Proposed rescheduling of PENTOBARBITAL to S8

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 9000 members come from all fields within the veterinary profession, including clinical practice, government, public health, industry, research and teaching. 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 for animals presently available. It is used extensively in small animal practice, equine practice, rural practice, shelter medicine, stray animal management, wildlife management and emergency response, and in veterinary and human research involving animals. Many of our members administer this drug multiple times over each working day or week, 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 and optimal animal welfare outcomes are of concern to AVA members.

The impact of any proposed scheduling changes must be considered in terms of what they are likely to practically achieve to improve human health and wellbeing. The proposed rescheduling of pentobarbital injection from S4 to S8 is driven by the desire to reduce the use of this substance as a means of suicide in veterinarians, veterinary nurses and others in the industry. The AVA and its members are absolutely committed to addressing the issue of suicide in the profession and associated industry.

The implications of S8 scheduling are twofold: (i) secure storage is required, as well as (ii) the requirement to centrally record each use in a Drugs of Addiction Register.

Using the *NSW Poisons and Therapeutic Goods Regulation 2008* (the regulation) as an example:

1. **Secure storage**: S8 Drugs must be kept in a safe, cupboard or other receptacle securely attached to part of the premises and kept locked when the drugs are not in immediate use. Emergency supplies can be carried in a bag as long as the bag is in a locked room or locked vehicle when not in immediate use.

2. **Register of Drugs of Addiction –** a central "Register of Drugs of Addiction" must be kept for S8 drugs, in which the quantity used is recorded, as well as the balance in stock after every transaction.

Most veterinarians already meet the secure storage requirements for pentobarbital as described in (1) above, and those surveyed indicated they do not object to tighter regulations that mandate this secure storage. It should be noted that the storage in NSW can be in a safe OR cupboard OR other receptacle, so long as it is securely attached to a part of the premises and kept locked. This distinction is important, as not all dedicated S8 safes are large enough to store bottles of pentobarbital. The option to store pentobarbital in a fixed, locked, cupboard or other receptacle thus becomes important, and is supported.

However, the requirement under (2) above, to record each use of pentobarbital in the practice's central Register of Drugs of Addiction is problematic, for the reasons explained later in the body of this submission.

The rationale for auditing against discrepancies in S8 drug volumes (requirement 2 above) is to detect recurrent discrepancies, as S8s are drugs of addiction, eg Methadone, Ketamine. Discrepancies can point to repeated misuse and be followed up with staff. Pentobarbital on the other hand, when taken for the purpose of suicide, is typically stolen as a one-off event, and used very soon thereafter. Six-monthly auditing for discrepancies will not prevent a one-off misappropriation of the drug, and will do nothing to alert to the situation ahead of time. The AVA believes it is the secure storage of the drug which will do the most to prevent its use in suicide.

In the NSW regulation, there is a category of S4 drugs known as "prescribed restricted substances", which appear as Appendix D (S4D). S4D substances kept in (human) hospital wards must be stored to an equivalent level of security as S8s (which in NSW is: within a safe or cupboard or other receptacle, securely fixed to the premises and locked when not in immediate use), but there is not the need for recording and auditing using an S8 Register of Drugs of Addiction. Pentobarbital is already classified as S4D in NSW. The AVA suggests that this scheduling compromise would be an ideal model for pentobarbital in veterinary practice.

Suicide in the veterinary profession is a well recognised issue. A study into suicide in veterinarians 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.[1] Another Australian study (over the period 1990–2002 in two states)[2] reported veterinarian suicide rates around 4 times that of the general population. High veterinary suicide rates have also been reported in international studies.[3,4]

The most common method of veterinarian suicide identified is pentobarbital injection. The AVA contends that the proposed up-scheduling of pentobarbital 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 impact of rescheduling pentobarbitone on veterinary nurse and other non-veterinary staff access to the drug, and the consequent impact on its use in suicide attempts, must also be considered.

The AVA members were asked to consider these issues in 2016. At the time we received feedback from 2,031 members. In 2020, members were again asked to provide feedback on the issue. Due to the short time frame involved, the level of feedback this time has not been as extensive, however the comments which have been received have been consistent with previous member research.

