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FDA & MHRA Revoke COVID-19 Authorisations for Hydroxychloroquine

The U.S. Food and Drug Administration has revoked its emergency use authorisation for chloroquine and hydroxychloroquine as treatments for COVID-19. The U.K. Medicines and Healthcare products Regulatory Agency has followed suit, but Brazil criticised the decision and expanded the drugs' use.

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The Food and Drug Administration (FDA) has stated that the controversial drugs were "unlikely to be effective in treating COVID-19." Emergency use authorisation (EUA) allowed for donation of two malaria drugs to the Strategic National Stockpile to be used for treating those patients hospitalised with COVID-19 for whom a clinical trial was unavailable or unfeasible. The EUA withdrawal, as well as the original EUA back in March, was requested by the Biomedical Advanced Research and Development Authority.

The FDA also cited concerns about safety, particularly serious cardiac events, saying that "the known and potential benefits of chloroquine and hydroxychloroquine no longer outweigh the known and potential risks for the authorized use."

The U.K. Medicines and Healthcare products Regulatory Agency (MHRA) has also instructed clinical trialists using hydroxychloroquine to treat or prevent COVID-19 to suspend recruitment of further participants "until further data which justifies [the trials'] continuation have been provided, and any additional safety measures have been implemented."

The European Medicines Agency has also warned about the serious side effects that can result from treatment in COVID-19 patients with chloroquine and hydroxychloroquine as "their beneficial effects in this patient population are not established."

In April, the U.S. Centers for Disease Control and Prevention (CDC) removed the guidance for using hydroxychloroquine as a potential treatment for the new coronavirus.

A large study, published in The Lancet last month, found that hydroxychloroquine associated with an increased risk of in-hospital mortality. It prompted the World Health Organization (WHO) to pause the clinical trials of the two drugs, and the French government to revoke authorising hospitals to prescribe the drug for COVID-19 patients. However, the study has since then been retracted by the authors. WHO was reported to resume the trials, but on 17 June announced that they were being stopped. Last week the world's largest clinical trial of potential coronavirus treatments, the Randomised Evaluation of COVID-19 Therapy trial ('RECOVERY') released preliminary results showing no effect on mortality from the use of hydroxychloroquine in patients admitted to hospital with COVID-19.

By contrast, hours after the FDA's decision Brazilian health authorities announced that hydroxychloroquine would be recommended to use in children and pregnant women for early treatment of COVID-19, and criticised the FDA's approach, CNN reports. "The studies referenced by the FDA today cannot be used as examples for Brazil or for the rest of the world," Mayra Pinheiro, a Health Ministry official said during the press conference claiming that the "quality of their methodology is terrible."

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