

# OPEN LETTER

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## **Re: Call for an Urgent Review of the NCCET Recommendation regarding the use of ivermectin in the management of Covid-19 within 14 days**

I refer to the current recommendation by the National Covid Clinical Evidence Taskforce (NCCET) regarding the use of the drug ivermectin for the management of Covid-19.

The NCCET serves an important role in reviewing and recommending treatment for Covid-19 to peak health professional bodies across Australia. The current recommendation (Communique Ed. 48 - 5.8.21) regarding the use of the drug ivermectin is as follows:

*“The available research evidence does not yet provide reasonable certainty to recommend for or against the use of ivermectin and therefore the Taskforce recommends ivermectin not be used outside of randomised trials. The certainty of the current evidence base varies from low to very low depending which on outcome is being measured, as a result of serious risk of bias and serious imprecision in the 18 included studies.*

*In addition to uncertainty around benefits for patients with COVID-19, there are common side effects and harms associated with ivermectin, including diarrhoea, nausea and dizziness. Given this uncertainty of benefit, and concerns of harms; we recommend that ivermectin only be provided in research trials, where there is the potential to generate further evidence on the effectiveness, or otherwise, of ivermectin.” ....*

*“This is a high priority recommendation and will be updated as soon as new evidence becomes available.”*

Ivermectin has been the subject of more than 60 clinical trials, including more than 30 randomised controlled trials and used successfully in national Covid-19 mass treatment campaigns in India, Mexico and several other countries to reduce the number of cases and prevent serious complications of the disease leading to hospitalisation and death.

Despite this, and in the absence of NCCET members' personal experience in treating COVID-19 patients with ivermectin, the NCCET has selected in an arbitrary and imprecise manner a small number of published clinical trials (18) upon which to base its current negative recommendation for ivermectin use. NCCET has failed to apply sophisticated, defined, and detailed meta-analysis techniques as employed in widely

discussed published reviews on ivermectin (see references attached). When lives are at risk, the highest standards of evaluation are required.

The emphasis on minor and generally uneventful “harms associated with ivermectin, including diarrhoea, nausea and dizziness” contained in the above NCCET statement demonstrates a total lack of therapeutic perspective in relation to the much more serious side effects of other drugs used to treat COVID-19. Including many over the counter non-prescription drugs and the dire consequences of a lack of effective therapeutic management of COVID-19 individuals.

The NCCET has sought to respond to critics of its recommendation on ivermectin in the Communique of 5 Aug. 2021 by justifying its limited consideration of the ivermectin literature by posing, and then, answering its own question in the following way:

***NCCET: “But hasn’t ivermectin been shown to be effective as an early COVID-19 treatment in randomised controlled trials overseas?”:***

***NCCET: “Despite some early suggestions that ivermectin may provide both prophylactic and therapeutic benefit, the available research evidence does not yet provide reasonable certainty to recommend for or against the use of ivermectin. More robust, well-designed randomised controlled trials are needed to demonstrate whether or not ivermectin is effective.”***

***“Some widely discussed meta-analyses of ivermectin studies (e.g. The British Ivermectin Research Development ([BIRD](#)) Group meta analysis) have significant weaknesses, for example they include a large trial which has been discredited and retracted (Elgazzar et al.). Even in these reviews, when patient populations are separated by severity and comparisons to active treatments removed, no meaningful effect is found.”***

Given the national importance of the NCCET advice on ivermectin, I invited internationally recognised and experienced literature review specialist (Tess Lawrie MBBCh PhD) and Edmund Fordham (PhD FInstP) of Evidence Based Medicine Consultancy Ltd (UK) and EbMCsquared, a Community Interest Company located in Bath, England, to comment on the above NCCET interpretations of the literature. Their expert analysis is attached and entitled, “Commentary upon NCCET Statement” dated 7 August 2021.

The analysis reveals and details (with references) serious flaws in the selective NCCET interpretation of the ‘cherry picked’ literature. It ignores the broad sweep of clinical evidence from other randomised controlled clinical trials, observational trials and national treatment programs and demands (in the NCCET’s own words) as a matter of high priority to review this recommendation in the national interest.

In addition, related to the current NCCET recommendation is the statement by the TGA (18 Aug 2021):

“There is currently insufficient evidence to support the safe and effective use of ivermectin, doxycycline and zinc (either separately, or in combination) for the prevention or treatment of COVID-19. More robust, well-designed clinical trials are needed before they could be considered an appropriate treatment option.” requires

immediate review in light of the information herein provided.” In reality, there is insufficient evidence not to support the use of ivermectin while new and expensive drugs are being expedited through the regulatory process and given provisional approval with far less clinical trial, efficacy and safety data supporting their use.

Australia is in the grip of a pandemic of enormous consequences. Every possible useful therapeutic approach is needed in this crisis. Ivermectin, especially in combination with zinc and doxycycline has shown to be effective in relation to COVID-19 management. Other new antiviral medications have been recently approved by the TGA with relatively minimal safety and efficacy data by comparison to ivermectin.

Ivermectin has been in use for more than three decades. Four billion doses have been administered, it is on the World Health Organisation List of Essential Drugs and is one of the world’s most useful and well tolerated drugs available. Its breakthrough discovery is attributed to Prof. Satoshi Omura and Irish biologist William Campbell, who were awarded the Nobel Prize in Medicine in 2015, reflecting the magnitude of their achievement and the importance of ivermectin to medicine.

The current approach to symptomatic COVID-19 individuals is largely to do nothing and simply observe until they either get better or get worse, perhaps much worse, and need to go to hospital. The do-nothing approach places enormous strain on our health care system. Evidence for this ‘do nothing, watch and observe’ approach is lacking. Ivermectin offers a potentially effective, low cost, safe and rational approach to the management of such individuals with little or no disadvantage. The NCCET recommendation on ivermectin is considered to be misinformation by many experts and is viewed as contributing to needless hospitalisation – but for this recommendation, many Covid-19 infected individuals could be receiving early effective treatment.

Hon. Greg Hunt MP, Minister for Health and Aged Care, has written regarding ivermectin in a reply to Sen. Malcolm Roberts (27 July 2021).” It remains open for doctors to prescribe existing medicines ‘off-label’ based on their own clinical judgement”. Indeed, this has always been the case previously.

Given the evidence available, doctors should be able to prescribe ivermectin as monotherapy or in combination without stigma or hindrance by a restrictive recommendation from the NCCET or the TGA. Both the NCCET and the TGA should re-examine the accumulating international experience with ivermectin from all sources supporting its safe and effective use and should actively support and encourage ongoing efforts by many to clarify the important role of ivermectin in the management of COVID-19.

**I request the NCCET review and issue revised recommendations for the use of ivermectin within 14 days in light of the submitted information as a matter of urgent priority and national interest.**

Please confirm receipt of this Open Letter by return email.

Regards,  
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## REFERENCES

Bryant, A, Lawrie, TA, Dowswell, T, Fordham, EJ, Mitchell, S, hill, SR and Tham, TC.  
Ivermectin for Prevention and Treatment of COVID-19 infection: A Systematic Review, Meta-analysis, and Trial Sequential Analysis to Inform Clinical Guidelines.  
American Journal of Therapeutics 28, e434-e460 (2021).

Kory,P, Meduri, U, Varon, J, Iglesias, J and Marik, PE.  
Review of the Emerging Evidence Demonstrating the Efficacy of Ivermectin in the Prophylaxis and Treatment of COVID-19.  
American Journal of therapeutics 28, e299-e318 (2021).