

[REDACTED]

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**From:** [REDACTED]@health.gov.au>  
**Sent:** Wednesday, 27 May 2020 3:41 PM  
**To:** [REDACTED]; [REDACTED]  
**Cc:** [REDACTED]  
**Subject:** RE: www.tga.gov.au web publishing request - Update to hydroxychloroquine advice [SEC=OFFICIAL]

Because it goes to off label use and that it wasn't very good in treating people with serious disease.  
I may be missing the nuisance though.  
This is what we sent:

Will the department of health / TGA be changing its advice that critically ill patients in hospitals who are NOT part of clinical trials can be given the drug by medical staff?  
The Department will be updating its advice that hydroxychloroquine use in treating COVID-19 is **strongly discouraged** including in hospitalised patients **unless the patient is enrolled in a clinical trial**, noting that currently numbers hospitalised in Australia are very low, at this stage only 30 and there are fewer than 500 active cases across Australia.

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**From:** [REDACTED]@health.gov.au>  
**Sent:** Wednesday, 27 May 2020 3:37 PM  
**To:** [REDACTED]@health.gov.au>; [REDACTED]@health.gov.au>  
**Cc:** [REDACTED]@health.gov.au>; [REDACTED]@health.gov.au>; TGA Website <tga.website@tga.gov.au>  
**Subject:** RE: www.tga.gov.au web publishing request - Update to hydroxychloroquine advice [SEC=OFFICIAL]

Thanks, well aware of the WHO move but wondering why we would be providing clinical advice to hospitals treating COVID people ?

[REDACTED]  
**Department of Health**  
(The Health Products Regulation Group comprises the Therapeutic Goods Administration and the Office of Drug Control)

PO Box 100 Woden ACT 2606 Australia

[REDACTED]  
[health.gov.au](http://health.gov.au)

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**From:** [REDACTED]@health.gov.au>  
**Sent:** Wednesday, 27 May 2020 3:30 PM  
**To:** [REDACTED]@health.gov.au>; [REDACTED]@health.gov.au>  
**Cc:** [REDACTED]@health.gov.au>; [REDACTED]@health.gov.au>; TGA Website <tga.website@tga.gov.au>  
**Subject:** RE: [www.tga.gov.au](http://www.tga.gov.au) web publishing request - Update to hydroxychloroquine advice [SEC=OFFICIAL]

The halting of the WHO solidarity trial.

You saw the media yesterday and I spoke to [REDACTED].

[REDACTED]

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From: [REDACTED]@health.gov.au>  
Sent: Wednesday, 27 May 2020 3:29 PM  
To: [REDACTED]@health.gov.au>; [REDACTED]@health.gov.au>  
Cc: [REDACTED]@health.gov.au>; [REDACTED]@health.gov.au>; TGA Website <tga.website@tga.gov.au>  
Subject: RE: [www.tga.gov.au](http://www.tga.gov.au) web publishing request - Update to hydroxychloroquine advice [SEC=OFFICIAL]

What's been the driver for this ?

[REDACTED]  
[REDACTED]  
Department of Health  
(The Health Products Regulation Group comprises the Therapeutic Goods Administration and the Office of Drug Control)

PO Box 100 Woden ACT 2606 Australia

[REDACTED]@health.gov.au

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From: [REDACTED]@health.gov.au>  
Sent: Wednesday, 27 May 2020 3:24 PM  
To: [REDACTED]@health.gov.au>; [REDACTED]@health.gov.au>  
Cc: [REDACTED]@health.gov.au>; [REDACTED]@health.gov.au>; TGA Website <tga.website@tga.gov.au>  
Subject: RE: [www.tga.gov.au](http://www.tga.gov.au) web publishing request - Update to hydroxychloroquine advice [SEC=OFFICIAL]

Thank you this is cleared.

[REDACTED] – it is line with our media response yesterday with wording from [REDACTED].

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From: [REDACTED]@health.gov.au>  
Sent: Wednesday, 27 May 2020 3:20 PM  
To: [REDACTED]@health.gov.au>  
Cc: [REDACTED]@health.gov.au>; [REDACTED]@health.gov.au>; [REDACTED]@health.gov.au>; TGA Website <tga.website@tga.gov.au>  
Subject: FW: [www.tga.gov.au](http://www.tga.gov.au) web publishing request - Update to hydroxychloroquine advice [SEC=OFFICIAL]

Hi [REDACTED]

Please find below a request to add the following text to the top of <https://www.tga.gov.au/alert/amendments-new-restrictions-prescribing-hydroxychloroquine-covid-19> in an update box.

