. Any reprogramming of an HSS or CSO support grant of 15% or more of the annual value of a budget sub-heading of the program needs to be referred to an IRC and then the EC or Board. These sums are often small, particularly for smaller countries, and by the time this process has been completed, the re-programming may no longer be relevant. We can improve the impact and management of programs by being more responsive to country needs.

Governance and accountability

Coming out of discussion held at the Board retreat in Oslo, the Board rightly made it clear that it holds the Secretariat accountable for meeting the Alliance's goals by coordinating the Alliance. This means working with all of the partners round the GAVI table in different ways in different circumstances depending upon the comparative advantages of each partner; and holding the members of the Alliance accountable for meeting our agreed collective goals.

We need to make sure that our governance processes are as effective and efficient as possible. In looking at how the secretariat spends its time, a significant proportion is devoted to preparing papers and meetings. By the end of this year there will have been more than 75 Board, committee or task team meetings. So far, there have been 312 board papers with a conservative estimate of 22,000-35,000 person hours on the preparation, writing, editing, approving and presenting these papers.

It is undoubtedly one of the strengths of the Alliance and of public private partnerships that we work to align the views of individuals and organization which naturally have different perspectives but which share common goals. The result is that we have coherence where there would otherwise be competing approaches. So it is entirely right that governance should take up a significant proportion of all of our time. The question I would like to consider with the Board is whether all of the governance processes are as efficient as they can be. We have examples of task team papers travelling up to the Board, and then back down again to another task team with a related but different remit, and then back to the Board again. And committees assembled at short notice to re-examine issues. I know that there has been at times more engagement by the Board in detail due to a lack of confidence in the Secretariat, but we stand ready to move to a more efficient system with the Secretariat taking a more active role in managing day to day operations with partners and policy coordination, with the Board moving to a more strategic governance role.

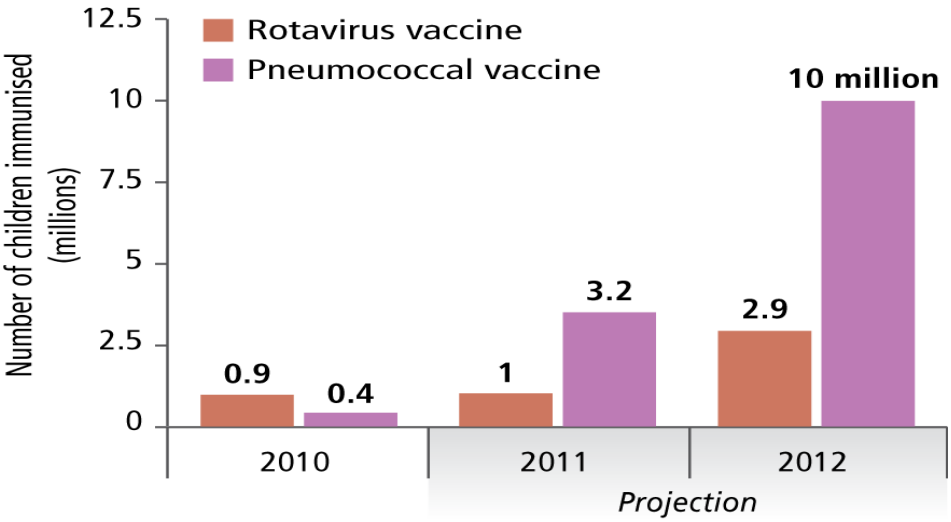
An example of an improvement in governance is the simplification of the IFFIm/GFA structure which we will be discussing at the meeting. Legal and commercial analysis has been completed on the potential for the retirement of the GFA. The analysis concluded there are no legal barriers, and commercially there are cost savings of up to $1.4m per year. As a result, there is a process underway to consult donors and, if our recommendation is accepted, remove the GFA from the IFFIm structure.

The Governance Committee will review conflict of interest and ethics policies for GAVI shortly before the Board meeting. I was aware before I joined GAVI that the members of the Alliance were passionate about our mission. We need to align our individual interests with the collective interests of the Alliance; in some cases, however, we will need to agree that not every member of the Alliance can participate in every debate or decision. Naturally different members of the Alliance will have different perspectives on these issues, but we need to look at potential conflicts structurally and the Chair of the Board will be leading this process with the Governance Committee.

