[redacted]

From: [redacted]
Sent: Tuesday, 28 April 2020 10:10 AM
To: [redacted]
Subject: FW: FDA MedWatch: Hydroxychloroquine or Chloroquine for COVID-19: Drug Safety Communication [SEC=OFFICIAL]

From: [redacted]
Sent: Tuesday, 28 April 2020 10:10:04 AM (UTC+10:00) Canberra, Melbourne, Sydney
To: [redacted]
Cc: [redacted]
Subject: RE: FDA MedWatch: Hydroxychloroquine or Chloroquine for COVID-19: Drug Safety Communication [SEC=OFFICIAL]

Hi [redacted]

I agree worth considering. There is a meeting re HCQ under the ACCC exemption today at 3 (we haven't received the invite yet but can forward it to you), which I expect will touch on comms as well as supply/distribution matters.

Kind regards
[redacted]

From [redacted]@health.gov.au>
Sent: Tuesday, 28 April 2020 9:51 AM
To: [redacted]@health.gov.au>; [redacted]@health.gov.au>; [redacted]@health.gov.au>
Cc: [redacted]@health.gov.au>; [redacted]@health.gov.au>
Subject: FW: FDA MedWatch: Hydroxychloroquine or Chloroquine for COVID-19: Drug Safety Communication [SEC=OFFICIAL]

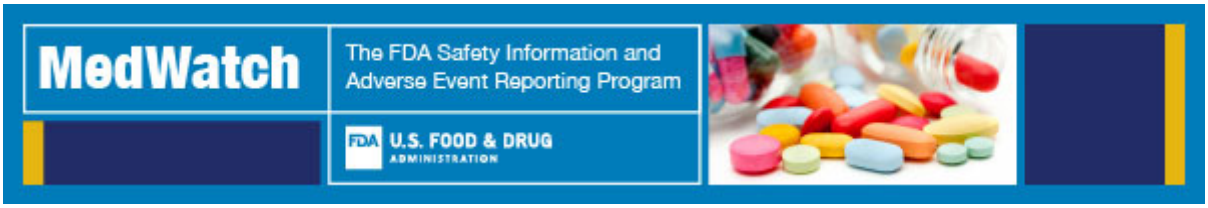
Hi All,

Another FYI – supports the need for the DHCPL from Sanofi, and I wonder whether we should revisit the question of the need for a web statement (though given the number of COVID cases in Australia it may not be warranted). Health Canada have also published something similar: https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2020/72885a-eng.php

Kind regards,
[redacted]

From: U.S. Food and Drug Administration <fda@info.fda.gov>
Sent: Saturday, 25 April 2020 12:20 AM
To: [redacted]@health.gov.au>
Subject: FDA MedWatch: Hydroxychloroquine or Chloroquine for COVID-19: Drug Safety Communication [SEC=No Protective Marking]

. . .



MedWatch - The FDA Safety Information and Adverse Event Reporting Program

A *MedWatch* Safety Alert was added to the FDA *MedWatch* webpage.

TOPIC: Hydroxychloroquine or Chloroquine for COVID-19: Drug Safety Communication - FDA Cautions Against Use Outside of the Hospital Setting or a Clinical Trial Due to Risk of Heart Rhythm Problems

AUDIENCE: Consumer, Patient, Critical Care Medicine, Infectious Disease, Health Professional

ISSUE: FDA is concerned that hydroxychloroquine and chloroquine are being used inappropriately to treat non-hospitalized patients for coronavirus disease (COVID-19) or to prevent that disease. We authorized their temporary use only in hospitalized patients with COVID-19 when clinical trials are not available, or participation is not feasible, through an Emergency Use Authorization (EUA). These medicines have a number of side effects, including serious heart rhythm problems that can be life-threatening.

