Coroners Act 1996
[Section 26(1)]

Western *Australia*

RECORD OF INVESTIGATION INTO DEATH

Ref: 20/14

I, Barry Paul King, Coroner, having investigated the death of ***Daniel Lahengking*** *with an inquest held at the* ***Esperance Court House, Dempster Street, Esperance,*** *on* ***28 and 29 May 2014*** *find that the identity of the deceased person was* ***Daniel Lahengking*** *and that death occurred on* ***15 August 2009*** *at* ***Royal Perth Hospital*** *from* ***multiple organ failure associated with the combined effects of complications of methotrexate toxicity, vasculitis and atherosclerotic cardiovascular disease*** *in the following circumstances:*

Counsel Appearing:

Ms K Ellson assisting the Coroner
Mr T Palmer appearing on behalf of Dr Dian Harun

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INTRODUCTION

1. Daniel Lahengking (the deceased) died on the afternoon of 15 August 2009 after a lengthy admission as a patient at Royal Perth Hospital (RPH).

2. The deceased was an Indonesian national who had been visiting his daughter and her husband, Deivy and David Graham, in Esperance when he saw Dr Dian Harun for what he understood was rheumatoid arthritis.

3. Dr Harun diagnosed the deceased as suffering from rheumatoid arthritis and then prescribed the medication methotrexate at an incorrectly high dosage. The pharmacist who was asked to fill the prescription, Alison McPherson, noted that the dosage was incorrect but dispensed the methotrexate after informing Mr Graham about the usual dosage.

4. The deceased took the methotrexate at the prescribed dosage and suffered stomach pain, vomiting and excessive urination. He returned to Dr Harun who diagnosed him with a urinary tract infection. Over the next four days his symptoms persisted and he began to experience diarrhoea and mouth ulcers. He was admitted into Esperance Hospital where he was treated by Dr Donald Howarth for methotrexate poisoning and septicaemia and then transferred to RPH.

5. Following his initial admission into RPH, the deceased appeared to overcome the symptoms caused directly by the methotrexate overdose, but he developed other on-going conditions, especially tuberculosis, gastrointestinal bleeding and sepsis, which in the context of other medical conditions led to his death.

6. On 28 and 29 May 2014 I held an inquest at the Esperance Court House into the death of the deceased. The documentary evidence comprised three volumes of materials[1] compiled by the police officer who investigated the death, Senior Constable Eric Langton of the Coronial Investigation Unit, as well as: a statement by the deceased's daughter, Ms Graham,[2] an email from neuropathologist Dr Vicki Fabian containing neuropathological findings,[3] and materials specifically relevant to the prescribing and dispensing of methotrexate.[4] Oral evidence was provided by Dr Howarth, Ms McPherson, consultant physician Dr Michael McComish, forensic pathologist Dr Judith McCreath, Mr Graham and Dr Harun.

[1] Exhibits 1, 2 and 3
[2] Exhibit 4
[3] Exhibit 6
[4] Exhibits 5, 7 and 8

7. The issues to be investigated through the hearing of an inquest were identified by Ms Ellson in her opening address as: 'Whether the cause of death could be clarified?' and 'What role, if any, methotrexate played?'

8. A further issue arising during the inquest related to the respective responsibilities of prescribing doctors and dispensing pharmacists when the type or dosage of a medication on a prescription appears to the pharmacist to be wrong.

9. Following the hearing in Esperance, the Court through Ms Ellson obtained a copy of a photograph of the container in which the methotrexate was dispensed to the deceased. The label on the container directed the deceased to check with Dr Harun if he was unsure of the usage.

10. Ms Ellson contacted the Pharmacy Board of Australia to inquire as to the appropriateness of that direction. Copies of the photograph and the response received from the chairperson of the Pharmacy Board were provided to Dr Harun's counsel, Mr Palmer, and to Ms McPherson.

11. Submissions were provided at the close of the hearing by Ms Ellson and Mr Palmer.

12. After being provided with copies of the photograph and the Pharmacy Board's response, Mr Palmer made written submissions on behalf of Dr Harun, and Ms McPherson provided submissions through her lawyers, Meridian Lawyers in Sydney, New South Wales.

