IN THE CORONERS COURT
OF VICTORIA
AT MELBOURNE

COR 2017 003664

FINDING INTO DEATH WITHOUT INQUEST

Form 38 Rule 63(2)

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

Findings of:	AUDREY JAMIESON, Coroner
Deceased:	SM
Date of birth:	6 November 1925
Date of death:	27 July 2017
Cause of death:	1(a) Complications of cerebrovascular and ischaemic heart disease in a man post anaphylactic reaction to diltiazem
Place of death:	Monash Health, Dandenong Hospital, 135 David Street, Dandenong, Victoria, 3175

INTRODUCTION

1. On 27 July 2017, SM was 91 years of age when he died at Dandenong Hospital. At the time of his death, he was a resident of Bupa Aged Care Berwick ("Bupa Berwick") in Narre Warren North, an aged care facility operated by Bupa Aged Care Australia Pty Ltd ("Bupa Aged Care"). He first entered aged care in October 2013 when his family observed signs of dementia.

2. Mr SM is survived by his three children, A B and C, and his grandchildren. His medical history included dementia, anxiety, chronic obstructive airway disease, gastro-oesophageal reflux disease, heart disease, chronic lung disease, hypertension, atrial fibrillation, congestive cardiac failure and hyperlipidaemia. He was prescribed a number of medications in relation to his medical conditions. He was known to be allergic to diltiazem[1] and cephalexin[2] (Keflex[3]).

3. Mr SM's care was managed by an in-house general practitioner (**GP**) Dr Deep Joseph and geriatrician Dr Ah Choy Chan. Dr Chan was also a consultant geriatrician at Monash Health[4] and provided consultative medical services to residents in aged care facilities, including Bupa Berwick.

THE CORONIAL INVESTIGATION

4. Mr SM'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 or violent or result from accident or injury.

5. 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.

---

[1] Diltiazem is used to treat high blood pressure and control angina (chest pain). Diltiazem is in a class of medications called calcium-channel blockers. It works by relaxing the blood vessels, so the heart does not have to pump as hard. It also increases the supply of blood and oxygen to the heart.

[2] Cephalexin is used to treat certain infections caused by bacteria such as pneumonia and other respiratory tract infections and infections of the bone, skin, ears, genital, and urinary tract. Cephalexin is in a class of medications called cephalosporin antibiotics. It works by killing bacteria.

[3] Keflex is one of cephalexin's trade names.

[4] Dr Chan commenced attending Mr SM following a referral by Dr Joseph in April 2017.

6. 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.

Conduct of my investigation

7. Mr [redacted] son, [redacted], first raised concerns in relation to the medical care and treatment that his father received from Bupa Berwick and Dandenong Hospital in two respective emails to the Court on 1 August 2017 and 26 September 2017. Specific concerns were raised about the overall oversight by the healthcare professionals that provided Mr [redacted] care and treatment at Bupa Berwick.

8. Having regard to the circumstances of Mr [redacted] death and the concerns that [redacted] raised, I requested the Coroner's Prevention Unit[5] (**CPU**) to assist me with my investigation in reviewing the prescription, dispensing and administration of diltiazem.

9. The primary focus of the coronial investigation into Mr [redacted] death was the circumstances in which he died, specifically the factors that led to oversight of his allergy to diltiazem and the events that ultimately led to administration of diltiazem.

Sources of evidence

10. Statements were obtained from Louise Willett, general manager of Bupa Berwick, James McConville, Partner of GM Pharmacy, Katie Cooley, National Aged and Community Care Manager of MPS, Drs Chan and Joseph.

11. An internal investigation was also commenced by Bupa Aged Care's Clinical Safety and Assurance Team, which later generated a Root Cause Analysis (**RCA**) report. All statements, including the RCA report by Bupa Aged Care formed part of the Coronial Brief.

12. This finding draws on the totality of the coronial investigation into the death of [redacted] 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.

[5] 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.

BACKGROUND

13. The available evidence indicates that Bupa Aged Care engaged MPS Hold Co. Pty Ltd ("**MPS**"), a third-party medication packaging company, to provide Bupa Berwick with medication packaging services and a local pharmacy, Gunn and McConville Pharmacy ("GM Pharmacy") to provide pharmaceutical services.

14. GM Pharmacy was responsible for managing patients' medication charting, ordering, dispensing and delivery of medications to Bupa Berwick. In doing so, GM Pharmacy uses its in-house software, Fred and MPS' software, HealthStream.

15. HealthStream was an MPS-written proprietary software that facilitated medication packaging and dispatching between GM Pharmacy and MPS. Although MPS creates and hosts HealthStream, the data in HealthStream was majorly entered and managed by GM Pharmacy and Bupa Berwick.

