

## BIOVISION PRE-CONFERENCE REPORT FORMAT

### **INTRODUCTION**

BioVision introduces a NEW ARCHITECTURE by adding 9 Pre-conferences in 2006 and a web Forum hosted by BioVision NXT. and will take place between March and October 2006.

The Pre-conferences will ensure continuity, between the two successive forums by enlarging the circle of participants in order to better meet the needs of the key BioVision participants: Science, Society and Industry.

### **OBJECTIVE**

The OBJECTIVE of Pre-conferences is to explore and develop the topics for debate and discussion at BioVision Forum.

The WORK PRODUCT of a pre-conference will consist of an EXECUTIVE SUMMARY of the discussion, RECOMMENDATIONS FOR ACTION and CONCLUSIONS recorded in table format specifically spotting the key issues in the field and the viewpoints of the communities: Science, Society and Industry.

### **METHODOLOGY**

Pre-conferences will consist of small meeting of up to 10 participants to develop the key issues for the BioVision Parallel Conferences in three sectors: Health, Agriculture and Environment.

Each Pre-conference will have Host Partners. The Host Partners with BioVision support will organize the meeting, choose the participants.

The topic recommendations of the Pre-Conferences will be honed and refined for the BioVision Forum. Due to time limitations of the Forum, not all identified topics and issues may be covered in the Forum.

## PRE-CONFERENCE TITLE: IMMUNIZATION FOR ALL

### TOPIC DESCRIPTION: Immunization for all

Immunization and the MDGs: opportunities and implications, including immunization as a public health strategy to improve access to healthcare; role and opportunities for the vaccine industry.

**LOCATION:** Lyon, France

**DATE:** October 9, 2006

**HOST PARTNER:** Lyon Biopole

#### BIOVISION PARTICIPANTS:

**Jean Michel Roy**  
ENS-LSH / BioVision Human Sciences Advisor

**Dianna Derhak**  
Programme Director

**Marc Girard**  
CEA/ Biovision advisor for health

#### MODERATOR:

Jacques François Martin, President of Parteurop  
François Guillemin, Lyon Biopole General Director

#### PARTICIPANTS:

- ▶ **Philippe DUCLOS**, WHO
- ▶ **François GASSE**, UNICEF
- ▶ **Pascal PERRIN**, Sanofi-Pasteur
- ▶ **Ali ALOOUECHE**, Chrion-Novartis
- ▶ **Walter VANDERSMISSEN**, GSK
- ▶ **Michel ZAFFRAN**, GAVI

### AGENDA:

1. Welcome by host partner and introduction of participants
2. Overview of BioVision New architecture
3. Debate
4. Conclusions

### EXECUTIVE SUMMARY:

How to make the greatest number enjoy the benefits of immunization is an important question to address when analysing the possible contributions of the life sciences to the Millenium Development Goals, the point of focus of Biovision 2007. It relates in particular to Goals 4, 5 and 6 that deal respectively with child mortality, maternal health and the fight against infectious diseases such as AIDS and malaria. But it is also connected with the problem of global partnership addressed by Goal 8. In addition, a higher degree of health protection is an important factor of economic development and access to education, and consequently an indispensable instrument in the fight against poverty and illiteracy.

Substantial efforts have already been deployed for the past twenty five years by international institutions such as WHO, UNICEF or GAVI, with the help of governments and foundations, in order to increase the level of immunization protection in the world population, especially in the children population of developing countries. While in the early 1980's less than 20% of children in these countries were immunized against six childhood diseases, today about 75% of them are. However, the 1990-2000 decade saw an overall decline in immunization coverage for a variety of reasons, leading to the creation of new initiatives such as GAVI. In spite of these renewed efforts, the situation of immunization coverage remains unsatisfactory. Between 2 and 3 million children still die every year of easily vaccine preventable diseases, and close to 30 millions do not enjoy basic immunization, while a child can be

fully immunized for about 30 dollars.

In order to remedy this situation, it is necessary to find ways of improving on what has already been achieved and to give a new impulse to the immunization dynamics. These efforts should deal on one side with increasing the access to immunization based on currently available vaccines, especially in children, and on the other side with developing new forms of immunization (vaccines for still not preventable diseases such as malaria, AIDS or diarrheal affections, and improved vaccines for other diseases in order to overcome problems resulting from insufficient response, inadequacy to certain population segments, evolution of pathogen agents...). In addition, it is important that the role of immunization as an access vector to healthcare be strengthened as well.

Although it is natural to concentrate on developing countries in addressing the current situation of immunization coverage because these countries face the most urgent difficulties, developed countries should not be neglected. They also know access problems to currently available vaccines, and the need for new vaccines, such as an AIDS vaccine, is a universal one. In addition, in the words of one expert, "infectious diseases have no frontiers", especially as a result of the globalization of economical activity and of the important migrations of populations currently under way in the world. It should be reminded that the main sources of measles in Latin America are in Europe and Japan, and that tropical diseases have started to appear at certain spots of the northern hemisphere. Accordingly, the efforts needed for improving immunization coverage should be seen as global, even though the problems vary with each country and region and these local differences should be fully taken into account. The issues of access and affordability are for instance prevalent in the developing countries, while developed countries are facing a growing underutilization of old vaccines.

