April 1, 2020

**COM-2020-023**

Dear provider of pharmaceutical services,

As the 2019 coronavirus disease (COVID-19) pandemic continues to evolve, providers of pharmaceutical services have an important role in the front lines of this global public health issue. We want to thank you for every effort taken by your team to continue to provide essential services to our communities. Know that we are committed to support you and keep you informed regarding rapidly changing measures taken in response to COVID-19.

On March 28, 2020, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) to allow some oral products of hydroxychloroquine sulfate and chloroquine phosphate donated to the Strategic National Stockpile (SNS) to be distributed and used for certain hospitalized adolescent and adult patients with COVID-19, when a clinical trial is not available or feasible.[1] Of note, the authorized use of hydroxychloroquine sulfate and chloroquine phosphate is limited to products supplied by the SNS.

**STRATEGIC NATIONAL STOCKPILE (SNS)**
The SNS is the nation's largest supply of life-saving pharmaceuticals and medical supplies for use in a public health emergency severe enough to cause local supplies to run out.[2]

Hydroxychloroquine sulfate and chloroquine phosphate are not FDA-approved for the treatment of COVID-19. However, the FDA is issuing this EUA in an effort to facilitate the availability of hydroxychloroquine sulfate and chloroquine phosphate to be used when appropriate during this COVID-19 pandemic. The FDA concluded that the emergency use of hydroxychloroquine sulfate and chloroquine phosphate meet criteria for an EUA because:

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 on the totality of scientific evidence available to FDA, it is reasonable to believe that chloroquine phosphate and hydroxychloroquine sulfate may be effective in treating COVID-19, and that, when used under the conditions described in this authorization, the known and potential benefits of chloroquine phosphate and hydroxychloroquine sulfate when used to treat COVID-19 outweigh the known and potential risks of such products; and*
3. *There is no adequate, approved, and available alternative to the emergency use of chloroquine phosphate and hydroxychloroquine sulfate for the treatment of COVID19.*

Please refer to the full letter of authorization for additional important details such as the scope of authorization, the specific conditions that must be met, etc.


2 Street 1, Suite 500 Guaynabo, PR 00968 | Tel. 787.522.5252 | Fax 1.866.912.2830 | www.pharmpix.com

Additional information can be found at the FDA's Emergency Use Authorization portal (https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization).

The situation with the COVID-19 pandemic is dynamic and constantly changing. We strongly encourage the frequent revision of updated information provided by the FDA, the Centers for Disease and Control Prevention (CDC), and the World Health Organization (WHO), to assure that your practices are consistent with the most actualized information.

On PharmPix we are committed to the health and wellness of our members. It is our priority to offer high quality services and support practices for health promotion and diseases prevention. If you have any questions or wish to have more information regarding this document, you can call us at 787-522-5252, extension 137.

Regards,

Clinical Department

References:

1. Emergency Use Authorization - Therapeutics. (2020). Retrieved March 2020, from https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#covidtherapeutics
2. Strategic National Stockpile. (2020). Retrieved March 2020, from https://www.phe.gov/about/sns/Pages/default.aspx



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