May 27 2022

AMA Insurance Brokers & Financial Services
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Drug Free Australia would like to bring to your urgent attention a recent letter we sent to the Australian Medical Association regarding grave concerns regarding their outdated website on information about medicinal cannabis (medical marijuana). This also included information on the Therapeutic Goods Administration's (TGA's) apparent disregard for safety, quality or effectiveness of Medical Marijuana.

- Please find, **attached,** a copy of the letter to the AMA.
- Please also find their response, at **Point 3 below**, which abdicates AMA responsibility and moves it directly to the TGA.

However, of even greater concern is that there is also a strong indication that the TGA is lacking in due diligence in relation to several of its responsibilities.

For example:

1. Recent public comments by Dr Peter Keller, for TGA official, who led the regulator's inspection program from 2017 to 2022 included that a lack of independence of clinical trials is a 'ticking time bomb that risks the safety of people in drugs studies'.

2. Recent correspondence from Professor Keith McNeil Acting Deputy Director-General and Chief Medical Officer, Prevention Division and Chief Clinical Information Officer Queensland Health letter dated 17/05/2022 Reference C-ECTF-22/6798 email MMU@health.qld.gov.au
   2a. 'Most medicinal cannabis products are unapproved therapeutic goods, *which means they have not been assessed by the Therapeutic Goods Administration (TGA) for safety, quality or effectiveness. However, where clinically appropriate, there are pathways for doctors to access medicinal cannabis products for their patients. The Commonwealth Department of Health, Therapeutic Goods Administration (TGA) has published a range of information to help health professionals learn more about medicinal cannabis products, including guidance, external research and clinical evidence. Health practitioners who are considering treating a patient with an 'unapproved' therapeutic good must acknowledge that it has not been evaluated for quality, safety or efficacy and it has not been approved by the TGA. The TGA cannot guarantee the quality, safety or efficacy of an 'unapproved' product. In prescribing an unapproved therapeutic*

good, the prescribing health practitioner must consider the available evidence to support the use of the unapproved product and any potential risks for the individual patient.

Current Commonwealth guidance advises that medicinal cannabis products containing delta-9 tetrahydrocannabinol (THC) are generally not appropriate for patients who are pregnant, planning on becoming pregnant, or breastfeeding. I note that THC does not currently appear on the Commonwealth Department of Health, prescribing medicines in pregnancy database. This database is intended to provide information to health professionals planning the medical management of pregnant patients or patients intending to become pregnant'.

2b. Queensland Health dated Q Script April 27 2022 email mmu@health.qld.gov.au

Most medicinal cannabis products are unapproved therapeutic goods, which means they have not been assessed by the Therapeutic Goods Administration (TGA) *for safety, quality or effectiveness. However, where clinically appropriate, there are pathways for doctors to access medicinal cannabis products for their patients. As indicated on the TGA website, the TGA has published a range of information to help health professionals learn more about medicinal cannabis products, including guidance, external research and clinical evidence. Health practitioners who are considering treating a patient with an 'unapproved' therapeutic good must acknowledge that it has not been evaluated for quality, safety or efficacy and it has not been approved by the TGA. The TGA cannot guarantee the quality, safety or efficacy of an 'unapproved' product. In prescribing an unapproved therapeutic good, the prescribing health practitioner must consider the available evidence to support the use of the unapproved product and any potential risks for the individual patient. The responsibilities of the prescribing health practitioner include adhering to relevant standards of good medical practice and obtaining informed consent. The prescribing health* ***practitioner also accepts responsibility*** *for the use of an 'unapproved' therapeutic good and any associated adverse reactions. Relevant specialist medical colleges are a source of information to their members, with many having released position statements in relation to medicinal cannabis and its therapeutic use. You may wish to consider approaching relevant colleges with the research being collated for their consideration in informing and educating health professionals.*

3. **AMA email reply to Drug Free Australia from** Anita Mills <amills@ama.com.au>
   Subject: FW: D22/1425 RE: AMA stance on Medicinal Cannabis
   Dear Mr Christian Thank you for contacting the AMA regarding your organisation's position on medicinal cannabis. Your letter has been passed on to me for reply. I advise that the AMA does not make clinical recommendations or undertake clinical research. You therefore may wish to write to the Therapeutic Good Association regarding your concerns, noting the the role of the Therapeutic Goods Administration (TGA), as the regulator of medicines in Australia. The AMA notes that it is important that all medicines go through the TGA approval processes (i.e. to become registered on the Australian Register of Therapeutic Goods, ARTG) to ensure that medicines meet appropriate standards for quality, safety and efficacy. ***Only two medicinal cannabis products have been through this process and are registered on the ARTG – Nabiximols (for patients with moderate to severe spasticity due to multiple sclerosis) and Epidyolex*** *(for seizures associated with Lennox-Gastaut Syndrome or Dravet syndrome).*

Currently, there is insufficient evidence to use medicinal cannabis products more broadly and the evidence base varies across conditions. This is why there are not more medicinal cannabis products registered on the ARTG.

Drug Free Australia has made several other submissions to the TGA, including correspondence to inform them of action by the FDA in the United States, regarding unapproved medical claims for medicinal marijuana products involving misbranding and false claims, together with violations of the FD&CA. Such products can be bought online and shipped to Australia. On these matters, the **TGA didn't even give DFA the courtesy of a written response.**

Taking into account all of the above, it is clear that the TGA as abdicated from basic responsibility and has placed all the liability of these unapproved products onto the shoulders of the Doctors. We hope that you, as insurers, will take this up at appropriate levels and rectify such questionable and highly dangerous practices. We would appreciate updates on your decisions in this regard, in the interests of the Australian community and ongoing public health and safety.

Yours sincerely

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Prevent. Don't Promote Drug Use.
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