



QUEENSLAND  
COURTS

## CORONERS COURT OF QUEENSLAND

### FINDINGS OF INQUEST

**CITATION:** Inquest into the death of Donna Cowley-Persch

**TITLE OF COURT:** Coroners Court

**JURISDICTION:** Brisbane

**FILE NO(s):** 2013/3407

**DELIVERED ON:** 21 February 2017

**DELIVERED AT:** Brisbane

**HEARING DATES:** 22 August 2016, 5 - 6 October 2016

**FINDINGS OF:** John Hutton, Coroner

**CATCHWORDS:** Coroners: inquest; dog groomer suicide; Veterinary clinic; animal euthanasia drug; Pentobarbitone / Pentobarbital injection; Lethabarb; 'green dream'; Pentobarbitone toxicity; Pentobarbitone storage, access control, recording, monitoring and auditing; Schedule 4 and 8 drugs.

#### REPRESENTATION:

Counsel Assisting: Mr Peter De Waard

Office of Fair and Safe Work Queensland: Mr Bruce Matthews

Department of Health (Queensland): Mr Andrew Luchich  
(instructed by Corrs  
Chambers Westgarth)

Ascot Veterinary Surgery Pty Ltd: Ms Jennifer Rosengren  
(instructed by Meridian  
Lawyers)

Virbac Australia Pty Ltd: Mr Damien Atkinson  
(instructed by Coleman  
Greig Lawyers)

## Introduction

1. Ms Donna Cowley-Persch was 58 years of age and employed as a dog groomer at the Ascot Veterinary Surgery Pty Ltd at the time of her death. She died by suicide at her work premises on 19 September 2013 by injecting herself with an animal euthanasia drug named 'Lethabarb'. The generic drug name is 'Pentobarbitone'.
2. An inquest was held into Ms Cowley-Persch's death from 5 – 6 October 2016. A comprehensive brief of evidence was tendered and distributed to the parties. In addition, I heard oral evidence from the following witnesses:
  - a. Ms Kate Bernays, Practice Manager of the Ascot Veterinary Surgery Pty Ltd;
  - b. Dr Benjamin Charlton, Veterinary Surgeon and Co-Owner of the Ascot Veterinary Surgery Pty Ltd;
  - c. Dr Jennifer Byrnes, Senior Technical Product Manager; and Ms Sarah Hunter, Commercial Manager for Sales and Marketing, at Virbac Australia Pty Ltd (the manufacturer of 'Lethabarb' in Australia);
  - d. Dr Sue Ballantyne, Specialist Medical Advisor, Office of Chief Medical Officer and Healthcare Regulation Branch, Prevention Division, at the Queensland Department of Health;
  - e. Ms Kareena Arthy, Chief Executive Officer; and Mr Alan Norden, Executive Director, Registration Management and Evaluation, at the Australian Pesticide and Veterinary Medicines Association; and
  - f. Dr Timothy Greenway, Principal Medical Advisor; Mr Avi Rebera, Acting First Assistant Secretary; and Dr Kaylene Raynes, Director of Scheduling and Committee Support functions, at the Therapeutic Goods Administration, Commonwealth Department of Health.
3. These findings address the issues identified at a Pre-Inquest Conference on 22 August 2016, as follows:
  - a. The identity of the deceased, when, where and how she died and what caused her death;
  - b. The adequacy of the product labelling and instructions provided with Pentobarbitone in relation to the safe storage of the drug to prevent intentional misuse;
  - c. The adequacy of the Pentobarbitone storage and access control procedures of the Ascot Veterinary Surgery in the circumstances;

- d. The adequacy of the current national and Queensland regulatory regime in relation to storage, access control, monitoring and auditing of Pentobarbitone in Veterinary Clinics; and
  - e. Whether any recommendations can be made to reduce the likelihood of deaths occurring in similar circumstance or otherwise contribute to public health and safety or the administration of justice.
4. Prior to making my findings, I allowed and considered written responses to Counsel Assisting's submissions from three organisations which were not parties to this inquest: the Australian Veterinary Association, the Veterinary Surgeons Board of Queensland, and Provet Pty Ltd.

### **Findings required by s. 45**

5. Pursuant to s. 45(2) of the *Coroners Act 2003* (Qld), I find:
- a. *Identity of the deceased* – The deceased person was Donna Cowley-Persch.
  - b. *How she died* – As per the circumstances outlined below.
  - c. *Place of death* – Donna Cowley-Persch died at the Ascot Veterinary Surgery Pty Ltd premises located at 223 Lancaster Road, Ascot, in the state of Queensland.
  - d. *Date of death* – Donna Cowley-Persch died on 19 September 2013.
  - e. *Cause of death* – The medical cause of Donna Cowley-Persch's death was Pentobarbitone toxicity.

### **Findings on the issues**

#### ***The adequacy of the product labelling and instructions provided with Pentobarbitone in relation to the safe storage of the drug to prevent intentional misuse***

- 6. All product labels for Pentobarbitone in injectable form for the purposes of animal euthanasia that are sold in Australia contain guidance about matters such as the requirement to store the drug at a certain temperature. However, they do not provide guidance about the best way to store the drug for human safety purposes.
- 7. I find that this approach to product labelling was adequate in the past, given that the prevalence of suicide through misuse of the drug does not

appear to have been well known by manufacturers. It will not, however, be adequate in the future, once these inquest findings are published and the prevalence of the human misuse problem is known. Product labels should provide warnings about the need to store the drug in a locked safe/vault/receptacle.

8. Drug Safety Data Sheets are important hazard communication tools, which can be considered by Veterinarians when putting in place ways to mitigate risk in the workplace.
9. I find that the current Lethobarb Safety Data Sheet is adequate because it provides that the drug “*must be stored in a locked vault*” at all times, except when it is being used. This is one of the most effective ways to minimise misuse of the drug by those who do not require access to it.
10. Similar instructions do not appear to have been included by other companies manufacturing Pentobarbitone in their Safety Data Sheets. Whilst this was adequate in the past, it will not be adequate in the future.

***The adequacy of the Pentobarbitone storage and access control procedures of the Ascot Veterinary Surgery in the circumstances***

11. I find that at the time of Ms Cowley-Persch’s death, the storage and access control procedures of the Ascot Veterinary Surgery were adequate in the circumstances. In future, once there is more awareness within the Veterinary industry about the Pentobarbitone misuse problem, I would not consider such storage and access control practices adequate.
12. The Ascot Veterinary Surgery complied with the applicable requirements under relevant health regulations and had been audited by Queensland Health the year before with no relevant issues identified.
13. Staff recognised that Ms Cowley-Persch’s demeanour had changed in the week prior to her death but had no cause to consider that she was suicidal.
14. Ms Cowley-Persch had submitted a detailed concerns letter to the Practice Manager three days prior to her death. The Practice Manager took reasonable steps to address Ms Cowley-Persch’s concerns and could not reasonably have known that Ms Cowley-Persch was suicidal at the time.
15. Both the Practice Manager and the Co-Owner of the Surgery had some awareness of past incidences involving people sourcing Pentobarbitone from Veterinary Clinics and committing suicide. However, the true extent of the problem within the veterinary industry was unknown and they reasonably, but mistakenly, assessed that the risk at their practice was low.

