



VETERINARY PRACTITIONERS REGISTRATION BOARD OF VICTORIA

14 January 2016

Ms Cheryl Vella
Coroners Registrar
Coroners Court of Victoria
65 Kavanagh Street
SOUTHBANK 3006 VIC
CONFIDENTIAL

Court Ref: COR 2014 004163

Dear Ms Vella,

Investigation into the death of Daniella F Sessarego

The Board acknowledges receipt of your correspondence of 27 October 2015, and the coroner's recommendations resulting from the investigation into the death of Ms Daniella Sessarego. The circumstances of Ms Sessarego's death are tragic, and the Board wishes to convey its sympathies to Ms Sessarego's family and friends.

The Board's commitment is to the protection of the public and as such it welcomes the opportunity to respond to the coroner's recommendations pertaining to this matter.

Recommendation 1

That the Veterinary Practitioners Registration Board of Victoria consider extending the application of its guideline for enhanced record keeping and labelling/dispensing of Schedule 8 drugs to pentobarbitone. In particular, that the Board recommends to its members that:

- a. All pentobarbitone transactions are recorded in a record book maintained separately from the patient's medical record;*
- b. Details of each pentobarbitone transaction, inclusive of the date and quantity of supply, the name of the veterinary practitioner involved in the transaction and his/her usual signature, are recorded;*
- c. The true balance of pentobarbitone is recorded following each transaction;*
- d. Pentobarbitone records are maintained in a manner that cannot be altered, obliterated, deleted or removed without detection.*

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Recommendation 2

That the Veterinary Practitioners Registration Board of Victoria recommends to its members that pentobarbitone is stored in a drug safe accessible only by a veterinary practitioner, or by a staff member under the direction of a veterinary practitioner, that is date and patient specific and includes a direction to account for or dispose of any unused portion of the drug.

Background provided by the Board

Scheduled Drugs

The classification of poisons into schedules is made under section 52D of the *Therapeutic Goods Act 1989*. The Poisons Standard, which consists of the *Standard for the Uniform Scheduling of Medicines and Poisons* (the SUSMP) lists poisons into nine schedules according to the recommended degree of control to be exercised over their availability to the public.

The *Drugs, Poisons and Controlled Substances Act 1981*, the *Drugs, Poisons and Controlled Substances Regulations 2006*, the *Agricultural and Veterinary Chemicals (Control of Use) Act 1992*, and the *Agricultural and Veterinary Chemicals (Control of Use) Regulations 2007* regulate the use of scheduled drugs in Victoria, including the statutory requirements for storage and recording keeping.

Guidelines

Pursuant to section 62(1)(e) of the *Veterinary Practice Act 1997* (the Act), one of the Board's functions is to issue guidelines about appropriate standards of veterinary practice and veterinary facilities.

In the case of disciplinary proceedings a hearing panel may inform itself by reference to those guidelines issued under section 62(1)(e) as to appropriate standards of veterinary practice and veterinary facilities.

The Board considers the guidelines to be the minimum standard expected from a registered veterinary practitioner exercising reasonable skill and care in the course of veterinary practice. The guidelines are issued to help clarify the Board's expectations on a range of issues, but are not statutory regulations. As such, strict liability does not apply and a breach of the guidelines does not automatically result in a finding of unprofessional conduct.

Guideline 6 – Supply and Use of Drugs, Scheduled Drugs and Other Medications in Veterinary Practice, is largely based upon the statutory requirements of the *Drugs, Poisons and Controlled Substances Act 1981* and *Regulations 2006*, and the *Agricultural and Veterinary Chemicals (Control of Use) Act 1992* and *Regulations 2007*.

Pentobarbitone and the Veterinary Profession

Research has indicated that the rate of suicide for veterinary practitioners and veterinary nurses is higher than that of the general population, and that the majority of these cases use pentobarbitone overdose as the method. The high use of this particular method of suicide is attributed to veterinary practitioners and veterinary nurses having both access to this drug and knowledge as to how to use it.¹

Board Response

In regard to the coroner's recommendations the Board provides the following response.

Recommendation 1

The recording keeping requirements for scheduled drugs are prescribed under Division 5 of the *Drugs, Poisons and Controlled Substances Regulations 2006*, and Regulations 7 to 9 of the *Agricultural and Veterinary Chemicals (Control of Use) Regulations 2007*.

Division 5 of the *Drugs, Poisons and Controlled Substances Regulations 2006* prescribes the record keeping requirements for all schedule 4, 8, and 9 poisons. While the provisions are generally similar for both schedule 4 and schedule 8 poisons there are additional record keeping requirements for

¹ AJ Milner, H Niven, K Page and AD LaMontagne, 'Suicide in veterinarians and veterinary nurses in Australia: 2001-2012' (2015) 9 Australian Veterinary Journal 308.

transactions involving schedule 8 drugs. These additional record keeping requirements correspond to those documented in the coroner's recommendation.

