[redacted]

From: [redacted]
Sent: Tuesday, 30 October 2018 6:05 PM
To: SKERRITT, John
Cc: [redacted]
Subject: Thorne Harbour Health [SEC=UNCLASSIFIED]
Attachments: Letter to Thorne Harbour Health from Ms Glenys Beauchamp [SEC=UNCLASSIFIED]

Follow Up Flag: Filed to: [E18-200399] COMMUNITY RELATIONS - Lia...Secretary and Secretary and Department of Health
Flag Status: Completed

Categories: Filed to TRIM

Good Afternoon,

Please be advised the attached has been emailed and posted. The hard copy is awaiting courier collection.

Kind Regards

[redacted]
[redacted] Office of the Secretary

☎ (02) [redacted]
[redacted]@health.gov.au

Department of Health
Mail: MDP 84, GPO Box 9848 Canberra ACT 2601
Street: Level 14, Scarbrough House, Atlantic St Woden ACT
[redacted]

[redacted]

From: [redacted]
Sent: Tuesday, 30 October 2018 6:04 PM
To: 'jonathan.meddings@thorneharbour.org'
Subject: Letter to Thorne Harbour Health from Ms Glenys Beauchamp [SEC=UNCLASSIFIED]
Attachments: Letter to Thorne Harbour Health.pdf

Good Afternoon,

Please find the attached letter to Mr Simon Ruth. Please be advised the letter will be sent in the post.

Kind Regards

[redacted]
[redacted] Office of the Secretary

☎ (02) [redacted]
[redacted]@health.gov.au

Department of Health
Mail: MDP 84, GPO Box 9848 Canberra ACT 2601
Street: Level 14, Scarbrough House, Atlantic St Woden ACT
[redacted]

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

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; and
(f) any other matters that I or my delegate consider necessary to protect public health.

Where existing substances, such as alkyl nitrites, are being considered for possible rescheduling, the TGA follows a legislated process that includes at least two

Phone: (02) 6289 8400 Email: Glenys.Beauchamp@health.gov.au
Scarborough House, Level 14, Atlantic Street, Woden ACT 2606 - GPO Box 9848 Canberra ACT 2601 - www.health.gov.au

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 Medicines Scheduling (a committee comprising professionals with specific scientific, medical and clinical expertise). The 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 people were also invited to make further submissions to the TGA. While this consultation period closed on 11 October 2018, I will ensure your letter's considered prior to any final decision being made.

The proposed scheduling of alkyl nitrites will be further reviewed at a joint sitting of The Advisory Committees on Medicines Scheduling and Chemicals Scheduling in early November. This will also include review of submissions received in response to the interim decision. They will then provide further advice to the delegate.

The final 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] 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

G. A. Beauchamp

Glenys Beauchamp

29 October 2018