Transcript Details
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FDA Issuance on Chloroquine & Hydroxychloroquine for COVID-19

Announcer:
You're listening to *The Drug Report* on ReachMD, hosted by Linda Bernstein, Pharm.D., Clinical Professor on the Volunteer Faculty of the School of Pharmacy, University of California, San Francisco.

Dr. Bernstein:
Welcome to *The Drug Report* with a special focus on the COVID-19 pandemic.

The US Food and Drug Administration has authorized clinicians to prescribe chloroquine and hydroxychloroquine for hospitalized patients with COVID-19, despite warnings from scientific advisers that no randomized controlled trial has been conducted to support the drugs' safety and efficacy in this population. The drugs would be distributed as part of the Strategic National Stockpile to public health authorities, and then ultimately to hospital systems and healthcare providers.

The agency acknowledged in the emergency use authorization issued on 28 March that the approval was based on "limited in-vitro and anecdotal clinical data."

According to the FDA, chloroquine phosphate and hydroxychloroquine sulfate are not FDA-approved for treatment of COVID-19. Some versions of chloroquine phosphate are approved by the FDA for other indications – for prophylaxis and acute attacks of certain malarial strains and for the treatment of extraintestinal amebiasis. Several versions of hydroxychloroquine sulfate are approved by the FDA for prophylaxis and treatment of malaria, treatment of systemic lupus erythematosus and treatment of rheumatoid arthritis. The safety profile of these drugs has only been studied for FDA approved indications, not COVID-19.

The FDA is encouraging the ongoing conduct and participation in randomized controlled clinical trials that may produce evidence concerning the effectiveness of these products in treatment of COVID-19. However, this issuance will facilitate availability of these agents during the pandemic to treat patients for whom a clinical trial is not available or participation is not feasible.

The FDA listed 3 criteria for their decision.

1. The SARS-CoV-2 can cause a serious or life-threatening disease or condition including severe respiratory illness to humans infected by this virus;
2. Based upon all the evidence available to the FDA, the drugs may be effective and when used under the authorized conditions, the "known and potential benefits outweigh the known and potential risks of such products"; and
3. There is no adequate, approved, and available alternative to the emergency use of the drugs for the treatment of COVID-19.

What does the authorization allow?

Chloroquine phosphate and hydroxychloroquine sulfate must be administered by a healthcare provider pursuant to a valid prescription of a licensed practitioner and only to treat adult and adolescent patients who weigh 50 kg or more and are hospitalized with the COVID-19 for whom a clinical trial is not available, or participation is not feasible. A fact sheet pertaining to emergency use will be available for healthcare providers and for patients and parent/caregivers. Hydroxychloroquine sulfate's approved package insert (for other indications) is also available as a reference.

Adverse event monitoring and compliance activities will need to be performed as is practical given emergency circumstances, including

completion of the MedWatch FDA Form. In addition, inventory control and other relevant patient information must be collected.

How are the experts reacting to this issuance?

Director of the National Institute of Allergy and Infectious Diseases and White House health advisor Dr. Anthony Fauci warned that Americans shouldn't assume hydroxychloroquine is a "knockout drug" in preventing or treating COVID-19. "We still need to do the definitive studies to determine whether any intervention, not just this one, is truly safe and effective."

Jerome R Hoffman, epidemiologist and emeritus professor of medicine at the University of California Los Angeles, told *The BMJ* that caution was needed because many treatments that initially seemed "promising" later proved to be harmful…and would likely to lead to increased prescribing of an unproven drug with well-known adverse neurological and cardiac effects, which could lead to another problem—difficulty in completing clinical trials quickly and efficiently. Hoffman said that once a drug was in widespread use, patients were reticent to be randomly assigned a drug, since they were convinced that the drug must be effective.

President of the American Medical Association, Dr. Patrice Harris stated on CNN, "There have been mixed results. Just because a molecule works in a lab or in a petri dish does not mean it's going to work on patients. There could be negative side effects. There could be deaths. This is a new virus so we should not be promoting any medication or drug for any disease that has not been proven and approved by the FDA."

In this case, the FDA has allowed emergency use of these two medications to treat hospitalized COVID-19 patients with the acknowledgement that they have not been proven to be safe or efficacious for the condition. Proceed with caution.

For *The Drug Report*, I'm pharmacist Dr. Linda Bernstein.

Announcer:
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