

[REDACTED]

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**From:** [REDACTED]@health.gov.au>  
**Sent:** Wednesday, 27 May 2020 2:12 PM  
**To:** [REDACTED]  
**Subject:** FW: Dep Sec Cleared : e media on WHO halting solidarity trial and Department response [SEC=OFFICIAL]

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**From:** [REDACTED]  
**Sent:** Wednesday, 27 May 2020 2:11:37 PM (UTC+10:00) Canberra, Melbourne, Sydney  
**To:** [REDACTED]  
**Cc:** [REDACTED]  
**Subject:** RE: Dep Sec Cleared : e media on WHO halting solidarity trial and Department response [SEC=OFFICIAL]

Hi [REDACTED],

I'm happy with that.

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**From:** [REDACTED]@health.gov.au>  
**Sent:** Wednesday, 27 May 2020 2:08 PM  
**To:** [REDACTED]@health.gov.au>  
**Cc:** [REDACTED]@health.gov.au>; [REDACTED]@health.gov.au>  
**Subject:** RE: Dep Sec Cleared : e media on WHO halting solidarity trial and Department response [SEC=OFFICIAL]

What do you think of (CCing you in [REDACTED] for your awareness – this relates to a media from yesterday)?

The TGA is updating its advice regarding hydroxychloroquine use in treating COVID-19 below. 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 with appropriate 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 is very low.

The international data we are referring to is chiefly:

[https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(20\)31180-6/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)31180-6/fulltext)

and these remarks by the WHO: <https://www.who.int/dg/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---25-may-2020>

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**From:** [REDACTED]@health.gov.au>  
**Sent:** Wednesday, 27 May 2020 12:30 PM  
**To:** [REDACTED]@health.gov.au>  
**Cc:** [REDACTED]@health.gov.au>; [REDACTED]@health.gov.au>  
**Subject:** RE: Dep Sec Cleared : e media on WHO halting solidarity trial and Department response [SEC=OFFICIAL]

Hi [REDACTED],

If we want to address the WHO trial (and I'm not suggesting that we do), I think we would need a full, separate statement about it. It would need to provide quite a lot of context for the information to be understood.

If we want to just go with an update, I think the quoted text is good with some minor tweaks.

The Department of Health has updated its 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. It is important to note that the number of patients currently hospitalised in Australia is very low and there are fewer than 500 known active cases of COVID-19 across Australia.

Happy to discuss further.

[REDACTED]

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**From:** [REDACTED]@health.gov.au>  
**Sent:** Wednesday, 27 May 2020 11:35 AM  
**To:** [REDACTED]@health.gov.au>  
**Subject:** FW: Dep Sec Cleared : e media on WHO halting solidarity trial and Department response [SEC=OFFICIAL]

Hi,

We would like to update our HCQ web statement to use some stronger words on its use – interested in your thoughts on how best to do this. Should we refer to the WHO? (see below)

Notably that,

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:** Tuesday, 26 May 2020 2:17 PM  
**To:** [REDACTED]@health.gov.au>  
**Subject:** FW: Dep Sec Cleared : e media on WHO halting solidarity trial and Department response [SEC=OFFICIAL]

FYI

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**From:** [REDACTED]  
**Sent:** Tuesday, 26 May 2020 1:28 PM  
**To:** [REDACTED]@health.gov.au>  
**Cc:** [REDACTED]@health.gov.au>  
**Subject:** FW: Dep Sec Cleared : e media on WHO halting solidarity trial and Department response [SEC=OFFICIAL]

Hi [REDACTED]

Please see the final response below for the media from this morning – Jane has asked that this be passed back to the teams so they can see what was cleared. The red text was provided by [REDACTED].

**Cleared Response:**

You will have seen that WHO has halted all studies of hydroxychloroquine as it reviews the findings from recent studies which found the drug is either ineffective or can cause harm.

What is the department of health/ TGA response to WHO halting trials? What does it mean for Australian stocks of hydroxychloroquine, and studies underway?

