

MEMORANDUM OF UNDERSTANDING

between

**the World Health Organization,
20 avenue Appia, 1211 Geneva, Switzerland
("WHO")**

and

**The Coalition for Epidemic Preparedness Innovations ("CEPI")
c/o Norwegian Institute of Public Health
Lovisenberggata 8, 0456 Oslo, Norway**

WHEREAS WHO, aims to promote faster and more effective R&D response to public health emergencies of international concern (PHEIC) ;

WHEREAS the aims of CEPI, a coalition of governments, foundations, academia, industry and civil society, are to develop a streamlined approach to the development of vaccines for infections of epidemic potential;

WHEREAS WHO and CEPI, hereinafter also referred to as "the Parties", believe that technical collaboration between the two organizations will contribute to the shared goals of researching and developing safe, effective, and affordable interventions to address infections of epidemic potential;

WHEREAS the Parties furthermore believe that agreement in advance on certain aspects of individual collaborative projects (as the Parties may identify on a case-by-case basis) will facilitate the early implementation of such projects, in particular by facilitating the conclusion of the agreements to which such projects would be subject;

NOW, therefore, the Parties hereby agree as follows:

1. Areas of collaboration

The scope of the collaboration under this MOU aligns with the three key approaches outlined in the WHO R&D Blueprint Plan of Action: 1) Improving coordination and fostering an enabling environment for R&D; 2) Accelerating the R&D processes without sacrificing scientific rigor or public safety; 3) Developing new norms and standards adapted to and appropriate for an epidemic context.

Key WHO core activities which have specific relevance to this collaboration are listed below.

- WHO develops policy advice through its various advisory and expert committees, and this advice is shared with Member States and other interested stakeholders.
- WHO convenes representatives from national and regional regulatory authorities to facilitate regulatory alignment and optimization and to provide scientific advice on vaccine development.



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- WHO facilitates international regulatory collaboration to accelerate regulatory input into and review of vaccine clinical trial applications as well as ethical review of protocols.
- WHO holds the responsibility for identifying PHEIC as defined under the International Health Regulations (2005).

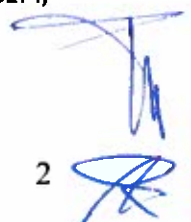
Key CEPI strategic objectives relevant to this collaboration are the following:

- Preparedness: advance late-stage Emerging Infectious Diseases (EID) vaccine development to enable testing in the initial stages of an outbreak
- R&D response speed: build technical and institutional platforms to accelerate research, development, manufacturing, and evaluation in an outbreak
- Market predictability: secure industry participation through partnerships that share the risks and benefits of vaccine development
- Equity: support the long-term development of regional capabilities for EID vaccine preparedness

Where possible and appropriate, the Parties wish to collaborate in the following areas:

1.1 Meet public health needs through acceleration of R&D for pathogens with epidemic potential suffering from market failures

- CEPI will be invited as appropriate and as an observer to WHO's technical consultations for: identifying priority pathogens; development of Target Product Profiles and Preferred Product Characteristics for vaccines targeting diseases on WHO's list of priority pathogens;
- CEPI will prioritize vaccines in which to invest CEPI's vaccine R&D resources and efforts based on a WHO priority list of pathogens (to be updated annually), taking into account potential disease impact, scientific challenges, production feasibility, product safety, lack of a commercial market, and subsequent access requirements of the future vaccines.
- CEPI will use a transparent decision making mechanism to identify those pathogens for which a viable vaccine may be considered a likely and appropriate public health intervention.
- CEPI will consider available WHO guidance documents including WHO Target Product Profiles and Preferred Product Characteristics in its decision-making processes on funding.
- Should a pathogen not on the WHO list be considered of crucial importance for vaccine R&D preparedness and present opportunities for accelerated development within the CEPI partnership, CEPI will consult with WHO and other relevant partners as to whether or not to pursue this opportunity.
- CEPI will develop and maintain the ability to rapidly respond to outbreaks of new or unknown pathogens, in close coordination and cooperation with WHO.
- Through participating as an observer in the development and operations of CEPI, WHO will contribute to CEPI's effort to effectively deliver on its public health



objectives, addressing priority health needs, and promoting the affordability of any new vaccines .