***The adequacy of the current national and Queensland regulatory regime in relation to storage, access control, monitoring and auditing of Pentobarbitone in Veterinary Clinics***

16. I find that the current national and State regulatory regime in relation to the storage, access control, monitoring and auditing of Pentobarbitone in Veterinary Clinics is inadequate. This is because of the prevalence of misuse of the drug for the purposes of suicide.
17. However, I do not make any adverse inference against the regulatory agencies for failing to identify the inadequacies in the past, given that until this inquest, the prevalence of the Pentobarbitone misuse problem in the context of Veterinary Clinics does not appear to have been well known.
18. In the future, if no action is taken by national and State/Territory regulatory agencies to tighten controls in the face of what is now known, I would consider this inadequate.

**Recommendations**

19. Section 46 of the *Coroners Act 2003* (Qld) provides that a Coroner may comment on anything connected with a death that relates to public health or safety, the administration of justice, or ways to prevent deaths from happening in similar circumstances in the future.
20. I recommend that:
  - a. The Therapeutic Goods Administration (TGA) upschedule Pentobarbitone in injectable form to a Schedule 8 drug in the Commonwealth *Poisons Standard*;
  - b. Queensland Health and all relevant State and Territory regulatory authorities adopt the TGA's upscheduling of Pentobarbitone in injectable form to a Schedule 8 drug, and the stricter controls that this entails.
  - c. If the TGA 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.
  - d. Manufacturers of Pentobarbitone introduce a warning on Pentobarbitone animal euthanasia Product Labels and within Safety Data Sheets that the drug 'must be stored in a locked safe/vault/receptacle'. Contextual information as to why this is important should be included in the Safety Data Sheets;
  - e. Manufacturers of Pentobarbitone introduce measures to ensure Veterinarians are notified when important changes to Safety Data

Sheets are made (for example by notifying State Veterinary boards, who should in turn, publish a bulletin to registered Veterinarians);

- f. Distributors of Pentobarbitone ensure that appropriate safeguards are in place so that only authorised persons under the relevant regulations can order and take physical delivery of the drug. Delivery should not be made to any staff member of a Veterinary practice. It is not just the responsibility of the recipient to ensure that only authorised persons take possession of the drug. Distributors need to take more responsibility.
- g. Virbac Australia Pty Ltd should consider ways to encourage employees to report their knowledge of adverse events relating to their products (even if it is based on anecdotal evidence), to enable the company to investigate and pro-actively address such issues. Reliance should not be solely placed on the receipt of formal adverse reports from external parties to the company; and
- h. Veterinary professional organisations should improve the education and support they provide to the Veterinary industry about:
  - i. the obligation to manage Pentobarbitone and other dangerous drugs in a manner that is consistent with Workplace Health and Safety, Health, and criminal law regulations. It should be noted that compliance with minimum standards in health regulations (ie. Schedule 4 storage and access controls) will not necessarily result in compliance with Workplace Health and Safety or criminal law obligations;
  - ii. important changes to drug Safety Data Sheets. (For example, some drug manufacturers do not have direct contact with Veterinarians because they use distributors. In such cases, the manufacturers and Veterinary professional organisations should work together so that important drug safety information can be communicated through the professional organisations to their members); and
  - iii. suicide awareness and prevention (for example – increased advertising campaigns, mentoring programs, mental health first aid courses, and counseling hotlines).

## **Evidence, discussion and general circumstances of death**

### ***Discovery of Ms Cowley-Persch's body***

- 21. Donna Cowley-Persch was 58 years of age when she died by suicide on Thursday 19 September 2013. She was employed as a 'dog groomer' by the Ascot Veterinary Surgery, located in north Brisbane.
- 22. Ms Cowley-Persch was discovered deceased by co-workers at around

8:00am on 19 September 2013 in a toilet cubicle outside the Veterinary Surgery. The first ambulance officer at the scene stated that her temperature was still 33 degrees Celsius, indicating to him that Ms Cowley-Persch's death had only occurred around 1 – 2 hours earlier.

### ***Means of suicide***

23. It would appear that Ms Cowley-Persch obtained from her workplace a 450mL bottle of the animal euthanasia drug called 'Lethabarb' ('Pentobarbitone / Pentobarbital' is its generic name). She injected herself with the bright green liquid (sometimes also referred to as 'the green dream'), through a cannula attached to a line.
24. Although Ms Cowley-Persch was employed by the Surgery as a dog groomer, she had taken an interest in Veterinary procedures and was sometimes requested to assist with the euthanasia of animals. The Co-Owner of the Surgery, Dr Benjamin Charlton, explained that the Ascot Veterinary Surgery comprised of about 10 staff. All of his staff are multi-rolled because they are a small business. Most employees would at some stage have a role in euthanizing an animal.

### ***Medical cause of death***

25. An external post mortem examination was conducted on 24 September 2013. Toxicology testing of Ms Cowley Perch's femoral blood was conducted and a toxicology certificate of analysis produced on 22 October 2013. The autopsy report was concluded on 7 November 2013.
26. The forensic pathologist was of the opinion that the medical cause of Ms Cowley-Persch's death was Pentobarbitone toxicity. I have accepted the forensic pathologist's opinion in my findings.

### ***What is Pentobarbitone?***

27. In the past, Pentobarbitone was available in tablet form for human consumption in Australia for the purposes of sedation, management of epilepsy, and traumatic brain injuries. The concentration of Pentobarbitone in those tablets was very low but they still became the subject of misuse by people for the purposes of committing suicide.
28. Limited records are available but it would appear that as a result of the misuse of tablets containing Pentobarbitone, the tablets were listed as Schedule 8 drugs under the Commonwealth *Poisons Standard* in 1985, and subjected to the strictest of controls regarding their use and storage. It would also appear that due to the misuse of this medication, manufacturers withdrew it from the Australian market and it is no longer available.
29. Pentobarbitone is now only available in liquid (injectable) form in Australia for the purpose of euthanizing animals. The concentration of the drug in injectable form is significantly higher than the tablet form, which was

historically available for human consumption.

30. It would appear that Pentobarbitone in a concentrated form is used in some parts of the US for the purposes of administering the death penalty.
31. When used on humans, Pentobarbitone in injectable form, which is labelled and packaged for animal euthanasia, has the same effect as it does on animals. It depresses the neurological and respiratory systems, and reduces blood pressure (causing hypotension), which in combination can be rapidly fatal.

### ***What is Lethabarb?***

32. 'Lethabarb' is one of the main commercial product names for the Pentobarbitone animal euthanasia drug in Australia. It is manufactured by Virbac Pty Ltd and accounts for 95% of the market.
33. Lethabarb is currently only available in 450mL bottles. However, there are three other companies authorised to manufacture Pentobarbitone for animal euthanasia in Australia. One of those companies now offers the drug in 100mL and 250mL bottles. Virbac Pty Ltd is also looking at introducing smaller bottle sizes in the future.

### ***Why is Pentobarbitone dangerous?***

34. Pentobarbitone is rapidly fatal. It was estimated by Dr Charlton to only take around 30 seconds to kill an animal and is likely to have a similar effect on humans.
35. Pentobarbitone in liquid form for animal euthanasia is highly concentrated. It generally only takes 1mL per 2kg of body weight to effectively euthanize an animal. It is assumed that similar principles apply to humans.
36. This means that for an average Australian adult, only around 40mL of the drug would be required for rapid suicide. There is no anecdote, except for possibly CPR within a very small time frame.
37. There have also been cases where people have committed suicide by drinking the liquid, rather than injecting it.

