

DIRECTORATE FOR SCIENCE, TECHNOLOGY AND INDUSTRY  
COMMITTEE FOR SCIENTIFIC AND TECHNOLOGICAL POLICY

Cancels & replaces the same document of 30 October 2007

**Working Party on Biotechnology****OECD-IAVI-GI HOSTED POLICY MAKER WORKSHOP ON  
“INCENTIVES FOR PRIVATE SECTOR INVOLVEMENT IN INNOVATIVE  
AIDS VACCINE R&D”**

*The paper presents the Agenda and background paper for a Workshop to be held on 26 November 2007 at the OECD in Paris. At the Workshop the International Aids Vaccine Initiative and The George Institute for International Health will present the findings and recommendations of a study of how to increase the incentives for biotechnology firms to do R&D in AIDS vaccine. The purpose of the workshop is to garner policymaker comments to the study and its recommendations.*

*This paper, which was prepared by IAVI and the GI, is submitted to the 22nd Session of the Working Party on Biotechnology for discussion.*

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**NOTE BY THE SECRETARIAT**

Delegates will find attached a paper describing a joint workshop between the International Aids Vaccine Initiative (IAVI) and the Working Party on Biotechnology to be held November 26, 2007 at the OECD headquarters in Paris. This workshop will discuss a recent study by IAVI and the George Institute for International Health (GI) on how to incentivize R&D in AIDS vaccine development. This joint workshop follows on the discussions about accelerating the development and delivery of medicines, vaccines and diagnostics that occurred at the OECD High Level Forum on Medicines for Emerging and Neglected Infectious Diseases in the Netherlands in June 2007.

WPB delegates are asked to:

- **Note** progress on developing a joint workshop with IAVI on Incentives for Private Sector Involvement in Innovative AIDS Vaccine R&D.
- **Discuss** the proposed policy mechanisms for incentivising R&D in AIDS vaccines.
- **Nominate** experts and government representatives to attend the workshop.

**OECD-IAVI-GI HOSTED POLICY MAKER WORKSHOP ON  
“INCENTIVES FOR PRIVATE SECTOR INVOLVEMENT IN INNOVATIVE  
AIDS VACCINE R&D”**

**Objective and expected outcomes of the workshop**

1. The OECD will hold a workshop to present and discuss the findings and recommendations of a recent study done by International AIDS Vaccine Initiative (IAVI) and the George Institute for International Health (GI). The study assesses the barriers to and possible incentive mechanisms for greater private sector engagement in AIDS vaccine R&D.
2. The workshop is intended to introduce policy makers to the IAVI/GI study and to solicit OECD country reactions to its draft findings and recommendations. The recommendations include several mechanisms that might stimulate increased private sector innovation in AIDS vaccines. It is hoped that an additional outcome of the workshop will be a discussion of possible next steps, if there is an emerging consensus on which set of recommendations to take forward.
3. A short description of the study and its preliminary recommendations, as well as the draft agenda for the workshop, is included below to help delegates identify appropriate participants and to help these prepare for the meeting that will take place on November 26 at the OECD in Paris.

**Who should attend**

4. Ideally, participants to this workshop should be policy makers from OECD countries who are engaged in stimulating R&D and innovation in the private sector, especially in vaccine development for infectious or neglected diseases (such as AIDS, TB, Malaria).
5. Participants are expected contribute to the discussion by sharing their own experiences with health R&D policies and programs for innovation. Their comments and views on the preliminary recommendations proposed by IAVI and the GI will be actively solicited. The final recommendations emerging from the IAVI/GI study will take into account the discussion and comments received at this OECD workshop.

**The International AIDS Vaccine Initiative and the George Institute for International Health**

6. This workshop is jointly hosted by the Working Party on Biotechnology at the OECD and the International AIDS Vaccine Initiative. Its objective is to solicit OECD member country comment on the draft policy recommendations put forward in the study recently concluded by IAVI and the George Institute for International Health.
7. IAVI is a Product Development Public-Private Partnership (PDP) whose mission is to ensure the development of a safe, effective, accessible, preventive AIDS vaccine for use throughout the world. IAVI is funded by ten governments, the EU, World Bank, philanthropic organizations, individuals, as well as in-

kind support from private sector entities. The organization has an active research program that aims to leverage industry involvement but take R&D risks industry cannot take while promoting rational vaccine design. In addition, IAVI undertakes a policy research and advocacy program that aims to identify and promote policies which create an enabling environment for AIDS vaccine R&D and rapid global access. This project represents one such policy research initiative which it is hoped will bring benefits to the AIDS vaccine field as a whole through increased private sector involvement in Europe.

