From: Christensen, George (MP)
To: SKERRITT, John; [redacted]
Subject: Re: TGA decision on ivermectin prescription. [SEC=OFFICIAL]
Date: Monday, 13 September 2021 1:41:24 AM

Dr Skerritt,

As you've cc'ed me in this, let me respond. I agree with [redacted] email. The fact that someone with such an esteemed and credentialed background sees the error in the TGA's ways speaks volumes.

The TGA decision on banning GPs from prescribing ivermectin off-label was wrong and the primary reasoning for banning ivermectin was bizarre. The TGA has stated:

"… there are a number of significant public health risks associated with taking ivermectin in an attempt to prevent COVID-19 infection rather than getting vaccinated. Individuals who believe that they are protected from infection by taking ivermectin may choose not to get tested or to seek medical care if they experience symptoms. Doing so has the potential to spread the risk of COVID-19 infection throughout the community."

Really? What asinine reasoning! It could also be said that vaccinated people could "believe that they are protected from infection" and "choose not to get tested or to seek medical care if they experience symptoms" which could have "the potential to spread the risk of COVID-19 infection throughout the community." Perhaps the TGA wants to ban vaccines if this is the rationale you put up for ivermectin?

It seems to me like the TGA has made the decision to coerce more people into what was supposed to be a voluntary vaccination program. The constant closing of doors to those who don't want to take the vaccine has gone too far. And this decision is yet another one of those doors closed.

From your response to [redacted] I can see you have a completely closed mind in regards to all the literature out there on ivermectin so it's no use going through any of the evidence with you or the TGA. But I would note that the TGA does not have a monopoly on medical opinion and that many esteemed doctors, professors in medicine and immunologists I have spoken to see the benefit in ivermectin.

I am going to rage against this decision until it is changed. I have already spoken with Minister Hunt and the Deputy Prime Minister and will use whatever leverage I can in parliament to bring about a change. The TGA should leave the prescription of medicines that are freely available in Australia up to GPs and not engage in such heavy handed behaviour.

And, on a personal note, if one of my relatives or loved ones contracts COVID-19 and cannot get an ivermectin treatment to them as a result of the TGA decision and they subsequently die then I will begin legal action against the TGA and all of its individual members involved in the decision. Many more people might do the same.

The TGA and it's members should be thinking very carefully about the consequences of their decisions on people's lives. Quite frankly, I no longer think they do that anymore and

so any confidence I had in the TGA as a reputable regulator is now gone. I'm not the only one who thinks like that.

Regards,

George Christensen

PS I've organised a phone-in protest as a result of this decision. The TGA will probably get a few calls tomorrow as a result. I hope the phones are well staffed there.

From: SKERRITT, John <John.Skerritt@health.gov.au>
Sent: Sunday, September 12, 2021 8:14 pm
To: [redacted] SKERRITT, John
Cc: [redacted]
Hanson, Pauline (Senator); [redacted]
Christensen, George (MP); [redacted]
Subject: RE: TGA decision on ivermectin prescription. [SEC=OFFICIAL]

Dear [redacted]

Thank you for your email. I respectfully disagree with the assertions you have made for the following reasons:

- You wrote "*Ivermectin is easy and cheap to make, and, if Australian supplies fail, it can be imported from other countries.*"

Australia has had a recent national shortage for most of the month of August following a four-fold increase in prescribing in Australia from "normal" levels. Your assertion that this can be quickly fixed by ordering from overseas does not reflect an understanding of how medicines supply chains work in reality – it took 3 weeks for the national shortage to be resolved. Immediately after the national shortage there remained a local shortage of ivermectin in many pharmacies in western and southwestern Sydney. The consequence of this shortage was that people who had a desperate need for ivermectin because of infections such as scabies – quite often including those in residential aged care or in disadvantaged aboriginal communities – had delays in receiving this essential medicine.

- You also wrote *"Safe dosing is a matter of education for health care providers and the public".*

Unfortunately there have been a number of GOPs who have written prescriptions for doses 3-4 times higher than the approved daily dose of this medicine, and we are aware of individuals who have had to seek emergency department treatment as a result. Other individuals have simply taken several time the amount prescribed to them, or have attempted to illegally import this prescription medicine without valid approvals. While the new restrictions have been portrayed by some as an inappropriate constraint on the prescribing rights of GPs, it is important to emphasise that the RACGP president endorse TGA's move and the RACGP has also issued warnings against inappropriate prescribing of this medicine.

- You also wrote *" Proponents of early antiviral treatment are not necessarily opposed to vaccines: they see these as potentially complementary therapies. Antiviral agents, employed in the primary care environment, can cover acute exposure, prophylaxis after known, suspected or anticipated exposure, deficient vaccine supply, vaccine refusals, vaccine failures, new mutants and waning vaccine efficacy over time, (of which we are hearing more and more)".*

As a PhD-trained pharmacologist and head of the national medicines regulator I am well I am aware of the use of antivirals and how they complement vaccines for the purposes you outline. Indeed the TGA has approved several therapies for the treatment of COVID-19 to complement the vaccines and I am personally involved in regular pre-submission meetings with companies providing data on new antivirals for COVID-19. However, our lived experience, together with any scan of social media will demonstrate that there are a significant number of people who assert that ivermectin can be used instead of being vaccinated. This trend was repeated in the 100 or so emails and SMS texts I have received on ivermectin in recent days, with many assertions from the writers that vaccines are evil and/or they don't work and ivermectin is instead the solution.

- Finally, you wrote *"Our advisors at both state/territory and federal levels justify such suppression by citing lack of evidence of benefit of these agents. However, they have not disclosed what evidence among the current >65 existing reports they have reviewed, which ones they accept or reject, and how they reached those*

decisions."

Together with my senior medical staff I have personally reviewed the major published studies on ivermectin, and unfortunately many of the published studies suffer from bias or confounding factors . The most cited study on ivermectin and COVID-19 has been redacted by the journal in which it was published due to concerns re data fabrication. But I agree that there several other are studies underway and if these studies prove positive they could support a regulatory submission.

As we have indicated publically for many months, the onus is for a sponsor to make a regulatory submission to the TGA as there is a legal requirement for there to be an entity responsible for product stewardship and establishing a supply of approved pharmaceutical product. We have also met with the major Australian proponents of ivermectin and provided them with detailed verbal and written information on the process and data requirements to make a submission to the TGA for regulatory consideration.

However, we believe that the recent decision, which was made on the advice of the Ministerially-appointed Advisory Committee for Medicines Scheduling, which includes subject matter experts as well as representatives of health departments from every state and territory, is the appropriate one.

John Skerritt-

Adjunct Prof John Skerritt FTSE FIPAA (Vic)
Deputy Secretary for Health Products Regulation
Department of Health
(The Health Products Regulation Group comprises the Therapeutic Goods Administration and the Office of Drug Control)

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