CEPI

Coalition for Epidemic Preparedness Innovations

CEPI Interim Board Meeting
December 15-16, 2016
New Delhi, India

SUMMARY FROM BOARD PROCEEDINGS (CEPI/B2)

On December 15-16, 2016 proceedings of the Interim Board of directors of the Coalition for Epidemic Preparedness Innovations (CEPI) were hosted by the Department of Biotechnology and held by way of physical meeting at the Taj Palace Hotel in New Delhi. K. VijayRaghavan chaired items 1-7 and 9-10, whilst Peter Piot chaired items 8 and 11-17.

The following participated:

CEPI Interim Board members

- Adar Poonawalla
- Arnaud Bernaert
- Jane Halton
- Jeremy Farrar
- Joanne Liu
- John-Arne Røttingen (Observer)
- Julie Gerberding
- K. VijayRaghavan (Chair)
- Mark Feinberg (Observer)
- Moncef Slaoui
- Nick Adkin (delegate)
- Nicole Lurie
- Peter Piot (Vice Chair)
- Stephen Kennedy (Delegate)
- Tore Godal
- Trevor Mundel
- Victor Dzau

Board member participation on the phone

- Jane Halton
- Marie-Paule Kieny (observer)
- Nima Farzan

Board members elect participation

- Eduardo de Azeredo Costa
- Jeffrey Mphahlele
- Joachim Klein
- Yusuke Fukuda

Observers

Secretariat

- Astrid Helgeland
- Bjørg Dystvold Nilsson
- Frederik Kristensen
- Ole Kristian Aars

Other observers

- Bruce Altevogt
- Detlef Böcking
- Gagandeep Kang
- Jason Maddix
- Leena Manghaney
- Manisha Shridhar
- Mukesh Chawla
- Nancy Lee
- Penny Heaton
- Rohit Malpani
- Samia Saad
- Suresh Jadhav (Delegate)

Observers on the phone

- Laura Efros
- Tim Evans

Appologies

- Yifru Berhan
- Ruxandra Draghia-Akli

CEPI's mission: *We want to stop future epidemics by developing new vaccines for a safer world. Vaccines are one of the world's most important health achievements, but their life-saving potential hasn't yet been realised for many known and unknown epidemic threats.*

A majority of the initial Interim Board members participated and all of the Interim Board members elect had been given the opportunity to participate in the Board proceedings. The participating Interim Board members thus constituted a quorum. None of the Interim Board members had objections to the manner of proceedings, the notice, or the agenda.

The following matters were on the agenda:

1 Opening of 2nd CEPI Board Meeting

Conflict of Interest:
Vijay Raghavan opened the Board meeting and presented the stated Conflict of Interests received from Board members (including alternate Board members) prior to the meeting.

Decisions

The Interim CEPI Board endorsed the extension of the Interim Board with the following members:

- Eduardo de Azeredo Costa
- Joachim Klein
- Yusuke Fukuda
- Jeffrey Mphahlele
- Yifru Berhan

The Board was also informed of the following changes:

- Kesetebirhane Admasu is leaving the CEPI Board.
- Nicole Lurie has changed status to observer and liaison to USG.

Points discussed under this item

- It would be important to ensure that African, Asian and Latin American representatives and civil society are adequately represented at the Board. MSF stated that it cannot represent civil society.

2 Summary JCG proceedings

John-Arne Røttingen presented the main take-outs from the Joint Coordination Group meeting in Geneva on November 18.

Decisions

- Endorsement of setting up working groups, particularity on “procurement and stockpiles”. Gavi should be asked to take on a leading role on this, as it is important that CEPI is aligned with their vaccine investment strategy.
- Endorsement of setting up a larger all-inclusive partner forum. The Joint Coordination Group will be a smaller forum with the aim of aligning key actors.
- Resources must be managed when deciding on the scope of the Partner Forum and initiation of other CEPI-led activities. Have to weigh considerations of focusing priorities against broad stakeholder engagement.

