Inquest into the death of Donna Cowley-Persch

Donna Cowley-Persch died at the Ascot Veterinary Surgery on 19 September 2013 from pentobarbitone toxicity, a drug used for the purpose of animal euthanasia.

Coroner John Hutton delivered his findings on 21 February 2017.

The Queensland Government responds to recommendations directed to government agencies at inquests by informing the community if a recommendation will be implemented or the reason why a recommendation is not supported.

The departments named in this response will provide implementation updates until the recommendation is delivered. Further information relating the implementation of recommendations can be obtained from the responsible minister named in the response.

Recommendation 2

[If the Therapeutic Goods Administration upschedules pentobarbitone in injectable form to a Schedule 8 drug in the Commonwealth Poisons standard] Queensland Health and all relevant state and territory regulatory authorities adopt the Therapeutic Goods Administration's upscheduling of pentobarbitone in injectable form to a Schedule 8 drug, and the stricter controls that this entails.

Response and action: the recommendation was not implemented.

Responsible agency: The Therapeutic Goods Association, supported by Queensland Health.

On 25 January 2018 the Minister for Health and Minister for Ambulance Services responded:

After considering relevant scheduling history, international regulations and 32 public submissions, the Therapeutic Goods Administration—through the Joint Advisory Committee on Chemicals and Medicines Scheduling—determined on the 23 March 2017 there was no new evidence to alter the scheduling of pentobarbitone to a Schedule 8 drug. Therefore Queensland Health is unable to adopt the recommendation. Full details of the Therapeutic Goods Administration's decision is available on their website.

Recommendation 3

If the Therapeutic Goods Administration decides not to upschedule pentobarbitone in injectable form to Schedule 8, it is recommended that state and territory regulatory agencies introduce stricter regulations for the drug, in line with Schedule 8 controls anyway.

Response and action: the recommendation is agreed to in part, and implementation is complete.

Responsible agency: Queensland Health

On 25 January 2018 the Minister for Health and Minister for Ambulance Services responded:

The Department of Health is consulting with the veterinary and animal welfare management industry on this matter.

The outcomes of the consultation and any potential regulatory or policy changes in the management of pentobarbitone are yet to be determined.

On 9 April 2018 the Minister for Health and Minister for Ambulance Services responded:

The Department of Health consulted with the veterinary and animal welfare management industry

and concluded the introduction of stricter controls in line with Schedule 8 was not supported. However, stricter record keeping and storage and security requirements were supported in general by all groups consulted.

Hospital and health services and public health units will investigate processes to audit veterinary practices as part of the systematic compliance review activities planned for 2017/18 and beyond, and this will include information on pentobarbitone.

Regulatory options including the introduction of a storage standard for pentobarbitone will be explored as part of the development of the new Medicines and Poisons Act in 2018.

An educational intervention was developed in partnership with the Veterinary Surgeons Board of Queensland and the Australian Veterinary Association – Queensland Division. A Queensland Health factsheet or guideline relating to the safe use, storage and disposal of pentobarbitone, along with other scheduled drugs, will be developed in 2018 as part of the educational intervention.

Additionally, monitoring of compliance activities conducted by public health units will inform further need for education or regulatory change.

On 1 November 2018 the Minister for Health and Minister for Ambulance Services responded:

The Therapeutic Goods Administration—through the Joint Advisory Committee on Chemicals and Medicines Scheduling—determined there was no new evidence to alter the scheduling of pentobarbitone to a Schedule 8 drug. Full details of the Therapeutic Goods Administration's decision is available on their website.

To address the coroner's recommendation, hospital and health service public health units finalised a veterinary practices audit tool that includes a section on pentobarbitone controls. Veterinary practices are being audited by public health units as part of the systematic compliance review activities. The new *Medicines and Poisons Bill* (due to go to consultation in late 2018) contains stricter controls for pentobarbitone. The new regulations include provisions to require veterinarians to report lost or stolen pentobarbitone to the organisation's chief executive.

The Queensland Health factsheet/guideline relating to the safe use, storage and disposal of pentobarbitone, along with other scheduled drugs, is under development and will be completed once the consultation on the new Act and Regulations is completed. It will be marketed to veterinary surgeons and professional stakeholder groups as part of the roll out of the new audit tool for use in veterinary practices. These fact sheets and guidelines will be developed in conjunction with the Veterinary Board and key stakeholders.

On 2 June 2019 the Minister for Health and Minister for Ambulance Services responded:

The draft Medicines and Poisons Bill 2018 and the associated Medicines and Poisons (Medicines) Regulation 2018 was released for targeted consultation in September 2018.

Further guidance documents relating to the safe use, storage and disposal of pentobarbitone and other scheduled drugs may be developed as part of the suite of implementation materials when the Medicines and Poisons Bill 2018 and the associated Medicines and Poisons (Medicines) Regulation 2018 are passed by parliament.

