

CEPI

Coalition for Epidemic Preparedness Innovations

Note to the CEPI Scientific Advisory Committee

20 February 2018

Confidential

Non-confidential

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Purpose

The purpose of this document is to:

- Inform the SAC members on the role of the CEPI Scientific Advisory Committee

Key considerations

Document Administration

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Terms of Reference for CEPI Scientific Advisory Committee (SAC)

1 Establishment and function

1.1 Aim of the SAC

The Scientific Advisory Committee (SAC) is an independent body within the CEPI governing structure that provides scientific support, advice and challenge to the CEPI Secretariat.

1.2 Relation of the SAC to the CEPI governance bodies

The SAC reports to the CEPI Secretariat and is the principal scientific advisory group to the CEPI Board (“the Board”) and the CEPI Secretariat on scientific matters critical for the operations of CEPI. This document describes the Terms of Reference for the SAC, and provides guidance on the establishment, management and conduct of the SAC.

1.3 Objectives of the SAC

The activities of the SAC will include, but are not limited to:

- Recommending pathogens against which to support the development of vaccines.
- Advising on change of priorities in the event of public health emergencies or other triggering events caused by emerging pathogens with epidemic potential.
- Advising on the scope, objectives, and approach of Calls for Proposals and the process for selection of fundable proposals arising therefrom.
- Reviewing proposals submitted in response to CEPI’s Calls for Proposals and making recommendations about which to advance to negotiations, where appropriate, taking account of reviews by independent subject area experts.
- Monitoring scientific and development progress of CEPI’s overall vaccine portfolio, and reviewing the overall quality of progress of CEPI’s scientific operations.
- Updating the CEPI Board on important new research developments in science and technology relevant to CEPI’s mission.
- Providing scientific input, as requested by the CEPI Secretariat, to inform CEPI’s efforts to promote “end to end” development and delivery efforts for vaccines supported by CEPI.

The CEPI Secretariat may seek advice from the SAC or from individual SAC members for other scientific matters relevant to the operations of CEPI. Final decision-making about the issues addressed by the advice and recommendations from the SAC rests with the Board or the Secretariat, as appropriate.

The SAC has no executive function in the operations of CEPI. The CEPI Secretariat will facilitate the work of the advisory committee. The SAC as a body will act independently of all the governing structures of CEPI, including the CEPI Board, the CEPI Secretariat, the CEPI Joint Coordinating Group, and the CEPI Forum.

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1.4 Areas of Expertise and composition of the SAC

CEPI requires relevant expertise to support the implementation of its strategic objectives. The SAC will be composed of a group of qualified individuals, representing core areas of scientific expertise needed to advise the Secretariat on a diversity of issues related to vaccine research and development. The combined expertise of the advisory committee should reflect the spectrum of vaccine research and development, addressing but not limited to the areas of core scientific expertise described in Table 1.

The size of the SAC should not exceed 25 voting members, and be of sufficient size to:

- Cover the desired member competencies
- Assure a critical mass of expertise should some members need to be excluded from decision processes due to conflicts of interest
- Have representation from LMIC countries where epidemics may occur, and have gender diversity aiming towards equal male and female representation

Composition of the SAC:

- One (1) SAC Chair
- One (1) SAC Vice Chair
- Up to twenty-three (23) SAC Ordinary Members

SAC non-voting members:

- One (1) WHO representative
- Up to four (4) vaccine industry representatives
- External observers as invited per agenda topic, which may include representatives of research funding agencies

