

## **Memorandum on Strategic Priorities for Vaccination Research in Norway: Vaccination research for improved health in low and middle income countries**

**27 April 2006**

### **Norway's commitment**

Norway is strongly committed to support the Global Alliance for Vaccination and Immunization (GAVI; <http://www.gavialliance.org/>) through an annual donation of 500 million NOK. GAVI is a public private partnership (PPP) with the goal to save children's lives and protect peoples' health by extensive use of vaccines. Three core areas are emphasised: 1) strengthening of routine immunization services, 2) increased use of under-used vaccines and 3) accelerated development of and access to new priority vaccines and immunisation-related technologies. Norway has stressed that GAVI should not only be a supplier of vaccines, but that the organisation should also work to build health systems.

Norway also has a strong commitment to the United Nation's 4<sup>th</sup> millennium development goal (MDG 4), namely the reduction of child mortality by two thirds within 2015. To ensure that Norway's international engagement has a good knowledge basis, national competence within global health issues must be strengthened and expanded into new areas. Development of national competence groups within vaccination research is of great importance for supporting Norway's commitment to GAVI and MDG 4.

Norway has therefore decided to initiate a new long-term research initiative supporting projects within different fields of vaccination research. This initiative will be administered by the Research Council of Norway and will have an annual budget of 50 million NOK.

Norway has in addition started an initiative to promote Indian-Norwegian bilateral collaboration on several topics. Vaccination research collaboration between India and Norway is a part of the initiative mentioned above and is included in the Research Council's call for proposals (see website), with the possibility of having Indian components of projects funded by Indian partner institutions.

### **Norway's new Research Initiative on Vaccination Research**

The new large Vaccination Research and Global Health programme will consist of two components, one committed to vaccination research and one to global health in general - with separate budgets. The Research Council's programme on Global Health will continue to exist with a separate budget, so as to ensure that these aspects of global health, as described in the

Programme Plan for the Global Health Research Programme, can be covered through calls for applications and allocations to Norwegian research institutions. An appointed board will be responsible for allocation of funds for vaccination research in this call and for developing future calls for both vaccination research and global health. The budget for the vaccination research programme is fifty million NOK annually while the global health research budget is currently about 11 million NOK annually.

Funding of the vaccination research component of this programme has been provided by reallocating 2006 money already set aside for GAVI by the government. The Norwegian Government has requested a quick start for strengthening of vaccination research and the call for proposals is therefore launched already this spring, with the intention of allocating funds for projects starting end of 2006 – beginning of 2007. To enable interested parties to develop larger proposals with international partners, funding will also be available for planning projects intended to be submitted as full projects at the next call in June 2007 (see call for proposals).

### **Goals for the Vaccination Research Programme**

The main goal of this programme is to provide new/better vaccines and immunization strategies and to generate new knowledge about the role and effect of vaccines that can improve the health and lives of marginalized people, especially children, in low and middle income countries.

This includes:

- Development of new candidate vaccines
- Identification of optimal formulations and immunization regimens for new and available vaccines
- Increased availability and equitable coverage of existing vaccines
- Identification of surrogate markers of vaccine-induced protection
- Development of improved strategies for cost-effective production of vaccines
- Development of sustainable health systems with incorporated well-functioning routines for vaccination of population groups
- Contributions to more efficient use of existing vaccines, (including studies of total health effects of current vaccination programmes in different populations)
- Development of well-functioning international cooperation and cross-disciplinary vaccination research that includes Norwegian research groups

### **Priorities for the vaccination research call for proposals**

The aim of this initiative is to contribute to developing the best projects with participation of Norwegian research environments, preferably in collaboration with research environments in low and middle income countries. Relevance for the above-mentioned programme goals and probability of success are also important criteria for evaluation of the applications.

Research related to vaccines and vaccination against illnesses caused by enteric and respiratory pathogens that often affect children is prioritised in this call, although research on vaccination against other diseases such as HIV/AIDS will also be seriously considered.

Production of new vaccines and application of new immunization strategies must be relevant for the targeted health systems. The inclusion of partners from countries with a high infectious disease burden is highly recommended and in many cases a pre-requisite for success. International cooperation is therefore encouraged, especially with researchers and institutions in low- and middle- income countries. Cross-disciplinary research is also encouraged.

Support will be given to public and private Norwegian institutions involved in vaccination research and development, by funding of institutions/ researchers with the potential to be in the international forefront in this field. It is a condition for support that projects are GAVI-related and emphasize results in relation to the large health problems in low and middle income countries. Each project must define its position in the research-development-production-implementation pipeline for vaccines. Milestones for all projects (also those in an early stage of development) must be defined.

- ***New and improved vaccines***

All applications should specify for which populations the vaccines are intended and on which criteria this selection is based (disease prevalence, specific need etc.). All phases of vaccine development - pre-clinical and clinical - can in principle be funded, but studies of vaccines/vaccination strategies in late phases of clinical development will be prioritised. It is important that the applications also describe plans for development phases after the allocated funding from this programme is used.

Prioritized research areas in this call for proposals are development of new candidate vaccines including:

- identification of protective antigens/epitopes
- identification of optimal vaccine formulations (including the use of adjuvants) and modes of administration
- establishment of methods for assessing toxicity/side-effects
- determination of immunogenicity and vaccination outcomes.

- ***Production, private public partnerships (PPPs)***

- Studies on how vaccines can be produced locally and more cost-effectively are encouraged; it is especially important to describe production plans in more detail for vaccines that are close to the production stage.
- Projects close to the production stage or beyond will benefit strongly by having an industrial partner.
- Projects at an earlier stage in the development should also consider how to facilitate handling of the intellectual property right issues in the future. The proposal should reflect that potential intellectual property rights have been discussed openly between the partners and that mechanisms for fair sharing are agreed upon.
- As no vaccine can be produced without a proper quality control (QC), the technology for the proposed QC must be accessible and envisaged at an early stage.

- ***Health systems and availability of vaccines***

Anthropologic and cost-effectiveness studies, in particular studies involving both types of competence, are especially encouraged. In general, it is encouraged that practical issues with the potential to increase the success of vaccination procedures or give better

explanations to the lack of success are included in the proposals; some examples of issues/questions to address are:

- Which subpopulations are currently given vaccines, and which vaccine schedules are used?
- How can more equity (with regard to gender, geographic, socio-economic and other barriers) be obtained?
- Which cost-effective measures can realistically be introduced to increase availability of vaccines and how do countries set priorities for vaccination programs?
- What inhibits and what promotes/improves availability e.g. distance to health facility, interactions between personnel and users, introduction/use,

• ***Effects and implementation***

Important issues regarding the effects and implementation of vaccines and topics of interest include:

- How can improved scheduling/use of existing vaccines give better results?
- Proposed vaccine trials and observational studies should in addition to studies of side-effects and immune responses also include recording of unexpected adverse events and any beneficial effects beyond those conferred by protection against the targeted disease.
- Reliable diagnostic tests, usable in the relevant local settings and with high specificities and sensitivities, are needed to identify endpoints in clinical phase III and IV trials; development and evaluation of such tests are encouraged.
- Studies that attempt to disentangle why identical vaccines may give varying effects in different geographic areas might reveal information critical to improving vaccines and vaccination usage and are also encouraged.

The priorities as reflected in this Memorandum may not include all aspects of vaccination research that are covered by this call. Please refer to the call for proposals for specific requirements and types of applications.

The deadline for sending an application is 31st August, 18.00.

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