

FOR DECISION

Financial implications

At its June 2006 meeting the Alliance Board formally requested investment cases for the introduction of rotavirus and pneumococcal vaccines into the GAVI portfolio. These investment cases, developed by the GAVI ADIP teams, benefited from extensive inputs by the ADIP management Committee, the GAVI Working Group and other representatives of Alliance partners. They were reviewed by an Independent Review Committee (IRC) from 1 to 3 November 2006. The recommendations of the IRC are summarized in this note.

FOR DECISION: The GAVI Board is requested to:

- approve the proposed overall strategy for accelerating introduction of pneumococcal vaccination between 2007 and 2015. (See section #2, p.4)
- approve the proposed overall strategy for accelerating introduction of rotavirus vaccines between 2007 and 2015. (See section #3, p.7)
- approve an envelope of \$200 million for the GAVI Secretariat to support negotiations for pneumococcal and for rotavirus vaccines, as well as to support strategic and technical activities between 2007 and 2010.

Following a Board decision, the Secretariat will finalize a supply strategy and propose a procurement plan (including the recommendation of a procurement agent) for presentation to the GAVI Fund EC and GAVI Alliance Board in May. Detailed financial requests based on the proposed procurement contracts will be submitted to the ECs in September 2007.

GAVI investment in rotavirus and pneumococcal vaccines

1. Background

In 2002, the GAVI Research and Development Task Force recommended the creation of Accelerated Development and Introduction Plans (ADIPs) for new vaccines against pneumococcal and rotavirus infections. These two vaccines were identified as those most likely to rapidly have a substantial public health impact because:

- there was no registered vaccine, and/or the existing vaccine had drawbacks which limited their utility;
- the vaccine had a high potential impact; and could significantly reduce morbidity and mortality in children and/or adults;
- there was a high probability of success in short/medium term use of the vaccine;
- the vaccines were filling a strategic gap, (i.e., no other effort was currently focusing on them).

Four years later, rotavirus and pneumococcal vaccine products are now licensed or about to be licensed. The WHO Strategic Advisory Group of Experts (SAGE) discussed rotavirus and pneumococcal vaccines and is making recommendations to support the use of these vaccines in routine infant immunization programmes. With this in mind, in June 2006, the GAVI Alliance Board requested to be presented with investment cases for the introduction of rotavirus and pneumococcal vaccines, into the GAVI portfolio.

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Over the past three years, the ADIPs have:

- Established surveillance systems in key GAVI-eligible countries to demonstrate the burden of infection;
- Improved the rigour and accuracy of demand forecasts, an area where the public sector has traditionally been weak;
- Worked with partners to better and more accurately estimate the global, regional and country level burden of disease and communicated the value of the vaccination to address this public health problem
- Have sent signals to industry both multinational and emerging suppliers that rotavirus and pneumococcal vaccines would be purchased for use in developing countries thus encouraging the entry of a larger number of potential suppliers leading to a more healthy market and more affordable prices
- Supported clinical trials in Africa and Asia to determine whether rotavirus vaccines would be efficacious in all GAVI countries;

Link with long-term strategy

The activities outlined in the rotavirus and pneumococcal vaccines investment cases both fit within strategic goal 2 in the GAVI long-term strategy: “*Accelerate the uptake and use of underused and new vaccines and associated technologies and improve vaccine supply security*”.

Process for investment case development

These investment cases have been developed through extensive preparatory work by the partners and ADIP staff, with special consideration for disease burden and potential impact; cost-effectiveness; demand forecasting and supply strategies. Both cases have been discussed, reviewed and commented by stakeholders among the GAVI partners. The ADIP Management Committee and the GAVI Working Group have reviewed both investment cases and recommended that they be approved by the Alliance Board.

