International Pharmaceutical Federation

Addendum to FIP COVID-19 Guidance (November 2020)

17 November 2020

Vaccines

As of 19 October the World Health Organization reported that there are 44 candidate COVID-19 vaccines under clinical evaluation:

- Phase 1: 21 vaccines
- Phase 1/2: 11 vaccines
- Phase 2: 2 vaccines
- Phase 3: 10 vaccines.

There are nearly 275 COVID-19 vaccine candidates at various stages of development from more than 170 research teams world-wide. Further information is available here.

Two vaccines have been approved by the Russian Federation's Ministry of Health although neither has entered phase 3 clinical trials.

Interim results from the phase 3 trial of the Pfizer/BioNTech COVID-19 vaccine candidate have shown that it is 90% effective with no serious side effects reported. Data collection will continue into the third week of November after which approval will be sought from regulators. Until a formal evaluation of all the data has been conducted, no solid conclusions can be drawn, but the current results are encouraging. If regulatory approval is given quickly, first doses of the vaccine could be given to healthcare workers and people at high risk by the end of 2020. The mRNA vaccine was tested on 43,500 people in six countries and triggers an immune response involving both T-cells and antibodies. The dosing schedule is two doses, three weeks apart with 90% protection achieved seven days after the second dose. There are some concerns around the accessibility of this vaccine to everyone due to logistic requirements and economic capability of some countries and regions.

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Remdesivir

The US Food and Drug Administration has approved the antiviral remdesivir for the treatment of COVID-19 in adults and children over 12 years of age weighing at least 40 kilograms and who require hospital admission. The European Medicines Agency has approved remdesivir under conditional marketing authorisation for the treatment of COVID-19 in adults and adolescents (aged 12 years and older with a body weight of at least 40 kg) who have pneumonia requiring supplemental oxygen. Remdesivir should only be administered in a hospital or a healthcare setting able to provide acute care comparable to inpatient hospital care. (Further information). Other countries authorise conditional use of remdesivir. Important side effects include elevation of hepatic enzymes, gastrointestinal complications, rash, renal impairment and hypotension.

According to preliminary results from a World Health Organization Solidarity trial, remdesivir has little or no impact on survival, initiation of ventilation and length of hospital stay. This trial followed 11,266 adults at 405 hospitals in 30 countries and is awaiting peer review. There is some evidence from other trials, like the NIAID ACTT-1 Study, that remdesivir shortens recovery time of patients with COVID-19.

Outside of the use in clinical trials, remdesivir should be used according to the scientific evidence available at that moment.

Convalescent plasma

It has been postulated that SARS-CoV-2 antibody-rich plasma may be an effective treatment for COVID-19. This plasma is obtained from people who have previously had COVID-19 and have been cured.

Results of an open-label, parallel arm, phase 2, randomised controlled trial of convalescent plasma to treat moderate COVID-19 disease published in the *BMJ* found that use of convalescent plasma was not associated with a reduction in progression to severe COVID-19 or all-cause mortality. The trial involved 464 patients from 39 hospitals in India. More here.

With the information currently available, and given uncertainties over the efficacy and benefit-risk balance of this treatment, the use of plasma from convalescent patients should be limited to the clinical trial setting.

Neutralising antibodies

The US FDA has given Emergency Use Authorisation for Eli Lilly's LY-CoV555 neutralising antibody bamlanivimab for the treatment of mild-to-moderate COVID-19 in adult and paediatric patients.

WHO position on herd immunity

Attempts to reach herd immunity through exposing people to a virus are scientifically problematic and unethical, the World Health Organization said in October. At a media briefing, WHO Director General Tedros Adhanom Ghebreyesus said that not enough is known about immunity to COVID-19. He explained that herd immunity is a concept used for vaccination; measles requires about 95% of a population to be vaccinated and the remaining 5% will be protected, whereas for polio the threshold is around 80%. Until we better understand COVID-19 immunity, it will not be possible to know how much of a population is immune and how long that immunity lasts for. "Letting the virus circulate unchecked therefore means allowing unnecessary infections, suffering and death," Dr Tedros said.

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