RESEARCH AND DEVELOPMENT IN THE CONTEXT OF THE GAVI ALLIANCE

The global vaccine research community includes many diverse players, each contributing in different ways with vastly heterogeneous resources and distinct agendas. Much can be gained by coordinating agendas and goals to render efforts complementary, avoid duplication, and maximize the use of limited resources.

The many partners involved in vaccine research and development activities and epidemiological studies in both industrialized and developing countries are represented in the Alliance in a truly synergistic effort. Partners include governmental research institutes, academic research programs, large vaccine manufacturers, biotechnology companies, units within Ministries of Health, etc. There are also partners that are not primarily engaged in research but who, as implementers of immunization, will provide critical input to researchers to advise them on what is needed, feasible, and desired at the front lines of primary care, and in contrast, what cannot be readily incorporated into primary care regimens.

With all of the current activity in vaccine R&D, it is important that in the context of GAVI, efforts focus on identifying those gaps where an alliance can have a strategic advantage. Thus, while the GAVI partners recognize that a high priority lies in HIV/AIDS and malaria, given the massive global effort to these projects worldwide, the Alliance decided to prioritize other vaccines that are receiving less attention.

In addition, even if these vaccines become available, many of the poorest countries lack the infrastructure to put these vaccines into public health use efficiently. Therefore, initially, GAVI partners decided to initially place their R&D focus on vaccines that have a lower technical risk and a greater potential for more near-term development and introduction.

To identify these priority vaccines, members of the GAVI Task Force on Research and Development (R&D TF) conducted wide consultation with the R&D community to develop consensus.

The criteria for choosing the disease-specific projects were based on a number of considerations.

- Either no currently registered vaccine or for which the existing vaccines have notable drawbacks that severely limit their public health usefulness (e.g., the existing vaccines are not immunogenic in infants yet that age group is an epidemiological target for vaccination)
- High potential impact in terms of disease mortality rate and disability-adjusted life years (DALYs)
- Nonavailability of alternative solutions to managing the disease
- Good potential for changing/improving the immunization system for the future in terms of capacity building and promoting behavioral or system change
- High degree of feasibility with available tools and infrastructure; political commitment

The consultation process led to a consensus that the three vaccines that should receive high priority in the context of GAVI are: *Streptococcus pneumoniae*, rotavirus, and *Neisseria meningitidis* group A (which may be approached either as a monovalent group A, a bivalent group A/C, or a quadravalent group A/C/Y/W135 vaccine).

To accelerate the availability of these vaccines, in June 2002 the GAVI Board decided to fund special projects, called accelerated development and introduction plans (ADIPs), to focus on rotavirus and pneumococcal vaccines. The ADIPs define critical actions to *establish* the value of the vaccine, to *communicate* this value of to the key decision leaders, and to *deliver* the value by ensuring supply and delivery systems are in place. A meningococcal ADIP was not created at that time because funding had been already provided directly by the Gates Foundation to establish the Meningitis Vaccine Project.

In November 2006, the GAVI Alliance Board made the strategic decision to support countries to introduce rotavirus and pneumococcal vaccines. It will soon take a decision on which other new vaccines it will support in the future.

LOOKING TO THE FUTURE: ISSUES AND CHALLENGES

Vaccine Supply

The relatively small size (in revenues) of the developing country vaccine market has resulted in reduced private sector investment in relevant vaccines and thus reduced production capacity. GAVI, with private sector involvement and a long-term perspective, lends a much needed stability to delivery systems, demand creation, and vaccine supply. GAVI has already demonstrated that if the public sector can work to help make the developing country vaccine market more attractive to vaccine manufacturers, children living in the poorest countries will live healthier lives by having access to better and more effective vaccines.

Sustainability

Financial sustainability is crucial to the success of immunization programs in countries and will be the measure of GAVI's success in the long term. However, the challenge of creating systems that are sustainable beyond the initial time of investment is one of the most critical issues facing all areas of development—not just GAVI.

To clarify the aim of strategies developed to enhance the sustainability of programs, the GAVI Board adopted a new definition of financial sustainability: ''*Although self-sufficiency is the ultimate goal, in the nearer term sustainable financing is the ability of a country to mobilize and efficiently use domestic and supplementary external resources on a reliable basis to achieve target levels of immunization performance*.''

In this way GAVI partners recognize that for the foreseeable future, maintaining high quality immunization programs in the health systems of the poorest countries will require continued external support—from donor governments, NGOs, the private sector, and individuals, support that has flagged in too many countries in recent years.

Cofinancing, introduced by GAVI in 2007, means countries share the cost of the vaccines supplied by the GAVI Alliance. The intention is to ensure that immunization programs are sustainable in the long term.

GAVI-eligible countries have been grouped according to their expected ability to pay, and the cofinancing levels vary across the different groups. GAVI will conduct an evaluation of the cofinancing policy in 2009. On the basis of the outcomes of the evaluation, current cofinancing levels, country groupings, and eligibility criteria are expected to be revised in 2010.

Safety and Waste Management

Worldwide, each year, the overuse of injections and unsafe injection practices combine to cause an estimated 22.5 million hepatitis B virus infections, 2.7 million hepatitis C virus