

# Proposed rescheduling of PENTOBARBITAL when packed and labelled for injection

Therapeutics Goods Administration

Submission from the Australian Veterinary Association Ltd



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## About us

The Australian Veterinary Association is the national organisation representing veterinarians in Australia. Our 9500 members come from all fields within the veterinary profession. Clinical practitioners work with companion animals, horses, farm animals, such as cattle and sheep, and wildlife. Government veterinarians work with our animal health, public health and quarantine systems while other members work in industry for pharmaceutical and other commercial enterprises. We have members who work in research and teaching in a range of scientific disciplines. Veterinary students are also members of the Association.

## Executive summary

Pentobarbital injection (pentobarbitone) is an extremely important pharmaceutical for the veterinary profession. It is the most humane method of euthanasia in animals presently available. It is used extensively in small animal practice, equine practice, rural practice, shelter medicine, wildlife management, stray animal management and in veterinary and human research involving animals. Most of our members administer this drug multiple times over each working day, and the ability to do so in a timely manner can be extremely important from an animal welfare perspective. As such, any changes to the regulations around the control of pentobarbital injection that may significantly impede veterinary practice are very important to AVA members.

Suicide in the veterinary profession is a well recognised issue that our members are very concerned about. A study into suicide in veterinarians and veterinary nurses in Australia from 2001-2012 concluded that veterinarian suicide was significantly higher than that of the general population at around 1.92 times the rate of the general population.<sup>1</sup> In the same study it was found that while the suicide rate in veterinary nurses over the period was above that of the general population, this difference was not statistically significant. Another Australian study (over the period 1990–2002 in two states)<sup>2</sup> reported veterinarian suicide rates around 4 times that of the general population. High veterinary suicide rates have also been reported in international studies.<sup>3,4</sup>

The most common method of veterinarian suicide identified is pentobarbitone. The proposed up-scheduling of pentobarbital injection will not significantly reduce veterinary access to the drug, so we need to consider if this will have any impact on veterinary suicide statistics.

The AVA members were asked to consider these issues. We received feedback from 2031 members.

The majority of our members believe that rescheduling pentobarbital injection to Schedule 8 will not decrease suicide rates in veterinarians and their employees and consider that the recording requirements will impact veterinary practice significantly. Specifically, the increased recording requirements are likely to impede swift access during animal euthanasias and emergencies, and be thus problematic from an animal welfare perspective. Restriction of access may also significantly impact areas of use such as euthanasia of critically injured wildlife by authorised officers who currently have access to the drug. There is however, general support amongst our members for increased storage requirements for pentobarbital injection solutions.

## Recommendations

1. **The AVA does not support the rescheduling of pentobarbital injection to a Schedule 8 poison.**
2. The AVA does support the regulation of pentobarbital injection to require it to be stored in a locked cupboard, safe, or receptacle, both within veterinary premises and when in vehicles when not in use. The AVA would be willing to work with all state legislators to achieve this.

## Commentary

The following are the issues that should be examined when considering what effect rescheduling pentobarbital injection to S8 will have on veterinary practice and whether rescheduling will actually prevent the intentional misuse of pentobarbitone by veterinarians, other veterinary practice employees and people external to veterinary practice.

## Use of pentobarbital injection in veterinary practice

Below is information from some representative veterinary practices about pentobarbital injection. They were asked to describe how pentobarbital injection is used in their practices and some also provided a quick analysis of what impact rescheduling may have.

