

# IN THE CORONERS COURT OF VICTORIA AT MELBOURNE

Court Reference: COR 2019 7144

## FINDING INTO DEATH WITHOUT INQUEST

## Form 38 Rule 63(2) Section 67 of the Coroners Act 2008

Findings of:

## AUDREY JAMIESON, Coroner

Deceased:

31 October 1991

30 December 2019

Samantha Louise Leech

Date of birth:

Date of death:

Cause of death:

1(a) Complications of a seizure in the setting of prescription medication abuse (pregabalin)

Place of death:

Boronia. Victoria, 3155

## **INTRODUCTION<sup>1</sup>**

- 1. On 30 December 2019 Samantha Louise Leech was 28 years old when she had a seizure just after midnight. At 8.00am she was found, deceased, in her bedroom at home.
- 2. At the time of her death, Ms Leech lived in Boronia with her husband, Nathan Leech, her mother, Gayle Schwab and her younger sister.
- 3. Ms Leech had a history of schizophrenia, post-traumatic stress disorder (**PTSD**), bipolar disorder, asthma and Bart Pumphrey syndrome.<sup>2</sup> Her hearing was impaired and during her lifetime, she had undergone cochlear implant surgery. Ms Leech was also an Eastern Health outpatient in both the cardiology and the neurology departments, most notably at Box Hill Hospital and she had been a patient in the obstetrics department at the Angliss Hospital.
- 4. Ms Leech also had a long history of frequently visiting multiple general practitioners in quick succession citing neuralgic or neuropathic pain, amongst others, as her reason. Her requests for specific medication were documented by the medical practitioners she visited in their contemporaneous file notes.
- 5. The evidence indicates that, at some medical practices, Ms Leech either submitted an altered date of birth which made her a year younger or used her maiden name, Schwab.<sup>3</sup>
- 6. Ms Leech was identified by Medicare under the Prescription Shopping Programme and various medical practitioners were alerted to her propensity to visit numerous medical practitioners to request analgesic medication.<sup>4</sup>

<sup>&</sup>lt;sup>1</sup> Coronial File [**CF**], COR 20197144-LEECH, Samantha Louise. The facts and inferences in my Finding appear from the documentary evidence contained in the court file.

<sup>&</sup>lt;sup>2</sup> Bart-Pumphrey syndrome is also known as palmoplantar keratoderma. The condition is characterised by hyperkeratosis or thickening of the skin over the joints of metacarpal phalanges, digits of the hands. Another characteristic of the condition is impaired hearing.

<sup>&</sup>lt;sup>3</sup> Ms Leech, however, always used the same Medicare number during all her visits to general practitioners.

<sup>&</sup>lt;sup>4</sup> Between 27 December 2015 and 21 December 2019, about 40 visits to medical practitioners were recorded. At each session Ms Leech requested specific analgaesic medication including Endone (containing the opioid, oxycodone), Panadeine Forte (containing the opiate, codeine) and Lyrica (a proprietary name for Pregabalin, prescribed for neuropathic pain). She cited surgical procedures to her foot and pelvic pain as her reasons, amongst others.

7. However, some medical practitioners discounted the alert because of the discrepancy in her date of birth or surname. Others, on the other hand, found her requests plausible due to the reasons cited for her request(s).