8. The George Institute for International Health is a not-for-profit institution that seeks to improve global health through undertaking high quality research, and applying this research to health policy and practice. The GI focuses on activities that can deliver the greatest health improvements where they are most urgently needed. The GI's Health Policy Division focuses on research and analysis aimed at improving and supporting government health policy choices. This division has expertise in Industry R&D incentives and public and private R&D models for neglected diseases amongst other things, and has been commissioned on behalf of IAVI to help conduct this research project.

## **Background to the study**

### ***The Need for New / Improved R&D Financing and Incentives Mechanisms in Europe***

9. There is now an opportunity to increase private sector involvement in AIDS vaccine R&D in Europe, through implementation of structural changes and improved targeting of funding. Figures show that in Year 2006 the vast majority [84% (US\$776m)] of global AIDS vaccine R&D funding came from public sector sources, with the US being the predominant funder; European governments and the EC accounted for approximately 11% (US\$82m) of global public spending. However, private sector involvement remained strikingly low, accounting for only 8% (US\$79m) of global AIDS vaccine R&D spend. About one-third of this came from European companies.

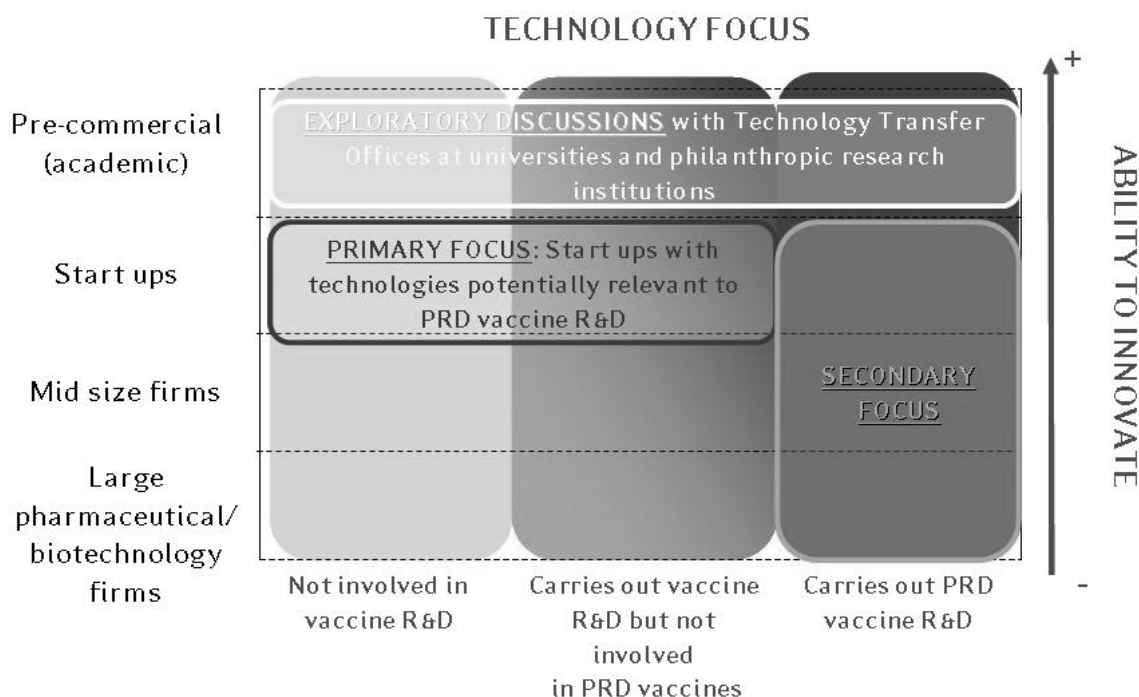
10. In recent years, various policies to stimulate private sector engagement in the search for technologies to fight poverty-related diseases (PRDs) have been discussed, implemented and funded by European and OECD governments. These policies, which include the Advance Market Commitment (AMC) for Pneumococcal vaccines, have tended to focus on *later* stages of R&D. However, for HIV/AIDS and many other PRDs, it is the early stages of R&D innovation that are crucial obstacles delaying successful product development. Innovation in these early stages of R&D is a high risk activity that primarily takes place in university labs and biotechnology companies. New incentives and financing mechanisms that address early-phase R&D funding issues (with respect to volume, focus, and flexibility) and improve the functioning of early links in the R&D chain in Europe are crucial to increasing innovation and engagement of private sector actors.

