

**SUBJECT:** IFFIm AND CEPI

**Agenda item:** 07

**Category:** For Decision

## **Section A: Introduction**

- Following a request from the Kingdom of Norway (Norway) to the Gavi Programme and Policy Committee in May 2018, the Secretariat has explored Norway's proposal that Gavi support the Coalition for Epidemic Preparedness Innovations (CEPI) subject to funds being made available by Norway and disbursed via IFFIm (the CEPI Arrangement). The CEPI Arrangement is to be fully funded by Norway and will therefore be cost-neutral to Gavi. The CEPI Arrangement will enable Norway's contribution to be frontloaded to CEPI.
- Having reviewed the proposed CEPI Arrangement, the Gavi Audit and Finance Committee (AFC) noted, at its meeting held on 12 October 2018, that the CEPI Arrangement would not have any material adverse impact on Gavi's finances or operations and provided guidance on implementing and executing the CEPI Arrangement as outlined in Section B.
- The IFFIm Board of Directors also reviewed the financial and risk implications of the CEPI Arrangement for IFFIm, at its meeting held on 16 October 2018. The IFFIm Board expressed support for the CEPI Arrangement and provided guidance for executing the related transaction(s) as outlined in Section B.
- The Gavi Programme and Policy Committee (PPC) was given an informational update on the proposed CEPI Arrangement at its meeting held on 18-19 October 2018.
- This report requests that the Gavi Board approve Gavi support to CEPI through the CEPI Arrangement, and requests the Secretariat to put in place the necessary measures to implement the CEPI Arrangement with IFFIm, CEPI and Norway, taking into account the guidance provided by the AFC.

## **Section B: Facts and Data**

### **1. Introduction**

- 1.1 CEPI is a new international non-profit association, established under Norwegian Law, to provide financing for late stage research and development (R&D) into new vaccines for vaccine preventable diseases of epidemic proportions for which no vaccines are currently available.

- 1.2 Norway has committed a total of NOK 1.6 billion to CEPI for the period 2017- 2025. CEPI's investments and operating costs over the next several years are likely to require all of CEPI's received pledges, including the portion of Norway's pledge that runs from 2022-2025, totalling NOK 600 million (approximately US\$ 77 million equivalent). Norway is therefore looking to frontload NOK 600 million to CEPI for disbursement in 2019. It is proposed that the pledge from Norway to CEPI is funded through Gavi via IFFIm.
- 1.3 IFFIm's structure allows IFFIm to fund Gavi programmes and these can be specific to countries (either vaccine support, health systems strengthening or cold chain equipment) or non-specific to address broader immunisation objectives and needs. These latter programmes are defined as "Gavi Non Country-Specific Programmes" and this would include the support proposed to CEPI. Therefore, CEPI would be required to make an application for funding to Gavi as a Gavi Non Country-Specific Programme, which would be funded through a disbursement from IFFIm.
- 1.4 If the Gavi Board approves the decisions set out in this paper, then the process for approval and disbursement of funding to CEPI will follow the steps set out in Annex B, including the review and evaluation by an ad hoc review and evaluation group of CEPI's application for funding.
- 1.5 The CEPI Arrangement would be subject to full funding being made available by Norway through IFFIm for the proposed support to CEPI and there being no material impact on Gavi or its existing programmes as well as on funding provided by other Grantors to IFFIm, i.e. the cost associated with the CEPI Arrangement should be entirely covered by Norway's pledge to support CEPI.
- 1.6 Supporting CEPI in this way would be cost-neutral to IFFIm and Gavi as all associated costs would be fully covered by the Kingdom of Norway.

## **2. Rationale for the CEPI Arrangement**

- 2.1 Gavi and the broader development community have acknowledged IFFIm's unique value as a financing mechanism. Through its support for CEPI, Gavi has the opportunity to collaborate with and make available the IFFIm structure to another global public health organisation, one working on vaccine development for developing countries.
- 2.2 IFFIm, and ultimately Gavi, will also benefit from the arrangement through the provision of additional resources to its capital base and a clear statement of IFFIm's relevance to one of its strongest rated donors. This would likely be positively received by rating agencies, strengthening IFFIm's position as an innovative financing solution for global health.
- 2.3 Gavi has had precedents of supporting programmes that are not managed by Gavi itself, such as the Global Polio Eradication Initiative, and formerly, the vaccine stockpile for Yellow Fever both in 2006. These were funded as

Gavi Non Country-Specific Programmes through IFFIm using its frontloading capability.

- 2.4 Gavi funds new and underused vaccines so there is a complementarity between CEPI and Gavi in contributing to different elements of the value chain to bring new vaccines to developing countries. Gavi is a core member of CEPI's Joint Coordination Group (JCG), with the aim to provide improved predictability to vaccine R&D and delivery all the way through to registration, manufacturing and stockpiling. Gavi has also been the chair of the CEPI initiated working group reporting to the JCG on questions related to stockpiling of emerging infectious diseases vaccines. Therefore ad hoc support for CEPI through IFFIm helps create organisational efficiencies through the use of an important financial tool without Gavi overstepping its mandate primarily focused on vaccine delivery.
- 2.5 Gavi's statutes include "facilitating the research and development of vaccines of primary interest to the developing world"<sup>1</sup> as one of the means by which Gavi will promote health. The Secretariat has consulted with Swiss counsel, who confirmed that support to CEPI would fall within the scope of Gavi's mandate. The circumstances of this situation are unique and the CEPI Arrangement is not a precedent for Gavi to support research and development of vaccines, or an adjustment to its strategy.

