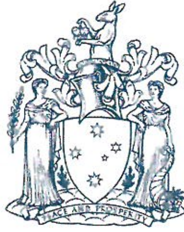

IN THE CORONERS COURT

OF VICTORIA

AT MELBOURNE

Court Reference: COR 2016 3703

FINDING INTO DEATH WITHOUT INQUEST

Form 38 Rule 60(2)

Section 67 of the ***Coroners Act 2008***

I, AUDREY JAMIESON, Coroner having investigated the death of MARGARET ANN YEOMANS

without holding an inquest:

find that the identity of the deceased was MARGARET ANN YEOMANS

born 19 October 1936

and the death occurred on 9 August 2016

at Northern Hospital, 185 Cooper St, Epping, VIC 3076

from:

1 (a) RHABDOMYOLYSIS IN A WOMAN WITH MULTIPLE MYELOMA AND RENAL IMPAIRMENT

Pursuant to section 67(1) of the **Coroners Act 2008**, I make findings with respect to **the following circumstances**:

1. Margaret Ann Yeomans was 79 years-of-age and residing in Epping at the time of her death. She lived with her husband, Peter Yeomans, and her daughter, Sue Yeomans. Mrs Yeomans medical history included multiple myeloma, chronic renal failure,

ischaemic heart disease, hypertension, high cholesterol, gout, and hypothyroidism. Eight years prior to the date of her death, Mrs Yeomans had commenced taking the cholesterol lowering medication simvastatin, following a heart attack. Her other medications were: aspirin, thyroxine, irbesartan (blood pressure), allopurinol (gout), vitamin D, dexamethasone 10mg weekly and prednisolone 5mg second daily and lenalidomide (for multiple myeloma).

2. On 25 July 2016 Mrs Yeomans presented to the Northern Hospital with three weeks of progressive weakness. She was found to have acute on chronic renal failure.[1] A renal tract ultrasound was conducted but Mr Yeomans' results were normal and provided no explanation for her deteriorating renal function. Hospital staff believed that the renal failure may be due to dehydration with possibly some contribution from both the steroid medication she was taking and the pre-existing myeloma which can cause large proteins to form in the kidneys, impairing function.

3. On 29 July 2016 the treating team became aware that there had been a pharmaceutical dispensing error and that Mrs Yeomans was dispensed rosuvastatin (40mg daily) instead of simvastatin (40 mg daily). Further testing indicated that Mrs Yeomans' creatinine kinase (CK level)[2] was moderately elevated.[3] Her treating team determined that, as this drug was excreted by the kidneys and there was pre-existing impairment of kidney function, an accidental relative overdose of statin drugs had contributed to rhabdomyolysis and worsening renal failure.[4]

4. On 2 August 2016, Mrs Yeomans' CK level had decreased[5] and renal function improved[6] but she had developed some respiratory compromise with some shortness of breath and low oxygen saturations on supplemental oxygen.[7] This was most likely due to fluid overload secondary to fluid replacement for the dehydration. Mrs Yeomans also developed a urinary catheter related infection.

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1 Baseline eGFR 45; on presentation eGFR 9. The eGFR is a measure of filtration rate in the kidneys and a lower number indicates less efficient function or renal failure.
2 A measure of muscle breakdown, a side effect of statin medications.
3 7000 (N<130)
4 Northern Health E-Medical Deposition Form, *Margaret Yeomans Admission Diagnosis: Statin Induced Rhabdomyolysis*, 9 August 2016.
5 (4074).
6 (eGFR 22).
7 92%.

5. On 5 August 2016 Mrs Yeoman's problem was described as "rhabdomyolysis with significant weakness and functional impairment" and to be "continuing to decline with respect to respiratory effort and functional state" and "was failing to thrive despite improvement in biochemistry". On this day there was a family meeting where Mrs Yeoman's condition was explained and there was "guarded prognosis" given.

6. On 6 August 2016, there was a further family meeting where treating medical practitioners explained to the family that, although there had been an improvement in biochemical parameters, there had been significant deterioration in Mrs Yeoman's condition. She had developed a sacral pressure sore, significant pain, distress, drowsiness and she was requiring morphine for comfort. Additionally, Mrs Yeoman's oral intake was considered insufficient to sustain her and the treating team stated that nasogastric feeding would be required to maintain adequate nutrition. Her family indicated they wanted all treatment possible, so the decision was made to aim for Mrs Yeoman's comfort, and, if she began to improve, the plan would change to more intensive treatment.