## THE CORONIAL INVESTIGATION

- 8. Ms Leech's death was reported to the Coroner as it fell within the definition of a reportable death in the *Coroners Act 2008* (the Act). Reportable deaths include deaths that are unexpected, unnatural, violent or result from accident or injury.
- 9. The role of a coroner is to independently investigate reportable deaths to establish, if possible, identity, medical cause of death, and surrounding circumstances. Surrounding circumstances are limited to events which are sufficiently proximate and causally related to the death. The purpose of a coronial investigation is to establish the facts, not to cast blame or determine criminal or civil liability.
- 10. Under the Act, coroners also have the important functions of helping to prevent deaths and promoting public health and safety and the administration of justice through the making of comments or recommendations in appropriate cases about any matter connected to the death under investigation.
- 11. The Victoria Police assigned an officer to be the Coroner's Investigator for the investigation of Ms Leech's death. The Coroner's Investigator conducted inquiries on my behalf, including taking statements from witnesses such as family, the forensic pathologist, treating clinicians and investigating officers and submitted a coronial brief of evidence.
- 12. This finding draws on the totality of the coronial investigation into the death of Samantha Leech, including evidence contained in the coronial brief. Whilst I have reviewed all the material, I will only refer to that which is directly relevant to my findings or necessary for narrative clarity. In the coronial jurisdiction, facts must be established on the balance of probabilities. <sup>5</sup>

<sup>&</sup>lt;sup>5</sup> Subject to the principles enunciated in *Briginshaw v Briginshaw* (1938) 60 CLR 336. The effect of this and similar authorities is that coroners should not make adverse findings against, or comments about, individuals unless the evidence provides a comfortable level of satisfaction as to those matters taking into account the consequences of such findings or comments.

#### MATTERS IN RELATION TO WHICH A FINDING MUST BE MADE<sup>6</sup>

#### Circumstances in which the death occurred

- 13. On 30 December 2019, just after midnight, Ms Schwab found Ms Leech in her bed, suffering a seizure. Ms Schwab remained with Ms Leech until the seizure had passed and reported that Ms Leech was alive, breathing and sleeping when she left her after the seizure had stopped. Ms Leech also suffered seizures in the days immediately preceding her death.
- 14. At approximately 3.00am, Mr Leech retired to bed and according to him, his wife was still breathing at the time. At approximately 8.00am when Mr Leech awoke, he discovered Ms Leech stiff and cold beside him. He called Ms Schwab to assist him to find a pulse. Ms Schwab called the emergency services number '000' and the call operator directed Ms Schwab to move Ms Leech to the floor and to commence cardiopulmonary resuscitation (CPR). Mr Leech and Ms Schwab were unable to administer CPR.
- 15. Ambulance Victoria (AV) paramedics arrived shortly after the emergency services number was called. The AV paramedics were unable to revive Ms Leech and declared her deceased at 08.15am.

#### Identity of the deceased

- 16. On 30 December 2019, the body of Samantha Louise Leech, born 31 October 1991, was visually identified by her husband, Nathan Leech who signed a formal Statement of Identification.
- 17. Identity is not in dispute and requires no further investigation.

#### Medical cause of death

- Senior Forensic Pathologist Dr Michael Phillip Burke from the Victorian Institute of Forensic Medicine (VIFM) conducted an autopsy on 3 January 2020.
- 19. Prior to conducting the autopsy Dr Burke considered the following:
  - i. He reviewed a post-mortem computed tomography (CT) scan,

<sup>&</sup>lt;sup>6</sup> If possible.

- ii. He referred to the Victoria Police Report of Death, Form 83; and
- 20. After Dr Burke had conducted the autopsy, he had recourse to and considered the medical records of Ms Leech held on file by Eastern Health. He provided a written report of his findings dated 16 April 2020.<sup>7</sup>
- 21. The post-mortem examination did not reveal any evidence of physical injury which could have contributed to or led to Ms Leech's death. Dr Burke further noted the following:
  - i. His review of the medical records from Eastern Health indicated that Ms Leech had suffered tachycardia on 6 April 2018; <sup>8</sup>
  - ii. At autopsy, there was no evidence of structural abnormality to her heart which could have led to sudden, unexpected death;
  - iii. Sudden, unexpected death following an epileptic seizure is well documented in the medical literature on the topic.<sup>9</sup>
- 22. Dr Burke also consulted Specialist Forensic Pathologist, Dr Linda Elizabeth Iles from the VIFM to obtain a neuropathology report following Ms Leech's history of epileptic seizures.
- 23. Dr Iles conducted her examination of the sample taken for neuropathology by Dr Burke on the 6 January 2020.
- 24. In conjunction with the sample, Dr Iles reviewed the neuropathology referral form by Dr Burke and the post-mortem **CT** scan. She conducted both a macroscopic and a microscopic examination on various sections of the sample.
- 25. In the written report of her neuropathological findings dated 30 April 2020, Dr Iles was unable to identify any epileptogenic pathology, in keeping with the history of this matter, that Ms Leech had suffered a seizure prior to her death.<sup>10</sup>