16. The process of inputting a resident's data into HealthStream and generating information on a patient's medications operated as follows[6]:

    i) When creating a resident's medication profile, Bupa Berwick staff fill out a Resident Admission Form (**RAF**) including information such as the resident's personal details and known allergies.

    ii) The RAF was then sent to GM Pharmacy, who uses it to create a medication profile on HealthStream. After that, MPS would provide physical and electronic copies of the resident admission documents to Bupa Berwick.

    iii) Two principal documents which were known as the MPS Summary Sheet ("summary sheet") and Universal Signing Sheet ("signing sheet"), were available to Bupa Berwick to facilitate medication management of the residents by means of a paper-based system. Pharmacists at GM Pharmacy were responsible for generating the summary and signing sheets and regularly enclosing them with the delivery of medication so that the sheets can be placed in the resident's room for accurate administration.

    iv) The treating physicians also used the summary sheet to make handwritten changes in the event of a change of mediation (such as changing, adding, or ceasing a medication for a resident). When a medication is added, it can be handwritten onto the remaining

[6] CB, Final Submissions by MPS, dated 1 May 2019.

columns of the list of medication in the medication summary sheet. If the medications were to be ceased, the physician would cross out the medication and make note indicating the medication is ceased.

v) The updated summary sheet is then faxed to the GM Pharmacy for entry into HealthStream.

MATTERS IN RELATION TO WHICH A FINDING MUST, IF POSSIBLE, BE MADE

Circumstances in which the death occurred

Documentation of Mr SM's allergies

17. The available evidence indicates that Mr SM's allergy was known and well recorded in his Bupa Berwick's admission database, care plans, resident register, pharmacy referral forms, summary and signing sheets. There were also numerous references to his allergy by means of patient stickers within the progress notes, assessment, and referral forms.

18. Mr SM's summary and signing sheets, each contained a defined patient details box that records his allergy. Keflex and diltiazem were indicated in red in the *"Drug Allergies"* row to alert the reader of his allergies.

The prescribing

19. On 12 July 2017, Dr Chan attended Bupa Berwick and reviewed Mr SM. On examination, Mr SM reported *"some cough"* but did not mention experiencing any cardiac symptoms.

20. Dr Chan noted signs of bronchospasm with generalised wheeze in both Mr SM's' lungs and found him *"not tolerating well"* with metoprolol[7]. Dr Chan then ceased metoprolol[8] and prescribed Mr SM diltiazem[9] and hydrochlorothiazide[10] as alternatives to manage his hypertension.

[7] Metoprolol is used alone or in combination with other medications to treat high blood pressure. It is also used to prevent angina (chest pain) and improve survival after a heart attack. Metoprolol also is used in combination with other medications to treat heart failure. Metoprolol is in a class of medications called beta-blockers. It works by relaxing blood vessels and slowing heart rate to improve blood flow and decrease blood pressure.

[8] As a beta-blocker commonly can exacerbate or lead to continuous coughing and wheezing in patients with underlying chronic obstructive airway disease (COAD).

[9] 180mg, slow-release and to be taken daily.

[10] Hydrochlorothiazide is used alone or in combination with other medications to treat high blood pressure.

21. During the review, Dr Chan asked Mr SM if he was allergic to diltiazem and hydrochlorothiazide, which he planned to commence him on. Mr SM replied he had no allergies to those medications.

22. Dr Chan stated that *"as [he] was writing his notes and making the changes to his [Mr SM] drug charts at the nursing station"*, he was "interrupted" by Mr SM .[11] Dr Chan recalled Mr SM went to the nursing station in "an anxious state" to ask him to ring his sons to take him home. Dr Chan stated he had to calm Mr SM down and then walked him back to his room.

23. Dr Chan proceeded to make an entry of events of the review in the progression note. He noted *"diltiazem and hydrochlorothiazide, to be commenced on 12 July 2017"* on the medication charts on the summary sheet. He then signed off a prescription sheet for diltiazem[12] and hydrochlorothiazide.

24. Mr SM's summary, signing and prescription sheets were later faxed to GM Pharmacy for dispensing.

<u>The dispensing</u>

25. At 2.27pm, the summary sheet which contained diltiazem and hydrochlorothiazide was entered by a dispensing pharmacist[13], Joanne Yeoh, into the HealthStream system and then the Fred system.

26. Ms Yeoh dispensed the medications, followed by a second pharmacist signing off the medications and ordered them for dispatch. There was no conversation between Ms Yeoh and Dr Chan concerning diltiazem being a contraindicated medication prior to these events.

27. On 18 July 2017, in the summary sheet, Dr Joseph signed on the two medication charts for diltiazem and hydrochlorothiazide and noted "reviewed". He signed off the summary sheet and dated it 21 July 2017.

[11] CB, Statement of Dr Ah Choy Chan dated 16 February 2018.
[12] Diltiazem was listed using a brand name and generic name, *"Vascardol CD – CAP/180mg [Diltiazem]"* on the medication chart in the MPS summary sheet.
[13] CB, Bupa Root Cause Analysis Investigation Report.

Events proximate to death

28. On the two consecutive mornings of 20 and 21 July 2017, diltiazem was administered to SM by two different Enrolled Nurses (**EN**).[14] The ENs did not check further his allergies before administering him diltiazem.

29. No immediate adverse effects to the medication were noted by nursing staff on the first day of administration on 20 July 2017.

30. On 21 July 2017 at 11.37am, Dr Joseph attended Mr SM. Dr Joseph noted a generalised itchy red rash but did not observe any swelling in Mr SM's tongue.[15] Although Mr SM did not mention any shortness of breath, he complained that his lips felt "different". At that time, Dr Joseph suspected it was either angioedema or anaphylaxis. Dr Joseph considered the cause was due to food-related allergies or possibly a bee sting[16] and then treated Mr SM with adrenaline and Phenergan.

