CEPI

Coalition for Epidemic Preparedness Innovations

CEPI Interim Scientific Advisory Committee (SAC) Meeting
October 20-21, 2016
International AIDS Vaccine Initiative (IAVI) office, 125 Broad Street, New York

SUMMARY OF THE SAC PROCEEDINGS (CEPI/SAC1)

The following Scientific Advisory Committee members participated:

Committee members elect:

- Mark Feinberg (Chairperson)
- Rick Bright (21 October)
- Jean-Francois Delfraissy (21 October, telephone)
- Bernard Fanget
- Jesse Goodman (21 October)
- Penny Heaton
- Cherry Gagandeep Kang
- Subash Kapre
- David Kaslow (telephone)
- Gunnstein Norheim
- Stanley Plotkin
- Helen Rees (21 October)
- Jim Robinson
- Amadou Sall
- Peter Smith

Apologies

- George Fu Gao
- Heinrich Feldman
- Maharaj Kishan Bhan
- Kathleen Neuzil
- Connie Schmaljohn

Non-voting members:

World Health Organization

- David Wood (telephone)

MNC representatives

- Kathrin Jansen (20 October, part of 21 October)
- Jean Lang
- Johan Van Hoof

Secretariat

- Dimitrios Gouglas
- Frederik Kristensen
- Nancy Lee
- Elizabeth Peacocke
- John-Arne Røttingen

Apologies

- Ali Alloueche

The following matters were on the agenda:

1. Opening of first CEPI SAC Meeting

There were no decisions under this item

Points discussed under this item:

- Welcome to members
- Round table of introductions
- Objectives for the meeting

2. Intention and scope of the Scientific Advisory Committee (SAC)

Decisions

- The CEPI Secretariat will develop procedures for the nomination and involvement of subject matter experts.

Points discussed under this item:

The Terms of reference state the mandate of the SAC is to:

1) Recommend priority pathogens for consideration of CEPI focus and support
2) Develop descriptions for Request for Proposals (RFPs)
3) Review RFPs for vaccine research and development (R&D)
4) Recommend proposals for funding to the Board
5) Recommend the continuation or cessation funding of CEPI-supported research efforts at the end of defined program milestones for CEPI-supported vaccine development programs
6) Monitor progress of CEPI's overall vaccine portfolio, and review the overall quality of progress of CEPI's scientific operations
7) Update the Board on important R&D relevant to achieving CEPI's mission
8) Provide scientific input, to inform the Board's efforts to advance and expedited "end to end" development and delivery efforts for vaccines targeting CEPI-prioritized pathogens

- Membership of the current acting SAC will be reviewed in September 2017
- SAC will meet 2 times per year, and by teleconferences as required.
- SAC members participate in their individual capacity, rather than representing an organisational interest.
- **Voting**: The SAC will strive for consensus, but in the case of disagreement, decisions are made by a majority vote. In the situation of a small majority, decisions will also reflect the opinions of the minority.
- On a case-by-case basis, the SAC may require to co-opt additional subject matter experts on specific diseases, vaccine technologies, clinical trial design or other technical matters as needed.
- The CEPI Secretariat will develop procedures for the appointment of SAC members and for additional experts.
- CEPI has two core functions, funding and facilitation. The main governance bodies of CEPI are the Board and SAC. The differences between the Board and the Joint Coordination Group (JCG) were discussed. The CEPI Board has a decision-making capacity, whereas the JCG promotes collaboration and coordination in the full end-to-end spectrum, including regulators, downstream actors (GAVI, Unicef) and civil society.
- **Conflicts of interest** need to be declared to the Chairperson and announced at the beginning of each meeting (in line with protocol at WHO meetings). There may be conflicts for many of members, therefore CEPI and SAC members need to be transparent of potential conflicts of interest.
- **'End-to-end'**: The role of CEPI in guiding the development of products 'end-to-end' will be pathogen specific. A joint understanding of what "end-to-end" means is needed for each pathogen, including whether this includes stockpiling, CMC scale up, phase III clinical trials and/or outbreak response.

