First Invitation to manufacturers of vaccines for prevention against mpox to submit an Expression of Interest for evaluation by the World Health Organization

August 2024

1. Introduction

The World Health Organization (WHO), through its Department of Regulation and Prequalification (RPQ), provides advice to the United Nations (UN) procurement agencies (United Nations Children's Fund (UNICEF)), other UN agencies, National Regulatory Authorities (NRA) and National Control Laboratories (NCL), as well as to vaccine manufacturers, on the acceptability of vaccines considered for purchase.

The goal of the WHO vaccines prequalification programme[1] 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.

Both the Emergency Use Listing and Prequalification assessment ensure that vaccines for use in national immunization services in countries are safe, effective, of assured quality and suitable for the target populations, at the recommended immunization schedules, and with appropriate concomitant vaccines.

The EUL procedure is specifically developed to expedite the availability of unlicensed medical products needed in public health emergency situations., using a risk-benefit approach, to provide a time-limited recommendation for unlicensed vaccines,, when available evidence of quality, safety and efficacy outweighs the foreseeable risks and uncertainties.

The following criteria for EUL must be met:

- The disease for which the product is intended is serious or life threatening and has the potential of causing an outbreak, epidemic or pandemic;
- Existing products have not been successful in eradicating the disease or preventing outbreaks;
- The product is developed and manufactured in compliance with current International recognized standards such as Good Manufacturing Practices (GMP), Good Clinical Practices (GCP) and Good Laboratory Practices (GLP);
- complies with mandatory characteristic for programmatic suitability[2];
- The national regulatory authority (NRA) responsible for the regulatory oversight of the vaccine has been assessed and documented as a "WHO listed authority"[3];

[1] https://extranet.who.int/prequal/vaccines/welcome-vaccines-prequalification
[2] http://www.who.int/immunization_standards/vaccine_quality/ps_pq/en/index.html
[3] https://www.who.int/initiatives/who-listed-authority-reg-authorities

- The NRA of reference has granted a regulatory approval (Emergency Use Authorization, conditional marketing authorization or equivalent)

2. Purpose of this invitation for EOI

The first call for submission of an EOI is open to candidate vaccines that fulfill the EUL requirements. Priority will be given to candidate vaccines that are expected to meet all or most of the WHO TPP characteristics.

Only those EOIs that are considered acceptable to proceed with the submission of a dossier, will be assessed according to the EUL procedure[4], prequalification standards[5] [6]and relevant guidance in the WHO Technical Report Series "Recommendations for the production and quality control of smallpox vaccine, revised 2003, Annex 1, TRS No 926".[7]

3. 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
b) Contact person
c) Email address
d) Description of the vaccine, presentation, indication
e) Current status of ongoing clinical trials
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

4. 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, 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

[4] https://www.who.int/publications/m/item/emergency-use-listing-procedure
[5] https://www.who.int/publications/m/item/TRS-978-61st-report-annex-6
[6] https://extranet.who.int/prequal/vaccines/who-technical-report-series
[7] https://www.who.int/publications/m/item/smallpox-vaccine-revised-2003-annex-1-trs-no-926

submissions and general requirement for data to be submitted. Please note that full dossier including relevant NRA approvals and assessment reports should be submitted for evaluation.

5. Contact information

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