31. At 2.40pm, Dr Joseph observed the rash was still persistent and became blistered. He repeated the same treatment with adrenaline and Phenergan. Dr Joseph did not immediately escalate his observations to Dr Chan as the rash gradually faded.

32. Overnight and into the early hours of 22 July 2017, Mr SM became "unsteady". His rash returned and became more pronounced. At 1.10am, a locum GP attended Mr SM and diagnosed him with measles.[17] The locum GP ordered a measles, mumps and rubella (**MMR**) serology testing.[18]

33. At 9.50am, Dr Joseph attended Mr SM and noted he was again showing a generalised red rash. The rash became more pronounced in the groin and armpit areas, and his lips became mildly swollen. His speech was not legible. Dr Joseph repeated a treatment with adrenaline and Phenergan and noticed Mr SM's rash had *"faded a little"* afterwards.

34. At that time, Dr Joseph instructed nursing staff to escalate Mr SM's care to a hospital if he did not show signs of improvement.

[14] CB, Bupa Root Cause Analysis Investigation Report.
[15] CB, Statement of Dr Deep Joseph.
[16] Ibid.
[17] CB, Bupa Aged Care RCA Report.
[18] Ibid.

35. At 12.10pm, an attending nurse assessed Mr SM and noted he had difficulty swallowing. It was determined that he ought to be transferred to hospital for further observation and management.

36. At approximately 2.00pm, an ambulance arrived and transferred Mr SM to Dandenong Hospital. He was first admitted to the Emergency Department (**ED**) for treatment of angioedema and anaphylaxis.

37. At approximately 5.40pm, a single dose of ceftriaxone was administered intravenously.

38. At approximately 9.00pm, Mr SM was transferred to the general ward for subsequent investigations. A biopsy of his rash was assessed by specialist dermatologists and they diagnosed his rash as Drug Reaction Eosinophilia and Systemic Symptoms (**DRESS**), a severe drug reaction that was determined to be associated with diltiazem.

39. Subsequently, hospital staff identified evidence of acute kidney injury, liver dysfunction and muscle injury. Further blood tests revealed inflammatory markers in the blood were significantly elevated. Mr SM's blood clotting time was also noted to be increasingly prolonged, despite that his warfarin was withheld since his admission to the hospital.

40. Throughout 23 and 24 July 2017, Mr SM's response to resuscitative measures was poor. His clinical course was characterised by significant delirium, ongoing features of DRESS, fever and some features indicating chest and urine infections.

41. On the evening of 26 July 2017, Mr SM suddenly deteriorated, and his Glasgow Coma Scale (**GCS**) reading was determined to be GCS 3[19]. His treating physicians suspected a brain haemorrhage but considered him too unstable to undergo a CT brain scan to ascertain a cause for further treatment.

42. In light of Mr SM's poor prognosis, his family decided to palliate him. All active treatments were redirected to comfort care.

43. Mr SM passed away at 7.50pm on 27 July 2017.

[19] The Glasgow Coma Scale (**GCS**) is used to objectively describe the extent of impaired consciousness in all types of acute medical and trauma patients. The scale assesses patients according to three aspects of responsiveness: eye-opening, motor, and verbal responses. The GCS values between 1 and 8 denote a severe brain injury.

Identity of the deceased

44. On 27 July 2017, SM, born 6 November 1925, was visually identified by his son, B.

45. Identity is not in dispute and requires no further investigation.

Medical cause of death

46. Senior Forensic Pathologist Dr Michael Burke from the Victorian Institute of Forensic Medicine (**VIFM**), conducted an autopsy on 1 August 2017, reviewed a post-mortem computed tomography (**CT**) scan and referred to the Victoria Police Report of Death (Form 83), E-Medical Disposition Form, medical records from Monash Health and Bupa Aged Care. Dr Burke provided a written report ("the Medical Examiner's Report, MER") of his findings dated 21 September 2017 and subsequently an amended report dated 14 February 2019.

47. The autopsy revealed a clot within the right middle cerebral artery. There was no asymmetric swelling noted to the brain.

48. The microscopic examination of the brain sections showed thrombus without evidence of vasculitis and eosinophils.

49. There was evidence of acute and chronic asthma changes within the lungs and bronchopneumonia. There was also significant heart disease with myocardial fibrosis associated with coronary artery atherosclerosis.

50. The post-mortem CT scan did not reveal an intracranial haemorrhage.

51. Dr Burke noted there was no evidence of any injury which would have contributed to or led to death.

52. Toxicological analysis of ante-mortem samples identified the presence of diltiazem, oxycodone, duloxetine, risperidone, and promethazine.

53. The toxicology analysis also identified tryptase and immunoglobulin (IgE) within normal levels.

54. Dr Burke ascribed the medical cause of death to *"internal carotid thrombus in a man with ischaemic heart disease"*.

Further review of the cause of death[20]

55. Considering the allergic response to the administration of diltiazem was sufficiently proximate to Mr SM's death and having perused the CPU's advice as to his cause of death, I consulted with Dr Burke and asked him to review the medical cause of death as ascribed in his first MER. I asked Dr Burke to consider whether Mr SM's anaphylactic reaction to diltiazem has a position within the cause of death.