### *Use of pentobarbital injection in practice*

1. Outer Sydney metropolitan suburb small animal practice  
This practice has 3 branches. They euthanase on average 23.5 animals weekly based on their computer records; they also estimate that they euthanase about 10 pro-bono wildlife cases per week. This practice does not do many house visits where they take pentobarbital injection with them - they estimate they do this about once or twice per fortnight. They do a council pound visit once weekly where they take the pentobarbital injection with them. They purchase on average 1-2, 500ml pentobarbital injection bottles per month. They keep about 800ml in stock which is presently stored in their drug safe. They estimate the time to comply with increased record requirement to be 3 minutes per patient and 8 minutes per order received, equating to a **minimum extra 101.5 minutes per week of veterinarian time** required to comply, assuming that there are no discrepancies to investigate. This practice's employer supports the requirement to keep pentobarbital injection in a locked safe, but does not support rescheduling to S8 due to the onerous record keeping requirements and because they believe that it will not decrease the likelihood of use in suicide.
2. Inner city small animal practice  
This practice estimates that they euthanase 15 animals per week plus 10 pro-bono wildlife, and stray kitten litter euthanasias. They keep two 500ml bottles of pentobarbital injection in stock, which presently

will not fit into their existing drug safe. They take pentobarbital injection on house visits on average once weekly, in these cases they take the pentobarbital injection in a syringe in the hospital bag. If pentobarbital injection was rescheduled to S8 they estimate 10 minutes per month to record purchases, and 5 to 10 minutes per patient to comply with recording requirements. This equates **to a minimum extra 127 to 252 minutes of veterinarian time** required to comply, assuming there are no discrepancies to investigate. This practice's employer supports the requirement to keep pentobarbital injection in a locked safe and would invest in one as required, but does not support rescheduling to S8 due to the onerous record keeping requirements and because they do not believe it will decrease the likelihood of use in suicide.

3. Equine practice

The practice euthanases 2 to 3 horses per week. Pentobarbital injection is kept in all vet vehicles at all times due to the high likelihood of needing it immediately (particularly in racetrack practice). The vets are on call 24 hours a day so it is not possible to replace it back in the practice safe between uses. The cars that have safes use them and if not, it is stored appropriately in the car boot out of view of the public. They presently stock about eight 500ml bottles of pentobarbital injection which would not fit in their current drug safe.

4. Cattle practice

In an average cattle practice, cattle veterinarians report that they are likely to always carry a "euthanasia box" in their cars which includes a captive bolt but also enough pentobarbital injection to euthanase at least one large animal such as a cow or horse. They would have concerns if they were unable to carry it with them in their cars as they "never know when they will need it" and to return to the base practice to collect could lead to very poor welfare for a suffering animal. These vets tend to voluntarily keep the pentobarbital injection locked up, but would have concerns if the recording requirements of an S8 drug were imposed. They commented that a requirement to return the bottle and record the required details for each euthanasia would be problematic, and especially if during emergencies or after hours. In rural practice, travelling distances between the base practice and clients can be very large.

5. Shelter veterinarians and inspectors

Veterinarians working in animal shelters train shelter staff including inspectors, veterinary nurses and lay operators, to safely and effectively euthanase animals at the shelter.

Some inspectors carry pentobarbital injection with them in a locked compartment in their cars, for situations where cats, dogs, livestock or wildlife need urgently to be euthanased, and to delay for transport to a veterinarian would be cruel. There may also be significant occupational health and safety implications for staff if they were forced to take injured wildlife to veterinary facilities to be euthanased, rather than being able to render assistance on the spot.

Any proposed amendments to regulations around use of pentobarbital injection must not impose restrictions on use by inspectors and rescue officers in these sorts of situations. This is essential from an animal welfare and human safety perspective.

6. Research

Animal care technicians who work in research laboratories and in field trials are often authorised to euthanase animals using pentobarbital injection. The ability to perform euthanasia in a timely manner can be extremely important from an animal welfare perspective, hence ready access without onerous and time-consuming recording requirements is equally important in the research setting.

7. Non-veterinary wildlife carers and rescuers

In certain jurisdictions, non-veterinary carers such as wildlife rescue organisations and rangers are able to become accredited to use and keep supplies of pentobarbital injection for the purpose of rapid euthanasia to alleviate suffering of wildlife. This is an important mechanism to prevent delay in euthanasia in cases where transport to a veterinarian would result in unacceptable suffering, or in locations where

veterinarians may not always be available to render assistance.

