



Australian Government

Department of Health

Deputy Secretary

Ms Dawn Wright
Manager Listings
Office of the State Coroner
WA Justice
PERTH WA 6000

Dear Ms Wright

I refer to your letter of 8 December 2021 regarding the inquest into the death of Elia Wani due to sodium nitrite-induced methaemoglobinaemia and Coroner Jenkin's subsequent recommendations to the Therapeutic Goods Administration (TGA).

The TGA, which is part of the Department of Health, acknowledges the concerning trend of the increasing misuse of sodium nitrite and the devastating impact that such misuse can have on Australians. The TGA also acknowledges that there are many legitimate uses for this substance in a wide variety of industries, including food, pharmaceuticals, explosives, and pesticides.

***Recommendation 1:** The TGA to consider whether products containing sodium nitrate should be the subject of similar restrictions as those about to imposed in relation to sodium nitrite, given the similar effect on the human body of both substances.*

I wish to clarify that on 12 October 2021, a delegate of the Secretary of the Department of Health published an interim decision to amend the Poisons Standard with regards to sodium nitrite.¹ A final decision is anticipated in January 2022.

The interim decision was to increase restrictions over access to preparations containing more than 15 per cent sodium nitrite by including them in Schedule 7 (Dangerous Poison) rather than Schedule 6 (Poison) of the Poisons Standard. Additional access restrictions are imposed on Schedule 7 poisons under state and territory legislation. The delegate made their interim decision in view of: the increasing reports of its misuse for self-harm; advice from the Advisory Committees

¹ www.tga.gov.au/scheduling-decision-interim/notice-interim-decisions-proposed-amendments-poisons-standard-sodium-nitrite-june-2021

on Medicines and Chemicals Scheduling; and submissions from health professionals, industry representatives and the wider public on the uses and risk of harm of this substance.

The TGA has considered the scheduling of sodium nitrate in the Poisons Standard given its chemical and toxicological similarity to sodium nitrite. The information obtained by the TGA to date about deliberate self-poisonings and deaths, including submissions to the public consultations on the scheduling of sodium nitrite, has not evidenced a trend for sodium nitrate misuse. As a result, the TGA is not giving further consideration to scheduling of sodium nitrate at this time, however will continue to monitor the available evidence. Should a potential risk to public health become evident, the TGA will initiate a process to formally consider an entry for sodium nitrate in the Poisons Standard to ensure access to and/or packaging and storage of this substance is appropriate.

***Recommendation 2:** The TGA should consider advising suppliers of products containing sodium nitrite that these products have been widely promoted as capable of causing death in the context of euthanasia and suicide, and suggesting that suppliers take all possible steps to ensure that the sodium nitrite products they sell are intended for legitimate purposes.*

In administering the Poisons Standard, the TGA routinely undertakes several actions that can assist in minimising the risks from substances being misused. Access requirements such as permitted uses, labelling and storage to alert suppliers and users of a substance to the hazards can be imposed through the Poisons Standard. The TGA also publishes public notices for all decisions on its website and these explain the reasons for the decision, including the risks that were considered by the scheduling delegate. Where appropriate, the TGA publishes guidance for stakeholders about the risks for substances that are used in therapeutic goods and redacts information from decisions and guidance that could promote misuse.

The TGA considers that mental health education and services, and training and education in the industrial chemical and food industries, will be critical to addressing the concerns arising from illegitimate use of sodium nitrite supplied for purposes other than therapeutic use. The TGA regularly engages with other areas of the Department, relevant state and territory authorities, and peak industry and health professional bodies to support their educational initiatives relating to the scheduling of poisons. The TGA is committed to doing so in relation to sodium nitrite to ensure the risks of this substance are addressed in the most effective manner.

Thank you for the opportunity to respond to Coroner Jenkins. Should you have any further questions, please do not hesitate to contact Mr Benjamin Noyen, Assistant Secretary, on 02 6289 7214 or benjamin.noyen@health.gov.au.

Yours sincerely



Adj. Professor John Skerritt
Health Products Regulation Group

22 December 2021