## **Objectives and Methods**

11. The International AIDS Vaccine Initiative (IAVI) and the George Institute for International Health (GI) conducted extensive consultations with academic entrepreneurs, university technology transfer offices (TTOs), and senior executives from biotech, large pharmaceutical, and venture capital (VC) firms to understand barriers to private sector involvement in vaccine R&D for PRDs and identify possible solutions in Europe. The firms targeted in the consultation varied by level of institutional development and technological focus (Figure 1).

Figure 1: Types of research-based organizations consulted

Figure 1.



## Results

### *Barriers to Private Sector Involvement in PRD Vaccine R&D*

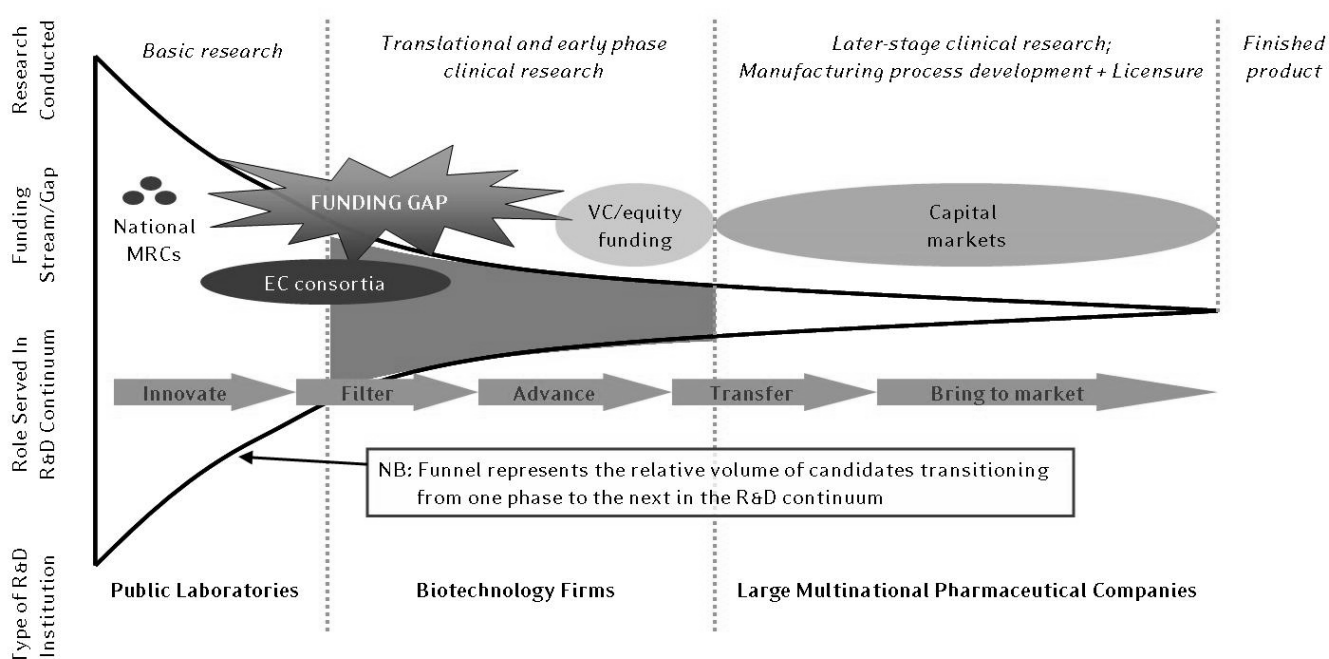
12. Breakthrough innovation usually originates in publicly-funded research institutions, but it is primarily biotechnology firms who filter these innovations to identify the most promising leads and who then develop them into product prototypes that can be transferred to larger companies for further development. However, a number of obstacles are preventing this system from operating smoothly, with the result that biotechnology firms are being deterred from greater involvement in PRD vaccine R&D.

13. Scarce and fragmented funding of European academic basic and applied research is limiting the quality and quantity of innovative ideas and technologies reaching biotechnology firms. For biotechnology firms, there is a large translational R&D funding gap between traditional public and private funding streams (see Figure 2), and vehicles for collaboration between public research labs and biotechnology firms are seen as lacking or inappropriate. Policies that address these gaps are seen as a much needed and an appealing catalyst to mobilize greater biotechnology involvement in PRD vaccine R&D; allowing biotechnology firms to be fed with more innovative leads, and improving their ability to transform these leads into viable product candidates.

