



**The Hon Greg Hunt MP**  
**Minister for Health and Aged Care**

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Dear Chair

I refer to your correspondence concerning Petition EN3364 asking the House to ensure the immediate repeal of the statement on ivermectin made by the Therapeutic Goods Administration (TGA) within my Department. I regret the delay in responding.

Ivermectin is an anti-parasite medication that is used to treat human and animal diseases. Oral ivermectin (Stromectol) is approved by the TGA for the treatment of river blindness (onchocerciasis), threadworm of the intestines (intestinal strongyloidiasis), and scabies.

On 10 September 2021, the TGA decision maker (delegate), acting on the advice of the Advisory Committee for Medicines Scheduling (Advisory Committee), placed restrictions on the prescribing of oral ivermectin through a change to its scheduling entry in the Poisons Standard. The Advisory Committee, which included senior medical officers and pharmacists as well as representatives from each state and territory, unanimously supported the change. The change is also supported by the two peak bodies representing general practitioners – The Royal Australian College of General Practitioners and Australian Medical Association.

The TGA decision is independent from Commonwealth parliamentary processes and is given effect through state and territory law and regulation. It should be noted that there are a significant number of other medicines that either cannot be prescribed by GPs, or alternatively require individual special authorisation (e.g. by the Chief Executive Officer of their state health department) to do so.

GPs can now only prescribe ivermectin for TGA-approved conditions (indications) such as scabies and certain parasitic infections. Certain specialists including infectious disease physicians, dermatologists, gastroenterologists, and hepatologists can prescribe ivermectin for other unapproved indications if they believe it is appropriate for a particular patient. Ivermectin is one of 30 substances for which only certain medical practitioners can prescribe. For these 30 substances, prescribers have either to be certain types of specialists, or have a specific prescribing approval from the Secretary of my Department or the head of a state or territory health department.

The TGA introduced these changes because of concerns with the prescribing of oral ivermectin for the claimed prevention or treatment of COVID-19. These concerns include the significant public health risks to an individual, and those around them, associated with taking ivermectin in an attempt to prevent COVID-19 infection rather than being vaccinated, the unsafe dosages being promoted, and to ensure continued access for those who need the medicine for the treatment of scabies and parasitic infections.

Ivermectin is not approved for the treatment of COVID-19 in Australia, or in any other comparable Organisation for Economic Co-operation and Development country. Its use by the general public for COVID-19 is strongly discouraged by the National COVID Clinical Evidence Taskforce, the World Health Organization, the United States of America's Food and Drug Administration, and the European Medicines Agency.

Merck, one of the major companies manufacturing ivermectin, publicly confirmed on 4 February 2021 that, to date, there is no scientific basis for a potential therapeutic effect against COVID-19 from pre-clinical studies, no meaningful evidence for clinical activity or clinical efficacy in patients with COVID-19 disease, and a concerning lack of safety data in the majority of studies.

In addition, a recent analysis of published ivermectin trials by the Cochrane Collaboration (Collaboration) concluded that ivermectin could not be recommended for COVID-19 treatment or prevention. The Collaboration is one of the key independent international bodies responsible for assessing clinical evidence for medical treatments and therapies. The Collaboration also found that the available evidence for ivermectin is of low to very low quality, and insufficient to come to any clinically meaningful conclusions.

If a sponsor holds the appropriate evidence, such as data demonstrating the safe and efficacious use of ivermectin for the treatment of COVID-19, they can make an application at any time to the TGA to register their medicine on the Australian Register of Therapeutic Goods. Any application must include a comprehensive data package to support the medicine's safety, quality, and efficacy for the intended end use.

My Department has published information on how evidence is used in the approach to COVID-19 treatments to keep Australians safe. I can assure the House that the TGA is regularly meeting with researchers, developers and manufacturers about a wide range of medicines for the prevention and treatment of COVID-19 in a variety of clinical settings.

The TGA ensures that effective treatments are made available to Australians in a manner that broadly protects public health. To date, the TGA has provisionally approved seven COVID-19 treatments: Remdesivir (VEKLURY), Sotrovimab (XEVUDY), casirivimab/imdevimab (RONAPREVE), tocilizumab (ACTEMRA), regdanvimab (REGKIRONA), nirmatrelvir + ritonavir (PAXLOVID) and molnupiravir (LAGEVRIO), and has provisionally designated one other COVID-19 medicine for evaluation through the provisional pathway. Up-to-date information about COVID-19 treatments available in Australia is on the TGA's website.

I note the petition seeks a firm assurance to the Australian people that 'overreach of this kind by a Federal Government agency will never again limit access to safe treatments in a non-consultative and unilateral manner'. I can assure the House that there has been no overreach as I have outlined. The TGA followed relevant policies and processes in the course of its consideration concerning this change.

Thank you for writing on this matter.

Yours sincerely

Greg Hunt