### ***The extent of the Pentobarbitone misuse problem in Australia***

38. The national statistics regarding the number of people who have committed suicide through the use of Pentobarbitone are alarming.
39. According to a recent National Coronial Information System report that I obtained for the purposes of this inquest:
  - a. Since July 2000 (when records were first kept), there have been 293 suicides in Australia as a result of Pentobarbitone toxicity. (That is an average of 18.3 deaths per year);



- b. In Queensland, there have been 6 reported deaths since 2001, due to Pentobarbitone toxicity;
  - c. The ages of the deceased range from as young as 15 years old to over 90 years of age;
  - d. For at least 33 suicides Australia wide, it would appear that the source of the Pentobarbitone has come directly from Veterinary Clinics.
  - e. Of those 33 suicides, many of the deceased are Veterinary Surgeons or Veterinary Nurses. However, there are also people who have sourced the Pentobarbitone from a Veterinary Clinic whom you would not expect to have ready access to the drug, such as students, an unemployed person, and a dog groomer in Ms Cowley-Persch's case.
40. For the majority of the deaths due to Pentobarbitone toxicity that are recorded in the National Coronial Information System report, the source of the drug is unknown.
41. There is anecdotal evidence that many people are obtaining Pentobarbitone illegally from overseas.
42. There are also a number of internet posts by people discussing the best way to obtain and administer Pentobarbitone for the purposes of suicide.
43. I note the remarks of the high profile and controversial euthanasia advocate, Mr Phillip Nitschke. Mr Nitschke is a former physician. He is the founder and current director of the pro-euthanasia group called 'Exit International'. In his 'Peaceful Pill Handbook', which is readily available on the internet, he states that:

*When asked about Nembutal [which is another brand name for Pentobarbitone] at Public Meetings and Workshops, I tell people that it can be very handy to know a vet...*

### **Current health regulations in relation to Pentobarbitone**

44. At the Commonwealth level, scheduling of medicines and poisons are recorded in the *Standard for the Uniform Scheduling of Medicines and Poisons* (also known as the Commonwealth 'Poisons Standard'). The Commonwealth *Poisons Standard* is administered by the Therapeutic Goods Administration (TGA), which belongs to the Commonwealth Department of Health.
45. The criteria and process applied to scheduling decisions by the TGA are set out in the *Therapeutic Goods Act 1989* (Cth) and the *Scheduling Policy*

*Framework.*

46. In tablet form, Pentobarbitone is listed as a Schedule 8 'controlled drug' in the Commonwealth *Poisons Standard*. Whereas, when packed and labelled for injection, Pentobarbitone is only listed as a Schedule 4 'restricted drug'.
47. In the Veterinary field, once a drug is Scheduled under the *Poisons Standard*, the Commonwealth Australian Pesticides and Veterinary Medicines Authority (APVMA) decides whether to approve the active constituents in Veterinarian products and whether to register the product under the *Agricultural and Veterinary Chemicals Code Regulations 1995* (Cth). The APVMA is also responsible for approving certain aspects of a veterinary product's Product Label.
48. The inquest heard that the TGA's scheduling of a drug at the Commonwealth level is adopted by all States and Territories for national consistency.
49. Limited reference is made to storage of scheduled drugs within the Commonwealth *Poisons Standard*. It is up to the States and Territories to legislate and enforce specific storage and access control requirements relating to the various drug Schedules.
50. In Queensland, Pentobarbitone in injectable form is listed as a Schedule 4 drug under the *Health (Drugs and Poisons) Regulation 1996* (HDPR). The HDPR is administered by Queensland Health.
51. In Queensland, a Schedule 4 drug such as injectable Pentobarbitone for animal euthanasia need only be stored in an unlocked cupboard away from public access. Only a Veterinary Surgeon may order the drug. Veterinary Surgeons, and Veterinary Nurses (with specified training) may take possession of, and access, the drug. However, only a Veterinary Surgeon can administer the drug.
52. Whereas, in Queensland, a Schedule 8 drug must be stored in a locked safe or receptacle. Only Veterinary Surgeons can order, take possession of, access, and administer Schedule 8 drugs approved for Veterinary purposes.

***Criminal law regime, which could apply to the management of Pentobarbitone in Queensland***

53. Section 289 of the *Criminal Code Act 1899* (Qld) provides:

**Duty of persons in charge of dangerous things**

It is the duty of every person who has in the person's charge or under the person's control anything, whether living or inanimate, and whether moving or stationary, of such a nature that, in the absence of care or precaution in its use or management, the life,

safety, or health, of any person may be endangered, to use reasonable care and take reasonable precautions to avoid such danger, and the person is held to have caused any consequences which result to the life or health of any person by reason of any omission to perform that duty.

54. This criminal law provision was the subject of much discussion during the inquest. However, I did not, in the end, form a reasonable suspicion that an offence under s 289 of the *Criminal Code Act 1899* (Qld) had been committed by any person in the circumstances of Ms Cowley-Persch's death.
55. I do note though that this criminal law duty of care forms part of the wider picture in terms of the legal landscape in Queensland that is potentially applicable to the management of Pentobarbitone by Veterinary practices. The witnesses called at the inquest did not appear to have had a good understanding of this provision, although they understood the concept. More education is required in this area.
56. It is important for the Veterinary industry to understand that the criminal law sits above any other minimum standards set in health regulations regarding the management of Pentobarbitone (ie. Schedule 4 controls), in much the same way as the workplace health and safety regulations do. The criminal law duty of care should therefore be a consideration for Veterinary practices in the future in terms of the way in which they manage Pentobarbitone.

### ***Storage of Lethabarb at the Ascot Veterinary Surgery***

57. Lethabarb was stored at the Ascot Veterinary Surgery in an unlocked cupboard (up high) in the treatment room. This was in accordance with the minimum requirements of the health regulations applicable to Schedule 4 drugs.
58. The treatment room was unlocked but the chances of a member of the public accessing the treatment room without being seen by staff was minimal.
59. All staff at the Surgery had access to the unlocked cupboard during business hours. There were no protocols regarding access by staff to the cupboard.
60. It was usual practice to leave Lethabarb bottles on the bench in the treatment area between procedures but this was only for periods of up to 10 minutes, until the Veterinary Nurse had a chance to place it back in the cupboard.
61. Dr Charlton explained that because his Surgery is a small business and staff are multi-rolled, it is possible that Ms Cowley-Persch may have been requested to retrieve a Lethabarb bottle in the past. However, he could not recall her ever being requested to do so.

62. After hours, the Ascot Veterinary Surgery is protected by an alarm system, connected to an on call security company. The only staff that have after-hours access to the surgery are the Practice Manager, Veterinary Surgeons, and Veterinary Nurses.

### ***Recording of Lethabarb use at the surgery***

63. In accordance with the minimum requirements for Schedule 4 drugs, the Ascot Veterinary Surgery did not record their use of Lethabarb in a separate record book. Notes were usually kept in the individual files of the animals being euthanized but not necessarily of the volumes of the drug used.
64. The Practice Manager of the Ascot Veterinary Surgery, Ms Kate Bernays, conceded that part bottles of Lethabarb could go missing from the surgery without anyone necessarily 'blinking an eye'.
65. The Practice Manager stated that prior to Ms Cowley-Persch's death, there were 3 bottles of Lethabarb held by the Surgery in an unlocked cupboard (1 full bottle and 2 half bottles). One of the Veterinary Surgeons had realised that one of the half bottles was gone, but it was assumed that the bottle had been used.