Review process

The investment cases were then reviewed by a special Independent Review Committee (IRC) of eight experts in health systems, epidemiology, health economics and vaccine research. The objectives of the review were:

- To provide the GAVI Alliance and Fund Boards with information so it can determine whether a given investment fits with overall GAVI Alliance and Fund principles and with the GAVI Alliance strategy
- To ensure that basic data analyses (e.g. cost effectiveness, feasibility, impact on vaccine markets) are available to the Board for evidence-based decisions on the use of limited GAVI Fund resources.

2. Independent review committee recommendations

The IRC recommendations are summarised below; the complete report of the IRC is also available in Annex A:

- ***Members of the IRC strongly recommended that both Investments Cases be supported by GAVI.***

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- *Both proposals address important and potentially preventable health problem particularly affecting developing countries. They are based on solid analysis of demand, cost effectiveness and supply and were found to be sufficiently clear, accurate, credible and consistent with GAVI principles.*
- *In both cases the IRC noted that the actual substantial impact on MDGs would only be achieved if the second stage (2011-2015) is implemented. It noted however that, at this point in time, a more limited roll out during the period 2007-2010 was justified.*
- *The IRC also emphasized that financial sustainability would depend on successful stimulation of a competitive market for the vaccines leading to substantial and sustained price reductions and that it was unlikely that the poorest countries would be able to sustain funding with their own resources from 2015.*
- *Both investment cases included proposals for continuing activities to support accelerated uptake. The IRC recognizes the importance of these activities and recommends that following a decision to proceed with the investment, GAVI assesses these in detail, and considers the process for commissioning them.*
- *Finally the IRC has made a few recommendations that GAVI and its partners may wish to take into account to support the introduction of these new vaccines.*

3. Rotavirus vaccine investment case**a. Objective**

To accelerate developing countries' access to and uptake of rotavirus vaccines and:

- By 2010: Prevent the deaths of 10,000 children.
- By 2015: Prevent the deaths of 370,000 children.

b. Rationale

Infants and young children with rotavirus infection suffer vomiting, fever, and diarrhea, and for children with severe disease, this combination of symptoms can progress to dehydration and death. An estimated 500,000 children die from rotavirus each year, and over 2 million are hospitalized with pronounced dehydration. Treatment and prevention options that address other causes of diarrhea are significantly less effective for children with severe rotavirus disease. As a result, vaccines represent the best hope for preventing the most severe episodes of rotavirus infection, especially in impoverished regions where access to medical care is limited. Two rotavirus vaccines were recently licensed by multinational manufacturers. A decision by GAVI to finance the introduction of these vaccines would further accelerate existing development efforts by emerging suppliers.

c. Strategy of the investment case

The Rotavirus investment case recommends a two-stage, judicious approach to accelerating the availability of rotavirus vaccine to GAVI eligible countries. The GAVI Alliance Board is being asked to make a decision to move forward with the first stage of investment which aims to provide currently available vaccines to Latin American and European countries with known disease burden, and where vaccine efficacy has been proven. Lessons from stage 1 will enable GAVI to make an evidence-based decision about expanding eligibility to additional countries in stage 2.

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- 1st stage - Europe and Latin America, 2007-10: two rotavirus vaccines have already been licensed by multinational manufacturers. GAVI -eligible countries in Latin America and Europe (14 countries in total) will be encouraged to apply to introduce these vaccines, starting in 2007. This investment will help to:
 - Prevent a total of 30,000 child deaths by 2015.
 - Prevent over 2 million hospitalisations and clinic visits by 2015
 - Save more than US\$ 11 million in direct medical costs

- 2nd stage (**Not for decision at this time)– Africa and Asia, 2011-15: GAVI-funded phase 3 clinical trials are currently underway in several countries in Africa and Asia, and are expected to be completed in 2009. Based on the findings of these trials, GAVI will be asked to consider expanding eligibility for rotavirus vaccine to all eligible countries in Africa and Asia. Such an investment would help to:
 - Prevent a total of 340,000 child deaths by 2015;
 - Prevent more than 12 million hospitalisations and clinic visits by 2015;
 - Save more than US\$ 60 million in direct medical costs.