The majority of members surveyed believe that the regulatory consequences of upscheduling pentobarbital to S8 will not contribute to achieving the desired outcome of decreasing suicide rates in veterinarians and their employees. Furthermore, there is concern that the regulatory reporting requirements will impede the delivery of timely and efficient veterinary services, and have potential animal welfare consequences as a result. Specifically, the increased recording and audit requirements associated with the S8 schedule would simply add an ineffective level of administration for no net public benefit. It will not prevent use of the drug for suicide. It is felt that a far better outcome in terms of reducing suicide rates and from a practical standpoint can be achieved via significant change in the regulations surrounding pentobarbital **access and storage** Australia-wide.

We support implementation of a requirement for pentobarbital to be stored in a locked safe, cupboard or other receptacle securely attached to the premises, and in a bag in a locked room or vehicle when taken off-site for emergency use. We do not believe that the additional S8 requirement to record each use in a Register of Drugs of Addiction will have any benefit in preventing suicide however. For this reason, an approach such as implementation of the NSW S4D scheduling model, is recommended.

Recommendations – summary

1. The AVA **does not support** the rescheduling of pentobarbital to a Schedule 8 poison.

2. However, the AVA **does support** a regulatory requirement that pentobarbital must be stored in a locked safe, cupboard or other receptacle securely attached to the premises (when not in immediate use), and in a bag in a locked room or vehicle when taken off-site for emergency use.

3. The AVA does not support the need for an S8 Register of Drugs of Addiction for recording and auditing purposes for pentobarbital, as, due to the volumes used, this will be impractical and will not prevent suicide (this is explained in detail in the body of the text).

4. The AVA supports the ongoing requirement that all use of pentobarbital must be recorded in clinical records as per the relevant state Veterinary Practice Acts and Drugs and Poisons regulations. This recording requirement is already in place. While it is very accurate and extensive, it is not to the level of S8 Register recording, nor is there a requirement for auditing the balance on hand versus volumes used, to identify discrepancies.

5. In NSW a schedule S4 Appendix D (S4D) exists. S4D substances kept in (human) hospital wards must be stored to an equivalent level of security as S8s (which in NSW is: within a safe or cupboard or other receptacle, securely fixed to the premises and locked when not in immediate use), but there is not the need for recording and auditing using an S8 Register of Drugs of Addiction. Pentobarbital is already classified as S4D in NSW. The AVA suggests that this scheduling compromise would be an ideal model for pentobarbital in veterinary practice.

Discussion

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

Use of pentobarbital injection in veterinary practice

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

Use of pentobarbital in practice

1. Inner city and metropolitan suburban small animal practices
   These sort of practices regularly euthanase 15 to 25 domestic animals and another 10 to 15 pro–bono wildlife cases per week. Practices performing council pound work may do even more than this. They would usually keep one to two, 500 ml bottles of pentobarbital in stock at any one time. Currently, these practices store pentobarbital either in compliant drug safes or under lock and key in cupboards that are in non-public access areas of the practice. Practice owners that were surveyed indicated that they would support more stringent requirements around the storage of the substance and can see the logic behind this. However the proposed requirements to record pentobarbital usage to the last millilitre and regularly audit this, was not supported, as it was a strongly held belief that this would have nil benefit in terms of reduced suicide.

2. Equine only practices.
   A busy equine-only practice can euthanase 2 to 3 horses per week. Pentobarbital is kept in all vet vehicles at all times due to the high likelihood of needing it immediately whilst in the field (particularly in racetrack practice). The vets are on call 24 hours a day and often have early starts going direct to outside calls from home, so it is not practical to replace it back in the practice safe between uses. Some vehicles have safes installed and use them to store pentobarbital. In vehicles that do not have safes currently pentobarbital is stored out of public view and it is routine procedure to ensure that vehicles are fully locked when unattended, thus securing the pentobarbital. A multi vet equine practice that has a number of vehicles equipped and on the road will hold in stock up to eight 500ml bottles of pentobarbital at any one time.

3. Mixed practice
   Mixed practitioners who operate in rural areas will often have to treat small and large ruminants, camelids, horses and occasionally wildlife whilst working in the field. Euthanasia in cattle and sheep in particular is often able to be performed using a firearm or captive bolt device. However these practitioners still need to carry pentobarbital with them at all times as it is not always possible or appropriate to use a firearm or captive bolt device. These practitioners would have concerns if they were unable to carry pentobarbital with them in their cars as they “never know when they will need it” and to return to the base practice to collect it from a central storage point is often impractical due to long distances travelled (potentially several hundred kilometres) and would inevitably lead to very poor animal welfare outcomes with distressed animals left to suffer for extended periods of time. These vets

tend to voluntarily keep the pentobarbital locked up securely in vehicles, as per the arrangements for equine vets described above, but would have concerns if the stringent recording requirements of an S8 drug were imposed. They commented that a requirement to collect and return the bottle from and to a central storage facility for each euthanasia would be problematic, especially during emergencies and after hours.