On 11 December 2019 the Minister for Health and Minister for Ambulance Services responded:

Queensland Health's public health units (PHUs) finalised a veterinary practices audit tool that includes a section relating to the safe use, storage and disposal of Pentobarbitone. Veterinary practices are continuing to be audited by PHUs as part of their systematic compliance review

activities. Pentobarbitone is a schedule 4 medicine and as such it is required to be stored out of public access and the increased compliance activities are focused on encouraging and enforcing veterinarians to comply with current legislation. In this incident the storage was not compliant with the Schedule 4 requirements so increased audit and compliance activities have been undertaken to mitigate this risk.

Pentobarbitone does not meet the scheduling requirements for Schedule 8 medicines and so the rescheduling was not endorsed by the Therapeutic Goods Administration (TGA). The definition of Schedule 8 in the Poisons Standard is primarily to 'reduce misuse, abuse and physical or psychological dependence'.

On 14 May 2019, the Hon Dr Steven Miles MP, Minister for Health and Minister for Ambulance Services introduced the Medicines and Poisons Bill 2019 (Bill) to Parliament and tabled the associated Medicines and Poisons (Medicines) Regulation 2019 (Regulation) at the same time. The Bill was passed by parliament on 17 September 2019 and became the *Medicines and Poisons Act 2019* on 26 September 2019.

Provisions in the draft Regulation require veterinary surgeons to report lost or stolen Pentobarbitone to the chief executive of Queensland Health and the police service as soon as practicable, and no later than the next business day after the incident occurs.

Further guidance documents relating to the safe use, storage and disposal of Pentobarbitone and other scheduled drugs may be developed as part of the suite of implementation materials when the Regulation is passed by parliament. In addition, the storage standard that appends the new legislation will compel that Pentobarbitone is stored in a locked cupboard when not in use by the veterinarian. Compliance with the new storage standard will be a component of the audit process going forward. Veterinarians who do not meet this standard will be in breach of the regulations.

On 3 June 2020 the Deputy Premier and Minister for Health and Minister for Ambulance Services responded:

The draft Medicines and Poisons Regulation 2020 (Regulation) elevates the actions and responsibilities required by those in possession of pentobarbitone and will further reinforce the regulatory framework for pentobarbitone storage.

Breaches of the Regulation will incur compliance action and referral to the Veterinary Board for consideration and action.

Following consultation, the Regulation will go through the usual processes until it is proclaimed.

On 2 October 2020 the Deputy Premier and Minister for Health and Minister for Ambulance Services responded:

The progress of the draft Medicines and Poisons Regulation 2020 (Regulation) was delayed by the public health emergency related to COVID-19. It is expected that consultation on the proposed Regulation will occur in early 2021 and implementation will commence in mid-2021. The regulatory framework for pentobarbitone is enhanced by moving it into the new Regulations.

Under the new Regulations pentobarbitone must be kept in a medicine store that can be locked and the keys to the store must be under the control of a person who is authorised to possess the medicines in the store.

The process to implement the draft Regulation is underway, in the meantime the public health units continue to undertake compliance activities in veterinary surgeries.

On 8 July 2021 the Minister for Health and Ambulance Services responded:

The progress of the draft Medicines and Poisons Regulation 2020 (Regulation) was delayed by the public health emergency related to COVID-19.

Consultation on the proposed Regulation commenced in early 2021 and implementation is anticipated to commence by late 2021. The regulatory framework for pentobarbitone is enhanced by moving it into the new Regulations.

On 17 December 2021 the Minister for Health and Ambulance Services and Leader of the House responded:

The Medicines and Poisons (Medicines) Regulation 2021 (Regulation) commenced on 27 September 2021. Note that in the Regulation, 'Pentobarbitone' is referred to as 'pentobarbital', which is its official name in the Commonwealth Poisons Standard, June 2021.

The intent of the recommendation is met by the additional controls in the Regulation, these include:

- increased compliance monitoring by public health inspectors of veterinary practices
- increased storage security requirements pentobarbital is not to be left outside a locked cupboard when not in immediate use. A penalty also applies to the person responsible for establishing and maintaining the medicines store if that store is not lockable
- clear provisions that a veterinary assistant has no authority to possess stock of pentobarbital. Trainee veterinary nurses and trainee veterinary surgeons may only possess pentobarbital under direct supervision of a veterinary surgeon
- increased reporting requirements for lost and stolen pentobarbital
- an offence for failing to prevent public access to waste from diversion-risk medicines (a category which includes pentobarbital)
- increased record keeping requirements for pentobarbital
- the requirement for wildlife rescue organisations to establish and implement a substance management plan to ensure increased risk management and governance of volunteers who euthanise injured animals with pentobarbital.