56. Given the evidence of 80% of stenosis in the vertebrobasilar arterial system of the brain and the GCS of 3, Dr Burke commented that it was likely Mr SM had a combined insult to both his vascular system and that was probably caused by an episode of hypotension.[21]

57. Having considered my postulation and the initial medical cause of death Dr Burke amended the medical cause of death to 1 (a) complications of cerebrovascular and ischaemic heart disease in a man post anaphylactic reaction to diltiazem.

CPU REVIEW[22]

58. As part of its review, the CPU reviewed the statements from Bupa Berwick, GM Pharmacy and MPS to identify the oversight surrounding the administration of diltiazem Mr SM

Prescribing by Dr Chan

59. The CPU identified many instances in which Dr Chan failed to notice Mr SM's allergy, most notably, from the patient sticker on the progress notes and the medication summary sheet and relied entirely on Mr SM's accounts and recollection of his medical condition.

60. Dr Chan acknowledged that Mr SM had significant dementia that might compromise his ability to provide accurate accounts of his drug allergies.[23] As opposed to his usual practices when prescribing a new medication to his patient, Dr Chan admitted that he did not seek further clarification from Dr Joseph or Mr SM's family about Mr SM's allergies.

[20] As discussed below, I initiated a further review of Mr SM's cause of death after the CPU review. This section precedes my discussion of the CPU review for the purposes of readability and completeness.
[21] CF, Dr Burke's email dated 14 August 2018.
[22] Any review undertaken by the CPU on behalf of the Coroner is intended to provide clarity to matters that are in dispute and assist the Coroner in determining whether further investigation is warranted, including by way of an expert report, or whether there is sufficient material on which to finalise the investigation.
[23] CB, Statement of Dr Ah Choy Chan dated 16 February 2018.

Signing off by Dr Joseph

61. Dr Joseph indicated that he was unaware Dr Chan had changed Mr SM's medications.[24] He did not receive any communication from staff at Bupa Berwick until 24 July 2017. Dr Joseph assumed the two medications that Dr Chan added to the medication charts of the summary sheet were Mr SM's *"usual medications"*.

Review and entry by the dispensing pharmacist

62. The CPU noted the Fred system had a "pop-up" feature that alerts the dispensing pharmacist when a contraindicated medication is entered into the system. Suppose a contraindicated medication cannot be identified from the list of medications in the system, in that case, the dispensing pharmacist was required to categorise the contraindicated medication into a group of medications. The dispensing pharmacist can dismiss the pop-up if it was deemed not to be "relevant".

63. Mr McConville considered that the pop-ups became "unnecessary" in Mr SM's situation as he previously had a prescription of a calcium channel blocker, Lercanidipine[25], which the Fred system identified as contraindicated.[26] The pop-ups triggered by subsequent contraindicated medications entered into the system became "not relevant".

64. Mr McConville explained that another way to identify contraindicated medication in the Fred system was through the patient notes section. The patient notes record the medications to which a patient is allergic and will show up during the entry of new medications.

65. Furthermore, when the dispensing pharmacist identified a contraindicated medication that was prescribed to a Bupa Berwick resident, the usual practice of GM Pharmacy was that the dispensing pharmacist would contact and clarify with the supervising nurse of the resident.

66. The dispensing pharmacist would consult about the prescribing and determine whether the medication had been prescribed with the knowledge of an allergy. Subsequently, if the dispensing pharmacist is not satisfied with the "background check", the dispensing pharmacist would consult the prescriber directly.

[24] CB, statement of Dr Deep Joseph.
[25] Which Mr SM was not allergic to.
[26] This is because Lercanidipine belongs to the calcium channel blocker group of medications.

67. Mr McConville emphasised that *"the dispensing pharmacist will be guided by the prescriber in [the] circumstances"*. If the dispensing pharmacist had notified the contraindicated medication to the prescriber, he or she is then to decide whether the prescription should be dispensed or altered and regardless of the decision made by the prescriber. The "checking" process would be documented in the patient history section in Fred for future reference.

68. In Mr SM's situation, no notifications were made to the supervising nurse at Bupa Berwick or Dr Chan. Mr McConville stated that Ms Yeoh had *"no acknowledgement"* of Mr SM's allergy to diltiazem and therefore *"the issues was not identified by her at the time"* of dispensing.

Supplying by MPS

69. MPS commenced packaging medications into an individual "packette" after medications were dispensed and the orders of medications were confirmed.[27] Each packette was labelled with a unique identifier, the resident's name, ward code, dispensing date and time, name of each medication and relevant dose contained in the packette.

70. Ms Cooley stated that MPS play no part in reviewing the patient's medication profile or medication orders during the packaging process. There was no automated alert function within HealthStream to call attention to any contraindicated medications being packaged into a specific packette.

71. The CPU noted that the names printed on the packette typically represent the brand name of the medicines, but not the generic or pharmaceutical name[28]. According to MPS, pharmaceutical names were printed on the last dose on the label of the packettes.[29]

72. The CPU found that in Mr SM's circumstances, diltiazem would only appear at the end of the label with the brand name "Cardizem" instead of the generic name diltiazem.