THE DECEASED

13. The deceased was born on 20 June 1943 in a small village in Indonesia. He was the third of four children.

14. The deceased was working as a fisherman when he met his wife-to-be, Clara Dungus. He took on her three children as his own and they had four more children together.

15. The deceased also worked as a builder, a carpenter and a well-digger. He was a loving and well-loved and respected father and grandfather who enjoyed fishing and playing with his grandchildren.

16. Ms Deivy Graham was the deceased's youngest child. She married an Australian man, David Graham, and at the material times they lived in Esperance. I infer from Ms Graham's statement that the

deceased would visit his daughter and Mr Graham in Australia from time to time.

17. In April 2009 the deceased and his wife were visiting the Grahams in Esperance. On this occasion Ms Graham had recently had a baby.[5]

18. The deceased had no history of medical conditions apart from a mild angina attack in 2005 or so and arthritis/gout for which for many years he had obtained medicine from a local market in Indonesia. He was a slightly built man of around 50kg.

THE PRESCRIPTION

19. While in Esperance in April 2009 the deceased ran out of his arthritis medication and the joints in his hands and feet became stiff and sore.[6]

20. On 17 April 2009 the Grahams persuaded the deceased to see a doctor in Esperance about his joints. They rang several doctors but were unable to find one that was available. At about 11.00 am they took the deceased to the Esperance Hospital emergency department where the deceased was referred to the nearby Genpar Medical Clinic for assessment by a general practitioner.[7]

21. The deceased was seen that afternoon at the Genpar Medical Clinic by Dr Harun. Ms Graham acted as his interpreter.

22. Dr Harun was a locum general practitioner who had been working in Esperance for some months by this time.[8] She had qualified as a doctor in Canada in 2002 and had practised in Malaysia before practising in Australia from 2007.[9]

23. Dr Harun examined the deceased and obtained a history of rheumatoid arthritis and of a mild angina attack about four years previously. She prescribed the deceased methotrexate at 5mg daily for five days to be followed by 10mg daily for seven days. She also prescribed the non-steroidal anti-inflammatory drug celebrex in capsule form, and she arranged for toradol, another non-steroidal anti-inflammatory drug, and celestone chronodose, a corticosteroid, to be administered by intramuscular injection at the clinic.[10]

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[5] Exhibit 1, Tab 4, p.2
[6] Exhibit 1, Tab 5; ts 87 Graham, D P
[7] Exhibit 1, Tab 5
[8] Exhibit 1 Tab 10; *cf* ts 95
[9] ts 94-95
[10] Exhibit 1, Tabs 10 and 14

24. The prescriptions were provided on the familiar form. In relation to methotrexate, the prescription form stated 'METHOTREXATE TABLET 10mg 1 tab. Daily'.[11]

25. Dr Harun also provided the deceased with a handwritten note indicating what she proposed as his ongoing management. She had been asked by Mr Graham to provide the note so that the deceased could take it back to Indonesia to show it to his treating doctor.[12] In relation to methotrexate, the note stated the following:[13]

> 1. methotrexate (10mg) Preventer
>
> start with ½ tablet once a day
>
> do this for 5 days then
>
> 1 tablet once a day x 1 week
>
> may need to increase twice a day
>
> = check kidneys → 1/12
>
> Full blood exams

26. Mr Graham took the prescriptions to a local pharmacy where he dropped them off, expecting to pick up the medications when he returned in 15 minutes. When he returned, he received the celebrex but was not given the methotrexate because of a query related to the dosage. His understanding was that there was a problem because there was no dosage provided on the prescription[14] but, as noted, a dosage of 10mg daily does appear on the prescription form.

27. While Mr Graham may have understood at the time that there was no dosage provided, in my view it is more likely that the reason why there was a delay in Mr Graham obtaining the methotrexate was that the dispensing pharmacist, Ms McPherson, was concerned about the prescribed dosage and was reticent to fill the prescription with that dosage on the label.

