EUROPEAN VACCINE INITIATIVE (EVI)

RULES OF PROCEDURE
OF
THE EVI BOARD OF STAKEHOLDERS

Version 1.0, 06th August 2010

as adopted by the Board 8th October 2010
Rules of Procedure

The Board of the European Vaccine Initiative has decided the following:

ARTICLE 1 - Appointment of the EVI Board of Stakeholders Chairperson and Vice-Chairperson

1. The EVI Board of Stakeholders (BoS) shall elect a Chairperson and one Vice-Chairperson from amongst its members, with a two-thirds (2/3) majority, for a term of three (3) years, with the possibility of one (1) renewal for a maximum of three (3) years. The EVI BoS Chairperson is a non-voting member of the EVI Board.

2. The EVI BoS Vice-Chairperson will carry out the duties of EVI BoS Chairperson in the absence of the Chairperson.

4. If the EVI BoS Chairperson resigns, a new Chairperson is elected.

5. The election of the EVI BoS Chairperson and the EVI BoS Vice-Chairperson shall take place at the EVI BoS meeting preceding that, at which the term of office is due to begin.

ARTICLE 2 - Designation of the Board of Stakeholders members

1. Each donor of EVI should designate a representative for the BoS.

2. The other members of the BoS should be two (2) representatives of the vaccine development industry, two (2) representatives of Developing Countries (DC), one (1) or two (2) representatives of the European Commission (EC) but not limited to. Each EVI Board member nominates three (3) individuals highly involved in Diseases of Poverty drug development to a panel of experts. One (1) of the nominated individual should come from outside EVI Board members’ own countries, and preferably from Developing Countries (DC).

Conflicts of Interest, i.e. where EVI BoS members and potential recipients of EVI support are the same or closely associated should be carefully avoided.
The panel of BoS members can be augmented by additional experts proposed either by EVI Board members, EVI BoS members or the EVI Secretariat with the approval of the EVI Board.

3. The EVI Board selects the four (4) members from industry and DC of EVI BoS from this panel. In the event that consensus cannot be obtained, decisions are reached by simple majority.

4. The EVI Board will periodically review the list of competencies and identify, with the advice from the EVI BoS and the EVI Executive Director (ED), priority areas to be covered. The nomination shall also be made public through the EVI web site.

5. The EVI BoS members are identified through an open selection process.

6. The members of the EVI BoS are designated by the EVI Board and they shall be appointed on a personal basis. The applicant shall undertake to act independently and outside any influence in the work of the EVI BoS. For this purpose designated members shall sign a Declaration of Commitment (Annex I).

7. EVI BoS members are designated in the first instance for a period of three (3) years. Renewal of designations can be made for new terms for periods of three (3) years on the basis of recommendation from the Chairman of the EVI BoS.

8. If an EVI BoS member does not attend three (3) consecutive meetings, the EVI BoS Chairperson is entitled to propose to the EVI Board withdrawal of the member’s designation.

9. To avoid possible conflict of interest, the members of the EVI BoS shall be asked to sign a Declaration of Interest (Annex II). All declarations shall be made in writing.

10. Members of the EVI BoS could have access to confidential data concerning EVI projects or confidential information in the applications to EVI call. To avoid any breach in confidentiality, the members of the EVI BoS shall be asked to sign a Confidentiality Agreement (Annex III).

11. The designation of and retention of an EVI BoS member is conditional on their signing the Declaration of Commitment, the Declaration of Interest and the Confidentiality Agreement.
ARTICLE 3 - Selection process of the EVI Board of Stakeholders members

1. The selection criteria of new members of the EVI BoS shall be:
   - Ability to analyse complex information;
   - Professional experience in a multi-disciplinary environment, preferably in an international context;
   - In the event of equal scientific excellence the need to ensure gender and geographical balance shall represent a further criterion.

2. The EVI Board designates, on recommendation from the Chairperson of the EVI BoS and the EVI ED, members of the EVI BoS.

ARTICLE 4 - Meetings of the EVI Board of Stakeholders

1. The EVI BoS shall meet once a year and shall be convened by its Chairperson on own initiative or at the request of at least 1/3 of the members. In addition, a meeting of the EVI BoS may be convened at the contemporaneous requests of the Chairperson of the EVI Board and the EVI ED.

