

Coalition for Epidemic Preparedness Innovation (CEPI)

Procurement and Stockpiling Working Group

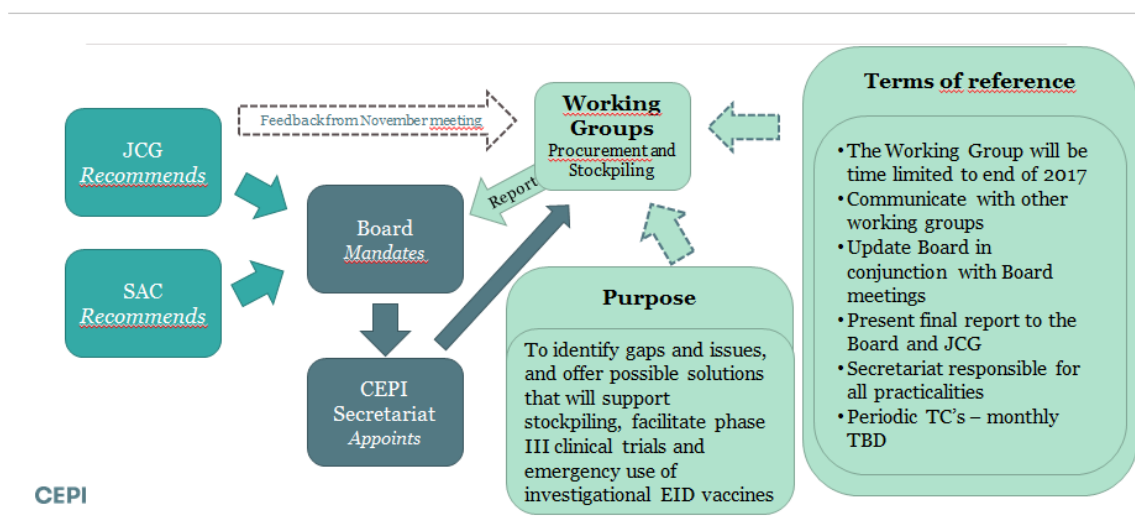
March 29, 2017

Teleconference I

Function

The function of the Working Group is 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. The Group will also discuss related questions for licenced vaccines, providing more clarity on possible paths to licensure for CEPI-funded vaccines. The Working Group will be appointed by the CEPI Secretariat from a CEPI Board mandate, in part based on recommendations from the Joint Coordination Group. The work will be led by the CEPI Procurement and Stockpiling working group, and supported by the CEPI Secretariat. The work will focus on specific solutions for three diseases prioritised by CEPI: Lassa, Nipah, MERS as well as Ebola and other flaviviruses. 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. The associated concept note for the working group explains in greater detail the expected outcomes.

Governance and ToR

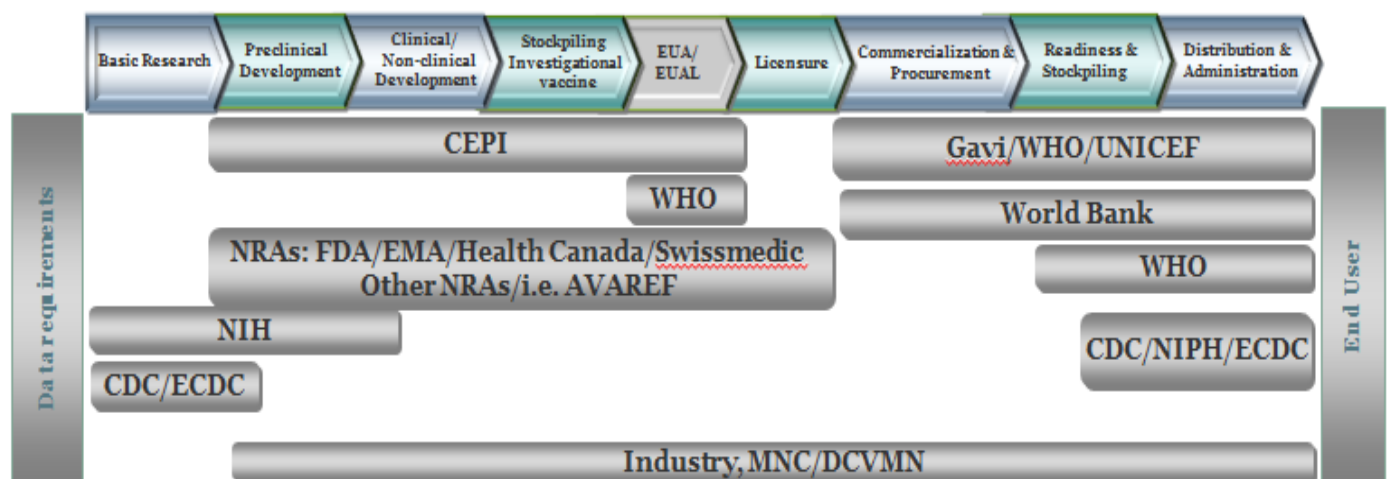


- The Joint Coordination Group (**JCG**) and the Scientific Advisory Committee (**SAC**), will give advice and recommendations to the **Board** mandate, whom, through the **CEPI Secretariat** will appoint and support the **Working Group**, whom, taking on account the Terms of Reference (**ToR**), the **Purpose** and the feedback from the JCG November meeting, will move forward and give a report to the board.