28. Ms McPherson's evidence comprised a statement signed in January 2012[15] and her oral evidence taken by video-link to South Australia. She recalled someone coming into the pharmacy, whom I infer was

[11] Exhibit 1, Tab 10
[12] ts 93, 112
[13] Exhibit 1, Tab 10. The fractions ½ and 1/12 were circled.
[14] Exhibit 1, Tab 5; ts 89-91
[15] Exhibit 1, Tab 8

Mr Graham, with a prescription for methotrexate. She recalled that the prescribed dosage was a daily dose, when it was normally taken weekly.[16]

29. Ms McPherson said that her normal practice in such circumstances was to call the prescribing doctor to check with the doctor before dispensing the medication. She would then amend the prescription form to what it should be.[17]

30. Dr Harun could not recall a phone call from Ms McPherson and Ms McPherson could not recall phoning a doctor to discuss the dosage on the form.[18] The form itself contains no amendments[19] and, as discussed below, the label on the container of methotrexate did not provide directions of the appropriate dosage.

31. There is other evidence which supports a finding that Ms McPherson had called Dr Harun, in particular Dr Howarth's evidence that Ms McPherson had spoken to him by telephone on, possibly, 7 May 2009 and that she had told him that she had concerns about the deceased being on the dose of methotrexate and that she had contacted the doctor who had prescribed it.[20]

32. Ms McPherson also says that the police investigator, Senior Constable Langton, informed her when he initially contacted her that the receptionist at Dr Harun's clinic remembered that she had called to speak to Dr Harun on 17 April 2009.[21]

33. Senior Constable Langton, who is currently attached to the State Coroner's Office, reviewed the police investigation file at my request. He has informed me that he does not recall telling Ms McPherson about a phone call and the only information on the file in relation to Ms McPherson calling the clinic is in the report of Dr Howarth.

34. Senior Constable Langton also contacted the Genpar Medical Clinic. He was told by the practice manager, Jane McCrea, that the current reception personnel at the clinic were the same people that worked in that position in April 2009. None of them recalled Ms McPherson calling in relation to the deceased, and the patient records for the deceased did not contain an entry for the call, as would have been expected unless the call was put straight through to the doctor who then failed to make an entry.

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[16] Exhibit 1, Tab 8
[17] Exhibit 1, Tab 8
[18] Exhibit 1, Tab 8; ts 32
[19] Exhibit 1, Tab 10
[20] ts 15-16, 37 per Howarth, D A
[21] Letter from McPherson, A to Ms Ellson dated 31 July 2014.

35. It is not possible for me to find with any confidence whether or not Ms McPherson had spoken to Dr Harun. On balance, it appears unlikely that she had spoken to Dr Harun given that both she and Dr Harun could not remember a phone call which, in the subsequent circumstances, would be quite memorable.

36. In addition, had Ms McPherson spoken to Dr Harun, she would have been more likely to have provided proper directions on the methotrexate container. It may be that she had called Dr Harun's clinic but had not spoken to Dr Harun.

37. In any event, when Mr Graham was not given the methotrexate upon his return to the pharmacy, he went out and retrieved from Ms Graham the note which Dr Harun had provided the deceased to take back to Indonesia and he showed it to staff at the pharmacy. Mr Graham was given the methotrexate as prescribed, apparently by Ms McPherson, who explained that the normal dosage for methotrexate was once a week and provided him with an information printout for the drug.[22]

38. Following the hearing, Ms Ellson was able to obtain photographs of the label on the medication container that had contained the methotrexate by contacting the Grahams' legal practitioner. The label did not provide directions on the dosage; instead, it contained the following: "No directions specified please check with prescriber if unsure of usage."

METHOTREXATE

39. Methotrexate is an immunosuppressive medicine that has been used to treat rheumatoid arthritis for more than 25 years. It works by blocking the production of a form of folic acid which is instrumental in the replication of cells. It is useful in the treatment of rheumatoid arthritis because it reduces the damage to joints rather than just relieving the pain. It is also used at doses between 1000mg and 5000mg in chemotherapy to treat some cancers.