Signing off by pharmacists

73. Mr McConville stated as part of GM Pharmacy's policy, a "buddy check" system was in place for two pharmacists to sign off on any new order of medications before dispatch to their clients.

[27] CB, statement of Katie Cooley
[28] Which contains the active ingredient(s) of a medicine.
[29] CB, Statement of Katie Cooley

74. Despite having such a system in place, the CPU found that the second pharmacist still failed to recognise Mr SM's allergies on the summary sheet during signing off on 19 July 2017.

Administration of diltiazem by nursing staff

75. The RCA report identified that one of the secondary causes that led to the administration of diltiazem was that the RNs did not check for Mr SM's allergies before administration.

76. The CPU considered the factors that likely contributed to an oversight by nursing staff were the absence of pharmaceutical or generic name of diltiazem on Mr SM's packette label and the signing sheet.

Conclusion

77. In conclusion, the CPU considered that the circumstances surrounding Mr SM's death highlighted many areas of oversight, including the prescriber's flawed assessment of a patient medical history, failure, and oversight at many points of check and lack of consistent use of brand names without the generic names.

78. The CPU also indicated to me there remained outstanding issues and then proposed the following recommended actions in addressing them:

    i) that GM Pharmacy's Fred system is to include acknowledgement and sign-off alerts;
    ii) that MPS is to alter its process in preventing packaging of a medication when its system indicates a contraindication;
    iii) that all medications chart labels should indicate the generic names when brand names are displayed; and
    iv) every packette is to be labelled with the generic name.

SUBSEQUENT ACTIONS AND RESPONSES

Bupa Aged Care

79. As mentioned, Bupa Aged Care's Clinical Safety and Assurance Team undertook an internal investigation that later generated an RCA report.

80. Ms Willett provided a statement on behalf of Bupa Aged Care dated 9 March 2018. Ms Willett advised me that Bupa Aged Care subsequently completed the following (primary) recommended actions as identified in their RCA Action Plan:

    - Complete 100% audit of all resident's medication charts and their allergies;

- Educate all registered staff on their roles, responsibilities and delegation; medication incident management; medication administration; medication records; health professional services and resident discharge home or transfer;
- Create a case study based upon the RCA[30], which was to be put forward for review at the Bupa Aged Care Australia's Clinical Leaders Forum[31]; and
- Undertake a formal human resources process for Bupa Aged Care's staff[32].

GM Pharmacy

81. Mr McConville provided a statement on behalf of GM Pharmacy dated 2 March 2018. Mr McConville conceded that GM Pharmacy *"has made an error"* for not picking up the contraindicated medications, and there were shortcomings in their in-house software, the Fred system.

82. Mr McConville advised that a meeting was held on 27 July 2017 with all staff to alert them to Mr SM's incident and to reinforce the importance of identifying contraindicated medication and the potential consequences.

83. Consequently, GM Pharmacy has instituted the following changes:
    - The second pharmacist who signed off on the changes of medications made under HealthStream is now required to check for contraindicated medications before signing[33];
    - Any discrepancies concerning a suspected allergy or contraindication noted at the dispensing or packaging stage are to be immediately communicated to the prescriber; and
    - The pharmacy is to directly request specific information from their clients, such as the severity of allergies or sensitivities.

Dr Chan

84. Dr Chan highlighted in his statement that he had since taken various steps within his clinical practice to prevent similar incidents.

[30] Focusing on individual steps where human errors or systemic issues arose and what actions should have occurred at each stage.
[31] In September 2019.
[32] Including the Care Manager, Clinical Manager, Registered Nurse, Enrolled Nurse and in-house GP.
[33] Mr McConville explained that this was previously an inferred expectation. As opposed to previous practice where staff were able to choose the sequence of entering, any changes to a client's medications are first entered into Fred before HealthStream.

85. Dr Chan advised that since Mr SM's death, he now:

- Maintains the highest levels of vigilance and thoroughness when checking patients' medical history. His current assessment approach involves checking and confirming allergy history with the patients themselves, their medical records, drug charts, GP(s) and family;
- Avoids all interruptions when he writes new medications or makes changes to medications on drug charts;
- Commits to better manage surrounding distractions and interruptions; and
- Aims to communicate and explain any significant changes in medications to patients' family; and
- Requires his patient's supervising nurse and GP(s) or hospitals to communicate with him as soon as possible when there are concerns regarding patient's health management plan, medication changes or changes in patients' clinical conditions after his review.

PRE-MENTION HEARING

86. Following the CPU's review, a CPU review report was disseminated to all parties for a response. All parties addressed some factual discrepancies by providing further information to clarify their evidence in relation to the circumstances of prescribing, dispensing and administration of diltiazem and the treatment provided Mr SM thereafter, except for Dr Chan.

Bupa Aged Care

87. On 22 March 2019, the Court received a letter from Head of Operations, David Webb, on behalf of Bupa Aged Care. Mr Webb, in substance, conceded the issues of human error and system failures as identified by the CPU in its review report and by Bupa Aged Care's RCA Report.