### ***Procedure for ordering Lethabarb at the surgery***

66. The Practice Manager stated that the Surgery usually only kept two bottles of Lethabarb on stock. One full bottle and one part bottle. The part bottle would be replaced as required, in case a large animal came in.
67. A Veterinary Nurse would generally do a stock take of all of the drugs held at the Surgery on Tuesdays and Thursdays each week. Adhoc drug orders could also be made on different days, if urgent.
68. The distributor that supplied Lethabarb to the Ascot Veterinary Surgery was a company by the name of 'Provet Pty Ltd'. Orders would generally be placed with them by the Surgery through an electronic ordering system.
69. Only Veterinarians, Veterinary Nurses, and the Practice Manager had password access to the electronic ordering system. After advice was provided to the Surgery by Queensland Health following an audit in 2012, all electronic orders for Lethabarb were reviewed and cleared by the Veterinarian before sending.
70. Dr Charlton stated that he imagined that it was not uncommon for Veterinary Nurses, through urgent phone calls placed to Provet Pty Ltd, to order Schedule 4 drugs and that such orders would be accepted by Provet Pty Ltd, despite there clearly being a Veterinary Nurse on the phone.

71. Provet Pty Ltd has responded in written submissions that they do not accept orders for Schedule 4 drugs over the phone. They only accept such orders via fax (which requires a Veterinarian's signature), or via 'eOrder' or 'My Inventory' (which both allow other staff to build orders, but orders must be sent via the Veterinarian's login).

***Procedure for accepting delivery of Lethabarb at the surgery***

72. Deliveries of Lethabarb would generally be on the same day as the order, provided the order was placed by a certain time.
73. When Provet Pty Ltd delivered Lethabarb to the Surgery, the delivery person would allow any person at the Surgery to take possession and sign for receipt of the drug. Schedule 4 drugs would arrive either in one big box or in multiple boxes and the boxes were not labelled, so it was difficult to know what its contents were. Schedule 4 drugs, such as Lethabarb, would be left in the Consultation Room of the Surgery and then later retrieved by the Veterinary Nurse and placed in storage.
74. Dr Charlton stated that it was possible that Ms Cowley-Persch could have taken delivery of a bottle of Lethabarb without anyone knowing. Invoices were provided separately for each order, so an individual order of Lethabarb would not necessarily show up on a group invoice, even if the drug arrived with other drugs delivered at the same time.
75. Provet Pty Ltd has responded in written submissions that their deliveries of Schedule 4 drugs are made by vans owned and operated by Provet or via courier companies. Upon delivery, orders are signed for by the Veterinarian or a staff member.
76. It is possible that Ms Cowley-Persch could have intercepted a bottle of Lethabarb at the time of delivery.
77. Provet Pty Ltd has submitted that it is the recipient's responsibility under the regulations to ensure that only persons who are endorsed to possess a (Schedule 4) restricted drug have possession of the drug. They have advised that all of their deliveries are clearly labelled.

***Persons authorised to use Lethabarb at the surgery***

78. Dr Charlton stated that the only people authorised to use Lethabarb at the Surgery were the Veterinary Surgeons. Veterinary Nurses and other staff members did not draw up the drug, or administer the drug.

***Ms Cowley-Persch's letter of concerns to the practice manager of the surgery prior to her death***

79. On or around Monday 15 September 2013 (three days prior to her death), Ms Cowley-Persch hand delivered a one page typed and signed letter to the Practice Manager of the Surgery. The letter outlined in detail a number of personal and work stressors in her life.

80. The Practice Manager, Ms Bernays, stated that this was the first time that Ms Cowley-Persch had ever given her such a letter. Ms Cowley-Persch had previously sent an email to her about sick leave and specialist appointments, but nothing of this nature.
81. In the letter, Ms Cowley-Persch made some general comments such as:
  - a. "I don't seem to be coping well. I have been taking half a Xanax once I have driven to work just to get me through the day this last week..."; and
  - b. "I don't know if my anxiety is totally work-related or not - I just seem to be losing my perspective. If I could come up with a solution I would suggest it. I feel it's just taking all my strength holding it together at the moment."
82. Ms Cowley-Persch also went into detail about a number of specific concerns she had, including her high workload and financial stressors. She stated that she had bought a new car, paid for an operation to address her sleep apnoea, and did not receive a regular level of pay due to the seasonal variations in her work. She was concerned that she had not received a pay rise in 3 – 4 years.
83. Ms Bernays stated that as a result of Ms Cowley-Persch's letter, she held an informal team meeting with the dog groomers either the same day or the next day. The outcome of the meeting was that some changes were implemented to help alleviate Ms Cowley-Persch's workload. However, the feedback Ms Bernays received from Ms Cowley-Persch after the meeting was that she was unsure whether the changes would resolve her issues.
84. Ms Bernays stated that she also offered Ms Cowley-Persch some time off work to address her issues and clear her head. She explained that Ms Cowley-Persch was an employee entitled to paid sick leave and holiday leave and would have understood that she could have taken leave on a paid basis. However, Ms Cowley-Persch declined the offer as she did not feel that time off from work would help her.
85. Ms Bernays also stated that on the afternoon of Tuesday 17 September 2013, she had a conversation with Ms Cowley-Persch about pay. Pay had been deposited late into staff members' bank accounts and Ms Cowley-Persch was concerned. Ms Bernays offered to lend her some of her own money until the pay went through. Ms Cowley-Persch thanked her but declined.
86. Dr Charlton stated that although Ms Cowley-Persch's letter had not been brought to his attention, he was aware of Ms Cowley-Persch's desire to

move from a wage to a salary due to seasonal variations in hours. This proposal had in the past been raised with him but they were unable to do this due to financial constraint on the practice.

### ***Ms Cowley-Persch's demeanour at work prior to her death***

87. Ms Bernays stated that in the week prior to Ms Cowley-Persch's death, she noticed that Ms Cowley-Persch was not her usual self. She was usually a consistently happy person but had told Ms Bernays that she didn't know what was going on with her and couldn't put her finger on it.
88. Ms Bernays stated that it never entered her mind that Ms Cowley-Persch was a suicide risk. This is because Ms Cowley-Persch was talking to her about her problems and she thought that they would be able to work through the work related issues together. Ms Bernays believes that Ms Cowley-Persch genuinely loved her job and that it was a happy place for her in general.
89. One of the staff members of the Surgery stated to police that during the last two weeks of Ms Cowley-Persch's life, he noted a change in her demeanour and that she had become more stressed.
90. Neither the Practice Manager, Co-Owner of the Surgery, or any other staff members considered that Ms Cowley-Persch was at risk of suicide at the time.