40. For the treatment of rheumatoid arthritis, methotrexate is usually prescribed initially at a dosage of about 7.5mg per week with increases to a maximum of 20mg per week,[23] though Dr McComish suggested that the usual range was 10mg to 20mg per week.[24]

[22] Exhibit 1, Tab 5
[23] Exhibit 5
[24] ts 54 per McComish, M

41. While methotrexate is generally a safe drug,[25] it is a toxic chemical which causes bone marrow depression and liver toxicity.[26] Bone marrow depression can lead to a drop in white cells causing a vulnerability to serious infection.[27]

42. Prior to prescribing methotrexate, it is important that doctors arrange for a full blood count, a renal function test and a liver function test.[28] The renal function test is important because methotrexate is excreted by the kidneys, so a dose given to a person whose kidneys are not functioning well would effectively receive a higher dose.

43. The size of the patient is also relevant when considering the appropriate dosage for methotrexate because a smaller person should receive a lower dose than a larger person.[29]

18 TO 26 APRIL 2009

44. The deceased commenced his prescription of methotrexate and celebrex on the evening of 17 April 2009. By the next morning his mobility had improved significantly and he had no problems during the day. That evening he took his second dose of the methotrexate.

45. The next day, 19 April 2009, the deceased again experienced no problems. He took his third dose of the methotrexate that evening. Overnight he was vomiting with pain in his stomach and was cold with a stiff and sore back. He had to urinate frequently.[30]

46. During the day on 20 April 2009 the deceased took paracetamol tablets but continued to experience the same symptoms. The Grahams' notes record that Ms Graham checked with a pharmacist at the chemist, presumably by telephone, about the dosage on Dr Harun's note because the dosage differed from that described on the information printout. The pharmacist apparently advised that methotrexate should be taken once a week. The identity of the pharmacist who spoke to Ms Graham at that time is not clear.[31]

47. That evening the deceased took his fourth dose of methotrexate.

[25] ts 13 per Howarth, D A
[26] ts 54 per McComish, M; ts 23 per McPherson, A
[27] ts 7 per Howarth, D A ; ts 57 per McComish, M
[28] ts 55 per McComish, M
[29] ts 7 per Howarth, D A; ts 64 per McComish, M
[30] Exhibit 1, Tab 5
[31] Exhibit 1, Tab 5

48. On 21 April 2009 the deceased was still vomiting and feeling cold with a sore back and pain in his stomach. He continued to urinate frequently. He took his prescription of celebrex but did not take the evening dose of methotrexate.

49. On 22 April 2009 the Grahams took the deceased back to see Dr Harun, who diagnosed him with a urinary tract infection and prescribed an antibiotic and an anti-nausea medication. She referred him for blood tests. She did not consider that the cause of his symptoms might be the methotrexate and she did not suggest that he stop taking the methotrexate. That evening the deceased took his new prescriptions and refrained from taking any more methotrexate.

50. Over the next three days the same symptoms continued with the added complaints of diarrhoea and mouth ulcers.

51. Near midday on 26 April 2009 Ms Graham took the deceased to the emergency department of the Esperance Hospital because his stomach pain had become unbearable. He was admitted into the hospital and was seen by Dr Howarth, a general practitioner with considerable experience practising in regional areas.

52. Dr Howarth noted that the deceased's white cell count was very low as was the percentage of neutrophils. The albumin level was also low. An abdominal x-ray revealed a staghorn calculus in the right kidney which would have impaired the function of that kidney. A chest x-ray showed old apical tuberculosis and a possibly distended heart. At that stage, the deceased had a normal temperature.[32]

53. Dr Howarth diagnosed the deceased with methotrexate poisoning. He noted that the deceased had been taking 5mg of methotrexate daily for four days and that his low renal function and low albumin would have increased the free methotrexate in his blood.[33] Of crucial importance in Dr Howarth's diagnosis was the existence of mouth ulcers which, when seen together with gastrointestinal problems, can be an indication of severe immune depression.[34]

54. On the next day the deceased had a high temperature and his white cells and neutrophil counts fell further. He was treated for gastric erosions and was given broad spectrum antibiotics on the assumption that he was developing septicaemia. That afternoon the deceased was transferred to RPH by the Royal Flying Doctor Service.[35]

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[32] Exhibit 1, Tab 11
[33] Exhibit 1, Tab 11
[34] ts 20, 42-43 per Howarth, D A
[35] Exhibit 1, Tab 11