3. Bridging the gap: from old, safe and slow vaccine platforms to rapid response platforms

There were no decisions under this item

Points discussed under this item:

Jim Robinson presented key perspectives on how to progress and mature new vaccine platform technologies fit for adaptation in the event of an outbreak with a hitherto unknown pathogen, or emerging pathogens with epidemic potential.

Main challenge of existing system is product-specific facilities. Desirable to innovate to get more adaptable vaccine platform technologies.

New platform technologies are not likely to accelerate the regulatory approval process, as regulators approve products not technologies. Regulatory strategy is critical – innovation can slow approvals: "Traditional" technologies (e.g. whole virion inactivated vaccines) may accelerate the review process as there is more experience and a regulatory track record with materials and platforms/systems that have showed CMC/Clinical safety than new (e.g. DNA based vaccines). This is why most organizations prefer to focus on proven technologies. "Plug and play" vaccine production platforms are relatively rare in today's industry.

- Seasonal influenza is a great example of a manufacturing platform where the requirement for clinical trials to provide sufficient evidence on safety and efficacy is reduced due to previous data utilising the same platform.
- There are two needs for platforms:
    - New platforms for rapid response to newly emerging pathogens
    - Existing platforms for specific pathogens
- Key is to focus on pathogens, and how to select the appropriate platforms for testing
- The SAC discussed the extent to which 'platform sharing' is possible: Transfer of existing platform technologies for large scale production in EID outbreaks pose challenges in terms of being tied to company commercial strategies and process production know-how.
    - Lack of tech transfer willingness will affect regional capability building objectives
    - What would the benefits for commercial strategy be to be involved in EID for multinational corporations?
    - 'Reputational risk' linked to utilising "commercial platforms" for EIDs: related to efficacy of platform with new pathogen, there is a perceived risk of EID vaccine production, in terms of quality of manufacturing if transferred to other facilities
- Proposal for CEPI in the longer term to fund development of a unique and new vaccine technology platform and build data on manufacturability, robustness/scalability, clinical safety and immunogenicity to enable use in response to newly emerging pathogens. This will entail high cost, high risk, and long timeline for approval.
- Key issues in discussion:
    - Define a realistic vaccine development process for tailoring to newly emerging pathogens, with cost estimates. Lower incremental levels of innovation may mean lower cost, lower risk (i.e, higher probability of technical and regulatory success (PTRS))

- Should CEPI invest in new platforms, or should it better leverage existing "proven" platforms – e.g. inactivated virus chosen for Zika virus vaccine for easier regulatory approval and track record of other flavivirus vaccines
- What are the comparative benefits/limitations of specific fixed facilities (e.g., a small number of dedicated facilities) versus a flexible manufacturing network?
- Need for 'multiple shots at goal' (i.e. multiple candidate platforms tested for same antigens) to reduce risk of failure of one of the platform/approaches,
- Concern about platforms that generate immunity to the vector, potentially making additional targets on that vector challenging (hence not a "platform" for multiple targets). Standardised animal models and immunogenicity testing required to provide head to head comparability of vaccine responses (reduce failure risk)
- Could CEPI "mix and match" technologies (e.g. prime – boost, adjuvants, antigens)?
- Innovation scope to be considered: antigen structure, formulation, delivery technologies

4. CEPI overview

There were no decisions under this item

Points discussed under this item:

John-Arne Røttingen presented the Preliminary Business Plan.

- CEPI Vision: Vaccines can prevent outbreaks of emerging infectious diseases from becoming humanitarian crises.
  - Developing vaccines before epidemics arise will allow the global health community to prevent outbreaks from becoming international public health emergencies. CEPI will prepare vaccine candidates for large efficacy trials and potential emergency deployment in an outbreak. Early intervention will contain loss of life, limit social and economic disruption and protect against future epidemics.
- Mission: CEPI will stimulate, finance and co-ordinate vaccine development against emerging infectious diseases (EIDs) with epidemic potential, especially in cases where market incentives alone do not achieve this.
- Scope: CEPI takes an end-to-end approach to vaccine development, with an initial focus on two priorities.
  1. Moving new vaccines through late preclinical studies to proof of concept and safety in humans; and
  2. Supporting vaccine platforms that can be rapidly deployed against known and unknown pathogens.