2. For each convocation the Chairperson of the EVI BoS shall notify each member of the date of the meeting not less than thirty (30) days before the date thereof. A draft agenda should be sent simultaneously, comprising the items to be examined and any preparatory documents.

3. Where at least 1/3 of the members request a meeting, the Chairperson of the EVI BoS shall convene a meeting within thirty (30) days and in accordance with the terms of paragraph 2 above.

4. Meetings of the EVI BoS shall normally be held at EVI’s venue.

5. The Chairperson of the EVI BoS may deviate from the general rule in paragraph 4 above in order to facilitate the conduct of business. On ad-hoc basis, the Chairperson of the EVI BoS could call for a teleconference.
6. EVI BoS members not participating in or otherwise contributing to three (3) consecutive EVI BoS meetings can be replaced by consensus of the other EVI BoS members.

ARTICLE 5 - Secretariat of the EVI Board of Stakeholders

1. EVI’s staff, appointed by the EVI ED, shall prepare and organise the work of the EVI BoS and shall provide secretarial assistance for meetings under the directions of the Chairperson of the EVI BoS.

2. Correspondence intended for the EVI BoS shall be addressed to the EVI Secretariat.

3. The EVI Secretariat is responsible for archiving EVI BoS papers and recommendations.

ARTICLE 6 - Agenda and proceedings at the meetings

1. At the beginning of a meeting, the EVI BoS shall adopt the agenda, comprising the items included in the draft agenda referred to in Article 4 paragraph 2 and any other item proposed by the Chairperson of EVI BoS or, in accordance with paragraph 2 of this Article, by one (1) or more of the members.

2. Any request by one (1) or more members of the EVI BoS for the inclusion of items on the agenda or the deletion or substitution of items shall state in writing the reasons on which it is based, and this shall be sent to the Chairperson of EVI BoS at least five (5) working days before the date of the meeting. The Chairperson of EVI BoS shall immediately bring any such request to the notice of the other members.

3. At the beginning of a meeting, any member may propose the inclusion of items on the agenda.

4. During a meeting, any member may propose the inclusion of items on the agenda for the subsequent meeting.

5. The presence of at least half of the EVI BoS members shall constitute a quorum. In the absence of a quorum, recommendations must be confirm by written procedure.
6. The Chairperson of EVI BoS shall direct the proceedings, giving precedence to those who wish to raise a point of order or a preliminary matter.

7. If a speaker departs from the subject and has already been called to order twice by the Chairperson, the Chairperson of EVI BoS may, if the speaker’s remarks are still not to the point, withdraw permission to speak.

8. If the Chairperson of EVI BoS or any member disputes the admissibility of a motion proposed by a member during the proceedings, the matter shall be put to a vote. The substance of such a motion may be discussed only with the consent of the majority, within the meaning of Article 7 paragraph 1 hereto.

9. If the Chairperson of EVI BoS considers that a motion may impede the proceedings, he/she shall forthwith put the matter to a vote without debate.

10. The EVI BoS may decide, on an ad hoc basis, to invite guests to attend meetings of the committee, when it is considered essential for EVI’s activities.

11. The EVI BoS may request the presence at its meetings of EVI staff qualified in matters under consideration.

ARTICLE 7 - Adoption of recommendations

1. Recommendations of the EVI BoS shall require a quorum (see Article 6 paragraph 4) in order to be adopted. In the absence of a quorum recommendations must be confirm by written procedure.

2. Motions to exclude questions from the EVI BoS or to postpone consideration of a matter shall be subject to a vote before dealing with the substance of the matter.

3. A motion, which deals with several questions, shall be divided into its individual parts if this is so requested.
ARTICLE 8 - Voting Arrangements

1. Voting shall be by show of hands, or by roll call in cases of dispute in a vote by show of hand. For matters involving persons, the vote will be secret, if a majority of members request it.

2. The voting figures shall be stated for each recommendation adopted by the EVI BoS. The recommendation shall be accompanied by a written statement of the minority view, where the latter so requests.

ARTICLE 9 - Closure of debates

1. The Chairperson of EVI BoS may move to close a debate when he/she considers that all members have had an opportunity to express their views. The members may also move for closure.

