Report of the Sixth Meeting of the IVR Vaccine Advisory Committee (IVAC)

Geneva, Switzerland
19-20 April 2007
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Abbreviations and acronyms

AAVP AfriCand Acquired Immunodeficiency Syndrome African AIDS Vaccine Programme
AFRO WHO Regional Office for Africa
BMGF Bill and Melinda Gates Foundation
CDS Communicable Diseases Cluster, WHO
GCP Good Clinical Practices
GVRF Global Vaccine Research Forum
HQ WHO Headquarters, Geneva
HIV Human Immunodeficiency Virus
HVI WHO-UNAIDS Joint HIV Vaccine Initiative Team, WHO/IVR
IVAC Initiative for Vaccine Research Vaccine Advisory Committee
IVB Department of Immunization, Vaccines & Biologicals, WHO
IVR Initiative for Vaccine Research, WHO
JE Japanese Encephalitis
LEG Office of the Legal Counsel, WHO
MVP Meningitis Vaccine Project (WHO - PATH)
PATH Programme for Appropriate Technology in Health
IMR Implementation Research Team, WHO/IVR
LAIV Live Attenuated Influenza Vaccine
QSS Quality and Safety of Vaccines Team, WHO
RPD Product Research and Development Team, WHO/IVR
R&D Research and Development
SAGE WHO Strategic Advisory Group of Experts
SEARO WHO Regional Office for South East Asia
TB Tuberculosis
TDR UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases
UNAIDS The Joint United Nations Programme on HIV/AIDS
WHO World Health Organization
Preface

Prof Ndumbe, IVAC chair, opened the meeting and convened to the committee apologies from three members who were unable to attend (Dr Clemens, Prof Delfraissy and Dr Ganguly).

Dr Kieny explained the new functions of the new committee, and reminded the members of the main expectations of WHO from IVAC: provide strategic advice, help to strengthen interaction with major stakeholders in the field of vaccine R&D and to optimize synergies. The advice provided will complement more technical input given by the disease-specific IVR advisory committees (list provided in Annex 2).

The specific objectives of the 2007 IVAC meeting were to:
- Present main achievements of IVR in the recent months;
- Seek advice on best approach for IVR to support global vaccine R&D efforts;
- Discuss how to build stronger collaboration with other stakeholders;
- Seek input for WHO's overall research strategy (2006-2009).

Overall Presentation of IVR activities

Dr Kieny presented IVR structure and gave an overall presentation on IVR strategy (detailed powerpoint presentation in Annex 3).

Discussion was then held about prospects for financing the Initiative in 2008-2009, and on the positioning of research among the six core functions of WHO.

Teams' presentations

Product Research and Development (RPD)

Dr Kieny gave the presentation "Vaccine Product Research and Development efforts at IVR" on behalf of Dr Aguado, absent from the meeting for pressing family reasons (detailed information in Annex 4).

Discussion

Participants raised questions concerning the global capacity to manufacture influenza vaccines in case of pandemic. The advantages of various technologies (inactivated vs live attenuated vaccines) were discussed.

IVAC emphasized that the Global Adjuvant Initiative project could be very important for the general vaccine R&D community, and should therefore constitute a priority for IVR.
It was further recognized that IVR has close partnership with industry and the private sector in the RPD area of work, and this was considered positively by IVAC.

**Implementation Research (IMR)**

Dr Hombach gave a presentation on IMR activities (detailed information under *Annex 5*).

**Discussion**

The general opinion of IVAC was that IMR is a very important area of work for WHO, and that emphasis should be given to these activities. Capacity building at country level on tools for decision-making was discussed, and some members cautioned IMR against the risk of over-training.

**Ethical, normative and regulatory agenda**

Dr Osmanov presented the "Cross-cutting IVR activities in the area of ethics, regulatory research and capacity strengthening" (detailed information in *Annex 6*).