CEPI Secretariat

- CEPI CEO and members of the CEPI Secretariat will host and attend all meetings

Table 1: Representative competencies that may be desirable for the SAC

<p>Public health</p> <ul style="list-style-type: none"> • Public health emergency preparedness and response • Infectious disease epidemiology • Infectious disease modelling • Biostatistics • Disease Area Specialists 	<p>Product and preclinical</p> <ul style="list-style-type: none"> • Early stage vaccine development • Genetic engineering and vaccine design • Vaccine adjuvants and delivery systems • Animal models and biological assays • Non-clinical toxicology • Containment laboratory experience 	<p>Clinical development</p> <ul style="list-style-type: none"> • Clinical operations (end-to-end) • Study design and statistical analysis • Pharmacovigilance • Vaccine immunology • Approaches to efficacy testing • Clinical trial expertise and review capability
<p>Chemistry, manufacturing & control</p> <ul style="list-style-type: none"> • GMP process development and scale-up • Large-scale product and bulk manufacturing • Vaccine formulation and devices • Platform technologies • Quality control and quality assurance 	<p>Regulatory and IP</p> <ul style="list-style-type: none"> • Regulatory affairs: strategy and operations • Vaccine safety • Vaccine risk/benefit assessment • IP management 	<p>Vaccine implementation</p> <ul style="list-style-type: none"> • Vaccine procurement • Stockpiling • Vaccine deployment during epidemic outbreaks • Biobanking and sample sharing • Bioethics

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2 Appointment and membership

2.1 Appointment

The process for the nomination and appointment of members is as follows:

1. The CEO and SAC Chair, with the support of the Secretariat, will assess the areas of expertise required for the SAC and reach out to the scientific community to request applicants. The Secretariat will compose a list of eligible candidates with representation from LMIC where epidemics may occur and representation by women, as level and depth of expertise permits.
2. Criteria guiding selection of members will include:
 - Technical expertise in the desired competency
 - Experience including in collaborative public health and preparedness/response enterprises relevant to CEPI's mission
 - Diversity of stakeholders (academia, governmental agencies, private sector, civil society/NGOs/patient organizations)
 - To ensure balanced representation, consultants and temporary advisers assigned to assist an expert committee are selected, as far as possible, from countries not represented on the committee's membership takes into account the desirability of achieving gender balance.

Where the SAC lacks the relevant expertise for a particular project or task, the SAC can call on appropriate experts or establish sub-groups or task forces to include such people on an ad hoc, time-limited basis.

2.2 Responsibilities of Chairs

The role of the Chair and the Vice-Chair is to achieve committee effectiveness. They will be responsible for:

- the operation and output of the committee, including assessing the workload and ensuring that the volume of work does not compromise the rigour of discussion;
- reviewing conflicts of interest of all members annually and at each meeting of the SAC
- ensuring that the full range of scientific input is considered;
- ensuring that any significant diversity of scientific and vaccine development input among the members of the committee is fully explored and discussed;
- ensuring that scientific views that cannot be reconciled, are accurately reflected in the minutes and any other relevant report of the discussions;
- using, where appropriate, a structured process which ensures that all views are captured and explored;
- reporting the committee's advice to the CEPI Secretariat, including alerting to new evidence likely to have an impact on current policy;
- ensuring that the Secretariat accurately documents the proceedings of the committee so that there is a clear audit trail showing how the committee reached its decisions;
- identifying gaps or redundancy in the skills and competency represented on the Scientific Advisory Committee;

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- ensuring that members have any necessary training to enable them to fulfil their role and keeping records of members performance as necessary;
- deciding if any part of SAC meeting should be conducted with the exclusion of any or all of the non-voting members or observers, in accordance with CEPI policies.