<sup>&</sup>lt;sup>7</sup> **CF**, Autopsy Report of Dr Michael Burke

<sup>&</sup>lt;sup>8</sup> Tachycardia is a heart rhythm disorder or arrythmia. According to the notes held on file, Ms Leech fell forward, then back She was pale, stiff and twitched. She did not bite her tongue and there was no ictal cry, a guttural vocalization commonly observed or associated with episodic epileptic seizures. She recovered rapidly, was thirsty upon recovery and remembered the attending paramedics whose contemporaneous notes indicated tachycardia.

<sup>&</sup>lt;sup>9</sup> Dr Burke opines that a possibility exists that the seizure led to a cardiac arrythmia or respiratory arrest as a mechanism of her death. He based his opinion on the oedema foam about the mouth of Ms Leech, observed at autopsy.

<sup>&</sup>lt;sup>10</sup> CF, Neuropatholgy Report of Dr Linda Iles.

- 26. However, her report articulates further that the inability to identify either macroscopic or microscopic pathology to confirm epileptic seizures is not uncommon in those dying in the setting of a seizure disorder and does not exclude a diagnosis of epilepsy during life.
- 27. An initial toxicological analysis report of the post-mortem samples, dated 24 March 2020, identified the presence of prescription medication in the blood sample taken in the following concentrations:
  - i. Methadone ~ 0.8 mg/L;<sup>11</sup>
  - ii. Oxycodone ~  $0,1 \text{ mg/L};^{12}$
  - iii. Nordiazepam ~ 0.03 mg/L;<sup>13</sup>
  - iv. Amitryptiline ~ 0.06 mg/L;<sup>14</sup>
  - v. Nortriptyline ~ 0,03 mg/L;<sup>15</sup>
  - vi. EDDP ~  $0.04 \text{ mg/L}^{16}$  and
  - vii. Pregabalin  $>30 \text{ mg/L}.^{17}$
- 28. Dr Burke provided an opinion that the medical cause of death was '1(a) Complications of a seizure'.
- 29. Dr Burke's comments, following his finding on the cause of death, incorporated the contents of the initial toxicology report by reference.

<sup>&</sup>lt;sup>11</sup> An opioid drug indicated for use in opiate dependency recovery or rehabilitation programs. It is also indicated for chronic pain management.

<sup>&</sup>lt;sup>12</sup> An opioid drug indicated for moderate to severe pain and is available in Australia under the proprietary name, Endone. Ms Leech specifically requested a prescription for Endone during her multiple visits to medical clinics.

<sup>&</sup>lt;sup>13</sup> A benzodiazepine derivative drug indicated for the treatment of anxiety disorders. It has a sedative or hypnotic effect.

<sup>&</sup>lt;sup>14</sup> An antidepressant also indicated for neuropathic pain.

<sup>&</sup>lt;sup>15</sup> A metabolite of amitryptiline.

<sup>&</sup>lt;sup>16</sup> An acronym for 2-Ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidene, a metabolite of methadone.

<sup>&</sup>lt;sup>17</sup> Pregabalin is clinically indicated for the treatment of partial seizures and neuropathic pain. It is available in Australia under the proprietary names Lyrica and Lypralin, amongst others. Ms Leech specifically requested a prescription for Lyrica during her multiple visits to medical clinics.

