

Essential medicines and health products

Public consultation on ideas for potential platforms to support development and production of health technologies for priority infectious diseases with epidemic potential (as posted on the

web at http://www.who.int/medicines/ebola-treatment/public_consult_platform-tech/en/,

accessed March 2016

The R&D Blueprint for infectious diseases with epidemic potential

An efficient and effective research response during an infectious disease epidemic requires preparedness – work done between epidemics to fill knowledge gaps, identify potentially useful candidate medical products and other interventions, and to ensure the timely availability of such when the next epidemic occurs.

Following a request from its Member States, the World Health Organization (WHO) is pioneering a global effort, through the R&D Blueprint, to increase R&D preparedness for future epidemics. The Blueprint will promote research to better understand the human-pathogen interface and to generate safety data from Phase 1 studies in man for the most promising experimental products for priority infectious diseases before the outset of an outbreak. It will also facilitate an enabling environment to conduct R&D during an emergency. This public consultation on ideas for platforms to develop and produce relevant health technologies is one activity within the Blueprint.

Executive Summary

The epidemic of Ebola Virus Disease (EVD) in West Africa showed that the world is unable to develop effective interventions in a timely manner for control of severe emerging infectious diseases using current R&D approaches to vaccine, drug and diagnostics development.

The WHO is soliciting ideas for platform technology solutions that are sufficiently flexible to develop and manufacture candidate products for clinical trials in a timely manner (months rather than years) against a variety of infectious disease threats. Such production platforms should focus on a prioritized list of 5 to 10 severe emerging diseases with the potential to generate a public health emergency.

Proposals should include plans for scaling up candidate products at an appropriate scale to contribute to epidemic control, if and when needed. Products resulting from this process should be available and affordable for public health use in low and middle income countries (LMICs). Proposals should explain what internal resources will be used and what external funding will be required to implement the platform concepts being proposed. Creative approaches are encouraged to develop options that include meaningful participation by entities in LMICs. Options that will result in a strategic geographic distribution of platform production sites, in countries with oversight by a WHO-recognized National Regulatory Authority, are especially welcomed.

Proposals received will be evaluated in a first round by a panel of experts convened by the World Health Organization (WHO). Proposers of the best Round 1 proposals will be invited to submit a more detailed plan as part of a Round 2 evaluation step.

While WHO does not intend to provide direct financial support to any proposal, the most meritorious plans emerging for Round 2 evaluation will be presented for consideration to WHO Member States and other organizations which fund Research and Development, in order to seek financial support for establishment of the platforms.

Background

Current, market-driven models of medical R&D do not cater for the application of medical technologies for diseases that are sporadic or unpredictable, especially when they occur in countries with low investment in health infrastructure and delivery. The challenge becomes even greater when faced with a wholly new disease such as SARS, MERS and Nipah virus infection, which are just three examples of diseases that have emerged at the human-animal interface in the last two decades.

The international community needs to invest to improve our ability to respond to new threats and to prepare itself with a novel R&D paradigm to address future epidemics.

Objectives

The World Health Organization (WHO) is inviting ideas on how to improve research and development readiness against priority infectious disease threats. Specifically, proposals are requested for flexible development and production platform technologies to manufacture candidate products for evaluation in Phase 1 clinical trials before any confirmed epidemic threat, as well as for Phase 2 and 3 clinical evaluations during a potential epidemic. The scope of health products which will be considered includes vaccines, therapeutics (drugs and blood products), and diagnostics against 5 to 10 top priority diseases, to be defined by WHO.

Candidate products developed through this mechanism and that are found to have a favourable benefit-risk profile should be available in sufficient quantity to enable potential use in disease control efforts. Therefore the proposals should go beyond preparing materials for Phase 1 clinical studies only and include strategies to assure readiness for production at an appropriate scale to contribute to epidemic control.

Candidate products developed through this process should be affordable for use in populations in which they are tested and/or needed. The priority pathogens may affect any country but options to address affordability in low and middle income countries (LMICs) need to be included in each proposal.

The manufacturing process must be capable of meeting WHO norms and standards, where they exist, and WHO-requirements for emergency listing of a product or, where appropriate, prequalification. Proposals that will result in a strategic geographic distribution of platform production sites, in countries with oversight by a WHO-recognized National Regulatory Authority, are especially welcomed.

Proposals received will be evaluated in a first round by a panel of experts convened by the World Health Organization (WHO). Successful Round 1 applicants will be invited to work with WHO to develop in Round 2 an operational and costed plan, with agreed milestones. WHO reserves the right to suggest the grouping of complementary proposals into a larger collaborative project. Round 2 plans will likewise be evaluated by a panel of experts, and the best proposals will be presented to potential funders for their consideration.

