Update on WHO approval process for COVID-19 vaccines

The World Health Organization (WHO), through its Department of Regulation and Prequalification (RPQ), provides advice on the acceptability, in principle, of vaccines considered for purchase. This is known as vaccine prequalification (PQ).

In addition, WHO has developed a time-limited Emergency Use Listing Procedure (EUL) to expedite the availability of medical products needed in public health emergency situations, such as COVID-19. The intention of EUL is to provide expert advice on the acceptability for use of specific products in the context of a public health emergency, based on an essential set of available quality, safety, and efficacy/immunogenicity/performance data.

Currently, over 220 vaccines are at some stage of development. Of these, at least 56 candidate vaccines are in human trial. About 14 are in phase III trials. WHO is already beginning to see preliminary results from phase III large-scale trials. While the news is encouraging, all of us need to wait for the efficacy and safety data that will be available after the primary endpoints of the trials are reached.

WHO maintains a draft landscape of candidate vaccines. On 2 October 2020, WHO published a call for expressions of interest for manufacturers of COVID-19 vaccines to apply for approval for emergency use listing. WHO is already discussing with some manufacturers and evaluating the data shared with WHO. On 25 November 2020, WHO released detailed guidelines for consideration to evaluate COVID-19 vaccines. This document provides advice to manufacturers on both the process and the criteria that will be used by the WHO to evaluate COVID-19 vaccines that are submitted either for prequalification or for Emergency Use Listing. The current status of development of a candidate Covid-19 vaccine, the extent of the available quality, safety and efficacy data and regulatory approvals by relevant NRAs will guide WHO's decision on which pathway (PQ or EUL) to follow for each vaccine. Only vaccines that have undergone phase IIb or phase III studies and have received authorization from a reference NRA should be submitted for consideration.

As of 21 December 2020, no COVID-19 vaccine has been validated by WHO. WHO will only validate vaccines that are shown to be safe and effective.

Sources:

1. https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines
2. https://www.who.int/publications/m/item/who-working-group-target-product-profiles-for-covid-19-vaccines
3. https://www.who.int/publications/m/item/considerations-for-the-assessment-of-covid-19-vaccines-for-listing-by-who
4. https://www.who.int/teams/regulation-prequalification/eul/eul-vaccines
5. https://www.who.int/immunization_standards/vaccine_quality/EUL/en/
6. https://www.who.int/immunization_standards/vaccine_quality/pq_revision2010/en/

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