



Summary of Minutes of Board meeting #22 Video/Teleconference

12:00-14:00 GMT | June 2023

Board members

- Jane Halton, Chair of the Board
- Anita Zaidi, Bill and Melinda Gates Foundation
- Cyrus Ardalan
- David Reddy
- Githinji Gitahi
- Rajeev Venkayya
- Rizka Andalucia, Ministry of Health, Indonesia
- Soumya Swaminathan
- Veronika von Messling, Federal Ministry of Education and Research
- Yashurio Suzuki, Ministry of Health, Japan

Non-voting members

- Richard Hatchett, CEO CEPI
- Emmanuel Hanon, CEPI SAC Chair
- Juan Pablo Uribe, World Bank
- Mike Ryan, WHO

Apologies

- Samba Sow
- Cherry Kang, CEPI JCG Chair

Observers

Investors council

- Austria: Norbert Feldhofer
- Australia: Margot Morris
- Canada: Mike Torunian
- Finland: Outi Kuivasniemi
- Gates Foundation: Hannah Cameron
- Germany: Julia Jasper
- Italy: Eugenia Palagi
- Indonesia: Roy Himawan
- Japan: Tetsuya Itani
- Luxemborg: Clarisse Geier
- Malaysia: Raha Abdul Rahim
- Mexico: Ambassador Ulises Canchola
- Norway: Daniel Hirsch
- Switzerland: Florian Folder
- UK: Sarah Legrand
- USAID: Cara Chrisman
- Wellcome: Katherine Andrea

Management

- Adam Hacker (item 4)
- Anand Ekambaram
- Mads Høgholen (item 1)
- Fernando Pons
- Frederik Kristensen
- Joseph Simmonds-Issler
- Melanie Saville
- Monina Vierendeza
- Rachel Grant
- Magnus Holme (item 5)
- Nicole Lurie
- Samia Saad
- Claire Willman (minutes)
- Sian Denereaz (logistics)

Item 1: Opening

- No new conflicts were declared.
- The Board delegated signature of the March 2023 meeting minutes to Jane Halton and Cherry Kang.
- Jeanette Vega Morales was noted as having been appointed to the Board, approved in Board closed session. Jeanette replaces the seat that was left vacant by the departure of Gagandeep (Cherry) Kang, who left her Board seat and transitioned to being Chair of CEPI JCG. Jeanette will serve an initial term of 2 years (effective 2 June 2023) and is also appointed to serve as a member of the ARC. The revised Board membership is provided as an appendix to these minutes.

Investors Council (IC) report

Outi Kuivasniemi presented on the IC's meeting pre-Board:

- Selected Board papers were previewed and discussed including Manufacturing and Regulatory.
- The CEPI CEO updated on CEPI's activities including a focus on the financial position.
- The WHO has declared the COVID-19 'PHEIC' over
- The IC welcomed updates on funding contributions, as well as country investments in work aligned with CEPI's objectives.
- Management updated on external engagement including with the Japanese and Korean governments, WHO, and at the G20. Investors asked that such activities be documented and shared on a more regular basis.
- The timeline for bringing amendments to the September Articles of Association to the Members meeting was discussed.

Opening discussion:

The Board Chair noted that CEPI's spend rate is an ongoing area of focus that has been discussed by the Chair and CEO and would be discussed in the meeting.

Item 2: Half Year Finances

- Mads Høgholen presented to the Board on CEPI's Half Year Finances, including updates on 2023 status of contributions, investments, operating costs and cash flow. He noted:
 - Contributions for 2023 are higher than budgeted by approximately USD 115M.
 - Operating expenses are at approximately 80% of the overall budget after 4 months into 2023 and it is unlikely that the full 2023 operating budget will be spent. A more detailed review will be undertaken over summer and an updated forecast will be brought to the September Board meeting.
 - There will be a positive net cash flow in 2023 and CEPI is also expected to carry a strong cash position also into 2024 and 2025.
- Melanie Saville noted:
 - Many projects have progressed slower than anticipated, partially due to the unpredictability of COVID-19. The spend rate is expected to accelerate as projects move from early to late-stage development, manufacturing, and licensure.
 - Accelerating R&D&M investments is a key focus for CEPI Management and steps to address this issue have been identified and initiated.
- Richard Hatchett noted that spend rate is a priority for CEPI Management, that focus areas for improvement have been identified, and that expenditure will not significantly change in the coming months but is expected to accelerate in 2024. Significant financial commitments are expected before year-end on priority pathogens and strategic partnerships and Richard asserted

that CEPI Management will report to the Board and Investors Council as to how efforts are developing.