7. On 7 August 2016, Mrs Yeoman's condition did not improve. The haematology registrar indicated to Mrs Yeomans' family that he thought she was dying and subcutaneous fluids were continued for hydration. On 8 August 2016 Mrs Yeomans' condition deteriorated further and she was demonstrating her discomfort by grimacing when moved. Mrs Yeomans died on 9 August 2016.

INVESTIGATIONS

Forensic pathology investigation

8. Dr Khamis Almazrooei, Forensic Pathologist at the Victorian Institute of Forensic Medicine, performed an autopsy upon the body of Margaret Ann Yeomans, reviewed a post mortem computed tomography (CT) scan and referred to the Victoria Police Report of Death, Form 83. Dr Almazrooei identified Mrs Yeomans' cause of death as Rhabdomyolysis in a woman with multiple myeloma and renal impairment. Toxicological analysis detected no common drugs nor poisons.

9. Dr Almazrooei commented that rhabdomyolysis can occur secondary to multiple causes including multiple myeloma, statins (including simvastatin and rosuvastatin), renal

failure and infection. The pathologist identified a broad range of conditions that made Mrs Yeomans susceptible to develop rhabdomyolysis. Dr Almazrooei said that it is difficult to determine whether rosuvastatin alone caused the rhabdomyolysis in this case.

Police investigation

10. Upon attending Northern Hospital after Mrs Yeomans' death, Victoria Police took initial statements from her medical practitioners, husband and daughter. Police officers contacted the local Crime Unit upon ascertaining that Mrs Yeomans was wrongfully dispensed rosuvastatin (40mg), prior to her admission to hospital.

11. Detective Senior Constable (DSC) Frank Marino was the nominated coroner's investigator.[8] At my direction, DSC Marino conducted an investigation of the circumstances surrounding Mrs Yeomans', death, including the preparation of the coronial brief. The coronial brief contained, *inter alia*, statements made by Mr Yeomans, general practitioner at Epping's Tristar Medical Group Dr Diana Petropoulos, Haematology Physician at Northern Health Dr Teresa Sing-Yan Leung, and pharmacist Ms Soha Henry.

12. In the course of the investigation, police learned that Mrs Yeoman's final prescription for Simvastatin was issued by Dr Colleen Toner of the Mill Park Super Clinic on 29 December 2015. Dr Toner was Mrs Yeoman's general practitioner for a period of one year. Subsequent to Dr Toner leaving the Mill Park Super Clinic, Mrs Yeomans consulted Dr Petropoulos at Epping's Tristar Medical Group.

13. On 11 April 2016, Mrs Yeomans consulted Dr Petropoulos for a general healthcare check-up. Dr Petropoulos stated that Mrs Yeomans felt well; she received flu-vaccinations and a blood test at the Tristar clinic. On 27 April 2016, she returned to the clinic for the test results. The results indicated that Mrs Yeomans was generally in good health but suffered a mild kidney impairment, which Dr Petropoulos explained was a result of her pre-existing multiple myeloma.

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[8] A coroner's investigator is a police officer nominated by the Chief Commissioner of Police or any other person nominated by the coroner to assist the coroner with his/her investigation into a reportable death. The coroner's investigator receives directions from a coroner and carries out the role subject to those directions.

14. On 7 June 2016, Mrs Yeomans consulted Dr Petropoulos for the final time. She had a chest infection but was otherwise medically stable. Mrs Yeomans was prescribed Augmentin Duo Forte (875mg/125mg) twice per day.

15. In his statement to police, Mr Yeomans revealed that he attended the pharmacy to collect prescription medication on behalf of his wife on many occasions since 2004. On 27 June 2016, he attended the Epping Plaza Chemmart (the Chemmart) to fill the prescription for Simvastatin issued by Dr Toner in December 2015. Mr Yeomans stated that he was well aware of what the tablets and medication container looked like, and on this occasion he noticed that both looked different. Furthermore the word '*rosuvastatin*' was written on the box. Mr Yeomans stated that he raised his concerns to a Chemmart staff member who said words to the effect of '*it's alright, maybe it's a different box'*.