We have reviewed case reports in the FDA Adverse Event Reporting System database, the published medical literature, and the American Association of Poison Control Centers National Poison Data System concerning serious heart-related adverse events and death in patients with COVID-19 receiving hydroxychloroquine and chloroquine, either alone or combined with azithromycin or other QT prolonging medicines. These adverse events included QT interval prolongation, ventricular tachycardia and ventricular fibrillation, and in some cases, death. We are continuing to investigate these safety risks in patients with COVID-19 and will communicate publicly when more information is available.

BACKGROUND: Hydroxychloroquine and chloroquine are FDA-approved to treat or prevent malaria. Hydroxychloroquine is also FDA-approved to treat autoimmune conditions such as chronic discoid lupus erythematosus, systemic lupus erythematosus in adults, and rheumatoid arthritis.

Hydroxychloroquine and chloroquine:

- should be used for COVID-19 only when patients can be appropriately monitored in the hospital as required by the EUA or are enrolled in a clinical trial with appropriate screening and monitoring. FDA is reviewing the safety of their use when used outside of the setting of hospitalized patients for whom use was authorized.
- have not been shown to be safe and effective for treating or preventing COVID-19.

- are being studied in clinical trials for COVID-19, and FDA authorized their temporary use during the COVID-19 pandemic under limited circumstances through the EUA, and not through regular FDA approval.
- being used under the EUA when supplied from the Strategic National Stockpile, the national repository of critical medical supplies to be used during public health emergencies.
- can cause abnormal heart rhythms such as QT interval prolongation
- can cause dangerously rapid heart rate called ventricular tachycardia.
- pose risks that may increase when these medicines are combined with other medicines known to prolong the QT interval, including the antibiotic azithromycin, which is also being used in some COVID-19 patients without FDA approval for this condition.
- should be used with caution in Patients who also have other health issues such as heart and kidney disease, who are likely to be at increased risk of these heart problems when receiving these medicines.

RECOMMENDATION:

Patients:

- Patients taking hydroxychloroquine or chloroquine for FDA-approved indications to treat malaria or autoimmune conditions should continue taking their medicine as prescribed.
- The benefits of these medicines outweigh the risks at the recommended doses for these conditions.
- Do not stop taking your medicine without first talking to your health care professional and talk to them if you have any questions or concerns.

Be aware that there are no proven treatments for COVID-19 and no vaccine. If you are receiving hydroxychloroquine or chloroquine for COVID-19 and experience irregular heartbeats, dizziness, or fainting, seek medical attention right away by calling 911.

Consumers:

- Do not buy these medicines from online pharmacies without a prescription from your health care professional.
- Do not take any form of hydroxychloroquine or chloroquine that has not been prescribed for you by a health care provider. Serious poisoning and death have been reported after mistaken use of a chloroquine product not intended to be taken by humans.
- If you have these medicines in your home, keep them in childproof containers out of the reach of children to prevent accidental poisoning.

Health Professionals:

- FDA recommends initial evaluation and monitoring when using hydroxychloroquine or chloroquine under the EUA or in clinical trials to treat or prevent COVID-19. Monitoring may include baseline ECG, electrolytes, renal function and hepatic tests.

- Be aware that hydroxychloroquine or chloroquine can:
  - cause QT prolongation
  - increase the risk of QT prolongation in patients with renal insufficiency or failure
  - increase insulin levels and insulin action causing increased risk of severe hypoglycemia
  - cause hemolysis in patients with Glucose-6-Phosphate Dehydrogenase (G6PD) deficiency
  - interact with other medicines that cause QT prolongation even after discontinuing the medicines due to their long half-lives of approximately 30-60 days

If a health care professional is considering use of hydroxychloroquine or chloroquine to treat or prevent COVID-19, FDA recommends checking www.clinicaltrials.gov for a suitable clinical trial and considering enrolling the patient. Consider using resources available to assess a patient's risk of QT prolongation and mortality.

Health professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report online.
- Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the form, or submit by fax to 1-800-FDA-0178.

Read Safety Alert

U.S. Food and Drug Administration
10903 New Hampshire Avenue, Silver Spring, MD 20993
1-888-INFO-FDA (1-888-463-6332)