2. Progress and updates

Since we last met at the Board meeting in July, five countries have introduced **pneumococcal** vaccine; 16 will have introduced by the end of the year; and the EC in September approved funding for an additional 18 countries. In spite of new supply agreements signed under the AMC, because of this increased demand,vaccine supply has become even tighter in 2012 and 2013. We are actively under discussions with the manufacturers to look for additional supply, but the current assumption is that there will be a number of countries unable to start introduction in 2012-13. Nevertheless, with production capacity increases coming through in 2013, it should be possible to reach the latest forecast of 58 countries introducing before the end of 2015 (up from 44 in the Business Plan).

Children immunized with pneumococcal and rotavirus vaccines



Source: WHO-UNICEF coverage estimates for 1980-2010, as of July 2011. Coverage projections for 2011-2012, as of September 2011. World Population Prospects, the 2010 revision. New York, United Nations, 2010 (surviving infants).

For **rotavirus** vaccines, the number of countries expected to introduce during this same period has increased from 33 to 47 under the new forecast. In July, Sudan became the first country outside Latin America to launch rota. The pace of introductions will now accelerate with 25 countries having submitted applications in the May round. We are seeking longer term contracts for vaccine supply; there is sufficient supply over the long-term to meet demand, with the exception of 2013 where there may be supply constraints.

To date, 12 countries have introduced **yellow fever** vaccine through preventive campaigns with GAVI support. In 2010, a campaign was conducted in Guinea and three more campaigns were approved for Ghana, Côte d'Ivoire, and Sudan which will take place in 2011 and 2012, reaching more than 22 million people. In relation to Meningococcal A vaccine, in addition to the campaigns in Burkina Faso, Mali and Niger, reaching nearly 20 million people to date, Cameroon, Chad and Nigeria are expected to introduce the vaccine later this year.

The task team on large countries made significant progress through its reflection and engagement with India and Nigeria. They documented that there are clearly different challenges in India and Nigeria and suggested that a customized approach needed to be developed on each (the application of such an approach may also have relevance for other large countries). My understanding is that the countries found it helpful that the partners came together at a senior level to give attention to the immunization issues that the countries faced.

India clearly has the resources to give immunization and new vaccines the greater role that they deserve; at the moment the political commitment to this is lacking in some parts, including in states with populations bigger than most countries. India has the largest number of unimmunized children both in absolute terms and per capita. The question is how we generate that commitment which must go well beyond the normal health apparatus. By the time of the Board meeting I will have made the first of what will be many visits to India, and I would welcome a discussion in the meeting about what we can collectively do to achieve this, building upon the recommendations of the task team.

For my part, one of the key elements of how we manage our relationship with India is the cap of $350m that we have had in place. Clearly, on the one hand, all of GAVI's funds could be spent in India and still leave some significant challenges. On the other hand, at present we are suffering from the opposite problem, of how we can politically engage with the country and have them take advantage of the funding which has already been committed. My view is that when we have sums in the order of $1bn committed to neighboring Pakistan, it sends the wrong signal to have a cap of $350m on India. If our political strategy is successful, India should fund most of its own program. It we are so successful that it looks likely that India will apply for funding that would exceed GAVI's resources then we will need to debate that issue at the Board. But I would propose that at this stage the Board allows the India cap to lapse at the end of this year; and our focus should be on working with India to generate stronger commitment to immunization at a senior level.

Nigeria has a range of different and difficult problems, but we are in a better place right now than we have ever been. We have a very dedicated and sympathetic Ministers of Health and Finance dedicated to efficient operations and development. A new health plan is waiting for final signoff with substantial financing. There is a renewed interest in polio and operationally vaccines are being rolled out. Clearly though, more support will be needed and if aligned with all of the above, is likely to take Nigeria to a new level.

GAVI, like other partners, has been working to understand the impact of the **Pakistan** Government's decision to abolish the federal health ministry as part of its devolution program. GAVI has over half a billion dollars committed between 2012 and 2015 to continue pentavalent supply and for the introduction of pneumococcal vaccine.