Points discussed under this item

- Cannot overlook the hardware that is necessary to conduct a clinical trial and the associated costs. Clarifying the funding scope is therefore crucial

- As West Africa is home to many emerging infectious diseases, individuals and organisations from these countries must be adequately represented in CEPI bodies, including in the JCG. The same goes for civil society, as MSF cannot be seen as an umbrella for such organisations.
- Expansion of CEPI bodies must be weighed against the need to take swift action. Excessive involvement might slow down ongoing processes. Bodies and groups initiated must therefore be focused.
- Regulatory involvement is crucial in CEPI processes, and one should therefor investigate creative approaches to allow for their active participation.
- The JCG governance structure should be clarified, including how the group differs from that of the SAC.
- Discussions on Board composition should be continued, as it cannot be an effective and operational Board with an excessive number of members. Gavi's constituency set-up can be used for reference, although a range of sub-committees is undesirable for the case of CEPI.
- CEPI must manage expectations on what in plans to deliver and clearly communicate this. When communicating this scope, one must have in mind that other organisations might take on activities that could otherwise be covered by CEPI in the future.
- There is benefit of involving governments that are hosting manufacturers, including for purposes of fast-track procedures.

3 Resource Mobilization Update

Tore Godal gave a short update on the status of the resource mobilization activities to date. Representatives from Wellcome Trust, the Bill & Melinda Gates Foundation and Germany announced that they will contribute to CEPI financially over a 5-year period. Australia is expecting to contribute both in-kind, and with a modest cash contribution. Representatives from India, Japan and Norway also confirmed their intent of providing funding. There are ongoing dialogues with representatives from Singapore and Canada on in-kind/core contribution. No contractual commitments are expected from any donors until the launch in Davos

Points discussed under this item

- Must be mindful not to duplicate efforts and rather use them for leveraging CEPI activities, including projects in Liberia where NIH, Wellcome Trust and the Bill & Melinda Gates Foundation are involved.
- Although the current interest is considerable, one must not forget that CEPI should aim for the $1 bn/5 year goal. Furthermore, the business plan will be revised, and estimated funding needs might therefore alter accordingly.
- CEPI should consider ask governments to provide assistance on regulatory pathways as in kind contributions.
- To show that CEPI can deliver, investments must be made accordingly. This includes prioritizing the Ebola question and ensuring that CEPI can quickly pivot it's funding towards emerging challenges.
- The CEPI secretariat is working on finding appropriate language for acknowledging in-kind contributions. The importance of these contributions should not be over communicated in order to nudge donors into providing core funding.

4 Regulatory Working Group Update

Frederik Kristensen presented the work in the Regulatory Working Group that is led by Daniel Brasseur (chair) and Mac Lumpkin (vice chair).

- The group cooperates closely with WHO and national and regional regulators to facilitate dialogue and help product developers get a better understanding of the regulatory and ethics processes around stockpiling.
- The working group is continuously reaching out to other stakeholders to get their input on suggested areas of work for CEPI, including at the pre-ICDRA that was held in Cape Town this November.
- In 2017, the working group will use questionnaires to get industry feedback, support a meeting of a reference group of regulators, liaise with WHO consultation processes related to PHEICs and EUAL and make recommendations to the SAC on future CEPI activities.

5 Ebola

Mark Feinberg presented the importance of finishing the job on Ebola vaccines and what CEPI will do to contribute through going through the work of the committee who has worked on Ebola on behalf of the Board.

Decisions:

- CEPI to organize a regulatory science meeting in Q1 2017 with key regulatory agencies (including EMA and FDA), the WHO, vaccine companies engaged in Ebola vaccine development and other key stakeholders with the aim to
    - Define criteria for expedited licensure, clinical data needed to support vaccine licensure as well as essential CMC information, for both
        - Ebola Zaire vaccines (including those for which efficacy data are not available)
        - Vaccines targeting other Ebola species and Marburg virus (no human efficacy data available for any candidate)
    - Develop a common understanding and shared solutions to enable timely licensure of vaccines against filovirus infections targeted by CEPI, also as a pathfinder approach for other pathogens where efficacy data may not be available/be feasible in advance of a large outbreak.
- CEPI to prepare a comprehensive assessment of current funding initiatives supporting the development, licensure and procurement of vaccines targeting Ebola Zaire and Sudan and Marburg virus
- CEPI to organize a meeting to develop consensus preferred product characteristics that will help inform and expedite the development of vaccines that can have the greatest public health impact as well as the greatest probability of technical and regulatory success, product development feasibility and program affordability.
    - Vaccine companies, the WHO, national/regional research and bio-preparedness agencies (e.g. BARDA, DTRA, NIH, IMI), global health philanthropies (e.g. BMGF and Wellcome Trust), vaccine finders and procurement agencies (GAVI and UNICEF), regulatory authorities, implementing partners (representatives from countries at risk for filovirus outbreaks and MSF) and other relevant stakeholders
- Gaps or inadequacies will be defined in light of recommended regulatory science strategies and used to provide the focus on a targeted CFP(s) to be issued by CEPI (potentially in collaboration with other funders) to support R&D efforts needed to complete the job on Ebola vaccine licensure. This CFP(s) will be targeted for Q2 2017
- Defining and implementing an advocacy strategy to activate stakeholders to finishing the job on Ebola

Points discussed under this agenda item:

- Information sharing: Full sharing of results will be a key priority for CEPI
- CEPI communication and positioning around finishing Ebola should be our top item
- Whether CEPI should focus on a monovalent vs multivalent vaccine will have an effect on the CFP. The same relates to the question on an emergency vaccine vs a fully licenced vaccine. Ebola can thus serve as a pathfinder for other CEPI-funded products.
- CEPI should take action before a state of emergency.
- Although CEPI should take an active role, it must be synergistic with existing efforts from other actors in the field, including affected communities. CEPI should take on a convening role and also look at actors outside of the usual scope, including from Russia and China. Competition, i.e. to have more than one vaccine, will also help ensure pricing that facilitates access.
- Pathways exist, but there needs to be more clarity on *which* pathway is preferred – that being the animal rule or other options.
- In maintaining authorization, regulatory inspection of the facility(ies) producing the vaccine will be required. Platforms are also relevant in this regard, including associated modelling and data sharing.
- As there may be need for more than one vaccine, this should be communicated thoroughly.

8 Permanent Secretariat

The Bill and Melinda Gates Foundation announced an RFP to host the permanent CEPI secretariat on October 24, 2016. Several entities indicated interest with queries at subsequent teleconferences and by email. Two entities submitted a full proposal. The proposals were reviewed and scored by the foundation RFP team based on several criteria and submitted to the assigned CEPI Board subcommittee. Members of the subcommittee unanimously agreed that the proposal submitted by the consortium including the Norwegian and Indian governments and Wellcome Trust was the superior proposal.

All parties directly or indirectly involved in the application for the permanent CEPI Secretariat left the room when this agenda item was discussed.

Decision:

- The board approved the proposal for a multi-nodal secretariat led and incorporated in Norway with India-DBT, Wellcome Trust, and a US institution leveraging resources and competencies of the host institutions.
- The CEO may decide where to be based, in either Oslo or London.
- The Board recommends that the permanent CEO present a proposal for a leaner organization.

Points discussed under this agenda item:

- Optimally the Board would have liked to see additional proposals come in and more insight into the ones provided. The short time frame for the RFP process was therefore a topic for discussion.
- Questions were raised about the operability of a three-node secretariat considering the logistical and communicative challenges.

- Different views on the location of headquarters: some argued that the organizational and geographic set-up should be made at the discretion of the CEO, whilst other were in favour of following the proposal as put forward.
- General agreement that the CEO does not have to be situated in Oslo, although there clearly has to be a close and frequent collaboration between the CEO and the main office in Oslo.
- A lean and unbureaucratic secretariat structure is desired, but relying on competence in hosting organizations can mitigate this. The new CEO should have a say in the final organizational set-up and present this to the Board.