16. In the following weeks, Mr Yeomans said that his wife's appetite declined. Mrs Yeomans was listless and her breathing was laboured; she would no longer walk around the shops when they went out and had lost energy. On 8 July 2016, Mr Yeomans returned to the Tristar clinic and saw Dr Petropoulos on behalf of his wife; he explained that she had recovered from the previous chest infection but was not feeling well and was losing energy. As it had worked well on the previous occasion, he sought a repeat of the Augmentin Duo Forte which Dr Petropoulos issued.

17. On 25 July 2016 at approximately 2.00am, Mrs Yeomans fell in her home. Her husband contacted emergency services and she was transported to Northern Hospital by ambulance. Mr Yeomans stated that, by this point, his wife's health had declined further and she had lost strength in her muscles.

18. Haematology Physician at Northern Health Dr Leung was the Consultant in charge of Mrs Yeomans from 25 July 2016 to 31 July 2016, inclusive. Dr Leung stated that, upon Haematology admission, Mrs Yeomans medical history was known to include multiple myeloma and renal impairment, for which she was undergoing long-term immunotherapy prescribed by another Haematologist.

Further Investigation & Family Concerns

19. At my direction, DSC Marino requested further information from the proprietor of the Chemmart, Paul Burniston, who adduced a statement inclusive of the pharmacy's

dispensing records on 9 September 2016. The records showed that Ms Soha Henry approved the dispensing of rosuvastatin (40mg) for Mrs Yeomans on 27 June 2016. The Chemmart's record indicates that there were two dispensing technicians rostered, however, there is no record kept of which technician dispenses medication.

20. Mr Burniston stated that, ultimately, the pharmacist is responsible for ensuring that the medication dispensed to the patient are in accordance with the prescription, which includes conducting a final check. Additionally, he said that a pharmacist must ensure that the medication is safe and appropriate, with regard to the patient's full medical history, general health, and medication regime. Mr Burniston indicated that, prior to the Mrs Yeomans' death, rosuvastatin and simvastatin were adjacently located on the stock shelves but have subsequently been separated.

21. Ms Henry adduced a statement to the court on 20 October 2016. Upon reviewing the pharmacy records, Ms Henry agreed that she was the pharmacist who conducted a final check on the wrongfully dispensed rosuvastatin for Mrs Yeomans on 27 June 2016. Although she does not independently recollect conducting the check, Ms Henry did recollect that it was a busy day and said that the Chemmart was understaffed.

22. In a letter to the Court dated 17 March 2017, Mr Yeomans queried whether his wife may have recovered, if she had not continued to consume the rosuvastatin during the first four days of her admission to Northern Hospital.

Coroners Prevention Unit Investigation[9]

23. In light of the proximity of wrongfully dispensed rosuvastatin to Mrs Yeomans health decline and subsequent death, I requested that the Coroners Prevention Unit (CPU) review the Coronial Brief, including medical records.

Forensic Medical and Scientific Investigation

24. The CPU noted Forensic Pathologist Dr Khamis Almazrooei's comment that rhabdomyolysis can occur secondary to multiple causes, including: multiple myeloma,

[9] 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, as well as assisting in monitoring and evaluating the effectiveness of the recommendations. The CPU comprises a team with training in medicine, nursing, law, public health and the social sciences

statins (including simvastatin and rosuvastatin), renal failure and infection. The pathologist identified a broad range of conditions that made Mrs Yeomans susceptible to develop rhabdomyolysis and said that it is difficult to determine whether rosuvastatin alone caused the rhabdomyolysis in this case.

Review and Assessment of Contributing Factors

Statins

25. Statins are a class of drug used to lower serum cholesterol. They are some of the most widely prescribed drugs worldwide, with approximately 27 million people in the US taking statins in 2017.[10] They are considered both effective and generally safe.

26. The CPU informed me that clinically significant myonecrosis[11] occurs in less than 0.5 percent of patients in large clinical trials. A review of one year of records for 1014 patients taking statins in a primary care practice found that 0.9 percent of patients had CK elevations more than five times normal, and none of these appeared to be related to statin use, indicating that, most commonly, CK elevations in the presence of statins, are due to causes other than statins.