ROYAL PERTH HOSPITAL

55. The deceased remained in RPH until he died on 15 August 2009.

56. At the time of transfer to RPH on 27 April 2009 the deceased was suffering from pancytopenia (simultaneous reduction in red blood cells, white blood cells and platelets), coagulopathy, abnormal liver function, renal impairment and small bowel obstruction.[36]

57. By 30 April 2009 the deceased's white cell count had improved and by 1 May 2009 it had returned to normal, indicating that the direct effect of the methotrexate toxicity on his immune system had passed.[37]

58. On 1 May 2009 the deceased underwent a laparotomy in an attempt to identify the cause of the small bowel obstruction, but no definitive cause was found.

59. After the operation he was returned to the intensive care unit (ICU) where he showed signs of gastrointestinal bleeding. [38] He stayed in the ICU until 19 June 2009.

60. Over the next month the deceased underwent seven gastroscopy procedures related to the bleeding. During his admission to RPH he underwent x-rays or CT scans almost daily.[39]

61. On 2 May 2009 the deceased was diagnosed with tuberculosis, which had likely been re-activated by the immunosuppression effect of the methotrexate.[40]

62. On 12 and 13 May 2009 a rheumatologist reviewed the deceased and determined that he had suffered from polyarticular tophaceous gout rather than rheumatoid arthritis. The deceased was treated with steroids as his condition limited the treatment options. He was also treated with continuous venovenous haemodialysis for deteriorating renal function.[41]

63. On 2 July 2009 the deceased's right kidney was removed.

64. From 27 to 31 July 2009 the deceased was urgently re-admitted to the ICU to be treated for ongoing sepsis. He was again admitted to the ICU on 2 August 2009 for sepsis and respiratory failure.

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[36] Exhibit 1, Tab 12
[37] ts 62 per McComish, M
[38] Exhibit 1, Tab 12
[39] Exhibit 2, Tab 17
[40] ts 64 per McComish, M
[41] Exhibit 1, Tab 12

Attempts were made to identify the source of the infection, but it remained undetected.

65. During the last admission to the ICU the deceased's condition continued to deteriorate despite exhaustive investigations and procedures. He finally died on the afternoon of 15 August 2009 with his family present.

CAUSE OF DEATH

66. Forensic pathologist Dr McCreath conducted a post mortem examination of the deceased on 18 August 2009. Apart from confirming the recent surgery and the gout, macroscopically she found probable infection in the lungs and on the surface of the heart, narrowing of the vessels supplying blood to the heart and scarring of the heart.[42]

67. Microscopically Dr McCreath found inflammation of the vessels in the heart, scarring in the heart, pneumonia and granulomatous inflammation in the lungs, amyloid deposits in the vessels of multiple organs, gouty tophi within the soft tissues of both knees and inflammation in the left knee. Neuropathological examination of the brain showed evidence of old strokes.[43]

68. Dr McCreath formed the opinion that the cause of death was multiple organ failure associated with the combined effects of complications of methotrexate toxicity, vasculitis (aetiology unknown) and atherosclerotic cardiovascular disease.

69. On the basis of Dr McCreath's opinion I find that the cause of death was multiple organ failure.

THE MANNER OF DEATH

70. On the available evidence, the answer to the issue of how the death occurred is dependent to some degree on the role of methotrexate in the death. If the deceased died because of the effects of the methotrexate, a finding of accident or misadventure would follow. If the death occurred because of the deceased's pre-existing conditions, the verdict would be that death occurred by way of natural causes.

[42] Exhibit 1, Tab 6
[43] Exhibit 1, Tab 6

71. In considering the question of causation in this area, it is usual to ascertain whether there was a precipitating event which led to the death.

72. On the face of the factual evidence, the deceased had underlying poor health, but he was not displaying life-threatening symptoms until he began to suffer from methotrexate poisoning. The immune system suppression that followed led to the reactivation of tuberculosis and, it seems, to gastrointestinal bleeding and sepsis from which the deceased never recovered.