**Discussion**

IVAC concurred with IVR that regulatory research activities, implemented by the HVI unit was well in line with WHO's mandate and core functions.

**Input of IVAC members**

**BMGF**

Dr Rabinovich identified neglected infectious diseases in general as a research and development gap. She mentioned that the BMGF cannot fund all projects, and that IVR must create opportunities for more independence towards its main donors, and notably towards the Foundation. She underlined the need for strict prioritization, and proposed a few directions:

- WHO is not well placed as a major research engine
- IVR must strive to strengthen the work of partners
- IVR should monitor and evaluate the work of others
- IVR should seek feedback from countries on the impact of vaccine introduction.
- IVR should reflect more on how to optimize delivery of immunization.
**EC**

Dr Romaris noted that WHO is a world leader in the field of health, and should take clear advantage of its strategic position. He suggested that IVAC, which gathers all major players in the field of vaccine R&D, could be used to unify and coordinate positions under the umbrella of IVR. He mentioned that the EC currently finances projects on four main areas of interest for IVR: Malaria, Tuberculosis, Influenza and HIV. There is a close collaboration between the EC and IVR, as Dr Kieny and Dr Osmanov are involved in EC advisory structures. The main recommendations offered to IVR included the following:

- IVR should participate in research activities funded by the EC or through the EDCTP.
- IVR and EC should have a closer collaboration to organize and follow up clinical trials.
- WHO/IVR should help to create more synergy between research capacity building and public health in Africa

**DCVMN**

Dr Jadhav reminded IVAC that 7 manufacturers with WHO-prequalified vaccines are located throughout the developing world: Brazil, Cuba, India, Indonesia. Dr Jadhav explained that IVR’s most important contribution has been to provide support for the development of rotavirus and meningococcal A Conjugate vaccines, and more recently its initiative to facilitate the establishment of manufacturing capacity for pandemic influenza vaccine in developing countries. He further provided the following advice to the programme:

- IVR should continue to give advice and guidance to DCVMN
- IVR should pursue its efforts in support of vaccine R&D projects in developing countries
- IVR should identify additional Public-Private Partnerships for new products/vaccines such as HPV, malaria, recombinant TB, HIV and new delivery systems, including new adjuvants.

**GAVI**

Mr Michel Zaffran reminded IVAC that, although GAVI is not a research-focused organization, it does finance downstream research in favor of accelerated introduction of new vaccines in developing countries. He emphasized that IVR should be aware of country needs and provide advice on vaccine introduction. He also proposed that IVR should remain active in product research and development for orphan products.
**IFPMA**

Although IFPMA contributes to all areas of work of IVR, R&D activities undertaken by industry may be less prone to collaboration with IVR because of concerns of potential conflicts of interest. Dr Quentin-Millet reminded IVAC that IVR has the unique capacity to bring experts and stakeholders together and that its competencies are well recognized. Moreover, WHO has privileged access to countries. Dr Quentin-Millet expressed some concerns about lack of financing of IVR projects, and about a potential loss of its independence if concentration mostly on funded projects were to take priority over investment into carefully selected programmes.

She further proposed that IVR and the IFPMA should increase their level of synergy in the area of capacity building.

**NIH**

Dr Heilman expressed the view that investment in basic or biochemical research should not be a priority for IVR. She reasoned that IVR, as a WHO technical component, has the ability to provide impartial and well respected advice with respect to priority needs. IVR has also the ability to synthesize, evaluate and communicate the multitude of efforts ongoing across the world and then identify and prioritize gaps.

She proposed that IVR should expand its involvement in the area of implementation research, provide "standardization/guidance" to donors involved in capacity building efforts, and be the focal point for identifying priority research gaps. IVR should further ensure the quality of analysis and make independent evaluation of data used to support policy recommendations.

**PATH**

Dr Elias underlined the positive partnership between IVR and PATH over the years (Meningitis, HPV, Malaria..). The strength of this partnership relies on the complementarity between the two entities, and on their common vision on research expectations.