However a number of mixed practice veterinarians stated that they would be amenable to upgrading storage facilities for pentobarbital in field vehicles either voluntarily or in response to changed regulations. Again, there is a strongly held belief that more stringent, but practically workable control measures around storage and access to pentobarbital can be justified and may well yield genuine outcomes in terms of reducing the suicide risk due to pentobarbital misuse, however S8 recording and audit requirements are simply a token gesture that will yield no such benefit.

4. Shelter veterinarians, inspectors, wildlife rescue and euthanasia

Veterinarians and animal welfare inspectors authorised under state legislation carry pentobarbital 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 them if they were forced to take injured wildlife to veterinary facilities to be euthanased, rather than being able to render assistance on the spot.

We have recently witnessed the need for mass euthanasia in the field of wildlife seriously injured by bushfires. These situations are only likely to become more common. In these situations large volumes are typically required, and recording requirements need to be practical. Any proposed amendments to regulations around use of pentobarbital 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.

Effect of rescheduling on veterinary practice

As has been outlined in the section above, many veterinarians from a variety of practice backgrounds can understand and support the need to have more stringent control measures around the storage of and access to pentobarbital, as they are acutely aware of the risk it poses to human life as a suicide modality of choice within the profession and associated vocations.

The single greatest objection to full Schedule 8 classification of pentobarbital is the associated requirement to record every single usage of the drug to the last milliliter, in a central S8 Register of Drugs of Addiction. Furthermore, S8 drugs are required to be regularly audited (for example 6 monthly in NSW) in order to verify that recorded usage tallies with actual volume of the drug present. The reason for auditing against discrepancies in S8 drug volumes is to detect recurrent discrepancies, as these are drugs of addiction. Discrepancies can point to repeated misuse and be followed up with staff. Pentobarbital on the other hand, when taken for the purposes of suicide, is typically stolen as a one-off event, and used very soon thereafter. Regular auditing for discrepancies will not prevent a one-off misappropriation of the drug, and will do nothing to alert to the situation ahead of time.

Most practices already have S8 drugs stored in their secure safe and fulfill the statutory recording and auditing requirements for these medications. Most veterinarians also report that they store pentobarbital in a similarly

secure way. However, they do not record pentobarbital in the Register of Drugs of Addiction. Recording pentobarbital volumes to this level of accuracy (nearest milliliter) would have no net effect on the prevention of suicide. This is due to the significantly different nature of pentobarbital as a drug, its presentation as a medication and the intended purpose for its misuse. In simple terms, S8 recording requirements as they exist presently are not fit for purpose for preventing the misuse of pentobarbital for the purpose of human suicide. To illustrate this point further, a number of specific issues have been identified by members as follows:

- Pentobarbital 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, euthanasia of badly injured horses at race meetings) in extremely demanding and high pressure situations. The drug is used "to effect" which means usually 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, general health and temperament of the animal. All these elements contribute to the fact that if veterinarians were required to report usage and wastage to the exact milliliter (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 meticulous S8 recording procedures, and the suicide would have occurred before the audit has detected the discrepancy.

    - Member comment: "*The sheer volumes of pentobarbital 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."*

- S8 recording requirements are designed to prevent the chronic and ongoing abuse of drugs of addiction such as Methadone and Ketamine. These drugs are, almost without exception, presented in much smaller bottle/package sizes than pentobarbital – 20 to 50 ml, as opposed to 250 to 500 ml. For these drugs, the S8 degree of recording, measuring and auditing is practically achievable, accurate and of significant value in preventing deliberate, illegal and ongoing misuse of these addictive substances.