73. On that basis, it might be thought that the deceased would not have died in the way that he did had it not been for the methotrexate toxicity. In other words, the use of methotrexate by the deceased started a chain of events which ultimately led to the death so could be said to have caused the death.

74. However, both Dr McComish and Dr McCreath considered that the issue was more complicated than that.

75. Dr McComish, a consultant physician, reviewed all the available medical notes and reports in order to provide the Court with a report about the deceased's medical management.[44] In that report he stated that the relationship between the pancytopenia caused by the methotrexate poisoning and the subsequent events is uncertain.[45]

76. When asked about the role of methotrexate in the death, Dr McComish said that the question was difficult because the dose of 20mg over four days would not be expected to lead to nausea and vomiting, but that the renal impairment meant that the dose was effectively higher. He said that the period of immunosuppression may have caused the tuberculosis to be reactivated which may have led to a vasculitis-like illness, but that the direct cause of the death was multi-factorial.[46]

77. Dr McComish said that ultimately the death was due to the disease of most of the blood vessels in the body which led to bleeding, a drop in blood pressure, and cerebrovascular disease. The connection with the initial insult was difficult to establish, he said.[47]

78. Dr McCreath thought that the methotrexate had precipitated the deceased's admission to hospital so had contributed to death in that sense, but the effects of the methotrexate toxicity had resolved and the deceased then had multiple insults with ongoing sepsis, a

[44] Exhibit 1, Tab 13
[45] Exhibit 1, Tab 13
[46] ts 64
[47] ts 70-71

source for which was never identified. She said that the vasculitis made the deceased very prone to a heart attack, but she did not know the cause of the vasculitis. She considered that the deceased's coronary artery disease was significant and the continued insults meant that his reserve for coping with severe coronary artery disease was lower.[48]

79. Dr McCreath agreed with Mr Palmer's suggestion that it was known that at the beginning of the timeline the methotrexate resulted in the hospital admission, and it was known that at the end of the timeline the deceased died from multiple organ failure, but that how we get from the beginning to the end is obscure because the deceased had a lot of different medical conditions.[49]

80. It appears to me at least arguable that a finding that death occurred by way of accident or misadventure would be tantamount to a finding that Dr Harun's prescription of methotrexate had to some degree caused the death.

81. In these circumstances, I consider that I should apply the well-known principle from *Briginshaw v Briginshaw* [1938] HCA 34; (1938) 60 CLR 336, roughly to the effect that the more serious the issue, the higher the level of satisfaction required by the fact-finder: *Anderson v Blashki* [1993] 2 VR 89.

82. Given the aforementioned evidence of Dr McComish and Dr McCreath, and given the absence of evidence to the contrary, I do not consider that I am able to find to a sufficient level of satisfaction that the methotrexate prescription caused the death. However, I am not satisfied that the death arose from natural causes.

83. I therefore make an open finding as to how the death occurred.

DR HARUN'S MANAGEMENT OF THE DECEASED

84. There is no doubt that Dr Harun wrongly prescribed the deceased methotrexate and that she prescribed it at the wrong dosage.

85. She failed to confirm that the deceased actually suffered from rheumatoid arthritis and she failed to obtain the essential precautionary blood tests before prescribing methotrexate.

86. The dosage of 5mg of methotrexate daily increasing to 10mg daily greatly exceeded the recommended dosage.

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[48] ts 80 per McCreath, J
[49] ts 81-82 per McCreath, J

87. When the deceased returned on 22 April 2009 with vomiting, soreness and frequent urination, Dr Harun failed even to consider the possible connection between his symptoms and the methotrexate she had prescribed five days earlier. She did not arrange for blood tests immediately as would have been expected.

88. The note which Dr Harun provided to the deceased in which she detailed with some deliberation the planned use of methotrexate precludes any possibility that Dr Harun's error in prescribing methotrexate was inadvertent.