d. Monitoring

The ultimate goal of introducing rotavirus vaccine in developing countries is the measurable reduction of morbidity and mortality from rotavirus disease. Towards that end, there are various success and process indicators that should be measured, including vaccine impact and programmatic impact. Given that this may be a challenge, particularly in the early stages, a detailed evaluation plan will be carefully outlined by the coordinating body and partners responsible for vaccine introduction in line with the recommendations of the ADIP evaluation. Broad guidelines and indicators are proposed below:

e. Milestones

- WHO pre-qualification of one rotavirus vaccine by early 2007, and a second by early 2008;
- Completion of an agreement with industry to supply vaccine for the period 2007-2010 by September 2007;
- Introduction of rotavirus vaccine into up to 13 countries in Latin America and the European region by 2010;
- Establish surveillance systems in all GAVI-eligible countries in Latin America and the European region that will track rates of rotavirus-associated hospitalization before, during and after vaccine introduction;
- Completion of clinical trials in Asia and Africa by 2009 (funded by GAVI through the Rotavirus ADIP).
- Ongoing disease surveillance in Africa and Asia to establish rates and patterns of rotavirus disease pre-vaccine introduction.

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The Boards would be updated annually on progress, including financial implications.

f. Risks

A risk analysis is provided below, showing level of risk and potential impact. Steps to mitigate the risk are proposed. A GAVI Supply Strategy Group has been formed and will submit a detailed strategy to the Boards in May 2007; this strategy will address the risks related specifically to supply.

- **Supplier cannot reach acceptable terms -- Moderate probability, high consequence**
 - New contractual agreements explored
- **Countries and local partners unsure about the value of vaccination -- Variable from low to high, depending on the country**
 - Continued efforts to establish and communicate the value of pneumococcal vaccination in the contexts of health, development, and poverty reduction
- **Serious adverse events -- Low probability, high consequence.**
 - The investment is proposed in two stages to allow GAVI's careful consideration of findings before reinvesting in 2010. However it should be noted that clinical trials have not demonstrated an association between the current GSK and Merck rotavirus vaccines and intussusception.
 - Surveillance activities are proposed to identify potential adverse events and prevent misinterpretation of findings.
- **One or both rotavirus vaccine are not efficacious in preventing severe rotavirus gastroenteritis in Africa and Asia -- Low to moderate probability, moderate consequence**
 - Rotavirus vaccines may be less efficacious in impoverished populations. However, in that case the impact may be substantial, given the high incidence of rotavirus disease and its severe consequences in the developing world.
 - The investment is proposed in two stages to allow GAVI's careful consideration of the results of the clinical trials before reinvesting in 2010.
- **Over time, vaccine price fails to fall to \$1, demand decreases -- Low to moderate probability, high consequence.**
 - Monitor emerging supplier progress to ensure timely availability of supply;
 - Communicate closely with all manufacturers to ensure adequate supply for current and anticipated demand.

4. Pneumococcal conjugate vaccine investment case

a. Objective

To accelerate developing countries' access to and uptake of pneumococcal vaccine and to:

- By 2010: Prevent the deaths of 47,000 children
- By 2015: Prevent the deaths of 446,000 children

b. Rationale

Streptococcus pneumoniae is a serious, common, and preventable global disease. Previous WHO

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estimates for pneumococcal deaths in children have been as high as 1 million deaths per year. The current estimate is 716,000 deaths per year in children and 1.6 million persons of all ages. This makes pneumococcal disease the No. 1 vaccine-preventable cause of child mortality. One 7-valent pneumococcal conjugate vaccine is currently licensed by a Multinational Manufacturers and two additional products (10 and 13-valent) are likely to be licensed by 2010. A decision by GAVI to finance the introduction of these vaccines would further accelerate existing development efforts by emerging suppliers

c. Strategy of the investment case

The Pneumococcal Investment Case outlines a 9 year strategy for the introduction of vaccine to GAVI eligible countries. This strategy is divided into two stages. The GAVI Alliance Board is being asked to make a decision to move forward with first stage of the strategy. Lessons from the initial part, and results of efficacy trials for next generation vaccines will help GAVI to make an evidence-based decision about providing support to introduce the next generation of vaccines in a broader range of countries during a stage 2.