The Government has recently decided to retain a national EPI management function to which funding is committed until 2015. This should help to avoid short term disruption in the EPI and GAVI vaccine programs. However, the Government has not decided if, or how, the federal government will continue to have a role in health systems strengthening. For now, GAVI's ISS and HSS cash programs are on hold. Finalizing a different approach in Pakistan will require continued intensive

engagement with government and partners; this is another example of where GAVI needs to develop a tailored approach.

The Alliance takes sustainability very seriously and **co-financing** of vaccines remains an impressive and important part of our approach. This year, only one country will remain in default (the DRC, which is having so many problems that other partners are considering withdrawing support). And we will be asking the Board for special permission to allow DRC to continue to provide support for Yellow Fever and Pentavalent, even if they are unable to pay their 2010 arrears. However, besides this one extremely challenging case, we understand the challenges generally associated with increasing cost commitments and graduation from GAVI. We are proposing to work more closely with partners such as the African Development Bank as well as the Sabin Institute this year on co-financing, in addition to the continuing work with the World Bank. We are hoping to have a meeting with selected Ministers of Finance with the World Bank at the Spring annual World Bank Meetings looking at these issues.

I have started to meet **civil society organizations** (CSOs) and hear their perspective. I am delighted that we are beginning to work more closely together for I am certain that CSOs have an important part to play in many aspects of our agenda, particularly in relation to vaccine advocacy and advocacy and implementation in large and underperforming countries as well as fragile states. One critical issue in having a closer knowledge of what is happening at country level will mean understanding the roles that CSOs play or potentially can play in these countries.

GAVI has recently been the subject of a number of **aid effectiveness** reviews. The DFID review which came out before the pledging conference and showed GAVI to be one of their highest performing investments – while also providing feedback on areas which needed to be strengthened – gave the UK government confidence to make an enhanced investment. Further reviews are underway by Australia and Sweden which we hope will be similarly positive. Beginning 2012, the Multilateral Organisation Performance Network (MOPAN including 16 donors) will carry out a comprehensive organizational assessment of GAVI, the first one ever for a global fund. I hope donors can build on this joint assessment to make best use of the available information. I plan to attend the 4th High Level Forum on Aid Effectiveness in Busan later this month and look forward to learning from other initiatives and presenting GAVI's business model.

At the pledging conference, we committed to doing a midterm accountability review in 2013. At the conference, Raj Shah announced the idea of holding a Washington **Vaccine Summit** in 2012 to keep the momentum going. We are working with UNICEF, USAID and the Gates Foundation on this meeting which is currently planned to be held in Washington, D.C. in June 2012. The timing of the Summit could have implications for GAVI's Board meeting; we will update you as soon as the dates for the Summit are confirmed.

Following the pledging conference, the UN Foundation with support from the Gates Foundation started a new campaign, **Shot@life**, to connect and empower Americans to champion vaccines as one of the most cost-effective ways to save the lives of children in developing countries. They are championing GAVI as one of the best mechanisms to support vaccines (along with the GPEI and the MEI) and we are working closely with them.

The **Decade of Vaccines** collaboration is a time limited gathering of leading figures from the international vaccine community, including many members of the Alliance, initiated by Bill and Melinda Gates at Davos in 2010, to create a global vaccine action plan. The vision of the Decade of Vaccines is closely aligned with the Alliance's vision (although their mandate goes well beyond GAVI's core business) and we continue to work closely with the different working groups. The plan will be put to the World Health Assembly for approval, to the Washington summit for further discussion, and we hope to a GAVI Partners' Forum for its formal launch.

GAVI has held regular Partners' Forums. The last one was in Hanoi in 2009, and given all that has happened since then and what we plan in the next year, it is time to bring the broader immunization coalition together again. So assuming the Board agrees and provides funds requested in the 2012 budget, we will hold a forum in late 2012 which we tentatively plan to hold in an African country.

Resource mobilisation

The extraordinary success of the pledging conference in June has not prevented us from continuing to vigorously work with our existing donors to improve the predictability of the receipt of pledges and seek new ones. I am in the process of setting up visits to major donors: I have visited France and the US, and I will shortly visit the European Commission, Japan (where Helen also recently visited), Korea, the UK, and Australia; and plans are underway to visit GAVI's other donors.