CEPI's gap-filling role

- CEPI will complement existing efforts by focusing on advanced vaccine development for priority EIDs, bridging the gap between discovery research and vaccine delivery as part of an end-to-end approach that will address global calls for:
  1) a global mechanism to align EID R&D funders, vaccine developers, regulators and policy makers (from low, middle- and high- income countries);
  2) coordinated and proactive R&D for and access to EID vaccines;
  3) supporting the development of clear, predictable, and coordinated regulatory processes (including WHO R&D Blueprint initiatives); and
  4) strengthening advanced development and manufacturing capabilities.

By 2021, CEPI will:

- **Expected Output 1**: have advanced four to six vaccine candidates against two to three priority EIDs to proof of concept and ready for Phase III trials.

SAC will support the following activities 2017-2021

  - Prioritize diseases against which vaccines will be developed
  - Conduct gap analyses and assess vaccine pipelines for priority EIDs
  - Design CEPI's vaccine development portfolio strategy and priorities in the EID space
  - Deliver at least one Phase II trial vaccine candidate outcome per prioritized target
  - Build dedicated partnerships with at least two vaccine manufacturing partners to leverage their capabilities for advanced vaccine development and manufacturing

- **Expected Output 2**: establish rapid response R&D capabilities and will test and refine these systems in the event of an epidemic

SAC will support the following activity 2017-2021

  - Set up new, or contract and sustain advanced development and manufacturing (ADM) facilities for pilot scale manufacturing, formulation, fill-finish, storage and maintenance and stockpiling of vaccines for Phase III testing in the event of a large outbreak or epidemic

- **Expected Output 3:** have expanded the number and types of financing and incentive mechanisms directly supported or facilitated by CEPI, increasing global capabilities for EID vaccine development and manufacturing worldwide
- **Expected Output 4**: have improved regional capabilities including in developing countries to support CEPI's core business model of advanced EID vaccine development and manufacturing, coordinated through partner networks in Asia, Africa, Europe, Central and South America

SAC will support the following activities 2017-2021

  - Map and utilize available capabilities for vaccine development and manufacturing across regions, with emphasis on regions where future outbreaks are likely to occur
  - Map and utilize available clinical trial networks across regions where outbreaks of a priority pathogen are likely to occur

Key milestones

What	**Date**	**Place**
SAC teleconference	mid November	
First meeting of Joint Coordination Group (JCG)	18 November, 2016	Geneva, Switzerland
Second meeting of Interim Board	16 December, 2016	Delhi, India
Launch Partnership at WEF	17 – 20 January, 2017	Davos, Switzerland
Launch of RFP	(timeline being updated)	
CEPI Scientific conference	February, 2017	INSERM, Paris, France.
Second SAC meeting	February, 2017	Paris, France
Review of proposals and selection for full reviews and interviews by SAC	(timeline being updated)	

Feedback from SAC on the business plan and objective

- CEPI goals are grand: adjust ambitions in accordance with likely funding envelope
- CEPI will have a critical need for project management infrastructure – do not underestimate

- Clarify roles with the Global Research Collaboration for Infectious Disease Preparedness (GLOPID-R) regarding response mode R&D
- Include funding for reference standards and standardisation of immunological assessment of vaccines – enables comparability including analytical assessment of vaccines, including modernizing potency and stability assays
- Expected output 1:
    - SAC members would like more clarity, as it is important to define what constitutes proof-of-concept in the context of CEPI; should this state "through" proof of concept? The term "to proof of concept and ready for phase 3" seems like it may leave a gap between the two points of reference.
    - Agreement on the pathogens is necessary before CEPI can agree to advance 4 to 6 candidates against 2 to 3 priority pathogens.
    - It was shared by many that it would be essential for CEPI to have at least one success quickly.
    - Questions to whether the term 'outcome' can be better defined.
    - The goal of dedicated partnerships needs more clarity – how is this defined, does it mean have development/production contracts in place with at least two companies?
- Expected output 2:
    - Some metrics may provide further clarity to this deliverable
- Expected output 4:
    - Are there cost estimates for regional capabilities?
    - How much will it cost to develop regional capacities, perhaps this could be a separate initiative, or closely tied to specific candidate vaccines.
    - The ambition is worthwhile, but has risks and is likely to be expensive.
    - Who is going coordinate this, who will determine the gaps?