He proposed that IVR should try and fill the gap between research and implementation, and collaborate rather than compete with the disease-specific PDPs. This could change the way donors invest into IVR activities.

**SAGE**

Dr Salisbury, Chair of SAGE, insisted that IVR should strive at being facilitators more than researchers. IVR, especially in its support to implementation research, should provide timely, appropriate added-value to SAGE, because of the crucial role of science and evidence in policy making.
Conclusions: what role and strategy for IVR in the coming months

The Chair of IVAC, Dr Ndumbe, summarized the discussions held over the two days of the meeting and consolidated IVAC recommendations as follows:

- The research and development work undertaken or facilitated by IVR should be tailored at providing the scientific information needed for the formulation of policy recommendations by SAGE;
- IVR should assist countries on operational research and for decision-making;
- IVR should advocate at a high level within WHO for more investment into vaccine R&D and research in general;
- IVR should try to find specific resources and be careful in the choice of projects;
- IVR should look for areas not explored by WHO yet;
- IVR should be a convenor;
- IVR should not be afraid at asking tough questions and impartially evaluate the value of evidence published by other stakeholders;
- IVR must maintain its neutrality and competent infrastructure.

Dr Ndumbe emphasized the value of the work proposed by IVR on a global adjuvant initiative and in the area of implementation research. He also proposed that the initiative investigates potential involvement into "MVP-like" product R&D projects.

Dr Ndumbe concluded that IVR should strive at maintaining its neutrality and independence, both at the financial and decision making levels.
Annex 1 - List of Participants

IVR ADVISORY COMMITTEE MEMBERS

Dr John Clemens (unable to attend)
Director
International Vaccine Institute
San 4-8, Bongcheon 7 dong, Kwanak-Ku
Seoul
Korea, Rep. of
TEL: +82 2 881 1100
FAX: +82 2 872 2803
EMAIL: jclemens@ivi.int

Prof Jean-François Delfraissy (unable to attend)
Director
agence nationale de recherche sur le sida
101 rue de Tolbiac
75013 Paris
France
TEL: 33 1 53 94 60 23
FAX: 33 1 53 94 60 01
EMAIL: jf.delfraissy@anrs.fr

Dr Christopher J. Elias
President
PATH
Program for Appropriate Technology in Health
1455 NW Leary Way
Seattle 98107 WA
USA
TEL: 1 206 285 3500
FAX: 1 206 285 6619
EMAIL: celias@path.org

Dr Nirmal Kumar Ganguly (unable to attend)
Director-General
Indian Council of Medical Research
Ansari Nagar
Post Box 4911
New Delhi 110029
India
TEL: 91 11 2651 7204/2658 9897
FAX: 91 11 2658 8662
EMAIL: gangulynk@icmr.delhi.nic.in

Dr Catherine Hankins
Chief Scientific Advisor
UNAIDS
Avenue Appia 20
1211 Genève 27
Switzerland
TEL: +41 22 791 3865
FAX: +41 22 7914746
EMAIL: hankinsec@unaids.org
Dr Carole Heilman
Director
Division of Microbiology and Infectious Diseases
National Institute of Allergy and Infectious Diseases, NIH
6610 Rockledge Drive
Room 6111
MSC 6603
Bethesda MD 20892-4528 MD
USA
TEL: 1 301 496 1884
FAX: 1 301 480 4528
EMAIL: CHEILMAN@niaid.nih.gov

Dr Suresh S. Jadhav
Executive Director
Quality Assurance & Regulatory Affairs
Serum Institute of India Ltd.
212/2, Hadapsar
Pune 411028
India
TEL: +91 202 660 2378/2379
FAX: +91 202 699 3945/3921
EMAIL: ssj@seruminstitute.com / ssj@vsnl.com

Professor Peter Martins Ndumbe
University of Yaoundé
1 Melen Street
B.P. 8445
Yaoundé
Cameroon
TEL: 237 231231 12 24
FAX: 237 231 2733
EMAIL: pndumbe@yahoo.com

