

Use of Emergency Use Listing procedure for vaccines against Covid-19 Q&A

NOTE: this Q&A should be read as a supplement to the general Q&A document for the EUL

What is the EUL?

The WHO Emergency Use Listing (EUL) is a procedure for assessing unlicensed vaccines, therapeutics and in vitro diagnostics during public health emergencies with the ultimate goal of expediting the availability of these products to people who need them.

When can the EUL be used?

The EUL is used during public health emergencies. When products are not licensed yet (still in development), WHO will assess the quality, safety and efficacy (or performance) data generated during development and conduct a risk-benefit assessment to decide if they can be used outside clinical trials.

Do the eligibility criteria for EUL apply to COVID-19 products?

Yes, all eligibility criteria are applicable. These are: the disease may cause an outbreak, epidemic or pandemic; there are no products available capable of eradicating or preventing the disease; products are manufactured in compliance with good manufacturing practices; and the applicant undertakes to complete the development of the product and apply for prequalification once it is licensed.

Does the EUL provide for products developed after a public health emergency has been declared?

Yes. The procedure provides for a situation where the vaccine can be assessed after the public health emergency of international concern/pandemic has been declared. In this particular instance, WHO may select a group of experts from the pre-established roster to accelerate the assessment and issue a recommendation within a short timeline.

How soon can a vaccine against Covid-19 be assessed under the EUL?

The EUL provides an assessment pathway for investigational products. The development of vaccines against Covid-19 did not start until after the outbreak, as the disease is caused by a novel virus. An unprecedented global effort has seen multiple vaccine candidates move into clinical trials (human studies). Early discussions between vaccine developers and WHO PQ are strongly encouraged. For an investigational vaccine to be considered fit for use in a

public health emergency, data should demonstrate that there is a benefit in the target population that outweighs the risk of its use.

Does WHO need to evaluate a product that has already been approved by a WHO listed authority for use during public health emergencies ?

When a product submitted for EUL has been assessed through other emergency mechanisms by a WHO Listed authority, WHO does not intend to duplicate work. However, WHO will assess the suitability of products from a global public health perspective and, on a case-by-case basis, may assess aspects of the quality, safety, efficacy and performance of the products .

Do clinical trials continue after a product has been assessed and listed under the EUL procedure?

Yes. The fact that the vaccines are granted a recommendation to be used in a public health emergency whilst they are still under development is only a temporary measure to ensure availability of preventive tools that present a favorable benefit-risk ratio in the context of the public health emergency (PHE). However, manufacturers commit to continue with the development and if completed successfully, will submit the product for registration and apply for prequalification. Manufacturers are expected to provide detailed guidance and a risk management plan.

Will the evaluation of Covid-19 vaccines continue after the PHE is no longer in effect?

Once the PHE is no longer in effect, those products assessed during the pandemic are expected to continue their development. Therefore, new quality, safety and efficacy data should be made available for assessment and the risk benefit assessment will be updated. If such products are registered, they will be eligible for prequalification and not for EUL assessment.

Does the EUL procedure ensure rapid availability?

The EUL allows products in development (not licensed) to be assessed by WHO for listing. WHO review is expedited to ensure timely evaluation. The manufacturer's diligence in addressing WHO's questions influences the assessment timelines as well. The procurement and distribution processes that have an impact on the timeline for availability of listed products is beyond the scope of the EUL procedure.

How will WHO interact with National Regulatory Authorities?

WHO actively promotes the principles of reliance for interactions with NRAs based on facilitated regulatory pathways, as was done for Ebola virus disease vaccine. Virtual meetings will be organized with the NRAs from target countries for vaccine deployment. However, identifying the target countries may be complex due to the changing Covid-19 situation. In addition, WHO is mapping the regulatory requirements of countries for emergency use of vaccines during a PHE. Further, subject matter experts from NRAs, and regulatory networks, will be involved in the EUL assessment process of candidate vaccines.