88. Mr Webb confirmed that Bupa Aged Care had completed recommended actions identified in the RCA Action Plan.

GM Pharmacy

89. On 25 March 2019, the Court received a second statement from Mr McConville on behalf of GM Pharmacy. Mr McConville, in substance, conceded the issues of human error and system failures as noted in his first statement.

MPS

90. On 29 March 2019, MPS filed a written submission through its lawyers from Ben and Patrick Associates to the Court.

91. In terms of the issue of data entry by GM Pharmacy, MPS explained that its accreditation process[34] mandates that GM Pharmacy must first enter a prescription or change of medication in Fred first before HealthStream. MPS noted that GM Pharmacy had been operating incorrectly by entering Mr SM's medications firstly into HealthStream before Fred.

92. In terms of the issue of brand and generic names on their packettes, MPS indicated that it *"only includes the brand names on the packettes, as permitted by Clause 1.2 [Labelling of DAAs]"* of the *Guidelines on Dose Administration Aids*[35] *and Stage Supply of Dispensed Medicines* ("the DAA guidelines").

93. Clause 1.2 of the DAA guidelines stipulates that overall:

> *The label on the DAA should maximise adherence, promote usability and minimise error associated with administration of the patient's medicines. It should also support the patient or carer's understanding of the dosing regimen and include suitable information to minimise adverse effects.*

94. Furthermore, Clause 1.2 also stipulates that:

> *In the case where only one name is included on the label, additional information should be provided to the patient and/or their carer(s) to ensure access to the active ingredient and brand name of all medicines packed into the DAA, for example through provision of a current medication list at every change of medication or brand of medication.*

[34] See paragraphs 127 and 128.
[35] Dose Administration Aids (DAA) is defined as a device or packaging system for organising doses of medicines according to the time of administration, which assists in medication management for a patient.

95. MPS explained that *"if both the brand and generic names were [to be] included on the label of a packette, the maximum number of medicines in each packette would have, so increasing the number of packette for a single dose event"*, risking some medicines being missed out from the label.

96. I accept this practice to be reasonable and note from MPS' submissions that Mr SM's summary sheet contained the generic name, diltiazem.

97. In terms of the issue of HealthStream lacking an alert function, MPS advised that it was working further to improve the allergen functionality by changing the signing sheet to include both generic and brand names; and adding an alert to the charts on the signing sheet if an allergen is prescribed.

98. Furthermore, MPS advised that incorporating an automatic refusal alert within HealthStream during packaging is not feasible for a third-party packaging company.

99. I accept this consideration to be reasonable and note from Clause 1.7 *Packaging by a third-party*, of the DAA guidelines that the supplying pharmacist (GM Pharmacy) *"is responsible for ensuring the packing pharmacist* (in this instance MPS) *has accurate details of the medicines to be packed"*.

100. Furthermore, Clause 1.7 stipulates that the supplying pharmacist "*must make an assessment of the measures, techniques and technology used by the packing pharmacist at the third-party packing facility to check packed DAAs for accuracy, to determine whether additional checking of a DAA is required prior to its supply to a patient or their agent*".

Dr Joseph

101. On 1 April 2019, the Court received a letter from Dr Joseph's lawyer Ms Ingrid Nunnik. The letter, in substance, clarified the factual discrepancies between Dr Joseph's observations of Mr SM following the administration of diltiazem, and the treatment that he provided to treat Mr SM's undetermined allergic reactions at the time.

MENTION HEARING

102. On 19 April 2019, I held a Mention Hearing with the aim of hearing from the parties about their respective views on whether my investigation would benefit from the holding of an Inquest, or, alternatively, an in-chambers Finding.

103. At the Mention Hearing, I indicated to all parties my preference of finalising the investigation into Mr SM's death "on the papers" by way of this Finding, given the sufficiency and adequacy of their responses. With the exception of Monash Health, I indicated further that the focus of my investigation was on the administration of diltiazem and thus far, have identified systemic issues, oversight of a number of individuals and entities involved in Mr SM's care and treatment, and led to significantly compromising him which ultimately led to his death.

104. All legal Counsels provided on behalf of their respective clients' concession and apologies for their oversight during their involvement of Mr SM's care and treatment.[36]

105. Since none of the parties sought an Inquest, I determined to finalise my investigation of Mr SM's death "in-chambers".

POST MENTION HEARING

Response by GM Pharmacy

106. By email dated 30 April 2019, the Court received a final statement from Mr McConville on behalf of GM Pharmacy.

107. Mr McConville advised that GM Pharmacy had been working with the respective software facilities for Fred and HealthStream to identify areas of improvement, particularly, on the systems' ability to override allergy alerts such that the alerts of potentially fatal allergies are not ignored.[37]

108. Mr McConville also advised that GM Pharmacy was in the process of establishing its packaging system with the "Best Dose" feature to highlight allergies when contraindicated medications are entered into its record system.

Response by Dr Joseph

109. By email dated 29 April 2019, the Court received a letter from Ms Nunnink on behalf of Dr Joseph.

[36] Mr Dawson and Mr Ryan did not make further submissions for their respective clients throughout the Mention Hearing.
[37] In response to CPU's the unresolved contributing factor concerning the Fred system as discussed in paragraph 84.