- 1st stage - 2007-10: Introduction of the existing vaccine (7-valent) into an estimated 6 early-adopting countries. With this first investment, GAVI can help to:
 - Prevent the deaths of 47,000 children by 2010;
 - Provide evidence-based policies and strategies for the introduction of future vaccines.
- 2nd stage - 2011-15: introduction of next generation vaccines (10 & 13-valent) into an additional estimated 20 countries. This investment will help to:
 - Prevent the deaths of 446,000 children by 2015.

d. Monitoring

The best indicators of success are to measure changes in pneumococcal disease mortality and morbidity in developing countries and changes in supplier intentions. Both of these can be difficult to measure or require a long period of observation before changes can be seen. Consequently, this case proposes some putative process and outcome indicators to help assess progress during the period 2007-2010:

e. Milestones

- WHO pre-qualification of the existing vaccine (7-valent) by end 2007 and one or more next generation pneumococcal vaccines by end-2009;
- Completion of an agreement with industry to supply vaccine for the period 2007-2010 by September 2007;
- Establish disease surveillance mechanisms in all early-adopting countries before vaccines are introduced;
- Completion clinical trials for future vaccines (10 & 13-valent) in Asia and Africa by 2010.

The Boards would be updated annually on progress, including financial implications.

f. Risks

A risk analysis is provided below, showing level of risk and potential impact. Steps to mitigate the risk are proposed.

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A GAVI Supply Strategy Group has been formed and will submit a detailed strategy to the Boards in May 2007; this strategy will address the risks related specifically to supply.

- **Supplier cannot reach acceptable terms -- Moderate probability, high consequence**
 - New contractual agreements explored
- **Supply interruptions – Variable probability, depending on supply and demand**
 - Strengthen supply chain and strategic demand forecasts through close communication between suppliers, countries and GAVI to keep demand and supply aligned with each other
- **Clinical trials for 10 and 13 valent vaccines fail to demonstrate efficacy in Africa and Asia -- -- Low probability, moderate consequence**
 - Clinical trials with 7 and 9 valent vaccines have shown significant efficacy; as the 10 and 13 build on this product it is unlikely efficacy would be lower.
- **Some countries are not able to sustain vaccine financing in 2016 -- From low to high probability depending on country, high consequence**
 - Extend GAVI financing beyond 2015, and mobilise alternative donor support after 2015,
 - Support efforts to increase overall health and immunization spending between now and 2015

5. Next steps for both rotavirus and pneumococcal vaccines

Following a positive Board decision on both the pneumococcal and rotavirus investment cases, a series of activities would ensue:

- **December 2006**
 - Co-financing levels set in consultation with GAVI partners
 - Letters sent to countries inquiring as to their interest in pneumococcal and rotavirus vaccines
- **January/February 2007**
 - Demand forecast revised as needed in line with countries expressed interest
- **May 2007**
 - Presentation to Alliance/Fund on the following:
 - Supply and procurement strategies
 - Outcome of the ADIP evaluation
 - Updated country application guidelines released
- **September 2007**
 - Deadline for the submission of country applications
 - Procurement contracts presented to Fund for financial approval

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- **October 2007**
 - o Independent Review Committee (IRC) assesses first applications for rotavirus and pneumococcal vaccines
 - o Procurement contract signed

- **November 2007**
 - o IRC recommendations presented to Alliance for programme approval and to Fund for financial approval

- **April 2008**
 - o First delivery of vaccines

6. Potential future financial implications

Rotavirus vaccines

Following initial roll-out of rotavirus vaccines in Latin America and Europe, and with positive results of trials in Africa and Asia, the Board would be asked in 2009 to consider an expansion of rotavirus support to all GAVI countries through 2015.