5. Disease prioritization

Decisions under this item

- CEPI's prioritisation of diseases will build on previous methodological exercises (as described during the presentations). The Secretariat will redesign and implement new prioritisation ahead of RFP1 disease scoping, this will include:
    - Providing a list of top pathogens from the various disease prioritization exercises which are within the WHO priority pathogens list
    - Describing a clear objective of what CEPI's prioritization list will be used for
    - Proposing criteria for prioritization, and where relevant engage with disease experts
    - Consulting and Surveying SAC members and/or subject matter experts to support prioritization of diseases
    - Clarifying what others are already funding, and current gaps for CEPI to fill
- The Secretariat will convene a teleconference on, or before, Friday 2 December to present voting and final decision before Board meeting.

Points discussed under this item:

Approaches to prioritize CEPI disease scope

There were three presentations of the following five examples of relevant prioritization approaches

- WHO R&D Blueprint process (Nov 2015) – presentation by Cathy Roth, WHO
- Foundation for Vaccine Research (Dec 2015) – presentation by Gunnstein Norheim

- Norwegian Institute of Public Health (Jan 2016) – presentation by Gunnstein Norheim
- UK Vaccine R&D Network (April 2016) – presentation by Gunnstein Norheim
- CEPI stakeholder process, TT1 SG1 (June 2016) – presentation by Stanley Plotkin

- To progress the objectives outlined in the preliminary business plan, the SAC needs to identify diseases for which it is likely that having a vaccine available will be feasible and have a high public health impact.
- R&D efforts need to be focussed on those likely to have an impact on: Preparedness, Disease prevention, and Response during outbreaks.
- Prioritization parameters are dependent on objectives and the use of tool. e.g.:
    - Potential impact of outbreaks on health, society, economy
    - Prioritize R&D for vaccines, drugs, diagnostics, other interventions
    - Feasibility and risk willingness for vaccine R&D ("low hanging fruit" or "neglected EIDs")
    - Target population: Who do we want to protect?

Summary from SAC discussion

- Feasibility for vaccine development was highlighted as a predominant criterion that will best support success for CEPI in the shortest possible time.
- Need to decide what can be funded now, and what can be funded in the future.
- Several questions were raised about the three questionnaires that were circulated before the meeting, (of note, there were only seven responses prior to the SAC meeting). A number of SAC members indicated that they did not have sufficient context to provide the most useful or informed input, but all felt that the in-person discussions at the SAC meeting were very helpful in this regard. The dialogue concerning pathogen prioritization at the SAC meeting was felt to be both useful and robust, although further discussion is warranted.
- The breadth of knowledge required to assess all WHO priority pathogens and vaccine candidates necessitates the involvement of subject matter experts to support SAC in decision making
- To complete the prioritisation exercise, the Secretariat will complete a gap-analysis on the current prioritisation models and propose a refined model. The Secretariat will consult SAC in model development and send out a revised and shortened survey, separating value from feasibility. A short list from this process will be presented back to SAC at a teleconference on, or before, Friday 2 December.
- It was noted that the WHO Prioritization list will soon be updated, and the SAC highlighted the importance of ensuring ongoing communication with the WHO as their process progresses.
- It is the preference of SAC members that CEPI works from a robust pathogen list that does not fluctuate with year to year changes.
- Will CEPI stand down from pathogens that are being addressed by other funding mechanisms? This needs to stated more clearly.
- Could final decisions be deferred until our face-to-face meeting in February?
- Whether a criteria for CEPI prioritization/choosing a pathogen should in some cases be that it may fill a public health need/gap based on existing public health challenges, even absent an outbreak? MERS would be an example with camel handlers, health care workers etc.
- High public health impact is ambiguous, as it depends on who is judging it. It also contradicts with the mission to have a vaccine ready for a "potential threat" ie. Preparedness which currently may not qualify to have a high public health impact but could have when outbreaks occur.
- Need to keep in mind that the vaccine will have beneficial indirect effects.