27. Furthermore, in large clinical trials, massive rhabdomyolysis with acute renal failure was not seen in patients who did not have other risk factors. Rhabdomyolysis has primarily been seen when a statin is given concurrently with other drugs.

28. The CPU reviewed the literature about the varying ability of statins to cause muscle injury, and informed me that myositis[12] primarily occurs at higher drug doses. With simvastatin, the incidence in clinical trials, was 0.02 percent at 20 mg/day, 0.07 percent at 40 mg/day, and 0.3 percent at 80 mg/day. Conversely, in a trial involving 17,802 apparently healthy adults, rates of muscle toxicity with rosuvastatin at 20 mg/day were similar to placebo. There have been reports of rhabdomyolysis with rosuvastatin, particularly in myopathy-prone patients treated with doses higher than those recommended by the FDA product labelling, and product labelling in Europe highlights this risk, particularly at the highest dose of 40 mg daily.

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[10] http://www.theaustralian.com.au/business/wall-street-journal/statins-study-warns-of-risks-for-patients-who-stop-taking-them/news-story/c2708454bc625b852ec01ba1ba446934.

[11] Muscle cell death which is defined as a serum CK elevation more than 10 times normal in association with muscle symptoms

[12] Any condition which causes inflammation of muscles.

Rosuvastatin

29. The CPU indicated that general dosing for rosuvastatin is recommended at 10 to 20 mg/day. Patients requiring less aggressive treatment or predisposed to myopathy (including patients of Asian descent) should commence at 5 mg/day.

30. In addition, the risk of myopathy/rhabdomyolysis is believed to be dose-related and is increased with concurrent use of other lipid-lowering medications, other interacting drugs, other drugs associated with myopathy (e.g., colchicine), age ≥65 years, female gender, uncontrolled hypothyroidism, and renal dysfunction.

Discussion

Summary of Contributing Factors

31. The CPU reiterated that Dr Almazrooei attributed Mrs Yeomans' death to rhabdomyolysis in a woman with multiple myeloma and renal failure. He observed that Mrs Yeomans had many risk factors which made her susceptible to develop rhabdomyolysis and commented on the difficulty of attributing the rhabdomyolysis solely to the medication. However, the CPU emphasised that the pathologist did include rosuvastatin as a contributing factor.

32. The CPU advised that, from the clinical perspective, it appears that there were many factors that contributed to both Mrs Yeomans' development of rhabdomyolysis and her subsequent deterioration. Factors which increased the likelihood of the development of rhabdomyolysis included: pre-existing renal impairment, pre-existing multiple myeloma, hypothyroidism (although controlled in this case), age and the dispensing of the incorrect statin medication at a high dose.

33. Furthermore, the CPU opined that additional factors contributing to Mrs Yeoman's decline were her age and the burden of her other illnesses, including: the development of a urinary tract infection during hospital treatment and respiratory compromise.

34. The CPU review indicated that many factors contributed to the development of rhabdomyolysis and increased Mrs Yeomans' risk of dying from this condition. The rhabdomyolysis in this case was not particularly severe and either may not have developed or would have been readily survivable in an otherwise healthy individual.

However, the CPU opined that it is likely that the statin and the dispensing error did contribute to her death, based on the clinical scenario, the proximate time of commencing the new statin to the development of rhabdomyolysis, and the likelihood of the statin causing rhabdomyolysis when taken at this dose.

Further Submissions

35. On 1 November 2017, I informed Meridian Lawyers, Ms Henry and Mr Burniston's legal representation, that I intended to include comments in the findings which may be considered adverse to their clients and gave them the opportunity to respond during a Mention Hearing or by written submissions. Meridian Lawyers elected to provide written submissions and were given the opportunity to review Mrs Yeoman's medical records contained in the Coronial Brief under the supervision of my Registrar.

36. On 19 January 2018, following subsequent correspondence, I indicated to Meridian Lawyers that I was not inclined to provide them with copies of Mrs Yeoman's medical records unless the investigation progressed to a public hearing, where the family would be informed of proceedings and of the provision of records. I also provided a summary of the extent of potential comments which may be considered adverse to their clients:

   The cause of Mrs Yeomans' death identified by the Forensic Pathologist and the review by the Coroners Prevention Unit indicate that her ingestion of rosuvastatin contributed to her death. To determine the degree of contribution would require an expert opinion from a clinical pharmacologist. However, in this case it is not necessary to establish the degree of contribution to satisfy the coronial legislation pertaining to cause of death.