9 Recruitment of CEO

On behalf of a Board sub group consisting of Vijay Raghavan, Peter Piot, Moncef Slaoui and Jane Halton, Nancy Lee briefly presented this agenda item.

With regard to process, three global search agencies were approached and one of the firms chosen to deliver according to this timetable:

- Appointment of search firm week of 12 December;
- Confirmation of job spec and accompanying details 15 December- Board to brainstorm potential candidates at Delhi Board meeting
- Search process with short list suggested to Board sub-group (23 January)
- Sub-group interview candidates: throughout Feb
- Sub-group to make recommendation to Board 27 Feb.

Decisions

The search company will finalize the job description and share with Board members, and description will then be approved by sub-group. The search company will share an email account to enable Board members to submit suggestions for CEO candidates. The current sub-group will be complemented by Victor Dzau and Stephen Kennedy.

Points discussed under this agenda item:

- The CEO should have the characteristics of being a global health leader, not just a business person
- The short time frame was brought up as a possible hindrance by some Board members for attracting the right candidates. In this regard, the secretariat will work together with the interim CEO to ensure a good transition and overlap even if the new CEO cannot formally start before summer 2017.

10 Call for Proposals

Vijay Raghavan updated the Board on the new composition of the Scientific Advisory Committee and Mark Feinberg summarized the main take-outs from their last meeting. John-Arne Røttingen gave an overview of the Analytic Support Framework for CEPI Investment Decisions, the disease prioritisation and the Call for proposals.

Decisions

- The CEPI Interim Board endorsed the following changes to the SAC Membership:

    - Rick Bright has left the Scientific Advisory Committee and has been replaced by Gary Disbrow.
    - Michael G. Kurilla from the US National Institutes of Health has been named as a new member.
- The CEPI Interim Board approved the SAC's recommendation for prioritization of diseases, with MERS, Lassa, Nipah at the top of the ranking and that the Marburg disease would be part of the "Finishing the Job on an Ebola-vaccine"

Points discussed under this agenda item:

Update SAC Membership

- Desire to limit the number of SAC members in the future.
- Ensure that there is a proper geographic distribution of members in the permanent SAC

Analytical Support Framework, disease prioritisation and call for proposals

- Important to have a broad perspective concerning inclusion of actors and perspectives in the disease prioritization. In this regard, the collaboration with WHO plays an important role.
- The disease prioritization list was supported and seen as helpful. Technology platforms were specifically highlighted as an area that should not be forgotten. Linking the prioritization list to the opportunity of using platforms was therefore seen as an advantage, although one cannot forget the challenges with setting up appropriate capabilities to support this work. In this regard, CEPI is also planning for a 2nd/3rd CFP to specifically target platform technologies. The SAC will however need more time, and the secretariat is coordinating with the Bill & Melinda Gates Foundation on an RFP they are planning.
- CEPI is encouraged to have a level of flexibility in its funding to ensure that there is response capacity in the event of an emergency.
- Active immunization is important, but cannot forget *passive* immunization, e.g. hyper-immunoglobulins and monoclonal antibodies.
- The vaccines that CEPI fund must be clearly guided by the need for a product that is accessible for vulnerable populations in need. This needs to be reflected in the associated CEPI policies, which also should address bridging research and manufacturing.
- Concern was expressed about the period of three years and the Secretariat took on to consider changing this to up to five years with clearly defined gates and progresses.
- On the call for proposals, one must weigh inclusiveness vs specificity. It is not in anyone's interest that CEPI becomes inundated by proposals that will not realistically have a chance of being selected. Many spoke the cause of making strategic decisions related to funding candidates with high probability of success, that in turn can show the effectiveness of the initiative within a short period of time.
- In order to not have chosen candidates that fail, it is important to identify potential weaknesses in pre proposal stage, and advice candidates to team up or to provide assistance.
- CEPI is not venture capital and should support reasonably advanced candidates, not driving for ultimate innovation.