Dr Marie-Jose Quentin-Millet
Chef de Service, Vice President R&D
Sanofi Pasteur
Campus Mérieux
1541 Avenue Mérieux
69280 Marcy l'Etoile
France
TEL: +33 4 37 37 3664
FAX: +33 4 37 37 3976
EMAIL: marie-jose.quentin-millet@sanofipasteur.com

Dr Regina Rabinovich
Director
Infectious Diseases, Global Health Program
The Bill and Melinda Gates Foundation
P.O. Box 23350
Seattle, WA 98107-5136
USA
TEL: +1 206 709 3490
FAX: +1 206 709 3170
EMAIL: regina.rabinovich@gatesfoundation.org

Dr Manuel Romaris
EDCTP Liaison Officer
HIV/AIDS Research
Infectious Diseases Unit
Research Directorate General
European Commission
Office SDME 7/33
B-1049 Brussels
Belgium
TEL: 32 2 296 4826
FAX: 32 2 295 5365
EMAIL: manuel.romaris@ec.europa.eu
Dr Ana Maria Henao-Restrepo
Scientist
Initiative for Vaccine Research
World Health Organization
20 Ave Appia
1211 Geneva 27
Switzerland

TEL: 41 22 791 3402
FAX: 41 22 791 4860
EMAIL: henaorestrepoa@who.int

Dr Joachim Hombach
Acting Coordinator, Implementation Research
Initiative for Vaccine Research
World Health Organization
Dept. of Immunization, Vaccines and Biologicals
20 avenue Appia
1211 Geneva 27
Switzerland

TEL: 41 22 791 4531
FAX: 41 22 791 4865
EMAIL: hombachj@who.int

Dr Raymond Hutubessy
Implementation Research
Initiative for Vaccine Research
World Health Organization
Dept. of Immunization, Vaccines and Biologicals
20 avenue Appia
1211 Geneva 27
Switzerland

TEL: 41 22 791 3253
FAX: 41 22 791 4865
EMAIL: hutubessyr@who.int

Dr Marie-Paule Kieny
Director
Initiative for Vaccine Research
World Health Organization
Dept. of Immunization, Vaccines and Biologicals
20 avenue Appia
1211 Geneva 27
Switzerland

TEL: 41 22 791 3591/4395
FAX: 41 22 791 4860
EMAIL: kienym@who.int

Dr Saladin Osmanov
Coordinator
WHO-UNAIDS HIV Vaccine Initiative (IVR/HVI)
World Health Organization
20 Ave Appia
1211 Geneva 27
Switzerland

TEL: 41 22 791 4393
FAX: 41 22 791 4860
EMAIL: osmanovs@who.int
Dr Laszlo Palkonyay  
Product Research and Development (RPD)  
Initiative for Vaccine Research  
World Health Organization  
Dept. of Immunization, Vaccines and Biologicals  
20 avenue Appia  
1211 Geneva 27  
Switzerland  
TEL: 41 22 791 3488  
FAX: 41 22 791 4860  
EMAIL: palkonyayl@who.int

Dr Marie-Pierre Preziosi  
Product Research and Development  
Initiative for Vaccine Research  
World Health Organization  
20, Avenue Appia  
1211 Geneva 27  
Switzerland  
TEL: 41 22 791 3744  
FAX: 41 22 791 4860  
EMAIL: preziosim@who.int

Dr Zarifah Reed  
WHO-UNAIDS HIV Vaccine Initiative (IVR/HVI)  
Initiative for Vaccine Research  
World Health Organization  
Dept. of Immunization, Vaccines and Biologicals  
20 avenue Appia  
1211 Geneva 27  
Switzerland  
TEL: 41 22 791 4760  
FAX: 41 22 791 4865  
EMAIL: reedz@who.int

