

Report of the ADIP Management Committee

In 2004 the ADIP Management Committee has had two full day meetings and additional telephone conferences to monitor progress and give guidance to the rotavirus vaccine and pneumococcal vaccine ADIPs. Based on this, the ADIP Management Committee is pleased to provide the following comments and recommendations to the GAVI Board:

1. The ADIP Management Committee commends both ADIPs for their diligent work and excellent progress during the year and notes with approval that both the activities and the spending of funds in 2004 closely match the work plans and budgets approved.
2. Based upon its review, the ADIP Management Committee recommends that the GAVI Board to approve of the proposed work plans and budgets for 2005, allocating for the Rotavirus ADIP a budget of \$11,035,594 (see ADIP attachment 1) and for the Pneumococcal ADIP a budget of \$8,752,909 for 2005 (see ADIP attachment 2).
3. The ADIP Management Committee notes with satisfaction the continued rapid progress of rotavirus vaccines developed by Glaxo SmithKline (Rotarix) and Merck (Rotateq). Rotarix is already approved in some Latin American countries and Rotateq may be registered for the US market as early as the end of 2005. The ADIP Management Committee strongly endorses the ongoing close collaboration of the Rotavirus ADIP with both manufacturers to ascertain that the evaluation and subsequent introduction of these vaccines in GAVI/Vaccine Fund eligible countries can take place as soon as possible based on appropriate evidence for each main region (Latin America, Africa, Asia).
4. The ADIP Management Committee welcomes that a Rotavirus Vaccine Supply Working Group has been established to link the evidence generated by the Rotavirus ADIP of the value of rotavirus vaccine with negotiations to procure vaccine from manufacturers. The ADIP Management Committee approves of the proposed terms of reference for this working group and recommends that these terms of reference be adopted by the GAVI Board (see Annex 1).
5. The ADIP Management Committee has taken notice of a recent CDC review report on post-marketing surveillance of the 7-valent pneumococcal vaccine (Prevnar) used for vaccinating children in USA since 2000. A reduction of more than 80% of all invasive pneumococcal disease was observed in vaccines with strong evidence also of a substantial indirect protection effect in the population due to herd immunity. The ADIP Management Committee requests the Pneumococcal ADIP to present to the next ADIP Management Committee meeting, taking into account these highly encouraging findings, a long-term supply strategy plan for pneumococcal vaccines, outlining available and future products, forecasts of the market volumes demands, levels of company investment and commitment for developing countries, and finance mechanisms to support pneumococcal vaccine introduction.
6. The ADIP Management Committee requests both ADIPs to initiate, in an evolving process to be further refined by the continued ADIP work in following years, the preparation of Preliminary Investment Plans for rotavirus and pneumococcal vaccines, respectively, with first drafts available for review at the next ADIP Management Committee meeting.

7. The ADIP Management Committee welcomes the proposal from the Hib Task Force to create an ADIP-like program for Hib vaccine, under the supervision of the ADIP Management Committee (with a revised membership to address the broadened mandate). Clear synergies and benefits should be possible through this mechanism and in particular through closely linking the experience and activities of the new HIB-ADIP with those of the existing Pneumococcal ADIP.

GAVI/Vaccine Fund's Rotavirus Vaccine Supply Working Group Terms of Reference

GAVI has funded the rotavirus ADIP with the primary objectives of establishing, communicating, and delivering the value of vaccination against rotavirus disease. Through the efforts of the ADIP, an evidence base, including information about disease burden, vaccine impact, cost-effectiveness, and demand for the vaccine, will be generated. The availability of relevant information will allow national and global decision makers to confidently make committed decisions regarding the value of rotavirus vaccination in developing countries.

Securing an affordable, sustainable supply of vaccines at volumes commensurate with demand in the developing world is critical to realizing the potential health impact of vaccination against rotavirus disease. The information generated by the ADIP and its partners on the value and need for rotavirus vaccines are essential to successful negotiations with the manufacturers for the long-term supply of rotavirus vaccines.

In recognition of the need to link the evidence generated by the ADIP regarding the value of the vaccine with negotiations to procure vaccine from manufacturers, the GAVI Board established a Rotavirus Vaccine Supply Working Group. The purpose of the Working Group was to explore initially with GSK and Merck the technical, scientific and cost characteristics required for early introduction of rotavirus vaccines in Vaccine Fund eligible countries. Price/volume negotiations would then be conducted with the companies.

Based on this initial experience the full TORs proposed are as follows:

1. To develop actionable proposals for the use of GAVI/VF resources to procure a sustainable, appropriate supply of quality rotavirus vaccines for VF-eligible countries.
2. On behalf of GAVI/VF, conduct negotiations with potential suppliers in relation to prices, volumes, product formulations, and other vaccine characteristics.

The responsibilities of the Working Group include:

1. Identify critical information, process and policy needs to ensure that GAVI/VF investments in rotavirus vaccines will lead to timely vaccine uptake and deliver the expected health returns.
2. Develop strategic plans for negotiations between GAVI/VF and individual rotavirus vaccine manufacturers, including general terms and timing of negotiations.
3. Ensure the support of GAVI partners for the terms of any proposed agreements.
4. Ensure that negotiations reflect the interests of GAVI/VF and help the Alliance to achieve its stated health impact objectives for rotavirus vaccination.
5. Working Group may seek advice on technical matters from outside experts as needed.
6. Working Group reports to the GAVI and VF Boards through the ADIP Management Committee.

The responsibilities of the individual members of the Working Group include:

1. Chair: The Director of GAVI's Rotavirus Vaccine ADIP will serve as the Chair of the Working Group, and, as such, is responsible for coordinating and planning the effort. In conjunction with the representative from UNICEF and the Co-Chair, the Working Group Chair is responsible for carrying out detailed contractual negotiations with the rotavirus vaccine manufacturers according to the terms developed by the Working Group.

2. The Co-Chair is responsible for supporting the efforts of the Chair to coordinate and lead the Working Group meetings. The Co-Chair will be selected from the membership of the ADIP Management Committee based on the expertise required at any one time. Mr. Kevin Reilly is suggested to be the initial Co-Chair.

3. Individual member as determined by the GAVI Board: John Wecker, Rotavirus ADIP Executive Director; Orin Levine, Pneumococcal ADIP Executive Director; Jan Holmgren, Chair of ADIP Management Committee; Kevin Reilly, Member ADIP Management Committee; Regina Rabinovich, Gates Foundation; Steve Jarrett, UNICEF Supply Division; Jacques-François Martin, The Vaccine Fund; Marie-Paule Kieny, WHO and Tore Godal, GAVI Secretariat. The membership of the Working Group may change from time-to-time in response to different situations.

The primary responsibility of the members of the Working Group is to support the Working Group to achieve its objectives by providing strategic and technical input, and, where appropriate, serving as a liaison to ensure support for Working Group decisions within their host institutions.