

CEPI

CEPI Procurement and Stockpiling Working Group

Concept note and proposed work plan

Working group timeline: February 2017 – December 2017

1 Purpose

To identify gaps and issues, and offer possible solutions that will support procurement, stockpiling, facilitate phase III clinical trials and emergency use of investigational EID vaccines. This work will be led by the CEPI Procurement and Stockpiling working group, and supported by the CEPI Secretariat. The work will in the beginning focus on specific solutions for three diseases prioritised by CEPI: Lassa, Nipah, MERS as well as Ebola and other filoviruses. The work will also bridge this further to potential solutions for stockpiling of these vaccines when licensed, especially in relation to CEPI's non-funding scope and efforts to align players in the field.

2 Background

Addressing challenges with procurement and stockpiling and use of investigational and licensed vaccines have been highlighted as a priority area by many CEPI stakeholders. This is linked to defining a role of CEPI in planning, financing or facilitating phase III clinical trials and emergency use of CEPI investigational vaccines. In partnership with Gavi, the World Health Organization (WHO) and other actors it has been suggested that CEPI can play an important role in this area. The issues were raised on the agenda of the first Joint Coordination Group (JCG) in Geneva on 18 November 2016 and was also discussed at the interim Board Meeting on 16 December.

2.1 The CEPI interim Board decision and discussions at the Board meeting in December 2016

The considerations that relate to CEPI's role in securing vaccine stockpiles, including the possibility of setting up a separate working group on this issue were presented to the Board. In addition the role of CEPI in planning, financing or facilitating phase III clinical trials in emergencies were presented. The options for CEPI presented include degrees of involvement between the two extremes of the spectrum i) no funding and no involvement and ii) funding from core CEPI budget. A summary of these Board discussions is provided in the Annex.

2.2 WHO Blueprint and MOU with CEPI

World Health Organization (WHO) representatives and CEPI have agreed a Memorandum of Understanding (MoU) that promotes and supports the implementation of the WHO R&D Blueprint and outlines areas of collaboration between the two organisations. The MoU is wide ranging, however there are several sections relevant for procurement, stockpiling and emergency use of investigational vaccines, these are:

- **Meet public health needs through acceleration of R&D for pathogens with epidemic potential suffering from market failures (1.1)**
- **Improve global coordination, investment, and incentives for advanced vaccine R&D (1.2)**
- **Ensuring global regulatory optimization and alignment, and strengthen global scientific advice on vaccine development for emerging infections (1.3)**
- **Developing and implementing new norms and standards for an epidemic context (1.4)**
- **Emergency operations in response to a declared Public Health Emergency of International Concern (PHEIC), or in situations where outbreaks of known or unknown pathogens are deemed to have the potential to trigger a PHEIC (1.6)**

The MoU clearly outlines the respective roles of WHO and CEPI, highlighting areas for continued collaboration

WHO role	CEPI role
<ul style="list-style-type: none"> • Federates global efforts with a view to unify and simplify regulatory guidelines when it comes to the use of pre-licensed vaccines in situation of emergencies, the clinical pathways to accelerate the development of priority vaccines, the liabilities of manufacturing parties in case of use of pre-licensed vaccines • In the event of a PHEIC or other emergency WHO will engage with CEPI as appropriate to accelerate vaccine R&D in significant public health emergencies, particularly operationally and in terms of regulatory processes through, for example, use of WHO's Emergency Use Assessment and Listing process for vaccines • As appropriate, CEPI will be invited as an observer to participate in WHO's ongoing work on addressing methodological issues concerning appropriate clinical trial designs during epidemics 	<ul style="list-style-type: none"> • Will develop and maintain the ability to rapidly respond to outbreaks of new or unknown pathogens, in close coordination and cooperation with WHO • Will support WHO's effort to ensure that available vaccine R&D capacity is effectively employed as part of an efficient global response to public health emergencies. • Will support the efforts of WHO to ensure that newly developed vaccines can be utilized safely and effectively in the context of an epidemic outbreak, or to prevent an outbreak of a new or re-emerging infectious disease. • In line with WHO normative guidance, CEPI will implement appropriate study design for relevant clinical trials. • CEPI will, as part of the response effort, effectuate measures to accelerate R&D of vaccines, working with partners to ensure rapid scale-up, delivery, and distribution, while adhering to WHO guidance on vaccine utilization, distribution, and access

3 Work structure

The CEPI Procurement and Stockpiling Working Group will be established during 1Q 2017. The group will convene over teleconference at specific times during 2017. The Chair of the Working Group will

be Aurelia Nguyen (Gavi), and other members will be invited based on an assessment from the CEPI Secretariat. Relevant members of CEPI Secretariat include Karianne Johansen, Ole Kristian Aars, Klara Henderson and Hinta Meijerink

3.1 Proposed areas to be further explored by the Working Group, but not limited to:

1) Mapping and landscaping of actors

- a. Map the potential actors in this space and discuss with other stakeholders in the field to get a better gap assessment: understanding of what is being done and what needs to be done.

2) Defining scope and implications for practice

- a. Comparison of gaps and respective organisations scope to determine the target scope for CEPI
- b. Align and support the work of other stakeholders and normative bodies on how EID vaccines will be used/dispersed in an outbreak setting
- c. Find ways of coordinating between multilateral organizations, procurement agencies, funders, developers and LMIC manufacturers. Ensure that the establishment and governance of vaccines stockpiles (including investigational) are aligned with normative regulatory standards and priorities of procurement agencies and funders – including Gavi and their vaccine investment strategy
- d. Draw from modelling work on stockpile forecasting to understand potential needs and implications for procurement and stockpiling
- e. Assess and use the input from the CEPI regulatory working group – on regulatory issues around stockpiling. Including an analysis and understanding of:
 - i. The key regulatory risks and challenges with the stockpiling of vaccines in the EID context, including its sustainability over extended periods of time.
 - ii. Clarifying regulatory and ethical issues surrounding the use of stockpiled product during outbreaks.

3) Define the way forward

- a. Give guidance on criteria and process for access of stockpiles that are in line with existing definitions and CEPI policies of equitable access
- b. Recommend (co)financing mechanisms for ensuring sufficient size of stockpiles, including its sustainability

3.2 Work plan January – December 2017

Timeline

What	When
Agree on concept and member of the Working Group	February
Establish the working group and set-up a first meeting	February – March
Agree on focus areas and work plan	February - March
Agree on timelines and milestones for the Working Group	March
Ongoing work presented to Interim CEPI Board	Q2 2017
Analysis and recommendations to the CEPI Board	Q4 2017

4 ANNEX

Summary of Board discussions 16.12.2016 related to procurement and stockpiling of vaccines

The Boards decisions on CEPI's role in securing vaccine stockpiles and in planning, financing or facilitating phase III clinical trials in emergencies

In planning, financing or facilitating phase III clinical trials in emergencies, there was positive feedback for a range of roles CEPI could take, although, the Board was supportive of CEPI taking a convener, planning and facilitation role, rather than a funder role.

The Board decided that CEPI's role in securing vaccine stockpiles should be worked through by setting up working group in collaboration with Gavi. Board members were encouraged to suggest members of the working group.

The CEPI Board discussed the following points under these items

- 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.
- The issue of stockpiling needs to be closely linked to the use of vaccines that are through phase 2 clinical development in 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.