Dr Robert Ridley  
Director  
Tropical Disease Research (CDS/TDR)  
World Health Organization  
Dept. of Immunization, Vaccines and Biologicals  
20 avenue Appia  
1211 Geneva 27  
Switzerland  
TEL: 41 22 791 3767  
FAX: 41 22 791 4854  
EMAIL: ridleyr@who.ch

Dr Duncan Steele  
World Health Organization  
IVR/BAC  
Vaccine and Biologicals  
Avenue Appia 20  
1211 Geneva 27  
Switzerland  
TEL: +41 22 791 3752  
FAX: 41 22 791 4860  
EMAIL: steeled@who.int
Dr Coumba Toure  
WHO-UNAIDS HIV Vaccine Initiative (IVR/HVI)  
World Health Organization  
20, Avenue Appia  
1211 Geneva 27  
Switzerland  
TEL: +41 22 791 4637  
FAX: +41 22 791 4860  
EMAIL: tourec@who.int

Dr Lara Wolfson  
Scientist  
Initiative for Vaccine Research, Implementation Research (IMR)  
World Health Organization  
20 Ave Appia  
1211 Geneva 27  
Switzerland  
TEL: 1 212 286 0424  
FAX: 1 212 286 9561  
EMAIL: gawh@igc.apc.org
### Annex 2 - IVR advisory committees

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<th>Committee</th>
<th>Focus</th>
<th>Participants</th>
<th>Scope</th>
</tr>
</thead>
<tbody>
<tr>
<td>IVAC</td>
<td>All aspects of IVR involvement</td>
<td>Global partners in vaccine R&amp;D</td>
<td>Strategy, cross-diseases synergies</td>
</tr>
<tr>
<td>MALVAC</td>
<td>Malaria vaccines</td>
<td>Scientific experts and stakeholders</td>
<td>Strategy, coordination of global agenda</td>
</tr>
<tr>
<td>VAC</td>
<td>HIV vaccines</td>
<td>Scientific experts and stakeholders</td>
<td>Ethical and regulatory frameworks, policy, review of protocols and proposals</td>
</tr>
<tr>
<td>STOP-TB Vaccine Working Group</td>
<td>TB vaccines</td>
<td>Scientific experts and stakeholders</td>
<td>Programme activities</td>
</tr>
<tr>
<td>HEAG</td>
<td>HPV vaccines</td>
<td>Scientific experts and stakeholders</td>
<td>Coordinate overall WHO programme with stakeholders; prepares for SAGE recommendation</td>
</tr>
<tr>
<td>SC on Diarrhoeal diseases</td>
<td>Enteric diseases vaccines</td>
<td>Scientific experts and stakeholders</td>
<td>Analysis of the field, review of proposals</td>
</tr>
<tr>
<td>AAVP (African AIDS Vaccine Programme) SC</td>
<td>HIV vaccines</td>
<td>African experts</td>
<td>Strategies for the programme, decisions on funding of AAVP work areas</td>
</tr>
<tr>
<td>Flaviviruses Vaccines SC</td>
<td>Dengue, Japanese encephalitis and other flaviviruses vaccines</td>
<td>Scientific experts and stakeholders</td>
<td>Analysis of the field, coordination of WHO agenda with that of other initiatives</td>
</tr>
<tr>
<td>Measles aerosol vaccine PDG</td>
<td>Measles aerosol</td>
<td>Scientific experts, vaccine developers, clinicians, regulators</td>
<td>Review of strategy, results and technical activities of the project</td>
</tr>
<tr>
<td>QUIVER</td>
<td>Quantitative implementation research</td>
<td>Scientific experts</td>
<td>TBD</td>
</tr>
<tr>
<td>Pandemic influenza vaccine Global Action Plan Oversight committee</td>
<td>Pandemic influenza vaccines</td>
<td>Country representatives, donors, major stakeholders</td>
<td>Oversee the implementation of the Global Action Plan</td>
</tr>
</tbody>
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