37. On 6 February 2018, Meridian Lawyers provided written submissions in response to the aforementioned correspondence. On behalf of their clients, Meridian Lawyers submitted that the cause of Mrs Yeomans death was rhabdomyolysis in a woman with multiple myeloma and renal impairment and that no contributing factors could be determined.

38. Firstly, the submissions relied upon evidence that Mrs Yeomans had multiple co-morbidities and was taking various medication, including simvastatin since 2014. The submissions indicated that simvastatin was the statin most commonly linked with the breakdown of muscle. The submissions included Forensic Pathologist Dr Almazrooei's

comment that these issues made it difficult to determine whether rosuvastatin alone caused Mrs Yeomans to suffer from rhabdomyolysis.

39. Secondly, Meridian Lawyers submitted that the effect of the authorities, namely *Briginshaw v Briginshaw,*[13] was that I should not make adverse findings against, or comments about, individuals unless the evidence provides a comfortable level of satisfaction that they caused or contributed to death. In determining what a 'comfortable level of satisfaction' means, they provided that, in considering the weight of the evidence, I should bear in mind:

    (a) The nature of the consequence of the facts to be proved;

    (b) The seriousness of an allegation made;

    (c) The inherent unlikelihood of occurrence alleged;

    (d) The gravity of the consequences from an adverse finding; and

    (e) If an allegation involves conduct of a criminal nature, weight must be given to the presumption of innocence, and the Court should not be satisfied by inexact proofs, infinite testimony or indirect inferences

COMMENTS

Pursuant to section 67(3) of the **Coroners Act 2008**, I make the following comments connected with the death:

1. The jurisdiction of the Coroners Court of Victoria is inquisitorial.[14] The Act provides for a system whereby reportable deaths are independently investigated to ascertain, if possible, the identity of the deceased person, the cause of death and the circumstances in which death occurred.[15]

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[13] *Briginshaw v Briginshaw* (1938) 60 CLR 336.

[14] Section 89(4) *Coroners Act 2008.*

[15] See Preamble and s 67, *Coroners Act 2008.*

2. It is not the role of the coroner to lay or apportion blame, but to establish the facts.[16] It is not the coroner's role to determine criminal or civil liability arising from the death under investigation, or to determine disciplinary matters.

3. The expression '*cause of death*' refers to the medical cause of death, incorporating where possible, the mode or mechanism of death.

4. For coronial purposes, the circumstances in which death occurred refers to the context or background and surrounding circumstances of the death. Rather than being a consideration of all circumstances which might form part of a narrative culminating in the death, it is confined to those circumstances which are sufficiently proximate to be considered relevant to the death.

5. The broader purpose of coronial investigations is to contribute to a reduction in the number of preventable deaths, both through the observations made in the investigation findings and by the making of recommendations by coroners. This is generally referred to as the '*prevention*' role.

6. Coroners are also empowered:

   a. to report to the Attorney-General on a death;

   b. to comment on any matter connected with the death they have investigated, including matters of public health or safety and the administration of justice; and

   c. to make recommendations to any Minister or public statutory authority on any matter connected with the death, including public health or safety or the administration of justice. These powers are the vehicles by which the prevention role may be advanced.

7. All coronial findings must be made based on proof of relevant facts on the balance of probabilities. In determining these matters, I am guided by the principles enunciated in *Briginshaw* v *Briginshaw*. As submitted by Meridian Lawyers on behalf of their clients Ms Henry and Mr Burniston, the effect of this and similar authorities is that coroners should not make adverse findings against, or comments about, individuals unless the

[16] *Keown v Khan* (1999) 1 VR 69.

evidence provides a comfortable level of satisfaction that they caused or contributed to the death.

8. In conducting this investigation, I have made a thorough forensic examination of the evidence including reading and considering the witness statements, medical records and other documents in the Coronial Brief.

9. By way of their legal representation, Ms Henry and Mr Burniston have submitted that, owing to those principles outlined in *Briginshaw v Briginshaw*, it is not open to me to find that the ingestion of rosuvastatin contributed to Mrs Yeomans death. They also submitted that I must pay particular heed to the nature of such an allegation, the consequences of the allegation, and that, where there is a criminal element, the presumption of innocence must be considered.

