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COVID-19: No Approval for Chloroquine from EMA

The European Medicines Agency has warned against widespread use of the drug chloroquine to treat COVID-19.

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An unproven medicine against COVID-19, chloroquine and the less toxic hydroxychloroquine are currently licensed to treat malaria and autoimmune diseases such as lupus.

The European drug regulator noted in a statement that the efficacy of these two medicines in treating COVID-19 was yet to be shown in studies. "It is very important that patients and healthcare professionals only use chloroquine and hydroxychloroquine for their authorised uses or as part of clinical trials or national emergency use programmes for the treatment of COVID-19," the agency stressed.

If you want to share your experience and perspective on COVID-19, please do.

If your company is interested in engaging with our COVID-19 community, please send us an email.

It is noted that both drugs can have serious side effects, especially at high doses or when combined with other medicines, and must not be used without a prescription and without supervision by a doctor. At the same time, prescriptions should be given for authorised uses only, with exceptions of clinical trials or nationally agreed protocols.

Notably, as recently as on 28 March, the U.S. Food & Drug Administration (FDA) allowed hydroxychloroquine sulfate and chloroquine phosphate products donated to the Strategic National Stockpile to be distributed and used for certain hospitalised patients with COVID-19.

In France, High Council of Public Health had not recommended using hydroxychloroquine "in the absence of a recommendation," but made an exception for "serious forms of hospitalisation and on the collegial decision of doctors and under strict medical supervision".

Most of the evidence to support use either of the drugs against the COVID-19 disease comes from a small trial in France. But the evidence has shown toxicity issues with chloroquine if used for an extensive period of time.

Despite the FDA and the French regulator granting an emergency licence to use chloroquine for COVID-19 treatment, the EMA has instead left the implementation of such programmes to national regulators.

Source: PharmaForum

Image credit: EMA

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