Overview

- **CEPI's funding scope is limited to preclinical up to phase 2b** (proof of concept and ready for phase III), **but seeks to play a role in the end-to-end** perspective by collaborating and facilitating discussion with other actors in the field. Of special importance in this regard is to **facilitate dialogue with WHO and national regulators** to obtain a clear route to licensure, or emergency use authorisations or other relevant mechanism such as WHO Emergency use and assessment listing (EUAL) to awardees, in the instances where this is possible. The work of **this Working Group will help give more clarity** on these issues **related to stockpiling and procurement of investigational vaccines** and potential **future licenced vaccines** funded by CEPI.
- **The MoU with WHO** 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.
- The CEPI Board has recently agreed on a **set of policies** on i) **equitable access**, ii) **management of IP** and iii) **shared risks/shared benefits**. These policies will in turn set the boundaries of CEPI's operations, including on procurement and stockpiling. This includes taking the necessary steps to ensure i) a sufficient volume of investigational vaccines in the event of an outbreak, and ii) equitable access to the licenced product.

Preliminary stakeholder mapping of potential actors in this space



Teleconference March 29th 2017. (Abstract)

1. Attendees:

Working Group Members

- Alejandro Costa, WHO
- Andrew Jones, Bill & Melinda Gates Foundation
- Ann Ottosen, UNICEF
- Aurelia Nguyen, Gavi
- Ludmila Frata, DCVMN (Sinergium Biotech)
- Myriam Henkens, MSF
- Pradeep Haldar, Ministry of Health and Welfare (India)
- Raymond Farkouh*, Multinational Companies (Pfizer)
- Takele Geressu, African Network for Drugs and Diagnostics Innovation
- Wilson Mok*, Gavi
- Wolfgang Phillip, European Commission

*Alternates

CEPI Secretariat

- Karianne Johansen
- Klara Henderson
- Ole Kristian Aars
- Sadie Regmie

2. Points discussed during the call

- a. A critical part of these discussions is **the release of stockpiles** and how to prioritize given a limited supply. Criteria for the release of stockpiles is therefore an important issue, and the guidance from the working group shall be in line with public health priorities, taking into account current definitions from public health actors, public health financiers, including that of GAVI.
- b. **WHO guidance** on use, allocation and implementation will serve as a point of departure for CEPI, but an important part of this working group will be to expand the thinking on this. Modelling will thus be important in informing this Working Group. The CEPI secretariat are invited to the relevant WHO modelling working groups and WHO group on study design /phase III clinical designs in case of an emergency outbreak.
- c. The **regulatory working group must also be consulted** to better understand the regulatory requirements prior to an outbreak in the preparedness phase, as well as **regulatory issues around the necessary stockpiling of investigational vaccine** and issues around phase 3 clinical trials. Although interlinked, **investigational and**

licensed vaccines must therefore be understood as two separate issues in our work going forward.

- d. In addition to the modelling, we need a better understanding of the state of knowledge to determine vaccination strategies, deployment plans etc. **This working group should as such perform a mapping of current actors in the field**, including implementers (countries, NGOs). Their plans and strategies can be used as a reference point for discussing criteria for allocation of the final product, and addressing identified gaps.

- e. **Different disease groups will have different demands** in terms of stockpiling and deployment, and should therefore be mapped out. This also relates to the question of ensuring an appropriate level of investigational vaccines either through i) stockpiles or ii) rapid production capacity.

3. Next steps

- a. Working group members are invited to
 - i. Provide **written feedback on the ToRs** and the concept note as soon as possible.
 - ii. Suggest **names of other stakeholders** who should be consulted as part of the mapping exercise
 - iii. Suggest **additional questions** for the mapping exercise.

- b. The secretariat will
 - i. Conduct separate interviews with members of the working group to get a better understanding of their views on the scope of the work going forward
 - ii. Collate the written feedback and provide a revised concept note and ToRs, including based on information from the interviews.
 - iii. Suggest a detailed work plan, with special attention to making a clear distinction between pre- and post-licensure requirements and issues around vaccines funded by CEPI

4. Work plan

What	When
Agree on concept and members of the Working Group	February
Establish the working group and set-up a first meeting	Early March
Agree on focus areas and work plan	Late April
Agree on timelines and milestones for the Working Group	Late April
Ongoing work presented to Interim CEPI Board	July
Ongoing work presented to Interim CEPI Board	September
Ongoing work and preliminary recommendations presented to the JCG, to feed into final report.	October
Analysis, recommendations and final report presented to the CEPI Board	November