2. Any members asking to speak on closure shall be given precedence.

ARTICLE 10 - Minutes of EVI Board of Stakeholders meetings

1. Minutes shall be taken of each meeting of the EVI BoS and shall include:
   - List of participants
   - Agreed agenda;
   - Record of proceedings;
   - Recommendations adopted with a record of the voting figures for each vote;
   - Any conflict of interest declared by EVI BoS members regarding the items on the agenda.

2. The draft minutes shall be submitted for review to EVI BoS members within fifteen (15) days after the meeting. The EVI BoS members present at the meeting will then have fifteen (15) days to amend the minutes by submitting their amendments in writing to the Chairperson of EVI BoS. The final draft should be submitted for
adoption within fifteen (15) days. Should the final draft not have been sent in time, the adoption will be held over until the following meeting.

3. The minutes and recommendations shall be signed by the Chairperson of EVI BoS to signify adoption.

4. Recommendations of the EVI BoS shall be made accessible to the public.

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**ARTICLE 11 - Revision of the Rules of Procedure and annexes**

1. The EVI Board decides on revision of the Rules of Procedure of EVI BoS.

2. Changes adopted shall take effect from the date of the next meeting of the EVI BoS. The members of the EVI Board and of the EVI BoS shall be provided with the revised Rules of Procedure as soon as possible by the EVI Secretariat.

3. The mandate and tasks of EVI BoS, as well as the process of developing EVI BoS recommendations or advice, are annexed to the Rules of Procedures (Annex IV).

Approved by the EVI Board on 8th October 2010

*SIGNED*

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Professor Marita Troye-Blomberg, representative of the Stockholm University
Approved by the EVI Board on 8th October 2010

SIGNED

Professor Dr. rer. nat. habil Bernhard Eitel, Rector of the Heidelberg University
Annex I

Declaration of Commitment
to the activities of the Board of Stakeholders of the European Vaccine Initiative

Name: ___________________________________________________

Expert in the field of ________________________________________

I, the undersigned, undertake:

To act independently and outside any influence in the work of the board of stakeholders.

Done at ___________________________ on ____________

Signature: ________________________________________________
Annex II

Annual declaration of EVI Board of Stakeholders member’s interest

Name: ____________________________________________

Information on direct or indirect interests of relevance to the mission of EVI

(1) Direct interest (financial benefits arising from, for example, employment, contracted work, investments, fees etc.): ____________________________________________

(2) Indirect interests (indirect financial, e.g. grants, sponsorships, or other kind of benefits): ____________________________________________

(3) Interests deriving from the professional activities of the member or his/her close family members: ____________________________________________

(4) Any membership role or affiliation that you have in organisations/bodies/club with an interest in the work of EVI: ____________________________________________

(5) Other interests or facts that the undersigned considers pertinent: ____________________________________________

Declaration:

I declare on my word of honour that the information provided above is true and complete.

I agree to immediately and truthfully declare to the Executive Director any changes, which may occur in the declaration.

I declare that I will actively participate in the EVI Board of Stakeholders meetings.

Done at _________________________ on ___________

Signature: ________________________________
Annex III

Confidentiality Agreement

Terms and conditions under which The European Vaccine Initiative (EVI) shall disclose detailed information regarding the development of vaccines (“the Information”).

1. Information provided by EVI orally or in written form shall at all times be and remain the property of EVI, and shall be used by the signatory for the sole purpose of generating an advisory report assessing the cost of bringing the current global portfolio of drug and vaccine candidates through the clinical stages of development, including identifying potential efficiencies and addressing clinical trial site capacity issues (“the Purpose”).

2. The information shall at all times be held in strict confidence and under conditions of secrecy, and shall not, without the prior written consent of EVI, be disclosed or used for any purpose other than for the Purpose, be disclosed to any third party or used for the benefit of any third party.

3. The provisions of Clause 2 shall not apply to any information:
   a) Which, at the time of receipt, is in the public domain;
   b) Which, after receipt becomes part of the public domain by publication or otherwise by lawful and proper means;
   c) Which can be established by competent proof was in your possession prior to receipt from EVI, and was acquired with free rights of disposal directly or indirectly from a source wholly independent of EVI;
   d) Which can be established by competent proof was independently developed by colleagues of the signatory who had no knowledge of the information disclosed hereunder;
   e) Which was subsequently received from a third party with good legal title thereto.