Our funding campaign continues both because we must continue to diversify our sources of funds, by focusing on new champions and funders including in emerging economies, and because the pledges received in London need to be fulfilled. We are constantly reminded that we live in challenging financial times. We have seen instability in the Eurozone and a tightening of public sector funding in many parts of the world. It is during difficult economic times that investments in vaccines make most sense as they are the most cost effective way to speed development, and we need to make this case so we can convert our June pledges into actual cash.

To take the example of one of our biggest donors, and where the process is in the public domain, we anticipate that the US Administration will request the resources necessary to fulfil their pledge of $450 million over three years. We know there remains strong support for this, but the funding must actually be decided on and appropriated annually by the US Congress. For the 2012 fiscal year, the first year of the US's new pledge to GAVI, the Administration requested $115 million for GAVI, a welcome increase over the previous year's appropriation (although less than a third of the $450m). Despite very strong support from the administration, the highest level recommended by the Congress so far in the appropriations process is $100 million.

Another example is the – again, very welcome – $330m pledges of matching funds by the UK Government and the Gates Foundation, in addition to their other very significant pledges, to encourage new public ($200m) and private ($130m) donors.

The **Matching Fund** for private sector contributions aims to bring new corporate and foundation partners into the GAVI family, as champions as well as funders. So far we have had contributions from Anglo-American, ARK Foundation, La Caixa, and JP Morgan. Since the last Board meeting we have bedded down the legal and financial architecture and have started a systematic marketing effort. We have a number of

other organizations engaged and hopefully more announcements soon. We are hoping to do an event at Davos in early 2012 and the Vaccine Summit in mid-2012 to secure even more engagement. We are working hand in hand with DFID and the Gates Foundation in this effort.

It is important for GAVI to have a vibrant and successful private sector resource mobilisation effort. This is particularly true in the United States which represents a large percentage of overall private sector funding. The **GAVI Campaign** has had areas of success but overall, despite the best efforts of its board and staff, it has not offered an acceptable return on the Alliance's investment. As a result, the Chairs of the Campaign and the Alliance jointly commissioned a rapid review of the Campaign. The review was then discussed in late September with a group of independent private sector funding experts and the Campaign Board both of which I participated in. There were two main conclusions: there was an advantage in retaining an independent but lean 501(c)(3) charitable entity to facilitate private sector outreach in the United States; however, it also should be fully aligned with the GAVI structure, operationally and strategically. The Campaign Board endorsed these conclusions as do I. We are awaiting further legal advice as to the minimal nature of independent governance and staffing required in the Campaign. Meanwhile, the GAVI managing director for Innovative Finance, David Ferreira, is providing interim leadership assuring alignment. A large percentage of the funds remaining in the Campaign will most probably be transferred to the Alliance and much of the work of Campaign staff is now directed towards the Matching Fund. Depending on legal advice and further review, there may be some consolidation of the staff into the secretariat.

IFFIm remains a key part of GAVI's funding infrastructure. IFFIm is important in providing long term confidence to countries and manufacturers that there is funding for vaccines; in providing flexibility; and may have particular usefulness if deployed to fund new vaccines. In 2012 we will be discussing a long term resource mobilisation strategy with the Board, and the role of IFFIm in this will be one of the areas for decision. I am pleased that Alan Gillespie will be joining us at the Board meeting and that the Board will have the opportunity to discuss these issues with him.

3. Key decisions for the Board meeting

New vaccine windows

As noted above, in 2007 and 2008 the secretariat worked with its technical partners to assess the impact of 18 diseases and the costs and challenges of introducing the associated vaccines, with the objective "to reduce the overall disease burden." With the conclusions of the assessment, the Board endorsed HPV, Japanese Encephalitis (JE), rubella and typhoid as key vaccines which could contribute to this goal, and also asked the secretariat to monitor the development of vaccines for malaria and dengue. Given the financial climate in 2008 the Board did not decide to fund the new vaccine investment strategy. In the light of GAVI's new funding position, the PPC has now recommended that the Board decide to begin funding for HPV and rubella vaccines. For **JE**, the PPC was very interested in providing a window for the counties in the regions affected; however, they chose to not recommend this until there was an appropriate pre-qualified vaccine. Finally, in relation to **typhoid**, the PPC recommends that we wait to open a window until a conjugated typhoid vaccine is developed and available.