14. A series of structured interviews showed that biotechnology firms already involved in PRD vaccine R&D were able to participate largely because they receive significant funding from public or philanthropic sources. Other biotechnology firms with expertise and technologies potentially relevant to

PRD vaccine development, who were not involved in vaccine R&D for PRD applications, said they could only participate in such vaccine R&D if their involvement were heavily subsidized in a sustained way. Therein lies the problem. In Europe, public funding to bridge this translational gap is lacking. Private sector financiers (e.g. Venture Capital funds), the traditional source of translational funding, are unwilling to directly fund PRD vaccine R&D and particularly AIDS vaccine R&D because of the scientific challenges that make this an extremely risky enterprise. We note, however, that most VCs suggest they are willing to allow technologies within their biotechnology portfolios tested for PRD vaccine applications if this does not affect, or divert funding from, the biotechnology firm's work on their mainstream commercial application.

**Figure 2: Funding streams within the innovation system**



### ***Possible Solutions for Consideration and Further Discussion***

15. The IAVI/GI recommendations seek to bridge the academic-industry innovation gap and thus facilitate translation of innovative ideas into viable PRD vaccine products, by:

- Stimulating biotechnology firm engagement in PRD vaccine R&D by supporting early-stage work and encouraging collaboration with academic partners;
- Extending academic involvement to allow ideas to be developed further before hand-over to industry.

16. The following is a short-list of possible solutions prioritized from an earlier list of fifteen proposals. These were reviewed with a focus group of key European biotechnology business leaders to validate the IAVI/GI findings and refine their recommendations, identifying those most likely to change firm behavior. While the recommendations are largely presented with respect to their application to AIDS

vaccine R&D, it is likely they would also be relevant and viable for other poverty related disease vaccine technologies.

**1. A European Vaccine R&D ‘Institute’ that would conduct translational research in priority areas**

17. The not-for-profit ‘institute’ would advance nascent ideas from academic labs, and possibly apply privately-owned vaccine technologies to HIV/AIDS (and other poverty related disease) targets. It might be hosted by 2-3 leading European universities located close to or within existing biotechnology clusters, and would have dedicated laboratory infrastructure and a mix of dedicated staff as well as temporary researchers (e.g. on yearly sabbaticals from firms and other public research institutions). Its mandate would potentially include: (1) conducting internal research; (2) funding the full costs of and participating in collaborative research by/with academia and biotechnology firms (allowing staff of partnering firm to come and work for defined periods within the institute); as well as possibly (3) brokering early-stage R&D partnerships. It is envisioned that the institute would be financed by public and philanthropic funding.

**2. Funding for University/Biotechnology Firm Collaboration to fill the funding gap and facilitate public-private cooperation**

18. This would involve designing and implementing translational research grants to foster European academic-industry partnerships in small collaborations (as opposed to large consortia, which were seen by scientists as too cumbersome and bureaucratic to manage and a cause of decreased research productivity). Existing European funding mechanisms already aim to engender small-scale public-private research collaborations, such as the grants awarded by the Wellcome Trust or the Danish National Advanced Technology Foundation mechanism. This proposal would create similar initiatives specifically targeting AIDS vaccine collaborative research projects.

19. In addition to these 2 policy proposals, which drew the most enthusiastic support across all interviewees, other proposals received some interest and could be considered as potential supplements to the two front-runners above. These include prizes, and packages of incentive and facilitative mechanisms for small companies.

*A prize/purchase fund mechanism:* It would aim to offer substantial economic returns as well as reputational benefits for biotechnology firms who either solve pre-specified technological challenges, or as purchase funds for validated candidates. This would create an interim market within a 1-3 year timeframe for solutions to scientifically challenging problems or for intermediary (e.g. phase I) candidates. Some interviewees felt prizes/purchase funds on their own could be an attractive proposition, while others felt milestone-based prizes would work best as supplemental incentives to grant-funded research, by motivating already-engaged firms to invest additional resources of their own and increase the vigor with which they pursue the challenge.

*A package of incentive and facilitation mechanisms:* to lower costs and remove administrative obstacles to HIV vaccine R&D. Such a package could include early regulatory support (i.e. advice, training etc.), the establishment of Europe-wide technology transfer standards and tool-kits for HIV vaccine-relevant technologies (including humanitarian licensing practice for universities), the establishment of standard access and IP guidelines for collaborative public/private HIV vaccine research, and fast-track regulatory approval for HIV vaccine candidates. Most of these were seen as attractive to biotechnology firms in terms of facilitating engagement, but not sufficient in themselves. The IP-facilitation measures are likely to have a higher impact in relation to encouraging applied university research.