89. To her credit, Dr Harun admitted without reservation that she had been in error. She said that when she looks at her note now it fills her with horror.[50]

90. In a letter to Ms Ellson dated 3 April 2014 Dr Harun stated that she was at a loss to explain how the error occurred and how she did not subsequently identify her error. Without offering an excuse, she stated that at the time she was very fatigued and had been diagnosed with an iron deficiency.[51] In oral evidence, Dr Harun did not offer this information as an explanation or excuse, but when I asked her about it, she said that she had been extremely tired and unwell at the time.[52]

91. Dr Harun stated in the letter that she has received treatment for her iron deficiency and no longer feels fatigued. She has undergone retraining and has updated emergency management for respiratory, airway, and International Trauma Life Support.[53]

92. Dr Harun stated that she was very upset about her error and sincerely and wholeheartedly apologised to the deceased's family.[54]

THE ROLE OF THE PHARMACIST

93. As noted earlier, the passage of time has made the circumstances surrounding Ms McPherson's dispensing of the methotrexate to the deceased difficult to ascertain.

94. It seems reasonably clear that Ms McPherson recognised that Dr Harun's prescription for 10mg of methotrexate daily was unusual and that she brought that fact to the attention of Mr Graham. It is also clear that she provided him with a printed information sheet

[50] ts 115
[51] Exhibit 1, Tab 10
[52] ts 115 per Harun, D
[53] Exhibit 1, Tab 10
[54] Exhibit 1, Tab 10

about methotrexate, which indicated that the drug is taken weekly rather than daily.

95. It is not clear whether Ms McPherson spoke to Dr Harun, though she said, and I accept, that would have been her normal practice in such circumstances. It is possible that she attempted to speak to her but was unable to do so.

96. It is clear on the basis of the photographs of the container in which the methotrexate was dispensed that, instead of providing dosage directions on the container, Ms McPherson provided a suggestion that the deceased check with Dr Harun if he was unsure of the dosage. Ms McPherson accepts that she erred in doing so.[55]

97. I must confess that prior to hearing the evidence at the inquest and subsequently receiving information from the Pharmacy Board of Australia and from the Pharmaceutical Society of Australia web-site, I had assumed that pharmacists would consider themselves obliged to comply with the directions of prescribing doctors. I have since been disabused of that misconception.

98. The Pharmacy Board of Australia developed the 'Guidelines for dispensing of medicines' under section 39 of the *Health Practitioner Regulation National Law Act 2009* (the Guidelines). The Guidelines are admissible in regulatory proceedings under that Act as evidence of what constitutes appropriate professional conduct or practice for the health professional.[56]

99. Guideline 1 of the Guidelines for dispensing of medicines is as follows:[57]

> 1. Dispensing precaution – safety of prescriptions
>
> A pharmacist must take reasonable steps to ensure that the dispensing of a medicine in accordance with a prescription or order is consistent with the safety of the person named in that prescription or order
>
> Guidelines
>
> In dispensing a prescription, a pharmacist has to exercise an independent judgement to ensure the medicine is safe and appropriate for the patient, as well as that it conforms to the prescriber's

[55] Letter from McPherson, A to Ms Ellson dated 31 July 2014.
[56] Exhibit 8
[57] Exhibit 8

> requirements. If there is any doubt, the prescriber is to be contacted. (underlining added)
>
> In conforming to the above principle, dose, frequency and route of administration, duration of treatment, the presence or absence of other medicines, the patient's illness, medication history and other relevant circumstances need to be taken into account.

100. Guideline 7.2 relates to dispensing label content. It relevantly provides that the dispensing label of a product is to include: specific directions for use, including frequency and dose.[58]

101. Guideline 8 relates to counselling patients about prescribed medicines. It relevantly provides:

> i) patient counselling is the final checking process to ensure the correct medicine is supplied to the correct patient;
>
> ii) the Board endorses the use of 'Consumer Medicine Information' leaflets;
>
> iii) More detailed advice is especially important when certain drugs are supplied and in certain circumstances, including: unusual frequency of use (e.g. alendronate, methotrexate) (underlining added)

102. The Pharmacy Board of Australia also produces a Code of Conduct for pharmacists in which the Overview contains the statement: 'Practitioners have a duty to make the care of patients or clients their first concern and to practise safely and effectively.'[59]

103. The Pharmaceutical Society of Australia produces professional practice standards for pharmacists.[60] The introduction to those standards states that 'pharmacists are in a unique position to optimise health outcomes for the community they serve' and that 'The primary responsibility of a pharmacist is to ensure safe and effective use of medicines and best possible health outcomes for consumers through the provision of pharmaceutical care'.

