Addendum to 23rd WHO Regulatory Update on COVID-19

04 December 2020

World Health Organization

Key Messages

The UKs medicine licensing authority (MHRA) has issued an emergency use authorization for the Covid-19 vaccine BNT162b2 supplied by Pfizer and BioNTech. WHO has received the data on the vaccine from the manufacturer and is reviewing it for possible listing for emergency use..

Highlights and main issues

- A technical brief from the COVAX Regulatory Advisory Group, including views on comparability studies to support manufacturing changes, and on the use of burden of disease as an end-point for vaccine efficacy, is provided as an annex to this document.
- ICMRA members, a global coalition of medicine regulators, have issued a statement in support of continuing COVID-19 vaccine trials to collect critical data to support regulatory actions and deployment, for as long as is feasible.
- The US FDA's Center for Biologics Evaluation and Research's (CBER), Vaccines and Related Biological Products Advisory Committee (VRBPAC) will meet in open session to discuss Emergency Use Authorization (EUA) of the Pfizer/BioNTech COVID-19 Vaccine on 10 December 2020, and also on 17 December 2020 to discuss EUA of the Moderna, Inc., COVID-19 Vaccine.
- The WHO Pharmacovigilance team will host a Global Webinar on the WHO COVID-19 Vaccines safety surveillance manual on 15 December 2020, 13:30-15:30 CET.

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Update on the ACT-Accelerator

Technical briefs from the COVAX Regulatory Advisory Group

The vaccine pillar, COVAX, of the ACT accelerator has established a Regulatory Advisory Group (RAG) which is co-lead by WHO and CEPI. The RAG has members from Regulatory Agencies covering all WHO regions, including Argentina, Australia, Brazil, Canada, Europe (EMA & EDQM), Ghana, Japan, Singapore and USA. The RAG was set up to give feedback on regulatory science questions of an agnostic nature raised by the COVAX teams in order to promote regulatory preparedness among COVID-19 vaccine developers. The RAG applies the Chatham House rules, and divergent views are reported as such without attribution. The feedback, in the form of technical briefs, is intended to serve as a means to make the wider community of Regulatory Authorities aware of questions and challenges vaccine developers are facing in development of COVID-19 vaccines.

> Annex to this Addendum: 1st Technical Brief: Regulation of COVID-19 vaccines – Synopsis from the August to October COVAX RAG meetings

Alignment of approaches by regulators

ICMRA Statement on continuation of vaccine trials

ICMRA members, a global coalition of medicine regulators, have issued a statement in support of continuing COVID-19 vaccine trials to collect critical data to support regulatory actions and deployment, for as long as is feasible. Initial positive evidence of the vaccine's safety and efficacy used to support a regulatory action may be based on planned interim or final analyses that occur when a pre-defined number of cases of COVID-19 disease have occurred in a clinical trial. In these situations, it will be of the utmost importance to continue gathering data about the vaccine safety and efficacy in the longer-term after the interim or final analysis is completed. Specifically, continued follow-up of clinical trial participants after a regulatory decision has been made can provide important additional and more precise information on longer-term safety and efficacy against specific aspects of SARS-CoV-2 disease or infection, including efficacy against severe disease, efficacy in important subgroups, potential risks of vaccine-induced enhanced disease and whether protection against COVID-19 disease wanes over time.

Thus, continued evaluation of the vaccinated and the unvaccinated (control subjects who do not receive a vaccine against COVID-19) groups in clinical trials for as long as feasible will provide invaluable information. For these reasons, investigators and sponsors should develop strategies to ensure continuation of follow-up of vaccinated and control groups for as long as possible after any regulatory approval that is based on planned analyses conducted while trials are still ongoing and after final analyses are completed. Therefore, unless maintaining participants in their randomized treatment groups (vaccinated or control) after a vaccine is approved is clearly infeasible, ICMRA recommends that clinical trials should proceed as initially planned with a follow-up of at least one year or more from completion of assigned doses.

> ICMRA Statement on continuation of vaccine trials

Vaccines

Temporary conditional authorization of a COVID vaccine

The UKs medicine licensing authority has temporarily authorized (under Regulation 174 of the Human Medicine Regulations 2012) specific batches of the Covid-19 vaccine BNT162b2 supplied by Pfizer and BioNTech, in response to the spread of COVID-19. The approval is not a market authorization, and there is therefore no general authorization to place this vaccine on the market. The Medicines and Healthcare products Regulatory Agency (MHRA) will continue conducting its rolling review of the

Pfizer/BioNTech vaccine.

MHRA Conditions of authorisation for Pfizer/BioNTech COVID-19 vaccine (02 Dec 2020)

Information for healthcare professionals and the public about the Pfizer/BioNTech vaccine

WHO is also in discussions with MHRA on the possibility of accessing some of the information from their EUL assessment, which could expedite WHO's emergency listing. In the meantime, WHO's Strategic Advisory Group of Experts on Immunization (SAGE) is also reviewing the vaccine and formulating policy recommendations on how best to use it.

WHO COVID-19 vaccine communication

Sign up to receive WHO COVID-19 vaccine communication updates:

- WHO COVID-19 vaccine content / assets / plans
- WHO COVID-19 Digital content update

Upcoming events:

US FDA Vaccines and Related Biological Products Advisory Committee

As described in the 23rd Regulatory Update, the US FDA's Center for Biologics Evaluation and Research's (CBER), Vaccines and Related Biological Products Advisory Committee (VRBPAC) will meet in open session to discuss Emergency Use Authorization (EUA) of the Pfizer/BioNTech COVID-19 Vaccine for the prevention of COVID-19 in individuals 16 years of age and older on 10 December 2020.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, any background material will be made publicly available at the time of the advisory committee meeting, and additional materials will be posted on FDA's website after the meeting.

Announcement of the CBER VRBPAC meeting on 10 Dec 2020

On December 17, 2020, the CBER VRBPAC will meet in open session to discuss Emergency Use Authorization (EUA) of the Moderna, Inc., COVID-19 Vaccine for the prevention of COVID-19 in individuals 18 years and older.

As above, FDA intends to make background material available to the public no later than 2 business days before the meeting. Any additional background material will be made publicly available at the time of the advisory committee meeting, and additional materials will be posted on FDA's website after the meeting.

Announcement of the CBER VRBPAC meeting on 17 Dec 2020

Webinar: WHO COVID-19 Vaccines safety surveillance manual

The WHO Pharmacovigilance team is hosting a Global Webinar on the WHO COVID-19 Vaccines safety surveillance manual on 15 December 2020, 13:30-15:30 CET.

Please contact gvsi@who.int for further information.

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Webinar: Accelerating access to COVID-19 Vaccine for pregnant and lactating women

COVAX Maternal Immunization Working Group within the COVAX Clinical Development & Operations and Enabling Sciences SWAT Teams is organizing the webinar workshop “Accelerating access to COVID-19 Vaccine for pregnant and lactating women: what do developers need to know?” on Wednesday, 16 December 2020, 16:16 – 19:00 CET.

The workshop webinar aims to provide developers and vaccine stakeholders with product-agnostic supportive information and a forum to communicate and address individual challenges they may face in order to facilitate the inclusion of pregnant women in ongoing or future clinical and observational studies.

To attend the workshop, please register by Monday, 14 December 2020