According to the strategy described in the investment case, the second investment could range from \$268- \$820 million, depending on the cost of the vaccine.

Pneumococcal conjugate vaccines

Following initial roll-out of pneumococcal vaccines in early adopter countries starting next year, and with positive results of clinical trials of new pneumococcal vaccines, the Board would be asked in 2009 to consider an expansion of pneumococcal vaccine support to all GAVI countries through 2015.

According to the strategy described in the investment case, the second investment in pneumococcal conjugate vaccine could range from \$440 - \$951 million, depending on the cost of the vaccine.

Should an advanced Market Commitment (AMC) pilot for pneumococcal vaccines be launched in 2007, this would provide additional earmarked funds for the roll-out of the future pneumococcal vaccines, such as 10 and 13 valent vaccine which are under development by multinational manufacturers, or other products from emerging suppliers.

7. Request to the Alliance Board: endorse budget envelope

Negotiations with industry for each vaccine required will begin once initial endorsement of the investment cases are received from the GAVI Alliance Board. The Alliance Board is being asked to authorise negotiations with a total envelope of \$200 million to be applied to purchase of vaccines and supportive activities for the years 2007-10.

Following a Board decision, the Secretariat will finalize a supply strategy and propose a procurement plan (including the recommendation of a procurement agent) for presentation to the GAVI Fund EC and GAVI Alliance Board in May. Detailed financial requests based on the proposed procurement contracts will be submitted to the ECs in September 2007.

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In addition to vaccine costs, the two investment cases include estimated budgets for strategic and technical activities to support the accelerated introduction of the vaccines from 2007-10: \$38 million for rotavirus and \$40 million for pneumococcal. These budgets will be finalised after the evaluation of the two Accelerated Development and Introduction Plans is complete so that the most appropriate entity to undertake the activities can be identified.

ANNEX 1**Investment Cases for the Accelerated Introduction of
Pneumococcal and Rotavirus Vaccines****Report of the Independent Review Committee****9 November 2006**

Members of the IRC

Hetherwick Ntaba (Chair)
Maureen Law (Co-chair)
Fred Binka
Bjarne Bjorvatn
Claire Broome
Rehan Hafiz
Robert Steinglass
Veronica Walford

Process of the Review

Drafts of the two proposals were provided to IRC members in early September for their preliminary review. During a conference call with the authors on 15 September 2006, IRC members had an opportunity to ask questions and make suggestions for improvements in the proposals. The final proposals were received on the 24th of October.

The final review meeting was held in Geneva 1-3 November 2006. During the review conference calls with the authors again provided an opportunity for the IRC member to clarify various points in the documents.

Outcome

The following conclusions and recommendations summarize IRC responses to a set of questions (A-E) provided by the GAVI secretariat for the two investment cases separately.

The IRC is also highlighting critical points that should be considered during the introduction of the respective vaccine at the country level.

Finally, the IRC makes a series of recommendations to GAVI partners and to the GAVI secretariat that are relevant for both investment cases.

Members of the Independent Review Committee strongly recommend that both Investment Cases be supported by GAVI.

Conclusions and Recommendations of the IRC with Respect to the Investment Case Proposals:**1. Rotavirus Vaccine:**

ANNEX 1**A. Is the proposal clear, accurate and credible?**

The proposal is sufficiently clear, accurate and credible. However there are some gaps in currently available knowledge, in particular with regard to efficacy and safety of the vaccine in Africa and Asia (the regions with 90% of the disease burden), including the safety and efficacy in children with HIV infection, and the importance of serotype distribution on vaccine impact. The planned trials in Africa and Asia are expected to address the efficacy aspects in both continents, and will provide some data in HIV infected children.

B. Is the proposal consistent with GAVI principles?

The proposal is consistent with GAVI principles. If the vaccine is found to be efficacious in Africa and Asia, the proposed investment would have a significant impact on the MDGs. The potential for financial sustainability depends on successful stimulation of a competitive market for the vaccine leading to substantial and sustained price reductions during the period. This requires active management by GAVI and partners. It is unlikely that the poorest countries will be able to sustain funding from their own resources from 2015.