## FURTHER INVESTIGATIONS

- 30. Upon closer scrutiny of the evidence presented in both the medical examiner's report and the toxicology report, I interrogated the ostensibly high level of Pregabalin identified by the toxicology report.<sup>18</sup>
- 31. Following my investigation, a further toxicology report, dated 16 November 2020, as well as a supplementary report by Dr Burke, dated 4 December 2020, was entered into evidence for my consideration.<sup>19</sup>
- 32. In his supplementary report, Dr Burke acknowledged the following:
  - i. High levels of Pregabalin present in all the samples tested;<sup>20</sup>
  - ii. Pregabalin has toxic effects which include low level consciousness, seizures and tachycardia;<sup>21</sup>
  - iii. The lack of features at the scene to indicate intentional overdose makes it unclear whether the raised level of Pregabalin caused the death of Ms Leech but that it may have been a contributing factor.
- After I perused the findings articulated in Dr Burke's supplementary report and considered its probative value, I requested a formal toxicology opinion from the VIFM.<sup>22</sup>
- Head of Forensic Services and Chief Toxicologist, Associate Professor (AP) Dmitri Gerostamoulos from the VIFM, provided a formal toxicology opinion dated 30 December 2020.<sup>23</sup>

<sup>&</sup>lt;sup>18</sup> I invited Dr Burke to comment on the concentration of Pregabalin in the blood sample being more than 30mg/L. In particular, I wanted to ascertain what concentration of Pregabalin would be considered a medically acceptable level.

<sup>&</sup>lt;sup>19</sup> **CF**, Supplementary Autopsy Report. After Dr Burke considered my queries in respect of the toxicology, he requested further analysis of the sample taken from the stomach contents and the hair sample.

<sup>&</sup>lt;sup>20</sup> The following concentrations were identified:

i. ~56mg/L in the sample of blood;

ii. ~5.3mg in the sample of stomach contents;

iii. >5ng/mg in each of the first and second segments of the hair sample; and

iv. ~5.0ng/mg in the third segment of the hair sample.

<sup>&</sup>lt;sup>21</sup> A conspectus of the evidence suggests that Ms Leech had been receiving ongoing treatment for tachycardia. Strikingly, the timelines provided for this condition correlates to her use of the analgaesic medication, identified by my investigation, for co-existing medical conditions. The evidence further suggests that Ms Leech sought out specific medication for these co-existing medical conditions. In this regard, refer to paragraphs 6 to 8 and 30 of my Finding and the references cited there.

<sup>&</sup>lt;sup>22</sup> Dr Burke suggested that obtaining a formal opinion in this regard may be of value.

- 35. AP Gerostamoulos reviewed the following material upon which he based his opinion:
  - i. The autopsy report dated 16 April 2020;
  - ii. The supplementary report dated 4 December 2020;
  - iii. The VIFM Toxicology report dated 18 November 2020;
  - iv. The factual matrix of the matter as contained in the court file; and
  - v. The Pharmaceutical Benefits Scheme Patient Summary Medicare record from 30 December 2018 to 30 December 2019.
- 36. In his report, AP Gerostamoulas observed the following:
  - i. Pregabalin, amitryptiline, oxycodone and methadone were detected in the samples taken from Ms Leech. AP Gerostamoulas isolated these drugs as relevant for the purposes of forming his opinion;<sup>24</sup>
  - ii. Ms Leech had filled prescriptions for pregabalin obtained from six prescribers at six pharmacies during December 2019, the month of her death.
  - iii. The consumption of the total amount of the pregabalin prescribed for December 2019 which Ms Leech had filled would result in Ms Leech having consumed in excess of nine times the medically prescribed monthly intake for any patient;<sup>25</sup> and
  - iv. The concentration of pregabalin in the sample was significantly high.<sup>26</sup>
- 37. From his observations, AP Gerostamoulas drew the following conclusions:
  - i. Used in combination, pregabalin, amitryptiline, oxycodone and methadone could suppress the central nervous system and lead to unconsciousness and death;
  - ii. Ms Leech's concomitant use of pregabalin and opioids, particularly methadone, significantly increased her risk of dying;<sup>27</sup>

<sup>&</sup>lt;sup>23</sup> CF, Toxicology Opinion of AP Gerostamoulos. The file was delivered to AP Gerostamoulos at my instance. AP Gerostamoulos was fully apprised of the factual matrix of this matter upon which he based his opinion but only takes into account the 12-month history leading to Ms Leech's death.