### ***Awareness by the surgery of the extent of misuse of Pentobarbitone in the veterinary industry***

91. Ms Bernays stated that prior to Ms Cowley-Persch's death, she was aware that a Veterinary Nurse and a Vet's son at two other Veterinary Clinics in Queensland had committed suicide with Lethabarb.
92. Ms Bernays thought that one of the Co-Owners of the Surgery may have told her about the death of the Vet's son and that an industry representative from Provet Pty Ltd may have told her about the death of the Vet nurse. She was not aware of the specific circumstances of their deaths. The most recent incident that she had heard of was the death of the Veterinary Nurse about a year before Ms Cowley-Persch's death.
93. Ms Bernays stated that they had general discussions about those deaths but they did not imagine there was any such risk in their practice.
94. Dr Charlton stated that he had discussed the storage of Lethabarb with other staff previously, as he was aware of suicides involving the drug. However, because his understanding was that the suicides were most often of other Veterinarians, it did not occur to him that other staff working at his practice would be at risk.
95. Dr Charlton was also unaware of the specific circumstances of the

suicides that he had heard about. He explained that such incidents were not openly aired within the industry. Suicide in general within the Veterinary industry appears to be a taboo subject.

96. Whilst both the Practice Manager and Co-Owner of the Ascot Veterinary Surgery accepted that they had a role in ensuring that the workplace was safe, they did not consider that there was any risk of suicide at their practice, nor that the storage of Lethabarb in an unlocked cupboard presented a risk.

### ***Audit of the surgery by Queensland Health in 2012***

97. Queensland Health has responsibility for monitoring and ensuring compliance with the *Health (Drugs and Poisons) Regulations (HDPR)*. They have also provided Guidelines to Veterinarians regarding their responsibilities.
98. Veterinary facilities may be the subject of routine and targeted audits and investigations. Each year, compliance plans are set to assess different aspects of the HDPR based on assessments of risk and public health concern.
99. On 7 June 2012, (the year before Ms Cowley-Persch's death), the Ascot Veterinary Surgery was audited by an Environmental Health Officer from the Metro North Hospital and Health Service Public Health Unit. The audit was part of a compliance survey of 58 Veterinary surgeries located in the Brisbane North region. The audit included checks for compliance with storage and access to Schedule 4 drugs (including injectable Pentobarbitone). No non-compliance matters were identified in relation to storage and access of Pentobarbitone.
100. Another systematic compliance review of Veterinary facilities in Queensland is scheduled for the 2017/18 year.

### ***Action taken by the Ascot Veterinary Surgery since Ms Cowley Persch's death***

101. Following Ms Cowley-Persch's death, the Ascot Veterinary Surgery voluntarily tightened their storage procedures in relation to Lethabarb, above that which is required by the regulations applicable to Schedule 4 drugs. They now store the drug in a locked safe.
102. They do not, however, keep a separate record to monitor the use of Lethabarb and are not required to do so under the current regulations applicable to Schedule 4 drugs.

### ***Action taken by Workplace Health and Safety Queensland***

103. Since February 2011, Workplace Health and Safety Queensland (WHSQ) has investigated three deaths that occurred at separate Veterinary clinics in the greater Brisbane area. These investigations included:



- a. The death of Ms Karlene Bradley on 28 February 2011. Ms Bradley was employed as a Veterinary Nurse by the Scarborough Veterinary Clinic. She was found deceased by staff in the front office of the workplace after she had accessed and self-administered Lethabarb intravenously;
  - b. The death of Ms Cowley-Persch on 19 September 2013 (the subject of this inquest); and
  - c. The death of Ms Melissa Peters on 17 September 2015. Ms Peters was employed as a Veterinary Nurse at the Red Hill Veterinary Clinic. She was found deceased late at night at her workplace after inserting a cannula into her arm, connected to an infusion pump leading to a bottle of Lethabarb.
104. WHSQ determined that the incidents did not give rise to any contravention under the *Work Health Safety Act 2011* (Qld).
105. Following the first two similar incidents, The Office of Safe Work Queensland wrote to the Queensland Division of the Australian Veterinary Association to remind its members of their primary duty of care under the *Work Health Safety Act*, especially as the Act applies to the safe use, handling and storage of substances. WHSQ also notified Work Safe Australia, so that other State and Territory jurisdictions could be alerted.

***Action taken by the Queensland Division of the Australian Veterinary Association***

106. Following prompting from the Office of Safe and Fair Work Queensland, the Queensland Division of the Australian Veterinary Association published an alert in their November 2013 electronic newsletter, alerting members to the two recent fatalities. They reminded Veterinarians of their primary duty of care in ensuring the safe use, handling, and storage of substances but did not appear to include any specific guidance.

***Action taken by the Veterinary Board of Queensland***

107. The Veterinary Board of Queensland went a step further than the Australian Veterinary Association with their guidance and should be commended. They issued (non-binding) guidelines in their December 2013 newsletter to Queensland Veterinarians recommending that all stocks of Pentobarbitone and other like branded euthanasia solutions be stored in a locked receptacle or in a controlled drug safe cupboard, accessible only to the Veterinarian on duty.
108. The Veterinary Board of Queensland has advised that whilst they have legislative authority to set standards for Veterinary premises, they do not have jurisdiction in the way in which drugs are stored within the premises.

109. The Veterinary Board of Queensland also communicated to me their view that injectable Pentobarbitone should be re-scheduled to a Schedule 8 drug to make it less accessible, and to minimise the opportunity for misuse.

***Action taken by the Therapeutic Goods Administration***

110. The decision to list Pentobarbitone in tablet form as a Schedule 8 drug and Pentobarbitone in injectable form as a Schedule 4 drug was made in August 1985 by the Pharmaceutical Sub-Committee of the Australian Drug Evaluation Committee within the TGA. Back then, the Committees were made up of representatives from each State and Territory and they had to reach consensus. The system has now changed so that the committees do not make the scheduling decisions. They provide advice only to independent (and anonymous) delegates who are ultimately responsible for making the decisions.

111. As a result of this inquest, the TGA gained a greater awareness of the number of people misusing Pentobarbitone in injectable form to commit suicide within Australia. This triggered the delegates to propose that Pentobarbitone in injectable form be upscheduled to Schedule 8. Public submissions were invited by 20 October 2016.

112. The TGA has announced that of the 32 submissions received, 7 supported and 25 opposed the delegate's proposal. A meeting between the advisory committee on medicine scheduling and the advisory committee on chemical scheduling occurred on or around 15 – 17 November 2016.

113. The committees then provided their advice to the delegates advised against rescheduling the drug. The delegates agreed with the committee's advice and their interim decision was made and published on the TGA's website on 2 February 2017.

114. During the inquest, I was advised by the TGA that the purpose of the delegates' interim decision is to provide more clarity around the intent of the delegates. There is still scope for the delegates to accept further submissions and my recommendations from this inquest will be considered by the delegates prior to them making their final decision.

***Action taken by Virbac Australia Pty Ltd***

**Recent changes to the Lethabarb Safety Data Sheet**

115. Prior to Ms Cowley-Persch's death, there were no instructions provided by Virbac Australia Pty Ltd in relation to the safe storage of Lethabarb to prevent potential human misuse for the purposes of suicide.

116. However, on 13 May 2016, the Safety Data Sheet for Lethabarb was amended. It now clearly states that the drug *must be stored in a locked vault* at all times, except when it is being used. It also now states that the Safety Data Sheet is a 'Hazard Communication tool' that should be used

to assist in the Risk Assessment in the workplace.