- Another consideration for prioritisation parameters: whether other efforts to develop these products are underway and if so, what unique role CEPI would play or how CEPI would facilitate.
- Ebola is seen as a priority to support confidence in CEPI, but it will not be one of the priority pathogens.

6. Request for proposal 1 (RFP1) (Call for proposal 1)

Decisions under this item

- Based on detailed discussions at the meeting including consideration of the approach to the development of the WHO R&D Blueprint, the SAC indicated that they would prefer a two stage selection process, rather than one step. CEPI will publish an Open Call for Expression of Interest/ Request for applications, before following up with an invitation for full application to selected developers. In this way, the SAC will be able to gain a broad awareness of the range of potential product development opportunities across the range of potential priority pathogens.
- The Secretariat will update the Call's evaluation framework based on SAC recommendations on evaluation criteria, scope and expected output considerations.
- The Call will be published in January to support momentum around the launch of CEPI at Davos, January 2017.
- New timelines will be drafted to reflect the outcome of SAC discussions.

Points discussed under this item:

- John-Arne Røttingen initiated the session and discussed the timeline. With Ebola-vaccines undergoing a dedicated gap analysis by a Board sub group, this will not be included in this RFP and will be a separate project. CEPI SAC should advise on what other disease-specific vaccines should be funded.
- By 2021, CEPI is expected to have advanced four to six vaccine candidates against two to three priority EIDs to proof of concept and ready for Phase III.
- CEPI needs "early success" projects to demonstrate its value in preparedness over the next few years. This could be either vaccine candidates already having progressed to advanced development stages, or to advance new vaccines quickly through late preclinical studies to proof of concept and safety in humans
- CEPI needs to assess feasibility of vaccine development against priority pathogens identified by the WHO R&D blueprint and other processes and fund vaccine preparedness efforts accordingly
- A proposed set of criteria for assessment of proposals were presented, for use to guide CEPI investment decisions. These had been sent to the SAC in advance for comments in a survey:
    - Scientific rationale
    - Technical and scientific feasibility
    - Time to completion
    - Potential impact on public health and preparedness
    - Clinical design and regulatory risk
    - Anticipated cost
    - Applicant capacities and project management
- The discussion included the following points:
    - More than one scientific strategy per pathogen is needed, and CEPI should fund multiple technologies for the same pathogen, more than one shot at each goal, and potentially more shots for the unknown scenarios. (2-3 per pathogen, 5 - 6 total) - with a time horizon of 3 years.
    - Every one of the WHO Blueprint diseases has a different R&D path: Need to define risk and pathogen specific endpoints

- It was suggested that CEPI should have an aggressive timeline of deliverables with the level of funding expected, including milestones and R&D funding tied to meeting those milestones.
- 2 stage process is needed: preliminary proposals, followed by full scale proposals, It was also noted that a similar process is used by BARDA, and it was communicated by BARDA representatives, that this has served them well.
- Vulnerability of local health system was mentioned as a potential criteria for the RFP
- Need a clear definition of success for CEPI, or what impact we are proposing. Also require clear objectives for the private sector. Utilisation of a vaccine is a key component of success.
- Need to balance early with late stage projects in the R&D portfolio, proposal to split the portfolio e.g., could have 70% funding towards short-term goals and 30% long-term goals.
- It was recommended that CEPI complete an analysis of the current vaccine development capabilities
- Suggested that we also focus on animal models, assays in addition to vaccines
- It is very complex to manage such a portfolio, BARDA has learned that ongoing monitoring of costs and outcomes cost collaboration and monitoring of projects is an essential element to success. Another member proposed that CEPI partner with a capable organisation to deal with some of these management issues.
- Need to complete the 'end-to-end' analysis so that the right vaccine is available when the outbreak occurs.
- Can CEPI define the target population for the vaccine? And how decisions will be made on testing of candidates?
- It was suggested that a multivalent Ebola/Marburg vaccine should be on the CEPI agenda, this could be an early success.
- There are other agencies funding Ebola, need to be conscious about not duplicating resources. A gap assessment needs to be done to determine is there is a need for further CEPI investment in the Ebola vaccine development.

