

Off-label use of medicines for COVID-19

Scientific brief
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No pharmaceutical products have yet been shown to be safe and effective for the treatment of COVID-19. However, a number of medicines have been suggested as potential investigational therapies, many of which are now being or will soon be studied in clinical trials, including the SOLIDARITY trial co-sponsored by WHO and participating countries.

In many countries, doctors are giving COVID-19 patients medicines that have not been approved for this disease. The use of licensed medicines for indications that have not been approved by a national medicines regulatory authority is considered “off-label” use. The prescription of medicines for off-label use by doctors may be subject to national laws and regulations. All health care workers should be aware of and comply with the laws and regulations governing their practice. Further, such prescribing should be done on a case-by-case basis. Unnecessary stockpiling and the creation of shortages of approved medicines that are required to treat other diseases should be avoided.

It can be ethically appropriate to offer individual patients experimental interventions on an emergency basis outside clinical trials, provided that no proven effective treatment exists; it is not possible to initiate clinical studies immediately; the patient or his or her legal representative has given informed consent; and the emergency use of the intervention is monitored, and the results are documented and shared in a timely manner with the wider medical and scientific community.

The decision to offer a patient an unproven or experimental treatment is between the doctor and the patient but must comply with national law. Where it is possible and feasible for the treatment to be given as part of a clinical trial, this should be done unless the patient declines to participate in the trial.

If it is not possible to give the treatment as part of a clinical trial, appropriate records of the use of the medicine must be kept, in compliance with national law, and outcomes for patients should be monitored and recorded.

If early results from an unproven or experimental treatment are promising, the treatment should be studied in the context of a formal clinical trial to establish its safety, efficacy, risks, and benefits.

Reference

1. World Health Organization. Monitored emergency use of unregistered and experimental interventions (MEURI), <http://www.who.int/ethics/publications/infectious-disease-outbreaks/en/>.

WHO continues to monitor the situation closely for any changes that may affect this interim guidance. Should any factors change, WHO will issue a further update. Otherwise, this scientific brief will expire 2 years after the date of publication.

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