### **Lack of awareness of the misuse of Lethabarb by Virbac Australia Pty Ltd**

117. Virbac Australia Pty Ltd has advised that the recent changes to the Safety Data Sheet were made as a result of a routine review by an external consultant, not as a result of Ms Cowley-Persch's death or any other deaths resulting from the misuse of their product.
118. Virbac stated that no complaint had been made by any party about the misuse of the drug, and whilst staff members within Virbac may have been aware of incidents involving Lethabarb, it was not an issue that had come to the attention of, or been addressed by, the company.
119. The two representatives of Virbac Australia Pty Ltd at the inquest admitted to having an awareness prior to 2016 of attempted suicides and suicides caused by misuse of Lethabarb, either through their direct knowledge or by hearing anecdotal evidence.
120. However, in what appeared to be scripted responses at times, the representatives denied that there were any problems within their company highlighted by the fact that they did not raise their knowledge of the potential misuse of Lethabarb with the company. They appeared to take comfort from the fact that much of their information was based on anecdotal evidence, or from information obtained before joining the company. They also stressed that no specific adverse reports had been received by the company. They appeared to place great weight on the fact that prior to 2016, the company's external consultants had not identified that more guidance within the Lethabarb Safety Data Sheet around the safe storage of the drug was necessary. They stressed that they relied on their consultants for this advice, yet they conceded that no one informed the consultants about their knowledge that the drug was being misused by humans for the purposes of committing suicide.
121. I note that advice from consultants is only ever as good as the information provided to them by the companies that hire them. I agree with Counsel Assisting's submission that this is a potential area for systemic improvement within Virbac Australia Pty Ltd. All employees should be encouraged to raise with the company any information of potential adverse incidents involving the company's products, regardless of whether it is anecdotal evidence, and especially where human lives could be in danger. This is important so that the company is then able to investigate anecdotal reports to obtain more information, and to address issues more pro-actively.

### ***Communication of changes to the Lethabarb Safety Data Sheet***

122. A concern was raised by Dr Charlton's legal representative that important changes, such as the amendment to the Lethabarb Safety Data Sheet in

May 2016, are not effectively communicated to Veterinarians.

123. Virbac sells Lethabarb to eight registered distributors, which then on sell the product to Veterinarians. Provet Pty Ltd is the distributor of Lethabarb to the Ascot Veterinary Association.
124. Virbac publishes the Lethabarb Safety Data Sheet on their webpage. They also advise their distributors when they make changes to the Safety Data Sheets. However, they do not appear to set any expectations with their distributors, in terms of the way in which the distributors should communicate such changes to their customers (the end users).
125. The representatives of Virbac expressed a willingness to consider whether there was a way for them to communicate future changes directly to the end users. In written submissions, Virbac submitted that because they do not have direct contact with clinics (who purchase the product from a distributor), the best way to achieve this would be to notify State boards that should, in turn, publish a bulletin to the registered Veterinarians.

***Willingness to consider changes to the Lethabarb product label***

126. Virbac has acknowledged that the product label for Lethabarb does not contain any guidance about ways to store the drug safely to prevent misuse by humans for the purposes of suicide. They have expressed a willingness to consider adding such a warning, subject to APVMA approval.

***Action taken by Provet Pty Ltd***

**Communication of changes to the Lethabarb Safety Data Sheet**

127. Provet Pty Ltd responded in written submissions to the concerns raised by Dr Charlton's legal representative regarding communication to end users of changes to the Lethabarb Safety Data Sheet.
128. Provet has advised that it routinely printed Safety Data Sheets to accompany orders. In 2011, Provet undertook a project to update all Safety Data Sheets for items that Provet stocks and loaded them onto the Provet System and onto 'MSDSonline'. MSDSonline is an online database of Safety Data Sheets.
129. This project helped to avoid multiple deliveries of the same Safety Data Sheets. Provet's Information Technology department coded the system such that a Safety Data Sheet would be printed for items on an order that were:
  - a. being purchased for the first time since the coding change;
  - b. being purchased for the first time ever by the clinic;
  - c. for new products on the market; or

- d. for products for which the Safety Data Sheet had been updated since the clinic last purchased.
130. Provet advised that the printed Safety Data Sheets are delivered with the order along with the invoice.
131. What is not clear to me is whether Provet communicated to recipients of Pentobarbitone the reason(s) why they were receiving updated Safety Data Sheets. It is all well and good to have a system for when to print and provide Safety Data Sheets to customers but if they do not know about the system, it is next to pointless. It is also impractical, in my view, to expect Veterinarians to sift through each Safety Data Sheet provided to them with multiple drug orders to ascertain whether there are any important changes since the last time they read them. Some more assistance from the drug manufacturers in particular (with the help of Veterinary professional organisations) is required here.

***Should Pentobarbitone in injectable form be upscheduled to a Schedule 8 drug?***

132. The reality is that although the States and Territories are responsible for providing detailed regulations around storage, access control, and recording of drugs in each jurisdiction, it is the TGA at the national level that is best placed to shape this through their scheduling decisions.
133. If the TGA were to upschedule Pentobarbitone in injectable form to Schedule 8, it is highly likely that most States and Territories will adopt the rescheduling in their own legislation. This will result in stricter controls under State/Territory regulations applying to the drug.
134. It is understood that the regulations in each State and Territory around storage, access control and recording of scheduled drugs are similar. However, this inquest did not analyse the nuances of each jurisdiction. My understanding is that in Queensland, the main changes that would result if Pentobarbitone in injectable form is upscheduled would be that:
- a. The minimum requirements for storage would change from an unlocked cupboard out of public view to a locked safe (or locked receptacle when travelling);
  - b. Veterinary nurses would no longer be able to access or handle the drug, only a Veterinarian could do this; and
  - c. A record would need to be kept for usage of the drug.
135. The Veterinary Surgeons Board of Queensland has advised that they understand that Veterinarians at risk of suicide will still have access to this product regardless of a change to its scheduling. However, they support

tighter controls and more accountability put in place to prevent access by persons such as nurses, groomers, cleaners and other contractors.

136. The Veterinary Surgeons Board of Queensland has pointed out that Veterinarians play a unique role in our society in that they are the only profession entrusted with the euthanasia of animals and as such this role also comes with some significant responsibilities with respect to the storage, access to and use of Pentobarbitone.
137. The Veterinary Surgeons Board of Queensland advised that Veterinary surgeries are currently required to have compliant Schedule 8 drug safes in order to be operational. Veterinarians who operate a Veterinary house call practice must have access to a locked receptacle to store the Schedule 8 drugs whilst undertaking house calls. They must also have a compliant Schedule 8 drug safe for storage of Schedule 8 drugs when they are not travelling.
138. The Veterinary Surgeons Board of Queensland acknowledges that the rescheduling of Pentobarbitone from Schedule 4 to Schedule 8 will have an impact on a Veterinarian's practice. However, it is their view that this would be minimal, as Veterinarians currently use a range of other Schedule 8 products in their practices and comply with the current requirements.
139. The Co-owner and Practice Manager of the Ascot Veterinary Surgery, Dr Charlton and Ms Bernays, were of the strong opinion that Pentobarbitone should be upscheduled. They were supportive of any change that reduces the risk of a death occurring in the workplace in similar circumstances.
140. Witnesses from State and Commonwealth regulatory authorities (i.e. the TGA, APVMA, and Queensland Health) could see no significant practical barriers to upscheduling the drug.
141. However, Virbac Australia Pty Ltd, the manufacturer of Lethabarb, which accounts for 95% of the current market, and the Australian Veterinary Association (AVA), oppose an upscheduling of the drug to Schedule 8.
142. The basis for Virbac's opposition can be summarised as follows:
  - a. Since Virbac Australia Pty Ltd does not currently manufacture Schedule 8 drugs, they are concerned that there would be significant additional costs and inconvenience at the point of manufacture and along the supply chain, including:
    - i. new vaults that would need to be constructed or expanded;