<sup>&</sup>lt;sup>24</sup> Traces of codeine, morphine, tapentadol, tramadol, diazepam and nordiazepam were also detected but not considered relevant. It merely indicated prior use.

<sup>&</sup>lt;sup>25</sup> The recommended maximum daily dose is 600mg, yielding a monthly recommended dose of 18,600mg. If Ms Leech had taken all the Pregabalin from the six prescriptions that she filled, she would have taken 163,800mg in December alone.

<sup>&</sup>lt;sup>26</sup> The concentration in Ms Leech's sample was ~56mg/L. AP Gerostamoulas articulates that, in his experience, a concentration of ~20-25mg/L is toxicologically significant.

- iii. Methadone can cause death by hypoxia as breathing is compromised. The risk of this happening is significantly increased when methadone is used in conjunction with oxycodone and pregabalin;
- iv. The finding that the death was caused by the complications of a seizure cannot be excluded;
- v. The possibility exists that the seizure could have been precipitated by the toxic effects of pregabalin; and
- vi. The high concentrations of pregabalin and methadone in combination with oxycodone and amitriptyline could have resulted in the death of Ms Leech.

## **CPU REVIEW**

- 38. In light of the toxicological concerns identified by my investigation, I requested that the Coroners Prevention Unit (**CPU**) review the court file, inviting input with regard to the over prescribing of pregabalin to Ms Leech.<sup>28</sup> The court file included the medical records from 25 clinics where pregabalin was prescribed to Ms Leech and statements from 20 clinicians who prescribed pregabalin to her.
- 39. Consequently, my investigation further identified the following systemic issues:
  - i. Ms Leech used false identities to acquire the prescriptions for pregabalin;<sup>29</sup>
  - ii. Many pregabalin prescribers only saw Ms Leech once;<sup>30</sup>
  - iii. The potential for use and misuse of pregabalin;<sup>31</sup>
  - iv. Safescript<sup>32</sup> did not assist the prescribers;<sup>33</sup>
  - v. The lack of awareness that Ms Leech was a prescription shopper;<sup>34</sup>

<sup>&</sup>lt;sup>27</sup> No records exist to support a view that Ms Leech had obtained a permit from the Department of Health and Human Services for opioid replacement therapy. Furthermore, the evidence does not support the existence of a prescription for methadone for reasons other than therapeutic use either.

<sup>&</sup>lt;sup>28</sup> The Coroners Prevention Unit (CPU) was established in 2008 to strengthen the prevention role of the coroner. The unit assists the Coroner with research in matters related to public health and safety and in relation to the formulation of prevention recommendations. The CPU also reviews medical care and treatment in cases referred by the coroner. The CPU is comprised of health professionals with training in a range of areas including medicine, nursing, public health and mental health.

<sup>&</sup>lt;sup>29</sup> At six clinics, Ms Leech adopted her maiden surname, Schwab and altered her birth year to 1992. All her

other details including her Medicare number, home address and contact telephone number remained the same. <sup>30</sup> Twelve prescribers only consulted with Ms Leech once, for the first time when they prescribed pregabalin.

<sup>&</sup>lt;sup>31</sup> Eleven prescribers were unaware that pregabalin was a drug with the potential for misuse. Ten doctors formed

the view that it was indeed a drug with the potential for misuse after their experience in treating Ms Leech.

<sup>&</sup>lt;sup>32</sup> The State of Victoria's real-time prescription monitoring system which became mandatory in April 2020.

<sup>&</sup>lt;sup>33</sup> Only four prescribers checked *Safescript* before prescribing pregabalin to Ms Leech. It is noted that the use of *Safescript* was not mandatory at the time of Ms Leech's death.