In considering **HPV** vaccine, two of the key issues are that the disease burden of cervical cancer is growing, with the number of cases expected to increase 1.5 times by 2030, and that the alternatives to prevention – screening and treatment – are expensive and unavailable for many people in the poorer developing countries. As a result, there has been enormous interest from developing countries in HPV roll out. There are clear challenges in relation to the introduction of HPV vaccine as it should be provided to 10-13 year old girls rather than infants up to one year old through the EPI. There have been a number of pilot programs, and in these countries, full roll-outs are possible. In fact, at the last board meeting, we heard a passionate, spontaneous description of the roll out in Rwanda. In other countries, we will be suggesting the creation of pilot programs to develop their own experiences before countrywide roll-outs. As a result, if the window is approved, we expect a rather gradual increase in country roll outs. As often occurs, this challenge also presents an opportunity, as girls in this age group are also a key target for other health interventions, such as maternal and child health information, family planning, HIV prevention. These and other interventions can be built around the introduction, increasing its cost effectiveness. I am also convinced from a range of discussions, including around the non-communicable diseases summit in New York, that HPV represents a great opportunity to engage with a range of new advocates for vaccines.

I am also excited by the prospects for **rubella** vaccine, both because it will allow us to spread the benefits of rubella control and because it represents an effective way of strengthening our support for measles control. The Measles-Rubella (MR) vaccine is inexpensive and can be relatively easily introduced into the EPI, and its introduction should not therefore be seen as having a high opportunity cost in relation to other vaccines.

Supply and procurement strategy

In the past, GAVI primarily relied on passive market forces to influence price and supply security which we learned was useful to achieve some price drops but not sufficient for our ambitions. For example, as the Advance Market Commitment (AMC) has shown, pull mechanisms can play an important role. With this new strategy, GAVI will be able to actively approach market shaping. Extensive consultation was held with all of the partners and the public and the high level roles and responsibilities for the different actors have been discussed and summarized in the paper. Although many in the external world see this as about pricing, it also needs to be about ensuring healthy vaccine markets. We have recently seen the de-listing of two of our Indian pentavalent suppliers. Luckily, some of our other suppliers have stepped up to the challenge to assure that there would not be major shortages. Critical, therefore, will be to assure that through our strategy there are multiple suppliers and adequate investments in Quality Assurance and Quality Control.

We are already working with vaccine companies, closely aligned with UNICEF supply division and the Gates Foundation as we work out our roles under the new strategy, playing to the strengths of each organization. One different aspect here is the need for each partner to respect commercial confidentiality and maximise the market impact of GAVI's funding power. Within these constraints, we will strive to be as transparent as possible.

One major challenge will be a continuing focus on assuring appropriate pricing for our graduating countries. We were happy to see our industry partners step up to this as

a number of them offered to allow graduating countries to continue to procure at GAVI prices. A more perplexing challenge is the wider tier of countries—the lower middle income countries. Today, there are large numbers of unimmunized children in these countries. Prices are not standardized, are often high, and can represent a significant burden. This goes to the heart of GAVI's commitment to equity in access to immunization for all children. We have been approached by a number of these countries and the Decade of Vaccine collaboration has highlighted this challenge. We are looking into ways that countries could band together to create some type of mechanism for them to procure at a reduced price even if not as low as the GAVI price. We will come back to the board on this issue when we have a better evidence base.

Performance based funding

Until the Health Systems Funding Platform started to be introduced, GAVI had provided cash support through its performance based immunization services support program, its health systems strengthening window, and pilot programs to fund CSOs to support immunization. In addition, GAVI has provided cash support to help with new vaccine introduction (at $0.30 per child in the first birth cohort or in the case of campaigns, per person in the target population).

The Health Systems Funding Platform aims to provide support through a single mechanism. The new Performance Based Funding (PBF) proposal would add a performance based element to this mechanism. The advantage of this approach is that it will encourage countries and other partners to focus on coverage rates – important for all vaccines, and not just those currently funded by GAVI.

At the same time, the proposed system puts a considerable weight on data that is not always robust. The policy already recognises that fragile states will need a different approach. However, it is not only fragile states where there is uncertainty about data. I have noted above the example of Ethiopia, and the steps which the government of Ethiopia is taking to address the issue. We have also seen significant changes in Nigeria's coverage estimates in the last year. The vaccine community needs to invest more in helping countries to assess and improve their data and advance innovation in the independent measurement of coverage, such as through the use of biomarkers. The questions for me on this performance based strategy are whether we should integrate another step in the process, so that there is a review of the robustness of coverage data before we provide performance based cash support to a particular country, and whether we should explore the use of household survey data to independently verify reported coverage levels.