110. In her letter, Ms Nunnink noted that Mr SM was administered an intravenous antibiotic, ceftriaxone during his admission on 22 July 2018, at 5:40pm, which was contraindicated given his allergy to Keflex. She stated that Dr Joseph did not intend to raise the administration ceftriaxone as a causative basis but sought to clarify Mr SM's medical treatment during his hospital admission.

111. Accordingly, I requested the CPU to review whether they were any issues pertaining to the administration of ceftriaxone.

Was ceftriaxone administered to Mr SM contraindicated due to his allergy to Keflex?

112. The CPU advised that both Keflex and ceftriaxone belong to the broad class of antibiotics known as cephalosporins[38]. Keflex is a first-generation cephalosporin, whereas ceftriaxone is a third-generation cephalosporin.

113. The CPU explained that having an allergy to Keflex does not imply an allergy to ceftriaxone, as the chemical structures are substantially different molecules whose structure differences may mean that allergy to one does not necessarily confer allergy to another with a different structure.

Did ceftriaxone further contribute to Mr SM's deterioration?

114. The CPU informed me that there was no evidence of any adverse events recorded concerning the administration of ceftriaxone. The CPU opined that it was unlikely ceftriaxone had contributed further to Mr SM's deterioration, given that his allergic reaction to diltiazem was already severe.

Response by MPS

115. On 1 May 2019, MPS filed a written submission through its lawyers. In its submission, MPS further outlined its roles and responsibilities in providing packaging services for aged care facilities and its in-house management software for contractor pharmacies. Its operations were regulated by multiple Commonwealth and State legislations, codes and guidelines. MPS explained that the cumulative effect of these regulations means that MPS had no discretion regarding prescribing, dispensing, delivery and administration.

[38] Cephalosporins are beta-lactam antimicrobials used to manage a wide range of infections from gram-positive and gram-negative bacteria. The five generations of cephalosporins are useful against skin infection, resistant bacteria, meningitis, and other infections.

116. MPS explained that as part of its operation, pharmacists were not employed concerning the dispensing of medications, but only in the organisational management, sales and advisory roles. MPS would enter into a licence agreement with local pharmacies, when engaged by aged facilities to provide DAA services. Hence, MPS rely solely on the supervision of patients' medical practitioners and contractor pharmacists in avoiding dispensing contraindicated medications.

117. As part of the licencing agreement, the contractor pharmacies were to complete the MPS' *"Agreed Care Accreditation Program"* to be accredited. Accordingly, they must undertake HealthStream trainings and follow an accreditation process that satisfies MPS' *"Aged Care Accreditation Standards"*.

Further responses and actions by MPS

Response to Recommended Action I[39]

118. MPS advised that following Mr SM's death until May 2019, it has invested $80,000 and 550 hours in refining and testing HealthStream, which would enhance the identification of potential medications that may cause adverse reactions in patients with known allergies. There are two points of identification where the HealthStream will address a patient's allergies — when patients' allergies are entered to the system and when a medication has been prescribed.

119. MPS advised that it is aiming to implement an algorithm that automatically matches any misspelt or medications that were incorrectly entered in comparison to other brand or generic drug names that are identical or similar. This is to ensure more consistency in data and reduce the possibility of prescribing an allergen that might be misspelt or incorrectly identified during entry.

120. MPS also advised it is in the process of refining HealthStream's allergen data entry function, where the data entered in the allergies field will force the user entering an allergy to nominate a generic drug type.[40] After identifying an exact match between the allergy and prescribed medications, a pop-up alert will appear. The pharmacist entering the allergies will be required to enter reasons why the prescription could proceed for dispensing and amend the notation accordingly.

[39] Recommended actions in this section refer to recommended actions by the CPU, see paragraph 84.
[40] This refinement, however, will not be possible to match for non-medication allergens such as insects, food or plants.

Response to Recommended Action II

121. MPS rejected the recommended action to alter its packaging processes to prevent the packaging of known allergens.

122. In its submissions, MPS noted that the treating physician might prescribe known allergens for "good reasons" when the contraindicated medication's benefits outweigh the adverse allergy's adverse effects.

123. MPS explained that there could also be instances when an allergy was a one-off event to an allergen or was recorded as a minor reaction. It also could be instances when multiple allergies were recorded due to the system's inability to single out specific allergies to a combination of allergens.

124. MPS explained further that adopting such action would incur risks affecting the continuity of medicines supply and is against the guiding principles for medication management in residential aged care facilities.[41]

Response to Recommended Action III

125. In response to this recommended action, MPS advised that the signing sheet has been amended to allow the recording of both generic and brand names and allergen alerts if a known allergen is prescribed.

126. Additionally, the HealthStream software now has an automatic function to include a prominent bright orange icon with the wordings "Allergy Alert" in red under a resident's profile photo on the summary and signing sheet, respectively.

Response to Recommended Action IV

127. In relation to addressing the issues of generic and brand names on the packette labels, MPS, in substance, reiterated its limitations as per Clause 1.2 of the DAA guidelines.

128. MPS advised that the packette labels can only include a maximum of ten medications with only the brand names. If both brand and generic names were to be included on the labels, the

[41] Guiding Principle 9, *Guiding principles for medication management in residential aged care facilities*, Department of Health and Ageing, October 2012, page 47-48.

maximum number of medications packed into a packette would be required to reduce to half of its original capacity.