104. It is apparent from the foregoing that pharmacists are expected to play a crucial checking role in ensuring as far as possible that patients receive appropriate medicine. As Stephen Marty, the Chair of the Pharmacy Board of Australia, put it:

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[58] Exhibit 8
[59] Pharmacy Board of Australia Code of Conduct 2014
[60] Professional Practice Standards Version 4 2010

> The pharmacist is the independent gatekeeper of safety between subscriber and patient to ensure that the patient receives the right drug in the right dose and frequency and that the patient understands the information provided to them in order to maximise therapeutic effectiveness and minimise any adverse effects.[61]

105. This was borne out by evidence from Dr McComish and Dr Harun who both stated that it was not unusual to be contacted by a dispensing pharmacist with a query about a prescription.[62]

106. If a pharmacist is not satisfied as to the appropriateness of a prescription, he or she is expected to withhold the medicine until communicating with the prescribing doctor. While the Guidelines are somewhat ambiguous, their overall tenor suggests that the pharmacist should only dispense the medicine in such cases if he or she is satisfied with the doctor's explanation. Mr Marty said:

> The pharmacist is expected to contact the prescriber and clarify the dose. If a pharmacist is not satisfied with the response from the prescriber and believes that supply is not consistent with the safety of the patient then a pharmacist should decline to dispense the prescription and refer the patient back to the prescriber.[63]

107. While it is not clear whether the Guidelines or the standards mentioned above were in place in 2009, Ms McPherson said that she normally contacted the prescriber if there was a doubt about a prescription. It appears that Ms McPherson queried the dosage on the deceased's prescription for methotrexate and that she counselled the deceased (through Mr Graham) with the use of a Consumer Medicine Information leaflet.

108. While it seemed to me that Ms McPherson's oral evidence was somewhat equivocal, perhaps because of lack of clarity in the questions I asked her, Ms McPherson appeared to say that she would not have dispensed the methotrexate if she had spoken to Dr Harun and Dr Harun maintained that the dosage was 10mg daily. However, as noted it is not clear whether she contacted Dr Harun, and it is clear that she dispensed the methotrexate without an appropriate label.

109. So, it seems that Ms McPherson was aware that she could have withheld the methotrexate because she was concerned that the prescribed dosage was incorrect but, for reasons that are unclear because she could not recall, she did not do so.

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[61] Letter Marty, S to Ms Ellson dated 11 July 2014, p.5
[62] ts 67-68 per McComish M; ts 110 per Harun , D
[63] Letter Marty, S to Ms Ellson dated 11 July 2014, p.2

110. Ms McPherson submits that she must have spoken to Dr Harun otherwise she would not have dispensed the methotrexate to the deceased. However, the fact that she failed to take the expected steps of providing proper directions on the container makes a conclusion based on what she would normally have done unreliable.

111. In the end, it seems inescapable that the gatekeeper function provided by a systemic check on Dr Harun's prescription by Ms McPherson was not effective, though it is not possible to determine precisely what occurred due to the lack of reliable records and the effect of the passage of time on memories.

COMMENTS IN RELATION TO PUBLIC HEALTH

112. The evidence discloses that the quality of medical care provided initially to the deceased was well below the standard reasonably expected in Australia.

113. The cause of the failure was an inexplicably incompetent error by a suitably qualified general practitioner, which error had been identified but not effectively corrected by an apparently competent pharmacist for reasons that cannot now be ascertained.

114. The circumstances of the failure warrant consideration by the Australian Health Practitioner Regulatory Agency, so it is appropriate that, under s50 of the *Coroners Act 1996*, I refer the matter to that agency.

CONCLUSION

115. There is no doubt that the deceased was let down by the health care he received in Western Australia.

116. It is a terrible irony that the deceased had come to Australia from a much less affluent society where he received apparently informal but effective treatment for a painful, but not life-threatening, condition. He was convinced to place his trust in modern western medical treatment, and the provision of that treatment not only failed him, it probably precipitated his death.

Barry King
Coroner
29 August 2014