I also believe that we need to take the opportunity presented by the PBF task team's work to take another step to strengthen our fiduciary controls. The Board decided in 2008 to introduce a new Transparency and Accountability Policy and our approach has been that we should assess and work with governments to strengthen management of fiduciary risk, starting with the countries deemed to present the most risk, for example, because there is a large program in the country. This has meant that where programs are already underway in countries, we have stopped disbursements while financial management assessments have been conducted. And in some cases, programs have been recommended by the IRC and approved by the Board in advance of a financial management assessment being conducted. For risk reasons and to make a close link between Board approval and implementation, I

believe that it would be better for us to conduct a financial management assessment in advance of approving a program, and make this assessment part of the judgment about whether we should approve the program.

Business plan

If we are to meet the challenges I have outlined in the rest of this report, the Alliance will need additional capacity. As noted above, program activity is expected to grow by 123% from 2010 to 2012, and continue at this higher level. This greater expenditure and the associated higher rate of vaccine introductions will require additional support from partners and the secretariat. As compared to 2010, the 2012 budget includes a request for an additional 23% budget allocation for the business plan. Even if these additional resources are allocated, this means that the business plan shows a reduction from 17% of Alliance expenditures in 2010 to 10% in 2012.

There are no changes in overall policy within the new budget; the strategy remains the same. We will continue to implement primarily by coordinating the work of partners and countries. The enhancements in the budget are focused on enabling additional activity central to vaccine delivery, including a more customised country-by-country approach, quality and timeliness of data and monitoring, actively shaping vaccine markets and enhanced fiduciary controls.

It is critical for the success of GAVI that we meet these challenges. I am concerned by the over-stretch and in some areas the thinness of expertise in the secretariat. So we have budgeted for a range of new activities and some new hires. GAVI is not a technical agency and should not become one. But if we are going to manage the risks and opportunities in cash based health system programs, we need health systems expertise as well as better intelligence on what is going on in the GAVI countries. If we are going to better monitor and address the challenges of vaccine wastage, we need some logistics expertise in the secretariat so we can participate properly in conversations with the partners and keep up to date with innovations in the area. We need to strengthen our capacity on disease surveillance and epidemiology so that we can engage better with the experts and monitor our funding in these areas. As has already been planned, and because it is at the heart of GAVI's business model, we need to move demand forecasting in-house. We also need to step up our efforts on market shaping which requires specialized expertise. And we need to build the Secretariat's professional project management capacity so that we can help monitor and coordinate the intense actives that the Alliance will be undertaking. Given that the budgeting process began before I arrived and my short time in the role, I have not evaluated all of our activities and prioritized changes. As a result, the budget also asks for some additional flexibility through a one-time CEO reserve of $2 million or 1% of the business plan budget. Of course, I will consult with the Chair and the EC on the new areas of work that would be funded by such a reserve.

I will also be looking to strengthen the way the Accelerated Vaccine Initiative (AVI) operates, so that it is optimized for the coordination of the implementation and scale up of vaccine roll out in addition to the early advocacy and preparation for vaccine introduction for which it was originally designed.

The AVI also has a special studies team that commissions and manages operational research critical to our vaccine products — pneumococcal and rotavirus vaccines.

Many of the studies commissioned by the group will be completed in 2012. However, there remain and are many new important questions that should be further evaluated in a timely fashion. For rotavirus some examples include the efficacy of rotavirus vaccine in low income settings, the efficacy of the current recommended dosing schedule, and external factors which might influence vaccine take like the timing of concomitant breast feeding. For pneumococcal vaccine, some examples include whether serotype replacement will lead to disease replacement, what will be the long term efficacy of the vaccine against disease, and whether serotypes for different regions will need adjustment. For both, there is a question as to what degree GAVI should be engaging in supporting countries in implementation and operations research as well as phase IV evaluations to look at post-licensure issues, for example on real world efficacy against disease. To do so, we will need to seek expert consultation on the key questions that should be tackled, which of these are already underway through other funders and which mission critical and appropriate for GAVI to support. Given that roll outs are underway, timing is critical. As such, this will be a priority early in the first quarter of 2012 and we expect to come back to the PPC and Board with our recommendations as well as assure that appropriate bridging mechanisms are in place for current studies if they are required.