129. MPS explained that including both the generic and brand names on the labels would create a risk for medications being missed from a patient's usual dosage. For example, if a patient has five or more medications to be administered at once, those medications will need to be packed into two packettes to accommodate the labelling issues.

FINDINGS AND CONCLUSION

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

1. I find the identity of the deceased was [redacted], born 6 November 1925 and that his death occurred on 27 July 2017 at Monash Health, Dandenong Hospital, 135 David Street, Dandenong, Victoria, 3175.

2. I accept and adopt the medical cause of death ascribed by Dr Michael Burke and I find that [redacted] died from complications of cerebrovascular and ischaemic heart disease following an anaphylactic reaction to diltiazem.

3. I make no adverse Finding against Bupa Aged Care Australia Pty Ltd, specifically Bupa Aged Care Berwick. I accept that although the circumstances of Mr [redacted] death reflect systemic shortcomings, Bupa Aged Care's responses are restorative and appropriate. I acknowledge the remedial actions are a reflection that they have appropriately responded to the circumstances of Mr [redacted] death and conceded that there were *"failure of basic checks, systems or alerts at various points"*[42].

4. I also make no adverse Finding against MPS given their restorative responses.

5. I acknowledge Dr Ah Choy Chan's concession of his departure from accepted clinical practice and his apology to Mr [redacted] family. I have also considered the subsequent response where he has endeavoured to improve his clinical practice. However, given the significance of Dr Chan's departure from accepted clinical practice, making specific Findings regarding the particular circumstances surrounding Mr [redacted] death remains necessary and appropriate.

[42] CF, Bupa Aged Care letter dated 22 March 2019.

6. The standard of proof for coronial findings of fact is the civil standard of proof on the balance of probabilities, with the Briginshaw gloss or explication.[43] Adverse findings or comments against individuals in their professional capacity, or against institutions, are not to be made with the benefit of hindsight but only on the basis of what was known or should reasonably have been known or done at the time, and only where the evidence supports a finding that they departed materially from the standards of their profession and, in so doing, caused or contributed to the death under investigation.

7. I find that there is clear and cogent evidence to support the following adverse Findings in relation to Dr Ah Choy Chan's involvement with Mr SM's care:

   a) Dr Chan departed from good clinical practice where he failed to practice medicine safely and effectively.[44]
   b) Notably, Dr Chan did not confirm whether Mr SM was allergic to diltiazem.[45] It was unreasonable for Dr Chan to rely on the fact that, Mr SM a 91-year-old man, said that he had no allergy reaction to diltiazem, to satisfy himself it was safe to prescribe it to his patient. The fact that Mr SM had dementia, is the further demonstration Dr Chan's imprudence of relying on that confirmation.
   c) Dr Chan also did not communicate with Dr Joseph the changes in Mr SM's medications.

8. In view of the above, I intend to distribute this Finding to the Australia Health Practitioner Regulation Agency (**AHPRA**) to inform their regulatory activities.

9. I find that there is a temporal relationship between the allergic reaction to the administration of diltiazem and Mr SM's death, as such I find that the allergic reaction contributed to the cause of his death. The degree of contribution is not discernible and nor is it relevant. It is evident Mr SM's clinical condition deteriorated following the administration of diltiazem. Whilst I acknowledge that Mr SM was also experiencing other significant medical conditions,

[43] *Briginshaw v Briginshaw* (1938) 60 CLR 336 at 362-363: "The seriousness of an allegation made, the inherent unlikelihood of an occurrence of a given description, or the gravity of the consequences flowing from a particular finding, are considerations which must affect the answer to the question whether the issues had been proved to the reasonable satisfaction of the tribunal. In such matters 'reasonable satisfaction' should not be produced by inexact proofs, indefinite testimony, or indirect inferences…".

[44] Good medical practice: a code of conduct for doctors in Australia, Code 2.1 Professional values and qualities of doctors.

[45] Ibid, Code 3.2 Good patient care and Code 4 Effective communication.

the additional insult to his clinical condition imposed by the allergic response cannot be ignored or minimised in importance.

10. I am satisfied that Dr Ah Choy Chan has been given reasonable notice of the content and scope of my adverse comments and Findings and he was afforded a reasonable opportunity to respond timeously to any adverse comments and Findings.

I express my sincere condolences to Mr SM's ' family for their loss. I also wish to acknowledge the distress the prolonged coronial process has caused them.

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

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

B

Henry Carus & Associates, Lawyers for C

Bupa Aged Care Australia Pty Ltd

Gilchrist Connell, Lawyers for Dr Deep Joseph

Dr Ah Choy Chan

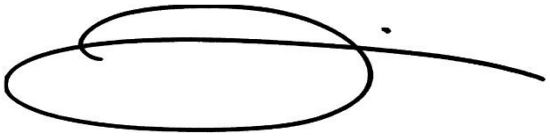
DLA Piper, Lawyers for Gunn & McConville Pharmacy

Patrick & Associates, Lawyers for MPS Hold Co Pty Ltd

Australian Health Practitioner Health Regulation

Monash Health

Signature:



AUDREY JAMIESON

CORONER

Date: 22 March 2023

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.