7. Request for Proposal for Vaccine platform technologies (RFP2)

Decisions under this item

- The Secretariat will facilitate the rethinking of purpose and content of RFP2, including through the setup of a SAC subgroup for the design of evaluation criteria for rapid response capabilities with the aim to fast track development of emergency vaccines for newly emerging pathogens.
- The secretariat will come back to the SAC on potential scope for a potential second call based on the work of the subgroup, further analyses, and the proposed timeline.

Points discussed under this item:

- Justification for this RFP based on CEPI objectives
  - by 2021, CEPI is expected to have established rapid response R&D capabilities and will test and refine these systems in the event of an epidemic
  - CEPI needs to support vaccine platform technologies that can be rapidly deployed against known and newly emerging pathogens
  - Rapid adaptation of vaccine technologies can limit or prevent future outbreaks of known or new disease

    - Platform technologies sufficiently tested for safety and immunogenicity could be sustained in 'readiness' state during non-epidemic periods and reduce the extent of clinical phase I/II trials required for adaptation to new pathogens in response mode
- Draft criteria presented for RFP2 for assessment of applications:
    - Scientific rationale
    - Technical and scientific feasibility
    - Time to completion
    - Impact on public health and response
    - Sustainable ADM capabilities
    - Clinical R&D capabilities in LMIC countries
    - Technical and regulatory risk
    - Anticipated cost
    - Applicant capacities and project management
- SAC requested greater understanding of what gaps the platforms are suggested to fill
- What is the definition of platform that CEPI agrees on? Vaccine technology platform definition to be refined, and include response to newly emerging pathogens and scalability of manufacturing.
- Members commented that RFP 2 is very different from RFP 1, members proposed if we could keep RFP 1 open to platforms and then have a separate invitation to those developers e.g., choose those platforms that indicate promise.
- It was suggested that the Secretariat will come back to the SAC with suggested selection criteria in RFP 1 to select platforms used for chosen target pathogens that may be useful for additional pathogens on the WHO priority list.
- Members discussed asking, as part of RFP1, whether the platform used for the target pathogen might be useful for additional pathogens on the CEPI/WHO/UK priority lists. This would increase the value of that specific program and lead to a platform, without necessarily burdening the proposal to simultaneously developing a platform.
- Questions were raised that in case a vaccine candidate is not immunogenic or demonstrating efficacy, this could be due to either the antigen or the platform technology
- Members requested more information on how much it will cost to fund/sustain platforms. Are other/similar organisations working in this area?
- It was discussed that RFP2 does not need to go to phase II, and can be focused on pre-clinical development
- The WHO platform technology consultation provided some early indication of current efforts, but it was noted that the definition of "platform" can vary depending on context and audience, and that CEPI will use needs to be clear to all stakeholders and potential applicants
- Many members supported focus around RFP1
- Others supported splitting the RFP into two:
    - Response mode/preparedness: dedicated facilities, using proven technology platforms to facilitate regulatory approval (near term)
    - Innovative platform technologies fulfilling gaps for response to newly emerging pathogens (longer term perspective)
- It was proposed to add Modularity ie. extension to multiple targets based on a model antigen to the draft criteria. This concept is key because it underlies the specificity of the RFP2. So far the only innovative tech candidates are DNA and RNA platforms.
- Comments on the draft criteria proposed for RFP2
    - Flexibility/adaptability to multiple pathogens, including unknown, would seem important so may want access to more than one platform or facility type
    - How will Impact on public health and response be applied for RFP2?
    - Why is clinical R&D capabilities in LMIC countries relevant to RFP2, specifically?