*Additional Notes on the Recommendations Based on Feedback from Private Sector Stakeholders*

20. These recommendations were discussed with a focus group of key biotech business leaders and other important stakeholders in the European innovation system to validate our findings, and refine our recommendations identifying those most likely to influence firms' behavior. Highlights from these discussions have been summarized below:

- There was significant interest in the R&D Institute and genuine excitement in the potential of such an initiative for early stage AIDS vaccine R&D. Nonetheless, a number of important operational questions were raised including:
  - How the initiative should be structured in order to attract the best researchers (crucial to its success).
  - How far it should continue its research (Should it stop at a pre-clinical stage or at phase 1?).
  - Where it should be located (at universities only or at research institutes like the Max Plank or the Pasteur).
  - How it can avoid duplicating, and diverting resources from existing AIDS vaccine initiatives.
- The collaborative research financing mechanisms were received with enthusiasm, although all suggested that (1) they would be comparatively less valuable than the R&D Institute, and (2) they could however potentially work synergistically with it.
- Similarly, stakeholders recognized the potential synergies that might exist between prizes and the Institute.
- However, many stakeholders felt that prizes alone would only be viable if supplemented with initial full grant funding, particularly in the first year of the research endeavor. If there was an indication (according to certain criteria) that this research should continue beyond the initial grant-funded period, prizes are likely incentivize and motivate firms to invest some of their resources in addition to the grant-funded work, and potentially increase the vigor with which they pursue the challenge.
- Package of facilitation mechanisms received more critical feedback, at least for some of the specific ideas within the packages. Waiving patent fees in particular were seen as having significant drawbacks that would prevent them being fit for purpose (potentially inhibiting innovation), while other suggested facilitation mechanisms were seen as only offering marginal (although nonetheless positive) benefits.



## Conclusions

21. There is significant scope for stimulating vaccine innovation and the translation of innovation into viable product candidates by the private sector, especially smaller biotechnology firms. This study identifies several policy measures that have the potential to substantially enhance innovation in AIDS vaccine R&D. The feasibility of these proposed solutions must now be discussed with public sector stakeholders while additional work must be undertaken to elaborate on the proposals to better define operational and logistical details (including costs). It is our hope that European and OECD governments will use this research as a starting point for consideration of measures to stimulate vaccine R&D.

22. The conclusions from the workshop and the final IAVI/GI report will be shared with participants in early 2008.

## Actions

WPB delegates are asked to:

- **Note** progress on developing a joint workshop with IAVI on Incentives for Private Sector Involvement in Innovative AIDS Vaccine R&D.
- **Discuss** the proposed policy mechanisms for incentivising R&D in AIDS vaccines.
- **Nominate** experts and government representatives to attend the workshop.

**ANNEX 1**

**OECD HOSTED POLICY MAKER WORKSHOP ON “INCENTIVES FOR INNOVATION IN AIDS VACCINE R&D”**

**Preliminary Draft Agenda**

**OECD Headquarters, Franqueville Room, 2 , Rue André Pascal, 75016 Paris  
26 November 2007, 10:00-18:00**

**09:30 – 10:00**

Registration - Tea/Coffee

- 10:00 –10:10** Welcome (Bénédicte Callan/Iain Gillespie, OECD)  
Presentation of the topic and the participants
- 10:10 –10:45** Introduction of IAVI and GI (Robert Hecht, IAVI)  
Workshop objectives and study overview (Gian Gandhi, IAVI)
- 10:45 – 11:15** Presentation of project and summary of findings (Anne-Laure Ropars, GI)
- 11:15 – 11:45** Overview of study recommendations (Anne-Laure Ropars, Gian Gandhi)
- Dedicated R&D institute
  - Funding mechanisms to encourage collaborative public groups/biotech R&D
  - Other mechanisms for conducting, funding and/or facilitating PRD vaccine R&D in Europe
- 11:45 – 12:15** Comments by private sector representatives
- Challenges for pharma (Michel Greco; Former President and COO of Aventis Pasteur, Former President and COO of Pasteur Mérieux MSD)
  - Challenges for biotechs (Dr. Camilo Colaco; Chief Scientific Officer and Founder of ImmunoBiology Ltd)
- 12:15 – 13:00** Discussion of key findings (Facilitated by Anne-Laure Ropars and Gian Gandhi)
- 13:00 – 14:15** – Buffet lunch (To be served in the hall of the Château)

**14:15 – 15:45** Continuation of discussions on key findings (Facilitated by Anne-Laure Ropars and Gian Gandhi)

**15:45 – 16:15 – Coffee Break**

**16:15 – 17:15**

- Discussion
- Summary of discussions (Robert Hecht )
- Policy coordination with other regional institutions such as EU, WHO and incoming G8 Presidency (Commission representative, Bart Wijnberg and Japanese representative)
- Next steps (Bénédicte Callan)

**17:15-17:30**

Concluding remarks (Iain Gillespie)