C. What are the key strengths of the proposal?

The proposal addresses an important albeit potentially preventable health problem particularly affecting developing countries. The proposal is based on solid analysis of demand, cost effectiveness and supply. It makes clear that a diversity of rotavirus vaccine manufacturers, including emerging manufacturers needs to be encouraged to secure the financial sustainability of the intervention. The proposal addresses the importance of post-licensure surveillance and suggests innovative methodologies for this with a view to ensuring long term safety and efficacy of the vaccine.

D. What are the key weaknesses of the proposal?

Experiences from the recent introduction of rotavirus vaccine in parts of Latin America are not fully presented. The IRC feels that additional field information is available which may be pivotal to successful introduction of the vaccine.

The current bulky packaging of the vaccine challenges appropriate introduction of the vaccine.

The resource requirements for non-vaccine costs associated with the introduction of a new vaccine at country level (Technical Assistance, IEC, training, shipping costs, cold chain) are not fully described. There appears to be an overall assumption that these costs will be borne through ISS/HSS support which the IRC feels may be a risky assumption.

There is additionally no analysis of affordability beyond 2015.

The monitoring section lacks a milestone regarding the availability of vaccines that meet WHO-recommended packed volume per dose.

E. What are the chances of success and what is the definition of key assumptions underlying this score?

It is probable that the investment case will reach 75% of its goals assuming that trials will show acceptable efficacy in Africa and Asia. If the vaccine does not prove to be efficacious in Africa and Asia, the Phase I investment would still have the benefits of reducing morbidity and mortality in Latin America and Europe, and would provide a signal to suppliers that

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GAVI is committed to rotavirus vaccine. It could also potentially prevent premature large-scale usage of the vaccine in Africa before the trial results are known.

Some points to consider during the introduction of this vaccine:

1. Approval now implies continued support for early adopters beyond 2010;
2. Post introduction monitoring (surveillance) will be particularly important in this case to ensure the safety of the vaccine, especially as the prescribed timing of the first vaccine dose (infants aged 6-12 weeks only) are unlikely to be strictly followed.
3. The costs of introduction at country level will be important, especially because of the bulky packaging of the vaccines. Whilst there should be scope to reduce the packaging volume and hence the cold chain requirements of the current products, further support from GAVI and partners may be required to cover the costs of vaccine introduction. There is an assumption that these will be met by HSS/ISS.
4. Since introduction in Africa and Asia will not begin until about 2010, there will be a special need for support for many African and Asian countries beyond 2015.

II. Pneumococcal Vaccine:

A. Is the proposal clear, accurate and credible?

The proposal is sufficiently clear, accurate and credible. The data and assumptions are reasonable.

B. Is the proposal consistent with GAVI principles?

The proposal is consistent with GAVI principles. Provided it is expanded beyond the group of 4-6 countries mentioned in the proposal, it will have a measurable impact on the MDG 1 and 4 goals. The potential of financial sustainability depends on successful stimulation of a competitive market for the vaccine leading to substantial and sustained price reductions during the period, which will require active management by GAVI and partners. It is unlikely that the poorest countries will be able to sustain funding from their own resources from 2015.

C. What are the key strengths of the proposal?

The investment case addresses an important but potentially preventable health problem in developing countries. Pneumococcal vaccine has demonstrated a highly significant impact on disease and mortality in Africa, including efficacy and safety in HIV infected children. Information on demands and forecasts is well described. The economics are generally clear including description of factors that could affect vaccine price reduction. The cost effectiveness analysis is robust and even at a higher vaccine price the cost per DALY would be within good value for intervention. The conclusions are well founded and supported by the analyses on the potential for disease prevention.

D. What are the key weaknesses of the proposal?

The source of financing for non-vaccine costs is not clear, and there is an inadequate account of the costs involved in supporting introduction at country level (Technical Assistance, IEC, training, shipping costs, cold chain).