- We need clarity on the defining of the perimeter of the projects submitted, judging a platform and the method of evaluating the progress and be able to have clear go/no go decision points to avoid getting stuck with a variety of developments showing similar outcomes and costs.
- Need clearer definition on the different desired outcomes of RFP1 and RPF2.
- A proven track-record is important and tends to predict success in advanced development/manufacturing, and lack thereof predicts problems.
- The following epidemic preparedness matrix was discussed

Epidemic preparedness matrix

	Indication for use	
	Emergency use	Outbreak prevention
Just-in-case vaccines (Prioritized pathogens)	RFP1a	RFP1b
Just-in-time vaccines (Newly emerging* or non-prioritized known pathogens)	RFP2	n/a

*including Black Swan Events

Conclusions on RFP2

1) More mapping and scoping of "most promising technologies" and needed to define CEPI gap filling role
2) Map critical steps in emergency response mode (scenario event planning and exercises)
3) Funding of concepts fulfilling gaps identified, best suited to address newly emerging pathogens

8. Finishing the job on Ebola vaccines – what role for CEPI?

Decisions under this item

- The Secretariat will complete a gap- and options analysis on Ebola vaccines, including both CEPI's role as a funder of advanced vaccine development and as a facilitator of the full 'end-to-end' spectrum covering regulatory issues and procurement.
- A Board sub-committee including Mark Feinberg (Chair of the SAC), Peggy Hamburg (Chair of the JCG), other voluntary members of the CEPI Interim Board and observers will come back to the Interim Board in its next meeting with an analysis and recommendations for a plan of action on CEPI's role in the end-to-end spectrum, using Ebola as a case.

Points discussed under this item:

- Mark Feinberg presented on why it is essential to finish the job on Ebola:
    - Ebola as an important public health threat
    - Ebola vaccine development as a fundamentally important and influential test case
- There are questions about the regulatory approval processes once a disease is not considered a Public Health Emergency of International Concern (PHEIC) anymore, as is the case with Ebola.
- Areas highlighted for possible CEPI action
    - Facilitating role
        - Regulatory approval process – convene manufacturers and regulatory agencies to identify path forward for approval
        - Move and accelerate on stockpiling issues
    - Funding of R&D

        - Trials identified to reach approval for monovalent vaccines
        - Next generation filovirus multivalent vaccine
        - Head to head testing in NHPs.
- A Board sub-committee has been established to develop a gap analysis and investment strategy, to support a Request for proposal for advancing Ebola vaccines
- Identify specific roles for CEPI as a facilitator in the broader end-to-end spectrum of Ebola-preparedness, beyond CEPI's role as a funder of advanced vaccine development
- Commented that much of the 'finish ebola' task may be underway, so it is important to identify any gaps and additional needs and collaborate efforts to avoid duplication etc. – and weigh against other priorities and definition of CEPI scope.
- Proposed objectives of the analysis are:
    - To analyse the gaps in development of an Ebola vaccine, with the purpose of identifying those that are actionable, and have a likely impact on future vaccine access and preparedness
    - Develop an overview of ongoing and existing initiatives and stakeholders in the Ebola development space, such as work carried out by WHO (i.e GEVIT, SAGE, ICG), GAVI, MSF, BARDA, IMI etc. in order to further clarify the role and gaps that could potentially be addressed by CEPI and not duplicate efforts by others
    - Identify opportunities for CEPI to support the WHO and other global emergency responders in having access to a safe, effective and pan-species Ebola vaccine in the event of future outbreaks

9. Planning of future SAC Meeting Arrangements for 2016-17

Decisions under this item

- The Secretariat will circulate a doodle with proposed dates to support high attendance.

Points discussed under this item:

There was no discussion on this agenda item.

10. Any other business

Decisions under this item

- The Secretariat will determine specifics on the meeting, including whether or not it will be an open or closed conference, and whether any community advocates/civil society will be invited.
- The Secretariat will circulate proposed dates, in combination with the SAC meeting dates.

Points discussed under this item:

A proposed CEPI Scientific conference in Paris was presented. This is likely to be in February 2017. Input from SAC requested on programme, speakers.

No other matters were on the agenda