Coalition for Epidemic Preparedness Innovations

Procurement and Stockpiling Working Group
March 29, 2017
Teleconference I

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

Overview

- This working group is appointed by the Secretariat, based on recommendations from the JCG, and a mandate from the Board. CEPI has two other working groups established on Regulatory affairs and Finishing the job on Ebola vaccines, which also would be important to consider in areas that overlap with that of this group.
- 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.

Points discussed during the call

- 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.
- 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.
- 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.
- 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.
- 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.

Next steps

- Working group members are invited to
    - Provide written feedback on the ToRs and the concept note as soon as possible.
    - Suggest names of other stakeholders who should be consulted as part of the mapping exercise
    - Suggest additional questions for the mapping exercise.
- The secretariat will
    - 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
    - Collate the written feedback and provide a revised concept note and ToRs, including based on information from the interviews.
    - Suggest a detailed workplan, with special attention to making a clear distinction between pre- and post-licensure requirements and issues around vaccines funded by CEPI