### ***Effect of rescheduling on impeding veterinary practice***

- Need for S8 recording procedures – while most practices already have S8 drugs in their secure pharmacies, recording pentobarbital injection would add an extra level of workload and complexity due to the amounts and the circumstances around its usage. Here is a list of some of the issues that have been identified by members:
  - Pentobarbital injection is used in veterinary practice in many and varied scenarios. Often these scenarios are emergencies, and/or include restraining difficult patients, multiple patients, and use out in the field (e.g. euthanasing wildlife after a bushfire emergency). The drug is used “to effect” which means often more than the recommended amount is drawn up, in case the initial dose is not immediately effective, and the dose delivered in increments until death of the animal is achieved. The quantities used range from 0.5ml to 200ml per patient, depending on the size of the animal. All these elements contribute to the fact that if veterinarians were required to report usage and wastage as required for Schedule 8 drugs there would be a high chance that inadvertent inaccuracies in recording would occur frequently.
  - The size of the bottle used in most practices (500ml) means that 20-30mls could be missing without anyone noticing until the bottle is close to empty, which could be a week or two. This would eliminate any benefit from the onerous S8 recording procedures.
    - Member comment: *“The sheer volumes of pentobarbital injection used in large animal practice would make accurate records near impossible. If a vet or nurse had the intention of suicide even the best record system would not prevent a “small” volume going astray and the average human lethal dose is about 15 to 20mls This volume could easily be put aside and go unnoticed during, say, a horse euthanasia, where you might use 120mls.”*
  - Pentobarbital injection is used a lot for injured wildlife and pro-bono work with injured strays in practice (e.g. stray kitten litters). At present this does not require any record keeping. If pentobarbital injection were rescheduled, each wildlife case would need a clinical record created, and to be recorded in the S8 register. This may see a decrease in the number of practices willing to undertake this important animal welfare and community service.
  - The veterinarian will be responsible for all recording of the use of pentobarbital injection. In human medicine, registered nurses have access to S8s so they can assist doctors when they are in surgery and are usually responsible for most of the record keeping.
  - S8 recording requirements are designed to prevent ongoing abuse of drugs and are not well suited to preventing a one-off use of a small amount of pentobarbital injection for the purposes of suicide.
  - If pentobarbital injection is rescheduled and a veterinary nurse uses it to suicide and the practice is found to have not complied with S8 regulations, the veterinarian may be liable under work health and safety legislation – while acknowledging that reasonable care should be taken with this drug, the ability to control as illustrated above puts a lot of onus of the veterinarian.
  - Virbac manufactures the brand of pentobarbital known as “Lethabarb” which is 95% of the euthanasia injection market. At the recent Coroner’s inquest a Virbac representative commented that it may have to consider if it is financially viable to continue manufacturing Lethabarb if it were rescheduled. If the other manufacturers think likewise this would be disastrous for veterinary practice and animal welfare.
- Need for storage – most of our members tell us that they now store their pentobarbital injection in safes or

locked cupboards. Some have however stated that they would need to purchase new drug safes if it was to be rescheduled due to the size and number of bottles stocked at the practice.

## Suicide in the veterinary profession

Suicide in the veterinary profession is a well recognised issue that our members are very concerned about. A study into suicide in veterinarians and veterinary nurses in Australia from 2001-2012<sup>1</sup> concluded that veterinarians suicide was significantly higher than that of the general population at around 1.92 times the population. In the same study it was found that while the suicide rate in veterinary nurses over the period were above that of the general population, this difference was not statistically significant. Another Australian study (over the period 1990–2002 in two states)<sup>2</sup> reported veterinarian suicide rates around 4 times that of the general population. High veterinary suicide rates have also been reported in international studies.<sup>3,4</sup> A 2016 Australian National Coronal Information System (NCIS) report identified 33 suicides associated with veterinary clinics from 2000-2016 using pentobarbitone.<sup>7</sup>

Suicide in veterinarians has many important contributing factors including access to lethal means and the knowledge of how to use them. There is a large number of drugs in a veterinary practice that could be used to the same effect as pentobarbital injection, for example potassium chloride, insulin and other anaesthetic agents.