Pentobarbitone is classified as a schedule 4 drug under the SUSMP, and is therefore not subject to the additional record keeping requirements for schedule 8 drugs, as prescribed by Division 5 of *Drugs, Poisons and Controlled Substances Regulations 2006*.

The current Guideline 6 issued by the Board does not prescribe the record keeping requirements for scheduled drugs; only that veterinary practitioners are required to comply with all *Drugs, Poisons and Controlled Substances* provisions. The coroner's recommendation that veterinary practitioners undertake the additional record keepings requirements as required for schedule 8 drugs would necessitate the re-classification of pentobarbitone to a schedule 8 poison, pursuant to section 52D of the *Therapeutic Goods Act 1989*, in order for it to be enforceable.

Pentobarbitone is used as a euthanasia agent in animals. The use of pentobarbitone by registered veterinary practitioners for this legitimate application is essential to animal welfare. Should pentobarbitone be re-classified as a schedule 8 drug the record keeping requirements would be both onerous and time-consuming for many practitioners. A requirement to record pentobarbitone transactions in a separate record book that documents the true balance following each transaction would not necessarily safeguard against misuse should a veterinary practitioner or other staff member elect to act unlawfully.

Recommendation 2

The storage requirements for scheduled drugs are prescribed under Division 4 of the *Drugs, Poisons and Controlled Substances Regulations 2006*.

Pursuant to Regulation 34 of the *Drugs, Poisons and Controlled Substances Regulations 2006* schedule 4 drugs (of which pentobarbitone is one) are required to be stored in a lockable storage facility, which must be secured to prevent access by persons not specifically authorised under the legislation unless a veterinary practitioner is present.

Regulation 35(1) of the *Drugs, Poisons and Controlled Substances Regulations 2006* requires storage of schedule 8 and 9 poisons in a lockable facility of specific security and strength (i.e. a drug safe), and to which access is prevented except when it is necessary to open it to carry out an essential operation in connection with the poisons stored within it. Subject to regulation 35(3) a veterinary practitioner must take all reasonable steps to ensure that the storage facility referred to in sub-regulation (1) is used only for the storage of schedule 8 poisons, schedule 9 poisons, and drugs of dependence. Pentobarbitone is not classified as a drug of dependence under the *Drugs, Poisons and Controlled Substances Act 1981*. Therefore the recommendation that pentobarbitone be stored in a drug safe would seem incompatible with regulation 35(3).

However, subject to regulation 37 of the *Drugs, Poisons and Controlled Substances Regulations 2006* the secretary may direct a person to whom regulation 34, 35 or 36 applies to provide more secure storage for schedule 4 poisons, schedule 8 poisons or schedule 9 poisons than that described in regulations 34, 35 and 36. If, in the opinion of the coroner the storage requirements for schedule 4 drugs are not adequate in preventing access by unauthorised persons to pentobarbitone, a direction made subject to regulation 37 would result in the recommendation to store pentobarbitone in a drug safe being enforceable.

The Board notes that regardless of whether a drug is subject to schedule 4 or schedule 8 storage requirements, access by veterinary practitioners (and in certain circumstances by veterinary nurses) is still permissible under the regulations and as such the potential for misuse will remain (although it may be diminished by increased regulation).

The second part of this recommendation relates to record keeping and would require pentobarbitone to be re-classified as a schedule 8 drug to be enforceable, as described above.

Summary

The recommendations of the coroner would require amendment to existing legislation and regulations (not administered by the Board) for them to be enforceable.

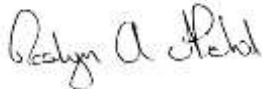
Alternatives to the Recommendations

As an alternative to the recommendations of the coroner, the Board respectfully suggests that this matter is brought to the attention of the Department of Health and the Therapeutic Goods Administration as the agencies responsible for the administration of the relevant legislation.

The Board will publish a summary of the coroner's recommendations on its website and in its newsletter to encourage veterinary practitioners to consider the matter, the recommendations, and what action they may take to mitigate any risk. The Board's next newsletter is due for publication in March/April 2016.

Should the coroner require further action by the Board or wish to discuss the matter further, please do not hesitate to contact me.

Yours sincerely,

A handwritten signature in black ink, appearing to read "Roslyn A. Nichol". The signature is written in a cursive, slightly slanted style.

Dr Roslyn Nichol
President
Veterinary Practitioners Registration Board of Victoria

Ref: DM