

## **Responses from the Therapeutic Goods Administration (TGA)**

### **What is the intent of applying the advertising conditions to good faith discussions about the vaccine?**

*The advertising rules do not apply to information that is not promotional, nor to conversations between a health professional and their patient. The TGA regulates therapeutic goods advertising in accordance with the Therapeutic Goods Act 1989 (the Act), which defines 'advertise' as "...to promote the use or supply of the [therapeutic] goods...". The advertising rules apply to advertising content that meets this definition.*

*The arrangements for advertising COVID-19 vaccines are no different from what is in place for the advertising of other prescription medicines, which the Act prohibits from being advertised to consumers except where such advertising has been authorised or approved by the Australian Government or an Australian state or territory government.*

### **What penalties apply?**

*The TGA uses a range of education and assistance through to enforcement options to manage compliance with the regulatory requirements for the advertising of therapeutic goods. Information is available in the Compliance and Enforcement Hub on the TGA website.*

### **Isn't this part of the code more intended to cover commercial sponsors to stop them getting key opinion leaders to endorse products for the public?**

*The protection of consumers is the key intent of the laws relating to the advertising of therapeutic goods. While these laws in the main capture the activities of commercial sponsors, the commercial interest or otherwise of the party disseminating promotional material is not relevant in assessing the compliance of that material with the law.*

### **Does it apply to academics and researchers who may also be registered doctors?**

*The requirements of the advertising provisions in the Act apply to any party. If material is in the public domain that promotes the use or supply of a prescription medicine the law applies. The advertising rules do not apply to information that is not promotional, nor to conversations between a health professional and their patient.*

### **If so, isn't this an interpretation of the act which suppresses freedom of academic discussion?**

*The intent of the advertising requirements in the Act is not to suppress freedom of academic discussion. If the discussion does not constitute advertising of prescription medicines, the rules do not apply.*

### **Does it apply to registered doctors who regularly appear in the media and are recognised as commentators?**

*The requirements of the advertising provisions in the Act apply to any party.*

**How is this different from doctors synthesising the scientific literature for their patients which they do all the time?**

*Information that is indiscriminately disseminated is very different from information that is made available to patients by doctors on an individualised basis. In the latter situation, a doctor is in the position to use their judgement, training, and experience to advise their patient in relation to the information.*

*Discussions and information shared between a health professional and their patient during a course of treatment (e.g. during a consultation) are not subject to the advertising requirements for therapeutic goods.*

*Information that is not promotional is also not subject to the advertising rules.*

**Can a doctor say publicly that COVID vaccination is a good thing?**

*It is possible for doctors to provide information about COVID-19 vaccination that does not meet the Act's definition of 'advertise'. For example, a doctor's opinion of vaccination generally may not have the effect of promoting the use or supply of a specific vaccine and information about a specific vaccine is less likely to meet the definition of 'advertise' if it is factual and balanced.*

**While you say that doctors should refer to the Government's website, that is not necessarily across the latest research; removing evidence-based commentary could bias coverage towards anti-vaxxers. Does this bother you?**

*Evidence-based commentary is not being removed. As set out in the TGA guidance on advertising the COVID-19 vaccine, evidence-based factual information that does not use promotional language is unlikely to fall within the definition of 'advertising' for the Act.*

*Information about the COVID-19 vaccine that would be more likely to have the effect of informing consumers, as opposed to having the effect of persuading them, will not constitute advertising. As set out in the guidance, examples of the types of information that are more likely to inform than persuade are:*

- *a doctor providing their general view in relation to vaccination broadly (provided they do not promote individual vaccines - COVID-19 or otherwise)*
- *technical information relating to how the vaccines were developed and manufactured*
- *sharing scientific reports from reputable sources (like the World Health Organization) about vaccination*
- *re-tweeting or sharing valuable news-worthy information from reputable sources about the COVID-19 vaccines that would not have the effect of promoting the vaccines; or*
- *presenting comprehensive information that doesn't emphasise the benefits over, for example, the risks and limitations.*