The TGA is updating the below advice regarding hydroxychloroquine use in treating COVID-19. Based on the latest international data, use of hydroxychloroquine to treat COVID-19 is **strongly discouraged**, including in hospitalised patients, unless the patient is enrolled in a clinical trial which will have safety monitoring protocols and oversight by a Human Research Ethics Committee. It is important to note that the number of COVID-19 patients currently hospitalised in Australia is very low.

If you are happy with it, please forward this email with attachments to [tga.website@tga.gov.au](mailto:tga.website@tga.gov.au) indicating your approval.

The usual wording is below.

To TGA Website,

Approval under subsection 61 (7) of the Therapeutic Goods Act 1989



Under subsection 61(7) of the Therapeutic Goods Act 1989, the delegate of the Secretary may release to the public therapeutic goods information where release is necessary to ensure the safe use of particular therapeutic goods or relating to the reasons for withdrawal of therapeutic goods from supply.

In relation to issues with hydroxychloroquine, I, as delegate of the Secretary for the purposes of section 61 of the Act, approve under section 61(7) of the Act the release to the public of the therapeutic goods information relating to these actions as set out below.

Cheers,

From: [REDACTED]@health.gov.au>

Sent: Wednesday, 27 May 2020 3:16 PM

To: [REDACTED]@health.gov.au>

Subject: [www.tga.gov.au](http://www.tga.gov.au) web publishing request - Update to hydroxychloroquine advice [SEC=UNCLASSIFIED]

## Web Publishing Request

### Instructions

You have been sent this email because Michael Pittman requested you review it before forwarding it to the approving officer.

**Message from [REDACTED]:**

Please review the information in the form, add any attachments required and forward this email to the appropriate approving officer. The approving officer must then send the email on to [tga.website@tga.gov.au](mailto:tga.website@tga.gov.au) indicating approval

If you have any questions or need to make changes to the request, please email [tga.website@health.gov.au](mailto:tga.website@health.gov.au).

## Section 61 approval required

This request includes a section 61 publishing request. Under section 61 you must give **explicit authorisation** for the publication of this information. Please use the standard words below:

I, **[insert name, insert work title]**, am a delegate of the Secretary under section 61 of the *Therapeutic Goods Act 1989* (the Act). As a delegate, I have decided to release the therapeutic goods information contained in the following attached document(s) for Internet publication to the public acting under **[insert subsection, e.g., 61(5A), 61(5C) or 61(7)]** of the Act.

Please ensure your email includes your electronic signature block.

## Request details

Website to update: [www.tga.gov.au](http://www.tga.gov.au)

Description of job: Please add the following in an update box at the top of <https://www.tga.gov.au/alert/amendments-new-restrictions-prescribing-hydroxychloroquine-covid-19>

The TGA is updating the below advice regarding hydroxychloroquine use in treating COVID-19. Based on the latest international data, use of hydroxychloroquine to treat COVID-19 is **strongly discouraged**, including in hospitalised patients, unless the patient is enrolled in a clinical trial which will have safety monitoring protocols and oversight by a Human Research Ethics Committee. It is important to note that the number of COVID-19 patients currently hospitalised in Australia is very low.

Existing pages to be updated: <https://www.tga.gov.au/alert/amendments-new-restrictions-prescribing-hydroxychloroquine-covid-19>

Source documents to be approved: none

Date to upload: Standard timeframe

Public consultation: No

Title length declaration: I understand that web page titles can be no longer than 70 characters (including spaces) and if any of my titles are longer than this the information will not be published until the title length is reduced.

Style manual declaration: I accept that minor changes (grammar, spelling, formatting) will be made if the content does not meet the standard requirements.

Review declaration: I am aware that content must be reviewed in accordance with the web content review requirements.

Add to news on homepage: Yes

**News text:**  
Update to advice for hydroxychloroquine

## Requestor's details

Full name: [REDACTED]

Email address: [REDACTED]@tga.gov.au

TGA Area: **Division:** Medicines Regulation Division  
**Branch:** Pharmacovigilance and Special Access Branch  
**Section:** Technical and Safety Improvement

## Approval

Approver name: [REDACTED]

Position: [REDACTED] Medicines Regulation Division

Message to approver:

Section s.61 approval required: Yes