Another general observation emerging from the preconference is that the situation of immunization can only be improved through the integration of a variety of complementary approaches, and that it would be illusory to reduce the problem to a purely scientific and technological one, even though scientific and technological progress is much needed. The establishment of new forms of global partnerships is considered as a crucial factor of success, as well as a stronger commitment of public authorities. The important GAVI initiative was for instance only made possible thanks to the determination of a number of partners to cooperate on a common set of goals.

In order to be able to find adequate improvements, the current bottlenecks to the implementation of global immunization programs must first be carefully identified, and the preconference focussed on this problem.

These bottlenecks can be divided into five main categories: scientific, technical, logistical, political and societal, and financial. The experts' discussion concentrated on the situation of developing countries, and a systematic distinction was introduced between the case of already available vaccines and the case of new forms of immunization.

Regarding the first case, access and logistics were considered to be the key problems, and they are likely to worsen with the availability of additional vaccines. The main difficulties are the excessive cost of logistics, the lack of trained health workers and the difficulty of keeping them on the job. They vary in nature and proportion with each country, and it is important not to neglect their local specificities in trying to answer them. Two solutions were discussed: grouping vaccination with other health interventions and launching vaccination campaigns. Both nevertheless present disadvantages. Grouping vaccinations with other health interventions runs the risk of overburdening health workers and of making excessive demands on them in terms of health competence. And campaigns are by definition temporary measures, while extending immunization requires a regular and sustained effort to reach the populations. The example of Tanzania shows that the key to success lies in developing stronger healthcare facilities.

The cost of vaccines is also preventing access to existing vaccines in developing countries. Indeed, if basic old vaccines are by far the cheapest and most cost-effective health interventions today, new vaccines (such as the recently developed ones against pneumococcus, rotavirus or papillomavirus) exceed the financial means of their governments and their populations.

Regarding the development of new forms of immunization, a first obstacle identified by the experts is the lack of a clear research strategy. The problem is in particular whether priorities should be established among diseases or research should develop on several fronts concurrently. There was no consensus on this matter. Although establishing priorities among diseases sounds like a reasonable divide and conquer policy, it raises important difficulties. It is unclear whether the order of priorities should be established primarily at the national or at the international level, and how to harmonize these two levels of decision. Which factors to take into account in

selecting a certain disease as priority for vaccine research and development is also a delicate issue. The importance of the disease in terms of public health is clearly a crucial element, but it no less clearly raises ethical questions. The contagious character of the disease and its interaction with other infections must also be taken into consideration.

Another important obstacle hindering the development of new vaccines is the lack of solid data and statistics about the disease burden, a difficulty that is not specific in fact to developing countries.

The excessive cost of the vaccine research and development process is also a well known major obstacle and an increase in financial help is necessary in order to overcome it. More financial help is also needed for ensuring better immunization coverage with already available vaccines, but it is important that enough resources be allocated to innovation.

Vaccine research and development was also criticized by the experts for being concentrated in the developed countries, and they recommended that developing countries play a more important role. This increased participation will require building up stronger research capacities, and in particular the constitution of an adequate body of researchers, technicians and engineers. Developing countries are however facing an important brain drain problem, especially at the level of basic and theoretical research. As a possible remedy the panel of experts suggested the establishment of long-term and reciprocal collaborations between north and south research institutions. In addition south - south collaborations should be encouraged in their opinion. Iran's research and development capacities are for instance underused.

From a purely scientific point of view, breakthroughs in the search for an Aids and a malaria vaccines would clearly represent a major progress for the extension of immunization. But more efforts should also be devoted to improving already available vaccines so as to make them more efficient, less costly, more flexible as well as more easily accessible. The administration schedule of vaccines could for instance be simplified in order to make them more easily accessible to populations, especially in countries with insufficient healthcare infrastructures. For the same reason, new forms of vaccinations should also be invented, following the model of animal vaccines that are administered in the form of sprays, water dissolvent capsules or food additives, and the possibility of easing the cold chain constraint investigated. Lowering the dose of antigen while increasing the quantity of adjuvants within certain limits would also represent a way of reducing the cost of vaccines, although the diminution of cost will not be proportional to the diminution of the dose of vaccine.

Finally, the research and development of new vaccines is slowed down by regulatory obstacles, well illustrated by the withdrawal from the market of the first rotavirus vaccine after a limited number of cases of intestine blockage (intussusception) that seem to be out of proportion with the number of victims caused by the withdrawal of the vaccine. These obstacles suggest that current approval and surveillance regulations might be too rigid, and therefore not suitable for developing countries, as well as for emergency situations such as a virulent epidemic. However, modifying these regulations should not lead to lower the levels of quality and safety of vaccines, but only to make them more adapted to the complexity of health realities, thereby maximizing the potential benefits of the fruits of research.

#### KEY QUESTIONS:

- ▶ How to improve the vaccine delivery system in developing countries?
- ▶ What are the best mechanisms to involve developing countries in the definition of immunization strategy?
- ▶ Should research and development of new vaccines be targeted on a number of priority diseases?
- ▶ How far can we simplify current forms of human vaccinations?
- ▶ To what extent can the current approval and monitoring mechanisms be made more flexible without putting the safety and quality of vaccines at risk?

#### RECOMMENDATIONS FOR ACTIONS:

- ▶ Stimulating the political will to improve the immunization coverage of populations throughout the world
- ▶ Developing innovative global partnerships on the model of the successful GAVI initiative
- ▶ Increasing the involvement of developing countries in the definition of immunization strategies
- ▶ Organizing an in-depth discussion about the regulatory and ethical aspects in the context of Biovision 2007