### **3. CEPI monitoring and oversight**

- 3.1 The CEPI Board is responsible for setting the strategic direction of the organisation and deciding on CEPI investments. Its Board includes representation from the Investors Council, a body composed of all CEPI's funders.
- 3.2 The Gavi Board would delegate its review of the application for funding from CEPI to an ad hoc review and evaluation group (which will be constituted by the Secretariat as an independent mechanism) and would not be involved in decisions related to CEPI's investments.
- 3.3 Subject to the approval of the CEPI Arrangement by the Gavi Board, Gavi, CEPI and Norway will enter into a grant agreement that will govern how the funds will be disbursed by Gavi to CEPI and detail the reporting and monitoring obligations of CEPI.
- 3.4 These reporting and monitoring obligations will include an annual report to be provided to the Gavi and IFFIm Boards, complemented by an update report on a semi-annual basis. The annual report would be submitted by the CEPI Secretariat after approval by the CEPI Board and the semi-annual update report would be provided by the CEPI CEO. It is proposed that these reports are timed to be available to the Gavi and IFFIm Boards in time for their consideration at the Gavi and IFFIm semi-annual Board meetings.

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<sup>1</sup> Gavi Alliance Statutes Article 2 (ii).

- 3.5 With these reports, CEPI would outline its approved R&D programmes; the funds that have been spent on these approved programmes; R&D outcomes from the approved programmes; and any newly approved programmes. Please see Appendix 1 for a description of CEPI, its mandate and programmes.

#### **4. Guidance on the CEPI Arrangement from the Gavi Board Committees and the IFFIm Board of Directors**

- 4.1 The AFC noted at their meeting held on 12 October 2018 that the CEPI Arrangement would not have any material adverse impact on Gavi's finances or operations, subject to the following guidance:

- a) The Gavi Secretariat takes every possible steps to make this arrangement cost neutral.

*The IFFIm bond transaction and related costs will be netted from the bond proceeds. Norway and the Gavi Secretariat have agreed in principle to formulate an arrangement and process for recovery of reasonable Secretariat costs while supporting the CEPI Arrangement.*

- b) The Gavi Secretariat, the IFFIm Board of Directors and IFFIm's treasury manager ensure that IFFIm's legal agreements need not be amended.

*There is no requirement to amend the IFFIm core legal documents, which would include the Financial Framework Agreement, as confirmed by the Gavi Secretariat, the IFFIm Board of Directors and IFFIm's treasury manager, the World Bank.*

- c) The Gavi Secretariat performs appropriate programme management that would look after the CEPI Arrangement once agreed upon and executed.

*The funds disbursed to CEPI will be monitored and reported upon in line with a framework that is agreed with CEPI and provides sufficient oversight. This will be reflected in the grant agreement to be entered into between CEPI, Gavi and Norway.*

- 4.2 The IFFIm Board reviewed, at their meeting held on 16 October 2018, the financial and risk implications of the CEPI Arrangement and provided the following guidance:

- a) IFFIm's treasury manager should study the relevant market(s) and confirm to the IFFIm Board of Directors that the contemplated frontloading transaction is feasible. In addition to the confirmation of the feasibility of the planned bond transaction(s) the treasury manager should confirm the issuance strategy with indicative pricing terms under current market conditions.

- b) IFFIm's treasury manager must offer assurance that the CEPI Arrangement does not have any material adverse impact on IFFIm's ability to access capital markets efficiently.

*The World Bank has been actively involved in this project since its inception, and has provided analyses and inputs on the planned transaction. Both of the above processes are underway and the Gavi Secretariat is liaising with the World Bank.*

- 4.3 The PPC was informed, at their meeting held on 18-19 October 2018, of the programmatic implications of the CEPI Arrangement.

### **Section C: Actions requested of the Board**

The Gavi Alliance Board is invited to consider Gavi supporting the Coalition for Epidemic Preparedness Innovation (CEPI) subject to funds being made available by the Kingdom of Norway and disbursed via IFFIm (the CEPI Arrangement) and, if it deems appropriate, to:

- a) **Approve** the CEPI Arrangement;
- b) **Note** that the CEPI Arrangement will be considered as a Gavi Non Country-Specific Programme consistent with IFFIm's requirements;
- c) **Note** further that the CEPI Arrangement does not constitute a precedent for Gavi to fund research and development; and
- d) **Request** that the Secretariat puts in place the necessary measures to implement the CEPI Arrangement with IFFIm, CEPI and the Government of Norway, taking into account the guidance provided by Gavi's Audit and Finance Committee.

### **Annexes**

**Annex A:** Risk implication and mitigation

**Annex B:** Overview of the arrangement for Gavi support for CEPI

### **Additional information available on BoardEffect**

**Appendix 1 (in October 2018 AFC meeting book):** Annex A to Doc 03  
*Background on CEPI*

**Appendix 2 (in October 2018 AFC meeting book):** Annex B to Doc 03  
*Background on IFFIm*