1.2 Improve global coordination, investment, and incentives for advanced vaccine R&D

- CEPI, along with other stakeholders, will contribute to WHO's efforts to develop a balanced and transparent partnership approach to prioritization, implementation, and access to vaccine R&D pathways.
- CEPI will take an implementing role in developing a new partnership model for the development of vaccines for epidemic preparedness.
- CEPI will be invited as appropriate and as an observer to participate in: WHO's work on data sharing norms, including addressing the barriers to rapid information sharing during a disease outbreak of significant public health importance; and WHO's development of a global R&D coordination mechanism to streamline global stakeholder collaboration.
- CEPI will be responsive to the global coordination mechanisms established by WHO, and will provide a mechanism to coordinate and communicate across global vaccine development stakeholders.
- CEPI will support WHO's ongoing work on strengthening open access to research resources for preparedness and vaccine R&D activities related to the priority pathogens.
- CEPI 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.

1.3 Ensuring global regulatory optimization and alignment, and strengthen global scientific advice on vaccine development for emerging infections

- WHO will liaise with CEPI and other stakeholders in the global health community as appropriate and will provide technical and other regulatory strengthening assistance to member states as requested by the member states.
- WHO will facilitate 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.
- CEPI will implement guidance and standardized templates for issues such as data and sample sharing and liability, as developed by WHO and regulatory authorities or other competent national bodies to optimize the vaccine development process.
- CEPI will facilitate that regulatory guidance and globally aligned scientific advice provided through WHO can be utilized by its implementing partners.
- CEPI will utilize expertise from national and regional regulatory authorities to inform CEPI's priorities, policies, investment decisions and portfolio management.

1.4 Development and implementation of new norms and standards adapted to and appropriate for an epidemic context

- CEPI 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.
- CEPI will be invited as appropriate and as an observer to participate in WHO's ongoing work on addressing methodological issues concerning appropriate clinical trial designs during epidemics.
- CEPI will implement, in line with the normative guidance of WHO, appropriate study design for clinical trials with respect to preparedness for, emergency response to, and post-emergency continued learning about an epidemic or other significant public health emergency.
- CEPI will support WHO's efforts to promote norms and standards and related capacity building with respect to vaccine R&D for epidemics and other significant public health emergencies when member states so request.

In addition to the above-mentioned activities, WHO and CEPI will collaborate in further areas as outlined below:

1.5 Strengthen global regulatory capacity to address outbreaks of epidemic potential and public health emergencies

- CEPI will support WHO's work on strengthening global regulatory capacity for vaccine development addressing the scope of CEPI and the R&D Blueprint.

1.6 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

- In the event of a PHEIC or other emergency scenario of epidemic potential, CEPI will recognize and be responsive to WHO leadership and advice on rapid research response.
- 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
- 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.
- CEPI reserves the right to initiate vaccine R&D in response to outbreaks of known or unknown pathogens independent of WHO's procedures to declare a PHEIC, but will coordinate its activities with relevant WHO senior leadership

2. Collaborative activities

Any collaborative activity as outlined in article 1 above shall be subject to the availability of sufficient financial and human resources for that purpose, as well as

each Party's programme of work, priority activities, internal rules, regulations, policies, administrative procedures and practices. Each collaborative activity shall thus be agreed on a case-by case-basis, subject to a separate exchange of letters or agreement.

3. Funding

- 3.1 Each Party hereto shall be fully responsible for the funding of its activities under this Memorandum of Understanding, except as may otherwise expressly be agreed in any subsequent letter of agreement.
- 3.2 Each Party shall administer the funds handled by it in accordance with its financial regulations, rules and administrative practices.

4. Confidentiality

It is acknowledged that each Party may possess confidential information, which is proprietary to it or to third parties collaborating with it. Any such information shall only be shared between the Parties under a separate confidential disclosure agreement, specifically covering such information.

5. Publications

- 5.1 Subject to each Party's proprietary rights and/or the proprietary rights of others, and without prejudice to obligations of confidentiality, the results of any collaborative activity under this Memorandum of Understanding may be published by either Party. The Parties are encouraged to publish the results of their joint work in a collaborative fashion. Guidelines for authorship of major, international, peer-reviewed journals will be used to establish authorship of collaborative publications. In regard to separate publications, it is agreed that in order to avoid prejudicing proprietary rights and the confidentiality of information, the publishing Party shall transmit to the other party for its review the material intended to be published at least 60 days before a proposed publication is submitted to any editor, publisher, referee or meeting organizer. In the absence of any objection by the other Party within that 60 day period, concerning prejudice to proprietary rights or confidentiality of information, the publication may proceed. Any publication as referred to above shall duly acknowledge both Parties. In addition to review of the content of publications as referred to above, each Party shall have the right to review the acknowledgement and request reasonable changes to the use of its name, or request that its name be deleted altogether.
- 5.2 Copyright in any jointly prepared publications resulting from or relating to any of the collaborative activities under this Memorandum of Understanding shall be vested in WHO and CEPI jointly, who shall each independently and severally be entitled to exploit such copyright in any manner and for any purpose as they may each in their sole discretion deem appropriate, except that no use shall be made of such publications for or in conjunction with commercial and/or promotional purposes.
- 5.3 Copyright in any publications resulting from or relating to any of the collaborative activities under this Memorandum of Understanding, and prepared by one of the Parties hereto on its own, shall be vested in that Party, provided however, that any

