FAQ: Did Hydroxychloroquine Receive FDA-approval for Treatment of COVID-19?

On March 28, 2020, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for hydroxychloroquine and chloroquine for treatment of COVID-19.\(^1\) This authorization has led to confusion about whether or not these agents have received “FDA approval” for treatment of COVID-19. This FAQ highlights key takeaways from the FDA’s authorization:

- Hydroxychloroquine and chloroquine did **not** receive “FDA-approval” for treatment of COVID-19
- The FDA recognizes there are no current therapies approved to treat COVID-19 and encourages all investigational agents, including hydroxychloroquine, be administered in the setting of a randomized controlled trial
- This EUA applies to hydroxychloroquine or chloroquine sourced directly from the Strategic National Stockpile (SNS) to treat COVID-19 patients for whom a clinical trial is not available or participation is not feasible
- This EUA does not apply to hydroxychloroquine or chloroquine sourced from your pharmaceutical supplier
- The purpose of this EUA is to provide a legal basis upon which clinicians can prescribe an agent supplied by the SNS for an “unapproved” or “off label” indication (e.g., COVID-19) outside of a clinical trial setting; it may also provide access to some formulations of chloroquine which are not specifically FDA approved, but determined safe by the FDA through this declaration
- If your hospital has or intends to receive a supply of these agents from the Strategic National Stockpile, the following documents must be made available to healthcare providers and patients when these agents are prescribed outside of a clinical trial:
  - Chloroquine Fact Sheet for Healthcare Providers
  - Chloroquine Fact Sheet for Patients
  - Hydroxychloroquine Fact Sheet for Healthcare Providers
  - Hydroxychloroquine Fact Sheet for Patients
- If your hospital does not intend to receive a supply of these agents from the Strategic National Stockpile, the use of these agents for COVID-19 outside of a clinical trial is considered “off label” use

**How to Access the Strategic National Stockpile:**

Many have asked how to best request these resources for your individual facility. Accessing the SNS requires coordination between the federal and state authorities.\(^2\) It is the ultimate decision of the federal government to determine if the request from the state (governor or designee) is needed and what components of the SNS are needed.

References:

Reviewed on 4/1/20.

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