Management update

Since my arrival in early August I have made it a priority to get to know and understand the Secretariat's priority areas for delivery, the skills and the resources available. I have been impressed by the commitment and hard work of staff and their warm welcome to me, but I am also concerned about what I see as quite major and concerning gaps in particular skills sets that are to my mind essential if, as an Alliance, we are to delivery on our commitments. Some of my early conclusions are reflected in the enhancements proposed in the business plan update and then reflected in the budget. I have also found it useful to line up my impressions in my first months with the results of the Staff Engagement Survey run in May this year. In that survey it was pleasing to see that, despite the significant changes in leadership and the uncertainty around resources over the fifteen months since the previous survey, there has been a steady improvement in staffs' opinion of GAVI as employer. Much of this I credit to Helen Evans's excellent leadership. However there were four clear areas where staff registered a decline in satisfaction. These were the areas of: system and processes (i.e. too much bureaucracy); change (staff are concerned that change is occurring too fast for them to be able to do a good job); well-being (with burn out being a concern particularly for longer serving staff, a concern that has been highlighted also by our Internal Auditor); rewards and recognition (this includes particularly non-financial rewards).

It is now three years since the major governance changes that created the GAVI Alliance as an independent Swiss Foundation and the decision to focus the Secretariat significantly in Geneva. At that time there was an external review and a restructure of the Secretariat. It is therefore timely to consider the changes that have occurred since that time both in the scope of our business, the strengths and challenges of the current teams and the current structure. This year for the first time we introduced 360 degree appraisals starting with executive leadership team and we have just extended that to the next level of senior management. In discussion with Helen, I am actively considering where strengthening of skills and capacity and some restructuring should occur. In making any changes we will also be very mindful of our

very significant commitment to deliverable results and the need therefore to balance any change with continuity.

On the concern about internal bureaucracy, as a small independent Swiss Foundation, I find this is unacceptable. Some is a legacy of adopting UNICEF procedures when the transition occurred and also the mix of work practices and procedures that comes with a public private partnership — of balancing the expectations of public sector donors with the more streamlined approach of the private sector. But we have already started a process of looking at all of our internal business operations to see how they can be streamlined and simplified including setting up focus groups of staff to tease out what excessive bureaucracy means to them and what can be changed. Interestingly it was not only internal processes around travels, procurement and HR that staff are concerned about. Governance processes were seen to put a significant demand on staff resources and staff questioned whether some of it was the most efficient use of Alliance resources and I have commented on that elsewhere in this report. The pace of change is unavoidable and staff who come to work at GAVI are largely very mission driven, although there are ways to mitigate the fallout from the pace of our operations and we will be investigating those. Finally, we will be looking at instituting internal recognition and awards for both individual performance but also for team accomplishments. I was surprised to learn that there is currently no differentiation in pay for performance. In 2011 there was a salary freeze for all staff and we are now looking at to how we can link any salary increases to a performance pay system. This also requires us to review and improve our current staff appraisal system.

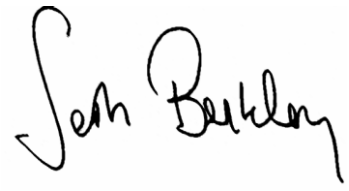
4. Conclusion

I come back to the starting point of this report: it gives me great pleasure to provide you with these early thoughts on this extraordinary Alliance of ours. For all the lively, intense – I know that these words are sometimes euphemisms – debate we see in the Alliance, we're all proud to be on this mission.

If I have focused in this report more on the challenges than the successes that is because I want to give you a candid assessment of my impressions. I have presented a number of new possibilities and perspectives: however, I want to reassure you that I understand it is our shared critical task to deliver on the programmes which the Board has already approved and which are being implemented. I have absolute confidence that we can deal with the obstacles before us by building on the strengths of each of the partners. Together we can make a difference to so many millions of people around the world.

I am looking forward to seeing you all in Dhaka.

Best,



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