- vi. A credible medical complaint gave Ms Leech an advantage as a prescription shopper;<sup>35</sup> and
- vii. A lack of further investigation before prescribing pregabalin.<sup>36</sup>
- 40. Having considered these systemic issues identified by my investigation, reviewed in conjunction with the factual matrix of this matter as contained in the court file, the evidence indicates that:
  - i. Ms Leech was successful in obtaining approximately 4000 pregabalin tablets with relative ease in the three months immediately prior to her death;
  - ii. Pregabalin was not a target drug monitored by S*afescript* at the time when Ms Leech was able to obtain the tablets;
  - iii. Medical practitioners who prescribed pregabalin did so without due regard to any risks associated with its misuse or abuse;
  - iv. At the time of Ms Leech's death the Victorian Department of Health and Human Services (as it was then known) failed to cause pregabalin to be added to the list of drugs monitored by the *Safescript* real-time system, despite numerous opportunities to do so;
  - v. The ease with which pregabalin was available to Ms Leech and the timing of Medicare's Prescription Shopping Programme (**PSP**) warning to alert the prescribers that she was prescription shopping correlates to the failure to monitor the drug on the *Safescript* real-time system.<sup>37</sup>

## COMMENTS

Pursuant to section 67(3) of the Act, I make the following comments connected with the death.

 Pregabalin is a GABA and gabapentin analogue clinically used for treatment of partial seizures and neuropathic pain.<sup>38</sup> According to the toxicologist's comments,

<sup>&</sup>lt;sup>34</sup> Eleven prescribers were alerted by Medicare that Ms Leech was 'prescription shopper'. Seven were alerted after they had already prescribed the drug and four did not attribute the warning to their patient because Ms Leech had altered her surname and date of birth.

<sup>&</sup>lt;sup>35</sup> All the prescribers found Ms Leech's request for pregabalin reasonable or plausible for neuropathic pain because of her recent orthopaedic surgery.

<sup>&</sup>lt;sup>36</sup> All the prescribers acknowledged that they did not fully investigate their patient before prescribing pregabalin to Ms Leech. Only one of the four prescribers who checked *Safescript* contacted Medicare's Prescription Shopping Programme for further information. That prescriber was told that no record exists for Samantha Schwab, the altered name provided by Ms Leech.

<sup>&</sup>lt;sup>37</sup> The alerts by Medicare's **PSP** are only prompted after the prescription has been generated on the system and issued to the patient and not in 'real-time' as with the *Safescript* alerts.

<sup>&</sup>lt;sup>38</sup> CF, Toxicology Report

gabapentinoids (gabapentin and pregabalin) lack the *wanting* characteristic of traditional drugs of abuse but could become addictive in patients with prior substance use disorder, particularly opioid-dependent patients. People who are drug dependent administer gabapentinoids to potentiate experienced euphoria and reduce withdrawal symptoms whilst producing minimal adverse effects. Pregabalin has a higher addiction risk compared to gabapentin due to its faster onset of action.

- 2. There are growing concerns about increased prescribing and abuse of pregabalin and its contribution to overdose deaths in Victoria. Analysis of coronial data from 2010 to 2019 shows that pregabalin was not implicated in any coronial deaths in 2010 to 2012 inclusive. Pregabalin was implicated in 17 deaths in 2013; 27 in 2014; 34 in each of 2015 and 2016; 52 in 2017; 69 in 2018 and 66 in 2019,<sup>39</sup> when there was a decrease in overall overdose deaths in Victoria for the first time in a decade. In 2019, pregabalin was the sixth highest contributing drug in overdose deaths behind diazepam, heroin, methamphetamine, methadone and alcohol.
- 3. Since 1 April 2020, it is mandatory to check *SafeScript*, Victoria's real-time prescription monitoring system, prior to writing or dispensing a prescription for those medications or drugs which are monitored through the system.<sup>40</sup>
- 4. Pregabalin prescribing and dispensing is not monitored by *SafeScript* despite a substantial body of evidence demonstrating that it is a drug that is abused and misused; that it is a substantial contributor to Victorian overdose deaths annually; and that it has been shown not to be effective for many of the clinical indications it was initially approved to treat.
- 5. The other relevant limitations of *SafeScript* pertains to Ms Leech's use of her maiden surname and her altered date of birth. She also appeared to have given plausible explanations for her attendance as a patient and accessed significant quantities of potent medicines from several GPs. *SafeScript* relies on the patient's details being accurately recorded and will not generally pick up unsafe prescribing or dispensing if the patient is using a different name or surname. The only "penalty" for the patient will be the need to