11 Zika vaccine development – status, gaps and needs

Nicole Lurie presented Zika Vaccine Development: The Coordinated US Approach, Status Update, and Remaining Gaps and Needs. The USG experience with Zika can be seen as a case study for CEPI in terms of managing its future projects.

Decisions

- The Board advised CEPI for its first period not to invest in Zika vaccine development given the large activity and investments already being made in this field.

Points discussed under this agenda item:

- The USG approach to Zika is to invest in a number of projects to ensure a successful outcome. It also shows the complexity of the endeavor, and gives an indication of the level of resources needed for CEPI on related projects.
- CEPI must collaborate closely with partners and awardees to ensure an efficient and predictable pipeline for developers.

12 CEPI Core Policies

John-Arne Røttingen introduced the proposed new policies on equitable access, shared risks/shared benefits and management of intellectual property.

Decisions

- Revise policy with the aim of making it more coherent across sections and bring more clarity on sections related to sub-licensing and pricing. Keep MSF, WHO, BIO and MNC's involved in the process. Secretariat to present revised version to the Board for sign off in a teleconference mid-January
- CEPI's core mission should be to provide accessible vaccines to the population in need. When redrafting the policies one should be mindful of not downplaying this message.

Points discussed under this agenda item:

- It would be difficult for MNCs to accept the current language on intellectual property and tech-transfer, although optional language was voiced related to circumstances where sub-licencing could be agreeable.
- Difficult to decide on a set price at the start of a program. The policy documents should therefore be interpreted as guidance. Guidance documents that complement the policies on cost of goods etc., and contracts themselves will bring a larger degree of detail.
- It was suggested to consider language referencing tiered pricing arrangements – possibly linking to GDP. This would take into account the notion of affordability. Such an arrangements would however entail that CEPI will take a larger part in the benefit-sharing mechanism. Other Board members were quite explicit about the inability to change language into something that decreases access for populations in need and that a GDP-reference could lead to poorer countries being down prioritized in situations of vaccine shortage.
- There is a large difference between taking a product to the start, or the end of phase 2. Accordingly, there also needs to be a clear differentiation between CFPs for end of phase 2

versus large-scale manufacturing. Moreover, smaller companies do not necessarily have the opportunity to take the long-term value of a product into account.

- Funding during an emergency will require companies to reallocate resources quickly and is thus inextricably tied to opportunity costs.

13 FUND HOLDER ARRANGEMENTS

The CEPI Board was invited to decide on whether a World Bank based Financial Intermediary Fund (FIF) should be pursued as an option for holding CEPI funds.

On behalf of the World Bank, Mukesh Shawla and Tim Evans, presented reasons why the World Bank would be a preferred partner for hosting a FIF for development of vaccines and ensuring that they are advanced past the Phase II stage of clinical development. Advantages of such a fund holder arrangement includes:

- the World Bank can twin the financing for development of vaccines with several ongoing initiatives
- the World Bank's suite of emergency responses and lending instruments strategically complement vaccine development and deployment objectives
- the World Bank has extensive experience in managing similar large-size FIFs and providing fiduciary oversight as a custodian of donor and government resources.

Decisions

- Given that both CEPI and the World Bank's Pandemic Emergency Financing Facility (PEF) are in early stages of development, upstream linkages between the two will be examined at a later stage when both initiatives have attained a higher level of maturity and are better institutionalized.
- The CEPI Interim Board authorized the Secretariat to go into negotiations with the World Bank for them to be a fiduciary trustee. The Secretariat will prepare the resolutions to be approved at the next board meeting and among other things clarify the way the market access will be handled.

Points discussed under this agenda item:

- PEF could be available for clinical trials and procurement of new vaccines at the time of the outbreak, thereby securing a linkage between phase 2 and 3 trials. Triggers for dispensing such funds kick in at an earlier stage than that of a PHEIC.
- Bond issuance cannot be easily used to pivot quickly as a stand alone. There is however an option to set aside liquidity to facilitate such rapid response in addition to synergies that can be leveraged through IDA 18.
- The revised version of the proposal should include a section of the possibility of granting CEPI a line of credit.