In discussion:

- The Board emphasised the importance of continuing to focus on high quality investments.
- The inherent risks involved in R&D investments will remain despite some of the positive changes CEPI is making.
- A fragmented portfolio with multiple small grants is less efficient for moving capital and achieving impact, and strategic partnerships can contribute to more efficient capital deployment model in future.
- Volatility of exchange rates and differences in financial regulation across countries, can present complexity in reporting. CEPI does have a hedging strategy, and Management noted that its banks have strong ratings and stability records.

Resolutions:

- CEPI Management to report to the Board around spend rate *Ongoing*
- CEPI Management should consider introducing confidence estimates to budget figures, with percentages of certainty attached to each and brief explanations about potential variants impacting outcomes *Ongoing*
- CEPI Management to report back to the ARC/Board on any obligations relating to CEPI's non-profit status in its various jurisdictions **H2 2023**

Item 3: Manufacturing Strategy

Anand Ekambaram presented an updated version of CEPI's Manufacturing Strategy for approval. Since the March Board, the strategy was discussed with the SAC, and key evolutions include:

- Elaborating policy enablers and caps and the potential roles CEPI can play as a funder, advocate and catalyst in the global ecosystem.
- Identifying four strategic goals: 1. External engagement to ensure buy-in and offer CEPI's technical support to partner initiatives where relevant, 2. Establishing a partner network, 3. CMC roadmaps with early engagement with regional bodies, 4. Innovation to ensure speed, cost savings, and equitable access.
- Potential risks and mitigation actions have been outlined.

In discussion:

The Board broadly endorsed the Strategy with some issues and requests expressed:

- CEPI management should prepare a case study on what the manufacturing strategy looks like in practice on one of CEPI's priority pathogens, in part to help those who are non-expert understand the strategy in practice. The Board advised Management to use Chik for this case study.
- Line of sight to platform fit will be critical and could be further fleshed out, building on the experience of COVID-19 where CMC was often the point of failure.
- CMC has historically been an afterthought to clinical governance. Separate stage gates might be required to avoid repeating issues experienced during the COVID-19 pandemic.
- It is important to ensure the strategy is achievable:
 - CEPI risks being held accountable for unrealistic commitments that are unlikely to be realised in the near term, or by CEPI alone. This was expressed particularly in relation to geographical focus, which is currently wide, and concerns that cost of goods from new manufacturers will not be able to compete with established large volume manufacturers – it was suggested a focus on packaging and drug product might be preferable in this regard.
 - It will be essential to identify realistic targets that can be achieved in the next 5-10 years. Current focus is too broad, be specific about where CEPI can be an enabler, encourage focus rather than taking too broad a responsibility. Very important to have partners on board. Start with a few countries (2-3) and a few sites (2-3)
 - Specific priority regions and countries should be selected for short- to medium- term focus, to avoid over committing to full ecosystem overhaul.

- Emerging manufacturers should be partnered with more established companies to ensure successful development.
- Market fragmentation is a key risk and identifying existing capacity – including for inter-pandemic periods – is important.
- Clear criteria for identifying partners should be developed, especially given the multiplicity of actors entering the market.
- Buy-in from governments, regulators, G7/20, civil society, Gavi and other partners will be essential to sustained success of efforts, as will commercial viability.
- It was suggested CEPI management could bring a landscape analysis to the Board on how various elements of the ecosystem view intellectual property, TRIPS and related issues with recommendations on practical advocacy positions on which CEPI should focus.
- Market failure gaps should guide CEPI's role in advocacy, funding and catalysation in this area.

Resolutions:

- An implementation plan for the manufacturing strategy in relation to a priority pathogen (Board recommended Chik) should be developed and presented to the Board **H2 2023**
- CEPI Management to bring a landscape analysis to the Board on how various elements of the ecosystem view intellectual property, TRIPS and related issues with recommendations on practical advocacy positions on which CEPI should focus. **Due: to be confirmed with Board Chair/EIC**