- ii. compliance costs in terms of the location of the vaults and associated security arrangements, including alarm systems and cameras; and
  - iii. potential additional costs in relation to transport, if it is mandated that security requirements apply;
- b. Increased costs at the manufacturing and distribution level may result in reduced demand for the product;
- c. Reduced demand for the product and inconvenience may result in the company deciding that it no longer wishes to manufacture the product. This may lead to other, less humane alternatives being used at the cost of animal welfare;
- d. There are many other non-Schedule 8 drugs that can still be misused for the purposes of suicide;
- e. Pentobarbitone does not meet all of the 'Factors for Controlled Drugs (Schedule 8) in the AHMAC Scheduling Policy Framework for Medicines and Chemicals' dated 1 February 2015;
- f. The additional regulation would place more stress on staff in Veterinary clinics, especially the smaller practices with limited resources, because they will be required to account in some detail for a drug that is used repeatedly;
- g. There may be further requirements placed on Veterinarians in terms of equipping their vehicles, which may be especially problematic in rural and remote settings where they are required to travel large distances to treat domestic and wild animals;
- h. In many situations, there would be no realistic prospect of people misusing the product, so the measure would have limited utility;
- i. The product would still be accessible to Veterinarians and most likely Veterinary Nurses;
- j. The measure would only displace the problem. If staff other than Vets and Vet Nurses working at Veterinarian Clinics are suffering from a mental health illness and wish to commit suicide, they may simply find an alternative method of suicide; and
- k. The measure would draw more attention to Pentobarbitone, which may result in the drug being the subject of higher misuse or theft.

143. Virbac has proposed that Pentobarbitone remain in Schedule 4, but that there be an additional requirement that the drug is stored securely. They

have suggested that in effect, all that would need to be done is to adopt the current New South Wales and Tasmanian Schedule 4D classification.

144. The AVA conducted an online survey with its members, which resulted in 2031 survey responses and 1013 written comments. However, I have reservations about the way in which the questions were posed to members and the lack of information provided to members about the scope of the issue.

145. The basis for the AVA's opposition can be summarised as follows:

- a. Recording of Pentobarbitone injections would add an extra level of workload and complexity. For example:
  - i. Two AVA members provided estimates of the extra time that it would take them to record their use of the drug if it were upscheduled to Schedule 8. One member estimated 3 minutes per animal (noting that they euthanize 23.5 animals on average per week) and 8 minutes per month when placing a drug order. The other member estimated 5 – 10 minutes per animal (noting that they euthanize on average 25 animals per week) and 10 minutes per month for drug orders. The argument is that although these are relatively small amounts of time per animal and drug order, this can add up to a number of additional hours of work per week for a Veterinarian; and
  - ii. In emergencies, restraint of difficult animals, multiple animals, and use out in the field, the drug is used "to effect". This means that often more than the recommended dose is drawn up in case the initial dose is not immediately effective, and delivered in increments until the death of the animal is achieved. The quantities used range from 0.5ml to 200ml, depending on the size of the animal. If Veterinarians were required to record usage and wastage, there would be a high chance that inadvertent inaccuracies in recording would occur frequently;
- b. The size of a bottle of Pentobarbitone (around 500ml in most practices) means that 20-30mls (the amount they say is required for a human to commit suicide) could go missing without anyone noticing until the bottle is close to empty, which could be a week or two later. This would eliminate any benefit from recording its use;
- c. Each wildlife case would now need a clinical record created, and to be recorded in the Schedule 8 Register. This may result in a



decrease in the number of practices willing to undertake animal welfare as a community service;

- d. If Pentobarbitone injections are rescheduled and a staff member uses it to commit suicide, the Veterinarian may be liable under work health and safety regulations if they have not complied with the Schedule 8 regulations. This puts a lot of onus on the Veterinarian in circumstances where their ability to control small amounts of the drug from going missing is limited;
- e. Virbac may consider that it is not financially viable to continue manufacturing Lethabarb if it is rescheduled. If other manufacturers think likewise, this would be disastrous for Veterinary practice and animal welfare;
- f. Some Veterinarians would need to purchase new drug safes due to the size and number of Pentobarbitone bottles stocked at their practice;
- g. The biggest risk of intentional misuse lies with Veterinarians and Veterinarian Nurses. An upscheduling will not affect a Veterinarians access to the drug. For Veterinary Nurses, although they are not legally permitted to have access to Schedule 8 drugs, in many busy practices they will be given access;
- h. The potential hazard of intentional misuse by staff other than Veterinarians and Veterinarian Nurses, where the drug is sourced from a Veterinary Practice, is not widespread;
- i. There are many lethal means available in Veterinary practices so rescheduling Pentobarbitone injections will not stop suicide. Instead, addressing the actual risk factors, which lead to suicide is far more important. There should be a holistic approach to suicide prevention in the Veterinary profession; and
- j. Of the survey responses received from AVA members currently working in clinical practice, 64.1% did not support rescheduling. This is made up of 72.1% who were employers but only 57.8% who were employees. (I should note that I have reservations about the way in which the question was framed and the lack of awareness that respondents to the survey would have had about the scope of the problem – ie the national statistics and NCIS report).

146. The Australian Veterinary Association has essentially proposed the same outcome as Virbac. They do not support an upscheduling of Pentobarbitone in injectable form to Schedule 8 but they do support a change to the regulations to require the drug to be stored in a locked

cupboard, safe, or receptacle, both within Veterinary premises and when in vehicles when not in use.

147. The TGA delegates' interim decision regarding their recent review is that the current scheduling of Pentobarbitone in injectable form remains appropriate. They have published that their reasons for decision, which can be summarised as follows:

- a. Pentobarbitone is not registered for human use. It is intended for animals;
- b. Pentobarbitone is a cheap and efficient medicine, the preferred agent, and is widely used for the humane euthanasia of animals in multiple settings;
- c. Pentobarbitone in 500mL bottles is widely used (predominately in the field) due to the large doses required to humanely euthanize large animals or multiple livestock;
- d. A wide range of authoritative organisations opposed the upscheduling on the basis of reasonable and practical grounds;
- e. The impact that no change to the scheduling of Pentobarbitone will make is unclear. But is thought to be low when considering the available suicide data and the people that are misusing Pentobarbitone for suicidal purposes.

148. It is not clear from the interim decision which particular grounds raised by the 'wide range of authoritative organisations', which opposed the upscheduling were considered by the TGA delegates to be 'reasonable' and practical'. I will, however, address a number of recurring issues below.