- In contrast, the misuse of pentobarbital is, without exception, for the purpose of suicide. This is, in most cases, a one-off event with a final and tragic outcome. Assuming that pentobarbital were to be rescheduled as an S8 substance, let us use the NSW requirement of six monthly S8 audits in veterinary practice (performed in March and September) to demonstrate the shortcomings of this regulatory requirement in achieving its stated purpose of reducing pentobarbital induced suicide. Any person with suicidal intent that can potentially access pentobarbital has a six month window in NSW, in which to illicitly obtain a relatively small volume of the drug, without detection, in order to attempt suicide. Even if the theft were to occur literally within hours of the six monthly audit, there is no conceivable way that any immediately effective corrective or preventative action could be taken to avert the likely loss of life. The same S8 recording and consequent auditing procedures that work so effectively for traditional S8 drugs of addiction, do not lend themselves in any practical way to the prevention of one-off thefts of

relatively small volumes of pentobarbital for the purposes of suicide.

- Even without the stringent record keeping requirements that accompany an S8 classification of pentobarbital, private veterinary practices Australia wide are required, by their state Veterinary Practice Acts to keep detailed and accurate case records for all animals that they treat. This extends to any case when an animal is euthanased. At a minimum, these records will include the identity of the animal being euthanased, the name of the owner, the treating vet, the date of euthanasia, drug used and any other relevant case notes. Therefore, it can be strongly argued, that a practical and enforceable level of recording of pentobarbital use already exists in all states of Australia. However it does not carry with it the impractical and impotent requirement for recording volumes used to the level of fractions of a milliliter, and regular auditing. This needs to be taken into account when any discussion of the most practical means of regulating pentobarbital is undertaken.

- The whole issue is well summarized in the following member comment which we received during the current consultation period:

"(Clinic name redacted) has introduced S8 safes large enough to accommodate 450ml bottles of [redacted] *in all of our clinics since 2016. We insist* [redacted] *is stored in these and, of course, only vets have the access codes. This has been very successful. For approximately 2 years, we asked our team members to record* [redacted] *usage in a separate S8 log book and audit it monthly. We trialed that system faithfully but have decided to remove that request. Many clinics still choose to keep a written record, but we don't ask them to audit it.*

The difficulties were in how to audit the bottle. There was a huge discrepancy in the amount of liquid that individual bottles carry and in the weight of glass of each bottle. We even approached the manufacturers to get some insight on this, but they could not change anything and freely admitted there was much variance.

To be able to audit a bottle, you either needed to measure the contents by volume, by weight or by eyeball. The volume method was ridiculous with bottles containing 450ml so attempting to withdraw that liquid out into syringes becomes silly. Weight didn't work because of the disparity in glass weight and volume liquid. Eyeball was not accurate. The change of [redacted] *bottles from glass to plastic will help with the glass irregularity, but you still have the volume variances.*

We also looked at it from whether it would change behaviour of someone who was planning to commit suicide and could not see that it would. A sad example within our team was a vet taking her life using this substance. The bottle was locked in the safe and that particular clinic did keep a written (S8 level) log book too, but she still went ahead."

Suicide in the veterinary profession

Suicide in the veterinary profession is a well recognised issue that AVA members are very concerned about. A study into suicide in veterinarians and veterinary nurses in Australia from 2001-2012[1] concluded that veterinarian 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)[2] reported veterinarian suicide rates around 4 times that of the general population. High veterinary suicide rates have also been reported in international studies.[3,4]. A 2016 Australian National Coronial Information System (NCIS) report identified 33 suicides associated with veterinary clinics from

2000-2016 using pentobarbitone.[7]

Suicide in veterinarians has many important contributing factors including access to lethal means and the knowledge of how to use them. There are a large number of drugs in a veterinary practice that could potentially be used to the same effect as pentobarbital, for example potassium chloride, insulin and other anaesthetic agents. However there is no doubt that pentobarbital is the only one of these that is widely recognized as a means of suiciding.

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.[6] Many veterinarians suffer from high levels of anxiety, depression, stress and burnout, and high personal expectations.[1] 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.[1]

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 humane killing 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.[5]

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 provides Mental Health First Aid Training to assist practice staff in identifying employees who may be experiencing mental health issues, 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 the AVA has free telephone counselling for veterinarians, an AVA HR Advisory service, seminars and lectures around resilience, wellness and mental health issues, individual collegial support where a specific need is identified, a Veterinary Benevolent Fund to support vets in financial crisis or need, and many other related programs.

The AVA believes there must be holistic approach to suicide in the veterinary profession, taking all of the above into account.

One member commented:

"This issue here isn't the accessibility of pentobarbital, 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."

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