Evaluation of the Accelerated Development and Introduction Plans (ADIPs) and the Hib Initiative
Summary, recommendations and follow up

BACKGROUND

The *Accelerated Development and Introduction Plans* (ADIPs) for rotavirus and pneumococcal vaccines were created in 2002 to expedite the introduction of these vaccines in GAVI-eligible countries. The GAVI Fund Board approved an initial envelope of $30 million for each ADIP for the period 2003 – 2007. PneumoADIP is housed at the Johns Hopkins Bloomberg School of Public Health in Baltimore; RotaADIP or the Rotavirus Vaccine Program is housed at PATH in Seattle. In the past four years, the ADIPs have been building the evidence base for both vaccines and have worked with industry, WHO and other partners to lay the foundations for their safe and efficacious use in GAVI-eligible countries. More specifically the ADIPs have:

- Established *surveillance* systems in key GAVI-eligible countries to demonstrate the burden of disease; developed accurate data on global, regional and national burden of disease;
- Communicated the value of vaccination through global and regional *advocacy*;
- Improved the rigour and accuracy of *demand forecasts*, an area where the public sector has historically been weak;
- Collaborated closely with the vaccine *industry* to demonstrate that a developing country market exists for rotavirus and pneumococcal vaccines, in order to help establish a more diverse supplier base for these vaccines and eventually greater affordability;
- Supported studies (*clinical trials and effectiveness studies*) to assess the immunogenicity, safety, efficacy and effectiveness of pneumococcal and rotavirus vaccines in developing countries;

The *Hib Initiative* was created in 2005 to support developing countries in making informed decisions regarding the introduction or continuation of Hib vaccines. The GAVI Fund Board approved an envelope of $31.4 million for the period of 2005 – 2009 for activities of the Hib Initiative, which is housed at the Johns Hopkins Bloomberg School of Public Health in Baltimore, in a consortium arrangement with the US Centres for Disease Control, the London School of Tropical Medicine and Hygiene, and the World Health Organization.

In June 2006, the GAVI Alliance Board requested the GAVI Secretariat to commission an independent *evaluation* of the ADIPs and the Hib Initiative in order to highlight lessons learnt through the innovative ADIPs and Hib Initiative approach and make recommendations to the GAVI Board on the structure and finance of its continued support in this priority area in the coming years. HLSP conducted the evaluation and presented the final report to the GAVI Boards in May 2007.

EVALUATION – CONCLUSIONS

The work of the ADIPs has accelerated the process of introduction of pneumococcal conjugate and rotavirus vaccines and has thus contributed to future lives saved and hospitalisations averted when the vaccines will be introduced in low-income countries. The HI has facilitated decision making in a number of countries. However, since the Hib Initiative was only halfway through its implementation period at the time of the evaluation in 2006, it was felt to be difficult to demonstrate or assess achievements at this stage

The ADIPs have influenced the entry of existing suppliers into the developing country market for pneumococcal conjugate and rotavirus vaccines. They have stimulated the pipeline of projects under development for the two vaccines, given their work to develop credible demand forecasts and business cases to demonstrate and secure the availability of funding sources and the interest of countries in taking up these products. The ADIP has also helped establish the credibility of emerging suppliers to foster future market competition.

While it is difficult to assess the absolute impact the ADIPs have had given the lack of a counterfactual, one could compare the status of rotavirus and pneumococcal conjugate vaccines today, poised to enter the GAVI market, with the status of Hib at the same stage in its life cycle to see the impact the ADIPs have had. Even if one were to compare the programme readiness of Hib four years ago, when the ADIPs were started, to the programme readiness today of rotavirus and pneumococcal conjugate vaccines, it is difficult to avoid the conclusion that there has been a contribution of the ADIPs to this process. There is also considerably greater awareness in countries of their pneumococcal and rotavirus disease patterns, due to the establishment of surveillance systems, and hence the expressed need and interest of countries to introduce vaccines against these debilitating and costly infectious diseases.

EVALUATION - RECOMMENDATIONS

Overall, it was recommended that GAVI create a new mechanism for supporting the vaccine introduction process in three areas: 1) scanning the vaccine pipeline, 2) preparing for vaccine introduction work ("ADIP" activities), 3) implementation of vaccine introduction.

The report makes recommendations on the structure and management of possible future "ADIPs" (area 2):

1. ADIPs should be focused in a single organisation, with a strong manager, and be target-oriented, time-limited and milestone-driven.

2. ADIPs should justify on a regular basis to the GAVI Board the continuing relevance of their product.

3. ADIPs should carefully define their interactions with GAVI Partners at country level.

4. The GAVI Board should ensure that there is collaboration and coordination among all groups performing an ADIP-like function by convening open forums where they can report latest results and resolve potential issues.

Furthermore the report makes a number of recommendations regarding the *management* of this process, in particular for the implementation phase (area 3):

5. GAVI should consider an implementation mechanism either within the GAVI Secretariat, housed at a GAVI Partner organisation or at an outside organisation selected through an RFP process.

6. Oversight of activities needs to involve the GAVI Board, through a Management Committee selected with appropriate skills, and with liaison through specifically charged GAVI Secretariat teams.

7. The Requests for Proposals, mandate, and the governance structures must be clear and appropriate

EVALUATION – FOLLOW UP

The recommendations on scanning the pipeline (area 1) as part of a mechanism for supporting vaccine introduction are being considered in two ways; first, through strengthened Secretariat engagement with industry on the vaccines and through the post-ADIP structure, but also as part of the Vaccine Investment Strategy which is currently being developed and is looking at the pipeline of vaccines available in the next five years.

In November 2006 the GAVI Boards authorised an *extension* of both ADIPs through end 2008, in order to ensure continuity of the process of rolling out the investment cases which were approved at the same meeting. The continuation of the ADIPs presented an opportunity to implement some of the recommendations for potential future "ADIPs" (area 2) in the existing projects for the last year of their lifespan:

- Two additional members (with the status of permanent observer) were appointed to the Management Committee to broaden skill sets and experience of the Committee as a whole. The following members were selected:
    - A health expert from Burundi with longstanding experience in implementing vaccine introduction in developing countries
    - A communications professional with broad experience in designing and implementing advocacy and communication strategies for health development, including immunisation programmes, in resource-poor settings
- GAVI's Chief Technical and Policy Officer, was installed as a permanent member on the Management Committee in 2006, subsequently replaced by the Director of Policy in 2007. In addition GAVI Secretariat representation on the Committee was strengthened by adding two permanent observers:
    - Senior Programme Officer for Accelerated Vaccine Introduction
    - Senior Programme Officer for Country Support
- A Grants Manager was recruited by the GAVI Fund office in Washington DC to increase capacity for managing grant compliance for the ADIPs and Hib Initiative.

In relation to the third area of supporting the vaccine introduction process - implementation of vaccine introduction - the GAVI Boards requested in May 2007 that the GAVI Secretariat work with partners to specify the activities and identify a mechanism to *support the implementation* of the investment cases for introduction of pneumococcal and rotavirus vaccines and possibly other future vaccines. The GAVI Secretariat is now working with partners to identify the additional support required for the introduction of rotavirus and pneumococcal vaccines, who should implement them, and what level of funding would be required, while ensuring a smooth transition of ongoing activities currently implemented by the ADIPs. A costed proposal will be presented to the GAVI Boards in June 2008.