[redacted]

From: [redacted]@health.gov.au>
Sent: Friday, 19 October 2018 3:48 PM
Subject: response cleared by John and relevant line areas [DLM=For-Official-Use-Only] [D18-11099366] alkyl nitrites Thorne Harbour Health secretary response - 16 October 2018.DOCX; [D18-11097463] Letter rec d for Secretary - decision under the TG Regs - Amending the Poisons Standards - Alkyl Nitrites - 10 October 2018.PDF
Attachments:

Good afternoon [redacted]

This was handed to John at his 1:1 with the Secretary.

Please find attached the letter drafted for the Secretary's signature and also the original correspondence that was received.

Thanks

[redacted]

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Australian Government
Department of Health

Secretary

Mr Simon Ruth
Chief Executive Officer
Thorne Harbour Health
Level 5, 615 St Kilda Road
MELBOURNE VIC 3004

Dear Mr Ruth

Thorne Harbour Health submission on the proposed amendment to the Poisons Standard in relation to alkyl nitrites

Thank you for your letter of 10 October 2018 regarding your concerns about the interim decision, published on 10 September 2018, to consider amending the Poisons Standard in relation to alkyl nitrites.

As part of my department, the Therapeutic Goods Administration (TGA) helps to safeguard and enhance the health of the Australian community through the effective and timely regulation of therapeutic goods. In addition, senior staff members from the TGA, acting as my delegates, determine how medicines and chemicals are made available to the public through a process known as scheduling. Medicines and chemicals are classified into Schedules in the Poisons Standard to protect public health and safety. The implementation of the Poisons Standard, as it affects access to and supply of medicines and poisons, is given legal effect through relevant state and territory drugs, poisons and controlled substances legislation.

As part of the legislative requirements in making scheduling decisions, the delegate must take certain matters into account in exercising their powers when considering scheduling applications , including:

(a) the risks and benefits of the use of a substance;
(b) the purposes for which a substance is to be used and the extent of use of a substance;
(c) the toxicity of a substance;
(d) the dosage, formulation, labelling, packaging and presentation of a substance;
(e) the potential for abuse of a substance;
(f) any other matters that the Secretary considers necessary to protect public health.

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Where existing substances, such as alkyl nitrites, are being considered for possible rescheduling, the TGA follows a legislated process that includes at least two opportunities for the general public, interested parties and experts to provide evidence or comment on the proposed scheduling change. These consultation periods occur when the initial announcement regarding rescheduling is made and after an interim decision is published.

Prior to announcing the interim decision on alkyl nitrites, the delegate took into consideration the first round of public submissions as well as advice from the Advisory Committee on Medicine Scheduling (a committee comprising professionals with specific scientific, medical and clinical expertise). The delegate's reasons for the interim decision are provided on the TGA web site at https://www.tga.gov.au/scheduling-decision-interim/publication-interim-decisions-proposing-amend-or-not-amend-current-poisons-standard-september-2018 and included health risks such as methaemoglobinaemia (impaired ability of haemoglobin to carry oxygen in the blood), maculopathy, tachycardia, hypotension, headache, flushing, dizziness, nausea, and syncope (fainting). At that time, interested persons were also invited to make further submissions to the TGA. While this consultation period closed on 11 October 2018, I will ensure that the delegate receives a copy of your letter to be considered prior to any final decision being made.
The proposed scheduling of alkyl nitrites will be further reviewed by the Advisory Committees for Medicines and Chemicals Scheduling, which meet in early November. This will also include review of submissions received in response to the interim decision of the delegate. They will then provide further advice to the delegate.

The delegate's final decision, which may confirm, vary or set aside the interim decision, is expected to be announced on 29 November 2018 on the TGA web site at https://www.tga.gov.au/scheduling-delegates-final-decisions. The announcement will also include the reasons for the decision and any applicable implementation date.

Should you have any further queries please do not hesitate to contact [redacted] Regulatory Engagement and Planning Branch (Contact details: [redacted]@health.gov.au; telephone [redacted]. [redacted] has responsibility for the scheduling process and can assist with any questions you may have.

I appreciate you taking the time to outline your concerns and trust that the above information is of use.

Yours sincerely

Glenys Beauchamp

October 2018