Requirements

Only proposals that can address more than three priority pathogens will be considered. Products developed through the platform technologies will need to comply with target product profiles, or at least clearly be compatible with developing country needs, and to obtain regulatory approval before use in research studies, and thus proposals utilizing technologies that are known to regulatory authorities will be prioritized.

Completely novel platform technologies are not excluded but will require inclusion of a realistic regulatory plan. Furthermore, products developed through the platform technologies must be capable of meeting, in due course, WHO prequalification requirements.

Award

This public consultation on ideas will not result in funds being awarded. Rather, it will enable a selection of appropriate proposals to be presented to potential funders for decision-making. Proposers are expected to include a justified budget needed to operationalize the plans contained in the proposal. The proposals should also explain what internal resources will be used and what external funding will be required to implement the platform concepts being proposed.

Collaborations

A key goal of this consultation is to encourage the development of options that include meaningful participation by entities in LMICs. The strength of the collaborations included in the application will be one of the evaluation parameters. The scope of the collaborations is not pre-specified by WHO, and we welcome creative ideas. WHO reserves the right to suggest additional collaborations, based on our knowledge of potential partners for the proposed work. Any such additional collaborations would be subject to agreement by the original proposers.

Application process

A. Key dates

- a. Submission of applications by Friday 5 February 2016, 1700 Geneva time
- b. Workshop to present the ideas, by 4/6 April 2016
- c. Notification of invitation to submit a phase 2 proposal by 25 April 2016
- d. Phase 2 proposal deadline (invited proposals only) by Friday 27 May 2016, 1700 Geneva time
- e. Selections completed and notifications sent by end of June 2016

B. Eligibility

The public consultation on ideas is open to non-profit organizations, for-profit companies, international organizations, government agencies and academic institutions.

C. How to apply

Proposals should be submitted electronically to the following email addresses: woodd@who.int with a copy to gracet@who.int

D. Format

The proposal should clearly communicate the platform being proposed in not more than 5 pages. The proposal should cover the following elements:

1. **Concepts and ideas:** Describe and justify the rationale for the proposal and the impact the idea will have on R&D readiness.
2. **Proposed technical approach:** Succinctly describe the technical details of the technology platform, including any prior use or experience with other products, and scientific and technical justifications why the platform would be useful for products to address the priority pathogens. It will also be necessary to describe how the technology lends itself to rapid scaling up on demand at the time of an outbreak.
3. **Proposed collaborative approach:** Succinctly describe how meaningful participation by entities in LMICs will be achieved, and the intended strategic geographic distribution of platform production sites. Include a description of the how collaborations between partners will be structured and managed.
4. **Costs and timelines:** Include estimates of costs, per year, of the proposal. Indicate what resources the proposers will donate to the project and, with justifications, what external resources are requested. Indicate what deliverables, in terms of candidate products for the priority pathogens, will become available and over what timelines. Also indicate how affordability of products for LMICs developed through this proposal will be addressed.

Evaluation and selection process

The application review process will be as follows:

1. An initial screening of applications by the WHO secretariat to determine if they are within scope of the request for ideas. Proposals that are out-of-scope will be removed from further consideration, and the applicant informed.
2. Reviews of proposals that are within scope will be conducted by an ad hoc Advisory Group convened by WHO specifically to provide advice on the proposals. This review will be preceded by a workshop at which the responses to the public consultation will be presented with participation from all stakeholders.
3. Experts selected for the ad hoc group will undergo WHO declaration of interest review to identify and manage conflicts of interest. This group will advise WHO on the strengths and weaknesses of the proposals to improve R&D readiness for the priority pathogens. The review will also address the likelihood of meaningful participation by entities in LMICs, and the strengths of the proposed organizational and management structures.
4. Decisions on the proposals that will be invited to submit detailed plans for round 2 will be made by WHO. Additional instructions will be provided at that time. Proposals selected to go forward to round 2 may be subject to suggested modifications.
5. Evaluation of the round 2 proposals will be made by the ad hoc Advisory Group, who will identify proposals that merit consideration for funding support
6. WHO will conduct due diligence reviews of the selected proposals, and propose the platforms for consideration by potential funders.

Contacts

Technical and administrative questions about this Public Consultation should be directed to Dr David Wood (woodd@who.int) with a copy to Theo Grace (gracet@who.int)

Global access and intellectual property

Management of intellectual property (IP) rights is likely to play an important role for the viability of the platform(s). The proposals should explain how IP issues will be managed to ensure fair and equitable access, especially for LMICs, to any product(s) developed through the proposed platform(s).