2.3 Responsibilities of Members

- SAC members are expected to provide independent scientific advice on topics where their expertise is relevant and as requested by the CEPI Secretariat.
- SAC members should stay current with developments in their field which are of relevance to CEPI, including through contact with their professional bodies, academic institutions and research communities.
- SAC members are required to comply will all CEPI policies, including [the CEPI Transparency and Confidentiality Policy](#), [Policy for Managing Conflicts of Interest](#), and [Travel Policy](#).
- Any potential alternates for members must be pre-approved by CEPI Secretariat
- SAC members are expected to act in accordance with the following principles:
 - **Selflessness:** SAC members should act solely in terms of the public interest.
 - **Integrity:** SAC members must avoid placing themselves under any obligation to people or organisations that might try inappropriately to influence them in their work. They should not act or take decisions in order to gain financial or other material benefits for themselves, their family, or their friends. On an annual basis and at every meeting, they must declare conflicts of interests and relationships.
 - **Objectivity:** SAC members must act and take decisions impartially, fairly and on merit, using the best evidence and without discrimination or bias.
 - **Accountability:** SAC members are accountable to CEPI for their decisions and actions and must submit themselves to the scrutiny necessary to ensure this.
 - **Openness:** SAC members should act and take decisions in an open and transparent manner.
 - **Honesty:** SAC members should be truthful.
 - **Leadership:** SAC member should exhibit the above principles in their own behaviour. They should actively promote and robustly support the principles and be willing to challenge poor behaviour wherever it occurs.

2.4 Role of SAC non-voting members and observers

SAC non-voting members are invited to SAC meetings to provide additional insight, but cannot vote on recommendations made by the SAC. Non-voting members and observers will be required to comply with the CEPI Transparency and Confidentiality Policy and Policy for Managing Conflicts of Interest.

Non-voting members and observers should not seek to exert undue influence on the decisions of the committee. If this occurs the chair will take appropriate action.

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3 Independence, objectivity and transparency

- a) The members of the SAC will serve in their personal capacity as independent experts, and should not promote the views and policies of their institutions or others with vested interests.
- b) Prior to being considered for membership, nominees shall be required to complete a Declaration of Interests form. An updated Declaration of Interests form must be submitted for review to the CEPI Board 14 days prior to each Scientific Advisory Committee meeting. Potential conflicts of interest will be managed in accordance with CEPI's conflict of interest policy.
- c) Members shall be required to declare conflicts of interest in relation to any item under discussion at a SAC meeting.
- d) Any member with a conflict of interest related to a specific issue shall be excluded from the discussion or decision on the issue, and shall not receive any documents relating to the issue giving rise to the conflict.
- e) Any member who fails to declare a conflict of interest, which subsequently becomes evident, may be expelled from the SAC on the recommendation of the Board.
- f) All documents and discussions at SAC meetings are confidential, unless stated otherwise, and must not be disclosed.
- g) SAC members should neither represent or present their personal views as those of CEPI nor imply that they can represent CEPI's views or policies in any way.
- h) The SAC should operate from a presumption of openness. The condensed proceedings of the committee will be made public by the CEPI Secretariat as long as it is compatible with the requirements of confidentiality.

4 Working practice

- a) The SAC will meet as need arises, generally twice a year, and hold periodic teleconferences.
- b) The provisional agenda for each meeting will be prepared by the CEO in consultation with the Chair.
- c) Except in exceptional circumstances, documents for scientific review will be sent to SAC members at least 14 days in advance of a meeting.
- d) Prior to making recommendations for a particular topic, the SAC should agree on the mechanisms by which the committee is to reach its final position or advice. Members should understand when they are expected to reach a consensus on particular issues and when other approaches to arrive at a recommendation is preferred.
- e) The SAC will normally make recommendations by consensus of SAC voting members only, not including non-voting members, observers and invited experts. Members with potentially conflicting interests will deal with such conflicts in accordance with the conflict of interest policy. If a consensus cannot be reached decisions on recommendations may be taken by a vote, including the Chair. In the event of a tie, the Chair shall have the casting vote.

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- f) For specific topics and as appropriate, the Chair, in consultation with the SAC, may invite external experts to address specific issues.
- g) SAC members may be asked in their individual capacity to work with the CEPI teams managing specific projects, so as to leverage the expertise present in the SAC in support of CEPI's vaccine development efforts. Such work will be compensated and is wholly voluntary.
- h) As two advisory bodies to CEPI, the SAC and the Joint Coordination Group will act independently of each other. The CEPI Secretariat will facilitate information exchange between the SAC and the Joint Coordination Group.