# ADIP Management Committee Meeting Report
# 10-12 June 2004, Geneva

## Executive Summary

Progress with each ADIP team has been according to plan. Early indications suggest that disease burden is high.

Progress in the private sector regarding Rotavirus vaccines has been more rapid than anticipated. The two leading companies, Glaxo SmithKline (GSK) & Merck, are fully committed to making the products available early in Vaccine Fund eligible countries. One of the candidates (from GSK) is expected to register in the first country this year.

The Rotavirus ADIP should continue to work with both vaccine manufacturers.

The Rotavirus ADIP should also explore opportunities to participate in testing and pilot introduction of the GSK candidate to address issues of strategic importance to GAVI & The Vaccine Fund. Issues include assessing the feasability of the vaccine's introduction in poor settings with weak health infrastructure.

The ADIP Management Committee recommends to the GAVI Board the establishment of a small, time-limited group (UNICEF Supply Division/Vaccine Fund/ADIP Management Committee/ADIP Management) to explore with GSK (at this stage) the technical, scientific and cost characteristics required for early introduction of rotavirus vaccine in Vaccine Fund eligible countries. Price/volume negotiations would then be conducted with the company.

Introduction & Purpose of the meeting

This 2nd ADIP Management Committee meeting reviewed the progress of the two ADIP projects: pneumo ADIP and rota ADIP and presented the GAVI Board with an update. It also had a special focus session dedicated to review the rapid development in the field of Rotavirus Vaccines.

One outstanding issue from the previous ADIP management committee meeting was that the Rota ADIP/UNICEF/VF MOU is still not signed. The day before the meeting the response from the legal parties at UNICEF/VF arrived following a 2-month waiting period. The ADIP Committee believes that the finalisation of the MOU can be achieved though will be actively monitoring the agreement negotiation.

ADIP projects progress reports and MC recommendations

Rota-ADIP progress (Annex I)

Pneumo-ADIP progress (Annex II)

The 7-valent Wyeth vaccine will be the only vaccine to be available before 2009.
The Pneumo ADIP was encouraged to investigate the possibility of early introduction of the 7-valent vaccine in a limited number of countries that specifically express a demand and have an ability to manage the potential risks (e.g. monitoring potential serotype conversion) associated with the vaccine. This introduction should be placed in a long-term perspective envisaging the

subsequent introduction of the 9-valent vaccine and should therefore be introduced within the context of intensive surveillance programs. In addition, ADIP should continue to screen for opportunities within the development portfolios of other manufactures.

Review of the ADIP's ongoing plans and future ADIP milestones

Both ADIPs reported minimal amendments to the existing plans and presented the committee with detailed justifications where these arose. The Rota ADIP is projected to experience a delay in initiating trials in Bangladesh and South African. These facts were discussed within the context of the rota-ADIP GSK negotiation and RAPID partnership collaboration. Budgets have not been changed and spending proceeded according to the approved plans.

Discussion topics**:**

*A) ADIP Investment Case and VF future financial policies*
The Investment Case framework, developed by the World Bank, is perceived as offering a tool that will enable GAVI to ensure successful investment. If approved by the Board the Investment Case Framework could form a basis for the ADIP Investment Case to be presented to GAVI/VF in 2006-2007. VF should receive in advance the range of calculations including an ideal and conservative investment case. This will help to set the budget ceiling as well as to start working on advocacy for rota and pneumo vaccine funding investments.
Producers have indicated that the price for the newly developed vaccines should be expected to be much higher than for the basic vaccines.
Currently several mechanisms of new vaccine financing are under discussion:
- Time limited, 5 year contribution
- Proportional contribution (mature price plus VF contribution)
- Decreasing partial contribution
- Volume induced maturation

ADIPs should suggest to the VF the best way how to accelerate the price maturation of pneumo and rota vaccines as well as preferential ways of financing.
ADIPs should prepare plans based on their best assumptions with understanding that their plans will be competing with other investment projects for VF funding.

The Committee noted that there is an overwhelming necessity to sustain the HepB/Hib in the VF countries immunization programs before introducing rota and pneumo.

*B) Identification of potential early adopter countries*
Both ADIPs have nearly completed their analysis for selecting potential early adopter countries following regional representation.
The Committee recommends:

- Early adopters country selection should be presented more than currently the case within the context of Long-Term ADIP strategy and wide VF countries vaccine uptake
- To choose countries to target, ADIPs should liaise with other initiatives and between themselves and take into account the prevailing Hib situation so as not to place an overwhelming burden on the same countries.
- After completing consultation with the regional UN offices, ADIPs should initiate consultations at the country level. The GAVI Secretariat proposed to facilitate this process if deemed necessary.
- The countries, on recommendation of and support by the ICCs, should make the final decision on the choice of introducing new vaccines.