10. Of note, Ms Henry conceded that her signature on the pharmacy records indicate that she was the dispensing pharmacist and that she conducted the final check upon the wrongfully distributed rosuvastatin. Although there is no suggestion that the wrongful dispensing is of a criminal nature, Ms Henry's concession is an exact proof of the incident.

11. In addition, Forensic Pathologist Dr Almazrooei opinion when considered in conjunction with the review by CPU, indicates that Mrs Yeomans ingestion of rosuvastatin contributed to her death. Mrs Yeomans did, however, suffer from a number of comorbidities, including: pre-existing renal impairment, pre-existing multiple myeloma, and controlled hypothyroidism. Mrs Yeoman's age and the development of a respiratory compromise and a urinary tract infection which developed during hospital treatment, also likely played a role and contributed to her death. The CPU noted that Mrs Yeomans may have survived the development of rhabdomyolysis had she been younger and healthier.

12. To determine the degree of contribution of Mrs Yeoman's ingestion of the wrong statin at a high dose would require an expert opinion from a clinical pharmacologist. In this case it is not necessary to establish the degree of contribution to satisfy the coronial legislation pertaining to cause of death.

13. In acknowledging their own dispensing error, the Epping Plaza Chemmart has taken steps to avoid repeating it, and have separated the storage of rosuvastatin and simvastatin. The instigation of this preventative measure, however, does not address the situation where a customer queries the correctness of dispensed medication, as Mr Yeomans did.

RECOMMENDATIONS

Pursuant to section 72(2) of the **Coroners Act 2008**, I make the following recommendations:

1. In the interests of contributing to a reduction of preventable deaths, **I recommend** that the Epping Plaza Chemmart institute a policy whereby, when issues that concern dispensed medication are raised by a customer, the concern is referred to the pharmacist for review.

2. **I further recommend** that the National Council of the Pharmacy Guild of Australia review the circumstances of Mrs Yeoman's death, for the purposes of education, awareness and the creation of robust dispensing policies and guidelines.

FINDINGS

The investigation has identified that, on 27 June 2016, Pharmacist Soha Henry of Epping Plaza Chemmart wrongfully dispensed rosuvastatin for Mrs Yeomans instead of the prescribed simvastatin. The final check was conducted in error by the dispensing pharmacist and a further error by an unknown staff member, who reassured Mr Yeomans that the medication was accurately dispensed, meant that Mrs Yeomans received rosuvastatin incorrectly.

I find clear and cogent evidence that Margaret Anne Yeomans was dispensed the wrong medication by the Pharmacist, Soha Henry, of Epping Chemmart Pharmacy.

I accept and adopt the cause of death as identified by Dr Almazrooei, and **I find** that Margaret Ann Yeomans, a woman with multiple myeloma and renal impairment, died from rhabdomyolysis.

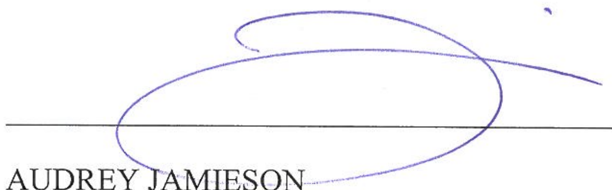
I further find that there is clear and cogent evidence that the commencement of ingestion of the incorrect statin at a high dose occurred proximate to Margaret Ann Yeomans' rapid decline in health and subsequent death, and was a contributing factor to her death.

AND I find that the death of Margaret Ann Yeomans was also contributed to by: her age, the presence of pre-existing renal impairment and pre-existing multiple myeloma, controlled hypothyroidism, respiratory compromise and the development of a urinary tract infection in hospital.

Pursuant to sections 72(5) and 73(1) of the *Coroners Act 2008* (Vic), I direct that the Findings be published on the internet.

I direct that a copy of this finding be provided to the following:
Peter Yeomans
Meridian Lawyers on behalf of Soha Henry & Paul Burniston
Jackie Petrov, Legal Coordinator Northern Health
National Council of the Pharmacy Guild of Australia
Australian Health Practitioner Regulation Agency

Signature:



AUDREY JAMIESON
CORONER
Date: **19 February 2018**