<sup>&</sup>lt;sup>39</sup> Note that the annual frequency of Victorian overdose deaths fell in 2019, after a decade of consistent year-onyear increases. While the magnitude of the decrease was not particularly substantial (from 542 deaths in 2018 to 516 deaths in 2019, a decline of 26 deaths or 4.8%) it occurred against a backdrop of Victoria's continually growing population. Victoria's crude overdose death rate per 100,000 population, declined quite notably in 2019 for the first time in a decade – from 6.2 per 100,000 population in 2010, steadily increasing to 8.4 in 2018 and decreasing to 7.8 in 2019.

<sup>&</sup>lt;sup>40</sup> There are exceptions in some circumstances, including when treating patients in hospitals, prisons, police gaols, aged care and palliative care settings.

pay for the consultation privately and to pay for the medicine without the benefit of a Pharmaceutical Benefits Scheme subsidy, if there is one. For patients who are seeking to obtain a drug in excess of clinical need and/or are drug dependent, and who have the financial means to pay for consultations or scripts, this is not much of a disincentive.

- 6. In the Finding into the Death, Form 38, of Mr A, delivered 31 October 2019, Coroner Gebert recommended that in order to reduce the risk of harm associated with pregabalin, the Victorian Department of Health and Human Services, as it was then known (the Department) include pregabalin in the drugs monitored by *SafeScript* system. In its response, the Department refused to add pregabalin to the drugs monitored by *SafeScript* and, in so doing, set out its rationale, including its intention to continually monitor and review the addition of new medicines in *SafeScript*.<sup>41</sup>
- Similarly, in the Finding into the Death, Form 38, of Diane Maria Hillgrove delivered on 28 January 2021, Coroner Bracken made a similar recommendation. The Department has responded to Coroner Bracken's recommendation by means of a reference to its response to the recommendations in the Finding into the Death, Form 38, of Mr AAC delivered on 9 February 2021, by Coroner Spanos. In its response, the Department has agreed to review the case for including pregabalin to be monitored in *Safescript*.
- 8. In the interests of public health and safety, I concur with the recommendations previously made to the Department.
- 9. Furthermore, I acknowledge the Department's response to Coroner Spanos' recommendations. I further acknowledge that the Department and the *SafeScript* Expert Advisory Group, in accepting Coroner Spanos' recommendations, are abreast of coroners' concerns about pregabalin given its now established and ongoing contribution to Victorian overdose deaths.<sup>42</sup> However, Ms Leech's death is yet another statistic of a

<sup>&</sup>lt;sup>41</sup> The following is an excerpt from the Department's response – "While the 2019 review did find evidence of increasing harm from pregabalin, its overall scale of harm was found to be proportionate to supply and was less than medicines currently monitored in *SafeScript*. The review also found evidence of risk when pregabalin was used in combination with opioids or benzodiazepines, which are monitored through *SafeScript*, rather than when used alone. Based on this, the *SafeScript* Expert Advisory Group concluded that pregabalin in *SafeScript* was not the appropriate regulatory control at this stage, especially given clinicians are adjusting to the new system. A framework has been developed and published to guide future consideration of the addition of new medicines in *SafeScript*. Using this, the department will continue to observe data and review any new evidence of harm for pregabalin and other medicines not currently monitored."