Adverse psychosocial working conditions have been linked to veterinarian suicide, such as long working hours, high workloads, poor work–life balance, the attitude of clients and stress about performing euthanasia.<sup>6</sup> Many veterinarians suffer from high levels of anxiety, depression, stress and burnout, and high personal expectations.<sup>1</sup> Many veterinarians are working in an isolated environment, often in one man practices in rural areas. Studies have shown that over half the deaths identified occurred in individuals from rural or regional areas (52%) compared with city or metropolitan areas.<sup>1</sup>

An additional risk factor is the potentially permissible attitude that veterinarians may have to suicide. Veterinarians are often involved in ending the lives of animals through euthanasia, or assisting with the slaughter of livestock, often in order to release an animal from suffering. According to Joiner's interpersonal theory of suicide, the risk of suicide rises as individuals become habituated to death, as this results in lowering of inhibitions about suicide.<sup>5</sup>

The AVA has resources and programs that aim to address some of these risk factors and to assist with responding when veterinarians or their staff are identified as being at risk or in a crisis situation.

The AVA introduced a Graduate Mentoring Program in 2015 that pairs newly-graduating veterinarians with an experienced colleague in a different practice from the one they are employed in. All mentors are given training on mentoring, including some mental health training to assist with recognising problems in their mentees and how to refer if needed.

The AVA in October this year has started to roll out Mental Health First Aid Training to assist practice staff in identifying employees who may be experiencing mental health issues and help them know how to respond and offer assistance and referral appropriately. The goal is to eventually have a Mental Health First Aid Officer in every veterinary workplace in Australia.

Alongside this there is an AVA counselling line, an AVA HR Advisory service, seminars and lectures around resilience, wellness and mental health issues, individual collegial support where a specific need is identified and many other related programs.

Many of the comments from members stressed that there are many lethal means available in veterinary practices and therefore rescheduling pentobarbital injection won't stop suicide. Instead, addressing the actual risk factors which lead to suicide is going to be far more important in reducing suicide in the veterinary profession. The AVA believes there must be holistic approach to suicide in the veterinary profession.

One member commented: *"This issue here isn't the accessibility of pentobarbitone, or any other substance that could be used to commit suicide. This issue here is the mental health of those employed within the Veterinary*



*Industry. Until there is greater understanding, education, and support for all, this will continue to be an issue.”*

## Member consultation

AVA members were asked to consider whether the rescheduling of pentobarbital injection to Schedule 8 would decrease suicide in veterinarians and/or veterinary nurses and whether they supported the rescheduling. This issue produced an unprecedented response rate from our members. We received 2031 survey responses from members, including 1013 members who included written comments.

### **Survey results**

Of the respondents 62.3% (1266) of our members do not support rescheduling, while 37.2% (755) do support the rescheduling and 0.5% (10) did not give a response to this question.

When asked if they thought rescheduling pentobarbital injection would decrease the incidence of suicide in veterinarians 78.5% (1594) said no, 15.5% (314) said they were not sure, 6.0% (121) said yes and 0.1% (2) did not give a response.

When asked if they thought rescheduling pentobarbital injection would decrease the incidence of suicide in veterinary nurses and other practice employees 58.4% (1114) said no, 22.9% (466) said they were not sure and 22.2% (451) said yes.

Restricting the responses to those who were presently in clinical practice (n=1745) resulted in 64.1% (1118) not supporting rescheduling.

Restricting the response to those working in clinical practice who are employers (n=667) resulted in 72.1% (481) not supporting rescheduling

Restricting the response to those working in clinical practice who are employees (n= 1021) resulted in 57.8% (590) who not supporting rescheduling.

## Risk-benefit analysis

This analysis is based on the TGA's risk/benefit template provided in their Scheduling Policy Framework in the context of the factors for controlled schedule 8 drugs.