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The current packaging of the vaccine would require major expansion of the cold chain which challenges appropriate introduction of the vaccine.

There appears to be an overall assumption that these non vaccine costs will be borne through ISS/HSS support which the IRC feels may be a risky assumption.

The monitoring section should address programme implementation issues and lacks a milestone regarding the availability of vaccines that meet WHO-recommended packed volume per dose.

There is additionally no analysis of affordability or financial sustainability beyond 2015 beyond an indication that the price could eventually fall to \$2 per dose – which could still be a challenge for some countries. The factors that could affect vaccine price reduction are well described, but there remains substantial uncertainty about the timeframe for the expected price reduction.

E. What are the chances of success and what is the definition of key assumptions underlying this score?

There is a strong probability that the Investment Case will achieve at least 75% of the stated objectives.

Some points to consider during the introduction of this vaccine:

1. Approval now implies continued funding for early adopters after 2010.
2. Expanding coverage to more countries as soon as possible is highly desirable but, if implemented, adequate vaccine supply must be guaranteed.
3. There is a need to ensure that the costs of introduction at country level have been fully documented and that funding of these has been ensured. The implications for the cold chain are especially significant because of the current packaging.
4. An evaluation of “catch up” campaigns for children 1 through 4 years old is being proposed for two countries to evaluate potential accelerated impact from herd immunity.

Other Recommendations

GAVI Board and Partners

1. There is a significant implementation cost (cold chain, shipping, storage, training, IEC etc.) associated with the adoption of new vaccines. In both cases there was an assumption that this would be met by HSS or ISS. The GAVI board and partners need to ensure that these costs are properly estimated in all investment proposals and that there are funds available to address them.
2. The IRC notes that there may be more countries than the 6 estimated in the investment case proposal interested in the initial introduction of the pneumococcal vaccine. We encourage GAVI not to cap the resources available for implementation in Phase I if additional countries apply - provided that there is a sufficient supply of the vaccine to extend coverage to other countries. At the same time, the IRC notes that the level of co-payment for the vaccine and implementation costs will be a major factor in the level of uptake.

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3. There is a need for a sound support mechanism for providing technical assistance for introduction at country level and for monitoring. Post introduction surveillance will be especially important for the rotavirus vaccine.
4. The IRC notes that there will be a need for support for the purchase of vaccines for the poorest countries beyond 2015. This is likely to be especially true for the African and Asian countries which would not introduce rotavirus vaccine until at least 2010.
5. The IRC recommends that GAVI ensure support for clinical trials for emerging suppliers.
6. The IRC recommends that GAVI work to ensure that trials of new vaccines are carried out as early as possible in GAVI eligible countries.
7. Both investment cases included proposals for continuing activities to support accelerated uptake. Whilst the range of activities proposed appears relevant, the proposal was not sufficiently detailed for the IRC to judge the specific proposals and their cost effectiveness. Instead the IRC recommends that GAVI assesses these in detail, and considers the process for commissioning the activities, following a decision to proceed with the investment.

GAVI Secretariat

1. The IRC strongly urges GAVI to use its resources to stimulate the market to produce adequate supplies to meet demand, achieve lower prices and to initiate negotiations with vaccine producers not only about price but also about presentation and packaging of vaccines that can better meet the needs of GAVI eligible countries. The committee noted that Merck has asked for a consensus about what is needed for appropriate presentation.
2. The IRC notes that if the implementation costs for these or future investments are to be covered in whole or in part by HSS, it will be necessary to coordinate these requests with the current country proposals for HSS support.
3. When reviewing country proposals for support GAVI needs to ensure that the countries are fully prepared to adopt the new vaccine(s), including awareness of the implementation costs and provisions for shipping, storage, cold chain arrangements, training and IEC.
4. The IRC recommends that in future the Investment Case Format pays greater attention to issues of affordability and that it includes international shipping costs in its estimates.