14 Role of CEPI in financing or facilitating phase 3 trials in emergencies

John-Arne Røttingen presented discussions that have taken place on what role CEPI should take on planning for, financing or facilitating phase III clinical vaccine trials in emergencies. Options for CEPI include degrees of involvement between the two extremes of the spectrum i) no funding and no involvement and ii) funding from core CEPI budget.

Decisions

- Although there was positive feedback for a range of roles CEPI could take, the Board was supportive of CEPI taking a convener, planning and facilitation role, rather than a funder role.

Points discussed under this item

- CEPI should set up discussion with other stakeholders in the field to get a better understanding of what is being done and what needs to be done. The JCG could be a relevant platform to initiate such discussions. There seems to be a consensus to start having these conversations early and that CEPI could work proactively in reaching out to such stakeholders.
- Funding phase 3 trials could be a desirable solution when the product has a viable commercial opportunity and thereby allowing CEPI to recoup some of the benefits. Other Board members asked for more caution about funding, and that CEPI should rather act as a facilitator within this space. Funding can be considered on rare occasions where there is an identified gap.
- CEPI could consider using stockpiles for phase 3 trials and should leverage partnering organisations in how modelling can be used for getting a better understanding of distribution of stockpiles.
- CEPI should bring in the modelling groups to see how we can organize the deployment from stockpiles to for instance 100 000 frontline workers. Such an implementation could be designed to get good efficacy estimates, even if not as traditional phase 3 trial designs.

15 Role of CEPI in securing vaccine stockpiles

Frederik Kristensen presented considerations that relate to CEPI's role in securing vaccine stockpiles, including the possibility of setting up a separate working group on this issue.

Decisions

- Set up working group in collaboration with Gavi.
- Board members to suggest members of the working group.

Points discussed under this item

- The issue needs to be closely linked to the use of stockpiles in phase 2 emergency settings.
- Manufacturing should be seen as a complement to engaging in clinical trials. There should also be a clear signal on when manufacturing should be scaled up to meet demands.
- Ethical considerations should be central to CEPI when deciding on CEPI's work within stockpiling.
- CEPI must be clear on whether one is seeking mid-stage validation or taking something into phase 3 clinically for full validation.

16 CEPI's potential future roles on diagnostics and therapeutics

John-Arne Røttingen presented suggested areas of complementarity between CEPI and the organizations FIND and ICAV that has approached CEPI independently. Although CEPI's present focus, both as a funder and coordinator, is on vaccines, the Board's guidance was sought on CEPI's potential future role in diagnostics and therapeutics.

- ICAV is championing a 'Global Network of Advanced Manufacturing Facilities' with globally distributed rapid response capacity for the manufacture of biologicals. Their strategy includes manufacture of both monoclonal antibodies and vaccine candidates, with special emphasis on stockpiling interventions for viruses on the WHO priority pathogen list.
- FIND is a global product development and delivery partnership developing a semi-open molecular and immunoassay platform which could play a key role in vaccine development efforts if focused at CEPI-related diagnostic needs.

Decisions

- The Board recommended that CEPI at this stage should not engage as a funder of either diagnostics nor therapeutics, but keep the investment focus on vaccines. Strategic collaborations on the diagnostics side were welcomed to facilitate complementing work.

Points discussed under this item

- CEPI should take a role in clearing obstacles for innovation. This includes collaboration and facilitation of dialogue and information sharing.
- In terms of engaging in partnerships there might be benefit in CEPI taking a step back and decide on who to approach instead of acting on the first proposals put forward. Board members might also assist in forming these partnerships through established contacts.
- CEPI's name suggests that it will work outside of the pillar of vaccine development. One must, however, manage expectations, as CEPI is currently not in a place to actively engage in diagnostics and therapeutics.

17 2017 Board meetings

- The Third Interim Board meeting to take place in Oslo on February 27, 2017.
- Teleconference to take place before the launch in Davos on January 19
- Subsequent Interim Board meetings to take place in late July and November 2017. Berlin and Tokyo were discussed as possible venues.