### What is the hazard?

- Intentional misuse for the purpose of suicide by veterinarians
- Intentional misuse for the purpose of suicide by other veterinary practice employees
- Illicit and intentional misuse by people outside of veterinary practice for the purpose of suicide

### How widespread is the hazard?

The best available data is presented in the NCIS report CR16-39: <sup>7</sup>

- Intentional misuse for purpose of suicide by veterinarians and other veterinary practice employees – the NCIS report identified 33 cases associated with veterinary practice over the period 2000-2016. Only the details of 29 cases are given in the report. There are 14 cases clearly identified as veterinarians and 6 as other veterinary practice employees. There are 3 cases where it is not clear whether they are veterinarians or veterinary nurses and three where it gives no details as to their employment role.
- Intentional misuse by people outside of veterinary practice for the purpose of suicide –the NCIS<sup>7</sup> report clearly identifies 74 deaths from pentobarbitone sourced from overseas. For deaths from pentobarbitone of an unknown source, there is no clear evidence that this is being sourced from pentobarbitone registered for use by veterinarians in Australia. In fact, it would appear that for cases without direct connection to a

veterinary practice due to employment, that it was sourced either from overseas or unknown. There is clear evidence that at present “Nembutal” and other non-veterinary pentobarbitone sources in tablet, liquid and powder form can easily be acquired from overseas either via the internet or by someone bringing it into Australia on their person after an overseas trip.<sup>8</sup>

#### In what circumstances will the hazard arise?

- This drug is only really misused for the purposes of suicide. The hazard will arise when there is access to veterinary practice employees who have suicidal intention. There is potential for theft from veterinary practices for use by those outside of veterinary practice for suicide.

#### What is the likelihood of the hazard occurring?

- **Intentional misuse for suicide in veterinarians** – while acknowledging that there is a level of intentional misuse in veterinarians, rescheduling will not reduce access to pentobarbital injection by veterinarians and as such is unlikely to reduce the hazard from occurring. They require access to perform their job.
- **Intentional misuse for suicide in other veterinary practice employees** – in veterinary practices employees other than veterinarians may have access to pentobarbital injection, mostly when supervised by a veterinarian. Veterinary nurses unlike registered nurses in human medicine are presently legally not allowed to access safes containing Schedule 8 drugs. However, in a busy practice many are likely to be able to gain access.

Veterinary nurse training continues to improve in Australia. The much-needed improved training and role of veterinary nurses in Australian veterinary practice may actually inadvertently be contributing to an increase in the use of pentobarbital injection as a method of suicide. Placing catheters in patients now is the role of many veterinary nurses. Of the 6 cases reported in veterinary nurses in the NCIS report, 5 were injected, most via a catheter.

In a recent coroner’s case Queensland Health discussed the likelihood that over the next few years veterinary nurses will become registered (already the case in Western Australia), and that their training will include the use of S8s so that they might be awarded access to S8s similar to what occurs in human medicine.

- **Intentional misuse and illicit use outside of veterinary practice** – while there are deaths listed in the NCIS Report as cause of death pentobarbitone of an unknown source, there is presently no clear evidence that this is being sourced from pentobarbitone registered for use by veterinarians in Australia. There is clear evidence that “Nembutal” and other non-veterinary pentobarbitone sources in tablet and liquid form can easily be acquired from overseas either ordered over the internet or by someone bringing into Australia on their person after an overseas trip.

#### Who or what is at risk?

- Veterinarians and others employees in their practice

#### What are the consequences of the hazard in terms of severity (morbidity and mortality) and duration?

- Those that intentionally misuse pentobarbital injection are highly likely to die. We are not aware of any available evidence on ongoing morbidity associated with intentional misuse of pentobarbital injection.

#### **Benefit**

Pentobarbital injection is an essential tool that all veterinarians need ready access to. It is the most humane method of euthanasia in animals presently available. Without appropriate access, animal welfare will be severely compromised and the suffering of animals will certainly be prolonged. Pentobarbitone at the high concentration presently available in the products manufactured for euthanasia of animals ensures the procedure is quick and efficient. This minimises the potential risk to the person who is performing the euthanasia from either aggressive



animals or animals moving violently due to a slower euthanasia procedure.

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