The Department will consider the decision of the WHO to halt the trials pending analysis of the trial outcomes to date and determine what if any action needs to be taken.

In Australia clinical trials are not undertaken by the Department . The decision about halting or stopping a trial is a decision of the Human Research Ethics Committee who has approved the Trial, the TGA will be contacting investigators of trials in Australia as to their planned action given the WHO advice decision to halt the Solidarity Trial.

Will the health department halt any importations/ stockpiling of the drug?

Hydroxychloroquine is used for a variety of disease conditions and so importation will not be ceased. The current stockpile levels are sufficient to continue clinical trials if it is safe to do so. There is no current intention to procure any further hydroxychloroquine for the national stockpile at this point.

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.

Kind regards,



Medicines Regulation Division | Health Products Regulation Group  
Australian Government Department of Health

[\[redacted\]@health.gov.au](mailto: [redacted]@health.gov.au)

PO Box 100, Woden ACT 2606, Australia

*The Department of Health acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.*

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**From:** [redacted]  
**Sent:** Tuesday, 26 May 2020 12:18 PM  
**To:** [redacted]@health.gov.au; [redacted]@health.gov.au  
**Cc:** [redacted]@health.gov.au; [redacted]@health.gov.au; [redacted]@health.gov.au; [redacted]@health.gov.au; [redacted]@health.gov.au; [redacted]@health.gov.au  
**Subject:** RE: e media on WHO halting solidarity trial and Department response [SEC=OFFICIAL]

Hi [redacted]

Thanks for sending this through. [redacted] has cleared this now with me verbally and I will forward onto the media team for final clearance through [redacted].

I'll provide this version to you in case there are any further changes.



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From: [REDACTED]@health.gov.au>  
Sent: Tuesday, 26 May 2020 11:25 AM  
To: [REDACTED]@health.gov.au>  
Subject: RE: e media on WHO halting solidarity trial and Department response [SEC=OFFICIAL]

Can do [REDACTED], is after AHPPC ok at 2pm or would you like a response before then?

[REDACTED]  
[REDACTED]  
[REDACTED]  
Australian Government Department of Health  
[REDACTED]@health.gov.au  
GPO Box 9848, Canberra ACT 2601, Australia

*The Department of Health acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.*

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From: [REDACTED]@health.gov.au>  
Sent: Tuesday, 26 May 2020 11:18 AM  
To: [REDACTED]@health.gov.au>  
Subject: e media on WHO halting solidarity trial and Department response [SEC=OFFICIAL]

Hi [REDACTED]  
can you give me a ring about some media on WHO halting solidarity trial and Department response. Number is [REDACTED]  
[REDACTED]

Below is my proposed response but wondered what OHP and the Deputy CMOs were thinking.

Response:

You will have seen that WHO has halted all studies of hydroxychloroquine as it reviews the findings from recent studies which found the drug is either ineffective or can cause harm.

What is the department of health/ TGA response to WHO halting trials? What does it mean for Australian stocks of hydroxychloroquine, and studies underway?

The Department will consider the decision of the WHO to halt the trials pending analysis of the trial outcomes to date and determine what if any action needs to be taken.

In Australia clinical trials are not undertaken by the Department . The decision about halting or stopping a trial is a decision of the Human Research Ethics Committee who has approved the Trial, the TGA will be contacting investigators of trials in Australia as to their planned action given the WHO advice decision to halt the Solidarity Trial.

Will the health department halt any importations/ stockpiling of the drug?

Hydroxychloroquine is used for a variety of disease conditions and so importation will not be ceased. The current stockpile levels are sufficient to continue clinical trials if it is safe to do so. There is no current intention to procure any further hydroxychloroquine for the national stockpile at this point and future procurement will be considered in light of the Lancet trial and further clinical trials

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.

Thanks



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Medicines Regulation Division | Health Products Regulation Group  
Australian Government Department of Health  
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136 Narrabundah Lane, Symonston  
PO Box 100, Woden ACT 2606, Australia



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