



Australian Government
Department of Health and Aged Care

Deputy Secretary

Coroner Audrey Jamieson
Coroners Prevention Unit
Coroners Court of Victoria
65 Kavanagh St
Southbank VIC 3006
cpuresponses@coronerscourt.vic.gov.au

RE: COR 2020 002323, Anna Lawrence

Dear Coroner Jamieson

Thank you for your letter regarding the death of Anna Lawrence and use of baclofen for alcohol use disorder. I was very sorry to learn of Ms Lawrence's death.

I am writing in response to the specific recommendation that the Therapeutic Goods Administration (TGA) consider whether, by revising the Australian Register of Therapeutic Goods (ARTG) entry for Baclofen to include alcohol use disorder as an approved indication, safer Baclofen prescribing practices could be achieved. The Coroner's recommendation is unable to be implemented independently by the Therapeutic Goods Administration (TGA), and the below information outlines the process for how indications are approved for medicines included in the ARTG.

The TGA approves prescription medicines for use in Australia on the basis that the benefits outweigh the risks for their intended use. This intended use is outlined on the entry into the Australian Register of Therapeutic Goods (ARTG). Before a medicine, or a new indication for a medicine, can be included on the Australian Register of Therapeutic Goods (ARTG), the TGA must receive an application from an Australian pharmaceutical Sponsor. This Sponsor must be willing to accept the responsibilities of selling prescription medicines in Australia. The TGA's role is to regulate the actions of the Sponsor, including ensuring that the product meets requisite standards of quality, safety, and efficacy for the proposed indication(s). This requires a rigorous scientific evaluation of data submitted by the sponsor, drawing on expertise from several scientific fields. Registration for an approved indication depends on the ability to confirm a positive benefit-risk balance of the medicine for patients with that condition.



For products containing baclofen to be registered for alcohol use disorder, an incorporated body or resident of Australia would need to be willing to accept responsibility as the Australian Sponsor for this extended indication and submit the relevant supporting data to the TGA. The TGA cannot compel a sponsor to make an application for a new indication for an approved medicine. Furthermore, in the absence of a formal application, the TGA does not have the legal authority to grant approval, nor initiate an evaluation of the product for an extension of indication.

The approved Product Information (PI) and Consumer Medicines Information (CMI) documents for use by prescribers and consumers include information on the safety of a medicine in its proposed use, including contraindications, precautions, interactions with other medicines and adverse effects. The indication alone is not intended to achieve safe use of a medicine. The PI and CMI for baclofen containing products were updated in 2019 on request of the TGA to include a warning about the risk of suicide and suicide-related events, recommending close supervision of patients with alcohol use disorder, depression and/or a history of previous suicide attempts. These are available on our website: www.ebs.tga.gov.au.

In summary, the TGA has carefully considered your recommendation for COR 2020 002323 and whilst we do not have the regulatory power to extend the registered indication for baclofen to include alcohol use disorder, we will consider the need to re-iterate the existing warning on suicide and suicide related events through a Medicines Safety Update article. Recommendations concerning clinical practice matters including off-label prescribing should be raised directly with the Australian Commission on Safety and Quality in Health Care (ACSQHC) and the Australian medical colleges who are responsible for training and clinical guidance documents for medical practitioners, including prescribing practices.

Yours sincerely



Tracey Duffy
A/g Deputy Secretary
Health Products Regulation Group

10 May 2023