such publication shall be submitted to the other Party for review and comment in accordance with paragraph 5.1 above.

6. Products resulting from the collaboration

6.1 The Parties shall make appropriate arrangements to promote that any product which may result from collaborative research and development work undertaken as a result of this Memorandum of Understanding, shall be made widely available to the public on reasonable terms, including in particular to the public sector of developing countries on preferential terms. Any possible additional benefits, including royalties, shall be granted to each Party with due account being taken of the relative value of each Party's financial, intellectual and other contributions to the product (provided that priority shall always be given to the objective of the Parties set forth in the first sentence of this paragraph 6.1).

6.2 Ownership of any intellectual property rights arising from collaborative activities under this Memorandum of Understanding shall be agreed by the Parties on a case-by-case basis. However, regardless of whether the Parties shall agree that ownership of the intellectual property rights of a particular collaborative activity shall be vested in WHO and CEPI jointly, or WHO or CEPI alone, or in any third party, the Parties agree that the industrial or commercial exploitation of such rights shall be designed to achieve the objectives set forth in paragraph 6.1 above, and shall be subject to and exercised in accordance with an agreement to be negotiated in good faith between WHO and CEPI, or WHO, CEPI and the third party concerned, as the case may be.

7. Liability

7.1 Each Party shall be solely responsible for the manner in which it carries out its part of the collaborative activities under this Memorandum of Understanding. Thus, a Party shall not be responsible for any loss, accident, damage or injury suffered or caused by the other Party, or that other Party's staff or sub-contractors, in connection with, or as a result of, the collaboration under this Memorandum of Understanding.


7.2 The Parties shall make appropriate arrangements to cover liability risks for any collaborative activities involving product research and development.

8. Use of the Parties' names

Except as explicitly provided in this Memorandum of Understanding, neither Party shall, in any statement or material of a promotional nature, refer to the relationship of the other Party to the collaboration pursuant to this Memorandum of Understanding, or otherwise use the other Party's name, acronym and/or emblem, without the prior written consent of the other Party.

9. Relationship of the Parties

For the purposes of this Memorandum of Understanding, each Party is an independent contractor and not the joint venturer, agent or employee of the other Party. Neither Party shall have authority to make any statements, representations, or



commitments of any kind, or to take any action which shall be binding on the other Party, except as may be explicitly provided for in this Memorandum of Understanding or authorized in writing by the other Party.

10. Termination

This Memorandum of Understanding may be terminated by either Party, subject to 6 months' advance written notice to the other Party. Notwithstanding the foregoing, it is agreed that any termination of this Memorandum of Understanding shall be without prejudice to: (i) the orderly completion of any ongoing collaborative activity; and (ii) any other rights and obligations of the Parties accrued prior to the date of termination of this Memorandum of Understanding.

11. Amendments

This Memorandum of Understanding may only be amended in writing by mutual consent of the Parties.

12. Settlement of disputes

Any dispute relating to the interpretation or execution of this Memorandum of Understanding, or of any subsequent exchange of letters or agreement with respect to individual collaborative activities shall, unless amicably settled, be subject to conciliation. In the event of failure of the latter, the dispute shall be settled by arbitration. The arbitration shall be conducted in accordance with the modalities to be agreed upon by the Parties, or in the absence of agreement, in accordance with the rules of arbitration of the International Chamber of Commerce. The Parties shall accept the arbitral award as final.


13. Privileges and Immunities of WHO

Nothing contained herein shall be construed as a waiver of any of the privileges and immunities enjoyed by WHO under national or international law, and/or as submitting WHO to any national court jurisdiction.

Agreed and accepted:

For the World Health Organization

For CEPI

Signature: 
Name: Marie-Paule KIENY

Signature: 
Name: John-Arne Røttingen

Title: Assistant Director-General
Health Systems and Innovation

Title: Interim CEO

Date: 15 September 2016

Date: 15 September 2016