<sup>&</sup>lt;sup>42</sup> I note the following information that appears on the *SafeScript* website regarding the drugs that are monitored: "In the leadup to *SafeScript* becoming mandatory in April 2020, and update of the literature review was

preventable death and given my obligation as a coroner to contribute to a reduction in the number of preventable deaths in Victoria, pertinent Recommendations now follow.

#### RECOMMENDATIONS

Pursuant to section 72(2) of the Act, I make the following recommendation on a matter/s connected with the death, including recommendations relating to public health and safety or the administration of justice:

- 1. With the aim of promoting public health and safety and preventing similar deaths, <u>I</u> recommend that the Victorian Department of Health review the circumstances of Ms Leech's death including but not necessarily limited to the apparent ease with which she presented to multiple clinics, registered as a patient under her maiden surname and altered date of birth and was prescribed significant quantities of pregabalin, implicated in her death.
- 2. With the aim of promoting public health and safety and preventing similar deaths, <u>I</u> recommend that the Victorian Department of Health's review should be expedited and aimed at including pregabalin to the list of medicines monitored through the *SafeScript* system and any other measures that could enhance patient safety in this regard.

#### FINDINGS

Pursuant to section 67(1) of the Coroners Act 2008 I make the following findings:

- 1. (a) the identity of the deceased was Samantha Louise Leech, born 31 October 1991;
  - (b) the death occurred on 30 December 2019 at Boronia, 3155;
  - (c) I accept that Dr Burke has ascribed the medical cause of death as the 'Complications of a Seizure'. However, I find that the circumstances in which Samantha Louise Leech's death occurred, particularly the high level of pregabalin in her bloodstream as evidenced by the post- mortem toxicology report, more accurately depicts the cause of

commissioned in early 2019 to determine if there was any significant new evidence of harm associated with medicines not currently monitored in *SafeScript*. These findings were then reviewed by the *SafeScript* Expert Advisory Group. Medicines looked at in detail in the updated review included pregabalin (used for neuropathic pain), tramadol(a synthetic opioid pain reliever) and olanzapine (treatment for psychiatric conditions). The Expert Advisory Group did not recommend any new medicines be added to the list of those currently monitored."

death. Accordingly, I find that Samantha Louise Leech died from the complications of a seizure in a setting of prescription drug abuse (pregabalin);

2. AND, having considered all the circumstances, the weight of the available evidence supports the view that Samantha Louise Leech was abusing a number of prescription medicines for at least the last three months of her life and I find a contributing factor to her death was the unintended consequence of the intentional ingestion of prescription drugs, particularly pregabalin.

Pursuant to section 73(1B) of the Act, I order that this finding be published on the Coroners Court of Victoria website in accordance with the rules.

Pursuant to section 49(2) of the Act, I direct the Registrar of Births, Deaths and Marriages to amend the cause of death to the following: "Complications of a seizure in the setting of prescription drug abuse (pregabalin)".

I direct that a copy of this finding be provided to the following:

Nathan Leech,

Professor Euan Wallace, The Secretary, Victorian Department of Health

Dr Anita Munoz, Chair, Victoria Faculty Council, Royal Australian College of General Practitioners

Professor Nicholas Lintzeris, Committee Chair and President, Australasian Chapter of Addiction Medicine, Royal Australasian College of Physicians

Mr John Jackson, Victorian Branch President, Pharmaceutical Society of Australia

Australian Health Practitioner Regulation Agency

Denise Aydin, MDA National Insurance, on behalf of Pubudu Wijesena

Scott Shelly, Barry Nilson Lawyers, on behalf of Shilpa Adinarayaniah

Senior Constable Matthew Cook, Coroner's Investigator

Signature:



**AUDREY JAMIESON** 

CORONER

Date: 20 August 2021

NOTE: Under section 83 of the *Coroners Act 2008* ('the Act'), a person with sufficient interest in an investigation may appeal to the Trial Division of the Supreme Court against the findings of a coroner in respect of a death after an investigation. An appeal must be made within 6 months after the day on which the determination is made unless the Supreme Court grants leave to appeal out of time under section 86 of the Act.