4. Access to information shall be restricted by the signatory to the minimum number of employees and colleagues necessary for the Purpose herein, and such employees shall be made aware that the information is confidential, and shall be bound by confidentiality obligations at least as strict as those contained herein. Upon completion of the Purpose and in absence of any further written agreement with EVI, information, which is in tangible form, shall be promptly returned to EVI, except for one copy, which may be retained in legal files for the sole purpose of determining continuing legal obligations hereunder. Such return shall not affect the obligation under Clause 2 to keep information confidential.

5. Nothing in this Confidentiality agreement shall be construed as a grant of rights to the Information, or as placing EVI under any obligation to grant future rights to information in any subsequent agreement.

6. This Confidentiality Agreement constitutes the entire understanding of the parties hereto with respect to the subject matter hereof, and shall not be modified, except by written mutual agreement.
7. This Confidentiality Agreement takes effect from the date of signature, and shall be governed by the laws of Germany. The confidentiality obligations shall expire five (5) years after the date of disclosure of the information.

I the undersigned, by my signature, agree to the above terms and conditions.

Date
Place
Name
Signature

Date
Place  Heidelberg
For  European Vaccine Initiative
Name  Dr Odile Leroy, Executive Director
Signature

European Vaccine Initiative
UniversitätsKlinikum Heidelberg • Im Neuenheimer Feld 326 • 69120 Heidelberg • Germany
Secretariat: Odile Leroy, Executive Director
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Annex IV

EVI Board of Stakeholders mandate and tasks

A. THE EVI BOARD OF STAKEHOLDERS MANDATE AND TASKS

The EVI Board of Stakeholders has a mandate with four (4) major tasks:

• To provide recommendations to the EVI Board regarding strategic decisions of new or existing initiatives,

• To provide recommendations to the EVI Board regarding the governance and management of the funds,

• To approve the annual report of EVI

• To provide recommendations to the EVI Board regarding appropriate measures to be taken to prevent irregularity, fraud or corruption regarding the use of EVI-EEIG resources

The recommendations of the EVI BoS shall be published.

The tasks of the EVI BoS can within this mandate be defined as follows within the four (4) categories of activities:

1. To provide recommendations to the EVI Board regarding strategic decisions of new or existing initiatives

Examples here would be consultation on the 5-year strategic plan, as well as consultation within the period of implementation of the strategic plan, to support the choices made during implementation of the strategic plan:

• Recommendation on the 5-year strategic plan;

• Consultation on the EVI links to the Research and Scientific communities in Europe.

2. To provide recommendations to the EVI Board regarding the governance and management of the funds

Examples would be general review of the composition/recruitment plan of the scientific staff in view of the EVI Strategy and Annual Management Plans.
3. To approve the annual report of EVI

Examples would be:

- Review of an outline of a planned EVI report;
- Consultation/participation in quality reviews of annual report and specific chapters in annual report;
- Approve of a final EVI report.

4. To provide recommendations to the EVI Board regarding appropriate measures to be taken to prevent irregularity, fraud or corruption regarding the use of EVI-EEIG resources

B. PROCESS OF DEVELOPING A RECOMMENDATION OR ADVICE FROM THE EVI BOARD OF STAKEHOLDERS

Questions to the EVI BoS can be raised from two (2) sources:

Question to the EVI BoS from the EVI Board / EVI Executive Director

EVI BoS registers the question

- First discussion of the subject
- Provides advice to the EVI Executive Director and/or the EVI Board - extract of minutes to be delivered in a paper as appropriate.

If the EVI BoS Chairperson considers it necessary or more EVI BoS input is requested, the committee proceeds towards developing a recommendation. The EVI Executive Director / EVI Board chair then confirms this.

Receipt of the draft EVI BoS recommendation

- EVI BoS debates and approves the recommendation at the following EVI BoS meeting,
- EVI BoS secretariat ensures delivery of the final recommendation to the EVI Board.

EVI publishes the EVI BoS recommendation on the web-site.