149. I accept Counsel Assisting's submission and I recommend that the TGA upschedule Pentobarbitone in injectable form to Schedule 8. I make this recommendation because:

- a. As a matter of common sense, stricter controls around storage, use and recording of the drug at Veterinarian clinics is likely to reduce the number of people who are able to access the drug from those facilities. This in turn is likely to reduce the numbers of suicides by such means;
- b. The administrative and financial burden of such a change is relatively minor when weighed against the benefit of saving human lives;
- c. The argument that only a small number of human lives will be saved by this measure fails to recognize the value of human life. Even if

only one human life is saved as a result of stricter controls, wouldn't it be worth it?;

- d. It should not matter that this drug is intended for animal use and not human use. The fact is that humans are misusing this drug for the purposes of suicide. In Veterinary workplaces, we know that at least two people a year are dying from this drug;
- e. The argument that there are other non-Schedule 8 drugs in Veterinary practices and in society in general, which can be misused suicide fails to understand that Pentobarbitone is different. In injectable form, Pentobarbitone is highly concentrated and rapidly fatal. The product is clearly marked as a euthanasia drug. It's sole purpose is to kill. Such a drug that is so clearly dangerous and where its potential for misuse is obvious, should not be allowed to be stored in an unlocked cupboard, with its usage unrecorded;
- f. I agree that the high suicide rate in the Veterinary industry requires a holistic solution. The approach must involve increased education and support around mental health. But that is not the end. The holistic approach also necessitates the introduction of measures for when increased education and support does not work. There needs to be stricter controls around dangerous drugs, which are rapidly fatal and known to be the target of misuse;
- g. It is acknowledged that upscheduling will not affect the access that Veterinarians currently have to Pentobarbitone and is unlikely to make any difference to the number of Veterinarians who misuse the drug for suicide. However, this is not a valid excuse for not taking action to minimise suicide rates in relation to other people in the Veterinary workplace. Such people include Veterinary Nurses, administrative staff, groomers, cleaners, contractors and members of the public;
- h. A large proportion of the people in Veterinary workplaces committing suicide through misuse of Pentobarbitone are Veterinary Nurses. Under Queensland's health regulatory regime at least, Veterinary Nurses would not be allowed access to the drug if it were upscheduled to Schedule 8. Providing that practices comply with the law, this is likely to minimise the incidence of Veterinary Nurses using Pentobarbitone to suicide;
- i. There is an argument that busy Veterinary practices will ignore the regulations if Pentobarbitone is upscheduled and allow Veterinary Nurses access to the drug unlawfully. However, this assumes that Veterinarians will be willing to break the law. Such instances should also be minimised as a result of the increased auditing and scrutiny

that Schedule 8 brings, as well as the deterrents in place for non-compliance;

- j. There is an argument that people will just commit suicide by another means if Pentobarbitone is inaccessible. This is an uneducated argument and goes against the research in this area. It is true that in some cases, there is no stopping someone who is intent on suicide. However, suicides are often unplanned. Making it more difficult for a people to suicide often results in people pausing, reconsidering their decision, and even seeking help;
- k. The fact that there is a much bigger problem in the general community regarding the illicit trade of Pentobarbitone, most likely from overseas sources, is not an excuse for failing to take measures to make Veterinary workplaces safer;
- l. There is no logical reason why Pentobarbitone in injectable form would be listed as a Schedule 4 drug when Pentobarbitone in tablet form is listed as a Schedule 8 drug. The statistics indicate that a number of people have been willing and able to inject themselves with Pentobarbitone for the purposes of suicide. There are also cases where people have committed suicide by drinking the liquid, which is designed for injection. Pentobarbitone in injectable and tablet form should therefore be granted the same protections. They should both be Schedule 8.
- m. A brief scan of the internet demonstrates that it is relatively well known that Pentobarbitone can be used for suicide and that the drug can be sourced from Veterinarians. It is nonsensical to suggest that the drug should not be upscheduled in case this raises the profile of the drug and increases misuse. It is impossible to keep information about the potential misuse of this drug a secret. It is therefore logical to instead increase security around the storage of the drug to deter and prevent people from misusing it and stealing it from Veterinarians;
- n. All Veterinary surgeries in Queensland are currently required to have compliant Schedule 8 drug safes in order to be operational. Veterinarians who operate a Veterinary house call practice must have access to a locked receptacle to store Schedule 8 drugs whilst undertaking house calls. I would be surprised if this was not the case for most Veterinarians nationwide. This should minimise any additional expenditure caused by having to purchase new safes or receptacles;
- o. It is not clear whether the TGA delegates are aware that Pentobarbitone in injectable form is currently available in 100mL and 250mL bottles and that Virbac is also about to introduce a smaller

than 500mL sized bottle to the market. In any event, I accept that some Veterinarians may not currently have large enough safes to store 500mL bottles and that some Veterinarians may require this size bottle to euthanize larger animals and multiple stock. In such circumstances, Veterinarians would need to purchase a larger safe/receptacle. Dr Charlton advised that it would be relatively cheap to do so. I cannot see how this should be a significant impediment to upscheduling;

- p. It is doubtful that Veterinary practices would cease euthanizing wildlife humanely as a community service, due to additional recording requirements caused by an upscheduling, as suggested by the AVA. This argument underestimates the values held by the Veterinary profession. In any event, the potential to save human lives through increased recording should be given more weight than an administrative burden;
- q. There appears to be an argument made to the TGA that upscheduling the drug would result in staff safety being compromised in locations that require the transportation of sick and injured animals to external sites with Veterinarians. It is implied in this argument that in some jurisdictions, non-Veterinarians currently have authority to administer Pentobarbitone. If this is the case and there are sound reasons for doing so, States and Territories should simply carry over this authority / exemption to a Schedule 8 listing of Pentobarbitone;
- r. There are simple recording processes in place for recording spillage and wastage. Also, there would be no reason why in the case of an emergency, animal welfare would need to be jeopardized due to recording. I would be surprised if the requirement in most jurisdictions would be to record as soon as practicable. Therefore these issues should not be a barrier to introducing a requirement to record;
- s. As for the possibility that skimming may still occur with any recording system and not be detectable until the bottom of the bottle, I cannot see why this should be a reason not to record at all. The fact that a record keeping system is not perfect is no excuse not to have one. In Ms Cowley-Persch's case, the Veterinary surgery held two bottles of Lethabarb for use at any one time. No records were kept of the volumes used along the way. A Veterinarian noticed that a part bottle was gone but assumed that it had been used on an animal. At least a record keeping system will detect when part bottles go missing; and
- t. I note that at the time of the inquest, Virbac had not yet had an opportunity to estimate the increase in their costs that would be

caused by an upscheduling of the drug. I therefore do not necessarily accept that the increase would be 'significant', as submitted by them. I also do not accept that demand for the drug would be significantly affected if increased costs were to be passed on to consumers. Pentobarbitone is currently the only drug available in Australia to euthanize animals humanely. In such circumstances, it is difficult to see how demand for the drug would not continue. There are also three other competitors currently in the market who would no doubt consider filling the gap if Virbac were to discontinue production of the drug.

150. I do not agree with Virbac's suggestion that a new category be introduced by each of the States and Territories, in line with Schedule 4D in New South Wales and Tasmania. This category only appears to deal with storage issues. Access and recording controls remain an issue. Schedule 8 is a well-known and understood category nationwide. In my view, it is the category that achieves the appropriate degree of regulation for a drug of this nature in the circumstances.

I offer my condolences to the family and friends of Ms Cowley-Persch.

I close the inquest.

John Hutton  
Coroner  
Brisbane  
21 February 2017