Focus session: rotavirus vaccine. New development and ADIP fit

*Rotarix GSK presentation*

*GSK participants (for this session only):*
*Walter Vandersmissen, Director, Public Partnerships*
*Debbie Myers, Director, External and Government Affairs and Public Partnerships*
*Alain Brecx, Director, Business programs, Paediatric Vaccines*
*Johan Heylen, Associate Director, Life Cycle Management*

Progress to date on the clinical development and the regulatory plan of the Rotarix vaccine were presented. Rotarix is a live attenuated, human, monovalent (G1), oral, lyophilized vaccine that has completed the majority of the core elements of regulatory clinical development. The efficacy and safety data are currently under evaluation by the Mexican NRA; conditional to the registration approval the introduction in Mexico is planned in 2004, expected to be followed by the roll-out in other Latin American countries and further registration in Europe.

Currently, the projected timeline of international roll-out of the vaccine after the Mexican approval depends on the speed of theWHO evaluation of the Mexican NRA to obtain a recognized qualification.

GSK expectations from collaboration with rota ADIP were stated as:
- Investigating the possibility to include Rotarix in the GAVI/VF workplan
- Working together towards pilot introduction of Rotarix to selected early adopter VF countries
- ADIP support for Bangladesh/South African Phase III trials
- Access to data on African surveillance
- Working together on awareness of rota disease and communication for rota vaccine health value

Conditional to successful collaboration with public sector the company envisages the possibility of introducing Rotarix to VF countries in 2006.

*Rotateq Merck presentation*

*Merck participants:*
*Elaine Esber, Executive Director, Medical Affairs International*
*Thomas Netzer, Senior Director, Marketing Planning*

The clinical progress of the RotaTeq vaccine was presented. RotaTeq is a pentavalent, human/bovine reassortant, liquid, oral vaccine that is in Phase III clinical development, targeting US filing in 2005.

The company reconfirmed their earlier stated commitment to corporate social responsibility for the international and developing countries market as well as a commitment to the notion of differential pricing.

Expectations from collaboration with ADIP were formulated as:
- ADIP championship in PRD and introduction at the developing country level
- Working together on worldwide demand forecast:
  Including analysis of product profile impact on developing countries

demand and forecast of dynamic of the vaccine uptake
- Future funding. Establishing supply agreements

Conditional to successful collaboration with the public sector the company envisages the possibility of introducing RotaTeq to VF countries. Additional efficacy and vaccine interaction (OPV, wDTP) trials as well as developing countries introduction support will be required.

ADIP Management Committee recommendations for rota ADIP:

- Encourage ADIP to continue to work with both vaccine candidates manufactures to maximise the probability of success.
- ADIP should stay open to other competitors that might arise in the field in the next several years.
- ADIP should explore the opportunity to participate in the pilot introduction of Rotarix in Nicaragua and Honduras, recognizing the importance of obtaining real life and large scale safety and effectiveness data for further strategic decisions.
- Future efficacy studies in Asia and Africa is a high priority for GAVI to move forward the introduction of the rota vaccines into these regions.
- ADIP should put emphasis on developing/preparing clinical trial sites in Africa to the standards of international GCP regulations.

The Committee recommends the establishment of a small time-limited group (UNICEF/Vaccine Fund/ADIP Management Committee/ADIP Management) to explore corporate mechanisms to clarify the technical, scientific and price/volume characteristics required for early introduction of rotavirus vaccine in Vaccine Fund eligible countries.

WHO intends to start the Mexican NRA evaluation in October 2004. The ADIP MC expresses the wish that, while of course keeping this process unbiased, WHO will be able to expedite evaluation and if necessary follow-up interventions, recognizing the benefit of early rota vaccine introduction to developing countries.

Functioning of ADIP Management Committee

It was decided that it will be favourable to introduce regular teleconferences (every 2 months) in addition to the Management Committee meetings. Prior to each teleconference, ADIP leaders will submit short progress reports and materials for 1-2 topics in detail.

The tentative schedule for the next meeting and teleconferences were proposed to be:

- Teleconference on 30 August 2004 (4pm Geneva time)
- Teleconference on 14 October 2004 (4pm Geneva time)
- 3rd ADIP Management Committee Meeting from 22-23 November 2004, London, U.K.

*Meeting participants:*
*Committee members and members' representatives*: Jan Holmgren, Regina Rabinovich*, Jacques-François Martin, Harry Greenberg, Brian Greenwood, Kevin Reilly, Enkhsaikhan Dashdondog*;*

*Other participants & Observers: Orin Levine, John Wecker, Chris Elias, Mathuram Santosham, Stephen Jarret, Liliana Chocarro, Tore Godal, Irina Serdobova*

*All participants signed confidentiality agreements. Kevin Reilly has disclosed that he is a Wyeth shareholder, and he will abstain from participating in the Wyeth product introduction discussions.*