Item 4: Regulatory Strategy

- Adam Hacker presented CEPI's Regulatory Strategy for the Board's comment:
 - The Strategy takes a portfolio approach and is built around CEPI's priority pathogens, with engagement structured around clusters of relevant regulatory authorities according to disease.
 - COVID-19 put CEPI front and centre on pandemic preparedness and response regulatory issues. CEPI's role in COVAX – including co-chairing the Regulatory Advisory Group with WHO – has accelerated thinking on regulatory issues/ partnerships, these have proven a strong model for engaging regulators.
 - Bringing new and future partners along and engaging external organisations will be essential to progress both incremental and paradigm innovations, including a range of regulators, industry organisations, WHO and other international organisations.
 - One critical area of focus for CEPI's regulatory work is supporting the ability to achieve the 100 Days Mission. In preparing CEPI's report on "What Will It Take", there was extensive engagement with regulators and partners, including WHO – which builds on platform and efficacy data from COVID-19 and other recent epidemics/ pandemics.
 - Use of case studies is critical for effective conversations with regulators who may be resistant to the 100 Days Mission concept, using e.g. COVID-19 or Chikungunya to elucidate innovations in platform data, correlates of protection and efficacy, and so on.

In discussion:

The Board welcomed the presentation and CEPI's work to date in identifying regulatory issues and developing potential solutions through partnership. The Board suggested:

- Clarity on regulatory pathways through successful case studies, such as Chikungunya, can play an important role in demonstrating CEPI's value and could help to catalyse investment in this space and bring more products to market to address high risk diseases.
 - Chikungunya also makes a useful study because it demonstrates the value of this work outside an international pandemic such as COVID-19.
 - The r-21 malaria vaccine in development could also be instructive and reflects evolving trends in the regulatory space.
- CEPI will need to be aware of sensitivities from Global South countries given experiences during Covid where countries had to rely on Global North regulatory EULs.
- Licensure process/ issues in epidemic versus pandemic situations should be clarified, as well as those administered in inter-pandemic/ epidemic periods.

- At the Board's request, CEPI management provided an update on latest regulatory engagements/ advocacy as pertains to Nipah and Lassa, noting the COVID-19 pandemic provided an historic dataset on efficacy and immune-bridging which is informing strategies for other CEPI priority pathogens.
- Safety concerns will be central to buy-in from partners and the public, especially regarding confidence in new technologies.

Resolution: The Board was supportive of the work noting how critical CEPI's engagement in this area has been. They encouraged thought on how to make high value impact in future and as this work progresses.

Item 5: Committees

- **EIC:** Richard gave an overview of recent discussions at EIC on flu, catalysed by recent H1N1 mammal to mammal transmission data. He noted that CEPI Management will come back to the Board with further analysis, but that CEPI's potential value-add is understood by the EIC to be Equitable Access
- **NCDIC:** It was noted that the Board had appointed Jeanette Vega Morales as a Board member, serving an initial term of 2 years, effective 2 June 2023. Jeanette will also serve on the ARC.
- **ARC:** the ARC Chair updated the Board on recent meetings and activities:
 - Discussions have focused on CEPI's risk management framework which will come to the Board in September
 - Adrian Hennah has been appointed as an independent member of the ARC.

Resolutions:

- CEPI management to bring further analysis around what role CEPI should or should not have in relation to pandemic flu. *Due: H2 2023*
- The Risk Management Framework to be brought to the Board *Due: September 2023 Board*
- The Board noted the Committee update papers.

Item 6: Items to Note, AOB, and Close

The Board noted the plan for the September 2023 meeting to be held in Senegal and discussed plans for 2024 Board meetings and timings.

AOB:

- The Board requested an update on CEPI's plans as regards WHO Pandemic Treaty discussions, and planned advocacy positions, as well as UNGA 2023 where the future PPR landscape will be discussed. It was confirmed that there would be high level engagement at UNGA by CEPI leadership.
- The Board would like to follow up on marketing authorization holders for vaccines that are coming to licensure, and to discuss the challenges to enabling access. *Due: to be confirmed with Chair*

Resolutions:

- The Board noted actions since last meeting paper.
- CEPI Management to share policy positions for key international fora to year-end with Board and Investor Council *Ongoing*
- CEPI's advocacy positions on ecosystem developments to be considered in future Board meetings. *Ongoing*

Appendix 1: Updated Board composition following appointment of Jeanette Vegas (effective June 2 2023)

Independent Members

Jane Halton (Chair)
Cyrus Ardalan
Githinji Gitahi
David Reddy
Samba Sow
Soumya Swaminathan
Jeanette Vega Morales
Rajeev Venkayya

Investor Members

Rizka Andalusia
Hiro Suzuki
Veronika Von Messling
Anita Zaidi

Indonesia
Japan
Germany
Gates

Non-voting members

Mike Ryan
Juan Pablo Uribe
Emmanuel Hanon
Gagandeep Kang
Richard Hatchett

(WHO)
(World Bank)
(Chair CEPI SAC)
(Chair CEPI JCG)
(CEPI CEO)