First Invitation to manufacturers of vaccines against Covid-19 to submit an Expression of Interest (EOI) for evaluation by the WHO (Prequalification and/or EUL)

1. Introduction:
The World Health Organization (WHO), through its Department of Regulation and Prequalification (RPQ), provides advice to the United Nations Children’s Fund (UNICEF) and other United Nations (UN) agencies on the acceptability, in principle, of vaccines considered for purchase by such agencies. The purpose of the WHO prequalification assessment is to provide assurance that candidate vaccines: (a) meet the WHO recommendations on quality, safety and efficacy, including compliance with WHO recommended Good Manufacturing Practice (GMP) and Good Clinical Practice (GCP) standards; and (b) meet the operational specifications for packaging and presentation of the relevant UN agency. This is to ensure that vaccines provided through the UN for use in national immunization services in different countries are safe and effective, and are suitable for the target populations, at the recommended immunization schedules, and with appropriate concomitant products.

Several conditions apply for PQ evaluation (a) the vaccine is considered a priority for UN supply, (b) complies with mandatory characteristic for programmatic suitability http://www.who.int/immunization_standards/vaccine_quality/ps_pq/en/index.html, (c) the National regulatory authority (NRA) responsible for the regulatory oversight of the product has been assessed by WHO as “functional”, and (d) a marketing authorization (MA) or emergency use authorization (or equivalent) has been granted by the relevant NRA.

The PQ process takes into account needs from WHO programmes (e.g. Immunization, Vaccines and Biologicals) and the International Health Regulations to comply with eradication, elimination or control initiatives as well as recommendations of WHO’s Strategic Advisory Group of Experts (SAGE) on immunization.

WHO RPQ has also developed the Emergency Use Listing (EUL) process to expedite the availability of unlicensed medical products needed in public health emergency situations. The process assists interested UN procurement agencies and Member States in determining the acceptability of using specific products in the context of a public health emergency (PHE), based on an essential set of quality, safety, and efficacy/immunogenicity data.

The EUL procedure defines (a) the steps that WHO will follow to establish eligibility of unlicensed products for assessment under this procedure, (b) the essential information required, and (c) the process to be used in conducting the assessment to determine whether an unlicensed product can be listed on a time limited basis, while further data are being gathered and evaluated. In addition, draft points to consider for the assessment of Covid-19 vaccines have been developed and published.
The WHO EUL is not equivalent or an alternative to WHO prequalification, and should not be thought of as such. The EUL is a special procedure for unlicensed vaccines, (and also for medicines and in vitro diagnostics) in the event of a PHE when the community/public health authorities may be “willing to consider the use of vaccines that have had critical information on efficacy and safety available”. EUL is intended to provide a time-limited listing for unlicensed products in an emergency context when available evidence of quality, safety and efficacy outweighs the risk. As part of the EUL, it is expected that the manufacturer will complete the development of the product and submit for licensure and WHO prequalification.

Based on the current status of development of Covid-19 vaccines candidate, the extent of the available quality, safety and efficacy data and regulatory approvals by relevant NRAs, WHO will determine whether to follow either the EUL process or Prequalification.

2. Purpose of this invitation for EOI
   The first call for submission of EOI is open to candidate vaccines in phase IIb/III clinical trials that are expected to be submitted for evaluation by a National Regulatory Authority within the next 6 months. Priority will be given to candidate vaccines that are expected to meet all or most of the WHO published TPP characteristics (https://www.who.int/publications/m/item/who-target-product-profiles-for-covid-19-vaccines). Those EOIs that are considered acceptable to proceed with the submission of a dossier, will be assessed according to either the EUL procedure (https://www.who.int/publications/m/item/emergency-use-listing-procedure) or PQ https://www.who.int/immunization_standards/vaccine_quality/vq_index/en/ and relevant guidance in the WHO Technical Report Series
   https://www.who.int/biologicals/Relevant_WHO_documents_for_SARS-CoV-2_vaccines_and_other_biologicals.TZ.IK.7_Apr_2020.pdf?ua=1

3. Evaluation criteria
   Criteria that will be used to assess clinical trial design, endpoints, and statistical criteria described in the recently published draft considerations document-.
   https://www.who.int/medicines/regulation/prequalification/prequal-vaccines/WHO_Evaluation_Covid_Vaccine.pdf?ua=1

   Criteria that will be used to assess clinical trial design, endpoints, and statistical criteria described in the recently published draft considerations document-

4. How to submit an EOI
   Interested manufacturers will submit expressions of interest for vaccines evaluation by a letter to the Vaccines & Immunization Devices Assessment Team (whoeul@who.int). The letter should include the following information:
   a) Name of the product

*Call for EOI Covid-19_V8-FINAL_01/10/2020*
b) Contact person

c) Email address

d) Description of the vaccine, presentation, indication

e) Current phase of clinical trial, date of initiation and completion

f) High level details of interactions with national regulatory authorities

g) Agreement in principle to allow national regulatory authorities to share confidential information with WHO to facilitate collaboration

h) Status of interactions with COVAX

5. Pre-submission meeting

Manufacturers that meet the criteria in point 1) and have submitted a complete EOI as per point 2) will be contacted to schedule a pre-submission meeting to discuss the assessment procedure to be used (EUL/PQ), assessment pathway, date of submission of the dossier, readiness of submission package, upcoming availability of supplemental data and other important information that will help the manufacturer make decision on the submission and will help WHO coordinate resources to assess the dossier within the shortest possible timeline, details of rolling submissions and general requirement for data to be submitted.

6. Contact information

Please submit your Letter of EOI to whoeul@who.int